

Regional Comprehensive Economic Partnership

Intellectual Property Chapter and the Impact on Access to Medicines

This briefing note details Médecins Sans Frontières/Doctors Without Borders (MSF)'s analysis of the Regional Comprehensive Economic Partnership (RCEP) intellectual property chapter draft negotiating text. It highlights in particular the numerous provisions within this chapter that have implications for access to medicines and makes recommendations to RCEP negotiators of how to ensure that these provisions do not impede access to affordable medicines for the millions of people in RCEP-negotiating countries, and the millions more relying on affordable medicines currently produced in these countries.

Background

The leaked draft of RCEP's negotiating text,¹ particularly the proposed intellectual property (IP) chapter, reveals that some countries are pursuing provisions that threaten to undermine access to medicines beyond what is required under internationally-agreed rules in the World Trade Organization (WTO)'s Agreements on Trade-related Aspects of Intellectual Property Rights (TRIPS). These proposed so-called 'TRIPS-plus' intellectual property measures could undermine access to affordable medicines across the Asia Pacific region by creating additional monopolies that delay the entry of affordable generic medicines onto the market.

The draft RCEP negotiating text contains several of the same damaging provisions that have made the Trans-Pacific Partnership (TPP) trade agreement the 'worst trade deal ever for access to medicines'. These provisions have been tabled in the RCEP negotiations by Japan and South Korea.

IP barriers lead to dramatically high prices for new drugs to treat hepatitis C (HCV), tuberculosis (TB) and cancer, the need for affordable generic medicines and the continued use of public health-oriented TRIPS flexibilities is stronger than ever. It is critical that countries continue to make use of public health safeguards in their national patent laws and within WTO rules to enable access to affordable treatment for their most vulnerable citizens.

Since India is one of the countries included in the RCEP negotiations, these TRIPS-plus measures are all the more concerning. 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 in developing countries. Two-thirds of all the drugs MSF purchases to treat HIV, TB and malaria are generic medicines from India.

¹ Knowledge Ecology International, 2015 October 15 version: RCEP IP Chapter, Washington DC and Geneva: KEI. Available at: <http://keionline.org/node/2472>.

If accepted, the provisions proposed in the RCEP negotiating text would subject India to a more restrictive and burdensome intellectual property (IP) system, threatening access to medicines for millions of people across the developing world.

Furthermore, the current proposals do not reflect the rights of WTO members who are so-called ‘least-developed-countries’ (LDCs) to benefit from an extension period during which they do not have to introduce patent protection on pharmaceuticals. This extension offers a fundamental and necessary opportunity for LDCs to manage domestic developmental objectives and ensure access to affordable medicines for their public health systems. Yet the three RCEP-negotiating countries that are classified as LDCs may not have these WTO-enshrined rights respected under an RCEP deal based on the current draft text.

Among the negotiating parties, several countries have experience using TRIPS flexibilities to help protect public health. For instance, India’s patent law takes into account the need to balance the protection of patent rights with the public interest. The Thai and Indonesian governments have issued government use compulsory licenses on medicines to improve access, and the government of India and Philippines have developed strict patentability criteria for pharmaceuticals to tackle patent ‘evergreening’, alongside the introduction of other TRIPS flexibilities. These prior commitments to protect public health and promote access to medicines through relevant national laws and practices should be respected, acknowledged and referenced in RCEP negotiations when negotiating the intellectual property chapter.

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General Provisions

Article 1.1 Objectives

1. [ASN propose: Each Party confirms its commitment] : to [reduce distortion and impediments to trade and investment by promoting deeper [ASN/KR propose: economic integration and cooperation through effective and adequate creation, utilisation, protection and enforcement of intellectual property rights] [KR propose: ;]

[KR propose; IN oppose: to provide certainty for rights holders and users of intellectual property over the protection and enforcement of intellectual property rights; and

[KR propose:][ASN/KR propose: to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, [KR propose : taking into account:][ASN/AU propose; KR oppose: to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, [AU propose: and to a balance of rights and obligations] taking into account:]

- (i) the different levels of economic development and capacity and differences in national legal systems;
- (ii) [ASN/KR propose: the need to maintain an appropriate balance between the rights of intellectual property rights holders and the legitimate interests of users [AU/NZ/IN/ASN propose; KR oppose: including intermediaries and consumers,] and the public [KR oppose: interest]]; [KR oppose: and]]

[AU/NZ/ASN propose; KR oppose: (iii) the importance of facilitating the availability of information, knowledge, content, culture and the arts.]

Alt 2:

[JP propose; ASN/AU/KR/IN/NZ oppose: Each Party confirms the objectives and principles provided

for in Article 7 and 8 of the TRIPS Agreement.

OR

Replace Para 1 and 2 with text of TRIPS Articles 7 and 8, respectively]

This provision aims to define the objectives of the IP chapter and incorporates the chapter into a broader framework of RCEP. It includes text from both the WTO's TRIPS Agreement and the Trans-Pacific Partnership Agreement (TPP),³ including early TPP proposals from New Zealand.⁴

ASEAN and South Korea's proposal suggests that the creation, utilization, protection and enforcement of IP rights should be a commitment in the context of economic integration and cooperation. The 'cooperation' language might shed light on the request for a deeper, substantive harmonization of IP rules, envisaging it as a vehicle for economic integration. It fails to mention the need to balance IP rights with flexibilities, development needs and protection of access to medicines.

South Korea proposes a commitment to provide certainty for rights holders and users of IP over the protection and enforcement of IP rights. However, this proposal is ambiguous. When read together with the other provisions of the chapter, South Korea's proposal would promote a greater certainty for right holders, including certain legal protections and strong enforcement of IP rights. If this were supported by strong exceptions and safeguards in the text, certainty for users would be better assured.

South Korea and ASEAN's proposal on the promotion of technological innovation and transfer and dissemination of technology mimics the language of Article 7 of the TRIPS Agreement.⁵ However, it

³ Article 7 of TRIPS: Objectives: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations", and TPP, Article 18.2: Objectives: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

⁴ TPP Text submitted by New Zealand, CHAPTER "X":

"...3. The Parties recognise the need to achieve a balance between the rights of right holders and the legitimate interests of users and the community with regard to protected subject matter.

4. The Parties are committed to the maintenance of intellectual property rights regimes and systems that seek to:

- facilitate international trade, economic and social development through the dissemination of ideas, technology and creative works;

- provide certainty for right-holders and users of intellectual property over the protection and enforcement of intellectual property rights; and

- facilitate the enforcement of intellectual property rights with the view, inter alia, to eliminate trade in goods infringing intellectual property rights." See, Public Citizen, *TPP Text submitted by New Zealand, CHAPTER "X", INTELLECTUAL PROPERTY*, Washington DC: Public Citizen. Available at:

<http://www.citizen.org/documents/NewzealandproposedIPChaptertext.pdf>

⁵ TRIPS Article 7, Objectives:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users

merely states that the protection and enforcement of IP should contribute to the established goals, without establishing a principle.

Japan's proposal to replace the text with TRIPS Articles 7 and 8⁶ is important but not sufficient. Even though Articles 7 and 8 of TRIPS acknowledge the wider public interest agenda behind the TRIPS Agreement, they have not been enforced with actual legal effects under WTO law. They could only be "borne in mind"⁷ and are subject to the other substantive provisions and case law under TRIPS to make them a reality. Application of the objectives and principles set forth in Articles 7 and 8 would depend on the clarity of definitions, and sufficient safeguards in other substantive provisions of this chapter.

We recommend that the negotiating parties recognize and commit to the objectives and principles set forth by Articles 7 and 8 of TRIPS, and to realize those objectives and principles with well-balanced provisions in this chapter, especially to incorporate sufficient public health safeguards such as those enshrined under TRIPS.

Article 1.2 Principles

1. Parties affirm their existing rights and obligations under the TRIPS Agreement [ASN/AU/NZ/JP/KR propose; IN oppose: and any other [JP/KR propose: ASN/AU oppose: international] [ASN/AU propose; JP/KR oppose: multilateral] agreements relating to intellectual property to which they are parties]. [ASN/AU/JP/KR propose; IN oppose: To this end, nothing in this chapter shall derogate from existing rights and obligations that Parties have to each other under the TRIPS Agreement [IN oppose: or other [JP/KR propose; ASN/AU oppose: international] [ASN/AU propose; JP/KR oppose: multilateral] intellectual property agreements.]

2. Parties may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Chapter [and the TRIPS Agreement].

of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

⁶ TRIPS Article 8, Principles:

"1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

⁷ In Canada – Patent Protection of Pharmaceutical Products, the DSB rejected Canada's submission that Articles 7 and 8 are part of the legal and policy context within which the Article 30 exceptions to patent rights need to be read. They also acknowledge that Articles 7 and 8 are central to achieving that outcome. DS114. See World Trade Organization, *DISPUTE SETTLEMENT: DISPUTE DS114 Canada — Patent Protection of Pharmaceutical Products*, Geneva: WTO. Available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm

3. Appropriate measures, provided that they are consistent with the provisions of this Chapter, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which [AU/IN/ASN/NZ propose; KR/JP oppose: are anti-competitive or] unreasonably restrain trade or adversely affect the international transfer of technology. [AU propose; CN/KR/IN/JP oppose: FN1]]

This provision affirms the existing rights and obligations under the TRIPS Agreement and any other international/multilateral agreement relating to IP, and clarifies that nothing in the chapter would derogate from existing rights and obligations under the TRIPS Agreement and other international agreements.

All the RCEP parties are WTO members, which have TRIPS-compliant regimes. However, this provision becomes critical for other international agreements going beyond TRIPS in terms of the obligations at national level. In a situation where RCEP negotiators agree to remove harmful TRIPS-plus provisions such as patent term extensions and data exclusivity from the RCEP agreement (for which a precedent has already been set in the EU-India negotiations), RCEP countries that have also signed up to other FTAs (e.g. the US-Korea FTA) will not benefit from the less onerous provisions included in the RCEP. The potential consequences would be that even if the RCEP final text contains no TRIPS-plus provisions, countries that have signed and/or ratified other FTAs would still be obliged to implement TRIPS-plus provisions via their national laws owing to legal commitments under other FTAs.

Nevertheless, such countries can still aim to address TRIPS plus rules under other FTAs by seeking to renegotiate or suspend such FTAs.

The rest of the provision draws from Article 8 of TRIPS with an additional reference to anti-competitive practices.

We recommend that RCEP negotiating parties set a principle of alleviating TRIPS-plus provisions that are detrimental to access to medicines.

Article 1.4 Scope of Intellectual Property

[ASN/KR/CN/IN propose; AU oppose: Alt 1: 1. For purposes of this Chapter, intellectual property refers to all categories of intellectual property that are the subject of this Chapter.]

[AU propose; ASN/KR/CN/IN oppose: Alt 2: 2. For the purposes of this Chapter, intellectual property rights means copyright and related rights; rights in trademarks, geographical indications, industrial designs, patents, and layout-designs (topographies) of integrated circuits; rights in plant varieties; and rights in undisclosed information; as referred to in the TRIPS Agreement.]

[JP propose: Alt 3: 3. For the purposes of this Chapter intellectual property refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement.]

Alternative 1 could open the door to a broader, extended scope of other categories of intellectual property not covered by the TRIPS Agreement, i.e. data exclusivity. Alternatives 2 and 3 refer to the TRIPS Agreement and apply the term “intellectual property” to all categories of IP that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement. However, neither alternative includes other areas of law under TRIPS, in particular those related to competition set forth under Section 8 of Part II of TRIPS. They also do not establish a clear position on the issue of data exclusivity, which is not an obligation under TRIPS, in the context of the rights in undisclosed information concerning pharmaceuticals.

We recommend that RCEP negotiators adopt language in line with the scope of IP set forth under the TRIPS Agreement, without creating additional categories such as data exclusivity.

Article 1.7 TRIPS and Public Health

1. The Parties reaffirm [AU/KR oppose: the principles and flexibilities [JP/ oppose: established] [JP/ propose: provided] in] [AU/KR propose: their commitments to] the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO. The Parties agree that this Chapter does not and should not prevent Parties from taking measures to protect public health [AU oppose: in line with this Declaration.]

