

# Assessing Access to Medicines in Preferential Trade Agreements: From the Trans-Pacific Partnership to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership

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**Abstract** The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP or TPP11) is a trade agreement between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. CPTPP negotiations started after the Trans-Pacific Partnership Agreement reached a stalemate due to the withdrawal of the United States on 23 January 2017. This paper's aim is to provide an appraisal of some sensitive provisions of the CPTPP, and their impact on access to affordable medicines. As access to medicines is mainly related to the protection of intellectual property rights and in particular patents, a first part of the paper will focus on the international regulatory framework for patents, considering the main international conventions, the TRIPS Agreement and its relation with preferential trade agreements. The narration will then focus on the provision of the CPTPP relating to patents and pharmaceuticals, and those relating to investment. The discussion will revolve around whether said provisions significantly depart from the framework set by TRIPS, for instance, including TRIPS-plus provisions, notably criticised for their adverse repercussions on the fundamental right to health. As regards the provisions in the investment chapter, the analysis will focus on whether the wording of said chapter is equipped to strike a balance between protection of foreign investors and health regulation. A conclusion will follow, summarising the main findings of the paper.

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*L'époque la plus favorable pour la repression d'un abus,*

*c'est le jour où on le découvre*

– Aurélien Scholl

*La médecine, c'est un art qu'on exerce, en attendant qu'on le découvre*

– Émile Deschamps

## 1 Introduction – Access to Health Care as a Fundamental Right, CPTPP Negotiations

The clash between the dire necessity of providing adequate access to health and the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as “TRIPS” or “TRIPS Agreement”) should be read in parallel with the situation where pharmaceutical companies enjoy enhanced protection of their intellectual property rights, while countries, particularly developing ones, try to control diseases during health crises or emergencies.<sup>1</sup> Unarguably, developing countries<sup>2</sup> are nowadays experiencing a rapid growth in terms of GDP, as well as fast developments in terms of implementation of fundamental rights. Health is without doubt a fundamental right,<sup>3</sup> and actions to remove barriers to accessing affordable medicines have been the subject of various

<sup>1</sup> On access to health, developing countries and WTO/Preferential Trade Agreements, see, if you want, Pusceddu (2014a), pp. 104–112, Pusceddu (2014b), pp. 790–801.

<sup>2</sup> With the caveat that there is not an established definition of a developing country, the classification as a developing country has been made following the UNDP Human Development Index and the statistics released by UNCTAD. The UNDP HDI can be consulted at <http://hdr.undp.org/en/countries>, while the UNCTAD statistics can be consulted at [http://unctadstat.unctad.org/EN/Classifications/DimCountries\\_DevelopmentStatus\\_Hierarchy.pdf](http://unctadstat.unctad.org/EN/Classifications/DimCountries_DevelopmentStatus_Hierarchy.pdf).

<sup>3</sup> The right to health is well established in international law. Its first formulation can be traced to the World Health Organization's Constitution, in the principle “basic to the happiness, harmonious relations and security of all peoples”, as well as to the Universal Declaration of Human Rights, Art. 1(1). The realisation of such right was then detailed in the Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966, which provides the human rights basis of the pharmaceutical regime. Art. 15 of the ICESCR stipulates the need of protecting both public and private interests in knowledge creation and diffusion, recognising that, on the one hand, everyone has the right “[t]o benefit from the protection of the moral and material interests resulting from any scientific [...] production of which he is the author”, which is ample enough, as a definition, to include pharmaceutical patents, and the right of everyone, and, on the other hand, “to enjoy the benefits of scientific progress and its applications”. Art. 12, furthermore, recognises the right of everyone to the “enjoyment of the highest attainable standard of physical and mental health”. According to General Comment 14 to the ICESCR, the right to health requires access to medicines. Although this latter instrument is not binding, it represents an authoritative interpretation of states' commitment and may be indicative of the emergence of customary norms. The absence of a World Human Rights Court and the institutional and substantive fragmentation of the human rights system – namely the existence of different UN bodies with similar or different competences, and the existence of different treaties – hinder the proper realisation of the right to health. On this matter, see Vadi (2015), p. 123, Keller and Grover (2012), p. 132, Helfer (2007), pp. 971–1020, Helfer (2014), p. 317, Raustiala (2007), pp. 1021–1038, Yu (2007), pp. 1039–1149, Trechsel (2004), International Commission of Jurists (2011), Ajevski (2014), pp. 87–98, Payandeh (2015), p. 297.

initiatives. The climax was reached with the explosion of the AIDS crisis and the consequent intervention of many NGOs, putting pressure for a reconsideration of the impact of the TRIPS Agreement on access to health.<sup>4</sup> These actions eventually led to two further steps: the Doha Declaration on TRIPS and Public Health and the WTO 2005 Ministerial Declaration, introducing Art. 31<sup>bis</sup> in the TRIPS Agreement.

After the relation between the TRIPS Agreement and access to health was stabilised, one of the side paths pursued to foster stringent protection of IPRs has been the conclusion of preferential trade agreements (hereinafter referred to as PTAs) including what are commonly referred to as TRIPS-plus provisions. Among the recently negotiated agreements containing the aforementioned provisions the (now ineffective) Trans-Pacific Partnership (hereinafter referred to as “TPP”) should be mentioned. The TPP was an agreement between 12 Pacific-Rim countries representing approximately 40% of the world’s gross domestic product (hereinafter referred to as “GDP”) according to the World Bank statistics.<sup>5</sup> The agreement featured the presence of advanced economies, such as the US and Japan, but also a mix of developed and developing countries, including Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. Throughout its negotiations, the TPP has been at the centre of heavy criticism as regards some of its provisions, in particular those relating to access to affordable medicines.<sup>6</sup>

The TPP had a tormented fate: after the US withdrawal, in January 2017, the agreement seemed to be destined not to enter into force. In May 2017, however, the remaining 11 countries decided to resume the negotiations, announcing on October 2017 the reaching of the new agreement, called “Comprehensive and Progressive Agreement for Trans-Pacific Partnership” (hereinafter referred to as “CPTPP” or the “Agreement”). The text of the Agreement was announced in February 2018 and its signature occurred in March 2018. All together, the members of the new Agreement amount to more than the 13% of the world’s GDP.<sup>7</sup>

Moving a step back to the TPP, it should be noted that this agreement was negotiated when harmonisation of minimum standards of protection for IPRs had already been reached. In 1995, the World Trade Organization TRIPS Agreement entered into force, establishing common standards for the protection and enforcement of IPRs. As we will see below, with respect to patent rights, the TRIPS Agreement provides for a minimum term of 20 years of protection and forbids members from excluding patents on pharmaceutical products. TRIPS also has some flexibilities, such as: a transition period in order to ease compliance for least-developed and developing countries; the possibility for members to issue compulsory licences; a neutral approach as regards the exhaustion regime; and a margin of manoeuvre for countries as to defining their own standards of patentability and adopting exemptions such as research rights. Against this background, one of the most concerning chapters in the TPP was that on intellectual property, because it contained, among others, provisions on patentability, patent extension, test data exclusivity and patent linkage that might have had a dramatic effect on medicine prices.

<sup>4</sup> 't Hoen et al. (2011).

<sup>5</sup> World Bank Group (2016), p. 221.

<sup>6</sup> Barazza (2014), pp. 366–373; as regards a health impact assessment (unofficial) of the TPP, see Labonté et al. (2016), pp. 487–496.

<sup>7</sup> Greenfield and Packham.

In the same agreement, the investment chapter, protecting, *inter alia*, IP-related investments and providing for investor-state dispute settlement, would empower pharmaceutical companies with an adjunctive set of legal remedies to protect their IP rights. During the transition from the TPP to the CPTPP, these chapters have not been subject to amendments, although some provisions have been suspended.<sup>8</sup>

Based on such premises, the scope of this paper is to contribute to the academic debate on the relation between access to medicines and PTAs focusing on the CPTPP. The vast majority of the literature referred to in this paper underlines the perils of PTAs and TRIPS-plus provisions in relation to access to medicines, sometimes supporting these assumptions with economic considerations. As regards investment law, there is some similarity of arguments, i.e. the assumption that such provisions may restrain the right to regulate health matters and hence represent a danger for access to medicines. However, such assumptions should not be generalised, as an assessment of the impact of PTA provisions on access to medicines should take into consideration the actual wording of the treaty.

## 2 An Overview of the International Framework for Patents

A patent is defined as a “document issued, upon application, by a government office [...], which describes an invention and creates a legal situation in which the patented invention can normally only be exploited [...] with the authorization of the owner of the patent”.<sup>9</sup> It is understandable that, in relation to access to medicines, a patent holder has great power to charge a highly remunerative price, which may constitute a barrier for poor people or a budget concern for states.

The international framework for the substantive regulation under patent law may be summarised in the Paris Convention<sup>10</sup> and the TRIPS Agreement,<sup>11</sup> the latter playing a deeper role.<sup>12</sup>

### 2.1 The Paris Convention

The Paris Convention was the first instrument to introduce some important principles in substantive patent law. One may briefly recall:

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<sup>8</sup> See *infra* note 51.

