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JANUARY 21, 2019

NAFTA 2.0

CHAPTER 20

PHARMACEUTICAL-RELATED PATENT PROVISIONS



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PHARMACEUTICAL-RELATED PATENT PROVISIONS

The Intellectual Property (IP) Chapter of the revised North American Free Trade Agreement (NAFTA 2.0), rebranded by the Trump Administration as the U.S.-Mexico-Canada Agreement or USMCA, includes provisions that threaten to undermine critical efforts toward affordable health care and medicine.

The NAFTA 2.0 text that was signed on Nov. 30 includes significant and harmful changes to the original NAFTA IP provisions. These build on concepts included in other U.S. free trade agreements (FTA) on behalf of the pharmaceutical industry since NAFTA 1.0. This analysis reviews the pharmaceutical related patent provisions of that text.

Overall, the NAFTA 2.0 text includes improvements on some issues Public Citizen has long demanded, most notably Investor-State Dispute Settlement. The Nov. 30 text also reveals that more work is needed, especially with respect to ensuring the swift and certain enforcement of labor standards and environmental standards. However, one way in which, NAFTA 2.0 is dramatically worse than NAFTA 1.0 is that it would help pharmaceutical companies avoid generic competition and keep medicine prices high. The text closely mimics the language and structure of the original U.S.-proposed IP terms in the Trans-Pacific Partnership Agreement (TPP) – now known as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The TPP was fiercely criticized for the pharma-friendly patent-related provisions that put the health and well-being of people in the TPP countries at risk. Following the U.S. withdrawal from that agreement, many of those damaging provisions were suspended by the CPTPP countries.

NAFTA 2.0, however, incorporates almost all of these pro-monopoly pharma-friendly patent-related provisions. In some circumstances, it even goes beyond the original TPP. To comply with the terms of the Nov. 30 text, Mexico and Canada would need to change their existing laws to provide new exclusivities for pharmaceutical companies, which would limit generic competition and raise prescription drug costs. These terms would also lock the United States into policies that have contributed to making U.S. medicine prices the highest in the world.

The analysis below reviews the most controversial provisions that would affect pharmaceutical prices and availability of medicines in the United States, Canada, and Mexico. It only covers some of the main obligations of the IP measures relating to patents and pharmaceutical or regulated products in the final text. It should be noted that the interpretation of this Chapter is also likely to depend on provisions in other NAFTA 2.0 chapters.

¹ United States-Mexico-Canada Agreement (NAFTA 2.0), available at <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between>

Secondary Patents/Patentable Subject Matter (Article 20.36)

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.³⁰
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.
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.

FN30: 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.

The text of this provision is identical, word-for-word, to the TPP provision on secondary patents.²

Patentability criteria and patentable subject matter determine what will be patented and, correspondingly, are important to preserving space for generic competition. Overly permissive standards facilitate patent evergreening, the extension of patent-based monopolies through minor changes with little benefit to innovation.

A close reading of the provision reveals that some sort of secondary patenting (whether it is Swiss-type, method of use or process of use) is required.

A pharmaceutical patent typically consists of an active pharmaceutical ingredient. It usually provides exclusive control over not only the product itself, but also over all foreseen subsequent uses. But what about unforeseen uses, or uses of the known product that have unexpected outcomes?

Under the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property (TRIPS), countries have the flexibility to decide whether to grant such patent protection. Under NAFTA 2.0, they would lose that flexibility, as some sort of patent evergreening would be required.

² See, Article 18.37: Patentable Subject Matter, available at <https://www.mfat.govt.nz/assets/Trans-Pacific-Partnership/Text/18.-Intellectual-Property-Chapter.pdf>

A use claim can be a product or process depending on the context. European patent law and practice distinguishes between first and second uses, treating first medical uses as products and second medical uses as process claims.

U.S. law does not technically distinguish between first and second medical uses. However, use claims in the United States are regarded as process-of-use claims. The claim is targeted to a particular “method-of-use” that did not encompass protection of the product as such, rather than the use itself. The term “process” refers to process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter or material.

In order to identify evergreening practices, it is important to distinguish between first and second medical uses. The second use of a known product facilitates patent evergreening. Evergreening patents aim to extend the life of patent protection through patenting of minor changes in active pharmaceutical ingredients of existing products (polymorphs, salts, etc.), inert ingredients, formulations, dosages and combinations.

A claim directed to the first medical use includes a known compound with no previously known medical use.

—————

“Compound X for use in therapy” or “Substance X for use as a medicament”

A claim directed to the second medical use includes a known compound with a known medical use. It usually describes the therapeutic method of treatment of a human or animal body. A second medical use of a known product makes no changes to the structure of the chemical entity or active ingredient.

—————

“The use of compound X to treat condition Y” or “Substance X for use in the treatment of condition Y”

The TRIPS exclusion of “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body” from patentability applies to claims relating to the second medical use of a known product. Indeed, there is no real difference between patent claims relating to a use of a known product and a therapeutic procedure.

In both cases a new medical activity is patented, i.e., a new way of using one or more known products. The NAFTA 2.0 provision provides options for parties to grant patents on “new uses,” “new methods” or “new processes” of using a known product. In practice, new uses, new methods or new processes may all refer to second use claims such as use of a medicine to treat a certain disease. Accordingly, a Swiss-type claim (a process for use rather than a use) can satisfy this requirement very easily even though the Parties exclude diagnostic, therapeutic and surgical methods from patentability.

