

# COMPREHENSIVE AND PROGRESSIVE AGREEMENT FOR TRANS-PACIFIC PARTNERSHIP

## CHAPTER 18

### INTELLECTUAL PROPERTY

#### Section A: General Provisions

##### Article 18.1: Definitions

1. For the purposes of this Chapter:

**Berne Convention** means the *Berne Convention for the Protection of Literary and Artistic Works*, as revised at Paris, July 24, 1971;

**Budapest Treaty** means the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* (1977), as amended on September 26, 1980;

**Declaration on TRIPS and Public Health** means the *Declaration on the TRIPS Agreement and Public Health* (WT/MIN(01)/DEC/2), adopted on November 14, 2001;

**geographical indication** means an indication that identifies a good as originating in the territory of a Party, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin;

**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;

**Madrid Protocol** means the *Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks*, done at Madrid, June 27, 1989;

**Paris Convention** means the *Paris Convention for the Protection of Industrial Property*, as revised at Stockholm, July 14, 1967;

**performance** means a performance fixed in a phonogram unless otherwise specified;

with respect to copyright and related rights, the term right to authorise or prohibit refers to exclusive rights;

**Singapore Treaty** means the *Singapore Treaty on the Law of Trademarks*, done at Singapore, March 27, 2006;

**UPOV 1991** means the *International Convention for the Protection of New Varieties of Plants*, as revised at Geneva, March 19, 1991;

**WCT** means the *WIPO Copyright Treaty*, done at Geneva, December 20, 1996;

**WIPO** means the World Intellectual Property Organization;

for greater certainty, **work** includes a cinematographic work, photographic work and computer program; and

**WPPT** means the *WIPO Performances and Phonograms Treaty*, done at Geneva, December 20, 1996.

2. For the purposes of Article 18.8 (National Treatment), Article 18.31(a) (Administrative Procedures for the Protection or Recognition of Geographical Indications) and Article 18.62.1 (Related Rights):

a **national** means, in respect of the relevant right, a person of a Party that would meet the criteria for eligibility for protection provided for in the agreements listed in Article 18.7 (International Agreements) or the TRIPS Agreement.

## **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.

## **Article 18.3: Principles**

1. A Party may, in formulating or amending its 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.

2. 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 unreasonably restrain trade or adversely affect the international transfer of technology.

#### **Article 18.4: Understandings in Respect of this Chapter**

Having regard to the underlying public policy objectives of national systems, the Parties recognise the need to:

- (a) promote innovation and creativity;
- (b) facilitate the diffusion of information, knowledge, technology, culture and the arts; and
- (c) foster competition and open and efficient markets,

through their respective intellectual property systems, while respecting the principles of transparency and due process, and taking into account the interests of relevant stakeholders, including right holders, service providers, users and the public.

#### **Article 18.5: Nature and Scope of Obligations**

Each Party shall give effect to the provisions of this Chapter. A Party may, but shall not be obliged to, provide more extensive protection for, or enforcement of, intellectual property rights under its law than is required by this Chapter, provided that such protection or enforcement does not contravene the provisions of this Chapter. Each Party shall be free to determine the appropriate method of implementing the provisions of this Chapter within its own legal system and practice.

#### **Article 18.6: Understandings Regarding Certain Public Health Measures**

1. The Parties affirm their commitment to the Declaration on TRIPS and Public Health. In particular, the Parties have reached the following understandings regarding this Chapter:

- (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all. Each Party has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

- (b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the WTO General Council of August 30, 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), as well as the Decision of the WTO General Council of December 6, 2005 on the *Amendment of the TRIPS Agreement*, (WT/L/641) and the WTO General Council Chairperson's Statement Accompanying the Decision (JOB(05)/319 and Corr. 1, WT/GC/M/100) (collectively, the "TRIPS/health solution"), this Chapter does not and should not prevent the effective utilisation of the TRIPS/health solution.
- (c) With respect to the aforementioned matters, if any waiver of any provision of the TRIPS Agreement, or any amendment of the TRIPS Agreement, enters into force with respect to the Parties, and a Party's application of a measure in conformity with that waiver or amendment is contrary to the obligations of this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the waiver or amendment.

2. Each Party shall notify, if it has not already done so, the WTO of its acceptance of the *Protocol amending the TRIPS Agreement*, done at Geneva on December 6, 2005.

#### **Article 18.7: International Agreements**

1. Each Party affirms that it has ratified or acceded to the following agreements:

- (a) *Patent Cooperation Treaty*, as amended September 28, 1979;
- (b) Paris Convention; and
- (c) Berne Convention.

2. Each Party shall ratify or accede to each of the following agreements, if it is not already a party to that agreement, by the date of entry into force of this Agreement for that Party:

- (a) Madrid Protocol;
- (b) Budapest Treaty;

- (c) Singapore Treaty;<sup>1</sup>
- (d) UPOV 1991;<sup>2</sup>
- (e) WCT; and
- (f) WPPT.

### **Article 18.8: National Treatment**

1. In respect of all categories of intellectual property covered in this Chapter,<sup>3</sup> each Party shall accord to nationals of another Party treatment no less favourable than it accords to its own nationals with regard to the protection<sup>4</sup> of intellectual property rights.

2. With respect to secondary uses of phonograms by means of analog communications and free over-the-air broadcasting, however, a Party may limit the rights of the performers and producers of another Party to the rights its persons are accorded within the jurisdiction of that other Party.

3. A Party may derogate from paragraph 1 in relation to its judicial and administrative procedures, including requiring a national of another Party to designate an address for service of process in its territory, or to appoint an agent in its territory, provided that such derogation is:

- (a) necessary to secure compliance with laws or regulations that are not inconsistent with this Chapter; and

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<sup>1</sup> A Party may satisfy the obligations in paragraph 2(a) and 2(c) by ratifying or acceding to either the Madrid Protocol or the Singapore Treaty.

<sup>2</sup> Annex 18-A applies to this subparagraph.

<sup>3</sup> For greater certainty, with respect to copyrights and related rights that are not covered under Section H (Copyright and Related Rights), nothing in this Agreement limits a Party from taking an otherwise permissible derogation from national treatment with respect to those rights.

<sup>4</sup> For the purposes of this paragraph, “protection” shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as matters affecting the use of intellectual property rights specifically covered by this Chapter. Further, for the purposes of this paragraph, “protection” also includes the prohibition on the circumvention of effective technological measures set out in Article 18.68 (TPMs) and the provisions concerning rights management information set out in Article 18.69 (RMI). For greater certainty, “matters affecting the use of intellectual property rights specifically covered by this Chapter” in respect of works, performances and phonograms, include any form of payment, such as licensing fees, royalties, equitable remuneration, or levies, in respect of uses that fall under the copyright and related rights in this Chapter. The preceding sentence is without prejudice to a Party’s interpretation of “matters affecting the use of intellectual property rights” in footnote 3 of the TRIPS Agreement.

- (b) not applied in a manner that would constitute a disguised restriction on trade.

4. Paragraph 1 does not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

#### **Article 18.9: Transparency**

1. Further to Article 26.2 (Publication) and Article 18.73.1 (Enforcement Practices with Respect to Intellectual Property Rights), each Party shall endeavour to make available on the Internet its laws, regulations, procedures and administrative rulings of general application concerning the protection and enforcement of intellectual property rights.

2. Each Party shall, subject to its law, endeavour to make available on the Internet information that it makes public concerning applications for trademarks, geographical indications, designs, patents and plant variety rights.<sup>5,6</sup>

3. Each Party shall, subject to its law, make available on the Internet information that it makes public concerning registered or granted trademarks, geographical indications, designs, patents and plant variety rights, sufficient to enable the public to become acquainted with those registered or granted rights.<sup>7</sup>

#### **Article 18.10: Application of Chapter to Existing Subject Matter and Prior Acts**

1. Unless otherwise provided in this Chapter, including in Article 18.64 (Application of Article 18 of the Berne Convention and Article 14.6 of the TRIPS Agreement), this Chapter gives rise to obligations in respect of all subject matter existing at the date of entry into force of this Agreement for a Party and that is protected on that date in the territory of a Party where protection is claimed, or that meets or comes subsequently to meet the criteria for protection under this Chapter.

2. Unless provided in Article 18.64 (Application of Article 18 of the Berne Convention and Article 14.6 of the TRIPS Agreement), a Party shall not be

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<sup>5</sup> For greater certainty, paragraphs 2 and 3 are without prejudice to a Party's obligations under Article 18.24 (Electronic Trademarks System).

<sup>6</sup> For greater certainty, paragraph 2 does not require a Party to make available on the Internet the entire dossier for the relevant application.

<sup>7</sup> For greater certainty, paragraph 3 does not require a Party to make available on the Internet the entire dossier for the relevant registered or granted intellectual property right.

required to restore protection to subject matter that on the date of entry into force of this Agreement for that Party has fallen into the public domain in its territory.

3. This Chapter does not give rise to obligations in respect of acts that occurred before the date of entry into force of this Agreement for a Party.

### **Article 18.11: Exhaustion of Intellectual Property Rights**

Nothing in this Agreement prevents a Party from determining whether or under what conditions the exhaustion of intellectual property rights applies under its legal system.<sup>8</sup>

## **Section B: Cooperation**

### **Article 18.12: Contact Points for Cooperation**

Further to Article 21.3 (Contact Points for Cooperation and Capacity Building), each Party may designate and notify under Article 27.5.2 (Contact Points) one or more contact points for the purpose of cooperation under this Section.

### **Article 18.13: Cooperation Activities and Initiatives**

The Parties shall endeavour to cooperate on the subject matter covered by this Chapter, such as through appropriate coordination, training and exchange of information between the respective intellectual property offices of the Parties, or other institutions, as determined by each Party. Cooperation may cover areas such as:

- (a) developments in domestic and international intellectual property policy;
- (b) intellectual property administration and registration systems;
- (c) education and awareness relating to intellectual property;
- (d) intellectual property issues relevant to:
  - (i) small and medium-sized enterprises;
  - (ii) science, technology and innovation activities; and

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<sup>8</sup> For greater certainty, this Article is without prejudice to any provisions addressing the exhaustion of intellectual property rights in international agreements to which a Party is a party.

- (iii) the generation, transfer and dissemination of technology;
- (e) policies involving the use of intellectual property for research, innovation and economic growth;
- (f) implementation of multilateral intellectual property agreements, such as those concluded or administered under the auspices of WIPO; and
- (g) technical assistance for developing countries.

#### **Article 18.14: Patent Cooperation and Work Sharing**

1. The Parties recognise the importance of improving the quality and efficiency of their respective patent registration systems as well as simplifying and streamlining the procedures and processes of their respective patent offices for the benefit of all users of the patent system and the public as a whole.

2. Further to paragraph 1, 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. This may include:

- (a) making search and examination results available to the patent offices of other Parties;<sup>9</sup> and
- (b) exchanging information on quality assurance systems and quality standards relating to patent examination.

3. In order to reduce the complexity and cost of obtaining the grant of a patent, the Parties shall endeavour to cooperate to reduce differences in the procedures and processes of their respective patent offices.

4. The Parties recognise the importance of giving due consideration to ratifying or acceding to the *Patent Law Treaty*, done at Geneva, June 1, 2000; or in the alternative, adopting or maintaining procedural standards consistent with the objective of the *Patent Law Treaty*.

#### **Article 18.15: Public Domain**

1. The Parties recognise the importance of a rich and accessible public domain.

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<sup>9</sup> The Parties recognise the importance of multilateral efforts to promote the sharing and use of search and examination results, with a view to improving the quality of search and examination processes and to reducing the costs for both applicants and patent offices.



2. The Parties also acknowledge the importance of informational materials, such as publicly accessible databases of registered intellectual property rights that assist in the identification of subject matter that has fallen into the public domain.

#### **Article 18.16: Cooperation in the Area of Traditional Knowledge**

1. The Parties recognise the relevance of intellectual property systems and traditional knowledge associated with genetic resources to each other, when that traditional knowledge is related to those intellectual property systems.

2. The Parties shall endeavour to cooperate through their respective agencies responsible for intellectual property, or other relevant institutions, to enhance the understanding of issues connected with traditional knowledge associated with genetic resources, and genetic resources.

3. The Parties shall endeavour to pursue quality patent examination, which may include:

- (a) that in determining prior art, relevant publicly available documented information related to traditional knowledge associated with genetic resources may be taken into account;
- (b) an opportunity for third parties to cite, in writing, to the competent examining authority prior art disclosures that may have a bearing on patentability, including prior art disclosures related to traditional knowledge associated with genetic resources;
- (c) if applicable and appropriate, the use of databases or digital libraries containing traditional knowledge associated with genetic resources; and
- (d) cooperation in the training of patent examiners in the examination of patent applications related to traditional knowledge associated with genetic resources.

#### **Article 18.17: Cooperation on Request**

Cooperation activities and initiatives undertaken under this Chapter shall be subject to the availability of resources, and on request, and on terms and conditions mutually agreed upon between the Parties involved.

## **Section C: Trademarks**

### **Article 18.18: Types of Signs Registrable as Trademarks**

No Party shall require, as a condition of registration, that a sign be visually perceptible, nor shall a Party deny registration of a trademark only on the ground that the sign of which it is composed is a sound. Additionally, each Party shall make best efforts to register scent marks. A Party may require a concise and accurate description, or graphical representation, or both, as applicable, of the trademark.

### **Article 18.19: Collective and Certification Marks**

Each Party shall provide that trademarks include collective marks and certification marks. A Party is not obligated to treat certification marks as a separate category in its law, provided that those marks are protected. Each Party shall also provide that signs that may serve as geographical indications are capable of protection under its trademark system.<sup>10</sup>

### **Article 18.20: Use of Identical or Similar Signs**

Each Party shall provide that the owner of a registered trademark has the exclusive right to prevent third parties that do not have the owner's consent from using in the course of trade identical or similar signs, including subsequent geographical indications,<sup>11, 12</sup> for goods or services that are related to those goods or services in respect of which the owner's trademark is registered, where such use would result in a likelihood of confusion. In the case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.

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<sup>10</sup> Consistent with the definition of a geographical indication in Article 18.1 (Definitions), any sign or combination of signs shall be eligible for protection under one or more of the legal means for protecting geographical indications, or a combination of such means.

<sup>11</sup> For greater certainty, the exclusive right in this Article applies to cases of unauthorised use of geographical indications with goods for which the trademark is registered, in cases in which the use of that geographical indication in the course of trade would result in a likelihood of confusion as to the source of the goods.

<sup>12</sup> For greater certainty, the Parties understand that this Article should not be interpreted to affect their rights and obligations under Articles 22 and 23 of the TRIPS Agreement.

### **Article 18.21: Exceptions**

A Party may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that those exceptions take account of the legitimate interest of the owner of the trademark and of third parties.

### **Article 18.22: Well-Known Trademarks**

1. No Party shall require as a condition for determining that a trademark is well-known that the trademark has been registered in the Party or in another jurisdiction, included on a list of well-known trademarks, or given prior recognition as a well-known trademark.