<sup>9</sup> See the WIPO Intellectual Property (2004), p. 17.

<sup>10</sup> Convention for the Protection of Industrial Property, Paris, 20 March 1883, revised at Stockholm on 14 July 1967, and amended on 28 September 1979.

<sup>11</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights.

<sup>12</sup> Other conventions, such as the Patent Cooperation Treaty (1970) and the Patent Law Treaty (2001), are mainly focused on procedural aspects, aiming to unify filing procedures (such as the PCT application) or to harmonise some procedural aspects, such as the requirements to obtain a filing date in relation to a patent application or the form and content of a patent application. These international treaties are less important for our purpose, but are worth mentioning for the sake of completeness.

- the principle of national treatment<sup>13</sup> which requires that each member state grants the same level of protection to nationals of another member country as it grants to its own nationals;
- the right of priority in relation to the original filing of a patent application,<sup>14</sup> so that an applicant enjoying the Convention's benefits and filing a first patent in any of the countries of the Union can then file subsequent applications in other member countries that will have the date of the first filed application as the effective filing date;
- the independence of patent protection,<sup>15</sup> implying that a patent application in one member country is examined independently from applications for patents for the same or related inventions filed in other countries;
- compulsory licences<sup>16</sup> as a means to prevent abuses that might result from the exclusive rights conferred by a patent.

The Convention, however, does not define what is a patentable invention, hence leaving a gap that had to be filled by member states, as well as by subsequent international instruments.

## 2.2 The TRIPS Agreement

In 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was concluded in order to provide common standards for substantive IPRs,<sup>17</sup> with the aim of implementing standardisation<sup>18</sup> and enforcement of IPR laws,<sup>19</sup> eventually framing IP as a commodity.<sup>20</sup> In particular, some key provisions are relevant for our purpose:

- a definition of patentable subject matter,<sup>21</sup> as “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”, whereas the terms “inventive step” and “capable of industrial application” may be understood by a member state as synonymous with “non-obvious” and “useful” respectively. Member states are obliged to make patents available for qualified

<sup>13</sup> Art. 2(1).

<sup>14</sup> Art. 4.

<sup>15</sup> Art. 4<sup>bis</sup>.

<sup>16</sup> Art. 5A(2) and (4).

<sup>17</sup> A vision endorsed by Art. 7, which reads: “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.”

<sup>18</sup> Accomplished, for instance, by the mention that Art. 2 of TRIPS makes about previous IPR conventions.

<sup>19</sup> Velasquez and Boulet (1999), p. 17.

<sup>20</sup> Dreyfuss and Frankel (2015), p. 559.

<sup>21</sup> Art. 27(1). This provision creates problems in relation to the requirement of novelty, since some countries may implement stricter patentability requirements.

patentable subject matter. This provision had a deep impact on those developing nations that did not provide protection for some products, such as pharmaceuticals;

- the provision of exclusive rights for patent holders;<sup>22</sup>
- a standard period of enjoyment of patent rights of 20 years;<sup>23</sup>
- when a claim is filed by the patent holder that the invention is reproduced, the burden of proof is shifted on the accused party to demonstrate the uniqueness of its creation;<sup>24</sup>
- the inclusion of the most-favoured-nation (MFN) principle,<sup>25</sup> which implies that if a particular favourable treatment is granted to one country, it has to be granted to all the WTO members;
- the absence of guidance on which exhaustion regime countries should adopt<sup>26</sup> – national, regional, international<sup>27</sup> –, hence allowing members to resort to parallel importation, provided that the principles of national treatment and most-favoured-nation are respected.

After the conclusion of the Uruguay Round, these provisions have been the subject of debate and controversies, because many developing countries had to implement legislation giving full protection to pharmaceuticals products, which increased their price and restricted their availability. This situation created palpable opposition from civil society groups and local populations, arguing that TRIPS would have harmed the least-developed countries' (hereinafter referred to as LDCs) actions in the area of public health.

Despite the abovementioned concerns, and as already mentioned, the TRIPS Agreement retained some flexibilities that would have enabled LDCs to comply more easily with it. In particular, one may consider the transition period for compliance,<sup>28</sup> and the possibility of relying on compulsory

<sup>22</sup> Art. 28.

<sup>23</sup> Art. 33.

<sup>24</sup> Art. 34.

<sup>25</sup> Art. 4.

<sup>26</sup> Arts. 31 and 6.

<sup>27</sup> Cottier (2005), p. 1070. *National exhaustion* implies that the sale of a protected product in one country does not affect the enjoyment of the related intellectual property rights in another country. Hence, the sale of a product in a market brings the consequence of the exhaustion of the right to resale of the product only in that market. *International exhaustion*, on the contrary, means that there is no difference whether the product was first sold abroad or on the national market. Once the sale has occurred, the right holder cannot hinder parallel importation claiming intellectual property rights. If a product has been put on the market with the consent of the right holder, it can be imported to third countries where the international exhaustion regime applies. *Regional exhaustion* applies on the basis of treaty law and creates a regime of international exhaustion between the states that are signatories of the treaty, while sales to third countries are regarded through the national exhaustion lens.

<sup>28</sup> Musungu and Oh (2006), pp. 12, 14. The first transition period, from 1995 to 2000, required states to extend legal protection to both product and process patents and to recognise the 20-year duration of exclusive rights. The second period, from 2000 to 2005, required the extension of TRIPS to all fields, including pharmaceuticals and agrochemicals, and the employment of a "mailbox" system to store pending patent applications. The final period will end in 2016 and is the result of the Doha Declaration, which articulated the importance of public health to LDCs.

licences.<sup>29</sup> However, the second flexibility casts many doubts as to its effectiveness. In fact, issuing a compulsory licence requires a state to compensate the patent holder financially as well as to limit the scope and duration of the licence; to make the licence non-exclusive; and to restrict the licensed good to domestic use.<sup>30</sup> Moreover, it requires extensive background legal preparatory work, which increases the overall costs of the operation. Nonetheless, it is definitely a useful tool, provided that the issuing state has the technology to produce the licensed product, since importation under the original agreement was prohibited.<sup>31</sup>

The described IPR regime was perceived as unjust. Growing concern from developing countries, the explosion of the AIDS crisis and the intervention of many NGOs putting pressure for a reconsideration of the impact of TRIPS on access to health, led to major adjustments in 2001, 2003 and 2005. In 2001, the Doha Declaration on the TRIPS Agreement and Public Health recognised the right of states to interpret TRIPS provisions broadly when public health is at stake. The Declaration, however, was not able to address the problem of how states that lacked adequate manufacturing capacity could have used compulsory licences. In 2003, there followed the Decision of the TRIPS Council affirming states' ability to export and import pharmaceutical products, coupling it with a compulsory licence issued by the exporting member state, in exceptional circumstances. Eventually, the WTO 2005 Ministerial Declaration introduced TRIPS Art. 31<sup>bis</sup>,<sup>32</sup> which has made the effects of the 2003 decision permanent.

### 3 Access to Medicines and Preferential Trade Agreements

In the previous section we clarified the main issues related to TRIPS and public health, a topic of a consuming academic debate. Although developing countries welcomed the amendments to the TRIPS Agreement as a compromise between IPRs and health policies, subsequent negotiations on preferential trade arrangements at the bilateral or regional level might have jeopardised such hard-won success.

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<sup>29</sup> G. Velasquez and P. Boulet, *supra* note 19, p. 43, pointing out that a judicial or administrative authority "is allowed by law to grant a licence, without permission from the holder, on various grounds of general interest (absence of working, public health, economic development, and national defence)". As noted by S. Musungu and C. Oh, *supra* note 28, p. 27, "compulsory licences can therefore play a crucial role in ensuring that patent laws are able to meet public health needs, and that patent rights do not unnecessarily hinder or prevent access to affordable medicines".

<sup>30</sup> Art. 31, part 1.

<sup>31</sup> Coriat et al. (2006), p. 1042.

<sup>32</sup> This amendment will enter into force once two-thirds of the WTO's members accept the change. The latest General Council decision of 26 November 2013 (document WT/L/899) extended the deadline to 31 December 2015. The amendment implements the temporary waiver (the "August 30 WTO Decision") allowing WTO members to issue compulsory licences to export generic medicines to countries with insufficient or non-existent manufacturing capacity. It may be noted that while declarations have the less binding status of soft-law, an amendment to TRIPS implies a higher level of commitment, being binding on WTO members. On 23 January 2017, the amendment was formally built into the TRIPS Agreement, after acceptance of the amending protocol by two-thirds of the WTO members.