2. The Parties [AU oppose; ASN/IN propose: recognise [ASN/IN/CN/NZ propose; JP/KR oppose: their respective commitments to] [JP/KR propose; ASN/IN/CN/NZ oppose: the importance of]] [AU propose; ASN/IN oppose: reaffirm their commitment to contribute to the international efforts to implement] the Decision of the WTO General Council of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as well as the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.

[AU/ASN propose: 3. Each Party [JP/KR oppose: shall notify the WTO of its acceptance of] [JP/KR propose: shall endeavour to accept] the Protocol amending the TRIPS Agreement done at Geneva on December 6, 2005.]

[IN/CN/ASN/NZ propose; KR/JP/AU oppose:4. In interpreting and implementing the rights and obligations under this Agreement, the Parties shall ensure consistency with this Declaration and the Protocol [IN propose; NZ/AU oppose: and any other legal instrument that succeeds or modifies any of these instruments.]]

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted at the 4th Ministerial Conference,⁸ instructed the WTO Council for TRIPS to address how WTO Members lacking or with insufficient manufacturing capacity in pharmaceuticals can make effective use of compulsory licensing. Parties appear to have a consensus in the RCEP draft text to reaffirm the Doha Declaration and flexibilities therein for protecting public health.

However, they have conflicting positions with regard to the Decision of the WTO General Council of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as well as the Protocol amending the TRIPS Agreement.

The Protocol amending the TRIPS Agreement would be formally built into the TRIPS Agreement when two-thirds of the WTO's members have accepted the change. The initial deadline for acceptance has

⁸ See, World Trade Organization *WT/MIN(01)/DEC/2*, *Doha Declaration on the TRIPS Agreement and Public Health*, adopted on 14 November 2001, Doha: WTO. Available from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

been extended from 1 December 2007 until 31 December 2017.⁹ The amendment will take effect in those members who accept it, and will replace the 30 August 2003 waiver.

The effectiveness and sufficiency of the mechanism proposed under the Protocol have long been controversial as some governments see the procedure as being too restrictive and complex for an expedited solution to the pressing issue of access. There are also proposals to amend the Protocol to provide further flexibility of using the mechanism. For instance, proposals have called for national laws to incorporate the Protocol with broader flexibility by allowing inclusion of all countries that have insufficient capacity to be eligible as importing countries, regardless of the status of their WTO membership. Other suggestions called for the Protocol to be revised into an expedited and automatic mechanism for all essential medicines. The recent report published by the United Nations Secretary-General's High-Level Panel on Access to Medicines has recommended a possible revision of the Protocol.¹⁰ However, Australia and ASEAN's proposal is the most stringent as it requires countries to accept the Protocol. Japan and South Korea, on the other hand, propose vaguer language, which does not impose an absolute obligation to accept the Protocol.

India, China, ASEAN and New Zealand's proposal creates an obligation for parties to ensure consistency with the Doha Declaration and the Protocol while interpreting and implementing the rights and obligations under the RCEP Agreement. India further proposes to include any other legal instrument that succeeds or modifies any of the existing agreements and provisions.

We recommend that RCEP negotiators adopt the language from India's proposal as it provides the opportunity for flexibility of future amendments and reform of the Paragraph 6 system.

⁹World Trade Organization, *General Council decision of 30 November 2015 (document WT/L/965)*, WTO. Available at: https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

¹⁰United Nations Secretary-General's High-Level Panel on Access to Medicines, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines*, September 2016. Available at: <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

Patent Provisions

Article 5.1 Patentable Subject Matter

[ASN/IN/CN/NZ/KR propose:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 3 of this Article and SECTION 12 (Special and Differential Treatment, Transitional Period and Transitional Arrangements) below, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

1. Parties may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Parties may also 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. However, Parties shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. [AU/KR oppose: This provision shall be [NZ/IN/ASN propose reviewed upon any] amendment of Article 27.3(b) of the TRIPS Agreement.]

Footnote 29: [ASN/IN/CN/NZ/KR propose: For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Party to be synonymous with the terms "non-obvious" and "useful", respectively.]

In August 2016, India's Commerce Minister announced in parliament that Indian negotiators had successfully opposed a provision relating to evergreening – the abusive practice of claiming unjustified secondary patents on medicines to extend monopolies – leading to its removal from the proposed text of RCEP. Although this is an important first step against the potential negative impact of RCEP on access to medicines, further harmful measures remain on the negotiating table.

While the current provision within the leaked draft mirrors Article 27 of the TRIPS Agreement and would not require RCEP parties such as India to change their laws, it incorporates the differences in patent standards between the countries. However this provision may have a negative impact on the LDC negotiating countries unless the Agreement explicitly recognises and respects the pharmaceutical

transition period wherein LDCs do not have to apply or enforce TRIPS provisions concerning patents (See Section 12, Special and Differential Treatment, Transitional Period and Transitional Arrangements).

Australia and South Korea explicitly oppose the exclusion of plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals from patentability. This is at odds with obligations under TRIPS.

New Zealand, India and ASEAN propose a review process for the provision, if 27.3(b) of the TRIPS agreement is amended in the future.

We recommend that RCEP negotiating parties respect and confirm the right to exclude certain subject matter from being patentable, as enshrined under TRIPS, and that RCEP negotiating parties commit to encourage strict patentability criteria to limit patent evergreening for pharmaceuticals.

Article 5.2 Exceptions to Rights Conferred

Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[AU/NZ/IN propose: ~~Other use without the authorization of the right holder~~ 2. For greater certainty, nothing in this Agreement shall limit a Party's rights and obligations pursuant to Article 31 of the TRIPS Agreement, including any waiver or amendments thereto.]

This provision mimics the language of Article 30 of the TRIPS Agreement, while the Australia/New Zealand/India proposal refers to Article 31 of TRIPS concerning the right to use compulsory licensing and aims to confirm that RCEP should not affect compulsory licensing rights of the countries.

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not 'unreasonably' conflict with the 'normal' exploitation of the patent. The negotiating history for Article 30 suggests that a flexible approach should be taken in its interpretation. The TRIPS Agreement makes no mention of specific examples of acceptable, non-infringing uses and adopts a more generalized and flexible approach, for instance those under Article 9(2) of the Berne Convention¹¹ as its model. The RCEP provision should be interpreted in a similarly flexible manner.

¹¹ Berne Convention for the Protection of Literary and Artistic Works, World Intellectual Property Organisation, entered into force on September 09, 1886, as amended on September 28, 1979. Article 9 (2): "It shall be a matter

Article 30 of the TRIPS Agreement bears distinctive objectives from those under Articles 31 on compulsory licenses (other use¹² without authorization of the right holder).¹³ As interpreted by the report of the WTO Dispute Settlement Panel in *the European Commission vs. Canada* on pharmaceutical patents case involving the stockpiling of generic products under ‘Bolar’ exceptions,¹⁴ the application of Article 30 indicates “the discretion to limit the full application of patent rights in light of the particular circumstances”,¹⁵ while Article 31 “permitted measures that curtailed the rights of patent holders only where specified conditions were met”.¹⁶ Although both provisions could be used in achieving the balance between patent protection and other social welfare, they have substantively different objectives and procedural requirements in law. Accordingly, Article 30 cannot be used in lieu of Article 31, and *vice-versa*. Countries should reserve discretions and flexibilities enshrined by both provisions, and invoke either of these provisions according to their needs and circumstances

We recommend that RCEP negotiating parties create a separate provision to reinforce the rights enshrined under Article 31 of TRIPS and the protocol under the August 30 decisions concerning the use of compulsory licensing.

Article 5.3 Experimental Use of a Patent

[AU/KR propose:

Without limiting ~~paragraph~~ Article 5.2, each Party shall provide that [IN/CN oppose: a third person][IN/CN propose: any person] may do an act that would otherwise infringe a patent if the act is done [CN/IN propose: solely] for experimental[CN propose; AU oppose: and/] [IN/CN propose; AU oppose: or research] purposes [IN propose; AU/KR oppose: including the imparting of instruction to pupils] relating to the subject matter of a patented invention.]

Experimental use of a patent, widely known as the Bolar exception in the United States, helps speed generic medicines to market. It is a safe harbor provision that permits generics manufacturers to make batches of a generic version of a patented medicine in order to apply for marketing approval before the patent expires without risk of liability for infringement.

for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”

¹² “Other use” refers to use other than that allowed under Article 30.FN 7, the TRIPS Agreement.

¹³ Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: [...]

¹⁴ World Trade Organization, WTO Dispute Settlement Panel Report ([WT/DS114/R](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm)), *European Commission vs. Canada*, March 17, 2009. Available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

¹⁵ *Ibid.*

¹⁶ *Ibid.*

Negotiating parties have conflicting positions on the scope of the provision. India and China propose to extend the application of the provision to experimental and research purposes including imparting of instruction to pupils (for educational purposes).¹⁷

In the interest of accelerating entry of generic competition to facilitate access to more affordable medicines, a broad approach to experimental use exception should be adapted. In particular, the current proposal does not explicitly cover the development and submission of a registration dossier for a generic version of a patented medicine to drug regulatory authorities (DRA). India should also consider proposing language from its own Bolar provision S.107A which describes acts not to be considered as infringement which include making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product. This covers the regulatory process of importing the API, preparing and submitting a dossier to the drug regulatory authority, conducting bioequivalence and stability studies and any other information that may be required by the Indian DRA or any other DRA.

We recommend that RCEP countries propose and adopt the Indian approach to the Bolar provision in addition to Article 5.3 in which India and China’s proposal seeks to safeguard third parties against patent infringement suits for acts performed for experimentation, research and imparting of instruction to pupils.

Article 5.4 High Quality Rights

AU propose:

Each Party shall:

- (a) continue to work to enhance its examination and registration systems, including through improving examination procedures and quality systems so as to provide a high degree of certainty in the application for and protection of intellectual property rights;
- (b) provide applicants with a communication in writing, of the reasons for any refusal to grant or register an intellectual property right;
- (c) provide an opportunity for interested parties to oppose the grant or registration of an intellectual property right or to seek revocation, cancellation or invalidation of an existing intellectual property right;
- (d) require that opposition or revocation decisions of general application to be reasoned and in writing; and
- (e) for the purposes of this Article writing and communication in writing includes writing and communications in an electronic form.]

¹⁷ See, Section 47 of the Indian Patent Act.

Australia’s proposal on high quality patents reflects Australia's IP commitment to issuing “high quality” patents for the benefit of Australia.

The quality standards apply to all aspects of examination carried out by patent offices – e.g. first reports, further, voluntary amendments, re-examination, international searches, and international preliminary examination.

However, the provision does not define practices and procedures, nor reflect a shared understanding of ‘patent quality’. It shall be read in consideration with the practices and procedures detailed in the patent examination guidelines at the national level. In addition, the issue of ‘patent quality’ is ambiguous and could refer to either administrative processes as the current proposals entails, or imply substantive standards. When used substantively, the current proposal can potentially be considered as a significant enabling step towards the global harmonization of substantive patent examination. If so, the flexibility for countries to tailor substantive patent laws to their national situation and needs would be squeezed. Such a possibility could be pursued through administrative collaborations, such as via the participation in the Patent Prosecution Highway.

We recommend that this proposal to be carefully examined with due caution by the negotiating parties, especially in light of the potential of imposition of substantive patent harmonisation.

Article 5.5 Grace Period for Patents

Note: this provision needs to be read closely with Article 5.12, as illustrated in later text.

[AU/KR/IN/JP propose; ASN/CN/NZ oppose:

Each Party shall disregard information contained in public disclosures [JP propose: used to determine] if an invention is novel or has an inventive step [JP propose:; at least in the following case;] if the public disclosure:

(a) was made or authorized by, or derived from, the [JP/KR oppose: patent applicant] [JP/KR propose: person having the right to obtain a patent] [IN propose; AU/KR oppose: or in case where he is not the true inventor, the person from whom he derives the title]; and

(b) occurred within [AU propose; JP oppose: 12 months prior to the date of] [JP propose; AU oppose: a certain period before the] filing of the application in the territory of the Party.] [JP propose:

]

The disclosure of the invention in any form before the filing of a patent application is taken as prior art and may destroy the novelty of the invention. A grace period is a period of time before the date of filing a patent application during which certain kinds of disclosures would not undermine the novelty of the invention. In other words, under a grace period system, an invention may still be considered new (and therefore patentable) even if it has been described publicly, for example, in a publication, before the patent application was filed. Disclosures to which the grace period applies are not taken into account as

prior art when assessing novelty or inventive step of the invention. This provision provides for an exceptional grace period and will expand patent applicants' rights beyond international law obligations and should be rejected.

