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# *MEXICAN PATENT LITIGATION, INTERNATIONAL INTELLECTUAL PROPERTY TREATIES AND THE EXTENSION OF PATENT TERM OF PROTECTION*

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*Abstract:* This article analyzes how the provisions on patent term adjustments contained in the new United States-Mexico-Canada Trade Agreement (USMCA) will be problematic for Mexico. To illustrate this point, the article revisits a patent litigation in Mexico. The plaintiff was a Japanese company who was suing over the infringement of its rights by a Mexican Lab. In this case, Transitory Article Twelve of the Mexican Industrial Property Act was applied to recognize a priority filing date seven years later than its original filing in Japan. The litigation involved several issues like the extension of the term of protection, and the alleged infringement by the defendant after authorities had extended the term of the patent. There are several principles and concerns discussed, such as the principle of patent independence, national treatment, and minimum term of protection, all of which are contained in the Paris Convention, Agreement on Trade-Related Aspects of Intellectual Property Rights and in the Patent Cooperation Treaty.

*Keywords*: Patent Litigation, PCT, National Treatment, Mexico, USMCA, NAFTA

1. Introduction

This article addresses a series of issues related to a specific patent litigation case in Mexico. It illustrates how these kinds of procedures work in the Mexican legal system. It also analyzes the interpretation that Mexican courts have given to several principles contained in applicable intellectual property international treaties. Principles such as the independence of patents and the national treatment principle, both contained in the Paris Convention.[1] In addition, it analyzes interpretation of the minimum term of protection of patents contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[2]

There is another important international development considered in this article. The discussion begins with an example of a litigation in which the issue was the extension of the patent term of protection. This case illustrates uncertainty and problems for both disputing parties, and this article encourages a reconsideration of the difficulty of handling provisions that extend the term of protection of patents. For the Mexican legal system, this is critical in these days. The new United States-Mexico-Canada Trade Agreement (USMCA) contains several provisions extending patent terms in two specific scenarios. These provisions will pose an extraordinary burden on the Mexican industrial property office, *Instituto Mexicano de la Propiedad Industrial* (IMPI), which already handles infringement litigation.

The patent base of the litigation that I will address expired on January 15, 2006. However, its owner, through a contentious administrative procedure, managed to extend the patent duration of a medicine. After that, it sued a laboratory that was already manufacturing and selling said medicine previously protected by that patent. The defendant laboratory was manufacturing and marketing the medicine because the patent was supposed to be in the public domain by that time.

The invention originated in Japan; the owner, a pharmaceutical company called *Takeda Pharmaceutical Company Limited* (*Takeda*), filed two applications there. The first one was dated January 19, 1985. However, it was abandoned in favor of another new application dated January 9, 1986.[3] That is to say, we are facing a priority date of 1985, which was not claimed in Mexico until 1992. The foregoing, of course, does not reflect the normal progression of an international application, neither by applying the principles of the Paris Convention for the Protection of Industrial Property (Paris Convention),[4] nor by applying those of the Patent Cooperation Treaty (PCT).[5] In 1986, they did not attempt to register the patent in Mexico because the Industrial Property Act of 1976, in force in those days, did not include patent protection for pharmaceutical products.

The time elapsed between the Japanese filings and the filing date in Mexico poses the problem of novelty, a fundamental requirement in order to obtain a patent. That is, to obtain protection, an invention is weighed against the state of the art, which is considered globally. Then, if it is determined that the invention has already been published, marketed, or previously used anywhere in the world, the novelty requirement is not fulfilled and the patent is denied, even if those acts were done by the inventor itself.

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[1] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979).
[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech (April 15, 1994).
[3] Extended practice in several legal systems. Lemley and Moore, 2004, p. 94; Shinall, 2012, p. 374.
[4] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979).
[5] Patent Cooperation Treaty, Washington (June 19, 1970).

