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Research Article

Review Of Industrial Property Rights In Patents In Relation To Applications For The Pharmaceutical Industry In Mexico, 2019 – 2020

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ABSTRACT

This research shows a review of the evolution of industrial property in Mexico based on the international trade treaties to which the country has adhered, in terms of its effects on the Federal Law for the Protection of Industrial Property published on July 1, 2020 in the Official Gazette of the Federation of Mexico. Specifically, the discussion focuses on the legal figure of patents, and the considerations for the pharmaceutical industry. In general, it is evident that there is a favorable regulatory scheme of protection, through patents, for this productive sector, from international trade treaties and that is denoted in the current Federal Law for the Protection of Industrial Property of Mexico.

Keywords: industrial property, patents, pharmaceuticals.

Introduction

The intellectual property system can be analyzed as a set of international and national intellectual property rights (IPR) rules aligned in an integral manner. In this sense, reference is made to the classification that exists with respect to these, since intellectual property is related to creations of the mind, such as inventions, literary and artistic works, as well as symbols, names and images used in commerce. Each of these figures must be protected by the corresponding legislation. As the balance between the interest of innovators and the public interest is achieved, the intellectual property system must seek to foster an enabling environment for creativity and innovation to flourish[1].

Intellectual property is an area of law in which this regulatory harmonization can be observed; this has led to the conclusion of various international and multilateral treaties. These treaties aim to harmonize national rules in order to make IPR protection processes easier and faster. However,within the normative structure, the part that corresponds to international treaties is hierarchically placed on a par with the federal constitution, and in the background to federal laws[2].

The Agreement on Trade-Related Aspects of Intellectual Property Rights[3] (TRIPS) links for the first time, as one of the most important aspects of this Agreement, the issues of intellectual property and trade. It becomes mandatory requiring all WTO member countries to incorporate universal minimum standards for IPRs. TRIPS

[1] Information Obtained from the World Wide Web in https://www.wipo.int/about-ip/es/

[2] Thesis P-LXXVII/99. Ninth Epoch. Instance: Plenary. Fountain. Judicial Weekly of the Federation and its Gazette, Volume X, November 1999. Constitutional matters. The Full Court considers it appropriate to abandon the criterion with respect to Thesis P.C/92, published in the Gazette of the Judicial Weekly of the Federation, Number 60, corresponding to December 1992, page 27 of the heading: "FEDERAL LAWS AND INTERNATIONAL TREATIES HAVE THE SAME NORMATIVE HIERARCHY".

[3] World Trade Organization. Enforcement of Intellectual Property Rights". Retrieved from the World Wide Internet Network in https://www.wto.org/spanish/tratop_s/trips_s/ipenforcement_s.htm

arose from the search for international standards to produce an effect of greater protection for Intellectual Property worldwide, the idea of linking trade with IP, which needed a great boost.
One of the objectives of TRIPS is undoubtedly the harmonization of international IP markets, the normative part helps to define the terms in which competition between countries is established, summarized in other words "TRIPS globalizes the criteria and rules of intellectual property".[4]
With the signing of TRIPS, a new paradigm in international relations is formed. For the first time in history, TRIPS involves the regulation of intellectual property explicitly and specifically for commercialization, and its basis is the internationalization process that began with the Paris Convention on Industrial Protection in 1967, and in 1971 with the Berne Convention for the Protection of Literary and Artistic Works. as well as the Rome Convention and the Treaty on Intellectual Property with respect to Integrated Circuits.
One of the main functions of TRIPS was to establish the line to be taken with respect to IPRs among the countries that are part of it. In this sense, what each country did was to adapt its internal legislation. The way in which TRIPS is structured is therefore outlined below.
The signatories recognize, among other things, that:
1) The applicability of the basic principles of the GATT 1991 and relevant international agreements or conventions on intellectual property.
2) The provision of appropriate rules and principles relating to the existence, scope and exercise of trade-related intellectual property rights.
3) The need for a multilateral framework of principles, rules and disciplines related to international trade in counterfeit goods.
4) Intellectual Property Rights are private rights.
5) Establish more mutually supportive relations between the WTO and the World Intellectual Property Organization.
Agree, inter alia, that:

- Nothing in Parts I to IV of this Agreement shall prejudice any obligations that members may have towards each other under the Paris Convention, the Berne Convention, the Rome Convention and the Intellectual Property Treaty with respect to Integrated Circuits.
- They apply the basic principles of national treatment and most-favoured-nation treatment.

The objective of the TRIPS, according to the text itself, is defined on the protection and enforcement of IPRs, which should contribute to the promotion of technological innovation, to the transfer and dissemination of technology for the mutual benefit of producers and users of technological knowledge, so as to promote social welfare, as well as the balance of rights and obligations (TRIPS. Article 20(2).
However, in the case of Mexico, in order to homogenize the legislation with international treaties, the Law on Inventions and Trademarks, in force from 1976 to 1991, was replaced by the Industrial Property Law, which was published in the Official Gazette of the Federation (DOF) on June 27, 1991, while the North [5]American Free Trade Agreement (NAFTA) was published in the DOF in 1993 and enters into force on January 1, 1994, which included Chapter XVII focused on IPRs, aligned with TRIPS. The agreement on the World Trade Organization (WTO) entered into force one year after the entry into force of NAFTA, on January 1, 1995. This was the biggest reform of international trade since the end of World War II, which is very important since the WTO and its agreements also cover trade in services and intellectual property (TRIPS). Mexico has been a member of the WTO since 1 January 1995.
For this reason, the conceptualization given to each of the legal figures of Intellectual Property is homogenized in all the countries that are part of both TRIPS and NAFTA, the latter was signed by three member states: Mexico, the United States and Canada, and also includes the principles of national treatment. most-favoured-nation treatment and transparency.
NAFTA, in Chapter XVII, provides that each party shall grant in its territory to nationals of another party adequate and effective protection and defense of intellectual property rights, while ensuring that measures aimed at defending those rights do not become obstacles to legitimate trade.
It is also provided that each Party may grant in its domestic legislation protection to IPRs broader than that required by this Treaty, provided that the protection is not incompatible with this Treaty.
The North American Agreement (NAFTA) is replaced by the Agreement between the United Mexican States, the United States of America and Canada, USMCA[6], published in the DOF in 2019. In this context, Mexico also became a member of the Trans-Pacific Partnership Agreement (TPP) in 2016, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership[7] (CPTPP) in 2018, for which Mexico modified its

[4] Drahos, P. (2005). 11 Intellectual property rights in the knowledge economy. *TEAM LinG*, 139.
[5] North American Free Trade Agreement of 1994. Official Gazette of the Federation on December 20, 1993. Retrieved from the World http://www.sice.oas.org/trade/nafta_s/indice1.asp Internet Network
[6] Agreement between the United Mexican States, the United States of America and Canada **(USMCA**), Retrieved from the World Internet Network in https://www.gob.mx/t-mec.
[7] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, signed in Santiago, Chile, on March 8, 2018 (TIPAT). Official Gazette of the Federation on November 2, 2018. Retrieved from the World Wide Internet Network in https://dof.gob.mx/nota_detalle.php?codigo=5545130&fecha=29/11/2018#gsc.tab=0

intellectual property regulation scheme. The object of study of this research is specifically with regard to industrial property in terms of patents.