Australia, South Korea, India and Japan's proposal introduces broad grace periods for any public disclosure that is authorized by or derived from the patent applicant. The duration of the proposed grace period is 12 months, which would double the grace periods in most RCEP negotiating countries, prolonging uncertainty, making it easier to get patents and delaying entry of inventions into the public domain.

The grace period system was originally designed as a special relief measure under the first-to-file system. At the international level, there is no harmonization of grace periods. Previous attempts to harmonize the grace periods have failed.

Patents originally filed in the US but subsequently filed in countries without a 12 month grace period cannot benefit from the grace period exception in the US. This disfavours US companies and is the reason why the US pushes trading partners to adopt grace periods. All US trade agreements, including the proposed TPP Agreement, require 12 month grace periods.

The criteria for determining the anticipation, as well as the availability of the grace period, are not uniform in all the jurisdictions. An invention may be considered novel in the US, but may be objected to for lacking novelty due to anticipation in places like Europe or India.

For example, in India under Section 31 of the Patent Act there is a grace period of one year, but only for disclosures within 12 months before the application is made by: (a) display or use of the invention with the consent of the inventor or his predecessor in title at an industrial or other exhibition notified in the Official Gazette; (b) publication of the invention in consequence of such display or use; (c) use of the invention during the period of the exhibition without the consent of the inventor or his predecessor in title; (d) description of the invention in a paper read by the inventor before a learned society, or published with his consent in the transactions of such a society. Section 32 further allows disclosures within one year before the filing date (priority date) if public working the invention for reasonable trial are necessary. Currently the provisions in India requires a careful assessment in each case to determine whether or not the grace period applies, whereas a standardized grace period under RCEP may not incorporate the conditions applied in India and will be used to promote patent applications which are not novel and inventive in nature.

We recommend that RCEP negotiators reject this provision in its entirety.

Article 5.6 Patent Amendments

[AU/ASN/JP/CN/NZ propose:

Each Party shall provide patent applicants with at least one opportunity to make amendments, corrections, [AU propose; ASN/KR oppose: and observations] in connection with their applications [CN propose: in accordance with each Party's laws, regulations and rules.] [ASN/CN propose: Footnote 31]

Footnote 31: [ASN/CN propose: The Parties understand that [NZ propose: the Parties will not be required to] [NZ oppose: amendments and corrections would not] allow an applicant to broaden the scope of the disclosure of the invention as of the filing date.]

Patent applications are generally amended to overcome an objection raised by a Patent Office. However, these amendments should not go beyond the scope of the original disclosure of the application as filed. The amendment should not provide an unfair advantage to the applicant or damage the legal security of third parties. A tactical amendment of a patent application may hold up legitimate competitors by reducing their ability and incentive to innovate.

We recommend that the provision specifies the limitations to patent amendments, and specifies that countries have no obligation to allow the patent amendment to broaden the scope of the invention as first filed.

Article 5.7 TRIPS Flexibilities on Compulsory Licenses and LDC Extensions

[ASN/AU/IN/NZ/CN propose; JP/KR oppose:

1. Parties have the right to grant compulsory licenses subject to TRIPS Article 31, and if applicable, the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2 of 20 November 2001, the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82), or the Decision on the Amendment of the TRIPS Agreement, adopted by the General Council, 6 December 2005 and the WTO General Council Chairperson's statement accompanying the Decision (WT/GC/M/100).]

2. [ASN/IN/NZ/CN propose: The Parties agree that the least-developed country Parties will not be obliged, with respect to pharmaceutical products, to implement or apply Paragraphs 1(a) of Article 4 (Patentable Subject Matter) and Paragraph 4 of Article 4 (Electronic Registration Regime) or to enforce rights provided for under these Paragraphs until 1 July 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.]

This provision reaffirms Parties' right to issue compulsory licenses in accordance with Article 31 of the TRIPS Agreement.

UN-classified LDCs are given an extended transition period vis-a-vis IP under the TRIPS Agreement during which LDCs are under no obligation to implement the IP provisions of the TRIPS Agreement. In accordance with Article 66.1 of the TRIPS Agreement, LDCs enjoy a number of exemptions and waivers to the implementation of the TRIPS Agreement. However, the second paragraph of the provision limits the scope of the TRIPS transition period to patentable subject matter and electronic registration regime and does not apply to other IP issues, such as data exclusivity. The provision clearly undermines the transition period LDCs are entitled to under the TRIPS Agreement.

In accordance with Article 66.1 of the TRIPS Agreement, LDCs enjoy a number of exemptions and waivers to the implementation of the TRIPS Agreement which are listed below for reference:

1. Pursuant to extension of transition period granted to LDCs in accordance with Article 66.1 of the TRIPS Agreement, LDCs are exempted from applying all TRIPS standards until 1 July 2021.¹⁸ This period must be extended by the TRIPS Council on LDCs submitting a duly motivated request.¹⁹ Thus far this transition period has been extended twice.
2. Further, LDCs have been granted a specific pharmaceutical transition period wherein LDCs do not have to apply or enforce TRIPS provisions concerning patents²⁰ as well as test data protection²¹ in relation to pharmaceutical products until 1 January 2033.²² This period must also be extended pursuant to a duly motivated request.
3. In addition, the WTO General Council has granted LDCs waivers until 1 January 2033 from obligations to make available a mechanism for filing patent applications for pharmaceutical products (mailbox) or to grant exclusive marketing rights to such applications.²³

We recommend that the provision recognize and uphold the current transition periods and waivers vis-a-vis intellectual property granted to LDCs as well as any further extensions by the

¹⁸ See TRIPS Council Decision (IP/C/64), 11 June 2013. This exemption has been extended twice so far upon LDCs submission of requests. Available at:

https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc64_e.pdf

¹⁹ Article 66.1 of the TRIPS Agreement

²⁰ Section 5 of the TRIPS Agreement

²¹ Section 7 of the TRIPS Agreement

²² World Trade Organization, TRIPS Council Decision (IP/C/73), *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, 6 November 2015. Available at:

https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/135698/q/IP/C/74.pdf

²³ World Trade Organization, WTO General Council Decision (WT/L/971), *LEAST DEVELOPED COUNTRY MEMBERS – OBLIGATIONS UNDER ARTICLE 70.8 AND ARTICLE 70.9 OF THE TRIPS AGREEMENT WITH RESPECT TO PHARMACEUTICAL PRODUCTS*, 2 December 2015. Available at:

https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/225405/q/WT/L/971.pdf

WTO. RCEP should encourage LDCs to fully utilize these transition periods. In addition, countries negotiating RCEP should not impose TRIPS-plus obligations on LDCs.²⁴

Article 5.9 18-Months Publication

[AU/NZ/JP/CN/IN/KR propose; ASN oppose:

1. Each party shall publish any patent application promptly after the expiry of 18 months from its filing date or, if priority is claimed, from its priority date, unless the application has been published earlier or has been withdrawn, abandoned or refused.
2. Each Party shall provide that the applicant may request the early publication of an application prior to the expiry of the period mentioned in paragraph 1.]

[AU/NZ propose: [PLACEHOLDER FOR SUBPARAGRAPH ON ESSENTIAL SECURITY INTERESTS, PUBLIC SAFETY OR PUBLIC ORDER, DEPENDING ON PRESENCE OF GENERAL PROVISIONS FOR THE ENTIRE AGREEMENT.]]

After a patent application is filed, it is published by the patent office for the public to view even if it hasn't been granted as a patent yet. Published patent applications can also be searched on the patent office's website. The Patent Cooperation Treaty (PCT) requires that all patent applications be published by 18 months from the earliest effective filing date. The applicant can also request early publication. Making it easier for applicants to publish earlier means there will be more prior art for subsequent applications to reconcile.

Australia and New Zealand propose a placeholder for the governments to prevent publication due to national security, public safety or other reasons, for instance cyber security.

Article 5.10 Patent Cooperation Treaty

Each Party shall endeavour to accede to the Patent Cooperation Treaty 1970 (as amended in 1979), where it is not already a Party to such treaty. In doing so, a Party can seek to cooperate with other Parties to support such accession.]³²

Footnote 32: Negotiators' Note: Australia/Korea/Japan support accession to the PCT, but prefers a chapter structure where treaties are dealt with under a single Article or Paragraph.

²⁴ See, Third World Network, *Intellectual Property and Least Developed Countries (LDCs), Protect Transition Period for LDCs, Civil Society Letter to Countries Negotiating Regional Comprehensive Economic Partnership (RCEP) Before The Auckland Round Of Negotiations*, 10 June 2016. Available at: <http://www.twn.my/title2/health.info/2016/hi160606.htm>.

The Patent Cooperation Treaty (PCT) is an international treaty with more than 145 Contracting States. The PCT makes it possible to seek patent protection for an invention in a large number of countries in an expedited manner through the mutual recognition of the filing procedures. Accordingly, PCT generates an ‘international’ patent application that is recognized procedurally by PCT member states, securing the priority rights of the first applicant in multiple countries simultaneously, and speeding up the filing process at national levels.²⁵ The provision requires Parties to ratify or accede the PCT, entailing the obligation of recognizing PCT patent filings at national levels. PCT does not extend mutual recognition of substantive patent standards.

For countries that are not PCT members, or have no obligation of receiving patent applications, this provision imposes additional obligations. For instance, with the exemption from implementation of TRIPS that has been granted to LDCs, these countries have no obligation to receive, examine and grant patents. Acceding to PCT on another hand would override this flexibility.

We recommend that the LDC RCEP-negotiating countries be exempt from the proposed obligation to join the PCT.

Note: More comments on the issue of LDC transition period are also read with Article 12 in later text.

Article 5.11 Client-Attorney Privilege

AU propose; ASN/IN/CN/KR oppose:

Each Party shall ensure that a communication made for the dominant purpose of, an intellectual property advisor providing professional advice on or relating to intellectual property rights to a client, shall be recognized as confidential to the client and shall be protected from any disclosure to third parties, unless it is or has been made public with the authority of that client.]

The attorney-client privilege protects confidential communication between a client and his or her attorney from public disclosure. This provision extends attorney-client privilege to IP advisors by characterizing the work of IP advisors providing professional advice on or relating to IP rights to a client as confidential.

Around the world, the scope and availability of the attorney-client privilege varies widely. In the United States, technical information conveyed from an inventor to a patent attorney is protected under the attorney-client privilege, as long as the purpose is to obtain legal advice and services. Attorney-client privilege in the European Patent Convention applies to any communication or document relating to (a) the assessment of the patentability of an invention; (b) the preparation or prosecution of a European

²⁵ World Intellectual Property Organization, *PCT – The International Patent System*, Geneva: WIPO. Available at: <http://www.wipo.int/pct/en/>.

patent application; (c) any opinion relating to the validity, scope of protection or infringement of a European patent or a European patent application.²⁶ In other legal systems, such as India, patent advisors are not granted the same privilege as lawyers.

The proposed provision has a very broad scope. There are variety of rules on privilege and a professional secrecy obligation, which is shaped by the civil procedure laws. Patent advisors, attorneys or agents in many countries are subject to significantly different professional qualification and regulations from other legal professions. Shielded by the new legal protection provided by client-attorney privilege, patent advisors may refuse full disclosure to patent offices and courts, which could prevent the authorities from getting full evidence needed to conduct examination and court proceedings.

This issue goes well beyond RCEP. At a global level, developing countries have long resisted calls by developed countries for the World Intellectual Property Organisation (WIPO)'s Standing Committee on the Law of Patents to develop non-binding standards on confidentiality of communications between patent attorneys and their clients. For instance, India has reiterated that neither the Paris Convention for the Protection of Industrial Property nor the TRIPS Agreement provided for any such privilege. India is concerned that harmonizing client-attorney privilege would imply harmonizing the exceptions to the disclosure requirement, and Indian law does not provide privilege to patent agents.²⁷

We recommend that RCEP negotiating parties reject this provision.

Article 5.12 Worldwide Novelty for Patents

(Note: This provision should be read in conjunction with Article 5.5.)