2. Article 6*bis* of the Paris Convention shall apply, *mutatis mutandis*, to goods or services that are not identical or similar to those identified by a well-known trademark,<sup>13</sup> whether registered or not, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the trademark, and provided that the interests of the owner of the trademark are likely to be damaged by such use.

3. Each Party recognises the importance of the *Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks* as adopted by the Assembly of the Paris Union for the Protection of Industrial Property and the General Assembly of WIPO at the Thirty-Fourth Series of Meetings of the Assemblies of the Member States of WIPO September 20 to 29, 1999.

4. Each Party shall provide for appropriate measures to refuse the application or cancel the registration and prohibit the use of a trademark that is identical or similar to a well-known trademark<sup>14</sup>, for identical or similar goods or services, if the use of that trademark is likely to cause confusion with the prior well-known trademark. A Party may also provide such measures including in cases in which the subsequent trademark is likely to deceive.

### **Article 18.23: Procedural Aspects of Examination, Opposition and Cancellation**

Each Party shall provide a system for the examination and registration of trademarks which includes among other things:

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<sup>13</sup> In determining whether a trademark is well-known in a Party, that Party need not require that the reputation of the trademark extend beyond the sector of the public that normally deals with the relevant goods or services.

<sup>14</sup> The Parties understand that a well-known trademark is one that was already well-known before, as determined by a Party, the application for, registration of or use of the first-mentioned trademark.

- (a) communicating to the applicant in writing, which may be by electronic means, the reasons for any refusal to register a trademark;
- (b) providing the applicant with an opportunity to respond to communications from the competent authorities, to contest any initial refusal, and to make a judicial appeal of any final refusal to register a trademark;
- (c) providing an opportunity to oppose the registration of a trademark or to seek cancellation<sup>15</sup> of a trademark; and
- (d) requiring administrative decisions in opposition and cancellation proceedings to be reasoned and in writing, which may be provided by electronic means.

#### **Article 18.24: Electronic Trademarks System**

Each Party shall provide:

- (a) a system for the electronic application for, and maintenance of, trademarks; and
- (b) a publicly available electronic information system, including an online database, of trademark applications and of registered trademarks.

#### **Article 18.25: Classification of Goods and Services**

Each Party shall adopt or maintain a trademark classification system that is consistent with the *Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks*, done at Nice, June 15, 1957, as revised and amended (Nice Classification). Each Party shall provide that:

- (a) registrations and the publications of applications indicate the goods and services by their names, grouped according to the classes established by the Nice Classification;<sup>16</sup> and

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<sup>15</sup> For greater certainty, cancellation for purposes of this Section may be implemented through nullification or revocation proceedings.

<sup>16</sup> A Party that relies on translations of the Nice Classification shall follow updated versions of the Nice Classification to the extent that official translations have been issued and published.

- (b) goods or services may not be considered as being similar to each other on the ground that, in any registration or publication, they are classified in the same class of the Nice Classification. Conversely, each Party shall provide that goods or services may not be considered as being dissimilar from each other on the ground that, in any registration or publication, they are classified in different classes of the Nice Classification.

#### **Article 18.26: Term of Protection for Trademarks**

Each Party shall provide that initial registration and each renewal of registration of a trademark is for a term of no less than 10 years.

#### **Article 18.27: Non-Recordal of a Licence**

No Party shall require recordal of trademark licences:

- (a) to establish the validity of the licence; or
- (b) as a condition for use of a trademark by a licensee to be deemed to constitute use by the holder in a proceeding that relates to the acquisition, maintenance or enforcement of trademarks.

#### **Article 18.28: Domain Names**

1. In connection with each Party's system for the management of its country-code top-level domain (ccTLD) domain names, the following shall be available:

- (a) an appropriate procedure for the settlement of disputes, based on, or modelled along the same lines as, the principles established in the *Uniform Domain-Name Dispute-Resolution Policy*, as approved by the Internet Corporation for Assigned Names and Numbers (ICANN) or that:
  - (i) is designed to resolve disputes expeditiously and at low cost;
  - (ii) is fair and equitable;
  - (iii) is not overly burdensome; and
  - (iv) does not preclude resort to judicial proceedings; and

- (b) online public access to a reliable and accurate database of contact information concerning domain name registrants,

in accordance with each Party's law and, if applicable, relevant administrator policies regarding protection of privacy and personal data.

2. In connection with each Party's system for the management of ccTLD domain names, appropriate remedies<sup>17</sup> shall be available at least in cases in which a person registers or holds, with a bad faith intent to profit, a domain name that is identical or confusingly similar to a trademark.

## **Section D: Country Names**

### **Article 18.29: Country Names**

Each Party shall provide the legal means for interested persons to prevent commercial use of the country name of a Party in relation to a good in a manner that misleads consumers as to the origin of that good.

## **Section E: Geographical Indications**

### **Article 18.30: Recognition of Geographical Indications**

The Parties recognise that geographical indications may be protected through a trademark or *sui generis* system or other legal means.

### **Article 18.31: Administrative Procedures for the Protection or Recognition of Geographical Indications**

If a Party provides administrative procedures for the protection or recognition of geographical indications, whether through a trademark or a *sui generis* system, that Party shall with respect to applications for that protection or petitions for that recognition:

- (a) accept those applications or petitions without requiring intercession by a Party on behalf of its nationals;<sup>18</sup>

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<sup>17</sup> The Parties understand that such remedies may, but need not, include, among other things, revocation, cancellation, transfer, damages or injunctive relief.

<sup>18</sup> This subparagraph also applies to judicial procedures that protect or recognise a geographical indication.

- (b) process those applications or petitions without imposition of overly burdensome formalities;
- (c) ensure that its laws and regulations governing the filing of those applications or petitions are readily available to the public and clearly set out the procedures for these actions;
- (d) make available information sufficient to allow the general public to obtain guidance concerning the procedures for filing applications or petitions and the processing of those applications or petitions in general; and allow an applicant, a petitioner, or their representative to ascertain the status of specific applications and petitions;
- (e) ensure that those applications or petitions are published for opposition and provide procedures for opposing geographical indications that are the subject of applications or petitions; and
- (f) provide for cancellation<sup>19</sup> of the protection or recognition afforded to a geographical indication.

### **Article 18.32: Grounds of Opposition and Cancellation<sup>20</sup>**

1. If a Party protects or recognises a geographical indication through the procedures referred to in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications), that Party shall provide procedures that allow interested persons to object to the protection or recognition of a geographical indication, and that allow for any such protection or recognition to be refused or otherwise not afforded, at least, on the following grounds:

- (a) the geographical indication is likely to cause confusion with a trademark that is the subject of a pre-existing good faith pending application or registration in the territory of the Party;
- (b) the geographical indication is likely to cause confusion with a pre-existing trademark, the rights to which have been acquired in accordance with the Party's law; and
- (c) the geographical indication is a term customary in common language as the common name<sup>21</sup> for the relevant good in the territory of the Party.

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<sup>19</sup> For greater certainty, for the purposes of this Section, cancellation may be implemented through nullification or revocation proceedings.

<sup>20</sup> A Party is not required to apply this Article to geographical indications for wines and spirits or to applications or petitions for those geographical indications.

2. If a Party has protected or recognised a geographical indication through the procedures referred to in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications), that Party shall provide procedures that allow for interested persons to seek the cancellation of a geographical indication, and that allow for the protection or recognition to be cancelled, at least, on the grounds listed in paragraph 1. A Party may provide that the grounds listed in paragraph 1 shall apply as of the time of filing the request for protection or recognition of a geographical indication in the territory of the Party.<sup>22</sup>

3. No Party shall preclude the possibility that the protection or recognition of a geographical indication may be cancelled, or otherwise cease, on the basis that the protected or recognised term has ceased meeting the conditions upon which the protection or recognition was originally granted in that Party.

4. If a Party has in place a *sui generis* system for protecting unregistered geographical indications by means of judicial procedures, that Party shall provide that its judicial authorities have the authority to deny the protection or recognition of a geographical indication if any of the circumstances identified in paragraph 1 has been established.<sup>23</sup> That Party shall also provide a process that allows interested persons to commence a proceeding on the grounds identified in paragraph 1.

5. If a Party provides protection or recognition of a geographical indication through the procedures referred to in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications) to the translation or transliteration of that geographical indication, that Party shall make available procedures that are equivalent to, and grounds that are the same as, those referred to in paragraphs 1 and 2 with respect to that translation or transliteration.

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<sup>21</sup> For greater certainty, if a Party provides for the procedures in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications) and this Article to be applied to geographical indications for wines and spirits or applications or petitions for those geographical indications, the Parties understand nothing shall require a Party to protect or recognise a geographical indication of any other Party with respect to products of the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Party.

<sup>22</sup> For greater certainty, if the grounds listed in paragraph 1 did not exist in a Party's law as of the time of filing of the request for protection or recognition of a geographical indication under Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications), that Party is not required to apply those grounds for the purposes of paragraph 2 or paragraph 4 of this Article in relation to that geographical indication.

<sup>23</sup> As an alternative to this paragraph, if a Party has in place a *sui generis* system of the type referred to in this paragraph as of the applicable date under Article 18.36.6 (International Agreements), that Party shall at least provide that its judicial authorities have the authority to deny the protection or recognition of a geographical indication if the circumstances identified in paragraph 1(c) have been established.



### **Article 18.33: Guidelines for Determining Whether a Term is the Term Customary in the Common Language**

With respect to the procedures in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications) and Article 18.32 (Grounds of Opposition and Cancellation), in determining whether a term is the term customary in common language as the common name for the relevant good in the territory of a Party, that Party's authorities shall have the authority to take into account how consumers understand the term in the territory of that Party. Factors relevant to such consumer understanding may include:

- (a) whether the term is used to refer to the type of good in question, as indicated by competent sources such as dictionaries, newspapers and relevant websites; and
- (b) how the good referenced by the term is marketed and used in trade in the territory of that Party.<sup>24</sup>

### **Article 18.34: Multi-Component Terms**

With respect to the procedures in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications) and Article 18.32 (Grounds of Opposition and Cancellation), an individual component of a multi-component term that is protected as a geographical indication in the territory of a Party shall not be protected in that Party if that individual component is a term customary in the common language as the common name for the associated good.

### **Article 18.35: Date of Protection of a Geographical Indication**

If a Party grants protection or recognition to a geographical indication through the procedures referred to in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications), that protection or recognition shall commence no earlier than the filing date<sup>25</sup> in the Party or the registration date in the Party, as applicable.

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<sup>24</sup> For the purposes of this subparagraph, a Party's authorities may take into account, as appropriate, whether the term is used in relevant international standards recognised by the Parties to refer to a type or class of good in the territory of the Party.

<sup>25</sup> For greater certainty, the filing date referred to in this paragraph includes, as applicable, the priority filing date under the Paris Convention.

## **Article 18.36: International Agreements**

1. If a Party protects or recognises a geographical indication pursuant to an international agreement, as of the applicable date under paragraph 6, involving a Party or a non-Party and that geographical indication is not protected through the procedures referred to in Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications)<sup>26</sup> or Article 18.32.4 (Grounds of Opposition and Cancellation), that Party shall apply at least procedures and grounds that are equivalent to those in Article 18.31(e) (Administrative Procedures for the Protection or Recognition of Geographical Indications) and Article 18.32.1 (Grounds of Opposition and Cancellation), as well as:

- (a) make available information sufficient to allow the general public to obtain guidance concerning the procedures for protecting or recognising the geographical indication and allow interested persons to ascertain the status of requests for protection or recognition;
- (b) make available to the public, on the Internet, details regarding the terms that the Party is considering protecting or recognising through an international agreement involving a Party or a non-Party, including specifying whether the protection or recognition is being considered for any translations or transliterations of those terms, and with respect to multi-component terms, specifying the components, if any, for which protection or recognition is being considered, or the components that are disclaimed;
- (c) in respect of opposition procedures, provide a reasonable period of time for interested persons to oppose the protection or recognition of the terms referred to in subparagraph (b). That period shall provide a meaningful opportunity for interested persons to participate in an opposition process; and
- (d) inform the other Parties of the opportunity to oppose, no later than the commencement of the opposition period.

2. In respect of international agreements referred to in paragraph 6 that permit the protection or recognition of a new geographical indication, a Party shall:<sup>27, 28</sup>

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<sup>26</sup> Each Party shall apply Article 18.33 (Guidelines for Determining Whether a Term is the Term Customary in the Common Language) and Article 18.34 (Multi-Component Terms) in determining whether to grant protection or recognition of a geographical indication pursuant to this paragraph.

<sup>27</sup> In respect of an international agreement referred to in paragraph 6 that has geographical indications that have been identified, but have not yet received protection or recognition in the territory of the Party that is a party to that agreement, that Party may fulfil the obligations of paragraph 2 by complying with the obligations of paragraph 1.

- (a) apply paragraph 1(b);
- (b) provide an opportunity for interested persons to comment regarding the protection or recognition of the new geographical indication for a reasonable period of time before such a term is protected or recognised; and
- (c) inform the other Parties of the opportunity to comment, no later than the commencement of the period for comment.

3. For the purposes of this Article, a Party shall not preclude the possibility that the protection or recognition of a geographical indication could cease.

4. For the purposes of this Article, a Party is not required to apply Article 18.32 (Grounds of Opposition and Cancellation), or obligations equivalent to Article 18.32, to geographical indications for wines and spirits or applications for those geographical indications.

5. Protection or recognition provided pursuant to paragraph 1 shall commence no earlier than the date on which the agreement enters into force or, if that Party grants that protection or recognition on a date after the entry into force of the agreement, on that later date.

6. No Party shall be required to apply this Article to geographical indications that have been specifically identified in, and that are protected or recognised pursuant to, an international agreement involving a Party or a non-Party, provided that the agreement:

- (a) was concluded, or agreed in principle<sup>29</sup>, prior to the date of conclusion, or agreement in principle, of this Agreement;
- (b) was ratified by a Party prior to the date of ratification of this Agreement by that Party; or
- (c) entered into force for a Party prior to the date of entry into force of this Agreement for that Party.

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<sup>28</sup> A Party may comply with this Article by applying Article 18.31 (Administrative Procedures for the Protection or Recognition of Geographical Indications) and Article 18.32 (Grounds of Opposition and Cancellation).

<sup>29</sup> For the purpose of this Article, an agreement “agreed in principle” means an agreement involving another government, government entity or international organisation in respect of which a political understanding has been reached and the negotiated outcomes of the agreement have been publically announced.

## Section F: Patents and Undisclosed Test or Other Data

### Subsection A: General Patents

#### Article 18.37: Patentable Subject Matter

1. Subject to paragraphs 3 and 4, each Party shall make patents 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>30</sup>

2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as 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. A Party may limit those new processes to those that do not claim the use of the product as such.

3. A Party 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 nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its law. A Party may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.

4. A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants.

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<sup>30</sup> 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 the prior art.