The TPP provision said “a Party may limit those new processes to those that do not claim the use of the product as such”. In other words, electing to grant process patents does not require a country to grant new use patents as part of the same category, which essentially is the U.S. practice. Unfortunately, Canada and Mexico may not have insisted on this limit on the obligation, given their existing practice of granting secondary use patents.

The line between Swiss-type claims and claims to a method of treatment is incredibly thin. Patentability rests on the method of treatment if the novelty lies in the nature of use, rather than in the end result at which that use aims. The distinguishing feature of the Swiss-type claim is the use to which that medicament is applied. This new medical use must be novel

– it cannot claim a modification of an existing treatment or a better method for treating the previously claimed disease for which the drug is already known to have an effect.

Patenting on the basis of secondary use and incremental innovation, while controversial, already takes place in the United States, Mexico and Canada. However, neither Mexican nor Canadian law requires it. The NAFTA 2.0 provision could cement the practice and block prospects for reform.

It should be noted that the scope of this provision is not only limited to pharmaceuticals, as it also applies to chemicals, agrochemicals, etc

Exceptions (Article 20.39)

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.

This provision mimics the language of Article 30 of TRIPS and TPP Article 18.40. The negotiating history for Article 30 suggests that a flexible approach should be taken in its interpretation. An earlier draft³ of Article 30 included a non-exhaustive list of permissible exemptions, such as prior use rights, experimental use rights and private, non-commercial use. However, the final text in TRIPS makes no mention of specific examples of acceptable, non-infringing uses and adopts a more generalized and flexible approach, using Article 9(2) of the Berne Convention as its model. This provision should be interpreted in a similarly flexible manner.

Other Use Without Authorization of the Right Holder (Article 20.40)

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.

Observers raised questions as to whether earlier drafts of the TPP IP chapter would abrogate compulsory licensing rights.⁴ Thus, Article 18.41 of the TPP included a clarification that the TPP should not affect compulsory licensing rights. This NAFTA 2.0 article mirrors Article 18.41 of the TPP and serves as a clarification that NAFTA 2.0 should not affect Parties' right to issue compulsory licenses.

Patent Term Extensions (*For Patent Examination Period*) (Article 20.44)

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 1990 Anell Draft of TRIPS.

⁴ See, KEI TPP Briefing note 2015:1 Compulsory licenses on patents and the 3-step test, available at <http://www.keionline.org/node/2231>

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.³⁶

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 occur during the processing³² of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable³³ to the granting authority; as well as periods of time that are attributable to the patent applicant.³⁴

FN32: For the purposes of this paragraph, a Party may interpret processing to mean initial administrative processing and administrative processing at the time of grant.

FN33: 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.

FN34: 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.

The provision is a word-for-word copy of Article 18.46 of the TPP. It is suspended in the CPTPP. It grants additional monopoly terms for pharmaceutical products for perceived delays in patent examination. Patent term adjustments – typically called extensions – significantly delay market entry of generics and thereby restrict access to affordable medicines and increase health system costs.⁵

In the United States, a patent term adjustment is determined using a complex set of rules that, in general, involve adding up prosecution times at the patent office but not compensating patent applicants for delays they have caused.

An issue subject to much debate during the TPP negotiations was how to define unreasonable delays. Countries settled on the later proposal of five years from the date of filing or three years after an examination request. This was a slight reduction from the initial U.S. proposal of four and two.

The provision is not prescriptive on delays attributable to actions of the patent owner; it is up to Parties to decide what is best for their interests. It allows for authorities to subtract from the calculation of a patent term extension the time taken to consider a third party's pre-grant patent opposition (as a period not attributable to the patent authority).

The grant of a patent might not be delayed beyond the periods defined as unreasonable – the later of five years from the date of filing or three years after an examination request.

The provision introduces new obligations for Canada and Mexico, as they do not offer patent extensions for patent office delays. Similar provisions in other U.S. FTAs did not result in the implementation of term adjustment mechanism in other countries (e.g., Australia).

⁵ In its review of Australia's IP arrangements, the Australian Government's Productivity Commission found that patent term extensions "(...) have proven largely illusory, resulting in a costly policy placebo. Poor targeting means that more than half of new chemical entities approved for sale in Australia enjoy an extension in patent term, and consumers and governments face higher prices for medicines."

Patent Term Extensions (*For Regulatory Review Period*) (Article 20.46)

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 that is subject to a patent, each Party shall make available an adjustment³⁹ 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. 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.

FN39: 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.

The first paragraph of the text follows the wording of the Article 18.48 of the TPP. It encourages countries to process patent applications and applications for marketing approval of pharmaceutical products in an efficient and timely manner.

The scope of the provision is limited to pharmaceutical products and does not cover methods of making or using pharmaceutical products. The provision does not prescribe limitations on the period and applicability of patent term extensions. Rather it allows Parties to provide for conditions and limitations within their own legal system and practice and encourages Parties to adopt or maintain procedures that expedite the examination of marketing approval applications.

