- 6. In the case of proposed rectifications to a Party's Annexes, the Party shall notify the other Party every two years, in line with the cycle of notifications provided for under the Agreement on Government Procurement, contained in Annex 4 of the WTO Agreement, following the entry into force of this Agreement.
- 7. A Party may notify the other Party of an objection to a proposed rectification within 45 days from having received the notification. If a Party submits an objection, it shall set out the reasons why it believes the proposed rectification is not a change provided for in paragraph 5 of this Article, and describe the effect of the proposed rectification on the mutually agreed coverage provided for in the Agreement. If no such objection is submitted in writing within 45 days after having received the notification, the Party shall be deemed to have agreed to the proposed rectification.

Article 19.19

Committee on Government Procurement

- 1. The Committee on Government Procurement, established under Article 26.2.1(e), is to be composed of representatives from each Party and shall meet, as necessary, for the purpose of providing the Parties the opportunity to consult on any matters relating to the operation of this Chapter or the furtherance of its objectives, and to carry out other responsibilities as may be assigned to it by the Parties.
- 2. The Committee on Government Procurement shall meet, upon request of a Party, to:
- (a) consider issues regarding public procurement that are referred to it by a Party;
- (b) exchange information relating to the public procurement opportunities in each Party;
- (c) discuss any other matters related to the operation of this Chapter; and
- (d) consider the promotion of coordinated activities to facilitate access for suppliers to procurement opportunities in the territory of each Party. These activities may include information sessions, in particular with a view to improving electronic access to publicly-available information on each Party's procurement regime, and initiatives to facilitate access for small and medium-sized enterprises.
- 3. Each Party shall submit statistics relevant to the procurement covered by this Chapter, as set out in Article 19.15, annually to the Committee on Government Procurement.

CHAPTER TWENTY

Intellectual property

Section A

General Provisions

Article 20.1

Objectives

The objectives of this Chapter are to:

- (a) facilitate the production and commercialisation of innovative and creative products, and the provision of services, between the Parties; and
- (b) achieve an adequate and effective level of protection and enforcement of intellectual property rights.

Nature and scope of obligations

- 1. The provisions of this Chapter complement the rights and obligations between the Parties under the TRIPS Agreement.
- 2. Each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement within its own legal system and practice.
- 3. This Agreement does not create any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and enforcement of law in general.

Article 20.3

Public health concerns

- 1. The Parties recognise the importance of the *Doha Declaration on the TRIPS Agreement and Public Health* ('Doha Declaration'), adopted on 14 November 2001 by the WTO Ministerial Conference. In interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with this Declaration.
- 2. The Parties shall contribute to the implementation of and respect the *Decision of the WTO General Council of 30 August 2003* on Paragraph 6 of the Doha Declaration, as well as the *Protocol amending the TRIPS Agreement*, done at Geneva on 6 December 2005.

Article 20.4

Exhaustion

This Chapter does not affect the freedom of the Parties to determine whether and under what conditions the exhaustion of intellectual property rights applies.

Article 20.5

Disclosure of information

This Chapter does not require a Party to disclose information that would otherwise be contrary to its law or exempt from disclosure under its law concerning access to information and privacy.

Section B

Standards Concerning Intellectual Property Rights

Article 20.6

Definition

For the purposes of this Section:

pharmaceutical product means a product including a chemical drug, biologic drug, vaccine or radiopharmaceutical, that is manufactured, sold or represented for use in:

- (a) making a medical diagnosis, treating, mitigating or preventing disease, disorder, or abnormal physical state, or its symptoms, or
- (b) restoring, correcting, or modifying physiological functions.

Sub-section A

Copyright and related rights

Article 20.7

Protection granted

- 1. The Parties shall comply with the following international agreements:
- (a) Articles 2 through 20 of the Berne Convention for the Protection of Literary and Artistic Works, done at Paris on 24 July 1971;
- (b) Articles 1 through 14 of the WIPO Copyright Treaty, done at Geneva on 20 December 1996;
- (c) Articles 1 through 23 of the WIPO Performances and Phonograms Treaty, done at Geneva on 20 December 1996; and
- (d) Articles 1 through 22 of the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, done at Rome on 26 October 1961.
- 2. To the extent permitted by the treaties referred to in paragraph 1, this Chapter shall not restrict each Party's ability to limit intellectual property protection that it accords to performances to those performances that are fixed in phonograms.

Article 20.8

Broadcasting and communication to the public

- 1. Each Party shall provide performers the exclusive right to authorise or prohibit the broadcasting by wireless means and the communication to the public of their performances, except where the performance is itself already a broadcast performance or is made from a fixation.
- 2. Each Party shall ensure that a single equitable remuneration is paid by the user if a phonogram published for commercial purposes, or a reproduction of such phonogram, is used for broadcasting by wireless means or for any communication to the public, and shall ensure that this remuneration is shared between the relevant performers and phonogram producers. Each Party may, in the absence of an agreement between the performers and producers of phonograms, lay down the conditions as to the sharing of this remuneration between them.