²⁶ European Patent Office, *Rule 153, The European Patent Convention*. Available at: <https://www.epo.org/law-practice/legal-texts/html/epc/2013/e/r153.html>.

²⁷ See Para. 203, SCP/23/6, Report of the 23rd Session of the Standing Committee on the Law of Patent, WIPO, Available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_23/scp_23_6.pdf, July 05, 2016. The Indian Delegation noted that, "in the Indian patent system, persons who graduated in science or engineering were qualified to practice as patent agents after passing the Indian Patent Agents examination, even without having a law degree. The Delegation explained that the Indian Evidence Act provided protection for lawyers from discovery proceedings, and that a patent agent, being a person of scientific background, did not fall under such protection. The Delegation observed that, since such disclosure might help the courts in the final determination of substantive issues such as novelty, inventive step, industrial applicability and sufficiency of disclosure, such privilege might be detrimental to the patent system".

[JP/NZ propose; ASN/IN oppose:

Each Party shall ensure that a claimed invention shall not be new, if it is [NZ propose: made available to the public by written or oral description or in any other way] [NZ oppose: [CN propose: known to the public] [CN oppose::publicly known], [CN oppose: described in a publication distributed or made available to the public through [JP propose: the internet]]] in any Party or in any non-Party before the filing date of the application for a patent, where priority is claimed, before the priority date of the application.]

According to the worldwide novelty requirement (absolute novelty), any public disclosure of the invention before the date of filing, or before the date of priority if a priority is claimed, potentially counts as the prior art. It is therefore imperative that the novelty will only be upheld if the application is filed (either in that country or in any other Paris Convention country) before the invention is made public, which includes written or oral disclosures, sales, demonstrations, use or disclosures made in any other way. China introduced absolute novelty during its patent law revision in 2008.

Absolute novelty provides a stricter patentability criterion on novelty. But how such criterion should be qualified requires more detailed provisions. Patent systems that are not based on searching both written and oral prior art for absolute novelty may promote granting of erroneous patents or other forms of misappropriation of genetic resources and traditional knowledge. The difference between “known to the public” and “publicly known” becomes critical. “Publicly known”, could require patent examiners to prove the information has not just been disclosed in written or oral forms (normally sufficient to establish the prior art), but is also well known to the public. China has therefore rightly opposed this terminology.. Requiring the information not only be publically disclosed but also be actually well known represents a more demanding standard that could be beyond what the conventional searching practices can achieve.

Although absolute novelty introduces stricter patentability on novelty, the implementation requires sufficient searching capacity of the national patent offices, and therefore no additional requirements should be imposed to the office to prove what is beyond what the searching and examination practices could achieve in practice.

We recommend that RCEP negotiating parties keep sufficient flexibility in introducing a worldwide novelty requirement, taking full consideration of the differences in national laws, practices and capacities. RCEP must not introduce excessive obligations in this regard.

Article 5.13 Patent Term Restoration

[JP/KR propose; ASN/IN/AU/NZ/CN oppose:

1. With respect to the patent which is granted for an invention related to pharmaceutical products, 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.]

[2. For the purposes of paragraph 1:

- (a) “compensatory term of protection” means an extension of a term of patent protection;
- (b) “marketing approval” means approval or any other disposition by the competent authorities that is intended to ensure the safety and, where applicable, efficacy of the pharmaceuticals as provided for in the relevant laws and regulations of each Party; and
- (c) the length of the compensatory term of protection shall be equal to the length of extension which the patentee requests, provided that the compensatory term of protection shall not exceed either the length of time during which the patented invention cannot be worked due to marketing approval processes, or a maximum term as provided for in the laws and regulations. Such maximum term shall be at least five years.]

[KR propose: ASN/IN/AU/NZ/CN/JP oppose: 3. Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this subparagraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays].]

Patent term extension, known as ‘Patent Term Restoration’ in the negotiations, is a straightforward tactic to extend a pharmaceutical company's monopoly by extending the life of a patent on a medicine beyond 20 years. The extra years added to the patent are additional years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.

Japan and South Korea’s proposed provision on patent term extension applies to patents related to pharmaceutical products. Patent term extensions significantly delay market entry of generic medicines and restrict access to affordable medicines.

The text prescribes the period of patent term extensions, i.e. the compensatory term of protection, which shall not exceed either the length of time during which the patented invention cannot be worked due to marketing approval processes, or a maximum term (at least five years) as provided for in the laws and regulations.

South Korea’s proposed provision introduces patent term extension for the patent examination period. The provision mimics the language of Article 18.8.6 (a) of the Korea-US trade agreement (KORUS), which requires patent term to be extended to compensate for unreasonable delays during prosecution (i.e., a delay after four years from filing or three years from requesting examination, whichever is later).

Patent term extensions for patent office delays not only allow patent owners to postpone patent expiry, but they increase regulatory uncertainty and place an unnecessary burden on patent offices.

In the negotiations leading to the WTO TRIPS Agreement, patent terms were extended to 20 years from the date of filing the application. At the time, developed countries provided for patent terms ranging from 15 to 17 years, whilst in certain developing countries, patents were granted for shorter terms of 5 to 7 years. For example, the mandatory 20-year period is 13 years longer than the period for which India previously granted patents, and takes into account the known delays in regulatory processes or examination system. Any further patent term extensions to compensate for regulatory delays in the marketing of new pharmaceutical products were raised in the Uruguay Round negotiations but firmly rejected by a number of countries. It is important to note that there is no obligation, from an international/legal perspective, to grant such extensions²⁸. There are no benefits vis-à-vis the development of new drugs as such a provision merely extends the patent term on an old medicine; and further prevents competition by delaying the entry of medicines into the public domain, undermining the goal of affordable access to existing medicines.

We recommend that RCEP negotiating parties reject any proposal to introduce patent term restoration.

Article 5.14 Ensuring Any Person May Provide Information that Could Deny Novelty or Inventive Step

JP/KR/IN/NZ/CN propose; ASN oppose:

Each Party shall establish or maintain a system which provides, before granting a patent, [NZ/CN/IN/KR propose: at least] one of the following:

- (a) an opportunity for any person to provide the competent authority with information that could deny novelty or inventive step of an invention claimed in the patent application; o
- (b) an opportunity for any person to file an opposition against the patent application.]

Third-party (pre-issuance submissions) and pre-grant oppositions are both important tools to assist the patent office in determining the patentability of the invention before the grant or rejection of the patent and to increase the validity and quality of the granted patents.

Provisions for third parties (pre-issuance submissions) are established in certain jurisdictions like the UK, EPO, US, China and the PCT.²⁹ Third-party submissions provide an opportunity for any person to

²⁸ WHO, *SEARO Briefing Note: "Data Exclusivity and Other TRIPS Plus"*, March 2006. Available at: http://donttradeourlivesaway.files.wordpress.com/2010/12/global_trade_and_health_gth_no3.pdf

²⁹ For more information of the third party observation and patent opposition mechanism in multiple countries, please refer to the working report of WIPO Standing Committee on the Law of Patents, 'Opposition Systems and Other Administrative Revocation and Invalidation Mechanism', SCP/18/4, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf.

make observations on pending patent applications, before the decision is made on the grant or rejection of the patent application in question, if they believe that the claimed invention either lacks novelty or inventive step. However pre-grant submissions or observations do not allow the person filing the opposition to be heard and so do not make him/her party to the proceedings.

Pre-grant opposition procedures usually permit broader participation. Any person, including researchers, NGOs, health organizations, and market competitors who oppose a patent application can submit any information or analysis to patent examiners and bring prior art (publications, prior use, and other forms of disclosures of existing knowledge that may pre-empt the requested patent) to their attention. If the opposition is found to be valid, a statutory procedure has to be followed – including hearings and providing all material filed by the patent application to the opponent before an examiner can decide whether a patent can be granted or not. Pre-grant opposition procedures improve transparency, quality and efficiency of patent office examinations, and can help safeguard access to affordable medicines.

However, third party submissions as proposed under this draft provision are limited to prior art on novelty and inventive step; third parties cannot challenge patent claims for failure to demonstrate “industrial applicability”. This is a narrow approach and does not reflect the existing practices of RCEP negotiating countries. For example, India’s patent law allows pre-grant opposition on grounds of non-compliance with the requirement of section 8, wherein details of the corresponding application are required to be provided to the Indian Patent Office and the provision also gives power to the Controller to ask for any information regarding the 'processing' of the application in a country other than India at any time before the grant of patent. It is pertinent to mention here that the failure to disclose information required under section 8 of the Act is a ground for pre grant opposition [section 25(1)(h)] of the Act.

This proposed provision should include all possible grounds for filing a pre-grant opposition or third party observation, and should be strengthened to include a pre-grant and post-grant opposition system permitting all stakeholders, including patient groups, to be party to the proceedings in challenging evergreening patent claims.

We recommend that the proposal for establishing pre-grant opposition or third party observation procedures to be strongly supported by RCEP negotiating parties with amendments to including all possible grounds of patentability criteria to be eligible for third party observations and pre-grant oppositions, and to introduce post-grant opposition procedure as a further safeguard.

Article 5.15 Prohibition of Requiring the Certification of Translation

[JP/KR propose; ASN/IN/NZ/AU/CN oppose:

A Party may require the certification of translation of an earlier application for a patent whose priority is claimed only when the office has reasonable doubt as to the accuracy of the translation.]

If the priority document is in a language other than the official language of a country where the patent application is filed, a patent office usually requires a translation of the priority documents to enable the examination and other legal proceedings. Japan and South Korea's proposed provision intends to restrict the current practices by many countries and could create an unnecessary burden (i.e. proof of reasonable doubt) for the patent offices and courts in carrying out examinations and legal processes based on documents untranslated in foreign languages.

We recommend that RCEP negotiating parties reject this proposal.

Article 5.16 Treatment of Test Data in Marketing Approval Procedure

JP/KR propose; ASN/AU/IN/NZ/CN oppose:

Each Party shall prevent applicants for marketing approval for pharmaceutical products which utilize new chemical entities from relying on or from referring to test or other data submitted to its competent authority by the first applicant for a certain period of time counted from the date of approval of that application. As of the date of entry into force of this Agreement, such period of time is stipulated as being no less than five years by the relevant laws of each Party.]

The practice of including data exclusivity provisions in trade agreements started with the US incorporating the terms in the Central American Free Trade Agreement (CAFTA) negotiations and pressuring Central American countries to accept. Since then, Japan, the European Commission and Switzerland have been pushing for data exclusivity provisions that favour their pharmaceutical industries in bilateral trade negotiations. In RCEP, Japan and South Korea's proposed provision provides very strict data exclusivity for the test or other data submitted to the marketing approval authorities. It only applies to small molecules (pharmaceutical products which utilize new chemical entities) and does not cover biologics. The exclusivity applies to the test or other data submitted by the first applicant in support of marketing approval, which may well be disclosed and in the public domain.

The provision prevents the drug regulatory authority from considering a generic applicant's dossier for marketing approval during the exclusivity term. Other applicants (generic companies) have to wait until the end of five years to make their application for marketing approval. This would, in practice, provide the first applicant (innovator) another one to two years of market monopoly after the data exclusivity period expires before a generic could be approved and enter the market. This is because it takes that long for the drug regulatory authority to analyse the generic's application and grant it marketing approval. This provision is more aggressive than the (market) exclusivity provision in the TPP.³⁰

³⁰Article 18.50 of the TPP (Protection of Undisclosed Test or Other Data):

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar⁵² product on the basis of:

(i) that information; or

Since a pharmaceutical manufacturer is not permitted to place an equivalent generic pharmaceutical product on the market without prior drug regulatory authority registration, it works as an effective barrier to competition.

The barriers posed by data exclusivity are not easy to overcome. Apart from the bio-equivalence data,³¹ which is currently required, producers of generic medicines, if they intend to get approval before the data exclusivity period concludes, will have to repeat clinical trials – country by country – to generate a new set of safety and efficacy data, a process that takes years and involves costs that these companies usually cannot afford. More importantly, repeating clinical trials – solely for registering a generic version of a treatment already proven to be safe and effective – is unethical.