Thus, by 1992, the year of the filing in Mexico, the required novelty had already been lost, not a surprising occurrence, since the publication done under the PCT mechanism 18 months after the priority date. Also, those made by several national patent offices at the national phase of PCT.[6] Moreover, the pharmaceutical product was already available in numerous countries.

At this point, a normative precept that is a central part of the litigation process enters the scene. This is Transitory Article Twelve of the Mexican Industrial Property Act.[7] If it had not been for this legal precept, the patent would not have been granted because it failed to comply with the novelty requirement.[8] The aforementioned transitory article created an unusual regime for this type of inventions, especially those that would not meet the novelty requirement because they had been previously published in their countries of origin during the prosecution process.[9] Specifically, Transitory Article Twelve benefits pharmaceutical products and inventions that the outdated Industrial Property Act of 1976 had not protected by a patent, but through an obsolete certificate of invention.[10]

When the statutory provision establishes as a requirement, that the priority date be established by came from a member state of the PCT, one might think that this refers to requests coming from the international search phase of the PCT. However, when analyzing the terms, it becomes clear that the provision does not refer to this type of filings,[11] because Transitory Article Twelve of the Mexican Industrial Property Act refers both to applications of patents as well as to granted patents.

Transitory Article Twelve of the Mexican Industrial Property Act offered an opportunity for certain inventions. However, it also created a huge problem, since it linked the termination date of the term of protection in Mexico to the termination date in the country of origin for those inventions."[12]

Moreover, Transitory Article Twelve of the Industrial Property Act provides a term of protection different from the one specified by Article 23 of the same statute. According to Article 23 of the Industrial Property Act, the term of protection for an invention patent is 20 years, starting from the filing date of the application in Mexico. Consequently, if the date of application of the patent subject to the controversy was on June 17, 1992, then the expiration date would have been accordingly on June 17, 2012. However, patents obtained under the scheme of Transitory article Twelve of the Industrial Property Act are not granted the general term of protection established by article 23 of the same regulation, which in this case would have meant an expiration date of June 17, 2012 and not January 15, 2006, the date originally indicated in the title. Therefore, not even with the extension of the term of protection ordered in the administrative litigation, as mentioned in the third paragraph, could the term of protection of the patent reach the deadline which was established by article 23 of the Industrial Property Act.

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[6] Farrand, 2006, p. 1266.
[7] Mexican Industrial Property Act (June 27, 1991).
[8] Solovy and Krishnamurthy,2017, p. 96. To illustrate this point, an application to protect the same invention called Thiazolidine Derivatives, was discarded for lack of novelty on April 6, 2001, by the National Institute of Industrial Property INAPI of Chile on April 6, 2001. Available at: https://ion.inapi.cl/Patente/ConsultaAvanzadaPatentes.aspx. Accessed January 6, 2019.
[9] Tobias *et al.*, 2009, p. 115; Pil, 2014, p. 358.
[10] Mexican Inventions and Trademarks Act (February 10, 1976), arts, 10 y 65 (no longer in force).
[11] Lapenne, 2010, p. 198.
[12] Mexican Industrial Property Act (June 27, 1991), Transitory Article 12.

Today, Transitory Article Twelve of the Industrial Property Act does not pose the same problems as before, since it requires that the filings in Mexico be made within 12 months from the date on which the Mexican Industrial Property Act came into force. Thus, time has corrected what the courts and the Mexican Congress did not.

However, this was not an isolated case, but a widespread problem. To illustrate this point, a journal note published on September 12, 2010, remarked how pervasive the problem was.[72] It also made reference to the present litigation: "... the problem says the national producers of generic medications, is that more than a quarter of drugs patents published today in the gazette exist because of a judicial mandate, that is to say, that a judge ordered the IMPI to protect them despite the fact that IMPI itself had refused to do so...." [73]

The journal note was not the only acknowledgement of how common the problem was. The Mexican Senate also recognized the problem and exhorted the FCAJ to limit itself to the literal terms of the statute and not extend the term of protection of patents based on Transitory Article Twelve of the Industrial Property Act. That is, the senators interpreted the statutory provision as not giving any basis to extend a patent term of protection.[74] However, none of them proposed amending the statutory provision in order to clarify its exact meaning.