According to Art. XXIV of GATT, WTO members may enter into a preferential trade agreement, which aims to increase freedom of trade by the development of closer ties between the economies of countries that are parties to such agreements.<sup>33</sup> A PTA is clearly an exception to the most-favoured-nation principle.<sup>34</sup>

It comes as no surprise that trade does not mean only goods and services, but also intellectual property rights to be protected and enforced. Even though the third pillar of the WTO, TRIPS, does not contain a clause similar to Art. XXIV of GATT, this has not prevented the US or the EU from proposing IPR norms when negotiating PTAs,<sup>35</sup> with provisions usually increasing the level of protection given to such rights. This premise can have profound consequences in its practical application. One may not disregard, as it will be shown in the following pages, that a PTA may undermine those flexibilities provided in the TRIPS Agreement, as well as in the Doha Declaration on TRIPS and Public Health, by requiring that the parties provide a level of IPR protection going directly beyond the TRIPS provisions and its flexibilities. When discussing access to medicines, this bypassing mechanism must be taken into account in appraising the impact of the provisions related to IP rights, particularly patents, contained in a PTA.

The IP chapter of a PTA is by no means the only cause for concern in the discourse on access to medicines, as IPRs may be the subject of a separate discipline contained in the investment chapter of a PTA, and be listed under the definition of “covered investment”.<sup>36</sup> Defining the notion of investment as encompassing IPRs may subject government measures affecting the intellectual property rights of foreign investors to the investment-related remedies provided in the PTAs, namely investor-state arbitration. In this regard, one of the most debated aspects is whether issuing a compulsory licence constitutes an instance of indirect expropriation;<sup>37</sup> however, amendments to the IP laws and regulations may also trigger respect of the legitimate expectations of an investor. The option of investor-state arbitration may be more appealing to investors, compared to court proceedings or state-to-state dispute settlement procedures. On the one hand, court litigation may be perceived as biased, slow, and not adequately equipped to deal with the peculiarities of the case; on the other, state-to-state dispute settlement does not feature a direct participation of the investor in the adjudicatory process. If compared to the brief considerations stated above, investor-state arbitration may offer a neutral venue to settle a dispute, allowing the disputing parties to appoint an arbitrator of their choice in the constitution of the arbitration tribunal. From the perspective of the investor, an

<sup>33</sup> Guzman et al. (2016), p. 353. A similar exception is provided by Art. V of GATS.

<sup>34</sup> In the WTO system, countries cannot discriminate between their trading partners. The most-favoured-nation principle implies that if a particularly favourable treatment is granted to one country, it has to be granted to all the WTO members. Such principle is a milestone in trade law, and is present in the GATT, GATS and TRIPS.

<sup>35</sup> Horn et al. (2010), pp. 1565–1588.

<sup>36</sup> Fink (2011), p. 401, pointing out how it is the case in the US agreements with Australia, CAFTA–DR, Chile, Morocco, Oman, and Singapore. The author also underlines that where an agreement does not contemplate a separate investment chapter, states may conclude bilateral investment treaties (BITs) that would likely mention IPRs in the definition of investment.

<sup>37</sup> *Ibid.*, noting that some PTAs exclude compulsory licensing from the reach of the expropriation measures.



eventual consideration is the possibility of seeking monetary reparations, and inducing a regulatory chilling effect.<sup>38</sup>

While initially scholars were not certain about the actual reach of investment agreements into the intellectual property domain,<sup>39</sup> recent cases have shown that IPRs can be subject to investor-state arbitration.<sup>40</sup>

## 4 From TPP to CPTPP. Provisions on IPRs and Pharmaceuticals

### 4.1 General Provisions

For the purposes of this paper, we will consider the provisions on patentability, test data exclusivity and patent linkage of the CPTPP contained in Chapter 18 (“Intellectual Property”). *Ratione materiae*, the chapter applies to all subject matter existing at the date of entry into force of the CPTPP;<sup>41</sup> *ratione temporis*, it does not give rise to obligations in respect of acts that occurred before the date of entry into force of the Agreement itself.<sup>42</sup>

The aim pursued by member states through the protection and enforcement of intellectual property rights is the promotion of technological innovation and dissemination of technology to the advantage of producers and users of technological knowledge so as to foster social and economic welfare and balance the rights and obligations of IPR holders and users.<sup>43</sup> In turn, this requires members to introduce or amend their laws and regulations, although with the safeguard that they may adopt those measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance for socio-economic and technological development.<sup>44</sup> Said endeavours should be read in the broader context of the commitments to the Declaration on TRIPS and Public Health. In this regard, member countries have reached a series of understandings. The obligations in relation to the IP chapter do not prevent a member from adopting those measures necessary to protect public health,<sup>45</sup> nor do they prevent the effective utilisation of the Declaration on TRIPS and Public Health,<sup>46</sup> which means that the IP chapter has to be interpreted and implemented in a manner supportive of the protection of public health and to promote access to medicines.<sup>47</sup> Each party then has the right to

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<sup>38</sup> *Ibid.*

<sup>39</sup> *Ibid.*, p. 402, citing Correa (2004a), p. 83.

<sup>40</sup> *Ibid.*, pointing out that some arbitral decisions have been criticised for having extensively interpreted BIT provisions, hence creating more onerous obligations than those originally negotiated and intended by the signatories.

<sup>41</sup> Art. 18.10.1.

<sup>42</sup> Art. 18.10.3.

<sup>43</sup> Art. 18.2.

<sup>44</sup> Art. 18.3.1.

<sup>45</sup> Art. 18.6.1 a).

<sup>46</sup> Art. 18.6.1 b).

<sup>47</sup> Art. 18.6.1 b).

determine what constitutes a national emergency or other circumstances of extreme urgency, which are (not restrictively) epitomised by public health crises such as those relating to HIV/AIDS, tuberculosis, malaria and other epidemics.<sup>48</sup> In order to comply with the TRIPS obligations, if any amendment or waiver of a provision of said agreement enters into force with respect to a member country of the CPTPP, a consultation is provided in order to adapt the IP chapter to the waiver or amendment.<sup>49</sup> Eventually, parties are not prevented from determining the exhaustion regime of intellectual property rights under their legal systems.<sup>50</sup>

## 4.2 Provisions on Patents

### 4.2.1 Patentability and Patent Term Extension

The prefatory provisions of the IP chapter pave the way to the regulatory framework on patents, which governs general aspects of patent protection and provides specific provisions for pharmaceuticals and biologics. The Agreement requires that members shall make patent protection available for “any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application”.<sup>51</sup> A subsequent provision – which has been suspended in the transition from the TPP to the CPTPP<sup>52</sup> – requires parties to confirm that patents be available for inventions claiming at least one of the following:

- new uses of a known product;
- new methods of using a known product; or
- new processes of using a known product.<sup>53</sup>

<sup>48</sup> Art. 18.6.1 b).

<sup>49</sup> Art. 18.6.1 c).

<sup>50</sup> Art. 18.11.

<sup>51</sup> Art. 18.37.1. The provision is assisted by a note stating that a member “may deem the terms ‘inventive step’ and ‘capable of industrial application’ to be synonymous with the terms ‘non-obvious’ and ‘useful’, respectively. In determinations regarding inventive step, or non-obviousness, each Party shall consider whether the claimed invention would have been obvious to a person skilled, or having ordinary skill in the art, having regard to the prior art”.

<sup>52</sup> See the Trans-Pacific Partnership Ministerial Statement (2017). As regards the IP chapter, the suspension has touched the following provisions: definition of the provision on patentable subject matter, as set out in Art. 18.37.2; patent term adjustment provisions, as set out in Arts. 18.46.3, 18.46.4, 18.48.2; protection of undisclosed test or other data, as set out in Arts. 18.50.1, 18.50.2, 18.51.

<sup>53</sup> Art. 18.37.2 leaves the possibility to limit new processes to those that do not claim the use of the new product as such. According to subsequent paragraphs 3 and 4, a party may exclude from patentability inventions for reasons related to protection of *ordre public* or morality, human, animal or plant life or health, or to avoid prejudice to nature or the environment. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals and animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes, may also be excluded from patentability. Eventually, a party may also exclude from patentability plants, other than microorganisms, provided that it makes patents available at least for inventions that are derived from plants. Art. 18.38.a) and b) deal with public disclosure that may be necessary to determine the novelty of a patent but that, on the other hand, may be detrimental to the success of the filing procedure. A grace period for public disclosure is granted if such disclosure has been

The CPTPP also introduces some important requirements as regards the patenting process. Members have a limited margin of manoeuvre as regards the possibility to cancel, revoke or nullify a patent, which can be done only on grounds that would have justified the refusal of granting the patent *ab origine*.<sup>54</sup> Member countries must also provide patent applicants with an opportunity to make amendments, corrections and observations in connection with the patent application<sup>55</sup> and introduce in their legislation patent term adjustment provisions for unreasonable delays in the issuing procedure<sup>56</sup> – a commitment suspended in the passage from the TPP to the CPTPP.<sup>57</sup>

The exclusive rights conferred to a patent holder are subject to limited exceptions (the Agreement, for instance, retains a regulatory review exception,<sup>58</sup> and restates the commitment to Art. 31 TRIPS, as well as any waiver or amendment to it<sup>59</sup>), provided that they do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.<sup>60</sup>

### 4.3 Provisions on Pharmaceuticals

#### 4.3.1 Definition of Pharmaceutical Product and Patent Term Extension

The general provisions relating to patents should be read in strict connection with those related to pharmaceutical products. In the Agreement's terminology, a new pharmaceutical product means a product not containing a chemical entity previously approved in a member state.<sup>61</sup> Seeking marketing approval is the subsequent step taken by a company holding a patent on a pharmaceutical product. In this regard, the CPTPP provides that the member parties should make their best efforts to avoid

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Footnote 53 continued

made: (i) by the patent applicant or by a person who obtained the information directly or indirectly from the patent applicant, and (ii) occurred within 12 months prior to the date of the filing of the application in the territory of the party.