Perhaps the key concern regarding data exclusivity is that it provides a backdoor for multinational pharmaceutical companies to ensure they continue to have a monopoly on off-patent products. Exclusive rights over pharmaceutical test data guarantees that a competing drug cannot be registered. Thus pharmaceutical companies can enjoy monopolies on a large number of medicines and can charge high prices even when the drug's patent was never filed, has expired, or if the drug has been found to be not patentable. By allowing for monopoly rights even when patents are not granted or have expired, data exclusivity protects pharmaceutical companies from price-busting generic competition.

One of the first examples of data exclusivity being applied to restrict access to affordable medicines is CAFTA's data exclusivity and patent rules as implemented in Guatemala through domestic law and regulation limiting access to some generic drugs. A 2009 paper reported that a number of drug companies that formerly sold registered generic versions³² of clopidogrel bisulfate used to treat myocardial infarction had their registration revoked in Guatemala.³³

In another example, as a part of the U.S.-Jordan trade agreement, Jordan implemented data exclusivity. A study by Oxfam found that of 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79% had no competition from a generic equivalent as a consequence of data

(ii) the marketing approval granted to the person that submitted such information, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

³¹ Bio-equivalence tests are much smaller in scale than full-fledged clinical and pre-clinical trials. Thus, they can be conducted faster and are considerably less expensive.

³² Ellen R Shaffer and Joseph E. Brenner, 'A Trade Agreement's Impact on Access to Generic Medicines,' *Health Aff September/October 2009 vol. 28 no. 5 w957-w968*. Available at:

<http://content.healthaffairs.org/content/28/5/w957.full> . Generic companies affected by the case include Roemmers S.A. (Uruguay), Piersan (Guatemala), Panalab S.A. (Argentina), and Biocross (Guatemala)

³³ Ellen R Shaffer and Joseph E. Brenner, 'A Trade Agreement's Impact on Access to Generic Medicines,' *Health Aff September/October 2009 vol. 28 no. 5 w957-w968*. Available at:

<http://content.healthaffairs.org/content/28/5/w957.full> .

exclusivity. The study also found that prices of these medicines under data exclusivity were up to 800% higher than in neighbouring Egypt.³⁴

A 2010 study also revealed that once Guatemala enacted data exclusivity, on the basis of the Dominican Republic-Central America FTA (DR-CAFTA), some medicine prices rose as much as 846% – even though just a handful of medicines were under patent protection. In this case, data exclusivity has provided a distinct monopoly from patent rights that has resulted in high prices.³⁵

The New England Journal of Medicine published an additional case study of how data exclusivity raises the price of medicines even when no patent exists. In the US, the price of colchicine, a treatment used mainly for gout, rose more than 5000% after data exclusivity was enacted. Colchicine has been in use for thousands of years (traditional medicine), costs almost nothing to produce, and cannot be patented. Therefore, generic formulations of the tablet have been widely available since the 19th century. However, a new monopoly on colchicine was created in 2009 when the FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma. URL Pharma subsequently sued to force other manufacturers off the market and raised prices from USD 0.09 to 4.85 per pill.³⁶

Key RCEP countries like India do not have access-restricting exclusivity rules, but rather allow generic companies to register products and come on the market through bio-equivalency demonstration at any point. In such countries, the only marketing monopoly companies receive is through the patent system rather than the registration system. This is a pro-access to medicines approach. This approach emphasizes that the registration of products should not erect barriers to otherwise legitimate competition. It holds, instead, that the registration system should promote price competition and access to more affordable medicines.

Another problem is that originator companies often register their medicines in developing countries very late, a delay known as ‘regulatory lag’, focusing first on the ‘wealthy markets’. When this is the case, data exclusivity can then provide them with additional incentives to delay registration as the period of a data exclusivity monopoly is calculated from the date of registration.

We recommend that all RCEP negotiating parties reject any proposal to introduce a data exclusivity obligation.

³⁴ Oxfam, ‘All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines’, March 2007. Available at <https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf> .

³⁵ Ellen R Shaffer and Joseph E. Brenner, ‘A Trade Agreement’s Impact on Access to Generic Medicines,’ *Health Aff September/October 2009 vol. 28 no. 5 w957-w968*. Available at: <http://content.healthaffairs.org/content/28/5/w957.full> .

³⁶ Kesselheim, AS, Solomon, DH, ‘Incentives for Drug Development —The Curious Case of Colchicine’, *N Engl J Med* 2010, 362:2045-2047.

Article 5.17 Patents Protection

[KR/JP propose; ASN/IN oppose: 1. 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.

[JP propose; ASN/IN oppose: 2] Recognizing the importance of improving the convenience of the applicants, each Party agrees to cooperate to enhance the accelerated examination system. Such cooperation may include:

- (a) reducing the pendency of accelerated examination;
- (b) expanding the eligibility for accelerated examination;
- (c) simplifying the procedural requirements for accelerated examination.]

[CN propose; ASN/IN/NZ oppose: 1. Procedures concerning the patent examination shall not be unnecessarily complicated, or entail unwarranted delays.]

[CN propose; ASN/IN oppose:

2. Each Party endeavour to provide an applicant with accelerated examination for the patent application in accordance with each Party's laws, regulations and rules.]

The accelerated examination system enables patent examination to be conducted more quickly than conventional patent examination. After a patent application has been filed, a patent applicant can request expedited examination, usually on the payment of additional fees. However, there is a real and present threat that this will lead to erroneously granted or low-quality patents, which are problematic for society because they reward undeserving parties and restrict access to the patented subject matter. The real problem is patent quality, not the pace of patent examination. Thus, the focus should be on improving the quality of patent examination globally and prioritizing quality over speed.

We recommend that all RCEP negotiating parties reject this provision.

Provision on LDC Transition

Section 12

Article 12 Transitional Periods and Arrangements [Please read with analysis of Article 5.7 TRIPS Flexibilities on Compulsory Licenses and LDC Extensions.]

ASN/IN/NZ/CN propose: SECTION12

AU oppose: SPECIAL AND DIFFERENTIAL TREATMENT]

[AU propose: ADDITIONAL FLEXIBILITIES FOR LDC], TRANSITIONAL PERIOD AND TRANSITIONAL ARRANGEMENTS

[JP oppose:

1. The Parties shall recognise [AU oppose: appropriate] [AU propose: the] forms of flexibility [AU oppose: as] agreed by the Council for TRIPS, including [AU oppose : provisions for special and differential treatment and] additional flexibilities accorded to least developed countries under Articles 65 and 66 of the TRIPS Agreement, and the provisions for patent protection of pharmaceutical and agricultural chemical products under paragraph 8 of Article 70 of the TRIPS Agreement, consistent with existing FTA obligations of the Parties, where applicable.]

2. Nothing in this chapter shall derogate from any transitional [JP oppose: period] [JP propose: measure] for implementing a provision of the TRIPS Agreement that has been or may be agreed [JP oppose: by the Council for TRIPS, established pursuant to Section IV of the WTO Agreement] [JP propose: under the WTO], either prior or subsequent to the entry into force of this Agreement.]

3. [JP propose: A Party shall not be obliged to apply the provisions of this Chapter, except Articles XX(FN47) as long as the Party is recognized as least-developed country by the United Nations and not required to apply the provisions of the TRIPS Agreement.]

Footnote 47: To be determined, at least including] National Treatment provisions and other provisions that the Party] can implement)

This provision addresses the transition period arrangements for LDCs and provides that the flexibilities and transitional arrangements for LDCs under Article 65 and 66 of the TRIPS Agreement shall apply. However, footnote 47 suggests that LDCs may still be required to implement some provisions in the draft RCEP IP Chapter. The Parties should recognize and uphold the current transition periods and waivers vis-a-vis intellectual property granted to LDCs as well as any further extensions of these transition periods and waivers by the WTO.

We recommend that the RCEP Agreement text encourage LDCs to fully utilize existing TRIPS transition periods. In addition, countries negotiating RCEP should not impose TRIPS-plus obligations on LDCs.³⁷

Enforcement: General Provisions

The draft RCEP text on enforcement omits several procedural guarantees, safeguards and protections in TRIPS with several proposals going beyond TRIPS in further protecting monopolies at the expense of access to medicines. RCEP provisions and those of the Anti-Counterfeiting Trade Agreement (ACTA) and TPP are uncomfortably close. It should be noted that even the controversial ACTA allows countries

³⁷ Third World Network, *Intellectual Property and Least Developed Countries (LDCs), Protect Transition Period for LDCs, Civil Society Letter To Countries Negotiating Regional Comprehensive Economic Partnership (RCEP) Before The Auckland Round Of Negotiations*, 10 June 2016. Available at <http://www.twn.my/title2/health.info/2016/hi160606.htm>

to exclude patents and test data from the scope of the civil and border enforcement provisions (Footnote 2 and 6 of the ACTA final text).

Article 9.3

AU/JP/NZ/KR propose; ASN oppose:

In implementing the provisions of this Section, each Party shall take into account the need for proportionality between the seriousness of the infringement, the interest of third parties, and the applicable measures, remedies and penalties.

Enforcement of IP rights should not be abusive or disproportionate. This provision concerning proportionality is not found in the TRIPS Agreement but in the European Directive on the enforcement of intellectual property rights (2004/48/EC) and ACTA. When applied to enforcement provisions, it requires assessment of the potential impact of those provisions with several other rights.

We recommend that RCEP negotiating parties reject this provision.

Article 9^{bis}.1

KR/AU propose; ASN oppose:

1. Each Party shall make available to right holders [39] civil judicial procedures concerning the enforcement of any intellectual property right covered by this Chapter.

Footnote 39: ¹[KR/AU propose: For purposes of this Article, “right holder” includes a federation or an association having the legal standing and authority to assert such rights, and also includes a person that exclusively has any one or more of the intellectual property rights encompassed in a given intellectual property.]

One of the most disturbing features of the proposed text on enforcement measures is its broad scope and coverage, which includes a range of obligations. Whilst part III of the TRIPS Agreement dealing with enforcement of intellectual property is inclusive and covers patents within its scope, it is important to note that the few stringent enforcement provisions and remedies required by the TRIPS Agreement are limited to trademark counterfeiting and copyright piracy only and not to allegations of patent infringement.³⁸ This distinction reflects the fact that claims of patent infringement are complex and cannot be determined easily. Such claims require a technical analysis of the extent of the patent claim

³⁸ See Articles 46, 51, 59 and 61 of the *TRIPS Agreement 1994*.

before any decision can be reached about whether an infringement has in fact occurred. The attempt to extend these provisions is TRIPS-plus.

As an important safeguard measure, we recommend that RCEP negotiating parties should insist on the deletion of patents and test data from the entire scope of the enforcement section.

Article 9^{bis}.2

[JP/KR/AU propose ; ASN/IN oppose: Article 9^{bis}.2]

Civil and Administrative Procedures and Remedies

Each Party shall provide that in civil judicial proceedings [JP/KR/AU propose: concerning the enforcement of intellectual property rights], its judicial authorities [KR/AU propose: shall] have the authority to order the infringer [JP/AU propose: who, knowingly or with reasonable grounds to know, engaged in infringing activity] to pay the right holder:

- (i) damages adequate to compensate for the injury the right holder has suffered as a result of the infringement [KR propose: ³⁹; or

[AU/KR propose : at least in the case of copyrights or related rights infringements and trademark counterfeiting,] the profits of the infringer that are attributable to the infringement which may be presumed to be the amount of damages referred to in clause (i). In determining [JP/AU propose: the amount of] damages [KR/AU propose: for infringement of intellectual property rights] [JP/AU/KR propose: referred to in the paragraph above], [JP/AU propose: a Party's] judicial authorities shall have the authority to consider, inter alia, [JP/KR propose: any legitimate measure of value the right holder submits, [KR/AU oppose: which may include lost profits,]] the value of the infringed [JP/KR/AU propose: goods or services], measured by the market price, [JP/AU/KR propose: or] the suggested retail price.]

This provision is unbalanced. Generic suppliers who infringe a trademark, and potentially a patent unless RCEP countries specifically opt - out of its application, may face disproportionate damages which include any measure of value (e.g. lost profits, market and retail price) that the right holders submits to judicial authorities, which could lead to bankruptcy in some cases.