Article 20.9

Protection of technological measures

- 1. For the purposes of this Article, **technological measures** means any technology, device, or component that, in the normal course of its operation, is designed to prevent or restrict acts, in respect of works, performances, or phonograms, that are not authorised by authors, performers or producers of phonograms, as provided for by the law of a Party. Without prejudice to the scope of copyright or related rights contained in the law of a Party, technological measures shall be deemed effective where the use of protected works, performances, or phonograms is controlled by authors, performers or producers of phonograms through the application of a relevant access control or protection process, such as encryption or scrambling, or a copy control mechanism, that achieves the objective of protection.
- 2. Each Party shall provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors, performers or producers of phonograms in connection with the exercise of their rights in, and that restrict acts in respect of, their works, performances, and phonograms, which are not authorised by the authors, the performers or the producers of phonograms concerned or permitted by law.

- 3. In order to provide the adequate legal protection and effective legal remedies referred to in paragraph 2, each Party shall provide protection against at least:
- (a) to the extent provided by its law:
 - (i) the unauthorised circumvention of an effective technological measure carried out knowingly or with reasonable grounds to know; and
 - (ii) the offering to the public by marketing of a device or product, including computer programs, or a service, as a means of circumventing an effective technological measure; and
- (b) the manufacture, importation, or distribution of a device or product, including computer programs, or provision of a service that:
 - (i) is primarily designed or produced for the purpose of circumventing an effective technological measure; or
 - (ii) has only a limited commercially significant purpose other than circumventing an effective technological measure.
- 4. Under paragraph 3, the term 'to the extent provided by its law' means that each Party has flexibility in implementing subparagraphs (a)(i) and (ii).
- 5. In implementing paragraphs 2 and 3, a Party shall not be obliged 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, so long as the product does not otherwise contravene that Party's measures implementing these paragraphs. The intention of this provision is that this Agreement does not require a Party to mandate interoperability in its law: there is no obligation for the information communication technology industry to design devices, products, components, or services to correspond to certain technological measures.
- 6. In providing adequate legal protection and effective legal remedies pursuant to paragraph 2, a Party may adopt or maintain appropriate limitations or exceptions to measures implementing the provisions of paragraphs 2 and 3. The obligations set forth in paragraphs 2 and 3 are without prejudice to the rights, limitations, exceptions, or defences to copyright or related rights infringement under the law of a Party.

Protection of rights management information

- 1. For the purposes of this Article, **rights management information** means:
- (a) information that identifies the work, the performance, or the 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 use of the work, performance, or phonogram; or
- (c) any numbers or codes that represent the information described in (a) and (b) above;

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

- 2. To protect electronic rights management information, each Party shall provide adequate legal protection and effective legal remedies against any person knowingly performing, without authority, any of the following acts knowing, or having reasonable grounds to know, that it will induce, enable, facilitate, or conceal an infringement of any copyright or related rights:
- (a) to remove or alter any electronic rights management information; or
- (b) to distribute, import for distribution, broadcast, communicate, or make available to the public copies of works, performances, or phonograms, knowing that electronic rights management information has been removed or altered without authority.

3. In providing adequate legal protection and effective legal remedies pursuant to paragraph 2, a Party may adopt or maintain appropriate limitations or exceptions to measures implementing paragraph 2. The obligations set forth in paragraph 2 are without prejudice to the rights, limitations, exceptions, or defences to copyright or related rights infringement under the law of a Party.

Article 20.11

Liability of intermediary service providers

- 1. Subject to the other paragraphs of this Article, each Party shall provide limitations or exceptions in its law regarding the liability of service providers, when acting as intermediaries, for infringements of copyright or related rights that take place on or through communication networks, in relation to the provision or use of their services.
- 2. The limitations or exceptions referred to in paragraph 1:
- (a) shall cover at least the following functions:
 - (i) hosting of the information at the request of a user of the hosting services;
 - (ii) caching carried out through an automated process, when the service provider:
 - (A) does not modify the information other than for technical reasons;
 - (B) ensures that any directions related to the caching of the information that are specified in a manner widely recognised and used by industry are complied with; and
 - (C) does not interfere with the use of technology that is lawful and widely recognised and used by the industry in order to obtain data on the use of the information; and
 - (iii) mere conduit, which consists of the provision of the means to transmit information provided by a user, or the means of access to a communication network; and
- (b) may also cover other functions, including providing an information location tool, by making reproductions of copyright material in an automated manner, and communicating the reproductions.
- 3. The eligibility for the limitations or exceptions referred to in this Article may not be conditioned on the service provider monitoring its service, or affirmatively seeking facts indicating infringing activity.
- 4. Each Party may prescribe in its domestic law, conditions for service providers to qualify for the limitations or exceptions in this Article. Without prejudice to the above, each Party may establish appropriate procedures for effective notifications of claimed infringement, and effective counter-notifications by those whose material is removed or disabled through mistake or misidentification.
- 5. This Article is without prejudice to the availability in the law of a Party of other defences, limitations and exceptions to the infringement of copyright or related rights. This Article shall not affect the possibility of a court or administrative authority, in accordance with the legal system of a Party, of requiring the service provider to terminate or prevent an infringement.

Article 20.12

Camcording

Each Party may provide for criminal procedures and penalties to be applied in accordance with its laws and regulations against a person who, without authorisation of the theatre manager or the holder of the copyright in a cinematographic work, makes a copy of that work or any part thereof, from a performance of the work in a motion picture exhibition facility open to the public.

Sub-section B

Trademarks

Article 20.13

International agreements

Each Party shall make all reasonable efforts to comply with Articles 1 through 22 of the Singapore Treaty on the Law of Trademarks, done at Singapore on 27 March 2006, and to accede to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, done at Madrid on 27 June 1989.

