TEXTO PROPUESTO POR LA UE	TEXTO SUGERIDO POR AMIIF	COMENTARIOS
Article 1 *Objectives* *1. The objectives of this Chapter are to:* *(a) facilitate the production and commercialization of innovative and creative products in each Party; and* *(b) achieve an adequate and effective level of protection and enforcement of intellectual property rights.*	Article 1 Objectives 1. The objectives of this Chapter are to: (a) facilitate the production and commercialization of innovative and creative products in each Party; and (b) achieve an adequate effective level of protection and enforcement of intellectual property rights.	
Article 9 *Patents*	*[placeholder: Commission may propose text on general patent provisions]* • Subject to paragraphs 3 and 4: 1. 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. 2. 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	
Article 9.2 *Patents and public health* *1. The Parties recognise the importance of the Declaration on the TRIPS Agreement and Public Health, adopted in Doha on 14 November 2001 by the Ministerial Conference of the WTO (hereinafter referred to as the "Doha Declaration"). In interpreting and implementing the rights and obligations under this article, the Parties shall ensure consistency with the Doha Declaration.* *2. The Parties shall contribute to the implementation and respect the decision of the WTO General Council of 30 August 2003 on implementation of paragraph 6 of the Doha Declaration, as well as the Protocol amending the TRIPS Agreement of 6 December 2005.*	Article 9.2 Patents and public health 1. The Parties recognize the importance of the Declaration on the TRIPS Agreement and Public Health, adopted in Doha on 14 November 2001 by the Ministerial Conference of the WTO (hereinafter referred to as the "Doha Declaration"). In interpreting and implementing the rights and obligations under this article, the Parties shall ensure consistency with the Doha Declaration. 2. The Parties shall contribute to the implementation and respect the decision of the WTO General Council of 30 August 2003 on implementation of paragraph 6 of the Doha Declaration, as well as the Protocol amending the TRIPS Agreement of 6 December 2005.	
Article 9.3 *Extension of the period of protection conferred by a patent on medicinal products.5* *1. The Parties recognise that medicinal products protected by a patent on their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the*	*Article 9.3* *Extension of the period of protection conferred by a patent on medicinal products.5* 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. If there are unreasonable delays in a Party's issuance	

application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent.	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 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. The time adjustment should not be less than the unreasonable delay. 1. The Parties recognize that medicinal products protected by a patent on their respective territory may be subject to an administrative authorization procedure before being put on their market. They recognize that the period that elapses between the filing of the application for a patent and the (*) authorization to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent.	*(no hay razón para limitar este razonamiento a la primera autorización)
2. Each Party shall provide for a further period of protection for a medicinal product which is protected by a patent and which has been subject to an administrative authorisation procedure, that period being equal to the period referred to in the second sentence of paragraph 1, reduced by a period of […] years.	2. Each Party shall make best efforts to process applications for marketing approval of pharmaceutical products in an efficient and	(se considera que es mejor el esquema de ajustar la protección después de la dilación, no por el tiempo que se

3. Notwithstanding paragraph 2, the duration of the further period of protection may not exceed […] years. *4. In the case of medicinal products for which paediatric studies have been carried out, and the results of those studies are reflected in the product information, the Parties shall provide for a further […] months extension of the period of protection referred to in paragraph 2.*	timely manner, with a view to avoiding unreasonable or unnecessary delays. With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment 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. 3. Notwithstanding paragraphs, the duration of the further period of protection may not exceed [**5**] years. 4. In the case of medicinal products for which pediatric studies have been carried out, and the results of those studies are reflected in the product information, the Parties shall provide for a further [**18**] months extension of the period of protection referred to in paragraph.	vea mermada la exclusividad que es más difícil de medir, por eso se sugiere esquema TPP, donde se obliga primero a no retrasarse y a ajustar o compensar).
Article 9.4 *Extension of the period of protection conferred by a patent on plant protection products6* *1. The Parties recognise that plant protection products protected by a patent in their respective territory may be subject to an administrative authorisation procedure before*	Article 9.4 Extension of the period of protection conferred by a patent on plant protection products 1. The Parties recognize that plant protection products protected by a patent in their respective territory may be subject to an administrative	