This article begins revisiting basic principles of international intellectual property treaties, such as the Paris Convention, the PCT and the TRIPS agreement, which I have called classic principles. This is followed by a chapter on the litigation, containing legal arguments, proven facts and court rulings. Since this was a complex litigation, I will revisit only the most important court opinions. The litigation shows the difficulty and uncertainty of extending patent terms of protection in the Mexican legal system. Therefore, in the last chapter I will discuss those difficulties and USMCA provisions extending patent terms.

## 2. International Law

This article analyzes a very basic issue within the Mexican legal system, litigation. But before moving on to the study of this specific case, it is important to provide some background and to make a general analysis of applicable international treaties.

The first one is the Paris Convention. It responded to the drawbacks derived from a fundamental principle of intellectual property, its territoriality. This means that national statutes in each country only grant protection within their respective territory, thus, leaving national intellectual property unprotected in the rest of the world. This principle allowed people to take advantage of said territoriality and copy inventions abroad, especially at international technology exhibitions; then, on return to their country of origin, they could register the copies as their own invention.[13]

Thus it became extremely difficult—almost impossible—to obtain protection abroad, since novelty, the essential and emblematic requirement of patents, was weighed differently in each country. In fact, some jurisdictions even made the absurd ruling that if the inventor himself, in his country of origin, filed for protection the day before the national filing date, said invention would not be considered novel,[14] an exaggerated appreciation of the state of

[72] El Economista, September 12, 2010.

[73] El Economista, September 12, 2010.

[74] Mexican Senate, April 26, 2007.

[13] Goldstein, 2008, p. 351.

[14] Mueller, 2009, p. 525.

the art. To avoid this problem, the application had to be filed simultaneously on the same day in all countries where protection was desired. The difficulty of the task can be better understood if we remember that the first version of the Paris Convention came into force in 1883.

The fundamental purpose of the Paris Convention was precisely to overcome the previously mentioned difficulties by establishing several principles. The first one is national treatment.[15] In addition, it establishes definitions and minimum protection parameters. However, the protection granted has never been automatic, so the inventor needed to apply for it, country by country. To facilitate filings in various jurisdictions, the Paris Convention establishes the principle of recognized priority, extending 12 months for invention patents and 6 months for trademarks, from the date of the first application.[16] This means that any filing by the applicant after the first filing date, in a member state within the aforementioned period, cannot be invalidated or denied, either by any previous application filed by a third party in that state, or by the publication of the application in the country of origin, or by the marketing of the product.[17] That is, this principle protects the priority date of the first application with respect to possible requests made by third parties, and also protects the novelty of the invention, which may be lost by the original application itself or by the commercialization of the product by the applicant.

Then, 12 months after the recognized priority date, the original patent application itself would cause the novelty of the invention to be lost abroad. This dilemma arises because intellectual property is territorial, but the state of the art is global. Although patents are granted by national offices and their scope is restricted to their country, the publication of the application by the national office will cause the invention to no longer be considered novel in a subsequent application filed in another country. This is because, in the majority of countries, once the application is filed, a publication of said application is made 18 months after the recognized priority date, if not before. In addition, once granted, the title is published, together with the application and the requested claims. Therefore, a patent application must be filed in all countries where protection is desired, almost at the same time.

Later, the PCT, which was negotiated at the initiative of the World Intellectual Property Organization (WIPO) appears. Its objectives are the simplification and uniformity of the various national patent application procedures through a single application format, as well as cost reduction of patenting inventions in various countries. Undoubtedly, the PCT was successful in its purposes since its member countries share a high degree of uniformity in the procedures to prosecute patents, in addition to having the same format. Likewise, the PCT has facilitated the titanic task of protecting an invention in several jurisdictions.