<sup>54</sup> Art. 18.39.1. A party may provide that fraud, misrepresentation or inequitable conduct may be the basis for cancelling, revoking or nullifying a patent or holding it unenforceable. Additionally, based on Art. 18.39.2, patent revocation may still be possible according to Art. 5A of the Paris Convention and the TRIPS Agreement.

<sup>55</sup> Art. 18.43.

<sup>56</sup> Art. 18.46.3. According to subsequent Art. 18.46.4, an unreasonable delay should include a delay in the issuance of a patent of more than five 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 has been made, whichever is later. From the determination of such delays a party may exclude: (i) periods of time that do not occur during the processing of, or the examination of, the patent application by the granting authority; (ii) periods of time that are not directly attributable to the granting authority; (iii) periods of time that are attributable to the patent applicant.

<sup>57</sup> See *supra* note 51.

<sup>58</sup> Art. 18.49.

<sup>59</sup> Art. 18.41.

<sup>60</sup> Art. 18.40.

<sup>61</sup> Art. 18.52.

unreasonable and unnecessary delays in the approval of pharmaceutical products,<sup>62</sup> providing for an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the patent term resulting from the marketing approval process<sup>63</sup> (a commitment suspended in the transition from the TPP to the CPTPP<sup>64</sup>), and adopting or maintaining procedures that expedite the processing of applications for marketing approval.<sup>65</sup>

#### 4.3.2 Test Data Exclusivity

As is common in PTAs, the discipline on pharmaceutical patents is assisted by provisions on undisclosed test or other data. The provision – suspended in the transition from the TPP to the CPTPP<sup>66</sup> – stipulates that if, as a condition for marketing approval of a new pharmaceutical, a member country requires the submission of undisclosed test or other data pertaining to the safety and efficacy of said product, that member country shall not permit third persons, who have not obtained the consent of the originator of said information, to market the same or a similar product, on the basis of either (i) that information, or (ii) the marketing approval granted to the information's originator, for a period of at least five years starting from the date of marketing approval of the pharmaceutical product in the territory of the member country.<sup>67</sup> A similar preclusion is provided in the case in which the condition for granting marketing approval for a new pharmaceutical product is based on the submission of evidence of prior marketing approval of the product in another member's territory.<sup>68</sup> The provisions on undisclosed test and other data also apply for a period of at least three years with respect to (i) new clinical information submitted in support of marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration,<sup>69</sup> or (ii) for a period of at least five years to new pharmaceutical products that contain a chemical entity that has not been previously approved in that member country.<sup>70</sup> As regards the protection of new biologics – defined as a product that is, or contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition<sup>71</sup> –, the protection of undisclosed test data is extended to eight years from the date of first marketing approval of that product, or alternatively five years, provided that this shorter period is backed up by additional market protection

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<sup>62</sup> Art. 18.48.1.

<sup>63</sup> Art. 18.48.2.

<sup>64</sup> See *supra* note 51.

<sup>65</sup> Art. 18.48.4.

<sup>66</sup> See *supra* note 51.

<sup>67</sup> Art. 18.50.1(a).

<sup>68</sup> Art. 18.50.1(b).

<sup>69</sup> Art. 18.50.2(a).

<sup>70</sup> Art. 18.50.2(b). Subsequent Art. 18.50.3 states that members are, however, able to take measures to protect public health in accordance with the Declaration on TRIPS and Public Health.

<sup>71</sup> Art. 18.51.2.

measures.<sup>72</sup> Eventually, each member is required not to alter the period of data protection provided for new pharmaceuticals and biologics in the event that these products are covered by a patent that expires on a date that is earlier than the period of data protection itself.<sup>73</sup>

#### 4.3.3 Patent Linkage

Test data exclusivity provisions are tied up with patent linkage ones. If a member country, as a condition of approving the marketing of a pharmaceutical product, permits persons, other than the one originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved – such as evidence of prior marketing approval by the member or in another territory –, that member shall provide a system allowing the patent holder to be notified, prior to the marketing of said pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent<sup>74</sup> or, alternatively, adopt or maintain a system (other than judicial proceedings) aimed at precluding the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent, unless by consent or acquiescence of the patent holder.<sup>75</sup> Eventually, member countries shall provide the patent holder with adequate time and opportunity to seek, prior to the marketing of an allegedly infringing product, available remedies such as judicial or administrative proceedings, expeditious remedies such as preliminary injunctions or equivalent effective provisional measures, aimed at a timely resolution of disputes concerning the validity or infringement of an applicable patent.<sup>76</sup> The provision on patent linkage has not been suspended. An explanation of why patent linkage has been kept in the text of the agreement is that, on the one hand, it is an ancillary provision to those establishing patent rights and, on the other, it still allows some level of control over IPRs in the member countries.

## 5 Do Such Provisions Prejudice Access to Medicines?

As stated earlier, after the TRIPS Agreement came into force, many concerns were raised as regards its impact on access to medicines.<sup>77</sup> This situation led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health which

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<sup>72</sup> Art. 18.51.1.

<sup>73</sup> Art. 18.54.

<sup>74</sup> Art. 18.53.1(a).

<sup>75</sup> Art. 18.53.2.

<sup>76</sup> Art. 18.53.1(b) and (c).

<sup>77</sup> Reichman (2009), p. 247. Developing countries accepted stringent patent protection rules in exchange for having access to developed markets for traditional manufactured goods, as well as a commitment of developed countries to stop unilateral trade sanctions for inadequate protection of foreign intellectual property rights.

stated the necessity of interpreting the TRIPS Agreement in such a manner as to grant members the right to protect public health and promote access to medicines. The Declaration was the starting point for the Decision of August 2003, a waiver of TRIPS Art. 31(f), and the amendment of the same provision through the introduction of Art. 31<sup>bis</sup>.<sup>78</sup> This reach, however, was far from accommodating all the interests, and in particular, one would argue, those of developed countries; more precisely, countries where pharmaceutical companies are likely to influence trade agendas.<sup>79</sup> TRIPS flexibilities have since then been eroded by the negotiation of (an increasing number of) PTAs imposing additional obligations to those provided by the TRIPS Agreement.

As regards the TPP, public opinion already expressed concerns about some of its provisions introducing, *inter alia*, TRIPS-plus standards. The object of this subparagraph will be the assessment of such provisions with an attempt to describe their impact on access to medicines. A caveat is however necessary, namely that, with the suspension of some of the most criticised provisions, the current detriment to access to medicines in the CPTPP may be dissipated, although the suspension itself is not definitive and may not ensure that said provisions will remain suspended in the future. Four controversial categories of provisions can be considered:

- provisions weakening patentability standards;
- provisions that extend the patent term to compensate for delays in the granting process or in marketing registration approval;
- provisions that introduce rights relating to undisclosed test data;
- provisions that link registration of generic products to the validity of a patent.

## 5.1 Lower Patentability Standards

The CPTPP provides for lower standards of patentability that allow what is commonly referred to as secondary patenting. The provision is, however, less burdensome than the original US proposals.<sup>80</sup> The provision on patentability is accompanied by a footnote establishing a threshold for inventiveness, absent in the TRIPS Agreement:

<sup>78</sup> *Ibid.*, pp. 248, 249; Dutfield (2008), p. 107; do Amaral (2005), p. 7; in general, see 't Hoen (2002), p. 27.

<sup>79</sup> As regards an empirical study on corporate support of PTAs' IP policies, see Osgood and Feng (2017).

<sup>80</sup> The actual text is less onerous than the original 2011 proposal that aimed at making patents available for every new use, new method use and new forms of existing products. See Gleeson et al. (2017), p. 8. Another proposal was contained in Art. QQ.E.1 of the May 2014 draft regarding patentable subject matter. The USA and Australia made a proposal on a provision that would have fostered patent "evergreening", i.e. patents covering minor developments around an existing medicine, like salts, formulations, polymorphs and so forth. The proposed text read as follows: "a Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application". Such proposal reminds us of those instances countering Sect. 3(d) of the Indian Patent Act, which does not consider as inventions new forms or some derivatives of known medicines, unless they have a significant increase in efficacy. See Correa (2017), p. 8.

For the purposes of this Section, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful” respectively. In determinations regarding inventive step, or non-obviousness, each Party shall consider whether the claimed invention would have been obvious to a person skilled, or having ordinary skill in the art, having regard to prior art.