However, current flexibilities in IP rules allow, for example, judicial discretion to balance commercial interests with the right to health in IP disputes involving lifesaving medicines. For example, in India in a

³⁹ [KR propose: In the case of patent infringement, damages adequate to compensate for the infringement shall not be less than a reasonable royalty.]

case involving the Swiss multinational pharmaceutical company Roche and the Indian generic company Cipla, the Delhi High Court observed that in the case of pharmaceutical products, courts have to tread with care.⁴⁰ In the case of an essential pharmaceutical product, courts may decide to award reasonable royalties and token damages.⁴¹

We recommend that RCEP negotiating parties, as a minimum, insist that the provision on damages apply to trademark counterfeiting on a commercial scale and not apply to infringement cases involving patents, test data and civil trademark disputes.

Article 9^{bis}.4

KR/AU propose; ASN oppose:

Each Party shall provide that its judicial authorities, [JP oppose: except in exceptional circumstances] [JP propose: where appropriate,] shall have the authority to order, at the conclusion of civil judicial proceedings concerning copyright or related rights infringement, [AU oppose: patent infringement,] or trademark infringement, that the prevailing party shall be awarded payment by the losing party of court costs or fees and reasonable attorneys' fees.]

This provision goes beyond the TRIPS Agreement. Article 45.2 of the TRIPS Agreement only requires that courts have authority to order the infringer to pay the right holder expenses, which may include attorneys' fees. IP infringement suits can be costly, especially when the right owner is a big company with expensive lawyers. Legal costs can pressure defendants to settle for fear of having to pay legal costs that cannot necessarily be predicted in advance. Thus, an award of attorneys' fees should stay within the court's discretion - there must be clear guidelines described in various cases for courts to follow to ensure that national IP regimes operate in the public interest. Reasonableness of a losing party's argument should be considered as an important factor when determining whether to award fees.

We recommend that South Korea and Australia withdraw this provision. India and ASEAN, and other negotiating parties should reject this provision.

⁴⁰ See *F. Hoffmann-La Roche Ltd v Cipla* (I.A 642/2008 IN CS (OS) 89/2008), 19 March 2008.

⁴¹ Basheer S, *Affordable Drugs Need a Compensatory Patent Commons*, The Wire,, 17 December 2015. Available at: <http://thewire.in/17509/affordable-drugs-need-a-compensatory-patent-commons/>

Article 9^{bis}.5

KR/AU propose; ASN oppose:

In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities shall have the authority to order the seizure of allegedly infringing goods, materials, and implements relevant to the act of infringement, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement.

This provision is clearly inspired by Article 18.75.3 of the TPP,⁴² which does not have an equivalent in the TRIPS Agreement. Counterfeit goods are defined as goods involving slavish copying of trademarks. A broad definition of trademark counterfeiting may risk wrongly detaining generic medicines, which may usefully communicate their bioequivalence to patients through similar trade names and packaging.

The provision is unbalanced as it affirms and broadens rights and protections for an IP owner seeking provisional measures, but omits most of the safeguards and limitations that TRIPS institutes around such orders,⁴³ such as:

- Parties affected must be given notice, without delay after the execution of the measures at the latest (TRIPS Art 50.4);
- A review, including a right to be heard, must take place upon the defendant's request with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed (TRIPS Art 50.4); and
- The measures must be revoked on the defendant's request if proceedings on the merits are not initiated within a reasonable period (not to exceed the longer of 20 working days or 31 calendar days) (TRIPS Art 50.6).

We recommend that RCEP negotiating parties reject this provision.

Article 9^{bis}.6

[JP/KR/AU propose ; ASN oppose: Article 9^{bis}.6

Destroying Infringing Goods and Materials and Implements

⁴²Article 18.75.3: "In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities have the authority to order the seizure or other taking into custody of suspected infringing goods, materials and implements relevant to the infringement, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement."

⁴³Kimberlee Weatherall, Section by Section Commentary on the TPP Final IP Chapter Published 5 November 2015 – Part 3 – Enforcement, Working Paper, November 2015. Available at: https://www.researchgate.net/publication/284755379_Section_by_Section_Commentary_on_the_TPP_Final_IP_Chapter_Published_5_November_2015_-_Part_3_-_Enforcement

1. With respect to at least pirated copyright goods and counterfeit trademark goods, each Party shall provide that, in civil judicial proceedings, at the right holder's request, its judicial authorities have the authority to order that such infringing goods be destroyed, except in exceptional circumstances, without compensation of any sort.

2. Each Party shall further provide that its judicial authorities have the authority to order that materials and implements, the [KR oppose: predominant] use of which has been in the manufacture or creation of such infringing goods, be, without undue delay and without compensation of any sort, destroyed or disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.]

[KR propose: 3. In regard to counterfeit trademarked goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce.]

Since this provision clearly allows for the physical seizure and destruction of goods, materials and implements used in the manufacture and/or creation of infringing goods, it is important to clearly and unambiguously ensure that in the final text the provision does not allow for any scope for the application of such measures to patents, test data and civil trademark disputes as this will have disturbing implications for access to medicines. Patients will suffer if their life-saving medicines are seized and the active pharmaceutical ingredients (API) and machinery used to make them are destroyed. Other less damaging remedies are usually prescribed by the courts in such cases, and is increasingly the norm in some common law countries.

We recommend that RCEP negotiating parties reject this provision.

Article 9^{bis}.7

[KR propose; ASN/AU/JP oppose: Article 9^{bis}.7

Each Party shall provide that in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities shall have the authority to order the infringer to provide the right holder or the judicial authorities with information that the infringer possesses or controls regarding the persons or means involved in the production and distribution of the infringing goods or services and their channels of distribution.]

Proposed by South Korea, judicial authorities would have the authority to order the infringer to disclose the identity of third parties involved in the production and distribution of the infringing goods to the right holder. This would provide the IP holder with information on the generic manufacturer's supply chain, which could be used for further legal action or the threat of legal actions against the third parties who may be part of this production and supply chain. This provision suggests that IP rights enforcement could also widen its scope to possibly embroil other third parties like treatment providers and the generic medicines distribution and supply chain, and put them at risk of civil litigation and court cases.

Even if this provision excludes patents, it does not distinguish between trademark counterfeiting on a commercial scale and civil trademark disputes. The World Trade Organization Dispute Panel notes that "trademark counterfeiting" is different from "trademark infringement".⁴⁴

It's worth noting here that trademark disputes will likely remain a common occurrence in the pharmaceutical field as companies will often chose brand names for medicines that sound inevitably similar in that they are derived from the drug's international non - proprietary name (INN). Regardless of whether similarly - named, coloured or shaped generic versions of medicines are ultimately found to infringe a valid trademark in civil litigation proceedings (and companies have the right to pursue these problems in the court), they should not be confused with trademark counterfeiting.⁴⁵ An example of civil trademark infringement was the dispute between the pharmaceutical companies Roche and Cipla before the Bombay High Court over Cipla's brand "Valcept" and Roche's "Valcyte" in respect of the antiviral drug whose INN name is valgancyclovir.

We recommend that RCEP negotiating parties ensure this provision unambiguously excludes patents, test data and civil trademark disputes from the scope of this section.

Article 9^{bis}.10 Provisional Measures

[JP/KR/AU propose; ASN oppose:

[JP propose: 1. With respect to at least pirated copyright goods and counterfeit trademark goods, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to adopt provisional measures to order the seizure or other taking into custody of suspected goods, and of materials and implements relevant to the act of infringement, and documentary evidence, either originals or copies thereof, relevant to the infringement.]

[KR/AU propose; AU propose; JP oppose: 2. Each Party shall provide that its judicial authorities have the authority to act on requests for provisional measures inaudita altera parte expeditiously.]

⁴⁴ World Trade Organization, China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362. Available at: http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds362_e.htm

⁴⁵ See World Health Organization, *Legal Aspects of Defining "Counterfeit Medicines"* (New Delhi: WHO Regional Office for South-East Asia, 2009).

[KR/JP/AU propose AU propose: 3.Each Party shall provide that its judicial authorities have the authority to require the applicant, with respect to provisional measures, to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty[AU propose: that the applicant is the right holder and] that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a reasonable security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse, and so as not to unreasonably deter recourse to such procedures.]

South Korean and Australian-proposed paragraphs mimic the TPP Agreement's Article 18.75 on provisional measures.⁴⁶ Article 50 of the TRIPS Agreement seems to be the closest equivalent with some important language differences.

Again, the provision does not distinguish between trademark counterfeiting on a commercial scale and civil trademark disputes. Further the provision does not specify what kind of provisional relief measures might be sought and omits most of the safeguards and limitations that TRIPS institutes around such orders.⁴⁷

We recommend that RCEP negotiating parties ensure this provision unambiguously excludes patents, test data and civil trademark disputes from the scope of this section.

Border Measures

The proposed RCEP text on border enforcement goes far beyond the enforcement requirements under TRIPS. For instance, the 1995 WTO TRIPS Agreement requires border measures to be used primarily on trademark counterfeiting and copyrights piracy and should not apply to 'goods in transit'. By contrast, the current RCEP text makes no reference to such an exception which is critical in safeguarding legal shipment of goods in transit and trading of generic medicines.

In addition, the TRIPS Agreement has strict procedural requirements for the right holders and other interested parties to initiate a request for border enforcement, including the obligation of providing

⁴⁶Article 18.75 of the TPP: Provisional Measures

1. Each Party's authorities shall act on a request for relief in respect of an intellectual property right inauditaaltera parte expeditiously in accordance with the Party's judicial rules.

2. Each Party shall provide that its judicial authorities have the authority to require the applicant for a provisional measure in respect of an intellectual property right to provide any reasonably available evidence in order to satisfy the judicial authority, with a sufficient degree of certainty, that the applicant's right is being infringed or that the infringement is imminent, and to order the applicant to provide security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to those procedures.

⁴⁷See, Weatherall on the TPP IP Chapter, supra note.

adequate evidence of infringement and sufficiently detailed description of the goods in dispute. Instead, the current RCEP text as proposed concerning border measures holds no requirement for the application to provide a detailed description of the goods, and also dilutes the burden of proof of the application by only asking for 'any information' that 'may' help the competent authority to enforce (See Article 9^{ter} 6 below).

Border measures that are too broad in scope or fail to include adequate safeguards can lead to customs error or abuse by the right holder, including the customs seizure of generic medicines.

The issue of abuse of border measures for IP enforcement on generic medicines is unfortunately not a new one. For example, in 2008, customs authorities, in particular in the Netherlands and Germany, detained shipments of legitimate generic drugs including antibiotics and HIV/AIDS medicines, which were in transit through the EU to patients in developing countries, on the grounds that infringed existing intellectual property rights (patents and trademarks) in the countries in transit. However, these medicines in-transit were not in actual violation of IP laws in the countries they came from or were going to, but were legitimately produced by mainly Indian generic companies and were being imported by Brazil, Peru, Colombia, Mexico, Nigeria and other developing countries at affordable prices. This resulted in the unnecessary and harmful delay of lifesaving medicine.

The relevant RCEP draft text provisions on border measures does not include the below safeguards introduced by the TRIPS Agreement:

- Article 53.2: requiring release in certain circumstances of goods involving industrial designs, patents, layout-designs or undisclosed information;
- Article 54: the importer (and applicant) shall be promptly notified of the suspension of the release of goods (this applies also to ex officio seizures: Article 58(b));
- Article 55: requiring release of the goods if within 10 working days (or 20, if extended), if the authorities have not been informed that proceedings have been initiated, or that the 'duly empowered authority has taken provisional measures prolong the suspension';
- Article 55: if proceedings have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether suspension measures shall be modified, revoked or confirmed (these to apply also to ex officio seizures: Art 58);
- Article 56: authorities to have the power to order the applicant to pay the importer, consignee and owner of the goods compensation for any injury caused to them through the wrongful detention of goods;
- Article 57: competent authorities shall have the authority to give the right holder and importer sufficient opportunity to have any detained goods inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected;

Article 58: with ex officio seizures, Parties are only allowed to exempt public authorities/officials from liability for remedial measures in those cases where actions are taken or intended in good faith (art 58(c)).

Article 9^{ter}.1 Suspension of IPR Infringing Goods by Right Holder's Request

JP/KR/AU propose; ASN oppose:

Each Party shall adopt or maintain procedures with respect to import shipments under which a right holder may request its competent authorities to suspend the release of,[AU oppose: at least,]suspected counterfeit trademark or pirated copyright goods [AU propose: in accordance with Article 51 of TRIPS].