Article 20.14

Registration procedure

Each Party shall provide for a system for the registration of trademarks in which reasons for the refusal to register a trademark are communicated in writing to the applicant, who will have the opportunity to contest that refusal and to appeal a final refusal to a judicial authority. Each Party shall provide for the possibility of filing oppositions either against trademark applications or against trademark registrations. Each Party shall provide a publicly available electronic database of trademark applications and trademark registrations.

Article 20.15

Exceptions to the rights conferred by a trademark

Each Party shall provide for the fair use of descriptive terms, including terms descriptive of geographical origin, as a limited exception to the rights conferred by a trademark. In determining what constitutes fair use, account shall be taken of the legitimate interests of the owner of the trademark and of third parties. Each Party may provide other limited exceptions, provided that these exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

Sub-section C

Geographical Indications

Article 20.16

Definitions

For the purposes of this Sub-section:

geographical indication means an indication which identifies an agricultural product or foodstuff 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 product is essentially attributable to its geographical origin; and

product class means a product class listed in Annex 20-C.

Article 20.17

Scope

This Sub-section applies to geographical indications identifying products falling within one of the product classes listed in Annex 20-C.

Listed geographical indications

For the purposes of this Sub-section:

- (a) the indications listed in Part A of Annex 20-A are geographical indications which identify a product as originating in the territory of the European Union or a region or locality in that territory; and
- (b) the indications listed in Part B of Annex 20-A are geographical indications which identify a product as originating in the territory of Canada or a region or locality in that territory.

Article 20.19

Protection for geographical indications listed in Annex 20-A

- 1. Having examined the geographical indications of the other Party, each Party shall protect them according to the level of protection set out in this Sub-section.
- 2. Each Party shall provide the legal means for interested parties to prevent:
- (a) the use of a geographical indication of the other Party listed in Annex 20-A for a product that falls within the product class specified in Annex 20-A for that geographical indication and that either:
 - (i) does not originate in the place of origin specified in Annex 20-A for that geographical indication; or
 - (ii) does originate in the place of origin specified in Annex 20-A for that geographical indication but was not produced or manufactured in accordance with the laws and regulations of the other Party that would apply if the product were for consumption in the other Party;
- (b) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good; and
- (c) any other use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention for the Protection of Industrial Property (1967) done at Stockholm on 14 July 1967.
- 3. The protection referred to in subparagraph 2(a) shall be provided even where the true origin of the product is indicated or the geographical indication is used in translation or accompanied by expressions such as 'kind', 'type', 'style', 'imitation' or the like.
- 4. Each Party shall provide for enforcement by administrative action, to the extent provided for by its law, to prohibit a person from manufacturing, preparing, packaging, labelling, selling or importing or advertising a food commodity in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its origin.
- 5. In accordance with paragraph 4, each Party will provide for administrative action in respect of complaints related to the labelling of products, including their presentation, in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their origin.
- 6. The registration of a trademark which contains or consists of a geographical indication of the other Party listed in Annex 20-A shall be refused or invalidated, *ex officio* if a Party's legislation so permits or at the request of an interested party, with respect to a product that falls within the product class specified in Annex 20-A for that geographical indication and that does not originate in the place of origin specified in Annex 20-A for that geographical indication.

7. There shall be no obligation under this Sub-section to protect geographical indications which are not or cease to be protected in their place of origin, or which have fallen into disuse in that place. If a geographical indication of a Party listed in Annex 20-A ceases to be protected in its place of origin or falls into disuse in that place, that Party shall notify the other Party and request cancellation.

Article 20.20

Homonymous geographical indications

- 1. In the case of homonymous geographical indications of the Parties for products falling within the same product class, each Party shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled.
- 2. If a Party, in the context of negotiations with a third country, proposes to protect a geographical indication identifying a product originating in the third country, if that indication is homonymous with a geographical indication of the other Party listed in Annex 20-A and if that product falls within the product class specified in Annex 20-A for the homonymous geographical indication of the other Party, the other Party shall be informed and be given the opportunity to comment before the geographical indication becomes protected.

Article 20.21

Exceptions

- 1. Notwithstanding Articles 20.19.2 and 20.19.3, Canada shall not be required to provide the legal means for interested parties to prevent the use of the terms listed in Part A of Annex 20-A and identified by one asterisk (¹) when the use of such terms is accompanied by expressions such as 'kind', 'type', 'style', 'imitation' or the like and is in combination with a legible and visible indication of the geographical origin of the product concerned.
- 2. Notwithstanding Articles 20.19.2 and 20.19.3, the protection of the geographical indications listed in Part A of Annex 20-A and identified by one asterisk (²) shall not prevent the use in the territory of Canada of any of these indications by any persons, including their successors and assignees, who made commercial use of those indications with regard to products in the class of 'cheeses' preceding the date of 18 October 2013.
- 3. Notwithstanding Articles 20.19.2 and 20.19.3, the protection of the geographical indications listed in Part A of Annex 20-A and identified by two asterisks shall not prevent the use of this indication by any persons, including their successors and assignees, who made commercial use of this indication with regard to products in the class of 'fresh, frozen and processed meats' for at least five years preceding the date of 18 October 2013. A transitional period of five years from the entry into force of this Article, during which the use of the above indication shall not be prevented, shall apply to any other persons, including their successors and assignees, who made commercial use of those indications with regard to products in the class of 'fresh, frozen and processed meats', for less than five years preceding the date of 18 October 2013.
- 4. Notwithstanding Articles 20.19.2 and 20.19.3, the protection of the geographical indications listed in Part A of Annex 20-A and identified by three asterisks shall not prevent the use of those indications by any persons, including their successors and assignees, who made commercial use of those indications with regard to products in the classes of 'dry-cured meats' and 'cheeses', respectively, for at least ten years preceding the date of 18 October 2013. A transitional period of five years from the entry into force of this Article, during which the use of the above indications shall not be prevented, shall apply to any other persons, including their successors and assignees, who made commercial use of those indications with regard to products in the class of 'dry-cured meats' and 'cheeses', respectively, for less than ten years preceding the date of 18 October 2013.