The procedure of prosecution through the PCT consists of two phases: one international before the WIPO; and the second national, in each of the countries in which protection is sought. The international phase includes: 1) international application to the PCT, which can be done directly with WIPO, with the option of filing online, or through one of the national patent offices of member states, which acts as receiver to prosecute the filing to WIPO; [18] 2) form examination; 3) an international search, on the novelty of the invention whose protection is requested and; [19] 4) international publication 18 months after the date of

[15] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979), art. 2.
[16] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979), art. 4.
[17] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979), art. 4(B).
[18] Patent Cooperation Treaty, Washington (June 19, 1970), arts. 3, 10.
[19] Patent Cooperation Treaty, Washington (June 19, 1970), art. 15.

recognized priority.[20] The following two phases are optional: 5) supplementary international search and 6) international preliminary examination.

A very convenient aspect of PCT is that applicants have up to 30 months after the priority date or first filing, to go to the national phase, country by country.[21] This term is much greater than the 12 months granted by the priority date principle established by the Paris Convention. In this regard, article 11 of the PCT establishes that the date of international filing will be the national filing date in each country in which protection is sought.[22] Therefore, during these 30 months, the applicant is able to assess whether the invention is profitable enough to warrant the prosecution in each country. In addition, this valuable time allows translations to be prepared in the language of each of the countries in which applicant intends to file for protection.[23] Additionally, the result of the international search on novelty and state of the art indicated in stage 3 of the international phase is highly persuasive at national offices, which will ultimately decide whether to grant the invention patent or not. In conclusion, a single international filing can be made, in one language, with the applicant paying a single set of rights and having the application filed in all requested member states, allowing to file the respective applications in those countries in 30 months.[24] Another advantage is that this international application can be submitted online.

We could not conclude this synopsis on international treaties on patents, without mentioning TRIPS Article 27. This is important because, with respect to patents for inventions, the Paris Convention does little more than establish national treatment, priority date, and the independence of rights. That is, it supports protection abroad through the patent, but does not define it, nor does it provide a minimum term of protection.[25] Hereof, the TRIPS agreement not only incorporates the Paris Convention itself, [26] but also defines patents for invention in the following broad terms: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[27] This inclusive language was specially designed so that certain countries would not exclude pharmaceutical or agricultural products from protection.[28] In addition, the TRIPS Agreement limits and regulates the cases in which member states can establish compulsory licenses, and it establishes minimum rights of holders over their patents, and establishes a minimum term of protection of 20 years counted from the date of application of the patent.[29]

Finally, the TRIPS agreement is the first international treaty on intellectual property that, at global level, contains a chapter about enforcement of intellectual property rights. That is, it regulates how litigation procedures should be conducted in case of infringement. It includes general aspects, preliminary injunctions, evidence, damages, as well as measures at the border. Although these measures are directed to judicial authorities, TRIPS Article 49 allows such procedures to be carried out before administrative authorities with jurisdictional

[20] Patent Cooperation Treaty, Washington (June 19, 1970), art. 21.
[21] Patent Cooperation Treaty, Washington (June 19, 1970), art. 22.
[22] Khoury, 2012, p. 209.
[23] Ilardi and Blakeney, 2004, p. 40.
[24] Abbott *et al.*, 2007, p. 219.
[25] Pires, 2005, p.71.
[26] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979), art. 2(1).
[27] Agreement on Trade-Related Aspects of Intellectual Property Rights Marrakech (April 15, 1994), art. 27(1).
[28] Mueller, 2009, p. 544.
[29] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech (April 15, 1994), arts. 31, 28 and 33. Markham, 2011, p. 124.

functions, as is the case of Mexico. The litigation described in this article shows how the Mexican legal system has assimilated these international obligations.

3. *Takeda v. Rimsa*.

Intellectual property litigation is a complicated business in Mexico. Unlike most legal systems where such litigation is brought before an ordinary court within the judicial sphere, in the Mexican legal system, patent and trademark holders have to bring infringement cases before the IMPI, which is the administrative authority that grants patents and registers trademarks. This peculiar jurisdiction complicates litigation because of the difficulty in consolidating various actions in a single procedure. In addition, since parties have at their disposal appeals and actions to combat unfavorable judgments, litigation turns complex and lengthy in almost all cases.