The consequences of weaker standards for patentability can be quite alarming. It has been reported, for instance, that over 800 different families of patents exist on the antiretroviral ritonavir,<sup>81</sup> with the result that the exclusive rights on such products have benefited from extended protection for additional years,<sup>82</sup> which can significantly affect their cost.<sup>83</sup> Secondary patents hence have a significant effect on the length of protection of pharmaceutical products and, consequently, on the possibility for generic medicines to enter the market.<sup>84</sup> When a country allows secondary patents, it may also happen that pharmaceutical products will be protected by a large range of patents added to the one protecting the original pharmaceutical ingredient.<sup>85</sup> As far as the CPTPP membership is concerned, should the suspension cease to operate, those countries that do not already contemplate secondary patents in their legislation – such as Vietnam and Peru – may have to lower the patentability requirement in their laws, with the likely outcome of significant delays in market entry for generic products.<sup>86</sup> On the other hand, those countries that already contemplate secondary patents in their legislation may face future policy barriers as regards raising the bar for patentability standards.<sup>87</sup>

## 5.2 Patent Extension

As previously discussed, unlike TRIPS, which provides that patents be protected for 20 years from the filing date, the CPTPP – as is common in PTAs promoted by the USA<sup>88</sup> – also includes patent extension, a provision granting term adjustment to compensate for unreasonable delays in the patent granting procedure and, in relation

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<sup>81</sup> WIPO (2011).

<sup>82</sup> Amin and Kesselheim (2012), pp. 2286–2294. Generally, and quite interestingly, on the relation between patent protection and innovation, see Boldrin and Levine (2013), pp. 3–22.

<sup>83</sup> Vernaz et al. (2013).

<sup>84</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 8.

<sup>85</sup> *Ibid.*, p. 8, reporting some studies in this regard. For instance, in the United States, from a total of 108 patents – granted or applied for – associated with two crucial HIV drugs, ritonavir and lopinavir/ritonavir, many were of minimal inventiveness and expected to extend the exclusive protection of these drugs for an additional 12 years after the expiry of the original pharmaceutical products’ patents. In Australia a study of patents on 15 high-priced drugs found the presence of 49 secondary patents, on average, for each of them.

<sup>86</sup> *Ibid.*, pp. 6, 7 the authors provide a chart showing the consistency of TPP members’ IP laws with the TPP provisions, as well as the transition period to implement legislative amendments. Such chart will be followed in this paper, considering that, in the transition from the TPP to the CPTPP, the IP chapter provisions have not been subject to amendment but merely suspended.

<sup>87</sup> *Ibid.*

<sup>88</sup> Correa (2006), pp. 400–402.

to pharmaceutical products, adjustment of the patent term for unreasonable curtailment caused by the marketing approval process. Patent extension provisions are generally advocated by the pharmaceutical industry with the justification that obtaining marketing approval of new chemical entities requires time, with the consequent reduction of the effective term of economic enjoyment of the patent, as well as the possibility of recouping research and development costs.<sup>89</sup> As regards the delay in the marketing approval, the text of the CPTPP does not mention whether such extension applies only in the country where such approval is sought or whether a delay in the country where the first approval was obtained should be considered as well.<sup>90</sup> Moreover, while the Agreement provides an indication of what may be understood as unreasonable delay in relation to issuing a patent, it does not define what constitutes unreasonable curtailment of the effective patent term as a result of the marketing approval process of a pharmaceutical, which will likely be the subject of elaboration at the national level and subsequent harmonisation within member countries.<sup>91</sup>

The justification provided by pharmaceutical companies advocating patent extension may not be convincing. On the one hand, it has been argued that research and development costs may be recouped after several months of sales (in a regime of monopoly) of a product.<sup>92</sup> On the other, there should be a distinction between those patents that are truly innovative and those that aim to protect a mere different use of a product, which is seen as potentially hindering competition.<sup>93</sup> Eventually, patent extension may not be a solution to improve the efficiency of the patent-issuing procedure, since it does not address a common problem in many developing countries, i.e. that “patent offices are under-staffed and delays are common”.<sup>94</sup> It is reasonable to assume, then, that patent extension may affect public health, delaying the availability of low-cost generic products.<sup>95</sup>

### 5.3 Test Data Exclusivity

Article 39(3) of the TRIPS Agreement requires that undisclosed test data be protected against unfair commercial use. This provision, however, does not create

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<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*, pointing out how this has been clarified, for instance, in the US-Bahrain Free Trade Agreement.

<sup>91</sup> Bearing in mind that the United States is not a member of the CPTPP, *see* the U.S. Code 35 § 156, which provides a detailed procedure as well as terms for extending patent validity. In the worst scenario, lacking coordination between member countries, it may happen that a patent that has expired in one country would be still valid in another.

<sup>92</sup> C.M. Correa, *supra* note 88, pp. 400–402.

<sup>93</sup> Correa (2004), p. 785.

<sup>94</sup> C.M. Correa, *supra* note 88, pp. 400–402.

<sup>95</sup> Baker (2016), Clift (2008), pp. 201–208. The latter analyses the impact of patent term extensions, finding that they add an average of 3.6 years to the period of exclusivity, and may account for nearly 20% of pharmaceutical sales in the US.



an obligation for members to grant exclusive rights over test data.<sup>96</sup> The CPTPP, as is common in PTAs negotiated by the US, provides for additional forms of protection by requiring its members to introduce test data exclusivity provisions. After a pharmaceutical product containing a new chemical entity has received marketing approval, both the relevant regulatory authority and the generic product applicant are precluded from relying on the undisclosed data submitted by the patent owner, or on a prior registration of the product for the purpose of establishing the equivalence of the generic product for a minimum period of five years, a period that can be prolonged by three years whenever the data originator submits new clinical information as regards a new indication, new formulation or new method of administration of a previously approved pharmaceutical product; or by five years for new pharmaceutical products containing a chemical entity that has not been *previously* approved in the member country.<sup>97</sup> It has been noted that such provision is more flexible than the original US proposal.<sup>98</sup> In particular, the data exclusivity provisions apply only to undisclosed data, i.e. data that are not already in the public domain. This would mean that members permitting literature-based submissions by manufacturers of generic medicines would be unaffected.<sup>99</sup>

Provisions on test data exclusivity should be considered carefully, since they may lead to the paradoxical result that off-patent medicines enjoy exclusive rights, which would prevent competition from generic market entry.<sup>100</sup> Producers of generic medicines may in fact face a barrier to entering the market, since they need to replicate costly and time-consuming tests in order to obtain marketing approval

<sup>96</sup> Correa (2004), p. 785, pointing out that Art. 39(3) of TRIPS does not provide for the granting of exclusive rights and that the necessity of a minimum period of protection is something that has been advocated by developed countries as a result of pharmaceutical companies' lobbying. The rationale is that the manufacturer developing the test data has put significant efforts into the development of the medicine and for this reason deserves a return on the investment. Not granting protection of test data would mean that generic competitors would face no barriers to the production and registration of an exact copy of the patented medicine. This argument, however, is more convincing as protection of an investment as such, rather than in the context of providing protection to a creative invention. Moreover, according to Correa, test data protection is a relief to extend protection to off-patent products, as well as biological products.

<sup>97</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 10.

<sup>98</sup> *Ibid.*, p. 10, underlining how such provision – Art. 18.50.2 – goes further than other trade agreements. However, the authors point out that the original US proposals did not include the second option for complying under Art. 18.50.2 (five years for new pharmaceutical products containing a chemical entity that has not been previously approved), which option is less onerous if a member state wishes to reduce the impact on pharmaceutical products' costs, as it applies to combination products (which are likely to be a small number) containing one new chemical entity (but noting that if the new chemical entity referred to has been registered as a stand-alone product, it will receive a five-year exclusivity). Another way in which the original US proposal for data exclusivity has been mitigated is that the provisions apply only to undisclosed data, i.e. data that are not already in the public domain. This means that in those countries that currently permit them, literature-based submissions by generic manufacturers would be unaffected.

<sup>99</sup> *Ibid.*

<sup>100</sup> C.M. Correa, *supra* note 88, pp. 400–402. See also D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 10. *Mutatis mutandis*, the authors cite two studies on the effects of test data exclusivity introduction in Jordan in 2001, along with other TRIPS-plus provisions. The first study, Malpani (2007), suggests that introducing data exclusivity has delayed the availability of generic medicine for 79% of medicines launched during the period 2002–2006. The second study, Abbott et al. (2012), pp. 75–85, evidences a 17% increase in medicine expenditure between 1999 and 2004, which was for the major part attributable to the introduction of data exclusivity provisions.

instead of relying on equivalence tests; moreover, unlike patents, data exclusivity is not subject to legal challenge.<sup>101</sup> The major part of the developed countries in the CPTPP Agreement, as well as two developing countries, Chile and Malaysia, provide for data exclusivity, but Brunei Darussalam, Mexico, Peru and Vietnam will need to implement the CPTPP's provisions on test data exclusivity,<sup>102</sup> should the effects of the suspension cease.