Analysis of the provisions relating to Intellectual Property in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TIPAT or CPTPP) and the Agreement between the United Mexican States, the United States of America and Canada (USMCA).

In Mexico, the Law for the Promotion and Protection of Industrial Property was replaced by the Industrial Property Law that was enacted in 1991, and which was repealed to give rise to the current Federal Law for the Protection of Industrial Property that entered into force on November 20, 2020. In this period, various reforms, additions or even repeals of the law have been carried out, as a result of the negotiations of international treaties, such as the USMCA, the TPP and the TIPAT, all focused on the area of intellectual property, in this research only the aspects related to patents that correspond to the area of industrial property will be addressed.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) is considered one of the most important due to the scope of the issues contained therein, as well as the integration of different geographical areas that include: North America, South America, Oceania and Asia. The States that are part of this are: Australia, Brunei Durursalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. It entered into force on December 30, 2018 for Australia, Canada, Japan, Mexico, New Zealand, and Singapore, on January 14, 2019, it entered into force between Mexico and Vietnam.[8]

It is important to mention that the difference between TPP and CPTPP lies in the exit of the United States, The "TPP" (*Trans-Pacific Partnership*) was signed in 2016 by 12 countries in the Asia-Pacific area: Australia, Brunei, Canada, Chile, the United States, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. However, in 2018 the United States withdrew from the treaty. This caused none of the 12 signatory countries to ratify the TPP. Thus, taking advantage of the departure of the United States, the United States was able to take advantage of the The remaining 11 countries negotiated a new text, suspending a set of provisions that were prima facie more convenient for the U.S. This is the case in the US, giving rise to the "CPTPP" (*Comprehensive and Progressive Agreement for Trans-Pacific Partnership*). This new version of the treaty was signed in Santiago, Chile, on March 8, 2018[9].

With respect to the TIPAT, the States Parties reaffirm the issues contained in the preamble to the Trans-Pacific Partnership. The Promulgating Decree of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, signed in Santiago, Chile, on March 8, 2018, was published in the Official Gazette of the Federation on November 29, 2018. In the latter Treaty, the parties agree that the provisions of the Trans-Pacific Partnership Agreement, signed in Auckland on February 4, 2016 (the TPP) are incorporated and form part of this Treaty *mutatis mutandi*.[10]

These Treaties become a mechanism to review the Intellectual Property system in Mexico. With respect to Intellectual Property, the TPP partners trust that what regulates and protects this area will be respected in terms of what the Treaty itself proposes, since there is consensus that the level of protection must improve, with respect to what is established in the TRIPS. Below is a table showing the most important articles within the Industrial Property chapters, specifically on patents, of both USMCA and TIPAT treaties.

Table 1. Comparative Table of the Main Patent Provisions of the USMCA of the TIPAT

TOPICS	USMCA (CAP 20)	TIPAT (CH 18)	REMARKS
	(ART. 20.8)	(Art.18.8)	In both treaties, national treatment is established in the same terms. Each Party shall accord to nationals of another Party treatment no less

[8] Information obtained from https://www.gob.mx/t-mec, https://www.gob.mx/se/prensa/el-tipat-entra-en-vigor-y-abre-nuevos-mercados-para-mexico and https://www.gob.mx/tratado-de-asociacion-transpacifico

[9] Information Obtained from the Internet Network in https://centrocompetencia.com/tpp-el-capitulo-de-propiedad-intelectual/

[10] Article 1: Incorporation of the Trans-Pacific Partnership Agreement 1. The Parties agree that, in accordance with the terms of this Agreement, the provisions of the Trans-Pacific Partnership, made in Auckland on 4 February 2016 ("the TPP") are incorporated, by reference, and form part of this Treaty mutatis mutandis (Changing What Is to Be Changed. Expression used when comparing situations that are different but have elements in common), with the exception of Article 30.4 (Accession), Article 30.5 (Entry into Force), Article 30.6 (Denunciation) and Article 30.8 (Authentic Texts).1 2. For the purposes of this Agreement, references to the date of signature in the TPP shall mean the date of signature of this Agreement. 3. In the event of any incompatibility between this Treaty and the TPP, when the latter is in force, this Treaty shall prevail to the extent of the inconsistency.