⁽¹⁾ For greater certainty, this paragraph applies equally to the term 'Feta'.

⁽²⁾ For greater certainty, this paragraph applies equally to the term 'Feta'.

- 5. If a trademark has been applied for or registered in good faith, or if rights to a trademark have been acquired through use in good faith, in a Party before the applicable date set out in paragraph 6, measures adopted to implement this Sub-section in that Party shall not prejudice the eligibility for or the validity of the registration of the trademark, or the right to use the trademark, on the basis that the trademark is identical with, or similar to, a geographical indication.
- 6. For the purposes of paragraph 5 the applicable date is:
- (a) in respect of a geographical indication listed in Annex 20-A on the date of signing of this Agreement, the date of coming into force of this Sub-section; or
- (b) in respect of a geographical indication added to Annex 20-A after the date of signing of this Agreement pursuant to Article 20.22, the date on which the geographical indication is added.
- 7. If a translation of a geographical indication is identical with or contains within it a term customary in common language as the common name for a product in the territory of a Party, or if a geographical indication is not identical with but contains within it such a term, the provisions of this Sub-section shall not prejudice the right of any person to use that term in association with that product in the territory of that Party.
- 8. Nothing shall prevent the use in the territory of a Party, with respect to any product, of a customary name of a plant variety or an animal breed, existing in the territory of that Party as of the date of entry into force of this Subsection.
- 9. A Party may provide that any request made under this Sub-section in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Party or after the date of registration of the trademark in that Party provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Party, provided that the geographical indication is not used or registered in bad faith.
- 10. The provisions of this Sub-section shall not prejudice the right of any person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public.
- 11. (a) The provisions of this Sub-section shall not prejudice the right of any person to use, or to register in Canada a trademark containing or consisting of, any of the terms listed in Part A of Annex 20-B; and
 - (b) Subparagraph (a) does not apply to the terms listed in Part A of Annex 20-B in respect of any use that would mislead the public as to the geographical origin of the goods.
- 12. The use in Canada of the terms listed in Part B of Annex 20-B shall not be subject to the provisions of this Subsection.
- 13. An assignment as referred to in paragraphs 2 through 4 does not include the transfer of the right to use a geographical indication on its own.

Amendments to Annex 20-A

- 1. The CETA Joint Committee, established under Article 26.1 (The CETA Joint Committee), acting by consensus and on a recommendation by the CETA Committee on Geographical Indications, may decide to amend Annex 20-A by adding geographical indications or by removing geographical indications which have ceased to be protected or have fallen into disuse in their place of origin.
- 2. A geographical indication shall not in principle be added to Part A of Annex 20-A, if it is a name that on the date of the signing of this Agreement is listed in the relevant Register of the European Union with a status of 'Registered', in respect of a Member State of the European Union.

- 3. A geographical indication identifying a product originating in a particular Party shall not be added to Annex 20-A:
- (a) if it is identical to a trademark that has been registered in the other Party in respect of the same or similar products, or to a trademark in respect of which in the other Party rights have been acquired through use in good faith and an application has been filed in respect of the same or similar products;
- (b) if it is identical to the customary name of a plant variety or an animal breed existing in the other Party; or
- (c) if it is identical with the term customary in common language as the common name for such product in the other Party.

Other protection

The provisions of this Sub-section are without prejudice to the right to seek recognition and protection of a geographical indication under the relevant law of a Party.

Sub-section D

Designs

Article 20.24

International agreements

Each Party shall make all reasonable efforts to accede to the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, done at Geneva on 2 July 1999.

Article 20.25

Relationship to copyright

The subject matter of a design right may be protected under copyright law if the conditions for this protection are met. The extent to which, and the conditions under which, such a protection is conferred, including the level of originality required, shall be determined by each Party.

Sub-section E

Patents

Article 20.26

International agreements

Each Party shall make all reasonable efforts to comply with Articles 1 through 14 and Article 22 of the Patent Law Treaty, done at Geneva on 1 June 2000.

Article 20.27

Sui generis protection for pharmaceuticals

1. For the purposes of this Article:

basic patent means a patent which protects a product as such, a process to obtain a product or an application of a product, and which has been designated by the holder of a patent that may serve as a basic patent, as the basic patent for the purpose of the granting of *sui generis* protection; and

product means the active ingredient or combination of active ingredients of a pharmaceutical product.