The CPTPP is also the first free trade agreement (in force) to include provisions on biologics,<sup>103</sup> which enjoy a longer period of protection as regards test data exclusivity.<sup>104</sup> Two options are set out for biologics: at least eight years of exclusivity for biologics, or five years of exclusivity assisted by other measures to deliver a comparable outcome in the market. From an economic perspective there is no strong evidence to justify such a longer protection period for biologics.<sup>105</sup> Biologics represent an important share of pharmaceutical companies' revenues and are often expensive: test data exclusivity provisions would negatively affect costs and probably innovation. Some studies, in fact, show that there is a relation between data exclusivity and an increase in prices that would negatively affect the access of biosimilar products.<sup>106</sup> As regards compliance with the abovementioned provision, Brunei Darussalam, Malaysia, Mexico, Peru and Vietnam will need to implement changes in their laws<sup>107,108</sup> if the suspension were revoked.

#### 5.4 Patent Linkage

The TPP also contemplates what is commonly known as “patent linkage”, as it requires a member party to deny marketing approval of a generic version of a product if a patent for said product is already in force, unless the patent owner has given permission. Such provisions basically link marketing approval for generic pharmaceutical products to the patent status of a drug. There is evidence suggesting

<sup>101</sup> Gleeson et al. (2015), pp. 306–308.

<sup>102</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 10.

<sup>103</sup> R. Labonte, A. Schram and A. Ruckert, *supra* note 6, pp. 487–496.

<sup>104</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 11. The authors point out that the United States sought to secure 12 years of data exclusivity for biologics, and that it was a key objective of the US-based biopharmaceutical industry.

<sup>105</sup> Federal Trade Commission (2009).

<sup>106</sup> Chakrabarti (2014), pp. 325–336, claiming that there is a relation between data exclusivity and price increases.

<sup>107</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, pp. 11–12, quoting note 160 to Art. 18.83.1.

<sup>108</sup> As regards the other countries, *see* D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 12, noting that the United States provides 12 years of data exclusivity for biologics; Canada provides eight years' exclusivity for all drugs; and Japan has an eight-year period of post-marketing surveillance that works similarly to data exclusivity. Australia and New Zealand, on the other hand, have stated that their regimes are compliant with the data exclusivity provisions for biologics. In both countries, legislation does not make any distinction between small molecule and biological medicines, both being eligible for five years of data exclusivity protection. Chile provides five years of data exclusivity for pharmaceutical products, which also applies to biologics, since its definition of new chemical entities does not distinguish between small-molecule drugs and biologics.

that patent linkage can be determinant in providing pharmaceutical firms with additional protection of their medicines from generic competition.<sup>109</sup> Additionally, such provisions may overburden patent authorities with the task of preventing possible infringements – particularly considering the fact that these authorities may not be able to build in a short time the capacity and the expertise to deal with patent claims<sup>110</sup> –, along with the risk of incurring monetary liability in case the generic product was improperly prevented from entering the market.<sup>111</sup> This task should be left to a court, or similar specialised venues, while regulatory authorities should merely carry out administrative tasks. The panorama on patent linkage is not homogeneous even if we take major developed economies as a benchmark, the USA and the EU in particular. The US Food and Drug Administration does not act as an enforcer of patent rights, although it informs patent owners of the existence of another application for the same drug, leaving the issue of patent infringement to be determined by a court.<sup>112</sup> In the EU, there is independence between the protection of a patent and its registration, the role of regulatory authorities being to ensure compliance with standards of quality, safety and efficacy of medicines.<sup>113</sup> With respect to patent linkage, the final version of the CPTPP is more nuanced than the original proposal, which aimed to assign member countries' regulatory agencies with the task of preventing patent infringements.<sup>114</sup> As regards the implementation, Brunei Darussalam, Malaysia and Vietnam would need to amend their laws to comply with the provision on patent linkage.<sup>115</sup>

## 6 The Investment Chapter of the CPTPP. Shifting Regime for IPR Litigation?

### 6.1 Regime-shifting

The TRIPS Agreement was the first of its kind to provide minimum standards of protection for IP rights, which did not entail an attempt to harmonise IP laws, hence leaving countries free to choose which IP regime to adopt according to their policy preferences.<sup>116</sup> The current practice of negotiating preferential trade agreements has, however, jeopardised such discretion, particularly considering the obligations

<sup>109</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 13.

<sup>110</sup> Report prepared by the United States House of Representatives Committee on Government Reform – Minority Staff Special Investigations Division, June 2005, for Rep. Henry A. Waxman, “Trade Agreements and Access to Medications under the Bush Administration”, [http://www.twn.my/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf](http://www.twn.my/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf).

<sup>111</sup> C.M. Correa, *supra* note 88, pp. 400–402.

<sup>112</sup> Federal Trade Commission (2002).

<sup>113</sup> C.M. Correa, *supra* note 88, pp. 400–402.

<sup>114</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 13.

<sup>115</sup> *Ibid.*

<sup>116</sup> Gathii and Ho (2017), p. 429.

of providing enhanced IPR protection, as well as in the light of protecting foreign investors.<sup>117</sup> In this regard, the *Philip Morris* and *Eli Lilly* cases are blatant examples.<sup>118</sup> An important distinction should be kept in mind when approaching the multifaceted protection of IPRs. PTAs contain provisions that, on the one hand, try to expand the minimum standards of protection granted by the TRIPS Agreement and, on the other, refer to IPRs as protected investments.<sup>119</sup> While the first type of provisions include obligations that have a vertical dimension (such as adhering to specific international treaties or enacting new legislation) and a horizontal one (such as providing rules of treatment and non-discrimination), the second type of provisions create only horizontal obligations, characterised by the requirement to grant, among others, fair and equitable treatment, compensation for expropriation and non-discrimination.<sup>120</sup> Investment provisions are often coupled with the option of settling IP-related claims before an arbitral tribunal and according to that body of law that goes under the name of investment law. Such option has been seen not only as a mere instance of forum-shopping – namely, the possibility that the claimant chooses the most convenient venue where to litigate the case –, but rather as a manifestation of what has been defined as “regime-shifting”,<sup>121</sup> and ultimately an attempt to rewrite those international and domestic provisions that struck a balance between IPR protection and the public interest.<sup>122</sup> If one considers the *Eli Lilly* case, where Canada’s decision to invalidate a patent was challenged before an arbitral tribunal, it is evident that such challenges may have the aim of destabilising those flexibilities contemplated by the TRIPS Agreement, and may create uncertainties as regards regulations protecting health. A wide range of provisions can be subject to litigation, for instance, those requiring companies to disclose clinical data, or those aimed at setting the price of medicines at a lower level.<sup>123</sup> Compulsory licensing<sup>124</sup> and regulations affecting trademarks can also be subject to litigation. It is also noteworthy to point out that such claims will likely create friction between the recommendations issued by the World Health Organisation and other United Nations’ agencies as regards the promotion of public health and the role of the investment regime protecting investors’ rights.<sup>125</sup>

<sup>117</sup> See in general Vanhonnaecker (2015), Morosini and Ratton Sanchez (2017), p. 353.

<sup>118</sup> *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7 (formerly *FTR Holding SA, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*); *Philip Morris Asia Limited v. The Commonwealth of Australia*, UNCITRAL, PCA Case No. 2012-12; *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2.

<sup>119</sup> Correa and Viñuales (2016), p. 93.

<sup>120</sup> *Ibid.*

<sup>121</sup> J. Gathii and C. Ho, *supra* note 116, p. 430; Helfer (2004), p. 10.

<sup>122</sup> *Ibid.*, p. 430. At p. 440, the authors point out that while regime-shifting involves a shift to a new forum, it is distinct from forum-shopping because in the latter there is a one-time shift to a new forum for the purpose of a single dispute, whereas the ultimate aim of a regime shift is pigeonholed in a long-term strategy seeking to create outcomes that have reverberations in other venues.

<sup>123</sup> *Ibid.*, p. 432.

<sup>124</sup> Gibson (2010), pp. 357–422, Rutledge (2012), pp. 149–164.

<sup>125</sup> J. Gathii and C. Ho, *supra* note 116, p. 432.

Giving an account of the definition of “regime” is central to our purpose. A regime is defined as a set of “implicit or explicit principles, norms, rules and decision-making procedures around which actors’ expectations converge in a given area of international relations”.<sup>126</sup> International law, in particular, has assisted a proliferation of regimes in several areas, which also goes under the name of fragmentation.<sup>127</sup> In the absence of clear rules to address conflicts between regimes covering similar areas, players – states and non-state entities – become more opportunistically explorative of the options that these regimes offer, by transmigrating from one regime to another with the view of assessing which would be better to foster their interests.<sup>128</sup> A regime shift has its phases, but, as a general proposition, it happens in the context of a regime complex, which is made of separate but related regimes.<sup>129</sup> As regards IPRs, they form the subject matter of different regimes:

- the World Trade Organisation;
- the World Intellectual Property Organisation;
- the World Health Organisation; and
- Bilateral Investment Treaties.