TOPICS	USMCA (CAP 20)	TIPAT (CH 18)	REMARKS
NATIONAL TREATMENT			favourable than it accords to its own nationals, with respect to the protection of intellectual property rights.
EXHAUSTION OF IP RIGHTS	(ART 20.11)	(Art.18.11)	In both treaties, the exhaustion of rights is established in the same way, referring to the first sale.
IPR COMMITTEE	(ART 20.14)	(Art. 18.14	This Committee that is indicated in the USMCA, in the TPP there is an article called: "Points of Contact for Cooperation" in which each party may designate and notify one or more points for the purpose of cooperation.
PATENT COOPERATION AND JOB SHARING	(ART.20.15)	(Art. 18.37)	Both Treaties establish Cooperation in Patents and Cooperative Work as a means of improving the quality and efficiency of each of the signatory countries through their patent offices.
PATENTABLE SUBJECT MATTER	(ART 20.36)	(Art. 18.38)	In the TPP In the part in which new uses of a known product are indicated, new methods of using a known product, etc. A Party may limit such new procedures to those that do not claim the use of the product as such. The terms of patentable subject matter remain by definition that such an invention is new, involves an inventive step. In the part on exceptions, the topic of plants is as follows: With respect to plants, any of the parties may exclude patentability that are not microorganisms, each party can confirm that patents will be available at least for inventions derived from plants.
GRACE PERIOD	(ART 20.37)	(Art. 18.39)	Either Party may limit the application of this Article to disclosures made by, or obtained directly or indirectly from, the inventor or co-inventor, which may be information contained in the public disclosure that was authorized by, or derived from, the patent applicant.
REVOCATION OF PATENTS	(Art. 20.38)	(Art.18.40)	It is important to note that a Party may provide that fraud, misrepresentation or unfair conduct may be the basis for cancelling, revoking or cancelling a patent.
EXCEPTIONS	(Art.20.39)	(Art. 18.41)	Both Treaties provide for the same exceptions
OTHER USES WITHOUT THE RIGHTHOLDER'S AUTHORIZATION	(Art. 20.40)	(Art. 18.43)	Both Treaties provide for the same exceptions
AMENDMENTS, CORRECTIONS, AND OBSERVATIONS	(Art. 20.41	(Art. 18.44)	Both Treaties provide for the same exceptions
PUBLICATION OF PATENT APPLICATIONS	(Art. 20.42)	(Art. 18.45)	Regarding the issue of Transparency, in both treaties it is established that: Each Party shall endeavour to publish online, its laws, regulations, procedures and administrative resolutions of general application relating to the protection and enforcement of intellectual property rights. In this regard, each Party shall endeavour to publish unpublished pending patent applications promptly, after 18 months from the date of filing or, if priority is claimed, from the earliest priority date.
INFORMATION REGARDING PUBLISHED PATENT APPLICATIONS AND GRANTED PATENTS	(Art. 20.43)	(Art. 18.46)	This article sets out the information for published and granted patent applications to be made available to the public that includes information such as; relevant prior art searches; and citations to patent-related and non-patent literature submitted by applicants and relevant third parties.
ADJUSTMENT OF PATENT DURATION FOR UNREASONABLE DELAYS BY MANDATORY AUTHORITY	(ART 20.44)	(ART. 18.47)	In this Article; is established as a measure to avoid unjustified delays in the processes that delay the granting of a patent, in this sense, each of the Parties that are party to these treaties will make their best efforts to process patent applications in an efficient and timely manner, in order to avoid unreasonable or unnecessary delays.
PROTECTION OF TEST DATA OR OTHER UNDISCLOSED DATA ON AGRICULTURAL CHEMICALS	(Art. 20.45)	(Art. 18.48)	One of the most important aspects of this article lies in the definition of a new agricultural chemical, as well as the authorizations to grant the commercialization of this type of product, taking into account as a fundamental element the presentation of test data or other undisclosed data concerning the safety and efficacy of the product.
ADJUSTMENT OF THE PATENT TERM FOR UNREASONABLE REDUCTION	(Art 20.46)	(Art. 18.49)	The adjustment of the patent term due to unreasonable reduction, unlike the article that talks about the adjustment of the patent term due to unreasonable delays by the mandatory authority, is that the latter refers to generating best practices to process patent applications, in an efficient and timely manner, in the case of the adjustment of the patent term, is to generate better efforts to process marketing authorization applications with a specific emphasis on pharmaceutical products. This same article in the TPP is called Adjustment of the Patent Term for Unreasonable Delays.
INTERPRETATION BASED ON THE REGULATORY REVIEW REVIEW	(ART. 20.47)	(Art. 18.50)	This Article provides that each party shall adopt an exception based on regulatory review for pharmaceutical products. That is, it is again specified that it is for pharmaceutical products. This implies that the Bolar Clause may not be applied in such a way as to cause unjustified harm to the holder of the corresponding patent.

TOPICS	USMCA (CAP 20)	TIPAT (CH 18)	REMARKS
PROTECTION OF TEST DATA OR OTHER UNDISCLOSED DATA	(Art. 20.48)	(Art. 18.51)	Each Party shall adopt an exception based on regulatory review for pharmaceutical products. as a condition for granting marketing authorization for a new pharmaceutical product, the submission of test data or other undisclosed data concerning the safety and efficacy of the product, that Party shall not permit third parties, without the consent of the person who previously submitted such information, to market the same product. The protection is during validation and 5 more years, to the database.
BIOLOGICAL	(Art. 20.49)	(Art. 18.52)	The issue of the protection of new biologics is related to the first marketing authorization of a new pharmaceutical product containing a biologic, at this point nothing obliges a Party to extend the protection of this paragraph to: 1. any second or subsequent marketing authorization of said pharmaceutical product; or 2. A pharmaceutical product that is or contains a previously authorized biologic. The foregoing, in accordance with what is established in the treaties themselves.
DEFINITION OF NEW PHARMACEUTICAL PRODUCT	(Art. 20.50)	(Art. 18.53)	What is new in both treaties is the definition they give to a "new pharmaceutical product" and the regulations that derive from it, as will be seen with the measures for the commercialization of pharmaceutical products.
MEASURES RELATING TO THE PLACING ON THE MARKET OF CERTAIN PHARMACEUTICAL PRODUCTS	(Art. 20.51)	(Art. 18.54)	It is important to mention the regulation that both treaties are giving to the measures related to the marketing of certain pharmaceutical products, the Parties establish the conditions for the authorization of pharmaceutical products based on evidence and information concerning the safety and efficacy of a product.
ALTERATION OF THE PROTECTION PERIOD	(Art 20.52)		This Article establishes the relationship that the article that refers to the Protection of Trial Data or Other Undisclosed Data may have with the period of protection provided in accordance with the same Treaty and that this period may not be altered.

Source: Authors' elaboration based on https://www.gob.mx/t-mec, https://www.gob.mx/se/prensa/el-tipat-entra-en-vigor-y-abre-nuevos-mercados-para-mexico and https://www.gob.mx/tratado-de-asociacion-transpacifico

As we can see in Table 1, there is not much difference between the provisions established in each of the treaties (USMCA and TPP), the most important is the regulation of patents that directly impacts the pharmaceutical industry; mainly in terms of the protection of pharmaceutical products. With the signing of these new treaties there are a series of changes, including the exceptions established to the subject matter that can be patented, defining what is a new pharmaceutical product or the incorporation of biological products, as well as the definition of a new agricultural chemical.

Another aspect to highlight is what is established in Article 20.36 of the USMCA and Article 18. 37 of the TPP respectively, for patentable subject matter, since the possibility of patenting inventions that are claimed in the case of new uses of a known product, new methods of using a known product or new processes of use of a known product was left open; in this regard, it is important to note that this paragraph was finally eliminated by the Protocol amending the USMCA agreed in 2019.

It emphasizes that, with respect to the issue of disclosure, in the case of patent applications, published and granted, the general public will be able to have information on search and examination results, non-confidential communications of applicants and citations of literature related to patents. In this regard, returning to the case of plants, it is established that, in accordance with the previous paragraph, each Party confirms that patents will be available at least for inventions derived from plants, it is reiterated not for plants themselves.

Another important point, as we mentioned above, the issue of complementary certificates, in the USMCA it is stated that, for the adjustment of the duration of a patent due to unreasonable delays by the granting authority, the change in the term of validity may be adjusted in the following cases:

a) More than 5 years from the date of filing the application,
b) 3 years from the date on which the examination of the respective patent application was required,
c) Periods of time that do not occur during the administrative processing of the patent application by the granting authority,
d) Periods of time that are not directly attributable to the granting authority.