- 2. Each Party shall provide a period of *sui generis* protection in respect of a product that is protected by a basic patent in force at the request of the holder of the patent or his successor in title, provided the following conditions have been met:
- (a) an authorisation has been granted to place the product on the market of that Party as a pharmaceutical product (referred to as 'marketing authorisation' in this Article);
- (b) the product has not already been the subject of a period of sui generis protection; and
- (c) the marketing authorisation referred to in subparagraph (a) is the first authorisation to place the product on the market of that Party as a pharmaceutical product.
- 3. Each Party may:
- (a) provide a period of *sui generis* protection only if the first application for the marketing authorisation is submitted within a reasonable time limit prescribed by that Party; and
- (b) prescribe a time limit of no less than 60 days from the date on which the first marketing authorisation was granted for the submission of the request for the period of *sui generis* protection. However, where the first marketing authorisation is granted before the patent is granted, each Party will provide a period of at least 60 days from the grant of the patent during which the request for a period of protection under this Article may be submitted.
- 4. In the case where a product is protected by one basic patent, the period of *sui generis* protection shall take effect at the end of the lawful term of that patent.

In the case where a product is protected by more than one patent that may serve as a basic patent, a Party may provide for only a single period of sui generis protection, which takes effect at the end of the lawful term of the basic patent,

- (a) in the case where all the patents that may serve as a basic patent are held by the same person, selected by the person requesting the period of *sui generis* protection; and
- (b) in the case where the patents that may serve as a basic patent are not held by the same person and this gives rise to conflicting requests for the *sui generis* protection, selected by agreement between the patent holders.
- 5. Each Party shall provide that the period of *sui generis* protection be for a period equal to the period which elapsed between the date on which the application for the basic patent was filed and the date of the first marketing authorisation, reduced by a period of five years.
- 6. Notwithstanding paragraph 5 and without prejudice to a possible extension of the period of *sui generis* protection by a Party as an incentive or a reward for research in certain target populations, such as children, the duration of the *sui generis* protection may not exceed a period of two to five years, to be established by each Party.
- 7. Each Party may provide that the period of sui generis protection shall lapse:
- (a) if the sui generis protection is surrendered by the beneficiary; or
- (b) if any prescribed administrative fees are not paid.

Each Party may reduce the period of *sui generis* protection commensurate with any unjustified delays resulting from the inactions of the applicant after applying for the market authorisation, when the holder of the basic patent is the applicant for market authorisation or an entity related to it.

8. Within the limits of the protection conferred by the basic patent, the *sui generis* protection shall extend only to the pharmaceutical product covered by the marketing authorisation and for any use of that product as a pharmaceutical product that has been authorised before the expiry of the *sui generis* protection. Subject to the preceding sentence, the *sui generis* protection shall confer the same rights as conferred by the patent and shall be subject to the same limitations and obligations.

- 9. Notwithstanding paragraphs 1 through 8, each Party may also limit the scope of the protection by providing exceptions for the making, using, offering for sale, selling or importing of products for the purpose of export during the period of protection.
- 10. Each Party may revoke the *sui generis* protection on grounds relating to invalidity of the basic patent, including if that patent has lapsed before its lawful term expires or is revoked or limited to the extent that the product for which the protection was granted would no longer be protected by the claims of the basic patent, or on grounds relating to the withdrawal of the marketing authorisation or authorisations for the respective market, or if the protection was granted contrary to the provisions of paragraph 2.

Patent linkage mechanisms relating to pharmaceutical products

If a Party relies on 'patent linkage' mechanisms whereby the granting of marketing authorisations (or notices of compliance or similar concepts) for generic pharmaceutical products is linked to the existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective rights of appeal.

Sub-section F

Data Protection

Article 20.29

Protection of undisclosed data related to pharmaceutical products

- 1. If a Party requires, as a condition for authorising the marketing of pharmaceutical products that utilise new chemical entities (¹) (referred to as 'authorisation' in this Article) the submission of undisclosed test or other data necessary to determine whether the use of those products is safe and effective, the Party shall protect such data against disclosure, if the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.
- 2. Each Party shall provide that for data subject to paragraph 1 that are submitted to the Party after the date of entry into force of this Agreement:
- (a) no person other than the person who submitted them may, without the latter's permission, rely on such data in support of an application for an authorisation during a period of not less than six years from the date on which the Party granted authorisation to the person that produced the data for authorisation; and
- (b) a Party shall not grant an authorisation to any person who relies on such data during a period of not less than eight years from the date on which the Party granted the authorisation to the person that produced the data for the authorisation, unless the person that produced these data provides permission.

Subject to this paragraph, there shall be no limitation on either Party to implement abbreviated authorisation procedures for such products on the basis of bioequivalence and bioavailability studies.

Article 20.30

Protection of data related to plant protection products

1. Each Party shall determine safety and efficacy requirements before authorising the placing on the market of a plant protection product (referred to as 'authorisation' in this Article).

⁽¹) For greater certainty, with respect to data protection, a 'chemical entity' in Canada includes a biologic or radiopharmaceutical which is regulated as a new drug under the Food and Drug Regulations of Canada.