### **Article 18.38: Grace Period**

Each Party shall disregard at least information contained in public disclosures used to determine if an invention is novel or has an inventive step, if the public disclosure:<sup>31, 32</sup>

- (a) was made by the patent applicant or by a person that obtained the information directly or indirectly from the patent applicant; and
- (b) occurred within 12 months prior to the date of the filing of the application in the territory of the Party.

### **Article 18.39: Patent Revocation**

1. Each Party shall provide that a patent may be cancelled, revoked or nullified only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for cancelling, revoking or nullifying a patent or holding a patent unenforceable.

2. Notwithstanding paragraph 1, a Party may provide that a patent may be revoked, provided it is done in a manner consistent with Article 5A of the Paris Convention and the TRIPS Agreement.

### **Article 18.40: Exceptions**

A 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.

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<sup>31</sup> No Party shall be required to disregard information contained in applications for, or registrations of, intellectual property rights made available to the public or published by a patent office, unless erroneously published or unless the application was filed without the consent of the inventor or their successor in title, by a third person who obtained the information directly or indirectly from the inventor.

<sup>32</sup> For greater certainty, a Party may limit the application of this Article to disclosures made by, or obtained directly or indirectly from, the inventor or joint inventor. For greater certainty, a Party may provide that, for the purposes of this Article, information obtained directly or indirectly from the patent applicant may be information contained in the public disclosure that was authorised by, or derived from, the patent applicant.

#### **Article 18.41: Other Use Without Authorisation of the Right Holder**

The Parties understand that nothing in this Chapter limits a Party's rights and obligations under Article 31 of the TRIPS Agreement, any waiver or any amendment to that Article that the Parties accept.

#### **Article 18.42: Patent Filing**

Each Party shall provide that if an invention is made independently by more than one inventor, and separate applications claiming that invention are filed with, or for, the relevant authority of the Party, that Party shall grant the patent on the application that is patentable and that has the earliest filing date or, if applicable, priority date,<sup>33</sup> unless that application has, prior to publication,<sup>34</sup> been withdrawn, abandoned or refused.

#### **Article 18.43: Amendments, Corrections and Observations**

Each Party shall provide a patent applicant with at least one opportunity to make amendments, corrections and observations in connection with its application.<sup>35</sup>

#### **Article 18.44: Publication of Patent Applications**

1. Recognising the benefits of transparency in the patent system, each Party shall endeavour to publish unpublished pending patent applications promptly after the expiration of 18 months from the filing date or, if priority is claimed, from the earliest priority date.

2. If a pending application is not published promptly in accordance with paragraph 1, a Party shall publish that application or the corresponding patent, as soon as practicable.

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<sup>33</sup> A Party shall not be required to apply this Article in cases involving derivation or in situations involving any application that has or had, at any time, at least one claim having an effective filing date before the date of entry into force of this Agreement for that Party or any application that has or had, at any time, a priority claim to an application that contains or contained such a claim.

<sup>34</sup> For greater certainty, a Party may grant the patent to the subsequent application that is patentable, if an earlier application has been withdrawn, abandoned, or refused, or is not prior art against the subsequent application.

<sup>35</sup> A Party may provide that such amendments do not go beyond the scope of the disclosure of the invention, as of the filing date.

3. Each Party shall provide that an applicant may request the early publication of an application prior to the expiration of the period referred to in paragraph 1.

#### **Article 18.45: Information Relating to Published Patent Applications and Granted Patents**

For published patent applications and granted patents, and in accordance with the Party's requirements for prosecution of such applications and patents, each Party shall make available to the public at least the following information, to the extent that such information is in the possession of the competent authorities and is generated on, or after, the date of the entry into force of this Agreement for that Party:

- (a) search and examination results, including details of, or information related to, relevant prior art searches;
- (b) as appropriate, non-confidential communications from applicants; and
- (c) patent and non-patent related literature citations submitted by applicants and relevant third parties.

#### **Article 18.46: Patent Term Adjustment for Unreasonable Granting Authority Delays**

1. Each Party shall make best efforts to process patent applications in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.

2. A Party may provide procedures for a patent applicant to request to expedite the examination of its patent application.

3. If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for such delays.<sup>36</sup>

4. For the purposes of this Article, an unreasonable delay at least shall 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. A Party may exclude, from the determination of such delays, periods of time that do not

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<sup>36</sup> Annex 18-D applies to this paragraph.

occur during the processing<sup>37</sup> of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable<sup>38</sup> to the granting authority; as well as periods of time that are attributable to the patent applicant.<sup>39</sup>

## **Subsection B: Measures Relating to Agricultural Chemical Products**

### **Article 18.47: Protection of Undisclosed Test or Other Data for Agricultural Chemical Products**

1. If a Party requires, as a condition for granting marketing approval<sup>40</sup> for a new agricultural chemical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product,<sup>41</sup> that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar<sup>42</sup> product on the basis of that information or the marketing approval granted to the person that submitted such test or other data for at least 10 years<sup>43</sup> from the date of marketing approval of the new agricultural chemical product in the territory of the Party.

2. If a Party permits, as a condition of granting marketing approval for a new agricultural chemical product, the submission of evidence of a prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of the person that previously submitted undisclosed

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<sup>37</sup> For the purposes of this paragraph, a Party may interpret processing to mean initial administrative processing and administrative processing at the time of grant.

<sup>38</sup> A Party may treat delays “that are not directly attributable to the granting authority” as delays that are outside the direction or control of the granting authority.

<sup>39</sup> Notwithstanding Article 18.10 (Application of Chapter to Existing Subject Matter and Prior Acts), this Article shall apply to all patent applications filed after the date of entry into force of this Agreement for that Party, or the date two years after the signing of this Agreement, whichever is later for that Party.

<sup>40</sup> For the purposes of this Chapter, the term “marketing approval” is synonymous with “sanitary approval” under a Party’s law.

<sup>41</sup> Each Party confirms that the obligations of this Article apply to cases in which the Party requires the submission of undisclosed test or other data concerning: (a) only the safety of the product, (b) only the efficacy of the product or (c) both.

<sup>42</sup> For greater certainty, for the purposes of this Section, an agricultural chemical product is “similar” to a previously approved agricultural chemical product if the marketing approval, or, in the alternative, the applicant’s request for such approval, of that similar agricultural chemical product is based upon the undisclosed test or other data concerning the safety and efficacy of the previously approved agricultural chemical product, or the prior approval of that previously approved product.

<sup>43</sup> For greater certainty, a Party may limit the period of protection under this Article to 10 years.



test or other data concerning the safety and efficacy of the product in support of that prior marketing approval, to market the same or a similar product based on that undisclosed test or other data, or other evidence of the prior marketing approval in the other territory, for at least 10 years from the date of marketing approval of the new agricultural chemical product in the territory of the Party.

3. For the purposes of this Article, a new agricultural chemical product is one that contains<sup>44</sup> a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product.

### **Subsection C: Measures Relating to Pharmaceutical Products**

#### **Article 18.48: Patent Term Adjustment for Unreasonable Curtailment**

1. Each Party shall make best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.

2. With respect to a pharmaceutical product<sup>45</sup> that is subject to a patent, each Party shall make available an adjustment<sup>46</sup> of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.<sup>47, 48</sup>

3. For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations, provided that the Party continues to give effect to this Article.

4. With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the processing of marketing approval applications.

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<sup>44</sup> For the purposes of this Article, a Party may treat “contain” as meaning utilise. For greater certainty, for the purposes of this Article, a Party may treat “utilise” as requiring the new chemical entity to be primarily responsible for the product’s intended effect.

<sup>45</sup> A Party may comply with the obligations of this paragraph with respect to a pharmaceutical product or, alternatively, with respect to a pharmaceutical substance.

<sup>46</sup> For greater certainty, a Party may alternatively make available a period of additional *sui generis* protection to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process. The *sui generis* protection shall confer the rights conferred by the patent, subject to any conditions and limitations pursuant to paragraph 3.

<sup>47</sup> Notwithstanding Article 18.10 (Application of Chapter to Existing Subject Matter and Prior Acts), this Article shall apply to all applications for marketing approval filed after the date of entry into force of this Article for that Party.

<sup>48</sup> Annex 18-D applies to this paragraph.

### **Article 18.49: Regulatory Review Exception**

Without prejudice to the scope of, and consistent with, Article 18.40 (Exceptions), each Party shall adopt or maintain a regulatory review exception<sup>49</sup> for pharmaceutical products.

### **Article 18.50: Protection of Undisclosed Test or Other Data<sup>50</sup>**

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,<sup>51</sup> that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar<sup>52</sup> product on the basis of:
  - (i) that information; or
  - (ii) the marketing approval granted to the person that submitted such information,for at least five years<sup>53</sup> from the date of marketing approval of the new pharmaceutical product in the territory of the Party.
- (b) If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted such information concerning the safety

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<sup>49</sup> For greater certainty, consistent with Article 18.40 (Exceptions), nothing prevents a Party from providing that regulatory review exceptions apply for purposes of regulatory reviews in that Party, in another country or both.

<sup>50</sup> Annex 18-B and Annex 18-C apply to paragraphs 1 and 2 of this Article.

<sup>51</sup> Each Party confirms that the obligations of this Article, and Article 18.51 (Biologics) apply to cases in which the Party requires the submission of undisclosed test or other data concerning: (a) only the safety of the product, (b) only the efficacy of the product or (c) both.

<sup>52</sup> For greater certainty, for the purposes of this Section, a pharmaceutical product is “similar” to a previously approved pharmaceutical product if the marketing approval, or, in the alternative, the applicant’s request for such approval, of that similar pharmaceutical product is based upon the undisclosed test or other data concerning the safety and efficacy of the previously approved pharmaceutical product, or the prior approval of that previously approved product.

<sup>53</sup> For greater certainty, a Party may limit the period of protection under paragraph 1 to five years, and the period of protection under Article 18.51.1(a) (Biologics) to eight years.

and efficacy of the product, to market a same or a similar product based on evidence relating to prior marketing approval in the other territory for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of that Party.<sup>54</sup>

2. Each Party shall:<sup>55</sup>

- (a) apply paragraph 1, *mutatis mutandis*, for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration; or, alternatively,
- (b) apply paragraph 1, *mutatis mutandis*, for a period of at least five years to new pharmaceutical products that contain<sup>56</sup> a chemical entity that has not been previously approved in that Party.<sup>57</sup>

3. Notwithstanding paragraphs 1 and 2 and Article 18.51 (Biologics), a Party may take measures to protect public health in accordance with:

- (a) the Declaration on TRIPS and Public Health;
- (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or
- (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.

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<sup>54</sup> Annex 18-D applies to this subparagraph.

<sup>55</sup> A Party that provides a period of at least eight years of protection pursuant to paragraph 1 is not required to apply paragraph 2.

<sup>56</sup> For the purposes of this Article, a Party may treat “contain” as meaning utilise.

<sup>57</sup> For the purposes of Article 18.50.2(b) (Protection of Undisclosed Test or Other Data), a Party may choose to protect only the undisclosed test or other data concerning the safety and efficacy relating to the chemical entity that has not been previously approved.

## Article 18.51: Biologics<sup>58</sup>

1. With regard to protecting new biologics, a Party shall either:
    - (a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic,<sup>59,60</sup> provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,
    - (b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:
      - (i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party,
      - (ii) through other measures, and
      - (iii) recognising that market circumstances also contribute to effective market protection
- to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

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<sup>58</sup> Annex 18-B, Annex 18-C and Annex 18-D apply to this Article.

<sup>59</sup> Nothing requires a Party to extend the protection of this paragraph to:

- (a) any second or subsequent marketing approval of such a pharmaceutical product; or
- (b) a pharmaceutical product that is or contains a previously approved biologic.

<sup>60</sup> Each Party may provide that an applicant may request approval of a pharmaceutical product that is or contains a biologic under the procedures set forth in Article 18.50.1(a) (Protection of Undisclosed Test or Other Data) and Article 18.50.1(b) within five years of the date of entry into force of this Agreement for that Party, provided that other pharmaceutical products in the same class of products have been approved by that Party under the procedures set forth in Article 18.50.1(a) and Article 18.50.1(b) before the date of entry into force of this Agreement for that Party.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.

#### **Article 18.52: Definition of New Pharmaceutical Product**

For the purposes of Article 18.50.1 (Protection of Undisclosed Test or Other Data), a **new pharmaceutical product** means a pharmaceutical product that does not contain<sup>61</sup> a chemical entity that has been previously approved in that Party.

#### **Article 18.53: Measures Relating to the Marketing of Certain Pharmaceutical Products**

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person 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 Party or in another territory, that Party shall provide:

- (a) a system to provide notice to a patent holder<sup>62</sup> or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
- (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing<sup>63</sup> of an allegedly infringing product, available remedies in subparagraph (c); and

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<sup>61</sup> For the purposes of this Article, a Party may treat “contain” as meaning utilise.

<sup>62</sup> For greater certainty, for the purposes of this Article, a Party may provide that a “patent holder” includes a patent licensee or the authorised holder of marketing approval.

<sup>63</sup> For the purposes of paragraph 1(b), a Party may treat “marketing” as commencing at the time of listing for purposes of the reimbursement of pharmaceutical products pursuant to a national

- (c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.

2. As an alternative to paragraph 1, a Party shall instead adopt or maintain a system other than judicial proceedings that precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent claiming that product, unless by consent or acquiescence of the patent holder.

#### **Article 18.54: Alteration of Period of Protection**

Subject to Article 18.50.3 (Protection of Undisclosed Test or Other Data), if a product is subject to a system of marketing approval in the territory of a Party pursuant to Article 18.47 (Protection of Undisclosed Test or Other Data for Agricultural Chemical Products), Article 18.50 or Article 18.51 (Biologics) and is also covered by a patent in the territory of that Party, the Party shall not alter the period of protection that it provides pursuant to Article 18.47, Article 18.50 or Article 18.51 in the event that the patent protection terminates on a date earlier than the end of the period of protection specified in Article 18.47, Article 18.50 or Article 18.51.

### **Section G: Industrial Designs**

#### **Article 18.55: Protection**

1. Each Party shall ensure adequate and effective protection of industrial designs and also confirms that protection for industrial designs is available for designs:

- (a) embodied in a part of an article; or, alternatively,
- (b) having a particular regard, where appropriate, to a part of an article in the context of the article as a whole.

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healthcare programme operated by a Party and inscribed in the Appendix to Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices).

2. This Article is subject to Articles 25 and 26 of the TRIPS Agreement.

### **Article 18.56: Improving Industrial Design Systems**

The Parties recognise the importance of improving the quality and efficiency of their respective industrial design registration systems, as well as facilitating the process of cross-border acquisition of rights in their respective industrial design systems, including giving due consideration to ratifying or acceding to the *Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs*, done at Geneva, July 2, 1999.