In addition, it provides for the possibility of adopting procedures that speed up the processing of applications for marketing authorization and sanitary registration of drugs, so as not to affect the effective term of the patent. Likewise, with respect to information on undisclosed test data or undisclosed information related to the safety and efficacy of a new pharmaceutical product submitted by the holder for obtaining a health registration or marketing authorization, third parties without authorization from the owner shall not be permitted to place the same or a similar product on the basis of that information or the marketing

authorization, considering various periods and conditions[11] (Article 20.48). This protection also applies to drugs that contain a biologic, which benefits the pharmaceutical industry.
In this international regulatory framework, the Federal Law for the Protection of Industrial Property in Mexico emerged in July 2020, which contains part of the provisions established in the TPP and the USMCA, on Intellectual Property. It has been Mexico's history in terms of IPR to have to adapt its domestic legislation to the changes and guidelines of other treaties that benefit from these new paradigms of legal protection in intellectual property.
Specifically, the Federal Law for the Protection of Industrial Property (LFPPI) in force in terms of patents establishes the following precepts:
a) Essential technical characteristics: Those necessary for an invention to solve the technical problem.
b) Cloning procedures, genetic modification in animals or to develop a human being and the use of human embryos for industrial or commercial purposes cannot be patented.
c) Protection of biological material by technical procedure
d) A third party may use, manufacture, offer for sale or import a product with a patent to generate evidence, information and experimental production in order to obtain sanitary registrations of medicines to market them once the patent expires.
e) Scope of application of the Mexican system of patent binding and marketing authorization of pharmaceutical products.
f) A patent shall not be granted in respect of subject matter that is already protected by another or whose essential characteristics are a non-substantial variation of the subject matter covered by it, even if the applicant is the holder of the first right.
g) The limitation of the right conferred by a patent is established, in order to enable substantive corrections without such corrections being intended to extend the protection conferred.
As we can see, the issue of patents, which applies to pharmaceutical and biochemical products, has an important notoriety in the regulations within the new treaties, and that is undoubtedly reflected in the LFPPI of Mexico.

Patentability in the Pharmaceutical Sector: From the USMCA to the Federal Law for the Protection of Industrial Property

With the internationalization of IP, the interpretation of treaties, and especially their application at the domestic level, becomes more important, either through introduction into the domestic legal system or through judicial interpretation by both domestic and international judges. In this regard, in Mexico, the corresponding modifications to the regulations were made with NAFTA. However, on May 18, 2017, the United States officially indicated that there was an intention to renegotiate the North American Free Trade Agreement (NAFTA) with Mexico and Canada, which resulted in the USMCA, a treaty that was signed on December 30, 2018, and entered into force on July 1, 2020.
One of the most controversial issues in the negotiation rounds of this new Treaty, the USMCA, and which meant that in Mexico the Congress of the Union had to work very quickly was, precisely, to harmonize domestic legislation on the subject of intellectual property, since as is well known, whenever a new Treaty is signed, and even more so in the case of the USMCA that annulled NAFTA, adjustments have to be made to national legislation regarding the areas regulated by these treaties, and in this case we are talking about that for the area of intellectual property, modifications had to be made to the Federal Copyright Law, as well as the creation of the LFPPI, specifically in the area of patents, which was contained in the USMCA in chapter 20 "Intellectual Property Rights".
In this context, as part of the regulatory adjustments that had to be made, the Congress of the Union approved the Federal Law for the Protection of Industrial Property (LFPPI),[12] in an extraordinary session on June 29 in the Senate and a day later in the Chamber of Deputies (DOF. 2020), repealing the previous law. Definitely, this decision generated various controversies between different sectors, including the developers of generic drugs, according to the document issued by the Senate of the Republic entitled *"The issue of patents in the Mexico-United States-Canada Agreement: An obstacle to the development of generic drugs in Mexico?[13]",* especially

[11] Final texts of the Agreement between Mexico, the United States and Canada. Retrieved from the https://www.gob.mx/t-mec/acciones-y-programas/textos-finales-del-tratado-entre-mexico-estados-unidos-y-canada-t-mec-202730?state=published World Wide Web
[12] DOF (01/07/2020). DECREE issuing the Federal Law for the Protection of Industrial Property and repealing the Industrial Property Law, in https://www.dof.gob.mx/nota_detalle.php?codigo=5596010&fecha=01/07/2020&print=true
[13] Senate of the Republic LXIV Legislature, Belisario Domínguez Institute. General Directorate of Strategic Research. "The issue of patents in the Mexico-United States-Canada Agreement: An obstacle to the development of generic drugs in Mexico?[13]" Temas estratégicos (Strategic Issues), number 86. 2020. Retrieved from the internet at chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/viewer.html?pdfurl=http%3A%2F%2Fbibliodigitalibd.senado.gob.mx%2Fbitstream%2Fhandle%2F123456789%2F5095