Currently, Mexico does not offer patent term extensions for regulatory delays. According to Article 20.K.1, Mexico has 4.5 years transition period from the date of entry into force of the Agreement to fully implement patent term extensions. Canada just introduced supplementary protection certificates for regulatory delays.⁶

Regulatory Review Exception (Article 20.47)

Without prejudice to the scope of, and consistent with, Article 20.F.4 (Exceptions), each Party shall adopt or maintain a regulatory review exception⁴⁹ for pharmaceutical products.

⁶ Art 47 (1) "(...) the Commissioner may, on the surrender of the patent within four years from its date (...) Certificate of supplementary protection (1.1) Subsection (1) also applies in the case where the original patent is set out in a certificate of supplementary protection and the original patent's term has expired, except that in that case the issuance of the new patent, whose term remains expired, is for the purpose of establishing the rights, privileges and liberties granted under the certificate".

The regulatory review exception, widely known as the Bolar exception in the United States, helps speed generic medicines to market. It is a safe harbor provision that permits generics manufacturers to make small batches and apply for marketing approval before the patent expires without risk of liability for infringement.

The provision mimics the language of Article 30 of TRIPS. It permits Parties to adopt a regulatory review exception: “Members 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.”

The TPP version of this provision⁷ included a footnote:

“FN49: 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.”

The NAFTA 2.0 version of the provision does not include such a clarification. It is ambiguous whether the provision only applies in case of tests conducted with the intent of seeking domestic regulatory review or if it extends to exports as well. Canada’s existing regime applies to products submitted for domestic regulatory review as well as products submitted for regulatory review in foreign jurisdictions. It is important not to limit Canada’s system.

Pharmaceutical Data Protection/Protection of Undisclosed Test or Other Data (Market Exclusivity) (Article 20.48)

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,⁴⁰ that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar⁴¹ 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 years⁴² from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

FN40: Each Party confirms that the obligations of this Article and Article 20.49 (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.

FN41: 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.

FN 42: For greater certainty, a Party may limit the period of protection under paragraph 1 to five years, and the period of protection under Article 20.49.1(a) (Biologics) to 10 years.

⁷Article 18.49 of the CPTPP.

Exclusivity rules delay generic drug approval for a specified period of time. They limit the ability of generics manufacturers and regulatory authorities to make use of an originator company's data and grant generics marketing approval.

This provision mirrors the language in the TPP⁸ and allows for at least five years⁹ of market exclusivity for new pharmaceutical products. The Parties shall not permit third parties to market the same or similar product using the same test or other data concerning the safety and efficacy of the product. It is important to mention that market exclusivity means that Parties can accept generic medicine applications during those five years, but cannot grant the marketing approval before five years pass from the date of marketing approval in the territory of the Party.

The provision distinguishes between the information required and permitted. If a Party relies on required undisclosed test or other data to grant a marketing approval, paragraph (a) applies. If a Party relies on the marketing approval conferred in a foreign country, then paragraph (b) applies. The scope of exclusivity is limited to undisclosed test or other data submitted and does not extend to information in support of marketing approval.¹⁰

Products that are considered to be the same as or similar to the reference product are excluded from relying on its protected data. Footnote 41 clarifies that a pharmaceutical product can be similar to a previously approved pharmaceutical product if the marketing approval of that similar pharmaceutical product is based upon the information concerning the safety or efficacy of the previously approved pharmaceutical product, or the prior approval of the reference product.

• Pharmaceutical Data Protection (Market Exclusivity) for New Clinical Information or New Compounds (Article 20.48.2)

2. Each Party shall:⁴³

- (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 a chemical entity that has not been previously approved in that Party.⁴⁴

FN43: A Party that provides a period of at least eight years of protection pursuant to paragraph 1 is not required to apply paragraph 2.

FN44: For the purposes of Article 20.48.2 (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.

Marketing exclusivity for new forms and uses of old medicines could be considered a form of evergreening. Since marketing exclusivity applies regardless of the patent status of a drug, even off-patent medicines presented in the forms and uses described below would not have a generic competitor.

⁸ Article 18.50 of the TPP

⁹ The footnote 42, clarifies that 'at least' doesn't mean Parties have to provide protection more than 5 small molecules or 10 years biologics.

¹⁰ The earlier versions of the TPP text conferred exclusivity for any 'information' submitted in support of marketing approval, even if it is disclosed and in the public domain.

The provision is a word-for-word copy of the Article 18.50 of the TPP. It is suspended in the CPTPP.

The provision requires Parties to choose one of two possible evergreening models to incorporate in their laws. Offering a choice between options which support different objectives seems to have little internal logic and presumably reflects a political compromise. Footnote 43 clarifies that additional exclusivity protection on submission of new chemical information does not extend to pharmaceutical products that receive eight years data exclusivity (as in the case of Canada).

Option (a): Three Years Additional Exclusivity for New Clinical Information

A new indication of a known medicine refers to a new use of that medicine. Depending on how indication is defined, this could mean the use of a known medicine for treatment of another disease or use of the known medicine for the same disease but for a different population of patients – such as children. Option (a) provides at least three years of Article 20.48.2-style market exclusivity for new clinical information supporting a new indication.