## **Section H: Copyright and Related Rights**

### **Article 18.57: Definitions**

For the purposes of Article 18.58 (Right of Reproduction) and Article 18.60 (Right of Distribution) through Article 18.70 (Collective Management), the following definitions apply with respect to performers and producers of phonograms:

**broadcasting** means the transmission by wireless means for public reception of sounds or of images and sounds or of the representations thereof; such transmission by satellite is also “broadcasting”; transmission of encrypted signals is “broadcasting” if the means for decrypting are provided to the public by the broadcasting organisation or with its consent;

**communication to the public** of a performance or a phonogram means the transmission to the public by any medium, other than by broadcasting, of sounds of a performance or the sounds or the representations of sounds fixed in a phonogram;

**fixation** means the embodiment of sounds, or of the representations thereof, from which they can be perceived, reproduced, or communicated through a device;

**performers** means actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore;

**phonogram** means the fixation of the sounds of a performance or of other sounds, or of a representation of sounds, other than in the form of a fixation incorporated in a cinematographic or other audio-visual work;

**producer of a phonogram** means a person that takes the initiative and has the responsibility for the first fixation of the sounds of a performance or other sounds, or the representations of sounds; and

**publication** of a performance or phonogram means the offering of copies of the performance or the phonogram to the public, with the consent of the right holder, and provided that copies are offered to the public in reasonable quantity.

#### **Article 18.58: Right of Reproduction**

Each Party shall provide<sup>64</sup> to authors, performers and producers of phonograms<sup>65</sup> the exclusive right to authorise or prohibit all reproduction of their works, performances or phonograms in any manner or form, including in electronic form.

#### **Article 18.59: Right of Communication to the Public**

Without prejudice to Article 11(1)(ii), Article 11*bis*(1)(i) and (ii), Article 11*ter*(1)(ii), Article 14(1)(ii), and Article 14*bis*(1) of the Berne Convention, each Party shall provide to authors the exclusive right to authorise or prohibit the communication to the public of their works, by wire or wireless means, including the making available to the public of their works in such a way that members of the public may access these works from a place and at a time individually chosen by them.<sup>66</sup>

#### **Article 18.60: Right of Distribution**

Each Party shall provide to authors, performers and producers of phonograms the exclusive right to authorise or prohibit the making available to the public of the original and copies<sup>67</sup> of their works, performances and phonograms through sale or other transfer of ownership.

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<sup>64</sup> For greater certainty, the Parties understand that it is a matter for each Party's law to prescribe that works, performances or phonograms in general or any specified categories of works, performances and phonograms are not protected by copyright or related rights unless the work, performance or phonogram has been fixed in some material form.

<sup>65</sup> References to "authors, performers, and producers of phonograms" refer also to any of their successors in interest.

<sup>66</sup> The Parties understand that the mere provision of physical facilities for enabling or making a communication does not in itself amount to communication within the meaning of this Chapter or the Berne Convention. The Parties further understand that nothing in this Article precludes a Party from applying Article 11*bis*(2) of the Berne Convention.

<sup>67</sup> The expressions "copies" and "original and copies", that are subject to the right of distribution in this Article, refer exclusively to fixed copies that can be put into circulation as tangible objects.



### **Article 18.61: No Hierarchy**

Each Party shall provide that in cases in which authorisation is needed from both the author of a work embodied in a phonogram and a performer or producer that owns rights in the phonogram:

- (a) the need for the authorisation of the author does not cease to exist because the authorisation of the performer or producer is also required; and
- (b) the need for the authorisation of the performer or producer does not cease to exist because the authorisation of the author is also required.

### **Article 18.62: Related Rights**

1. Each Party shall accord the rights provided for in this Chapter with respect to performers and producers of phonograms: to the performers and producers of phonograms that are nationals<sup>68</sup> of another Party; and to performances or phonograms first published or first fixed<sup>69</sup> in the territory of another Party.<sup>70</sup> A performance or phonogram shall be considered first published in the territory of a Party if it is published in the territory of that Party within 30 days of its original publication.

2. Each Party shall provide to performers the exclusive right to authorise or prohibit:

- (a) the broadcasting and communication to the public of their unfixed performances, unless the performance is already a broadcast performance; and
- (b) the fixation of their unfixed performances.

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<sup>68</sup> For the purposes of determining criteria for eligibility under this Article, with respect to performers, a Party may treat “nationals” as those who would meet the criteria for eligibility under Article 3 of the WPPT.

<sup>69</sup> For the purposes of this Article, fixation means the finalisation of the master tape or its equivalent.

<sup>70</sup> For greater certainty, in this paragraph with respect to performances or phonograms first published or first fixed in the territory of a Party, a Party may apply the criterion of publication, or alternatively, the criterion of fixation, or both. For greater certainty, consistent with Article 18.8 (National Treatment), each Party shall accord to performances and phonograms first published or first fixed in the territory of another Party treatment no less favourable than it accords to performances or phonograms first published or first fixed in its own territory.

3. (a) Each Party shall provide to performers and producers of phonograms the exclusive right to authorise or prohibit the broadcasting or any communication to the public of their performances or phonograms, by wire or wireless means,<sup>71, 72</sup> and the making available to the public of those performances or phonograms in such a way that members of the public may access them from a place and at a time individually chosen by them.
- (b) Notwithstanding subparagraph (a) and Article 18.65 (Limitations and Exceptions), the application of the right referred to in subparagraph (a) to analog transmissions and non-interactive free over-the-air broadcasts, and exceptions or limitations to this right for those activities, is a matter of each Party's law.<sup>73</sup>

### **Article 18.63: Term of Protection for Copyright and Related Rights**

Each Party shall provide that in cases in which the term of protection of a work, performance or phonogram is to be calculated:<sup>74</sup>

- (a) on the basis of the life of a natural person, the term shall be not less than the life of the author and 70 years after the author's death;<sup>75</sup> and
- (b) on a basis other than the life of a natural person, the term shall be:

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<sup>71</sup> With respect to broadcasting and communication to the public, a Party may satisfy the obligation by applying Article 15(1) and Article 15(4) of the WPPT and may also apply Article 15(2) of the WPPT, provided that it is done in a manner consistent with that Party's obligations under Article 18.8 (National Treatment).

<sup>72</sup> For greater certainty, the obligation under this paragraph does not include broadcasting or communication to the public, by wire or wireless means, of the sounds or representations of sounds fixed in a phonogram that are incorporated in a cinematographic or other audio-visual work.

<sup>73</sup> For the purposes of this subparagraph the Parties understand that a Party may provide for the retransmission of non-interactive, free over-the-air broadcasts, provided that these retransmissions are lawfully permitted by that Party's government communications authority; any entity engaging in these retransmissions complies with the relevant rules, orders or regulations of that authority; and these retransmissions do not include those delivered and accessed over the Internet. For greater certainty this footnote does not limit a Party's ability to avail itself of this subparagraph.

<sup>74</sup> For greater certainty, in implementing this Article, nothing prevents a Party from promoting certainty for the legitimate use and exploitation of a work, performance or phonogram during its term of protection, consistent with Article 18.65 (Limitations and Exceptions) and that Party's international obligations.

<sup>75</sup> The Parties understand that if a Party provides its nationals a term of copyright protection that exceeds life of the author plus 70 years, nothing in this Article or Article 18.8 (National Treatment) shall preclude that Party from applying Article 7(8) of the Berne Convention with respect to the term in excess of the term provided in this subparagraph of protection for works of another Party.

- (i) not less than 70 years from the end of the calendar year of the first authorised publication<sup>76</sup> of the work, performance or phonogram; or
- (ii) failing such authorised publication within 25 years from the creation of the work, performance or phonogram, not less than 70 years from the end of the calendar year of the creation of the work, performance or phonogram.<sup>77</sup>

#### **Article 18.64: Application of Article 18 of the Berne Convention and Article 14.6 of the TRIPS Agreement**

Each Party shall apply Article 18 of the Berne Convention and Article 14.6 of the TRIPS Agreement, *mutatis mutandis*, to works, performances and phonograms, and the rights in and protections afforded to that subject matter as required by this Section.

#### **Article 18.65: Limitations and Exceptions**

1. With respect to this Section, each Party shall confine limitations or exceptions to exclusive rights to certain special cases that do not conflict with a normal exploitation of the work, performance or phonogram, and do not unreasonably prejudice the legitimate interests of the right holder.
2. This Article does not reduce or extend the scope of applicability of the limitations and exceptions permitted by the TRIPS Agreement, the Berne Convention, the WCT or the WPPT.

#### **Article 18.66: Balance in Copyright and Related Rights Systems**

Each Party shall endeavour to achieve an appropriate balance in its copyright and related rights system, among other things by means of limitations or exceptions that are consistent with Article 18.65 (Limitations and Exceptions), including those for the digital environment, giving due consideration to legitimate purposes such as, but not limited to: criticism; comment; news reporting; teaching, scholarship, research, and other similar purposes; and facilitating access

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<sup>76</sup> For greater certainty, for the purposes of subparagraph (b), if a Party's law provides for the calculation of term from fixation rather than from the first authorised publication, that Party may continue to calculate the term from fixation.

<sup>77</sup> For greater certainty, a Party may calculate a term of protection for an anonymous or pseudonymous work or a work of joint authorship in accordance with Article 7(3) or Article 7*bis* of the Berne Convention, provided that the Party implements the corresponding numerical term of protection required under this Article.

to published works for persons who are blind, visually impaired or otherwise print disabled.<sup>78, 79</sup>

### **Article 18.67: Contractual Transfers**

Each Party shall provide that for copyright and related rights, any person acquiring or holding any economic right<sup>80</sup> in a work, performance or phonogram:

- (a) may freely and separately transfer that right by contract; and
- (b) by virtue of contract, including contracts of employment underlying the creation of works, performances or phonograms, shall be able to exercise that right in that person's own name and enjoy fully the benefits derived from that right.<sup>81</sup>

### **Article 18.68: Technological Protection Measures (TPMs)<sup>82</sup>**

1. In order to provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that authors, performers, and producers of phonograms use in connection with the exercise of their rights and that restrict unauthorised acts in respect of their works, performances, and phonograms, each Party shall provide that any person that:

- (a) knowingly, or having reasonable grounds to know,<sup>83</sup> circumvents without authority any effective technological measure that controls access to a protected work, performance, or phonogram;<sup>84</sup> or

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<sup>78</sup> As recognised by the *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled*, done at Marrakesh, June 27, 2013 (Marrakesh Treaty). The Parties recognise that some Parties facilitate the availability of works in accessible formats for beneficiaries beyond the requirements of the Marrakesh Treaty.

<sup>79</sup> For greater certainty, a use that has commercial aspects may in appropriate circumstances be considered to have a legitimate purpose under Article 18.65 (Limitations and Exceptions).

<sup>80</sup> For greater certainty, this provision does not affect the exercise of moral rights.

<sup>81</sup> Nothing in this Article affects a Party's ability to establish: (i) which specific contracts underlying the creation of works, performances or phonograms shall, in the absence of a written agreement, result in a transfer of economic rights by operation of law; and (ii) reasonable limits to protect the interests of the original right holders, taking into account the legitimate interests of the transferees.

<sup>82</sup> Nothing in this Agreement requires a Party to restrict the importation or domestic sale of a device that does not render effective a technological measure the only purpose of which is to control market segmentation for legitimate physical copies of a cinematographic film, and is not otherwise a violation of its law.

- (b) manufactures, imports, distributes,<sup>85</sup> offers for sale or rental to the public, or otherwise provides devices, products, or components, or offers to the public or provides services, that:
  - (i) are promoted, advertised, or otherwise marketed by that person<sup>86</sup> for the purpose of circumventing any effective technological measure;
  - (ii) have only a limited commercially significant purpose or use other than to circumvent any effective technological measure;<sup>87</sup> or
  - (iii) are primarily designed, produced, or performed for the purpose of circumventing any effective technological measure,

is liable and subject to the remedies provided for in Article 18.74 (Civil and Administrative Procedures and Remedies).

Each Party shall provide for criminal procedures and penalties to be applied if any person is found to have engaged wilfully<sup>88</sup> and for the purposes of commercial advantage or financial gain<sup>89</sup> in any of the above activities.<sup>90</sup>

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<sup>83</sup> For the purposes of this subparagraph, a Party may provide that reasonable grounds to know may be demonstrated through reasonable evidence, taking into account the facts and circumstances surrounding the alleged illegal act.

<sup>84</sup> For greater certainty, no Party is required to impose civil or criminal liability under this subparagraph for a person that circumvents any effective technological measure that protects any of the exclusive rights of copyright or related rights in a protected work, performance or phonogram, but does not control access to such that work, performance or phonogram.

<sup>85</sup> A Party may provide that the obligations described in this subparagraph with respect to manufacturing, importation, and distribution apply only in cases in which those activities are undertaken for sale or rental, or if those activities prejudice the interests of the right holder of the copyright or related right.

<sup>86</sup> The Parties understand that this provision still applies in cases in which the person promotes, advertises, or markets through the services of a third person.

<sup>87</sup> A Party may comply with this paragraph if the conduct referred to in this subparagraph does not have a commercially significant purpose or use other than to circumvent an effective technological measure.

<sup>88</sup> For greater certainty, for purposes of this Article and Article 18.69 (RMI), wilfulness contains a knowledge element.

<sup>89</sup> For greater certainty, for purposes of this Article, Article 18.69 (RMI) and Article 18.77 (Criminal Procedures and Penalties), the Parties understand that a Party may treat “financial gain” as “commercial purposes”.

A Party may provide that the criminal procedures and penalties do not apply to a non-profit library, museum, archive, educational institution, or public non-commercial broadcasting entity. A Party may also provide that the remedies provided for in Article 18.74 (Civil and Administrative Procedures and Remedies) do not apply to any of the same entities provided that the above activities are carried out in good faith without knowledge that the conduct is prohibited.

2. In implementing paragraph 1, no Party shall be obligated to require that the design of, or the design and selection of parts and components for, a consumer electronics, telecommunications, or computing product provide for a response to any particular technological measure, provided that the product does not otherwise violate a measure implementing paragraph 1.

3. Each Party shall provide that a violation of a measure implementing this Article is independent of any infringement that might occur under the Party's law on copyright and related rights.<sup>91</sup>

4. With regard to measures implementing paragraph 1:

- (a) a Party may provide certain limitations and exceptions to the measures implementing paragraph 1(a) or paragraph 1(b) in order to enable non-infringing uses if there is an actual or likely adverse impact of those measures on those non-infringing uses, as determined through a legislative, regulatory, or administrative process in accordance with the Party's law, giving due consideration to evidence when presented in that process, including with respect to whether appropriate and effective measures have been taken by rights holders to enable the beneficiaries to enjoy the limitations and exceptions to copyright and related rights under that Party's law;<sup>92</sup>
- (b) any limitations or exceptions to a measure that implements paragraph 1(b) shall be permitted only to enable the legitimate use of a limitation or exception permissible under this Article by its

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<sup>90</sup> For greater certainty, no Party is required to impose liability under this Article and Article 18.69 (RMI) for actions taken by that Party or a third person acting with the authorisation or consent of that Party.