[AU propose: Definition

“Competent authorities”; for purposes of this Chapter, unless otherwise specified, competent authorities includes the appropriate judicial, administrative, or law enforcement authorities under a Party's law.]

The provision provides border measures for suspected counterfeit trademark or pirated copyright goods. The language seems similar to Article 51 of the TRIPS Agreement, which only requires border measures for counterfeit trademark goods and pirated copyright goods. However, it does not have an explicit exception for goods in transit as it is enshrined under TRIPS Art 51, and the word “suspected” can create confusion and extended the scope of measures to trademark infringements, where there is suspicion or confusion, e.g. “confusingly similar”.

RCEP negotiating parties should ensure the provision unambiguously excludes patents, test data and civil trademark disputes from the scope of this section, and require the insertion of language that explicitly creates a safeguard for goods in transit by clearly referring to TRIPS Article 51.

Article 9^{ter}.2 Applications for Suspension or Detention

Each Party shall

(a) [AU/KR propose: provide that such applications remain in force for a period of not less than one year from the date of application, or the period that the good is protected by copyrights or the relevant trademark registration is valid, whichever is shorter] [AU/KR oppose : ensure that such request to suspend set forth in Article 9^{ter} 1 above remains in force for] [JP propose; AU/KR oppose: at least one year][] [AU oppose: ;or alternatively]

(b) [AU oppose: adopt or maintain procedures that enable a right holder to register its [JP propose: trademark or copyright] [KR propose: rights], which remains in force for at least one year, in order to request the competent authorities to suspend the release of suspected goods.]]

This proposal is a TRIPS-plus measure. There is no such procedural requirement to allow less than one year of validity of the application for suspension or detention, and allow the right holder to register its trademark or copyrights half way through to allow the suspension. Such requirements do not exist in TRIPS, and could possibly create illegitimate privileges for the right holder and disrupt the rule of law upon which enforcement can only occur on established registration of right rather than enabling the creation of new rights in the middle of the law enforcement.

We recommend that RCEP negotiating parties reject this provision.

Article 9^{ter}.10 Suspension of IPR Infringing Goods by Right Holder's Request

JP/KR/AU propose; ASN oppose:

Each Party shall adopt or maintain procedures with respect to import shipments under which a right holder may request its competent authorities to suspend the release of, [AU oppose: at least,]suspected counterfeit trademark or pirated copyright goods [AU propose: in accordance with Article 51 of TRIPS].

[AU propose: Definition

“Competent authorities”; for purposes of this Chapter, unless otherwise specified, competent authorities includes the appropriate judicial, administrative, or law enforcement authorities under a Party's law.]

This provision outlines what goods will attract the border detention and seizure measures on goods like pharmaceutical products that infringe IP. The provision provides border measures for suspected counterfeit trademark or pirated copyright goods. The language seems similar to Article 51 of the TRIPS Agreement, which only requires border measures for counterfeit trademark goods and pirated copyright goods and does not cover patents. However, the word “suspected” can create confusion and extended the scope of measures to trademark infringements, where there is suspicion or confusion, e.g. ‘confusingly similar’ trade names of a pharmaceutical product by an originator and generic company who often use part of the drug’s international non - proprietary name (INN) to develop their individual branded medicines. Detentions on grounds of trademark infringement can also disrupt supply of medicines and should also be taken into consideration.

The impact of overreaching IP enforcement border measures has already been documented. For example, in 2009 a consignment of generic amoxicillin, an essential antibiotic, was seized at Frankfurt airport by customs officials that suspected the drug had infringed the trademark ‘Amoxil’ owned by GlaxoSmithKline (GSK). It was released only once GSK confirmed that there was no trademark infringement as amoxicillin is an international non-proprietary name (INN) in the public domain, and as such is not the property of GSK. These antibiotics originated in India and were destined for Vanuatu, a

UN-classified ‘least developed country’⁴⁸. Such seizures delay the arrival of needed medicines and have been the subject of a WTO complaint by India, Brazil, Canada against the European Union.⁴⁹

While patented products have been excluded from the ‘enforcement of border measures’, a broad definition of trademark counterfeiting may risk wrongly detaining generic medicines. In the pharmaceutical field, companies will often chose brand names for medicines that sound inevitably similar in that they are derived from the drug’s international non - proprietary name (INN).

We recommend that RCEP negotiating parties include sufficient public health safeguards in the provisions concerning suspension of goods in transit, make explicit exception to legitimate generic medicines, and adopt strict procedural requirements for the rights holders in initiating such a process.

Article 9^{ter}.4 Information Provided by Competent Authorities to Right Holders

JP/KR/AU propose; ASN oppose

Without prejudice to a Party’s laws pertaining to the privacy or confidentiality of information, [AU propose: where its competent authorities have detained or suspended the release of goods that are suspected of being counterfeit trademark goods or pirated copyright goods, a Party may provide that its competent authorities have the authority to inform the right holder of] [AU oppose: with respect to import shipment, a Party shall authorize its competent authorities to provide a right holder with information about goods, including the description and quantity of the goods,] the name and address of the consignor, importer, exporter, or consignee, [AU propose: a description of goods, quantity of goods] and, if known, the country of origin of the goods [AU oppose:, and the name and address of the manufacturer of the goods, to assist in the determination of whether, at least, suspected counterfeit trademark or pirated copyright goods are infringing intellectual property rights.]]

AND

Article 9^{ter}.6 Information Provided by Right Holders to Competent Authorities

JP/KR propose; ASN oppose Each Party shall ensure that the right holder may provide within a reasonable period any information that may assist the competent authorities in the determination

⁴⁸ Medecins Sans Frontieres Access Campaign, *The enforcement provisions of the EU-India FTA: Implications for Access to Medicines*, January 2013, MSF. Available at: http://www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/Access_Brief_FTAEnforcement_ENG_2013.pdf

⁴⁹ See summary of the dispute to date, WTO Dispute Settlement DS-408. Available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm

of whether [AU oppose:, at least,] suspected counterfeit trademark or pirated copyright goods are infringing intellectual property rights.]

The above two proposed provisions read together consist of a TRIPS-plus measure concerning the burden of proof obligation undertaken by the right holders when requesting enforcement measures.

TRIPS says the applicant 'shall be required' to provide evidence to be adequate in satisfying the competent authority and to establish a *prima facie* infringement, with sufficiently detailed description of the goods.⁵⁰ In the above proposed provisions of RCEP, the requirements for evidence and description are very loose.

Under Articles 9^{ter} 4 and 6, there are no requirements at all for the applicants to provide sufficiently detailed description of the goods that are to be recognised by the authority, which is a requirement under TRIPS Article 52. Under TRIPS, in order to initiate border measures, right holders are required to “supply a sufficiently detailed description of the goods to make them readily recognizable by customs”.⁵¹ Instead, the Japan/Korea proposed provision obligates the competent authority to be the one to provide information to the application with description of the goods.

The provision under proposed Article 9^{ter} 6 dilutes every single requirement under TRIPS Articles 51 and 52 for custom authorities to initiate border measures. Instead of the applicant 'shall' provide evidence, the current text only says the applicant 'may' have such obligation. In addition, instead of requiring the evidence to be adequate in establishing *prima facie* case with detailed description of the goods, the current text only asks for 'any information'.

We recommend that RCEP negotiating parties reject these two provisions.

Article 9^{ter}.5 Suspension of IPR Infringing Goods by Ex-Officio Action

⁵⁰ Article 51 and 52 of TRIPS.

⁵¹ Article 51 and 52 of TRIPS.

JP/KR/AU propose; ASN oppose:

Each Party shall adopt or maintain procedures with respect to import and export shipments under which its [AU oppose: customs] [AU propose: competent] authorities may act upon their own initiative to suspend the release of [AU oppose: at least,] suspected counterfeit trademark or pirated copyright goods [KR propose; AU oppose: in case where there is clear evidence that the importation and exportation of the suspected goods take place].]

[AU propose: FN: A Party may comply with the obligation in this Article with respect to a determination that suspect goods under Article 9ter infringe an intellectual property right through a determination that the suspect goods bear a false trade description.]

Special, pre-emptive border measures are most logically applied only to wilful trademark counterfeiting on a commercial scale. Article 58 of the TRIPS Agreement allows for *ex officio* action to suspend and Article 51 requirements are only in relation to import. Under border measures proposed, it is certainly TRIPS-plus to require that border measures be applied to export (Art. 51 of the TRIPS agreement only requires application to IMPORTS). The provision covers imports and extends the scope to export but not to in transit goods.

A key issue is how and when the customs/competent authorities should be empowered to act. South Korea's proposal requires clear evidence that the importation and exportation of the suspected goods takes place in order to suspend the release of suspected counterfeit trademark or pirated copyright goods. On the other hand, Australia's proposal focuses on the infringing nature of goods and how infringement should to be determined. This requires a determination that the suspect goods bear a false trade description. The determination of infringing nature can be complicated in export cases where the final destination of goods may or may not be known at the time, measures are applied.

Increased enforcement of IP laws has already been used as a tool by pharmaceutical companies, which have used EU custom regulations to limit the legitimate trade in high-quality generic medicines between developing countries. Extending IP enforcement rules related to border measures to third countries through ACTA and bilateral trade agreements – which both go beyond the enforcement measures required in the TRIPS Agreement – is a US, Swiss, Japanese and EU strategy and often does not contain safeguards against abuse, widening the opportunities to disrupt the trade in generic medicines.

Overall, RCEP negotiating parties should reject border measures proposed in the agreement. They go beyond TRIPS requirements by mandating that border measures be applied to exports. Article 51 of the TRIPS Agreement only requires that countries apply border measures to imports; it does not require that border measures be applied to goods in transit or exports. This is particularly important to preserve the territoriality principle, a keystone rule of IP law. IP such as trademarks are territorial and it is for the importing country to decide if an import will breach national IP laws.

Besides patents, trademark infringement disputes that companies may have with generic competitors over similar named, coloured or shaped medicines or packaging should not be considered as wilful trademark counterfeiting (a deliberate intention to deceive) and therefore should be excluded from enforcement measures including those that authorize seizures and detention at the borders. As noted above, a safeguard limited to only excluding patents from border measures is unlikely to prevent the detention of generic medicines on grounds of trademark infringement. It is critical therefore that RCEP negotiators from India and ASEAN exclude both patents and trademark infringement disputes from the border measures proposed in the RCEP draft text.

We recommend that border enforcement in RCEP negotiations should be limited to the requirements of the TRIPS Agreement and as such should exclude exports, patents and trademark infringement. We recommend that RCEP negotiating parties give careful reading of the proposal, and reject any excessive obligations proposed that are beyond the obligations enshrined under TRIPS on suspension of infringing goods.

Criminal Remedies

The provisions on criminal remedies mostly mimic the TRIPS language, but in some instances there are similarities to the TPP provisions on criminal enforcement measures that go beyond the requirements of the TRIPS Agreement.

Article 9^{quarter}.1 Scope of IP Rights for Criminal Procedures

JP/KR/AU propose; ASN oppose:
[KR/JP propose: Each Party shall provide for criminal procedures and penalties to [KR propose: be applied; JP propose: apply] at least in cases of willful trademark counterfeiting or copyright [AU oppose: or related rights] piracy on a commercial scale.]
AU propose: Definitions
For the purpose of this Agreement; “pirated copyright goods” means any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.
For the purpose this Agreement; “copyright piracy” means making copies of material embodying content protected by copyright and/or neighbouring rights), without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the party.

The language mimics Article 61 of the TRIPS Agreement, which requires criminal procedures and penalties to apply to wilful trademark counterfeiting and copyright piracy on a commercial scale. Different from the TPP, the provision does not attempt to define “commercial scale”.⁵²⁵³

We recommend that this provision be renegotiated. The scope of IPR for criminal remedies should not go beyond the scope enshrined under the TRIPS Agreement.

Article 9^{quarter}.3 Scope of IP Rights for Criminal Procedures

[JP propose; ASN oppose:

Each Party shall provide for criminal procedures and penalties to apply in cases of willful importation [AU oppose: or production], and domestic use, in the course of trade and on a commercial scale, of labels or packaging:

- (a) to which a mark has been applied without authorization which is identical to, or cannot be distinguished from, a trademark registered in the Party; and
- (b) which are intended to be used in the course of trade in goods or supply of services, which are identical to goods or services for which such trademark is registered.]