- 2. Each Party shall provide a limited period of data protection for a test or study report submitted for the first time to obtain an authorisation. During such period, each Party shall provide that the test or study report will not be used for the benefit of any other person aiming to obtain an authorisation, except when the explicit consent of the first authorisation holder is proved.
- 3. The test or study report should be necessary for the authorisation or for an amendment of an authorisation in order to allow the use on other crops.
- 4. In each Party, the period of data protection shall be at least ten years starting at the date of the first authorisation in that Party with respect to the test or study report supporting the authorisation of a new active ingredient and data supporting the concurrent registration of the end-use product containing the active ingredient. The duration of protection may be extended in order to encourage the authorisation of low-risk plant protection products and minor uses.
- 5. Each Party may also establish data protection requirements or financial compensation requirements for the test or study report supporting the amendment or renewal of an authorisation.
- 6. Each Party shall establish rules to avoid duplicative testing on vertebrate animals. Any applicant intending to perform tests and studies involving vertebrate animals should be encouraged to take the necessary measures to verify that those tests and studies have not already been performed or initiated.
- 7. Each Party should encourage each new applicant and each holder of the relevant authorisations to make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing such test and study reports shall be determined in a fair, transparent and non-discriminatory way. An applicant is only required to share in the costs of information that the applicant is required to submit to meet the authorisation requirements.
- 8. The holder or holders of the relevant authorisation shall have a right to be compensated for a fair share of the costs incurred by them in respect of the test or study report that supported such authorisation by an applicant relying on such test and study reports to obtain an authorisation for a new plant protection product. Each Party may direct the parties involved to resolve any issue by binding arbitration administered under its law.

Sub-section G

Plant Varieties

Article 20.31

Plant varieties

Each Party shall co-operate to promote and reinforce the protection of plant varieties on the basis of the 1991 Act of the International Convention for the Protection of New Varieties of Plants, done at Paris on 2 December 1961.

Section C

Enforcement of Intellectual Property Rights

Article 20.32

General obligations

1. Each Party shall ensure that procedures for the enforcement of intellectual property rights are fair and equitable, and are not unnecessarily complicated or costly, nor entail unreasonable time-limits or unwarranted delays. 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. In implementing the provisions of this Section, each Party shall take into account the need for proportionality between the seriousness of the infringement, the interests of third parties, and the applicable measures, remedies and penalties.
- 3. Articles 20.33 through 20.42 relate to civil enforcement.
- 4. For the purposes of Articles 20.33 through 20.42, unless otherwise provided, **intellectual property rights** means all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement.

Entitled applicants

Each Party shall recognise as persons entitled to seek application of the procedures and remedies referred to in Articles 20.34 through 20.42:

- (a) the holders of intellectual property rights in accordance with the provisions of its law;
- (b) all other persons authorised to use those rights, if those persons are entitled to seek relief in accordance with its law;
- (c) intellectual property collective rights management bodies that are regularly recognised as having a right to represent holders of intellectual property rights, if those bodies are entitled to seek relief in accordance with its law; and
- (d) professional defence bodies that are regularly recognised as having a right to represent holders of intellectual property rights, if those bodies are entitled to seek relief in accordance with its law.

Article 20.34

Evidence

Each Party shall ensure that, in the case of an alleged infringement of an intellectual property right committed on a commercial scale, the judicial authorities shall have the authority to order, if appropriate and following an application, the production of relevant information, as provided for in its law, including banking, financial or commercial documents under the control of the opposing party, subject to the protection of confidential information.

Article 20.35

Measures for preserving evidence

- 1. Each Party shall ensure that, even before the commencement of proceedings on the merits of the case, the judicial authorities may, on application by an entity that has presented reasonably available evidence to support its claims that its intellectual property right has been infringed or is about to be infringed, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement, subject to the protection of confidential information.
- 2. Each Party may provide that the measures referred to in paragraph 1 include the detailed description, with or without the taking of samples, or the physical seizure of the alleged infringing goods, and, in appropriate cases, the materials and implements used in the production or distribution of these goods and the documents relating thereto. The judicial authorities shall have the authority to take those measures, if necessary without the other party being heard, in particular where any delay is likely to cause irreparable harm to the right holder or where there is a demonstrable risk of evidence being destroyed.

Right of information

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 intellectual property rights, its judicial authorities shall have the authority, upon a justified request of the right holder, to order the infringer or 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. This information may include information regarding any person involved in any aspect of the infringement or alleged infringement and regarding 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 those goods or services and of their channels of distribution.

Article 20.37

Provisional and precautionary measures

- 1. Each Party shall provide that its judicial authorities have the authority to order prompt and effective provisional and precautionary measures, including an interlocutory injunction, against a party, or where appropriate, against a third party over whom the relevant judicial authority exercises jurisdiction, to prevent an infringement of an intellectual property right from occurring, and in particular, to prevent infringing goods from entering into the channels of commerce.
- 2. Each Party shall provide that its judicial authorities have the authority to order the seizure or other taking into custody of the goods suspected of infringing an intellectual property right so as to prevent their entry into or movement within the channels of commerce.
- 3. Each Party shall provide that, in the case of an alleged infringement of an intellectual property right committed on a commercial scale, the judicial authorities may order, in accordance with its law, the precautionary seizure of property of the alleged infringer, including the blocking of its bank accounts and other assets. To that end, the judicial authorities may order the communication of relevant bank, financial or commercial documents, or access to other relevant information, as appropriate.

Article 20.38

Other remedies

- 1. Each Party shall ensure that the judicial authorities may order, at the request of the applicant and without prejudice to any damages due to the right holder by reason of the infringement, and without compensation of any sort, the definitive removal from the channels of commerce, or the destruction, of goods that they have found to be infringing an intellectual property right. Each Party shall ensure that the judicial authorities may order, if appropriate, destruction of materials and implements predominantly used in the creation or manufacture of those goods. In considering a request for such remedies, the need for proportionality between the seriousness of the infringement and the remedies ordered, as well as the interests of third parties, shall be taken into account.
- 2. Each Party shall ensure that the judicial authorities have the authority to order that the remedies referred to in paragraph 1 shall be carried out at the expense of the infringer, unless particular reasons are invoked for not doing so.