By way of illustration, the approval of previously known medicines for use in children may also be considered a new indication. Whether data/marketing exclusivity for new indications would apply for versions of the same medicine used in the treatment of children would depend on the definition used by the medicine regulatory authority concerned. Pediatric versions would also be considered new formulations of known medicines.¹¹

A new formulation of a known medicine refers to a different version of the same medicine including salts, esters, ethers, polymorphs, thermodynamically stable versions, different dosage forms, etc.

A new method of administration refers to a change in the means by which an active ingredient is delivered into a patient's body. It includes drug delivery methods such as pills, eye drops, ointments, and intravenous solutions drug entrapment in small vesicles that are injected into the bloodstream.

Option (b): New Combinations

Under option (b), a Party would provide five years exclusivity if a known product were combined with a new chemical entity that has not been previously approved. This kind of exclusivity would possibly apply to fixed combinations.

• **Public Health Safeguards (Article.20.48.3)**

3. Notwithstanding paragraphs 1 and 2 and Article 20.49 (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.

¹¹ For example, Nevirapine syrup. Invented in 1990, by the late 1990s, the hemihydrate or syrup form of this medicine was also known. It is this syrup version that is used for the pediatric treatment of HIV. By 2008, an extended release form of Nevirapine was also formulated.

¹² "...this language has little or no practical effect. It would not limit in any manner the obligations imposed by the agreement. The referred to Declaration only confirms the flexibilities allowed by the TRIPS Agreement in relation to public health matters (such as compulsory licenses and parallel imports), but it is unlikely to provide a sufficient legal basis to derogate from the obligations established by the TPP", Carlos M. Correa. Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines. South Centre Research Paper No. 62, September, 2015, <http://www.southcentre.int/research-paper-62-september-2015/>

¹³ For more information, please see the National Law Review, "In Mexico: Can the Minimum Period of 5 Years Established by NAFTA for Regulatory Data Exclusivity be Extended for Biological Medical Products?", available at <https://www.natlawreview.com/article/mexico-can-minimum-period-5-years-established-nafta-regulatory-data-exclusivity-be-e>

¹⁴ Article 20.K.1: Final Provisions

¹⁵ C.08.004.1 of the Food and Drug Regulations, Food and Drug Regulations, C.R.C., c. 870, available at http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf

The provision follows the TPP language in Article 18.50.3 that provides safeguards for Parties to take measures to protect public health in accordance with the TRIPS Agreement and Doha Declaration. It borrows the language from the May 10 Agreement and previous FTAs (Peru US FTA, Korea-US FTA).

Public Citizen, Third World Network and other observers including Carlos Correa¹² have suggested expanded language to provide a clear operational path for health exceptions to marketing exclusivity. The actual provision provides little specific guidance, but nevertheless references all NAFTA 2.0 exclusivity provisions. This should mean Parties may provide health exceptions to marketing exclusivity for biologics.

This provision is suspended in the CPTPP.

Mexico has no specific legislation on exclusivity periods for small molecules or biological medical products and new indications. However, the Federal Commission for Protection against Sanitary Risks (COFEPRIS) provides five years exclusivity for new chemical entities.¹³ Mexico is required to implement this provision, subject to a five-year transition period from the date of entry into force of the Agreement.¹⁴

Canada provides eight years of exclusivity through six-year data exclusivity (no-filing) and eight year market exclusivity (no approval) for innovative drugs including small molecules and biologics.¹⁵

Biologics (Article 20.49)

1. With regard to protecting new biologics, a Party shall with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic,^{45,46} provide effective market protection through the implementation of Article 20.48.1 (Protection of Undisclosed Test or Other Data) and Article 20.48.3 (Protection of Undisclosed Test or Other Data), *mutatis mutandis*, for a period of at least ten years from the date of first marketing approval of that product in that Party.
2. Each Party shall apply this Article to, at a minimum⁴⁷, a product that is produced using biotechnology processes and that is, or, alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition.

FN45: 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.

FN46: 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 20.48.1(a) (Protection of Undisclosed Test or Other Data subparagraph 1(a)) and Article 20.48.1(b) (Protection of Undisclosed Test or Other Data subparagraph 1(b)) on or before March 23, 2020, provided that other pharmaceutical products in the same class of products have been approved by that Party under the procedures set forth in Article 20.48.1(a) (Protection of Undisclosed Test or Other Data subparagraph 1(a)) and Article 20.48.1(b) (Protection of Undisclosed Test or Other Data subparagraph 1(b)) before the date of entry into force of this Agreement for that Party.

¹⁶ See Public Citizen & Third World Network Analysis: Ambiguity Leads to Fallacy: Biologics Exclusivity in the Trans-Pacific Partnership <https://www.citizen.org/sites/default/files/tpp-biologics-exclusivity-memo-november-2015.pdf>

¹⁷ E.g. Australia: <http://dfat.gov.au/trade/agreements/tpp/outcomes-documents/Pages/outcomes-biologics.aspx>; Chile: <https://ustr.gov/about-us/policy-offices/press-office/speechestranscripts/2015/october/transcript-trans-pacific>; New Zealand: http://tpp.mfat.govt.nz/assets/docs/TPP_factsheet_Intellectual-Property.PDF; Singapore: <https://www.politicopro.com/trade/story/2015/10/pro-trade-tppbiologics-behsudi-059493>.