Regime-shifting is hence not a new occurrence in IP law.<sup>130</sup> The WTO/TRIPS shifted IP law-making from the domestic domain to the international one, also adding a distinctive trade law component absent in previous international treaties touching upon IPRs.<sup>131</sup> Another shift occurred when the irreconcilability of the TRIPS Agreement with the needs of developing countries was balanced with the creation of counter-norms granting access to essential medicines in forums like the WHO and the UN human rights system,<sup>132</sup> and eventually such norms were inserted in TRIPS through the 2001 Doha Ministerial Declaration on TRIPS and Public Health.<sup>133</sup> A subsequent regime shift in response to the norms on public health happened through the conclusion of PTAs containing TRIPS-plus provisions.<sup>134</sup> It

<sup>126</sup> L. Helfer, *supra* note 121, p. 10. A regime is comprised of substantive, institutional and relational components: the substantive component implies principles, norms and rules prescribing a state’s behaviour; the institutional component is the cooperative arrangement used to create said principles, norms and rules; the relational component focuses on substantive issue areas included within a regime, and the ways they interact with other regimes.

<sup>127</sup> J. Gathii and C. Ho, *supra* note 116, p. 440. See also the Report of the Study Group of the International Law Commission, finalised by M. Koskeniemmi, “Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law”, UN Doc A/CN.4/L.682, 13 April 2006.

<sup>128</sup> J. Gathii and C. Ho, *supra* note 116, p. 440.

<sup>129</sup> *Ibid.*, p. 442.

<sup>130</sup> Yu (2004), p. 323.

<sup>131</sup> J. Gathii and C. Ho, *supra* note 116, p. 444.

<sup>132</sup> *Ibid.*

<sup>133</sup> *Ibid.*, p. 445.

<sup>134</sup> *Ibid.*

has now been argued that a fourth shift is happening, namely that from trade law to investment law.<sup>135</sup>

### 6.1.1 Regime-shifting Implications

Illustrating the dynamics of regime-shifting serves the purpose of understanding its concrete implications. One may consider not only the regulatory chill that investor-state arbitration can set in motion,<sup>136</sup> but also other features of investor-state arbitration vis-à-vis state-to-state dispute settlement. If one considers state-to-state litigation, the remedies for corporations are non-existent because they can neither be party to the proceedings, nor are compensation or other forms of monetary reparation available: remedies, on the other hand, are directed towards repealing the legislation inconsistent with trade commitments; investor-state arbitration, to the contrary, is designed to allow monetary reparation. A further difference lies in third parties' participation: while state-to-state dispute settlement provides for participation of third parties having an interest in the dispute, investor-state arbitration does not provide for such a possibility. Eventually, while investor-state arbitration awards can be directly enforced by the investor, a panel report implementation requires actions from the concerned state.

The assumption that regime-shifting is meant to destabilise another regime through the creation of conflicting norms may be confirmed by the tobacco companies' litigation strategy, which involved multiple fora – investor-state arbitration, WTO dispute settlement procedure and litigation before national courts.<sup>137</sup> Similarly, the *Eli Lilly* case focused on Canada's promise doctrine and was likely directed to impel an amendment of the Canadian case law and legislation, as well as to provide a background for the interpretation of the TRIPS Agreement that would have influenced the way TRIPS flexibilities would be used in the future.<sup>138</sup> It should also be carefully considered that, while the connection with harm to public health was easy to establish in the *Philip Morris* cases, where one may say a milestone has been set for future litigation on the same or similar subject matters,<sup>139</sup> disputes on pharmaceuticals might attract less interest from the public, although representing a significant threat for domestic regulations.<sup>140</sup> In other words, while smoking can be categorised as a public health hazard, entitling states to resort to their police power to regulate it, no univocal consensus exists as to limiting patent protection to promote public health.<sup>141</sup> More importantly, as said

<sup>135</sup> *Ibid.*, p. 447, arguing that evidence of such shift are the cases involving Philip Morris and Eli Lilly.

<sup>136</sup> *Ibid.* *Mutatis mutandis*, regulatory chill, as a result of investor-state arbitration, happens in other areas, such as water resources law. See Daza-Clark (2016).

<sup>137</sup> J. Gathii and C. Ho, *supra* note 116, p. 460.

<sup>138</sup> *Ibid.* However, as regards recent developments on the Canadian promise doctrine, see Mason et al. (2017).

<sup>139</sup> J. Gathii and C. Ho, *supra* note 116, p. 460.

<sup>140</sup> *Ibid.*, p. 461.

<sup>141</sup> *Ibid.*, pointing out that the WIPO, after the UN convened a High Level Panel on Access to Medicine, showed some criticism as to the assumption in the Panel mandate that there is “policy incoherence” between promoting innovation through IP and providing access to medicines.

above, the *Eli Lilly* case is relevant to regime-shifting because it could have jeopardised TRIPS flexibilities, in particular patentability requirements. Patent rights, and this assumption may be stronger for pharmaceuticals, have an impact on the cost of drugs, and thus on the access to affordable medicines.<sup>142</sup>

Not only patentability standards, but also compulsory licensing may trigger investor-state arbitration, which leads us to discuss the features of the CPTPP investment chapter and the main aspects of IPRs as investments.

## 6.2 The CPTPP Investment Chapter

The chapter follows US treaty practice and adopts an asset-based definition of investment,<sup>143</sup> providing a representative definition, which includes “every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk”,<sup>144</sup> coupled with some specific forms that an investment can take, including “intellectual property rights”, and “other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens, and pledges”.<sup>145</sup> On the other hand, an order or judgment entered in a judicial or administrative action is excluded from the reach of the term investment.<sup>146</sup> A reasonable explanation for such exclusion seems to be the necessity of preventing claims in relation to local decisions being perceived as substantially or procedurally unfair.<sup>147</sup>

The investment chapter provides for the following substantive commitments:

- national treatment in like circumstances (non-discrimination compared to local investors);<sup>148</sup>
- most-favoured-nation treatment;<sup>149</sup>
- minimum standard of treatment according to customary international law,<sup>150</sup> which includes fair and equitable treatment (and in particular the obligation not to deny justice through domestic adjudicatory proceedings) and full protection and security.<sup>151</sup> As regards this latter standard, the fact that a state measure may

<sup>142</sup> *Ibid.*, p. 463, quoting the Doha Declaration.

<sup>143</sup> Nottage (2016), p. 19.

<sup>144</sup> Art. 9.1.

<sup>145</sup> Art. 9.1.

<sup>146</sup> Art. 9.1.

<sup>147</sup> Art. 9.1, which also seems to leave open the possibility of treaty claims as regards non-enforcement of arbitral awards. *See generally* Paulsson (2005). *See* L. Nottage, *supra* note 143, p. 19, providing some literature on denial of justice and FET claims. Among them, Liebscher (2009), p. 105, Liddell and Waibel (2016), p. 145, Bjorklund (2016), p. 97.

<sup>148</sup> Art. 9.4.

<sup>149</sup> Art. 9.5. Art. 9.5.3 clarifies that the MFN does not encompass international dispute resolution procedures or mechanisms, such as the investor-state dispute settlement.

<sup>150</sup> Annex 9-A to the TPP investment chapter.

<sup>151</sup> Art. 9.6.

be inconsistent with an investor's expectations does not constitute an automatic violation of the FET standard, even if, as a result, there is loss of or damage to the covered investment;

- compensation for direct and indirect expropriation.<sup>152</sup> As regards this provision, it does not apply to compulsory licences granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation or creation of intellectual property rights, provided that such actions are consistent with the intellectual property chapter;
- limitation to the scope of investor protection, as regards the adoption of measures considered appropriate to ensure that investments are undertaken in a manner sensitive to environmental, health or other regulatory objectives, and provided that such measures are consistent with the investment chapter;<sup>153</sup>
- limitation of the protection available to investors in areas such as tobacco-control measures, which can be excluded from the reach of investor-state claims.<sup>154</sup>

### 6.3 Compulsory Licensing and Indirect Expropriation

The language of a treaty is important to understand where it contains clauses to safeguard public health. One of the most common is protection against direct and indirect expropriation. Expropriation is allowed under international law, as long as it is for a public purpose, non-discriminatory, in accordance with due process of law and on payment of (prompt, adequate and effective) compensation.<sup>155</sup> While direct expropriation implies measures that deprive the owner of his rights, indirect expropriation consists in a measure that does not deprive the investor of the property of the investment but rather in a radical deprivation of the enjoyment of the investment itself.<sup>156</sup> Regulatory measures can also be regarded as expropriatory measures, such as in the cases *Feldman v. Mexico*<sup>157</sup> or *ADC v. Hungary*,<sup>158</sup> and in health-related cases the claim may be that a measure had the effect of indirectly expropriating the investor's asset. There is no general rule to set a net distinction between indirect expropriation and legitimate regulation, and its assessment is on a case-by-case basis;<sup>159</sup> moreover, some investment treaties do not provide for further guidance in their texts.

Issuing a compulsory licence epitomises the aforementioned problem. In an attempt to bring clarity, the United States and other countries have adopted the practice of inserting interpretative guidance in the text of BITs, or investment

<sup>152</sup> Art. 9.7.

<sup>153</sup> Art. 9.15.

<sup>154</sup> Art. 29.5.

<sup>155</sup> Mercurio (2014), p. 521.

<sup>156</sup> *Ibid.*

<sup>157</sup> *Marvin Feldman v. Mexico*. ICSID Case No. ARB(AF)/99/1.