This complicated jurisdiction poses another problem. The IMPI has no authority to condemn damages in infringement cases. Therefore, a winning party prevailing at IMPI infringement action, and also prevailing in all appeals, does not obtain a damages award in her favor yet. She has to start all over again, this time in a federal or state court, in spite of, the litigation under analysis did not reach the action for damages. It should be noted that a firm resolution of the IMPI is a precondition to start the ordinary civil suit to recover damages. All of the above procedures can take up to a decade, in violation of the principle of effectiveness of enforcement procedures established by the first paragraph of TRIPS Article 41. This dual litigation set makes the already complicated patent litigation even more complex.[30]

To facilitate reading, I will refer to Takeda as plaintiff, since this company filed the infringement action. The defendant is *Representaciones e Investigaciones Médicas, S.A de C.V.* (Rimsa). These terms will apply, regardless of either party filing an appeal or any action called *amparo*, which at the end of the day is a further appeal in the Mexican legal system.

Before filing the infringement action, or requesting any preliminary injunction, the plaintiff Takeda filed an appeal, for practical purposes. Actually, it was a contentious administrative proceeding against a resolution issued by the IMPI on January 25, 2005. In this resolution, the IMPI ruled inadmissible any modification of the term of protection of the patent object of the litigation. This contentious administrative proceeding was carried out before the Specialized Chamber on Intellectual Property of the Federal Court of Administrative Justice (FCAJ), an independent administrative court system within the executive branch, which reviews all administrative resolutions and decrees.

Takeda began its arguments alleging that although the IMPI had denied extending the term of protection of the patent, this was not what it had asked the IMPI to do; instead it had requested the correction of the term of protection.[31] In this regard, Takeda alleged that it was originally granted an expiration date of January 15, 2006 because on that date the patent would end in the country whose priority date was recognized. However, Takeda argued that the original filing was withdrawn in favor of another one that it subsequently filed, and that new filing generated a patent that would expire on the requested date, that is to say on January 9, 2011. This took place because the application whose priority date was recognized in Mexico never became a patent. Likewise, the plaintiff argued that according to Transitory

[30] Andrews, 2011, p. 226.
[31] Case No. 14113/05-17-05-9, 2006, p. 4.

Article Twelve of the Mexican Industrial Property Act, the term of protection of a patent in Mexico, should be based on the term of protection of the patent granted in the country of origin, not on the date of filing, "since applications are not valid...." [32]

This argument is questionable. If the original application was withdrawn in favor of another, then it is not the same invention and should not have the same priority filing date. Moreover, the difference of years in the term of protection of both would assume that the invention of the second filing, supposedly the same as the first one, would not be novel even in the country of origin. [33] However, Takeda argued that, in Mexico, the medical compound claimed by both Japanese applications was protected; therefore, it was the same invention and that the priority date of the first one was relevant because "it should be considered as the first application filed in a ... country ..." member of the PCT. Takeda also argued the relevance of the second application, but to determine the term of protection of the patent in Mexico since it argued that it was the same compound as the first one. [34]

Another argument of Takeda was that in issuing its resolution, the IMPI held that extending the term of protection would be in violation of Article 28 of the Mexican Constitution, which is the basis of intellectual property protection in Mexico, establishing protection only for "limited times." Takeda's argument was that only federal courts are authorized to interpret constitutional provisions. Furthermore, it reasoned that in any case, the term of protection established by Transitory Article Twelve of the Industrial Property Act did not exceed the 20 years established by Article 23 of the same statute.

Finally, Takeda contended that while the IMPI transcribed Article 4 bis of the Paris Convention, it did not express how that international precept led to the denial of the extension of the term of protection of the patent.[35] In this regard, Takeda stated that the principle of independence of patents established by Article 4 bis of the Paris Convention is only for questions of nullity and expiration and that there is no inconsistency between said treaty provision and Transitory Article Twelve of the Industrial Property Act.