¹⁸ Article 18.52.2

¹⁹ Jinyou Zhang, Mammalian Cell Culture for Biopharmaceutical Product (Jan 2010), available at http://www.researchgate.net/profile/Jinyou_Zhang2/publication/225033892_Mammalian_Cell_Culture_for_Biopharmaceutical_Production/links/0fcfd4fbcfaf09b585000000.pdf.

²⁰ 42 USC § 262(i)(1)

²¹ In the previous leaked versions of the TPP IP chapter, there was a drafter's note clarifying that "the Parties understand that each Party may determine the meaning of

FN47: For greater certainty, for the purposes of this Article, the Parties understand that "at a minimum" means that a Party may limit the application to the scope specified in this paragraph.

The NAFTA 2.0 provision has changed significantly compared to the TPP. Which provided two options for the Parties. They could either:

- a) Provide **eight years** of market exclusivity counting from the date the biologic is approved in the country concerned, or
- b) Provide **five years** of market exclusivity counting from the date the biologic is approved in the country concerned and other measures to deliver a comparable market outcome.

Following the release of the TPP text, TPP countries issued conflicting statements regarding biologics exclusivity obligations embodied in this provision.¹⁶ A number of TPP governments had stated that this does not require them to change their existing systems of five years of biologics exclusivity.¹⁷ This provision was one of the first provisions that were suspended in the CPTPP.

NAFTA 2.0 goes beyond the TPP and provides only one option for the Parties; **10 years** of market exclusivity counting from the date the biologic is approved in the country concerned. This is a major change that will negatively affect health budgets and access to medicines.

The scope of the exclusivity is broader than in the TPP. In the TPP, exclusivity is provided for medicines that treat or cure human diseases or conditions or prevent them (e.g. vaccines) if they are proteins which are made using a biotechnology process.¹⁸ Since the majority of biologics are proteins¹⁹, defining biologic to include proteins, such as vaccines and blood products, excluded few products.

The new definition, however, explicitly covers viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, blood components or derivatives, allergenic products, proteins or analogous products as biologics if they are produced using biotechnology processes. This means that more products potentially would come under monopoly control.

US law defines "biological product" as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), but limits its application to the prevention, treatment or cure of a disease or condition of human beings.²⁰ The NAFTA 2.0 text only makes a reference to their production using biotechnology processes.

Biotechnology processes, however, can be defined in national law,²¹ which allows it to be updated as the science changes.

The side letter between Mexico and the United States further clarifies (if such clarification is needed) that the Parties are free to accept biosimilar applications when they choose.²² Parties simply may not grant approval until 10 years have passed. In other words, countries may have their own data exclusivity regime (or no data exclusivity for biologics), but they must apply a 10-year marketing exclusivity period.

The NAFTA 2.0 biologics provision is a marketing exclusivity rule, rather than a data exclusivity rule. The provision introduces new obligations for Canada and Mexico. Presently, Canada provides eight years of exclusivity for an innovator drug, which applies to both biologics and conventional small molecule pharmaceuticals.²³ Mexico does not provide any exclusivity for biologics products.²⁴ Mexico is therefore required to implement this provision and provide exclusivity for biologics within five years from the date of entry into force of the agreement.

biotechnology processes in its legal system and practice." This footnote disappeared in the final text but Parties still keep the flexibility and freedom to determine the meaning of biotechnology processes in their legal system and practice.

²² United States-Mexico Side Letter on Biologics, available at https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/MX-US_Side_Letter_on_Biologics.pdf

²³ C.08.004.1 of the Food and Drug Regulations.

²⁴ See, Erwin Cruz & Alejandro Luna, "Key issues for biotech products in Mexico", available at <http://www.iam-media.com/Intelligence/IAM-Life-Sciences/2015/Articles/Key-issues-for-biotech-products-in-Mexico>

Patent Linkage (Article 20.51)

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 holder⁴⁸ 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 of an allegedly infringing product, available remedies in subparagraph (c); and
- (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.

FN48: For greater certainty, for the purposes of this Article, a Party may provide that a "patent holder" includes a patent licensee or the authorized holder of marketing approval.

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.

Patent linkage is a regulatory mechanism that links medicine marketing approval to patent status. Under some forms of linkage, even spurious patents may function as barriers to generic medicine registration. Patent linkage can facilitate abuse, since the financial benefits to patent holders of deterring generic market entry may outweigh risks of penalties.

The provision mimics the TPP language on patent linkage²⁵ and provides Parties with two options:

This provision is similar to the "soft" linkage provision of the Peru-US FTA.²⁶ A Party must either create a system to provide notice to a "patent holder" (the authorized holder of marketing approval) or allow for notification prior to the marketing of a competing product, or a product for an approved use, claimed under a patent. A Party also needs to provide adequate time and opportunity for a patent holder to seek remedies including judicial and administrative proceedings, preliminary injunctions or equivalent effective provisional measures.