<sup>91</sup> For greater certainty, a Party is not required to treat the criminal act of circumvention set forth in paragraph 1(a) as an independent violation, where the Party criminally penalises such acts through other means.

<sup>92</sup> For greater certainty, nothing in this provision requires a Party to make a new determination via the legislative, regulatory, or administrative process with respect to limitations and exceptions to the legal protection of effective technological measures: (i) previously established pursuant to trade agreements in force between two or more Parties; or (ii) previously implemented by the Parties, provided that such limitations and exceptions are otherwise consistent with this paragraph.

intended beneficiaries<sup>93</sup> and does not authorise the making available of devices, products, components, or services beyond those intended beneficiaries;<sup>94</sup> and

- (c) a Party shall not, by providing limitations and exceptions under paragraph 4(a) and paragraph 4(b), undermine the adequacy of that Party's legal system for the protection of effective technological measures, or the effectiveness of legal remedies against the circumvention of such measures, that authors, performers, or producers of phonograms use in connection with the exercise of their rights, or that restrict unauthorised acts in respect of their works, performances or phonograms, as provided for in this Chapter.

5. **Effective technological measure** means any effective<sup>95</sup> technology, device, or component that, in the normal course of its operation, controls access to a protected work, performance, or phonogram, or protects copyright or related rights related to a work, performance or phonogram.

#### **Article 18.69: Rights Management Information (RMI)<sup>96</sup>**

- 1. In order to provide adequate and effective legal remedies to protect RMI:
  - (a) each Party shall provide that any person that, without authority, and knowing, or having reasonable grounds to know, that it would induce, enable, facilitate or conceal an infringement of the copyright or related right of authors, performers or producers of phonograms:
    - (i) knowingly<sup>97</sup> removes or alters any RMI;

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<sup>93</sup> For greater certainty, a Party may provide an exception to paragraph 1(b) without providing a corresponding exception to paragraph 1(a), provided that the exception to paragraph 1(b) is limited to enabling a legitimate use that is within the scope of limitations or exceptions to paragraph 1(a) as provided under this subparagraph.

<sup>94</sup> For the purposes of interpreting paragraph 4(b) only, paragraph 1(a) should be read to apply to all effective technological measures as defined in paragraph 5, *mutatis mutandis*.

<sup>95</sup> For greater certainty, a technological measure that can, in a usual case, be circumvented accidentally is not an "effective" technological measure.

<sup>96</sup> A Party may comply with the obligations in this Article by providing legal protection only to electronic RMI.

<sup>97</sup> For greater certainty, a Party may extend the protection afforded by this paragraph to circumstances in which a person engages without knowledge in the acts in sub-subparagraphs (i), (ii) and (iii), and to other related right holders.

- (ii) knowingly distributes or imports for distribution RMI knowing that the RMI has been altered without authority;<sup>98</sup>  
or
- (iii) knowingly distributes, imports for distribution, broadcasts, communicates or makes available to the public copies of works, performances or phonograms, knowing that RMI has been removed or altered without authority,

is liable and subject to the remedies set out in Article 18.74 (Civil and Administrative Procedures and Remedies).

Each Party shall provide for criminal procedures and penalties to be applied if any person is found to have engaged wilfully and for purposes of commercial advantage or financial gain in any of the above activities.

A Party may provide that the criminal procedures and penalties do not apply to a non-profit library, museum, archive, educational institution or public non-commercial broadcasting entity.<sup>99</sup>

2. For greater certainty, nothing prevents a Party from excluding from a measure that implements paragraph 1 a lawfully authorised activity that is carried out for the purpose of law enforcement, essential security interests or other related governmental purposes, such as the performance of a statutory function.

3. For greater certainty, nothing in this Article shall obligate a Party to require a right holder in a work, performance or phonogram to attach RMI to copies of the work, performance or phonogram, or to cause RMI to appear in connection with a communication of the work, performance or phonogram to the public.

4. **RMI** means:

- (a) information that identifies a work, performance or phonogram, the author of the work, the performer of the performance or the producer of the phonogram; or the owner of any right in the work, performance or phonogram;
- (b) information about the terms and conditions of the use of the work, performance or phonogram; or

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<sup>98</sup> A Party may comply with its obligations under this sub-subparagraph by providing for civil judicial proceedings concerning the enforcement of moral rights under its copyright law. A Party may also meet its obligation under this sub-subparagraph, if it provides effective protection for original compilations, provided that the acts described in this sub-subparagraph are treated as infringements of copyright in those original compilations.

<sup>99</sup> For greater certainty, a Party may treat a broadcasting entity established without a profit-making purpose under its law as a public non-commercial broadcasting entity.



- (c) any numbers or codes that represent the information referred to in subparagraphs (a) and (b),

if any of these items is attached to a copy of the work, performance or phonogram or appears in connection with the communication or making available of a work, performance or phonogram to the public.

### **Article 18.70: Collective Management**

The Parties recognise the important role of collective management societies for copyright and related rights in collecting and distributing royalties<sup>100</sup> based on practices that are fair, efficient, transparent and accountable, which may include appropriate record keeping and reporting mechanisms.

## **Section I: Enforcement**

### **Article 18.71: General Obligations**

1. Each Party shall ensure that enforcement procedures as specified in this Section are available under its law<sup>101</sup> so as to permit effective action against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies that constitute a deterrent to future infringements.<sup>102</sup> These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Each Party confirms that the enforcement procedures set forth in Article 18.74 (Civil and Administrative Procedures and Remedies), Article 18.75 (Provisional Measures) and Article 18.77 (Criminal Procedures and Penalties) shall be available to the same extent with respect to acts of trademark infringement, as well as copyright or related rights infringement, in the digital environment.

3. Each Party shall ensure that its procedures concerning the enforcement of intellectual property rights are fair and equitable. These procedures shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

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<sup>100</sup> For greater certainty, royalties may include equitable remuneration.

<sup>101</sup> For greater certainty, “law” is not limited to legislation.

<sup>102</sup> For greater certainty, and subject to Article 44 of the TRIPS Agreement and the provisions of this Agreement, each Party confirms that it makes such remedies available with respect to enterprises, regardless of whether the enterprises are private or state-owned.

4. This Section does not create any obligation:
- (a) to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of each Party to enforce its law in general; or
  - (b) with respect to the distribution of resources as between the enforcement of intellectual property rights and the enforcement of law in general.
5. In implementing the provisions of this Section in its intellectual property system, each Party shall take into account the need for proportionality between the seriousness of the infringement of the intellectual property right and the applicable remedies and penalties, as well as the interests of third parties.

#### **Article 18.72: Presumptions**

1. In civil, criminal and, if applicable, administrative proceedings involving copyright or related rights, each Party shall provide for a presumption<sup>103</sup> that, in the absence of proof to the contrary:
- (a) the person whose name is indicated in the usual manner<sup>104</sup> as the author, performer or producer of the work, performance or phonogram, or if applicable the publisher, is the designated right holder in that work, performance or phonogram; and
  - (b) the copyright or related right subsists in such subject matter.
2. In connection with the commencement of a civil, administrative or criminal enforcement proceeding involving a registered trademark that has been substantively examined by its competent authority, each Party shall provide that the trademark be considered *prima facie* valid.
3. In connection with the commencement of a civil or administrative enforcement proceeding involving a patent that has been substantively examined and granted<sup>105</sup> by the competent authority of a Party, that Party shall provide that

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<sup>103</sup> For greater certainty, a Party may implement this Article on the basis of sworn statements or documents having evidentiary value, such as statutory declarations. A Party may also provide that these presumptions are rebuttable presumptions that may be rebutted by evidence to the contrary.

<sup>104</sup> For greater certainty, a Party may establish the means by which it shall determine what constitutes the “usual manner” for a particular physical support.

<sup>105</sup> For greater certainty, nothing in this Chapter prevents a Party from making available third party procedures in connection with its fulfilment of the obligations under paragraphs 2 and 3.

each claim in the patent be considered *prima facie* to satisfy the applicable criteria of patentability in the territory of the Party.<sup>106, 107</sup>

### **Article 18.73: Enforcement Practices with Respect to Intellectual Property Rights**

1. Each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights:

- (a) preferably are in writing and state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based; and
- (b) are published<sup>108</sup> or, if publication is not practicable, otherwise made available to the public in a national language in such a manner as to enable interested persons and Parties to become acquainted with them.

2. Each Party recognises the importance of collecting and analysing statistical data and other relevant information concerning infringements of intellectual property rights as well as collecting information on best practices to prevent and combat infringements.

3. Each Party shall publish or otherwise make available to the public information on its efforts to provide effective enforcement of intellectual property rights in its civil, administrative and criminal systems, such as statistical information that the Party may collect for such purposes.

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<sup>106</sup> For greater certainty, if a Party provides its administrative authorities with the exclusive authority to determine the validity of a registered trademark or patent, nothing in paragraphs 2 and 3 shall prevent that Party's competent authority from suspending enforcement procedures until the validity of the registered trademark or patent is determined by the administrative authority. In those validity procedures, the party challenging the validity of the registered trademark or patent shall be required to prove that the registered trademark or patent is not valid. Notwithstanding this requirement, a Party may require the trademark holder to provide evidence of first use.

<sup>107</sup> A Party may provide that this paragraph applies only to those patents that have been applied for, examined and granted after the entry into force of this Agreement for that Party.

<sup>108</sup> For greater certainty, a Party may satisfy the requirement for publication by making the decision or ruling available to the public on the Internet.

## **Article 18.74: Civil and Administrative Procedures and Remedies**

1. Each Party shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered in this Chapter.<sup>109</sup>

2. Each Party shall provide that its judicial authorities have the authority to order injunctive relief that conforms to Article 44 of the TRIPS Agreement, including to prevent goods that involve the infringement of an intellectual property right under the law of the Party providing that relief from entering into the channels of commerce.

3. Each Party shall provide<sup>110</sup> that, in civil judicial proceedings, its judicial authorities have the authority at least to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

4. In determining the amount of damages under paragraph 3, each Party's judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

5. At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the infringer, at least in cases described in paragraph 3, to pay the right holder the infringer's profits that are attributable to the infringement.<sup>111</sup>

6. In civil judicial proceedings with respect to the infringement of copyright or related rights protecting works, phonograms or performances, each Party shall establish or maintain a system that provides for one or more of the following:

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<sup>109</sup> For the purposes of this Article, the term "right holders" shall include those authorised licensees, federations and associations that have the legal standing and authority to assert such rights. The term "authorised licensee" shall include the exclusive licensee of any one or more of the exclusive intellectual property rights encompassed in a given intellectual property.

<sup>110</sup> A Party may also provide that the right holder may not be entitled to any of the remedies set out in paragraphs 3, 5 and 7 if there is a finding of non-use of a trademark. For greater certainty, there is no obligation for a Party to provide for the possibility of any of the remedies in paragraphs 3, 5, 6 and 7 to be ordered in parallel.

<sup>111</sup> A Party may comply with this paragraph through presuming those profits to be the damages referred to in paragraph 3.

- (a) pre-established damages, which shall be available on the election of the right holder; or
- (b) additional damages.<sup>112</sup>

7. In civil judicial proceedings with respect to trademark counterfeiting, each Party shall also establish or maintain a system that provides for one or more of the following:

- (a) pre-established damages, which shall be available on the election of the right holder; or
- (b) additional damages.<sup>113</sup>

8. Pre-established damages under paragraphs 6 and 7 shall be set out in an amount that would be sufficient to compensate the right holder for the harm caused by the infringement, and with a view to deterring future infringements.

9. In awarding additional damages under paragraphs 6 and 7, judicial authorities shall have the authority to award such additional damages as they consider appropriate, having regard to all relevant matters, including the nature of the infringing conduct and the need to deter similar infringements in the future.

10. Each Party shall provide that its judicial authorities, if appropriate, have the authority to order, at the conclusion of civil judicial proceedings concerning infringement of at least copyright or related rights, patents and trademarks, that the prevailing party be awarded payment by the losing party of court costs or fees and appropriate attorney's fees, or any other expenses as provided for under the Party's law.

11. If a Party's judicial or other authorities appoint a technical or other expert in a civil proceeding concerning the enforcement of an intellectual property right and require that the parties to the proceeding pay the costs of that expert, that Party should seek to ensure that those costs are reasonable and related appropriately, among other things, to the quantity and nature of work to be performed and do not unreasonably deter recourse to such proceedings.

12. Each Party shall provide that in civil judicial proceedings:

- (a) at least with respect to pirated copyright goods and counterfeit trademark goods, its judicial authorities have the authority, at the right holder's request, to order that the infringing goods be destroyed, except in exceptional circumstances, without compensation of any sort;

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<sup>112</sup> For greater certainty, additional damages may include exemplary or punitive damages.

<sup>113</sup> For greater certainty, additional damages may include exemplary or punitive damages.

- (b) its judicial authorities have the authority to order that materials and implements that have been used in the manufacture or creation of the 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 minimise the risk of further infringement; and
- (c) in regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed is not sufficient, other than in exceptional circumstances, to permit the release of goods into the channels of commerce.

13. Without prejudice to its law governing privilege, the protection of confidentiality of information sources or the processing of personal data, each Party shall provide that, in civil judicial proceedings concerning the enforcement of an intellectual property right, its judicial authorities have the authority, on a justified request of the right holder, to order the infringer or, in the alternative, the alleged infringer to provide to the right holder or to the judicial authorities, at least for the purpose of collecting evidence, relevant information as provided for in its applicable laws and regulations that the infringer or alleged infringer possesses or controls. The information may include information regarding any person involved in any aspect of the infringement or alleged infringement and the means of production or the channels of distribution of the infringing or allegedly infringing goods or services, including the identification of third persons alleged to be involved in the production and distribution of the goods or services and of their channels of distribution.

14. Each Party shall provide that in relation to a civil judicial proceeding concerning the enforcement of an intellectual property right, its judicial or other authorities have the authority to impose sanctions on a party, counsel, experts or other persons subject to the court's jurisdiction for violation of judicial orders concerning the protection of confidential information produced or exchanged in that proceeding.

15. Each Party shall ensure that its judicial authorities have the authority to order a party at whose request measures were taken and that has abused enforcement procedures with regard to intellectual property rights, including trademarks, geographical indications, patents, copyright and related rights and industrial designs, to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of that abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

16. To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that

those procedures conform to principles equivalent in substance to those set out in this Article.

17. In civil judicial proceedings concerning the acts described in Article 18.68 (TPMs) and Article 18.69 (RMI):

- (a) each Party shall provide that its judicial authorities have the authority at least to:<sup>114</sup>
  - (i) impose provisional measures, including seizure or other taking into custody of devices and products suspected of being involved in the prohibited activity;
  - (ii) order the type of damages available for copyright infringement, as provided under its law in accordance with this Article;<sup>115</sup>
  - (iii) order court costs, fees or expenses as provided for under paragraph 10; and
  - (iv) order the destruction of devices and products found to be involved in the prohibited activity; and
- (b) a Party may provide that damages shall not be available against a non-profit library, archive, educational institution, museum or public non-commercial broadcasting entity, if it sustains the burden of proving that it was not aware or had no reason to believe that its acts constituted a prohibited activity.