because the LFPPI did not consider the agreements reached during the signing of the Amending Protocol in December 2019. This protocol refers to the flexibility of some aspects in terms of intellectual property in order to favor competition in the development of generic drugs in the face of the onerous prices of patent drugs.
In this sense, it is pointed out that these controversies arose from what had been established in the USMCA, and from the reforms that had to be made to adapt the legal regulation on industrial property. We can rescue some essential points of the USMCA; which are pointed out in the study carried out by the Senate of the Republic and which focus specifically on the pharmaceutical sector, for example:
1) "Regulatory exclusivity for biological products: The provision that allowed pharmaceutical companies to maintain the protection of their clinical data for 10 years was eliminated, so that, during that period, no generic company could conduct clinical trials using the reference data of the drug for commercial purposes, consequently, for biological medicines it must be maintained, at least, the general protection period of five years.
2) Exclusivity period: The 3-year period that prevented a generic manufacturer from using clinical data from a previously approved product for new indications was eliminated.
3) Regulatory Review: It was clarified that the regulatory review exception will allow a person other than the rights holder to use, sell, or import a product covered by an existing patent to generate information required to prepare the application for a business authorization (sanitary registration).
4) Availability of patents: The provision confirming the obligation to consider as patentable subject matter new uses, new methods of use or new processes of use of a known product was eliminated, given that the TRIPS agreement provides for the obligation to grant patents for inventions that meet the characteristics of "novelty", "industrial application", and "inventive step"
5) Adjustment of patent term: In the case of a pharmaceutical product subject to a patent, each Party shall have an adjustment to the term of the patent to compensate the patent holder for unreasonable reductions to the effective term of the patent resulting from the marketing authorization process. With respect to adjustments to these deadlines for unreasonable reductions, it was possible for each Party to limit the adjustment period in accordance with the following guidelines:
a) That the adjustment to compensate for the time it takes for the authorization is for a single occasion;
b) That it is based on the first authorization to market;
c) That it is for a maximum period of five years;
d) In the case of an additional adjustment sui generis or by the Parties, it shall not exceed two years.
6) Patent linkage that grants a period of marketing exclusivity to the first applicant to successfully assert the invalidity or non-infringement of the patent in accordance with the Party's marketing approval process. In Mexico, this process occurs through the link between the Mexican Institute of Industrial Property and the Federal Commission for the Protection of Sanitary Risks (COFEPRIS).
7) Bolar Clause: Whereby without prejudice to the scope and in accordance with Article 20.39 (Exceptions) each Party shall adopt or maintain an exception based on regulatory review for pharmaceutical products, the foregoing implies that the Bolar Clause may not be applied in such a way as to cause undue prejudice to the holder of the relevant patent.
8) Authorizations: It is established that a third party can notify the holder of a patent about its intention to obtain authorization for a product, and if the owner does not initiate an infringement action within 45 days, it will be presumed that he gave his consent to the application for sanitary authorization. It should be clarified that this measure could only be applied by Mexico in the event that it decided to abandon its current system."
Transition periods were also included for Mexico and Canada to fully comply with the new obligations set forth in Chapter 20 of the USMCA.
In the USMCA before the amending protocol, it stated that, with respect to Patentable Subject Matter, in Article 20.36: "*It may be obtained for any invention, whether a product or a process in all fields of technology, provided that such invention is new, involves an inventive step and is susceptible of industrial application. Patents are available for inventions that are claimed as at least the following:*
a) new uses of a known product,
b) new methods of using a known product,
c) or new procedures of some of a known product.
This is definitely significant, since in the USMCA it had originally been established that any technology can be patentable as long as the invention is new, although although it is true, it is one of the requirements to be able to obtain a patent, it is clear that an invention must be new, that is, it must comply with novelty, in addition to inventive step. However, by granting the possibility of granting patents for new uses, new products or new processes of already known products, it is not entirely clear how novelty can be recognized or that it is new, and these types of contradictions are what ultimately benefit the pharmaceutical sector, due to the type of patenting strategies they resort to. even though Article 20.50, specifically with respect to new pharmaceutical products, states that it must not contain a chemical entity that has been previously approved. Article 20.50

%2FTE%252086%2520Patentes%2520en%2520el%2520T_MEC.pdf%3Fsequence%3D1%26isAllowed%3Dy&clen=1100313

defines a new pharmaceutical product: "*A new pharmaceutical product means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party"*
As we can read in the original article 20.36 refers to the patentability of new uses, methods or procedures, of already known products, in article 20.50 it defines what a new pharmaceutical product is, which will be one that does not contain a chemical entity that has previously been protected.
For its part, Article 20.51 establishes that:
"1. If a Party allows, as a condition of the marketing authorization of a pharmaceutical product, persons other than the person who originally submitted the safety and efficacy information to rely on evidence or information concerning the safety and efficacy of a product that was previously authorized, such as evidence of a prior marketing authorization by the Party or in another territory, that Party shall:
(a) a system that provides notice to the patent holder or permits the patent holder to be modified, prior to the marketing of such pharmaceutical product, that that other person is seeking to market that product during the term of an applicable patent covering the authorized product or its authorized method of use,
(b) adequate time and opportunity for such patent owner to have recourse, prior to the commercialization of an allegedly infringing product, to the remedies available in subparagraph Procedures, such as judicial or administrative proceedings, and expeditious remedies, such as injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent covering a authorized pharmaceutical product or its authorized method.
2. A Party shall adopt or maintain an out-of-court system that prevents, on the basis of information in patent information submitted to the authority granting the marketing authorization by the patent holder or by the applicant for the marketing authorization, or based on direct coordination between the authority granting the marketing authorization and the patent office, the granting of marketing authorization to any third person who intends to place on the market a pharmaceutical product subject to a patent covering that product, unless he or she has the consent or agreement of the patent holder."

In this sense, Article 20.51 establishes the measures related to the marketing of certain pharmaceutical products, specifying that they are based on evidence or information concerning the safety and efficacy of a product that has been previously authorized. To this end, a system must be in place that provides notice to the patent holder or that allows him to modify it prior to its commercialization, thus having the appropriate time and mechanisms. This gives rise to the link between patents and sanitary registrations.
The linkage of the patent system is the regulation between the sanitary registration that an applicant who intends to incorporate an allopathic medicine into the market could obtain and the possible collision of this registration with the rights of the holder of a patent for a medicine in force other than the applicant for registration who had obtained the patent granted by the Mexican Institute of Industrial Property (IMPI). The bonding procedure is not a legal figure that has been gestated in Mexico, since it has its origins in the United States[14].
The TPP included an important article that is related to the obligation of the parties to maintain a system of linkage that prevents, among other things, the marketing of patent-infringing drugs. To this end, in the case of Mexico, since the Industrial Property Law existed, there was already a system of patent linkage between the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) and the IMPI, established in Article 167 bis of the Regulation of Health Supplies[15], which states, among other things, that the applicant for

[14]Arango, G. V. (2018). *Pharmaceutical industry, the right to health and intellectual property: the challenge of balance*. National Autonomous University of Mexico, Institute of Legal Research. and Alcaraz, G. (2018). The link between patents and sanitary registrations. *Pharmaceutical Industry, the Right to Health and Intellectual Property: The Challenge of Balance*, 41-67.
[15] Article 167 bis of the Health Supplies Regulations. The applicant for the registration of an allopathic medicine must attach to the application the documentation that proves that he is the owner of the patent for the substance or active ingredient or that he has the corresponding license, both registered with the Mexican Institute of Industrial Property. Alternatively, and in accordance with the list of products established in Article 47 of the Regulations of the Industrial Property Law, you may declare under oath that you comply with the applicable provisions on patents with respect to the substance or active ingredient that is the subject of the application. In this case, the Secretariat shall immediately request the technical cooperation of the Mexican Institute of Industrial Property so that, within its sphere of competence, it may determine, no later than within ten working days after receipt of the petition, whether current patent rights are invaded. In the event that the Mexican Institute of Industrial Property concludes that there are patents in force on the substance or active ingredient of which the applicant is not the owner or licensee, it shall inform the Secretariat so that it may warn the applicant in order to demonstrate that he is the owner of the patent or that he has the respective license. within the period determined by the Secretariat and which may not be less than five working days from the date on which the notification has taken effect. In the event that the applicant does not correct the omission, the Secretariat shall reject the application and inform the applicant of the reasons for this determination so that, if appropriate, it may settle them before the competent authority. Failure to respond from the Mexican Institute of Industrial Property within the period indicated shall be understood to be in favor of the applicant.

registration of an allopathic medicine must attach to the application the documentation that demonstrates that he is the patent holder of the substance or active ingredient and that he had the corresponding license, both registered with IMPI.