²⁵ Article 18.51 of the TPP

²⁶ Peru-US Free Trade Agreement, Article 16.10.03, <https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/pdfs/FTAs/peru/16%20IPR%20Legal.June%2007.pdf>

The second option is similar to the U.S. “hard” linkage system which prevents generics companies from getting marketing approval during the patent term unless by consent or acquiescence of the patent holder. A Party would create an extra-judicial system to prevent the applicant from marketing a product, or a product for an approved use, which are claimed under a patent. This system requires direct coordination between the marketing approval authority and the patent office. The obligation extends to cover the entire term of the patent, unless the patent owner has consented to, or acquiesced in, the use of the information.

The text offers no exclusion for biologics.

Canada²⁷ and Mexico²⁸ both provide for regulatory mechanisms that link medicine marketing approval to patent status which satisfy the requirements of this provision.

Market Exclusivity and Term of Patent (Article 20.52)

Subject to Article 20.48.3 (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 20.45 (Protection of Undisclosed Test or Other Data for Agricultural Chemical Products), Article 20.48 or Article 20.49 (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 20.45, Article 20.48 or Article 20.49 in the event that the patent protection terminates on a date earlier than the end of the period of protection specified in Article 20.45, Article 20.48 or Article 20.49.

This provision mimics the TPP’s Article 18.54 on alteration of period of protection. In certain cases, exclusivity may outlast patent protection. Some countries prefer to end the data/market exclusivity when the patent term ends. The United States Trade Representative has long been concerned about this practice.

The provision explicitly establishes that exclusivity and patent terms should be treated independently. It prohibits countries from altering or ending exclusivity when patent protection terminates. The provision would lead to longer monopoly protection for originator companies.

²⁷ See, Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, available at <http://laws-lois.justice.gc.ca/eng/regulations/sor-93-133/FullText.html>

²⁸ Article 147bis of the Mexican Industrial Property Regulations & Article 167bis of the Health Regulation

COMPREHENSIVE TABLE ON SELECTED PATENT PROVISIONS – CANADIAN, MEXICAN, U.S. LAW, NAFTA, TPP AND NAFTA 2.0

| ISSUE | NAFTA ¹ | TPP ² | CANADA | MEXICO | U.S. | NAFTA 2.0 ³ |
|---|--|--|--|--|---|---|
| Patentability Requirements (Secondary Patents) | <p>Art. 1709(1)</p> <p>1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application.</p> <p>For purposes of this Article, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful”, respectively.</p> | <p>Article 18.37</p> <p>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.³⁰</p> <p>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.</p> | <p>Section 2 Patent Act⁴</p> <p>Invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (invention)</p> <p>28.2 (1) The subject matter defined by a claim in an application for a patent in Canada (the “pending application”) must not have been disclosed.</p> <p>28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to</p> | <p>“Patents can protect a product, process, apparatus or means specially devised for its application, and combinations thereof; the requirements are novelty, inventive step, and industrial applicability.”</p> <p>There are no provisions restricting the secondary patenting of medical uses/ methods, as such. Claims on secondary uses shall comply with the definition of invention (Article 15), patentability requirements (Article 16) and must not fall within the exceptions provided in Article 16 and Article 19.⁵</p> | <p>U.S. law allows certain types of secondary patents. U.S. law does not technically distinguish between first and second medical uses. However, use claims in the U.S. are regarded as process-of-use claims. The claim is targeted to a particular “method-of-use” that did not encompass protection of the product as such rather than the use itself. The term “process” refers to process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter or material (35 U.S. Code § 100⁶).</p> | <p>Article 20.36</p> <p>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.</p> <p>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.</p> <p>3. A Party may exclude from patentability inventions, the prevention within their territory of the commercial</p> |

¹ North American Free Trade Agreements, Chapter Seventeen: Intellectual Property, available at <https://www.nafta-sec-alena.org/Home/Texts-of-the-Agreement/North-American-Free-Trade-Agreement?mvid=1&secid=b6e715c1-ec07-4c96-b18e-d762b2ebe511#A1709>

² The Transpacific Partnership Agreement, Chapter 18, Intellectual Property, available at <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf>

³ United States-Mexico-Canada Agreement Text, CHAPTER 20, Intellectual Property Rights, https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20_Intellectual_Property_Rights.pdf

⁴ Patent Act, R.S.C., 1985, c. P-4, available at <http://laws-lois.justice.gc.ca/eng/acts/P-4/page-1.html#h-2>

⁵ Ley de la Propiedad Industrial (texto refundido publicado en el Diario Oficial de la Federación el 1 de junio de 2016), available at http://www.wipo.int/wipolex/en/text.jsp?file_id=415518

⁶ 35 U.S. Code § 100 – Definitions, available at <https://www.law.cornell.edu/uscode/text/35/100>

| ISSUE | NAFTA | TPP | CANADA | MEXICO | U.S. | NAFTA 2.0 |
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| | | | <p>(a) (...) more than one year before (...)</p> <p>(b) (...) in such a manner that the information became available to the public in Canada or elsewhere.</p> | | | <p>exploitation of which is necessary to protect <i>ordre public</i> 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 be cause the exploitation is prohibited by its law. A Party may also exclude from patentability:</p> <p>(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;</p> <p>(b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.</p> <p>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.</p> |
| Patent Term Adjustment (for Patent Office Delays) | <p>Art. 1709(12)</p> <p>Each Party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the</p> | <p>Article 18.46</p> <p>1. Each Party shall make best efforts to process patent applications in an efficient and timely manner, with a</p> | <p>Section 44</p> <p>Subject to section 46, where an application for a patent is filed under this Act on or after October 1, 1989, the term</p> | <p>Article 23</p> <p>Patent term is 20 years from the filing of the application.</p> <p>No patent term extension for patent office delays.</p> | <p>35 U.S. Code § 154⁷</p> <p>(b) Adjustment of Patent Term.—</p> <p>(A) Guarantee of prompt patent and trademark office respons</p> | <p>Article 20.44</p> <p>1. Each Party shall make best efforts to process patent applications in an efficient and timely manner, with a</p> |