being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent. *2. Each Party shall provide for a further period of protection for a plant protection product which is protected by a patent and which has been subject to an administrative authorisation procedure, that period being equal to the period referred to in the second sentence of paragraph 1, reduced by […] years.* *3. Notwithstanding paragraph 2, the duration of the further period of protection may not exceed […] years.*	authorization procedure before being put on their market. They recognize that the period that elapses between the filing of the application for a patent and the **(*)** authorization to place the product on their respective market, as defined for that purpose by the relevant legislation. 2. Each Party shall provide for a further period of protection for a plant protection product which is protected by a patent and which has been subject to an administrative authorization procedure, that period being equal to the period referred to in the second sentence of paragraph 1, reduced by […] years. 3. Notwithstanding paragraph 2, the duration of the further period of protection may not exceed […] years.	*(no hay razón para limitar este razonamiento a la primera autorización)
Article 11.1 *Scope of protection of trade secrets* *1. …* *Article 11.2* *Civil judicial procedures and remedies of trade secrets*		En México no hay acciones civiles solo acciones penales
Article 11.3 *Protection of data submitted to obtain an authorisation to put a medicinal product on the market* *1. Each Party shall protect commercially confidential information*	Article 11.3 Protection of data submitted to obtain an authorization to put a medicinal product on the market	

submitted to obtain an authorisation to place pharmaceutical products on the market ("marketing authorisation") against disclosure to third parties, unless overriding public health interests provide otherwise. *2. Each Party shall ensure that for a period of […] from the first marketing authorisation in the Party concerned, the public body responsible for the granting of a marketing authorisation will not take into account confidential business information or the results of pre-clinical tests or clinical trials provided in the first marketing authorisation application and subsequently submitted by a person or entity, whether public or private, in support of another application to place a medicinal product on the market without the explicit consent of the person or entity who submitted such data, unless international agreements recognised by both Parties provide otherwise.* *3. During a […] year period, starting from the date of grant of the first marketing authorisation in the Party concerned, a marketing authorisation granted for any subsequent application based on the results of pre-clinical tests or of clinical trials provided in the first marketing authorisation will not permit placing a pharmaceutical product on the market, unless the subsequent applicant submits his own results of preclinical tests or of clinical trials (or results of pre-clinical tests or of clinical trials used with the consent of the party which had provided this information) meeting the same*	1. Each Party shall protect commercially confidential information submitted to obtain an authorization to place pharmaceutical products on the market ("marketing authorization") against disclosure to third parties, unless overriding public health interests provide otherwise. 2. Each Party shall ensure that for a period of [**5 years**] from the first marketing authorization in the Party concerned, the public body responsible for the granting of a marketing authorization will not take into account confidential business information or the results of pre-clinical tests or clinical trials provided in the first marketing authorization application and subsequently submitted by a person or entity, whether public or private, in support of another application to place a medicinal product on the market without the explicit consent of the person or entity who submitted such data, unless international agreements recognized by both Parties provide otherwise. 3. During a [**3**] year period, starting from the date of grant of the first marketing	

requirements as the first applicant. Products not complying with the requirements set out in this paragraph shall not be allowed on the market. *4. In addition, the […] year period referred to in paragraph 3 shall be extended to a maximum of […] years if, during the first […] years after obtaining the authorisation, the authorisation holder obtains an authorisation for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies.*	authorization in the Party concerned, a marketing authorization granted for any subsequent application based on the results of pre-clinical tests or of clinical trials provided in the first marketing authorization will not permit placing a pharmaceutical product on the market, unless the subsequent applicant submits his own results of preclinical tests or of clinical trials (or results of pre-clinical tests or of clinical trials used with the consent of the party which had provided this information) meeting the same requirements as the first applicant. Products not complying with the requirements set out in this paragraph shall not be allowed on the market. 4. **Each Party shall ensure that for a period of 12 years from the first marketing authorization which is, or contains a biologic product in the Party concerned, the public body responsible for the granting of a marketing authorization will not take into account confidential business information or the results of pre-clinical tests or clinical trials provided in the first marketing authorization application and subsequently submitted by a person or**	

	entity, whether public or private, in support of another application to place a medicinal product on the market without the explicit consent of the person or entity who submitted such data, unless international agreements recognized by both Parties provide otherwise. **5.** In addition, the [**3 and the 12**] year period referred to in paragraph **3 and 4** shall be extended to a maximum of [**3**] years if, during the first [**5**] years after obtaining the authorization, the authorization holder obtains an authorization for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies.	
Article 11.4 *Protection of data submitted to obtain marketing authorisation for plant protection* *Products* … *3. The period of data protection shall be at least […] years from the first authorisation granted by the concerned authority in that Party. In case of low risk plant protection products the period can be extended to […] years.*	3. The period of data protection shall be at least [**10**] years from the first authorization granted by the concerned authority in that Party. In case of low risk plant protection products the period can be extended to [...] years.	
Sub-Section 3.2		

Civil & administrative enforcement *Article 14* *Evidence* *…*	1. 2. 3. **4. Each Party should avoid duplication or multiple proceedings to recover damages derived from the violation of intellectual property rights.**	

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