In this context, although we know that the United States finally exited the TPP negotiations, finally on January 1, 2019, the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) entered into force for Mexico, which continues to point out the obligation of the Parties to this treaty to maintain a linkage system.

With respect to the USMCA, it is no exception, since in Article 20.51 both treaties prevent that the linkage system covers claims related to pharmaceutical products, however, in this issue the Amending Protocol among its changes included the obligation for Mexico that in its linkage system based on intergovernmental communication administrative procedures are established that allow a person from another of the signatory Parties to be directly affected by the administrative proceeding is afforded a reasonable opportunity to present facts and arguments in defense of that person's position prior to any final administrative action, when time, the nature of the proceeding, and the public interest permit[16].

Now, in the Federal Law on the Protection of Industrial Property regarding the subject of patent linkage, Article 162 establishes that

"The Institute shall periodically publish in the Gazette those applications, patents or registrations of utility models, industrial designs or layout designs of integrated circuits, with respect to which the exclusive right requested was not constituted or expired once granted; as well as technological information that is in the state of the art or that has been incorporated into the public domain. Exceptions to the above are those applications that are in the case provided for in Article 24 of this Law. The Institute shall publish at least every six months in the Gazette a list of patents related to inventions that may be used in allopathic medicines, in the terms provided for in Article 167 bis of the Regulation on Health Supplies, and shall coordinate with the competent health authority, to provide the information required within the marketing authorization process for allopathic medicines."

The point is that Article 20.51 of the USMCA implies that, if Mexico allows the commercialization of a pharmaceutical product, let's say a generic, based on the prior information of another previously authorized product (let's say the patent drug), COFEPRIS must notify the patent holder, and he will have the right to go to the administrative and judicial instances he deems appropriate. and in Mexico there must be a process to address these cases. This link between COFEPRIS and IMPI is considered to be detrimental to the introduction of generic drugs in the national market.

Part of all these processes contained in the USMCA is what is included in the new Law on Industrial Property in Mexico, the LFPPI, so below is a brief analysis of what was contained in this law, derived from the USMCA and, above all, to know how it is that importance is beginning to be given to how some practices that occur specifically in the pharmaceutical sector should be regulated. such as the Bolar clause or exception, among other issues.

In this context, among the main changes that were established in the LFPPI and that as we observed derive from what is established in the USMCA, are the following:

1. *The definition of "essential technical characteristics" (those necessary for an invention to solve the technical problem) is established*
2. *Cloning procedures, genetic modification in animals or to develop a human being, and the use of embryos for industrial or commercial purposes cannot be patented.*
3. *Modified biological material can be protected by a technical procedure*
4. *The Bolar Clause is included, which states that a third party may use, manufacture, offer for sale or import a product with a valid patent to generate tests, information and experimental production in order to obtain sanitary registrations of medicines to market them once the patent expires.*
5. *The scope of application of the Mexican system of linking patents and marketing authorizations for pharmaceutical products is clarified.*
6. *A third party may use a patent during the period of rehabilitation or expired registration (for failure to timely pay the fee, provided that the application is filed within 6 months of the grace periods and the missed payment plus surcharges is covered.*
7. *A change is proposed in the regulation of the "divisional" applications presented "voluntarily", since they must be presented together and in a single exhibition, excluding the possibility of filing divisional applications in cascade unless the IMPI considers it appropriate or requires it.*
8. *The submission of "divisional" applications must be made within two months of the granting of the main application.*
9. *A patent shall not be granted in respect of subject matter that is already protected by another or whose essential technical characteristics are a non-substantial variation of the subject matter covered by it, even if the applicant is the holder of the first right.*

[16] Luna, A. (2021). Evolution of the patent linkage system in Mexico. Legal Praxis No. 62. October 2021, No. 62, Edit BOSCH MEXICO

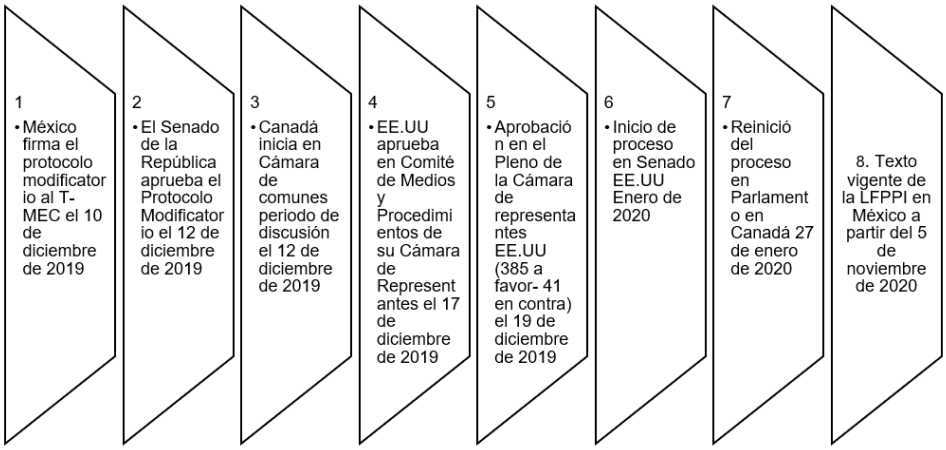
10. *The limitation of the right conferred by a patent is established, in order to enable substantive corrections without such corrections being intended to extend the protection conferred.*
11. *The IMPI must publish, at least every 6 months, a gazette containing the list of patents related to inventions that can be used in allopathic medicines.*
12. *The "complementary certificate" is established to adjust the validity of the patent for the two cases in which the granting procedure exceeds 5 years from the date of filing, due to the fact that the IMPI incurs in "unreasonable delays" in the corresponding procedure."*
13. *Parallel imports are eliminated, by virtue of which the patent holder is conferred the right to authorize or not the import of the patented products.*
14. *Mexico is also a signatory to the Doha agreement, which is why it includes public utility licenses for health reasons. Art. 57 section II and art. 153*