⁷ 35 U.S. Code § 154 - Contents and term of patent; provisional rights, available at <https://www.law.cornell.edu/uscode/text/35/154>

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| | <p>date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.</p> | <p>view to avoiding unreasonable or unnecessary delays.</p> <p>2. A Party may provide procedures for a patent applicant to request to expedite the examination of its patent application.</p> <p>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.³⁶</p> <p>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 occur during the processing³⁷ of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable³⁸ to the granting authority; as well as periods of time that are attributable to the patent applicant.</p> | <p>limited for the duration of the patent is twenty years from the filing date.</p> <p>No patent term extension for patent office delays.</p> | | <p>es.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to— (...)</p> <p>(iv) the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.</p> | <p>view to avoiding unreasonable or unnecessary delays.</p> <p>2. A Party may provide procedures for a patent applicant to request to expedite the examination of its patent application.</p> <p>3. If there are unreasonable delays in a Party's issuance of a patent, 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.</p> <p>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 occur during the processing of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable³³ to the granting authority; as well as periods of time that are attributable to the patent applicant.</p> |

| ISSUE | NAFTA | TPP | CANADA | MEXICO | U.S. | NAFTA 2.0 |
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| Patent Term Adjustment (for So-called Regulatory Delays) | <p>Art. 1709(12)</p> <p>Each Party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.</p> | <p>Article 18.48</p> <p>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.</p> <p>2. With respect to a pharmaceutical product⁴⁵ that is subject to a patent, each Party shall make available an adjustment⁴⁶ 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.^{47 48},</p> <p>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.</p> <p>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.</p> | <p>Art 47(1)</p> <p>47 (1) (...) the Commissioner may, on the surrender of the patent within four years from its date (...)</p> <p>Certificate of supplementary protection</p> <p>(1.1) Subsection (1) also applies in the case where the original patent is set out in a certificate of supplementary protection and the original patent's term has expired, except that in that case the issuance of the new patent, whose term remains expired, is for the purpose of establishing the rights, privileges and liberties granted under the certificate.</p> | <p>Article 23</p> <p>Patent term is 20 years from the filing of the application.</p> <p>No patent term extension for so-called regulatory delays.</p> | <p>35 U.S. Code § 156⁸</p> <p>(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154</p> <p>(b), if—(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;</p> <p>(2) the term of the patent has never been extended under subsection (e)(1) of this section;</p> <p>(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);</p> <p>(4) the product has been subject to a regulatory review period before its commercial marketing or use;(..)</p> | <p>Article 20.46</p> <p>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.</p> <p>2. 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.</p> <p>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.</p> <p>4. With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the process 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.</p> |

⁸ 35 U.S. Code § 156 - Extension of patent term, available at <https://www.law.cornell.edu/uscode/text/35/156>

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| Market Exclusivity (for Small Molecules) | <p>Arts. 1711(5)-(7)</p> <p>5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where 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 is protected against unfair commercial use.</p> <p>6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their</p> | <p>Article 18.50</p> <p>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,⁵¹ that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar⁵² product on the basis of:</p> <p>(i) that information; or</p> <p>(ii) the marketing approval granted to the person that submitted such information,</p> <p>For at least five years⁵³ from the date of marketing approval of the new pharmaceutical product in the territory of the Party.</p> | <p>C.08.004.1 of the Food and Drug Regulations⁹</p> <p>(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,</p> <p>(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and</p> <p>(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.</p> | <p>There is no specific legislation on data exclusivity for small molecules or biological medical products and new indications.</p> <p>Federal Commission for Protection against Sanitary Risks (COFEPRIS) provides five years data exclusivity for new chemical entities.¹⁰</p> | <p>21 CFR 314.108¹¹</p> <p>(2) If a drug product that contains a new chemical entity was approved after September 24, 1984, in an application submitted under section 505(b) of the act, no person may submit a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved new drug application, except that the 505(b)(2) application or abbreviated application may be submitted after 4 years if it contains a certification of patent invalidity or non-infringement described in § 314.50(i)(1)(i)(A)(4) or § 314.94(a)(12)(i)(A)(4).</p> | <p>Article 20.48</p> <p>1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of:</p> <p>(i) that information; or</p> <p>(ii) the marketing approval granted to the person that submitted such information, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.</p> |

⁹ Food and Drug Regulations, C.R.C., c. 870, available at http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf

¹⁰ For more information, please see the National Law Review, "In Mexico: Can the Minimum Period of 5 Years Established by NAFTA for Regulatory Data Exclusivity be Extended for Biological Medical Products?", available at <https://www.natlawreview.com/article/mexico-can-minimum-period-5-years-established-nafta-regulatory-data-exclusivity-be-e>