<sup>158</sup> *ADC Affiliate Limited and ADC & ADMC Management Limited v. The Republic of Hungary*. ICSID Case No. ARB/03/16.

<sup>159</sup> B. Mercurio, *supra* note 155, p. 521; Chaisse (2012), pp. 147–156.



chapters of PTAs. Such guidance sets some factors relevant to the determination of whether a measure can be considered as expropriation. Similar wording is present in the CPTPP text. In order to assert the existence of an indirect expropriation, one has to determine:

- whether there is an adverse economic impact, although such impact is not per se sufficient to prove the claim;
- the extent to which the government action interferes with distinct, reasonable investment-backed expectations;
- the character of the government action.<sup>160</sup>

Although such wording is helpful to governments in adopting measures pursuing public health outcomes, it may be of limited assistance if it does not provide a suggestion of how the aforementioned factors should be balanced. Subsequent treaties, and the CPTPP is no exception, then adopted a more refined wording so as to directly limit the impact of the expropriation standard in the case of measures taken with a public health aim. Wording such as

[t]his Article shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation or creation of intellectual property rights, to the extent that the issuance, revocation, limitation or creation is consistent with [the Chapter on Intellectual Property and] the TRIPS Agreement<sup>161</sup>

recognise the potential overlapping and inconsistencies in the IPR regime as set by international treaties and is meant to avoid that an instrument adopted according to the TRIPS Agreement be considered inconsistent with the investment regime.<sup>162</sup> Such a clause is, however, problematic for it leaves the arbitral tribunal the possibility of interpreting whether a provision is consistent with the TRIPS Agreement: on the one hand, such tribunal may not have enough expertise in WTO law,<sup>163</sup> on the other, the proper venue to consider whether a measure is consistent with the TRIPS Agreement should be the WTO dispute settlement mechanism itself.

Additional wording, also present in the CPTPP text, has been adopted to limit the possibility of broader investor protection vis-à-vis public health: “[n]on-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations, except in rare circumstances”.<sup>164</sup> The wording of such a clause reinforces the idea that, among others, health measures should not be regarded as indirect expropriation, limiting the reach of indirect expropriation claims based on a compulsory licence.<sup>165</sup>

<sup>160</sup> Annex 9-B to the CPTPP investment chapter.

<sup>161</sup> Art. 9.8.5.

<sup>162</sup> B. Mercurio, *supra* note 15, p. 522.

<sup>163</sup> *Ibid.*

<sup>164</sup> Annex 9-B to the CPTPP investment chapter.

<sup>165</sup> Annex 9-B to the CPTPP investment chapter. B. Mercurio, *supra* note 155, p. 522. Mercurio (2012), pp. 871–915.

The analysed wording does not imply that health-related measures are *ex toto* excluded from the reach of investor protection, which would be undesirable under the proposition that due process of law requires that governmental measures should be subject to scrutiny.<sup>166</sup>

#### 6.4 Investor-State Provisions

The substantive provisions of the CPTPP investment chapter are assisted by investor-state arbitration, a feature of increasing importance that has become accepted as a component of investment treaties entered into in the Asian region.<sup>167</sup> The inclusion of investor-state dispute settlement in the TPP, and the same justification should be held valid for the CPTPP, has been dictated, among other factors, by the involvement of developing countries, as well as middle-income ones, such as Malaysia, which has a complex political and legal environment;<sup>168</sup> eventually, it might have appealed to further countries to become parties to the Agreement.<sup>169</sup>

As regards the main procedural features of investor-state arbitration, the text of the Agreement provides for time preclusions for submitting claims;<sup>170</sup> a fork-in-the-road provision<sup>171</sup> requiring investors relying on arbitration proceedings to waive the right of initiating or continuing claims before the domestic courts of the host state; transparency provisions, and in particular public hearings<sup>172</sup> and *amicus curiae* briefs.<sup>173</sup> The tribunal may also issue a draft award available only to the disputing parties for comment, hence excluding the public and the investor's home country.<sup>174</sup> Eventually, an interstate Commission can issue interpretations of the CPTPP provisions that are binding for the arbitral tribunal, although it is debated whether the Commission can make a binding interpretation as regards a pending dispute,<sup>175</sup> which would be desirable, considering the limited value of precedents in investment arbitration, as well as the fact, as stated earlier, that arbitrators may not be acquainted with the complexities of trade law.

<sup>166</sup> B. Mercurio, *supra* note 155, p. 522, noting that another option is to insert general exception clauses modelled after those present in the WTO Agreements.

<sup>167</sup> Which has also led to more claims. See Nottage and Weeramantry (2011), p. 25, Malintoppi (2015), p. 12.

<sup>168</sup> L. Nottage, *supra* note 143, p. 25.

<sup>169</sup> *Ibid.* As regards the TPP, these countries include(d) Indonesia, and other potential candidates such as Korea and China.

<sup>170</sup> Art. 9.21.1.

<sup>171</sup> Art. 9.21.2.

<sup>172</sup> Art. 9.23.

<sup>173</sup> Art. 9.22.

<sup>174</sup> Art. 9.23.10. L. Nottage, *supra* note 143, p. 27, pointing out that this is a feature of the WTO dispute resolution, but also found in the 2004 US Model BIT, as well as in Australia's FTA investment chapters with Chile and Korea.

<sup>175</sup> Art. 9.25.3. L. Nottage, *supra* note 143, p. 27.

## 7 Conclusion

The discussion on the abovementioned provisions in the IP chapter of the CPTPP, which include TRIPS-plus standards, will have practical consequences for the signatories, should the suspension cease to be effective. A main claim is that in establishing standard trade rules the CPTPP will definitely level the playing field for its members.<sup>176</sup> Whether such a perspective can be shared is questionable since the reality shows a different scenario, as some developing member countries would need to introduce substantial amendments to their IP legislation in order to comply with the CPTPP obligations. Additionally, such requirements should be met according to the transition period which provides limited tolerance for delays.<sup>177</sup> On the other hand, developed countries party to the Agreement will need to make minor amendments to their IP legislation, although, as discussed, it may be detrimental to future IP and public health policy considerations;<sup>178</sup> additionally, the impact should be considered on test data exclusivity provisions for biologics in national health care programmes.<sup>179</sup>

We also discussed how the TRIPS-plus provisions in the CPTPP IP chapter may delay market access for generics and biosimilars: while developed countries may be able to sustain the additional costs, developing countries, on the other hand, may face budgetary problems when providing access to affordable medicines to their citizens.<sup>180</sup> In this regard, the suspension of the IP chapter provisions may entail rising public-health-related budgetary costs for developing member states.<sup>181</sup> On another note, there is also no clear connection between whether enhanced IP protection in developing countries will incentivise pharmaceutical companies to conduct research in the treatment of endemic diseases;<sup>182</sup> nor between patent protection and increased expenditure in research and development,<sup>183</sup> nor between

<sup>176</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 13, quoting Office of the United States Trade Representative (2016).

<sup>177</sup> D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 13, pointing out that Vietnam negotiated the option of requesting an extension to the transition period, and for a few provisions; on the other hand, New Zealand will introduce a patent term extension for the first time.

<sup>178</sup> *Ibid.*

<sup>179</sup> *Ibid.*, pp. 13–14, making reference to Gleeson et al. (2014).

<sup>180</sup> See D. Gleeson, J. Lexchin, R. Lopert and B. Kilic, *supra* note 80, p. 14. Arguing that there is no certainty as to whether the overall economic benefits of the TPP will compensate for the increased costs for the health care system – provided that any economic benefit accruing from the agreement will be used in such direction. The authors also make reference to some studies forecasting small aggregate economic benefits for most TPP countries. For instance, Petri and Plummer (2016), estimated that the benefit to the United States would be 0.5% of GDP by 2030. A similar study by the World Bank, *op cit.*, *supra* note 5, which echoes Petri's and Plummer's work, estimates the average impact on TPP countries as 1.1% of GDP by 2030 (with gains of 10% and 8% for Vietnam and Malaysia, and of 0.6% for Canada, Mexico and the United States on average). These studies are, however, based on a model that assumes full employment and invariant income distribution. On the other hand, a study using a different model – Capaldo and Izurieta (2016) – allowing for changes in employment and income distribution, shows small benefits for most countries and negative income growth for the United States and Japan.

<sup>181</sup> Walls et al. (2015), p. 14.

<sup>182</sup> Kyle and McGahan (2012), pp. 1157–1172.

<sup>183</sup> Park (2007), pp. 289–327.

the adoption of test data exclusivity provisions and the flow of investment by the pharmaceutical industry in a given country.<sup>184</sup>

As regards the investment chapter of the CPTPP, the presence of clauses that limit the applicability of expropriation when public health measures or tobacco regulations are concerned is certainly a signal that proper treaty drafting may balance the potential conflict existing between public health and investment law. Although such measures safeguard non-discriminatory health measures, there are some grey areas that will inevitably be filled by the interpretation of arbitral tribunals, with the caveat that investment arbitral awards do not strictly carry the value of precedent. The presence of such clauses, moreover, seems to contradict the fact that regime-shifting would have a destabilising effect on IPR regulation.

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