Injunctions

- 1. Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority to issue an order against a party to desist from an infringement, and among other things, an order to that party, or, where appropriate, to a third party over whom the relevant judicial authority exercises jurisdiction, to prevent infringing goods from entering into the channels of commerce.
- 2. Notwithstanding the other provisions of this Section, a Party may limit the remedies available against use by government, or by third parties authorised by government, without the use of authorisation of the right holders to the payment of remuneration provided that the Party complies with the provisions of Part II of the TRIPS Agreement specifically addressing such use. In other cases, the remedies under this Section shall apply or, where these remedies are inconsistent with a Party's law, declaratory judgments and adequate compensation shall be available.

Article 20.40

Damages

- 1. Each Party shall provide that:
- (a) in civil judicial proceedings, its judicial authorities have the authority to order the infringer who knowingly or with reasonable grounds to know, engaged in infringing activity of intellectual property rights to pay the right holder:
 - (i) damages adequate to compensate for the injury the right holder has suffered as a result of the infringement; or
 - (ii) the profits of the infringer that are attributable to the infringement, which may be presumed to be the amount of damages referred to in paragraph (i); and
- (b) in determining the amount of damages for infringements of intellectual property rights, its judicial authorities may consider, among other things, any legitimate measure of value that may be submitted by the right holder, including lost profits.
- 2. As an alternative to paragraph 1, a Party's law may provide for the payment of remuneration, such as a royalty or fee, to compensate a right holder for the unauthorised use of the right holder's intellectual property.

Article 20.41

Legal costs

Each Party shall provide that its judicial authorities, where appropriate, have the authority to order, at the conclusion of civil judicial proceedings concerning the enforcement of intellectual property rights, that the prevailing party be awarded payment by the losing party of legal costs and other expenses, as provided for under that Party's law.

Article 20.42

Presumption of authorship or ownership

- 1. For the purposes of civil proceedings involving copyright or related rights, it is sufficient for the name of an author of a literary or artistic work to appear on the work in the usual manner in order for that author to be regarded as such, and consequently to be entitled to institute infringement proceedings, unless there is proof to the contrary. Proof to the contrary may include registration.
- 2. Paragraph 1 shall apply *mutatis mutandis* to the holders of related rights with regard to the protected subject matter of such rights.

Section D

Border Measures

Article 20.43

Scope of border measures

1. For the purposes of this Section:

counterfeit geographical indication goods means any goods under Article 20.17 falling within one of the product classes listed in Annex 20-C, including packaging, bearing without authorisation, a geographical indication which is identical to the geographical indication validly registered or otherwise protected in respect of such goods and which infringes the rights of the owner or right holder of the geographical indication in question under the law of the Party in which the border measure procedures are applied;

counterfeit trademark goods means any goods, including packaging, bearing, without authorisation, a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which infringes the rights of the owner of the trademark in question under the law of the Party in which the border measure procedures are applied;

export shipments means shipments of goods which are to be taken from the territory of a Party to a place outside that territory, excluding shipments in customs transit and transhipments;

import shipments means shipments of goods brought into the territory of a Party from a place outside that territory, while those goods remain under customs control, including goods brought into the territory to a free zone or customs warehouse, but excludes shipments in customs transit and transhipments;

pirated copyright goods means any goods which are copies made without the consent of the right holder or person duly authorised by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the Party in which the border measure procedures are applied;

shipments in customs transit means shipments of goods that enter the territory of a Party from a place outside that territory and are authorised by customs authorities for transport under continuous customs control from an office of entry to an office of exit, for the purpose of exiting the territory. Shipments in customs transit that are subsequently approved for removal from customs control without exiting the territory are considered to be import shipments; and

transhipments means shipments of goods that are transferred under customs control from the importing means of transport to the exporting means of transport within the area of one customs office which is the office of both importation and exportation.

- 2. The references to the infringement of intellectual property rights in this Section shall be interpreted as referring to instances of counterfeit trademark goods, pirated copyright goods or counterfeit geographical indication goods.
- 3. It is the understanding of the Parties that there shall be no obligation to apply the procedures set forth in this Section to goods put on the market in another country by or with the consent of the right holder.
- 4. Each Party shall adopt or maintain procedures with respect to import and export shipments under which a right holder may request its competent authorities to suspend the release of, or detain, goods suspected of infringing an intellectual property right.
- 5. Each Party shall adopt or maintain procedures with respect to import and export shipments under which its competent authorities may act on their own initiative to temporarily suspend the release of, or detain, goods suspected of infringing an intellectual property right, in order to provide an opportunity to right holders to formally request assistance under paragraph 4.

- 6. Each Party may enter into an arrangement with one or more third countries to establish common security customs clearance procedures. Goods cleared pursuant to the terms of the common customs procedures of such an arrangement shall be deemed to be in compliance with paragraphs 4 and 5, provided the Party concerned retains the legal authority to comply with these paragraphs.
- 7. Each Party may adopt or maintain the procedures referred to in paragraphs 4 and 5 with respect to transhipments and shipments in customs transit.
- 8. Each Party may exclude from the application of this Article small quantities of goods of a non-commercial nature contained in travellers' personal luggage or small quantities of goods of a non-commercial nature sent in small consignments.