#### **Article 18.75: Provisional Measures**

1. Each Party's authorities shall act on a request for relief in respect of an intellectual property right *inaudita altera parte* expeditiously in accordance with that 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

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<sup>114</sup> For greater certainty, a Party may, but is not required to, put in place separate remedies in respect of Article 18.68 (TPMs) and Article 18.69 (RMI), if those remedies are available under its copyright law.

<sup>115</sup> If a Party's copyright law provides for both pre-established damages and additional damages, that Party may comply with the requirements of this subparagraph by providing for only one of these forms of damages.

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.

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.

### **Article 18.76: Special Requirements related to Border Measures**

1. Each Party shall provide for applications to suspend the release of, or to detain, any suspected counterfeit or confusingly similar trademark or pirated copyright goods that are imported into the territory of the Party.<sup>116</sup>

2. Each Party shall provide that any right holder initiating procedures for its competent authorities<sup>117</sup> to suspend release of suspected counterfeit or confusingly similar trademark or pirated copyright goods into free circulation is required to provide adequate evidence to satisfy the competent authorities that, under the law of the Party providing the procedures, there is *prima facie* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspect goods reasonably recognisable by its competent authorities. The requirement to provide that information shall not unreasonably deter recourse to these procedures.

3. Each Party shall provide that its competent authorities have the authority to require a right holder initiating procedures to suspend the release of suspected counterfeit or confusingly similar trademark or pirated copyright goods, to provide a reasonable security or equivalent assurance sufficient to protect the

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<sup>116</sup> For the purposes of this Article:

- (a) counterfeit trademark goods means any goods, including packaging, bearing without authorisation a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the Party providing the procedures under this Section; and
- (b) pirated copyright goods means any goods that are copies made without the consent of the right holder or person duly authorised by the right holder in the country of production and that 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 providing the procedures under this Section.

<sup>117</sup> For the purposes of this Article, unless otherwise specified, competent authorities may include the appropriate judicial, administrative or law enforcement authorities under a Party's law.



defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance does not unreasonably deter recourse to these procedures. A Party may provide that the security may be in the form of a bond conditioned to hold the defendant harmless from any loss or damage resulting from any suspension of the release of goods in the event the competent authorities determine that the article is not an infringing good.

4. Without prejudice to a Party's law pertaining to privacy or the confidentiality of information:

- (a) if a Party's competent authorities have detained or suspended the release of goods that are suspected of being counterfeit trademark or pirated copyright goods, that Party may provide that its competent authorities have the authority to inform the right holder without undue delay of the names and addresses of the consignor, exporter, consignee or importer; a description of the goods; the quantity of the goods; and, if known, the country of origin of the goods;<sup>118</sup> or
- (b) if a Party does not provide its competent authority with the authority referred to in subparagraph (a) when suspect goods are detained or suspended from release, it shall provide, at least in cases of imported goods, its competent authorities with the authority to provide the information specified in subparagraph (a) to the right holder normally within 30 working days of the seizure or determination that the goods are counterfeit trademark goods or pirated copyright goods.

5. Each Party shall provide that its competent authorities may initiate border measures *ex officio*<sup>119</sup> with respect to goods under customs control<sup>120</sup> that are:

- (a) imported;
- (b) destined for export;<sup>121</sup> or
- (c) in transit,<sup>122, 123</sup>

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<sup>118</sup> For greater certainty, a Party may establish reasonable procedures to receive or access that information.

<sup>119</sup> For greater certainty, that *ex officio* action does not require a formal complaint from a third party or right holder.

<sup>120</sup> For the purposes of this Article, a Party may treat "goods under customs control" as meaning goods that are subject to a Party's customs procedures.

<sup>121</sup> For the purposes of this Article, a Party may treat goods "destined for export" as meaning exported.

<sup>122</sup> This subparagraph applies to suspect goods that are in transit from one customs office to another customs office in the Party's territory from which the goods will be exported.

and that are suspected of being counterfeit trademark goods or pirated copyright goods.

6. Each Party shall adopt or maintain a procedure by which its competent authorities may determine within a reasonable period of time after the initiation of the procedures described in paragraph 1, paragraph 5(a), paragraph 5(b) and, if applicable, paragraph 5(c), whether the suspect goods infringe an intellectual property right.<sup>124</sup> If a Party provides administrative procedures for the determination of an infringement, it may also provide its authorities with the authority to impose administrative penalties or sanctions, which may include fines or the seizure of the infringing goods following a determination that the goods are infringing.

7. Each Party shall provide that its competent authorities have the authority to order the destruction of goods following a determination that the goods are infringing. In cases in which the goods are not destroyed, each Party shall ensure that, except in exceptional circumstances, the goods are disposed of outside the channels of commerce in such a manner as to avoid any harm to the right holder. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit the release of the goods into the channels of commerce.

8. If a Party establishes or assesses, in connection with the procedures described in this Article, an application fee, storage fee or destruction fee, that fee shall not be set at an amount that unreasonably deters recourse to these procedures.

9. This Article also shall apply to goods of a commercial nature sent in small consignments. A Party may exclude from the application of this Article small quantities of goods of a non-commercial nature contained in travellers' personal luggage.<sup>125</sup>

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<sup>123</sup> As an alternative to this subparagraph, a Party shall instead endeavour to provide, if appropriate and with a view to eliminating international trade in counterfeit trademark goods or pirated copyright goods, available information to another Party in respect of goods that it has examined without a local consignee and that are transhipped through its territory and destined for the territory of the other Party, to inform that other Party's efforts to identify suspect goods upon arrival in its territory.

<sup>124</sup> A Party may comply with the obligation in this Article with respect to a determination that suspect goods under paragraph 5 infringe an intellectual property right through a determination that the suspect goods bear a false trade description.

<sup>125</sup> For greater certainty, a Party may also exclude from the application of this Article small quantities of goods of a non-commercial nature sent in small consignments.

## Article 18.77: Criminal Procedures and Penalties

1. Each Party shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright or related rights piracy on a commercial scale. In respect of wilful copyright or related rights piracy, “on a commercial scale” includes at least:

- (a) acts carried out for commercial advantage or financial gain; and
- (b) significant acts, not carried out for commercial advantage or financial gain, that have a substantial prejudicial impact on the interests of the copyright or related rights holder in relation to the marketplace.<sup>126, 127</sup>

2. Each Party shall treat wilful importation or exportation of counterfeit trademark goods or pirated copyright goods on a commercial scale as unlawful activities subject to criminal penalties.<sup>128</sup>

3. Each Party shall provide for criminal procedures and penalties to be applied in cases of wilful importation<sup>129</sup> and domestic use, in the course of trade and on a commercial scale, of a label or packaging:<sup>130</sup>

- (a) to which a trademark has been applied without authorisation that is identical to, or cannot be distinguished from, a trademark registered in its territory; and
- (b) that is intended to be used in the course of trade on goods or in relation to services that are identical to goods or services for which that trademark is registered.

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<sup>126</sup> The Parties understand that a Party may comply with subparagraph (b) by addressing such significant acts under its criminal procedures and penalties for non-authorised uses of protected works, performances and phonograms in its law.

<sup>127</sup> A Party may provide that the volume and value of any infringing items may be taken into account in determining whether the act has a substantial prejudicial impact on the interests of the copyright or related rights holder in relation to the marketplace.

<sup>128</sup> The Parties understand that a Party may comply with its obligation under this paragraph by providing that distribution or sale of counterfeit trademark goods or pirated copyright goods on a commercial scale is an unlawful activity subject to criminal penalties. Furthermore, criminal procedures and penalties as specified in paragraphs 1, 2 and 3 are applicable in any free trade zones in a Party.

<sup>129</sup> A Party may comply with its obligation relating to importation of labels or packaging through its measures concerning distribution.

<sup>130</sup> A Party may comply with its obligations under this paragraph by providing for criminal procedures and penalties to be applied to attempts to commit a trademark offence.

4. Recognising the need to address the unauthorised copying<sup>131</sup> of a cinematographic work from a performance in a movie theatre that causes significant harm to a right holder in the market for that work, and recognising the need to deter such harm, each Party shall adopt or maintain measures, which shall at a minimum include, but need not be limited to, appropriate criminal procedures and penalties.

5. With respect to the offences for which this Article requires a Party to provide for criminal procedures and penalties, each Party shall ensure that criminal liability for aiding and abetting is available under its law.

6. With respect to the offences described in paragraphs 1 through 5, each Party shall provide the following:

- (a) Penalties that include sentences of imprisonment as well as monetary fines sufficiently high to provide a deterrent to future acts of infringement, consistent with the level of penalties applied for crimes of a corresponding gravity.<sup>132</sup>
- (b) Its judicial authorities have the authority, in determining penalties, to account for the seriousness of the circumstances, which may include circumstances that involve threats to, or effects on, health or safety.<sup>133</sup>
- (c) Its judicial or other competent authorities have the authority to order the seizure of suspected counterfeit trademark goods or pirated copyright goods, any related materials and implements used in the commission of the alleged offence, documentary evidence relevant to the alleged offence and assets derived from, or obtained through the alleged infringing activity. If a Party requires identification of items subject to seizure as a prerequisite for issuing a judicial order referred to in this subparagraph, that Party shall not require the items to be described in greater detail than necessary to identify them for the purpose of seizure.
- (d) Its judicial authorities have the authority to order the forfeiture, at least for serious offences, of any assets derived from or obtained through the infringing activity.
- (e) Its judicial authorities have the authority to order the forfeiture or destruction of:

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<sup>131</sup> For the purposes of this Article, a Party may treat the term “copying” as synonymous with reproduction.

<sup>132</sup> The Parties understand that there is no obligation for a Party to provide for the possibility of imprisonment and monetary fines to be imposed in parallel.

<sup>133</sup> A Party may also account for such circumstances through a separate criminal offence.

- (i) all counterfeit trademark goods or pirated copyright goods;
- (ii) materials and implements that have been predominantly used in the creation of pirated copyright goods or counterfeit trademark goods; and
- (iii) any other labels or packaging to which a counterfeit trademark has been applied and that have been used in the commission of the offence.

In cases in which counterfeit trademark goods and pirated copyright goods are not destroyed, the judicial or other competent authorities shall ensure that, except in exceptional circumstances, those goods are disposed of outside the channels of commerce in such a manner as to avoid causing any harm to the right holder. Each Party shall further provide that forfeiture or destruction under this subparagraph and subparagraph (c) shall occur without compensation of any kind to the defendant.

- (f) Its judicial or other competent authorities have the authority to release or, in the alternative, provide access to, goods, material, implements, and other evidence held by the relevant authority to a right holder for civil<sup>134</sup> infringement proceedings.
- (g) Its competent authorities may act upon their own initiative to initiate legal action without the need for a formal complaint by a third person or right holder.<sup>135</sup>

7. With respect to the offences described in paragraphs 1 through 5, a Party may provide that its judicial authorities have the authority to order the seizure or forfeiture of assets, or alternatively, a fine, the value of which corresponds to the assets derived from, or obtained directly or indirectly through, the infringing activity.

#### **Article 18.78: Trade Secrets<sup>136</sup>**

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention, each Party shall ensure that

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<sup>134</sup> A Party may also provide this authority in connection with administrative infringement proceedings.

<sup>135</sup> With regard to copyright and related rights piracy provided for under paragraph 1, a Party may limit application of this subparagraph to the cases in which there is an impact on the right holder's ability to exploit the work, performance or phonogram in the market.

<sup>136</sup> For greater certainty, this Article is without prejudice to a Party's measures protecting good faith lawful disclosures to provide evidence of a violation of that Party's law.

persons have the legal means to prevent trade secrets lawfully in their control from being disclosed to, acquired by, or used by others (including state-owned enterprises) without their consent in a manner contrary to honest commercial practices.<sup>137</sup> As used in this Chapter, trade secrets encompass, at a minimum, undisclosed information as provided for in Article 39.2 of the TRIPS Agreement.

2. Subject to paragraph 3, each Party shall provide for criminal procedures and penalties for one or more of the following:

- (a) the unauthorised and wilful access to a trade secret held in a computer system;
- (b) the unauthorised and wilful misappropriation<sup>138</sup> of a trade secret, including by means of a computer system; or
- (c) the fraudulent disclosure, or alternatively, the unauthorised and wilful disclosure, of a trade secret, including by means of a computer system.

3. With respect to the relevant acts referred to in paragraph 2, a Party may, as appropriate, limit the availability of its criminal procedures, or limit the level of penalties available, to one or more of the following cases in which:

- (a) the acts are for the purposes of commercial advantage or financial gain;
- (b) the acts are related to a product or service in national or international commerce;
- (c) the acts are intended to injure the owner of such trade secret;
- (d) the acts are directed by or for the benefit of or in association with a foreign economic entity; or
- (e) the acts are detrimental to a Party's economic interests, international relations, or national defence or national security.

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<sup>137</sup> For the purposes of this paragraph “a manner contrary to honest commercial practices” means at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties that knew, or were grossly negligent in failing to know, that those practices were involved in the acquisition.

<sup>138</sup> A Party may deem the term “misappropriation” to be synonymous with “unlawful acquisition”.

## **Article 18.79: Protection of Encrypted Program-Carrying Satellite and Cable Signals**

1. Each Party shall make it a criminal offence to:
  - (a) manufacture, assemble, modify,<sup>139</sup> import, export, sell, lease or otherwise distribute a tangible or intangible device or system knowing or having reason to know<sup>140</sup> that the device or system meets at least one of the following conditions:
    - (i) it is intended to be used to assist;
    - (ii) it is primarily of assistance; or
    - (iii) its principal function is solely to assist,

in decoding an encrypted program-carrying satellite signal without the authorisation of the lawful distributor<sup>141</sup> of such signal;<sup>142</sup> and

(b) with respect to an encrypted program-carrying satellite signal, wilfully:

- (i) receive<sup>143</sup> such a signal; or
- (ii) further distribute<sup>144</sup> such signal,

knowing that it has been decoded without the authorisation of the lawful distributor of the signal.

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<sup>139</sup> For greater certainty, a Party may treat “assemble” and “modify” as incorporated in “manufacture”.

<sup>140</sup> For the purposes of this paragraph, a Party may provide that “having reason to know” may be demonstrated through reasonable evidence, taking into account the facts and circumstances surrounding the alleged illegal act, as part of the Party’s “knowledge” requirements. A Party may treat “having reason to know” as meaning “wilful negligence”.

<sup>141</sup> With regard to the criminal offences and penalties in paragraph 1 and paragraph 3, a Party may require a demonstration of intent to avoid payment to the lawful distributor, or a demonstration of intent to otherwise secure a pecuniary benefit to which the recipient is not entitled.