The Senate of the Republic concludes that the set of provisions related to patents contained in the LFPPI are relevant both for the market of patent drugs and that of generic rights, since for the former they will provide security and legal certainty to carry out their pharmaceutical research, while for the latter they will make clear the rules of the game to start the manufacturing process of a generic from the years prior to the expiration of a patent.
In this order of ideas, it is important to mention that Article 50 of the LFPPI establishes that "*The institute, during the examination of the merits and in the granting of rights, must ensure the public domain and prevent the double patenting of the same invention*[17]". For its part, in Chapter VI On the Prosecution of Patents, Article 101 states that *"It shall not be granted with respect to subject matter that is already protected by another or whose essential technical characteristics are a non-substantial variation of the subject matter covered by it, even if the applicant is the holder of the first right*[18]*"*.
In the pharmaceutical industry there is a practice known as patent greening or *"evergreening*", [19]and one of the characteristics that define it is the function of double patenting of the same invention, in this context, as it is pointed out in Mexico, the LFPPI in its article 50 establishes that the IMPI must prevent the double patenting of the same invention. this provision did not exist previously, it arises with the new law (LFPPI).
In this sense, Article 101 of the LFPPI, identifies that a patent whose essential characteristics are a non-essential variation of the subject matter covered by it will not be granted, on the other hand, Article 45 of the LFPPI states that *"New, everything that is not in the state of the art. Any substance, compound or composition included in the prior art shall not be excluded from patentability, provided that it is new."*
This second part is the modification that was made to the concept of "new" when the LFPPI was approved, since in the Industrial Property Law everything that is not in the state of the art was defined as new. Now, the question is, is there a contradiction between what is established in Articles 50 and 101 of the LFPPI with respect to what is established in Article 45 of the same Law, in relation to the concept of new or novelty?
In this sense, Manuel Becerra points out that as a result of the process of approval of the USMCA, a modification arose within the U.S. Congress before entering into force, the transcendental thing about this point is that the aforementioned protocol makes modifications to several parts of the Treaty, in terms of Intellectual Property rules, and more specifically, For pharmaceutical companies, in terms of patents, according to the protocol, the paragraph that referred to new-use patents, which is what is known as "greening", is deleted. With this, second-use patents are no longer allowed[20].
In this sense, textually what is established in the Amending Protocol to the USMCA[21] "*in Article 20.36: (patentable matter), eliminate paragraph 2, renumber the subsequent paragraphs and the cross-references, as appropriate*[22]*"*.
Responding to the question raised as to whether there is a contradiction or in any case confusion regarding the new uses, Manuel Becerra is again quoted as saying, that in Mexico "*... by adopting in its Federal Law for the*

[17] Article 51 LFPPI
[18] Article 101 LFPPI
[19] Pérez Miranda, R. J. (2018). The expansion of the concept of invention, and of patentable subject matter, second uses, diagnostic, therapeutic and surgical methods and living organisms. *Becerra Ramírez, Manuel and Martínez Olivera, Roberto (coords.). Pharmaceutical industry, the right to health and intellectual property: the challenge of balance. Mexico: UNAM-IIJ-ANAFAM,* 195-220.. & Agranat, I., & Marom, H. (2020). In defense of secondary pharmaceutical patents in drug discovery and development. *ACS Medicinal Chemistry Letters*, *11*(2), 91–98. https://doi.org/10.1021/acsmedchemlett.9b00497

[20] Becerra Ramírez, M. (2021). The protocol amending the USMCA. Its reception in domestic law. *Mexican Yearbook of International Law*, *21*, 983-985.
[21] Protocol Amending the Treaty between the United Mexican States, the United States of America and Canada. Published on Thursday, December 12, 2019. Retrieved from the World Wide Web in https://www.senado.gob.mx/65/gaceta_del_senado/documento/103244
[22] Ibidem. T-MEC Modification Protocol

Protection of Industrial Property (LFPPI) on July 1, 2020, ... second-use patents, even in violation of the amending protocol of the USMCA"[23] this with respect to what is contained in Article 45 of the LFPPI. This is because, if we look at the following dates, as Manuel Becerra points out, there is a violation of said treaty[24].



Source: Prepared by the authors with data obtained from the Ministry of Economy T.MEC Report no. 27. Protocol amending the USMCA time route.

As we can see, the amending protocol by the Senate in Mexico was approved on December 12, 2019, so the Ministry of Economy worked with the competent agencies of the Federal Public Administration on a legislative package of legal and regulatory modifications necessary for the proper implementation of the USMCA and its amending protocol. and the LFPPI is in force as of November 5, 2020, in such a way that although as such it does not exist in the Law, the part relating textually *"In matters of intellectual property, the Protocol mainly provides for the following changes:*

- *The elimination of the second paragraph of Article 20.36, which established that each Party should provide for the possibility of granting patents for inventions that claim: a)* ***new uses of a known product****, b) new methods of using a known product, or c) new procedures for the use of a known product."*

The foregoing is contradictory to Article 45 of the LFPPI. This article 45, which recognizes the patent of new use, however, in a new use in the case of pharmaceutical products, the criteria of patentability of novelty and inventive step are questionable. Now, in this same order of ideas, in the LFPPI, in chapter X of the invalidity and revocation of patents and registrations, in article 154, it establishes that: *A patent may only be* ***null and void*** *in the following cases,*

Section I. When the protected subject matter is not considered an invention, the invention is not patentable, lacks novelty, inventive step or industrial application, in terms of this Law,

Section VII. When it has been granted in contravention of Article 50 of this Law[25]*,*

Derived from the above, it is important to talk about the enforcement of IPRs. In this sense, the observance of these rights does not prevent certain measures from being taken to prevent the abuse of the holders of these rights. While it is true that the USMCA established the issue of IPR enforcement, Article 8 of TRIPS states that members,... *In formulating or amending their laws and regulations, they may take such measures as may be necessary to protect the public health and nutrition of the population, or to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement*[26].

However, in the USMCA in Article 20.3 Principles, it states that:

a) A Party, in formulating or amending its laws and regulations, may take such measures as may be necessary to protect the public health and nutrition of the population, and to promote the public interest in sectors of vital importance to its socio-economic and technological development, provided that such measures are consistent with the provisions of this Chapter 2.

b) Appropriate measures, provided consistent with the provisions of this Chapter, may be necessary to prevent abuse of intellectual property rights by their owners or the use of practices that unjustifiably limit trade or adversely affect international transfer of technology.