¹¹ Title 21 - Food and Drugs, available at <https://www.gpo.gov/fdsys/pkg/CFR-1999-title21-vol5/xml/CFR-1999-title21-vol5-sec314-108.xml>

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submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

Biologics exclusivity

NAFTA only applies to small molecules:
 "If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities (...)"
 Arts. 1711(5)-(7)

Art. 18.51
 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,^{50 61} provide effective market protection through the implementation

Canada provides eight years of data protection for an innovator drug, which applies to both biologics and conventional small molecule pharmaceuticals.
 "innovative drug means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that

COFEPRIS guidelines do not provide data exclusivity for biologics products.¹²

42US C 262(k)(7).
 EXCLUSIVITY FOR REFERENCE PRODUCT.¹³—
 "(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL
 Approval of an application under this subsection may not be made effective by the Secretary until the

Article 20.49
 1. With regard to protecting new biologics, a Party shall, 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 through the implementation of Article 20.48.1

| ISSUE | NAFTA | TPP | CANADA | MEXICO | U.S. | NAFTA 2.0 |
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| | | <p>of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, <i>mutatis mutandis</i>, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,</p> <p>(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:</p> <p>(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, <i>mutatis mutandis</i>, for a period of at least five years from the date of first marketing approval of that product in that Party,</p> <p>(ii) through other measures, and</p> <p>(iii) recognizing that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.(...)_</p> | <p>is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.</p> | | <p>date that is 12 years after the date on which the reference product was first licensed under subsection (a).</p> <p>“(B) FILING PERIOD</p> <p>.-An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).</p> | <p>(Protection of Undisclosed Test or Other Data) and Article 20.48.3 (Protection of Undisclosed Test or Other Data), <i>mutatis mutandis</i>, for a period of at least ten years from the date of first marketing approval of that product in that Party.</p> <p>2. Each Party shall apply this Article to, at a minimum, a product that is produced using biotechnology processes and that is, or, alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition.</p> |
| Patent Linkage | There is no provision on linkage in NAFTA. | Art. 18.53 1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, | Patented Medicines (Notice of Compliance) Regulations ¹⁴ 5 (1) If a second person files a submission for a | “Applicants seeking marketing approval for generic pharmaceutical products in Mexico must certify that they that patent rights | 21 U.S. Code 355 Any person may file with the Secretary an application with respect to any drug subject to | Article 20.51 1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, |

¹² See, Erwin Cruz & Alejandro Luna, “Key issues for biotech products in Mexico”, available at <http://www.iam-media.com/Intelligence/IAM-Life-Sciences/2015/Articles/Key-issues-for-biotech-products-in-Mexico>

¹³ The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), available at <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf>

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| | | <p>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:</p> <p>(a) a system to provide notice to a patent holder⁵⁷ 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;</p> <p>(b) adequate time and opportunity for such a patent holder to seek, prior to the marketing⁵⁸ of an allegedly infringing product, available remedies in subparagraph (c); and</p> <p>(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 in-</p> | <p>notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall include in the submission the required statements or allegations set out in subsection (2.1).</p> <p>(2.1) The statements or allegations required for the submission of the supplement, as the case may be, are – with respect to each patent included on the register in respect of the other drug and with respect to each certificate of supplementary protection in which the patent is set out and that is included on the register in respect of the other drug – the following:</p> <p>(a) a statement that the owner of that patent has consented to the making, constructing, using or selling in Canada of the drug for which the submission or supplement is filed by the second person;</p> <p>(b) a statement that the second</p> | <p>are not infringed. Health regulatory authorities then check with the patent office, which must respond within ten days to confirm whether a patent is involved. While health authorities will accept an application of marketing approval during the patent period, grant of marketing approval will be delayed until the patent expires.¹⁵</p> | <p>the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could</p> | <p>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:</p> <p>(a) a system to provide notice to a patent holder 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;</p> <p>(b) adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and</p> <p>(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</p> |

¹⁴ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, available at <http://laws-lois.justice.gc.ca/eng/regulations/sor-93-133/FullText.html>

¹⁵ Article 147bis of the Mexican Industrial Property Regulations & Article 167bis of the Health Regulation

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| | | fringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use. | <p>person accepts that the notice of compliance will not issue until that patent or certificate of supplementary protection, as the case may be, expires; or</p> <p>(c) an allegation that</p> <p>(i) the statement made by the first person under paragraph 4(4) (d) is false,</p> <p>(ii) that patent or certificate of supplementary protection is invalid or void,</p> <p>(iii) that patent or certificate of supplementary protection is ineligible for inclusion on the register,</p> <p>(iv) that patent or certificate of supplementary protection would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed,</p> <p>(v) that patent or certificate of supplementary protection has expired, or</p> <p>(vi) in the case of a certificate of supplementary protection, that certificate of supplementary protection cannot take effect.</p> | | <p>reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).¹⁶</p> | <p>the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.</p> <p>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.</p> |

¹⁶ 21 U.S. Code § 355, available at <https://www.law.cornell.edu/uscode/text/21/355>