<sup>142</sup> The obligation regarding export may be met by making it a criminal offence to possess and distribute a device or system described in this paragraph. For the purposes of this Article, a Party may provide that a “lawful distributor” means a person that has the lawful right in that Party’s territory to distribute the encrypted program-carrying signal and authorise its decoding.

<sup>143</sup> For greater certainty and for the purposes of paragraph 1(b) and paragraph 3(b), a Party may provide that wilful receipt of an encrypted program-carrying satellite or cable signal means receipt and use of the signal, or means receipt and decoding of the signal.

<sup>144</sup> For greater certainty, a Party may interpret “further distribute” as “retransmit to the public”.

2. Each Party shall provide for civil remedies for a person that holds an interest in an encrypted program-carrying satellite signal or its content and that is injured by an activity described in paragraph 1.

3. Each Party shall provide for criminal penalties or civil remedies<sup>145</sup> for wilfully:

- (a) manufacturing or distributing equipment knowing that the equipment is intended to be used in the unauthorised reception of any encrypted program-carrying cable signal; and
- (b) receiving, or assisting another to receive,<sup>146</sup> an encrypted program-carrying cable signal without authorisation of the lawful distributor of the signal.

### **Article 18.80: Government Use of Software**

1. Each Party recognises the importance of promoting the adoption of measures to enhance government awareness of respect for intellectual property rights and of the detrimental effects of the infringement of intellectual property rights.

2. Each Party shall adopt or maintain appropriate laws, regulations, policies, orders, government-issued guidelines, or administrative or executive decrees that provide that its central government agencies use only non-infringing computer software protected by copyright and related rights, and, if applicable, only use that computer software in a manner authorised by the relevant licence. These measures shall apply to the acquisition and management of the software for government use.<sup>147</sup>

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<sup>145</sup> If a Party provides for civil remedies, it may require a demonstration of injury.

<sup>146</sup> A Party may comply with its obligation in respect of “assisting another to receive” by providing for criminal penalties to be available against a person wilfully publishing any information in order to enable or assist another person to receive a signal without authorisation of the lawful distributor of the signal.

<sup>147</sup> For greater certainty, paragraph 2 should not be interpreted as encouraging regional government agencies to use infringing computer software or, if applicable, to use computer software in a manner which is not authorised by the relevant licence.



## Section J: Internet Service Providers<sup>148</sup>

### Article 18.81: Definitions

For the purposes of this Section:

the term **copyright** includes related rights; and

**Internet Service Provider** means:

- (a) a provider of online services for the transmission, routing, or providing of connections for digital online communications, between or among points specified by a user, of material of the user's choosing, undertaking the function in Article 18.82.2(a) (Legal Remedies and Safe Harbours); or
- (b) a provider of online services undertaking the functions in Article 18.82.2(c) or Article 18.82.2(d) (Legal Remedies and Safe Harbours).

For greater certainty, Internet Service Provider includes a provider of the services listed above that engages in caching carried out through an automated process.

### Article 18.82: Legal Remedies and Safe Harbours<sup>149</sup>

1. The Parties recognise the importance of facilitating the continued development of legitimate online services operating as intermediaries and, in a manner consistent with Article 41 of the TRIPS Agreement, providing enforcement procedures that permit effective action by right holders against copyright infringement covered under this Chapter that occurs in the online environment. Accordingly, each Party shall ensure that legal remedies are available for right holders to address such copyright infringement and shall establish or maintain appropriate safe harbours in respect of online services that are Internet Service Providers. This framework of legal remedies and safe harbours shall include:

- (a) legal incentives<sup>150</sup> for Internet Service Providers to cooperate with copyright owners to deter the unauthorised storage and transmission of copyrighted materials or, in the alternative, to take

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<sup>148</sup> Annex 18-F applies to this Section.

<sup>149</sup> Annex 18-E applies to Article 18.82.3 and Article 18.82.4 (Legal Remedies and Safe Harbours).

<sup>150</sup> For greater certainty, the Parties understand that implementation of the obligations in paragraph 1(a) on "legal incentives" may take different forms.

other action to deter the unauthorised storage and transmission of copyrighted materials; and

- (b) limitations in its law that have the effect of precluding monetary relief against Internet Service Providers for copyright infringements that they do not control, initiate or direct, and that take place through systems or networks controlled or operated by them or on their behalf.<sup>151</sup>

2. The limitations described in paragraph 1(b) shall include limitations in respect of the following functions:

- (a) transmitting, routing or providing connections for material without modification of its content<sup>152</sup> or the intermediate and transient storage of that material done automatically in the course of such a technical process;
- (b) caching carried out through an automated process;
- (c) storage<sup>153</sup>, at the direction of a user, of material residing on a system or network controlled or operated by or for the Internet Service Provider;<sup>154</sup> and
- (d) referring or linking users to an online location by using information location tools, including hyperlinks and directories.

3. To facilitate effective action to address infringement, each Party shall prescribe in its law conditions for Internet Service Providers to qualify for the limitations described in paragraph 1(b), or, alternatively, shall provide for circumstances under which Internet Service Providers do not qualify for the limitations described in paragraph 1(b).<sup>155, 156</sup>

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<sup>151</sup> The Parties understand that, to the extent that a Party determines, consistent with its international legal obligations, that a particular act does not constitute copyright infringement, there is no obligation to provide for a limitation in relation to that act.

<sup>152</sup> The Parties understand that such modification does not include a modification made as part of a technical process or for solely technical reasons such as division into packets.

<sup>153</sup> For greater certainty, a Party may interpret “storage” as “hosting”.

<sup>154</sup> For greater certainty, the storage of material may include e-mails and their attachments stored in the Internet Service Provider’s server and web pages residing on the Internet Service Provider’s server.

<sup>155</sup> A Party may comply with the obligations in paragraph 3 by maintaining a framework in which:

- (a) there is a stakeholder organisation that includes representatives of both Internet Service Providers and right holders, established with government involvement;

- (a) With respect to the functions referred to in paragraph 2(c) and paragraph 2(d), these conditions shall include a requirement for Internet Service Providers to expeditiously remove or disable access to material residing on their networks or systems upon obtaining actual knowledge of the copyright infringement or becoming aware of facts or circumstances from which the infringement is apparent, such as through receiving a notice<sup>157</sup> of alleged infringement from the right holder or a person authorised to act on its behalf,
- (b) An Internet Service Provider that removes or disables access to material in good faith under subparagraph (a) shall be exempt from any liability for having done so, provided that it takes reasonable steps in advance or promptly after to notify the person whose material is removed or disabled.<sup>158</sup>

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- (b) that stakeholder organisation develops and maintains effective, efficient and timely procedures for entities certified by the stakeholder organisation to verify, without undue delay, the validity of each notice of alleged copyright infringement by confirming that the notice is not the result of mistake or misidentification, before forwarding the verified notice to the relevant Internet Service Provider;
  - (c) there are appropriate guidelines for Internet Service Providers to follow in order to qualify for the limitation described in paragraph 1(b), including requiring that the Internet Service Provider promptly removes or disables access to the identified materials upon receipt of a verified notice; and be exempted from liability for having done so in good faith in accordance with those guidelines; and
  - (d) there are appropriate measures that provide for liability in cases in which an Internet Service Provider has actual knowledge of the infringement or awareness of facts or circumstances from which the infringement is apparent.

<sup>156</sup> The Parties understand that a Party that has yet to implement the obligations in paragraphs 3 and 4 will do so in a manner that is both effective and consistent with that Party's existing constitutional provisions. To that end, a Party may establish an appropriate role for the government that does not impair the timeliness of the process provided in paragraphs 3 and 4, and does not entail advance government review of each individual notice.

<sup>157</sup> For greater certainty, a notice of alleged infringement, as may be set out under a Party's law, must contain information that:

- (a) is reasonably sufficient to enable the Internet Service Provider to identify the work, performance or phonogram claimed to be infringed, the alleged infringing material, and the online location of the alleged infringement; and
- (b) has a sufficient indicia of reliability with respect to the authority of the person sending the notice.

<sup>158</sup> With respect to the function in subparagraph 2(b), a Party may limit the requirements of paragraph 3 related to an Internet Service Provider removing or disabling access to material to circumstances in which the Internet Service Provider becomes aware or receives notification that the cached material has been removed or access to it has been disabled at the originating site.

4. If a system for counter-notices is provided under a Party's law, and if material has been removed or access has been disabled in accordance with paragraph 3, that Party shall require that the Internet Service Provider restores the material subject to a counter-notice, unless the person giving the original notice seeks judicial relief within a reasonable period of time.

5. Each Party shall ensure that monetary remedies are available in its legal system against any person that makes a knowing material misrepresentation in a notice or counter-notice that causes injury to any interested party<sup>159</sup> as a result of an Internet Service Provider relying on the misrepresentation.

6. Eligibility for the limitations in paragraph 1 shall not be conditioned on the Internet Service Provider monitoring its service or affirmatively seeking facts indicating infringing activity.

7. Each Party shall provide procedures, whether judicial or administrative, in accordance with that Party's legal system, and consistent with principles of due process and privacy, that enable a copyright owner that has made a legally sufficient claim of copyright infringement to obtain expeditiously from an Internet Service Provider information in the provider's possession identifying the alleged infringer, in cases in which that information is sought for the purpose of protecting or enforcing that copyright.

8. The Parties understand that the failure of an Internet Service Provider to qualify for the limitations in paragraph 1(b) does not itself result in liability. Further, this Article is without prejudice to the availability of other limitations and exceptions to copyright, or any other defences under a Party's legal system.

9. The Parties recognise the importance, in implementing their obligations under this Article, of taking into account the impacts on right holders and Internet Service Providers.

## **Section K: Final Provisions**

### **Article 18.83: Final Provisions**

1. Except as otherwise provided in Article 18.10 (Application of Chapter to Existing Subject Matter and Prior Acts) and paragraphs 2, 3 and 4, each Party

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<sup>159</sup> For greater certainty, the Parties understand that, "any interested party" may be limited to those with a legal interest recognised under that Party's law.

shall give effect to the provisions of this Chapter on the date of entry into force of this Agreement for that Party.<sup>160</sup>

2. During the relevant periods set out below, a Party shall not amend an existing measure or adopt a new measure that is less consistent with its obligations under the Articles referred to below for that Party than relevant measures that are in effect on the date of signature of this Agreement. This Section does not affect the rights and obligations of a Party under an international agreement to which it and another Party are party.

3. With respect to works of any Party that avails itself of a transition period permitted to it with regard to implementation of Article 18.63 (Term of Protection for Copyright and Related Rights) as it relates to the term of copyright protection (transition Party), Japan and Mexico shall apply at least the term of protection available under the transition Party's law for the relevant works during the transition period and apply Article 18.8.1 (National Treatment) with respect to copyright term only when that Party fully implements Article 18.63.

4. With regard to obligations subject to a transition period, a Party shall fully implement its obligations under the provisions of this Chapter no later than the expiration of the relevant time period specified below, which begins on the date of entry into force of this Agreement for that Party.

- (a) In the case of Brunei Darussalam, with respect to:
  - (i) Article 18.7.2(d) (International Agreements), UPOV 1991, three years;
  - (ii) Article 18.18 (Types of Signs Registrable as Trademarks), with respect to sound marks, three years;
  - (iii) Article 18.47 (Protection of Undisclosed Test or Other Data for Agricultural Chemical Products), 18 months;
  - (iv) Article 18.50 (Protection of Undisclosed Test or Other Data), four years;<sup>++</sup>
  - (v) Article 18.51 (Biologics), four years;<sup>++</sup>
  - (vi) Article 18.53 (Measures Relating to the Marketing of Certain Pharmaceutical Products), two years; and
  - (vii) With respect to Section J (Internet Service Providers), three years.

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<sup>160</sup> Only the following Parties have determined that, in order to implement and comply with Article 18.51.1 (Biologics), they require changes to their law, and thus require transition periods: Brunei Darussalam, Malaysia, Mexico, Peru and Viet Nam.

<sup>++</sup> If there are unreasonable delays in Brunei Darussalam in the initiation of the filing of marketing approval applications for new pharmaceutical products after Brunei Darussalam implements its obligations under Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics) in connection with subparagraphs (a)(iv) and (a)(v), Brunei Darussalam may consider adopting measures to incentivise the timely initiation of the filing of these applications with a view to the introduction of new pharmaceutical products in its market. To that end, Brunei Darussalam shall notify the other Parties through the Commission and consult with them on such a proposed measure. Such consultations shall begin within 30 days of a request from an interested Party, and shall provide adequate time and opportunity to resolve any concerns. In addition, any such measure shall respect legitimate commercial considerations and take into account the need for incentives for the development of new pharmaceutical products and for the expeditious marketing approval in Brunei Darussalam of such products.

- (b) In the case of Malaysia, with respect to:
- (i) Article 18.7.2(a) (International Agreements), Madrid Protocol, four years;
  - (ii) Article 18.7.2(b) (International Agreements), Budapest Treaty, four years;
  - (iii) Article 18.7.2(c) (International Agreements), Singapore Treaty, four years;
  - (iv) Article 18.7.2(d) (International Agreements), UPOV 1991, four years;
  - (v) Article 18.18 (Types of Signs Registrable as Trademarks), with respect to sound marks, three years;
  - (vi) Article 18.48.2 (Patent Term Adjustment for Unreasonable Curtailment), 4.5 years;
  - (vii) Article 18.51 (Biologics), five years;
  - (viii) Article 18.53 (Measures Relating to the Marketing of Certain Pharmaceutical Products), 4.5 years;

- (ix) Article 18.63(a) (Term of Protection for Copyright and Related Rights), with respect to life-based works, two years;
  - (x) Article 18.76 (Special Requirements Related to Border Measures), with respect to applications to suspend the release of, or to detain, ‘confusingly similar’ trademark goods, four years;
  - (xi) Article 18.76.5(b) and (c) (Special Requirements Related to Border Measures), with respect to *ex officio* border enforcement for in transit and export, four years; and
  - (xii) Article 18.79.2 (Protection of Encrypted Program-Carrying Satellite and Cable Signals), four years.
- (c) In the case of Mexico, with respect to:
- (i) Article 18.7.2(d) (International Agreements), UPOV 1991, four years;
  - (ii) Article 18.47 (Protection of Undisclosed Test or Other Data for Agricultural Chemical Products), five years;
  - (iii) Article 18.48.2 (Patent Term Adjustment for Unreasonable Curtailment), 4.5 years;
  - (iv) Article 18.50 (Protection of Undisclosed Test or Other Data), five years;<sup>++</sup>
  - (v) Article 18.51 (Biologics), five years;<sup>++</sup> and
  - (vi) Section J (Internet Service Providers), three years.