[23] Op. Cit. "The Protocol Amending the USMCA. Its reception in domestic law"

[24] Op. Cit. "The Protocol Amending the USMCA. Its reception in domestic law"

[25] Article 154 of the LFPPI

[26] Op.Cit TRIPS

Based on the above, it is a contradiction that in Mexico the patent has been maintained for new uses, when it was explicitly excluded from the USMCA. In this sense, the functionality of the intellectual property system consists of a balance between the rights of the owners and a social and economic benefit, so it is essential to have a suitable legal system that ensures the integrity and respect of these rights, avoiding their abuse.
The Agreement on Trade-Related Aspects of Intellectual Property Rights established the general principles for the enforcement of IPRs, requiring WTO members to establish effective, balanced and equitable procedures that provide for the necessary remedies while establishing safeguards against misuse[27]
Specifically, IPR enforcement should take into account the basic principles of national treatment, most-disadvantaged nation, non-discrimination as well as the general obligations relating to the set of principles of balance, fairness, transparency and due process that apply to all civil and administrative IPR enforcement procedures referred to in the TRIPS Agreement. with the aim that Members' national legislation allows the right holder to take effective action against any IPR infringement action[28].
For its part, the USMCA establishes what is related to the enforcement of intellectual property, as we have already pointed out previously in Article 20.3, in this article it is established in a general way that the parties to this treaty may formulate or modify their laws and regulations by applying the necessary measures to prevent the abuse of intellectual property rights. as well as the limitation of practices that affect trade and international transfer of technology.
Article 20.4[29] explains the harmonization of intellectual property goals, the parties in their respective national systems recognize the need to:
a) Promoting innovation and creativity
b) Facilitate the dissemination of information, knowledge, technology, culture and the arts
c) Foster competition by:
- Open and efficient markets through their respective intellectual property systems
- Respect for due process and transparency
- Take into account the interests of the relevant stakeholders including rights holders, service providers, users and the general public.

Article 20.9[30] Transparency provides that each party shall endeavour to publish online its laws, regulations, procedures and administrative rulings of general application relating to the protection and enforcement of IPRs.
With respect to this issue, the Federal Law on the Protection of Intellectual Property establishes that its provisions are of public order and of general observance throughout the Republic, without prejudice to the provisions of International Treaties, whose administrative application corresponds to the Federal Executive through the Mexican Institute of Industrial Property (IMPI). to prevent acts that infringe industrial property or that constitute unfair competition related to it and to establish sanctions and penalties with respect to them, etc[31]. Therefore, it is inconsistent that, being its purpose, and having the legal instruments that supported the elimination of the new-use patent, it has prevailed in Article 45 of the LFPPI.
In an article published in 2019[32], he points out that although the drug patent system aims to economically reward companies that invest in R+D, thus guaranteeing the return on investment, however, fewer and fewer companies are doing so in this way, by virtue of strong patent systems. such as the content of the current LFPPI of Mexico, making it easier for companies to extend their period of exclusivity for a drug by filing secondary patents, or any other type of legal strategy.
The two most common practices for extending artificial protection are "perennial" and "thickening," as Feldman points out[33] in a paper published in 2018; Breckenridge and his collaborators[34] acknowledge that there are cases in which it is highly questionable whether slight changes in molecules actually have an effect on the safety and efficacy of a new pharmaceutical product.

[27] Op. Cit "Enforcement of Intellectual Property Rights"
[28] Op. Cit "Enforcement of Intellectual Property Rights"
[29] Article 20.4 USMCA
[30] Article 20.9 USMCA
[31] Article 1-2 of the LFPPI
[32] Nawrat, A. (2019, November 11). *From evergreening to thicketing: exploring the manipulation of pharma patents*. Pharmaceutical Technology. https://www.pharmaceutical-technology.com/features/pharma-patents-manpulation/?cf-view&cf-closed
[33] Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences*, *5*(3), 590–647. https://doi.org/10.1093/jlb/lsy022
[34] Breckenridge, A., Feldschreiber, P., Gregor, S., Raine, J., & Mulcahy, L.-A. (2011). Evolution of regulatory frameworks. *Nature Reviews. Drug Discovery*, *10*(1), 3–4. https://doi.org/10.1038/nrd3348

Burdon and Sloper[35] define that a key element of any lifecycle management strategy is to extend patent protection beyond the basic term of the patent for as long as possible, by filing secondary patents that are effective in keeping generics out of the market.
Mexico's LFPPI, which should promote competition and innovative activity in Mexico, in the case of the Pharmaceutical Industry, encourages the use of legal strategies as a mechanism to stay competitive in the market, and not innovation.

Conclusions

The legal-normative importance of intellectual property rights is fundamental to understanding the evolution of their regulation at the national and international level. In this sense, the relevance of talking about legal regulation in patenting strategies should be in order to avoid the abuse of the protection of inventors by the right of their inventions, since finally, this translates into an affectation to society in general due to the issue of the availability of pharmaceutical products to society. The intellectual property system should strike a balance between the public interest and the interest of inventors, and create an environment conducive to the interaction between creativity and innovation.
The harmonization of intellectual property leads to an evolution in which, in order to integrate regulations at the national and international levels, international laws and treaties on intellectual property have had to be updated and renewed. International treaties are considered as one of the mechanisms to review the functionality of the intellectual property system since it generates a consensus among countries on the means and forms of protection.
In the case of Mexico, as a result of the signing of the USMCA, the need arose to create the New Federal Law for the Protection of Industrial Property, as part of the laws of this package. the LFPPI was published on July 1, 2020 and entered into force on November 5 of the same year. The signing of new international treaties and the new Federal Law for the Protection of Intellectual Property can be considered as a response to the accelerated innovation system, in order to continue promoting all areas that involve creativity.
The Federal Law for the Protection of Industrial Property (LFPPI) in force, in terms of patents, establishes very important criteria, for example; the protection of biological material by technical procedure, as well as a third party may use, manufacture, offer for sale or import a product with a patent to generate evidence, information and experimental production in order to obtain sanitary registrations of medicines to market them once the patent loses its validity. Another point of great interest is the scope of application of the Mexican system of linking patents and marketing authorizations for pharmaceutical products.
On the other hand, Article 101 of the LFPPI also establishes that patents will not be granted with respect to subject matter that is already protected by another or whose essential characteristics are a non-substantial variation of the subject matter covered by it, even if the applicant is the holder of the first right. As we can see, the issue of patents, which applies to pharmaceutical and biochemical products, has an important notoriety in the regulations within the new treaties, and that is undoubtedly reflected in the LFPPI of Mexico.
In Mexico, all the provisions relating to patents, derived from the Treaties and the LFPPI, are considered relevant to the medicines market since they provide legal certainty and security, with the aim of encouraging new pharmaceutical research, as well as promoting innovation and creativity. With the existence of a harmonized legal system at the national and international level, it is also sought that, among others, in the area of the pharmaceutical industry, competition is promoted through open and efficient markets through its own intellectual property systems. On the other hand, the relationship between IPRs and economic purposes is undeniable, since finally, this type of practice also affects economic competitiveness; therefore, pharmaceutical companies as economic agents that participate in free competition in the market.

[35] Burdon, M., & Sloper, K. (2003). The Art of Using Secondary Patents to Improve Protection. *Journal of Medical Marketing*, 3(3), 226-238. https://doi.org/10.1057/palgrave.jmm.5040125