This provision particularly addresses labels/packaging. There is no equivalent of this provision in the TRIPS Agreement but a similar provision appears in the TPP⁵⁴. The broad definition of counterfeiting may give rise to situations where there is an identical mark (i.e. colour or shape) used on packaging for a registered good, but the good is not a mere imitative substitute but a competing and even non-confusing product.

The colour, size and shape of a medicine are functional features that cannot be exclusively monopolized as trademarks. Even in the US, it is highly unlikely that valid trademark rights can ever be established for the appearance of a medicine. However, label and packaging of a medicine can be protected by a trademark (i.e. aspirin). This provision may be misused by the right holders to limit consumer access to cheaper generic medicines.

⁵²Article 18.77 of the TPP (Criminal Procedures and Penalties). See also, Weatherhall, TPP analysis, supra note, p. 46-51.

⁵³ The definition of the “commercial scale” has been subject to the WTO dispute in the context of IP enforcement. The WTO Panel confirmed that found the term ‘scale’ in Article 61 means “the magnitude or extent of typical or usual commercial activity with respect to a given product in a given market” and considering commercial scales means “compares certain things or actions in terms of their size. Some things or actions will be of the relevant size and others will not”. See World Trade Organization, *Panel Report, China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights—Report of the Panel*, WTO Doc WT/DS362/R, 26 January 2009.

⁵⁴Article 18.77.3 of the TPP

We recommend that RCEP negotiating parties reject this provision.

Cooperation and Consultation

Article 10.1 [AU/NZ oppose: Provision of Assistance] [AU/NZ propose: Cooperation: Dialogue and information exchange]

1. The Parties acknowledge the significant differences in capacity between some Parties in the area of intellectual property. Mindful of this, [AU/NZ propose : each Party shall, subject to the availability of resources, and on mutually agreed terms, upon request of any other Party engage in dialogue and information exchange on intellectual property issues.] [AU/NZ oppose: where a Party's implementation of this chapter is inhibited by capacity constraints, each other Party shall, as appropriate, and upon request, endeavour to provide cooperation to that Party to assist in the implementation of this chapter].
2. [AU/NZ oppose: At the request of a Party, any other Party may, to the extent possible and as appropriate, render assistance to the requesting Party in order to enhance the requesting Party's national framework for the acquisition, protection, enforcement, utilisation and creation of intellectual property, with a view to developing intellectual property systems that foster domestic innovation in the requesting Party].

Combined with trade-related pressures and economic power, capacity building has become an imperative tool for pushing TRIPS-plus provisions in developing countries. Given the unbalanced language of the provision focusing merely on protection and enforcement of IP, capacity building may push countries to implement RCEP early, limit use of their TRIPS and RCEP flexibilities and adopt laws that go beyond their obligations under RCEP.

Such provisions are now appearing in all trade agreements. They are troubling as it allows closed door discussions on key issues such as enforcement, which in practice leads to the increase of enforcement obligations and more restrictive application of other provisions, in ways that suits foreign right holders rather than local conditions and as such is an attempt to limit the policy space of developing countries.

We recommend that the provision to be carefully examined in the context of the impact on other public interests safeguards enshrined under TRIPS, and that RCEP negotiating parties provide sufficient flexibilities and make explicit exceptions when necessary to protect public health and public interests.

Article 10.2 Dialogue and Information Exchange

AU/NZ oppose:

The Parties agree to promote dialogue and information exchange on intellectual property issues, and, at the request of any other Party, may:

- (a) exchange information relating to intellectual property policies and developments in implementation of national intellectual property systems in their respective administrations;
- (b) encourage interaction between intellectual property experts in order to broaden understanding of each Parties' intellectual property systems;
- (c) exchange information relating to international conventions on harmonisation, administration and enforcement of intellectual property rights [CN oppose: and on activities in international organisations in international organisations, such as the World Trade Organisation and the World Intellectual Property Organisation]; and
- (d) exchange information relating to licensing of intellectual property.]]

This provision promotes dialogue and information exchange on IP issues among the Parties. Once again, the provision adopts right and protection-oriented language and fails to mention flexibilities, safeguards and exceptions.

We recommend that sufficient flexibilities and exceptions be included in such provision in conjunction with other substantive public interests safeguards enshrined under TRIPS.

Article 10.3 Cooperation

[AU oppose: Article10.3 Cooperation

AU/NZ propose: Article 10.2 Cooperation: Patent Examination, Border measures and IP Awareness]

[JP propose; IN/CN oppose: 1. [AU/NZ oppose: Each Party, recognizing ;][AU/NZ propose: Recognizing] the [AU/NZ oppose: growing] importance of protection of intellectual property in further promoting trade and investment among them, [AU/NZ oppose: in accordance with its respective laws and regulations] [AU/NZ propose: each Party shall, subject to the availability of resources, and on mutually agreed terms, upon request of another Party,][AU/NZ oppose: and subject to its available resources, shall endeavor to]cooperate with other Parties in [AU/NZ propose ; relation to Patent Examination, Border measures and IP awareness.] [AU/NZ oppose: the field of intellectual property.

Such cooperation may include:

- (a) enhancing mutual utilization of search and examination results, so as to improve quality and efficiency in its patent examination;
- (b) cooperation for the development of information technology infrastructure and database of the administrative authorities for patents of the other Parties, so as to promote efficiency and transparency in its patent examination;
- (c) in conducting training programs for patent examiners and other officials so as to

advance the capabilities of its patent offices;

(d) exchanging views and information on patent examination practice among the Parties;
and

(e) seeking improvement of patent examination practices.]]

2. [AU oppose: The Parties shall endeavour to cooperate in order to promote education and awareness regarding the benefits of effective protection and enforcement of intellectual property rights.]

3. The Parties shall cooperate on border measures [JP propose; ASN/IN oppose: such as exchanging information which is conducive to identification of suspects in importation, exportation or transit] with a view to eliminating trade which infringes intellectual property rights. Parties who are members of the WTO shall also cooperate with each other to support the effective implementation of the requirements relating to [JP propose; ASN/IN oppose: enforcement, including] border measures set out in Articles 51 to 60 of the TRIPS Agreement [JP propose; ASN/IN oppose: and this Chapter].

[AU/NZ propose; CN oppose:3bis. [AU propose: 2.] The Parties shall endeavour to cooperate among their respective patent offices to facilitate the sharing and use of search and examination work of other Parties in order to improve quality and efficiency in the Parties' patent systems. This may include making search and examination results available to the patent offices of other Parties, and exchanges of information on quality assurance systems and quality standards relating to patent examination.]

[AU propose: 4. The Parties shall endeavour to cooperate in order to promote education and awareness regarding the benefits of effective protection and enforcement of intellectual property rights.]

[ASN propose; AU oppose:4. All cooperation under this chapter is subject to the availability of resources and on terms and conditions mutually agreed upon between the Parties involved].

[AU oppose: 5. ; AU propose : 1.All cooperation under this chapter shall be harmonised with an existing regional structure such as the ASEAN Working Group on Intellectual Property Cooperation (AWGIPC).]

[JP/ASN propose; AU oppose: 6. Upon a request of a Party regarding the matters of the cooperation, protection and enforcement of the intellectual property, another Party agrees to cooperate and consider ways of reaching mutually satisfactory solution in accordance with that other Party's domestic laws and this Chapter.]

7. Each Party shall designate the contact points for the effective implementation of this paragraph.]

This provision pushes RCEP countries to accept cooperation in patent examination, including mutual search and examination results, patent examiner training and “awareness regarding the benefits of effective protection and enforcement of intellectual property rights”. The provision takes a rights-holder approach and promotes cooperation for more patents and more enforcement without mentioning the public policy priorities, public interest, technology transfer and development, etc. Training to include stricter patentability criteria are rarely supported by developed countries who usually fund capacity building trainings. In the context of medicines and other health-related products, training on patentability criteria should be sufficiently detailed and specific to ensure that patent examiners are able

to distinguish between what is and is not patentable to prevent evergreening. Evergreening can lead to spurious claims being granted and patent terms being extended. In the race to harmonise such training, important TRIPS flexibilities are continuously diluted.

The provision does not explicitly mention Patent Prosecution Highway (PPH); however, it suggests a future pathway to PPH. An applicant receiving a ruling from the Office of First Filing (OFF, which is very likely to be the USPTO) that at least one claim in an application filed in the OFF is patentable may request that the Office of Second Filing ((OSF), any other participating patent office) fast track the examination of corresponding claims in corresponding applications filed in the OSF. Seventeen country and regional patent offices including Australia, Japan, South Korea, the United States and European Patent Office participate in PPH. There is currently no international agreement in force that obligates states to harmonize patentability criteria, examination standards and decisions. The attempt to achieve this harmonization has not yielded to reality under World Intellectual Property Organization (WIPO) auspices while the Patent Law Treaty aiming for substantive harmonization has been heavily resisted by developing countries as unsuited for purpose. Yet, PPH provides a leeway to pursue substantive harmonization without multilateral agreement. Developed countries have been adjusting the global IP system or examination standards through this patent examination system, which remains a concern for the rest of the world.

This provision is potentially problematic as it encourages harmonisation of patent examination practices. Country-specific practices and differences in patent laws should not be diluted in view of the different development and health needs of each participating country. It should be borne in mind that within its existing framework, PPH fails to ensure the needs of all RCEP Parties, particularly India, a key producer of generic medicines, as well as the greater need of least developed members to increase access to affordable medicines. Therefore, in order to achieve a region-wide fair and balanced dialogue, cooperation efforts should not limit the freedom of Parties to prescribe, interpret and apply substantive conditions of patentability. Cooperation efforts also should not seek substantive patent law harmonisation or harmonisation of national search and examination procedures.

We recommend that RCEP negotiating parties make explicit limitations and exceptions of the scope of the application of this provision. Negotiating parties should prevent excessive implementations of the provision in the context of critical public interest safeguards.

Article 10.4 – Committee on Intellectual Property Rights

[KR/AU propose; ASN oppose: Article 10.4
Committee on Intellectual Property Rights]

[KR propose; ASN/AU oppose: 1. The Parties hereby establish the Committee on Intellectual Property Rights (hereinafter referred to in this Article as "the Committee") as specified in the Annex X-C of Chapter X (Institutional Provisions).]

[AU propose : 1. For the purposes of the effective implementation and operation of this Chapter, the Parties agree to establish a Committee on Intellectual Property.]

2. [AU oppose : For the purposes of the effective implementation and operation of this Chapter,]
[AU propose : the functions of the Committee shall include, but are not limited to:] the functions of the Committee shall include, but not limited to:

- (a) reviewing and monitoring the implementation and operation of this Chapter;
- (b) discussing ways to facilitate cooperation between the Parties;
- (c) exchange of information on laws, systems and other issues of mutual interest concerning intellectual property rights;

[AU oppose: (d) carrying out other functions as may be delegated by the Joint Committee in accordance with Article [X.X]; and]

- (e) [AU oppose: seeking to resolve] [AU propose : resolving] disputes that may arise regarding the interpretation or application of this Chapter.

[AU propose: (d) [AU oppose: reporting] [AU propose: report] its findings to the Joint Committee]

[AU oppose: 3. The Committee shall meet within one year after the date this Agreement enters into force and annually thereafter unless the Parties otherwise agree. The Committee shall inform the Joint Committee of the results of each meeting.]]

[AU propose: 3. The Committee shall be composed of representatives of each Party.

4. The Committee shall meet at venues, times, and by means as agreed by the Parties]

These committees are now appearing in all FTAs. They are troubling, as they are a form of continuous FTA negotiations as it allows closed door discussions on key issues such as test data or IP enforcement, which in practice leads to their application in a way that suits foreign right holders rather than local conditions and as such is an attempt to limit the policy space of India.

We recommend that RCEP negotiating parties – particularly India which is constantly under pressure to adopt TRIPS-plus measures - reject this provision.

Article 10.5

[CN propose; AU/JP/KR oppose:

Each Party will consider requests for assistance from any Party in a public health crisis in accordance

with this Article.

This provision seems intended to reinforce the public health safeguard, yet it is unclear with its current drafting what kind of assistance is envisaged by the drafters.

We recommend that RCEP negotiating parties improve the clarity of this provision and connect explicitly with TRIPS flexibilities and the Doha Declaration.