<sup>++</sup> If there are unreasonable delays in Mexico in the initiation of the filing of marketing approval applications for new pharmaceutical products after implementing its obligations under Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics) in connection with subparagraphs (c)(iv) and (c)(v), Mexico may consider adopting measures to incentivise the timely initiation of the filing of these applications with a view to the introduction of new pharmaceutical products in its market. To that end, Mexico shall notify the other Parties through the Commission and consult with them on such a proposed measure. Such consultations shall begin within 30 days of a request from an interested Party, and shall provide adequate time and opportunity to resolve any concerns. In addition, any such

measure shall respect legitimate commercial considerations and take into account the need for incentives for the development of new pharmaceutical products and for the expeditious marketing approval in Mexico of such products.

- (d) In the case of New Zealand, with respect to Article 18.63 (Term of Protection for Copyright and Related Rights), eight years. Except that from the date of entry into force of this Agreement for New Zealand, New Zealand shall provide that the term of protection for a work, performance or phonogram that would, during that eight years, have expired under the term that was provided in New Zealand law before the entry into force of this Agreement, instead expires 60 years from the relevant date in Article 18.63 that is the basis for calculating the term of protection under this Agreement. The Parties understand that, in applying Article 18.10 (Application of Chapter to Existing Subject Matter and Prior Acts), New Zealand shall not be required to restore or extend the term of protection to the works, performances and phonograms with a term provided pursuant to the previous sentence, once these works, performances and phonograms fall into the public domain in its territory.
- (e) In the case of Peru, with respect to:
  - (i) Article 18.50.2 (Protection of Undisclosed Test or Other Data), five years; and
  - (ii) Article 18.51 (Biologics), 10 years.
- (f) In the case of Viet Nam, with respect to:
  - (i) Article 18.7.2(b) (International Agreements), Budapest Treaty, two years;
  - (ii) Article 18.7.2(e) (International Agreements), WCT, three years;
  - (iii) Article 18.7.2(f) (International Agreements), WPPT, three years;
  - (iv) Article 18.18 (Types of Signs Registrable as Trademarks), with respect to sound marks, three years;
  - (v) Article 18.46.3 and Article 18.46.4 (Patent Term Adjustment for Unreasonable Granting Authority Delays), with respect to patents claiming pharmaceutical products, five years;^



- (vi) Article 18.46.3 and Article 18.46.4 (Patent Term Adjustment for Unreasonable Granting Authority Delays), with respect to patents claiming agricultural chemical products, five years;<sup>^</sup>
- (vii) Article 18.46.3 and Article 18.46.4 (Patent Term Adjustment for Unreasonable Granting Authority Delays), three years;<sup>161</sup>
- (viii) Article 18.47 (Protection of Undisclosed Test or Other Data for Agricultural Chemical Products), five years;
- (ix) Article 18.48.2 (Patent Term Adjustment for Unreasonable Curtailment), five years;
- (x) Article 18.50 (Protection of Undisclosed Test or Other Data), 10 years;\*/<sup>++</sup>
- (xi) Article 18.51 (Biologics), 10 years;\*/<sup>++</sup>
- (xii) Article 18.53 (Measures Relating to the Marketing of Certain Pharmaceutical Products), three years;
- (xiii) Article 18.63(a) (Term of Protection for Copyright and Related Rights), with respect to life-based works, five years;
- (xiv) Article 18.68 (TPMs), three years;
- (xv) Article 18.69 (RMI), three years;
- (xvi) Article 18.76.5(b) (Special Requirements Related to Border Measures), with respect to *ex officio* border measures for export, three years;
- (xvii) Article 18.76.5(c) (Special Requirements Related to Border Measures), with respect to *ex officio* border measures for in transit, two years;
- (xviii) Article 18.77.1(b) (Criminal Procedures and Penalties), three years;

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<sup>161</sup> Notwithstanding Article 18.10 (Application of Chapter to Existing Subject Matter and Prior Acts), for Viet Nam this Article shall apply to all applications filed after the conclusion of the three-year transition period under paragraph 4(f)(vii) or any applicable transition under paragraphs 4(f)(v) and 4(f)(vi) of this Article.

- (xix) Article 18.77.2 (Criminal Procedures and Penalties), with respect to importation of pirated copyright goods, three years;
- (xx) Article 18.77.2 (Criminal Procedures and Penalties), with respect to exportation, three years;
- (xxi) Article 18.77.4 (Criminal Procedures and Penalties), with respect to camcording, three years;
- (xxii) Article 18.77.6(g) (Criminal Procedures and Penalties), with respect to enforcement without the right holder's request for rights other than copyright, three years;
- (xxiii) Article 18.78.2 and Article 18.78.3 (Trade Secrets), three years;
- (xxiv) Article 18.79.1 (Protection of Encrypted Program-Carrying Satellite and Cable Signals), with respect to criminal remedies, three years;
- (xxv) Article 18.79.3 (Protection of Encrypted Program-Carrying Satellite and Cable Signals), with respect to cable signals, three years; and
- (xxvi) Section J (Internet Service Providers), three years.

<sup>^</sup> For transitions for Article 18.46.3 and Article 18.46.4 (Patent Term Adjustment for Unreasonable Granting Authority Delays) for patents claiming pharmaceutical products and agricultural chemical products, the Parties will consider a justified request from Viet Nam for an extension of the transition period for up to one additional year. Viet Nam's request shall include the reasons for the requested extension. Viet Nam may avail itself of this one-time extension upon providing a request in accordance with this paragraph unless the Commission decides otherwise within 60 days of receiving the request. No later than the date on which the additional one-year period expires, Viet Nam shall provide to the Commission in writing a report on the measures it has taken to fulfil its obligation under Article 18.46.3 and Article 18.46.4.

<sup>\*</sup> For transitions for Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics) for pharmaceutical products:

- (A) The Parties will consider a justified request from Viet Nam for an extension of the transition period for up to two additional years. Viet Nam's request shall include the reason for the requested extension. Viet Nam may avail itself of this one-time extension upon providing a request in accordance with this paragraph unless the Commission decides otherwise within 60 days of receiving the request. No later than the date on which the additional two-year period expires, Viet Nam shall provide to the Commission in writing a report on the measures it has taken to fulfil its obligation under Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics).
- (B) Viet Nam may make a further request for an additional one-time extension pursuant to Chapter 27 (Administrative and Institutional Provisions). Viet Nam's request shall include the reason for the request. The Commission shall decide pursuant to the procedures set forth in Article 27.3 (Decision-Making), whether to grant the request based on relevant factors, which may include capacity as well as other appropriate circumstances. Viet Nam shall make the request no later than one year prior to the expiration of the two-year transition period referred to in the first sentence of paragraph (A). The Parties shall give due consideration to that request. If the Committee grants Viet Nam's request, Viet Nam shall provide to the Commission in writing a report on the measures it has taken to fulfil its obligations under Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics) no later than the date on which the extension period expires.
- (C) Viet Nam's implementation of Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics) during three years after the conclusion of the extension period referred to in paragraph (A) shall not be subject to dispute settlement under Chapter 28 (Dispute Settlement).

<sup>++</sup> If there are unreasonable delays in Viet Nam in the initiation of the filing of marketing approval applications for new pharmaceutical products after Viet Nam implements its obligations under Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics) in connection with subparagraphs (f)(x) and (f)(xi), Viet Nam may consider adopting measures to incentivise the timely initiation of the filing of these applications with a view to the introduction of new pharmaceutical products in its market. To that end, Viet Nam shall notify the other Parties

through the Commission and consult with them on such a proposed measure. Such consultations shall begin within 30 days of a request from an interested Party, and shall provide adequate time and opportunity to resolve any concerns. In addition, any such measure shall respect legitimate commercial considerations and take into account the need for incentives for the development of new pharmaceutical products and for the expeditious marketing approval in Viet Nam of such products.

## **Annex 18-A Annex to**

### **Article 18.7.2**

1. Notwithstanding the obligations in Article 18.7.2 (International Agreements), and subject to paragraphs 2, 3 and 4 of this Annex, New Zealand shall:

- (a) accede to UPOV 1991 within three years of the date of entry into force of this Agreement for New Zealand; or
- (b) adopt a *sui generis* plant variety rights system that gives effect to UPOV 1991 within three years of the date of entry into force of this Agreement for New Zealand.

2. Nothing in paragraph 1 shall preclude the adoption by New Zealand of measures it deems necessary to protect indigenous plant species in fulfilment of its obligations under the Treaty of Waitangi, provided that such measures are not used as a means of arbitrary or unjustified discrimination against a person of another Party.

3. The consistency of any measures referred to in paragraph 2 with the obligations in paragraph 1 shall not be subject to the dispute settlement provisions of this Agreement.

4. The interpretation of the Treaty of Waitangi, including as to the nature of the rights and obligations arising under it, shall not be subject to the dispute settlement provisions of this Agreement. Chapter 28 (Dispute Settlement) shall otherwise apply to this Annex. A panel established under Article 28.7 (Establishment of a Panel) may be requested to determine only whether any measure referred to in paragraph 2 is inconsistent with a Party's rights under this Agreement.

## **Annex 18-B**

### **Chile**

1. Nothing in Article 18.50.1 or Article 18.50.2 (Protection of Undisclosed Test or Other Data) or Article 18.51 (Biologics) prevents Chile from maintaining or applying the provisions of Article 91 of Chile's Law No. 19.039 on Industrial Property, as in effect on the date of agreement in principle of this Agreement.
2. Notwithstanding Article 1.2 (Relation to Other Agreements), paragraph 1 is without prejudice to any Party's rights and obligations under an international agreement in effect prior to the date of entry into force of this Agreement for Chile, including any rights and obligations under a trade agreement between Chile and another Party.

## **Annex 18-C**

### **Malaysia**

1. Malaysia may, for the purpose of granting protection as specified in Article 18.50.1 and Article 18.50.2 (Protection of Undisclosed Test or Other Data) and Article 18.51.1 (Biologics), require an applicant to commence the process of obtaining marketing approval for pharmaceutical products covered under those Articles within 18 months from the date that the product is first granted marketing approval in any country.

2. For greater certainty, the periods of protection referred to in Article 18.50.1 and Article 18.50.2 (Protection of Undisclosed Test or Other Data) and Article 18.51.1 (Biologics) shall begin on the date of marketing approval of the pharmaceutical product in Malaysia.

## Annex 18-D

### Peru

#### **Part 1: Applicable to Article 18.46 (Patent Term Adjustment for Unreasonable Granting Authority Delays) and Article 18.48 (Patent Term Adjustment for Unreasonable Curtailment)**

To the extent that Andean Decision 486, *Common Industrial Property Regime*, and Andean Decision 689, *Adequacy of Certain Articles of Decision 486*, restricts Peru's implementation of its obligations set forth in Article 18.46.3 (Patent Term Adjustment for Unreasonable Granting Authority Delays) and Article 18.48.2 (Patent Term Adjustment for Unreasonable Curtailment), Peru commits to make its best efforts to obtain a waiver from the Andean Community that allows it to adjust its patent term in a way that is consistent with Article 18.46.3 (Patent Term Adjustment for Unreasonable Granting Authority Delays) and Article 18.48.2 (Patent Term Adjustment for Unreasonable Curtailment). Further, if Peru demonstrates that the Andean Community withheld its request for a waiver despite its best efforts, Peru will continue ensuring that it does not discriminate with respect to the availability or enjoyment of patent rights based on the field of technology, the place of invention, and whether products are imported or locally produced. Thus, Peru confirms that the treatment of pharmaceutical patents will be no less favourable than treatment of other patents in respect of the processing and examination of patent applications.

#### **Part 2: Applicable to Article 18.50 (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics)**

1. If Peru relies, pursuant to Article 18.50.1(b) (Protection of Undisclosed Test or Other Data), on a marketing approval granted by another Party, and grants approval within six months of the date of the filing of a complete application for marketing approval filed in Peru, Peru may provide that the protection specified in Article 18.50.1(b) (Protection of Undisclosed Test or Other Data) and Article 18.51 (Biologics), as applicable, shall begin with the date of the first marketing approval relied on. In implementing Article 18.50.1(b) (Protection of Undisclosed Test or Other Data) and Article 18.51.1(b)(i) (Biologics), Peru may apply the period of protection established in Article 16.10.2(b) of the *United States – Peru Trade Promotion Agreement*, done at Washington, District of Columbia, April 12, 2006.

2. Peru may apply paragraph 1 to Article 18.50.2 (Protection of Undisclosed Test or Other Data).



## **Annex 18-E Annex**

### **to Section J**

1. In order to facilitate the enforcement of copyright on the Internet and to avoid unwarranted market disruption in the online environment, Article 18.82.3 and Article 18.82.4 (Legal Remedies and Safe Harbours) shall not apply to a Party provided that, as from the date of agreement in principle of this Agreement, it continues to:

- (a) prescribe in its law circumstances under which Internet Service Providers do not qualify for the limitations described in Article 18.82.1(b) (Legal Remedies and Safe Harbours);
- (b) provide statutory secondary liability for copyright infringement in cases in which a person, by means of the Internet or another digital network, provides a service primarily for the purpose of enabling acts of copyright infringement, in relation to factors set out in its law, such as:
  - (i) whether the person marketed or promoted the service as one that could be used to enable acts of copyright infringement;
  - (ii) whether the person had knowledge that the service was used to enable a significant number of acts of copyright infringement;
  - (iii) whether the service has significant uses other than to enable acts of copyright infringement;
  - (iv) the person's ability, as part of providing the service, to limit acts of copyright infringement, and any action taken by the person to do so;
  - (v) any benefits the person received as a result of enabling the acts of copyright infringement; and
  - (vi) the economic viability of the service if it were not used to enable acts of copyright infringement;
- (c) require Internet Service Providers carrying out the functions referred to in Article 18.82.2(a) and (c) (Legal Remedies and Safe Harbours) to participate in a system for forwarding notices of alleged infringement, including if material is made available online, and if

the Internet Service Provider fails to do so, subjecting that provider to pre-established monetary damages for that failure;

- (d) induce Internet Service Providers offering information location tools to remove within a specified period of time any reproductions of material that they make, and communicate to the public, as part of offering the information location tool upon receiving a notice of alleged infringement and after the original material has been removed from the electronic location set out in the notice; and
- (e) induce Internet Service Providers carrying out the function referred to in Article 18.82.2(c) (Legal Remedies and Safe Harbours) to remove or disable access to material upon becoming aware of a decision of a court of that Party to the effect that the person storing the material infringes copyright in the material.

2. For a Party to which Article 18.82.3 and Article 18.82.4 (Legal Remedies and Safe Harbours) do not apply pursuant to paragraph 1 of this Annex, and in light of, among other things, paragraph 1(b) of this Annex, for the purposes of Article 18.82.1(a), legal incentives shall not mean the conditions for Internet Service Providers to qualify for the limitations provided for in Article 18.82.1(b), as set out in Article 18.82.3.

**Annex 18-F Annex**

**to Section J**

As an alternative to implementing Section J (Internet Service Providers), a Party may implement Article 17.11.23 of the *United States – Chile Free Trade Agreement*, done at Miami, June 6, 2003, which is incorporated into and made part of this Annex.