Application by the right holder

- 1. Each Party shall provide that its competent authorities require a right holder who requests the procedures described in Article 20.43 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 the competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to the procedures described in Article 20.43.
- 2. Each Party shall provide for applications to suspend the release of, or to detain, goods suspected of infringing an intellectual property right listed in Article 20.43, under customs control in its territory. The requirement to provide for such applications is subject to the obligations to provide procedures referred to in Articles 20.43.4 and 20.43.5. The competent authorities may provide for such applications to apply to multiple shipments. Each Party may provide that, at the request of the right holder, the application to suspend the release of, or to detain, suspect goods may apply to selected points of entry and exit under customs control.
- 3. Each Party shall ensure that its competent authorities inform the applicant within a reasonable period whether they have accepted the application. Where its competent authorities have accepted the application, they shall also inform the applicant of the period of validity of the application.
- 4. Each Party may provide that, where the applicant has abused the procedures described in Article 20.43, or where there is due cause, its competent authorities have the authority to deny, suspend, or void an application.

Article 20.45

Provision of information from the right holder

Each Party shall permit its competent authorities to request a right holder to supply relevant information that may reasonably be expected to be within the right holder's knowledge to assist the competent authorities in taking the border measures referred to in this Section. Each Party may also allow a right holder to supply such information to its competent authorities.

Security or equivalent assurance

- 1. Each Party shall provide that its competent authorities have the authority to require a right holder who requests the procedures described in Article 20.43 to provide reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance shall not unreasonably deter recourse to these procedures.
- 2. Each Party may provide that such 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, or detention of, the goods in the event the competent authorities determine that the goods are not infringing. A Party may, only in exceptional circumstances or pursuant to a judicial order, permit the defendant to obtain possession of suspect goods by posting a bond or other security.

Article 20.47

Determination as to infringement

Each Party shall adopt or maintain procedures by which its competent authorities may determine, within a reasonable period after the initiation of the procedures described in Article 20.43, whether the suspect goods infringe an intellectual property right.

Article 20.48

Remedies

- 1. Each Party shall provide that its competent authorities have the authority to order the destruction of goods following a determination referred to in Article 20.47 that the goods are infringing. In cases where such goods are not destroyed, each Party shall ensure that, except in exceptional circumstances, such goods are disposed of outside the channels of commerce, in such a manner as to avoid any harm to the right holder.
- 2. In respect of counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.
- 3. Each Party may provide that its competent authorities have the authority to impose administrative penalties following a determination referred to in Article 20.47 that the goods are infringing.

Article 20.49

Specific cooperation in the area of border measures

- 1. Each Party agrees to cooperate with the other Party with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, each Party shall establish contact points in its administration and be ready to exchange information on trade in infringing goods. Each Party shall, in particular, promote the exchange of information and cooperation between its customs authorities and those of the other Party with regard to trade in goods infringing intellectual property rights.
- 2. The cooperation referred to in paragraph 1 may include exchanges of information regarding mechanisms for receiving information from rights holders, best practices, and experiences with risk management strategies, as well as information to aid in the identification of shipments suspected of containing infringing goods.
- 3. The cooperation under this Section shall be conducted consistent with relevant international agreements that are binding on both Parties. The Joint Customs Cooperation Committee referred to in Article 6.14 (Joint Customs Cooperation Committee) will set the priorities and provide for the adequate procedures for cooperation under this Section between the competent authorities of the Parties.

Section E

Co-operation

Article 20.50

Co-operation

- 1. Each Party agrees to co-operate with the other Party with a view to supporting the implementation of the commitments and obligations undertaken under this Chapter. Areas of co-operation include exchanges of information or experience on the following:
- (a) the protection and enforcement of intellectual property rights, including geographical indications; and
- (b) the establishment of arrangements between their respective collecting societies.
- 2. Pursuant to paragraph 1, each Party agrees to establish and maintain an effective dialogue on intellectual property issues to address topics relevant to the protection and enforcement of intellectual property rights covered by this Chapter, and any other relevant issue.

CHAPTER TWENTY-ONE

Regulatory cooperation

Article 21.1

Scope

This Chapter applies to the development, review and methodological aspects of regulatory measures of the Parties' regulatory authorities that are covered by, among others, the TBT Agreement, the SPS Agreement, the GATT 1994, the GATS, and Chapters Four (Technical Barriers to Trade), Five (Sanitary and Phytosanitary Measures), Nine (Cross-Border Trade in Services), Twenty-Two (Trade and Sustainable Development), Twenty-Three (Trade and Labour) and Twenty-Four (Trade and Environment).

Article 21.2

Principles

- 1. The Parties reaffirm their rights and obligations with respect to regulatory measures under the TBT Agreement, the SPS Agreement, the GATT 1994 and the GATS.
- 2. The Parties are committed to ensure high levels of protection for human, animal and plant life or health, and the environment in accordance with the TBT Agreement, the SPS Agreement, the GATT 1994, the GATS, and this Agreement.
- 3. The Parties recognise the value of regulatory cooperation with their relevant trading partners both bilaterally and multilaterally. The Parties will, whenever practicable and mutually beneficial, approach regulatory cooperation in a way that is open to participation by other international trading partners.
- 4. Without limiting the ability of each Party to carry out its regulatory, legislative and policy activities, the Parties are committed to further develop regulatory cooperation in light of their mutual interest in order to:
- (a) prevent and eliminate unnecessary barriers to trade and investment;
- (b) enhance the climate for competitiveness and innovation, including by pursuing regulatory compatibility, recognition of equivalence, and convergence; and