In order to defend its January 25, 2005 resolution before the FCAJ, the IMPI argued that it was not authorized by any legal statutory provision to extend the term of protection of a patent. Likewise, it provided a series of arguments interpreting Article 4 bis of the Paris Convention maintaining that the patent regime of another country cannot be linked to the national regime, so that modifications in the term of protection made abroad must not be binding in Mexico. In addition, it maintained that Transitory Article Twelve of the Industrial Property Act only recognizes the priority date, and not subsequent filings made abroad.

The FCAJ considered the arguments presented by Takeda well founded. It began its decision by quoting parts of the legislative history of Transitory Article Twelve of the Mexican Industrial Property Act, stating that congressional intent was precisely to attract new technologies to the country. Outside of that, it assumed all the arguments made by Takeda as its own, starting from the one pointing out that it was a request for correction of the term of protection and not an extension of it, continuing to the argument that established that both Japanese requests dealt with the same invention, and finally even including the argument that

[32] Case No. 14113/05-17-05-9, 2006, p. 6.
[33] Unless it is a provisional application, such as those existing in several legal systems, so that the original application date does not affect the term of protection. Migliorini, 2007, p. 439.
[34] Case No. 14113/05-17-05-9, 2006, p. 8.
[35] Case No. 14113/05-17-05-9, 2006, p. 15.

said that an application that did not become a patent could not serve "to determine the expiration of the Mexican patent...."[36]

Regarding Article 4 bis of the Paris Convention, the FCAJ held that: "it does not apply to the specific case, because ... the plaintiff does not intend to extend the validity of its patent ... but rather the correct determination of it."[37] However, Article 4 bis of the Paris Convention does not prohibit extending the validity of a patent; what it prohibits is subjecting its term of protection to the patent's original priority filing date, which is precisely what the FCAJ did.

Article 4 bis of the Paris Convention establishes the principle of independence of rights in an "unrestricted sense," establishing that patents applied in one country shall been independent from those patents applied in other countries, regarding nullity, forfeiture, and the term of duration.[38] The wording of Article 4 bis left no doubts about the independence on the term of protection, even for patents obtained with the priority principle, establishing that their term of protection will be the same as those applied without such benefit. In the opposite sense, , , Transitory Article Twelve of the Mexican Industrial Property Act, links the term of protection of a national patent to the term of the country of origin, an occurrence that clearly violates the principle of independence of patents established by Article 4 bis of the Paris Convention.

Consequently, contrary to what the FCAJ held, Article 4 bis of the Paris Convention establishes the principle of the independence of patents in an "unrestricted sense," totally separating applied patents from each other. The absolute and literal character of the principle of independence underscores the contradiction between Transitory Article Twelve of the Industrial Property Act and Article 4 bis of the Paris Convention,[39] a reasoning that should have been sustained by the FCAJ.

The principle of independence regarding the term of protection has been unanimously supported by both[40] the doctrine and case law of several member states of the Paris Convention.[41] The literal terms, in which it is established, eliminate any doubt or interpretation to the contrary. The decision of the FCAJ fails to discuss the scope of the international principle of independence of patents and, in fact, avoids its analysis, assuming inapplicability based on the argument that the extension of the term of protection was not requested. That is, the decision does not analyze if the syllogism established by Article 4 bis of the Paris Convention fits into the legal situation in question. It is simply ignored. If analyzed, there is no logical reasoning that could sustain FCAJ's decision.

Although it was not argued in the litigation, I consider that Transitory Article Twelve of the Industrial Property Act, not only contradicts the principle of independence established by the Paris Convention, but also that of national treatment established both by the Paris Convention and the TRIPS Agreement. [42]

While it was laudable to create an exception to protect inventions that could not be protected before the Industrial Property Act entered into force, this does not exempt the

[36] Case No. 14113/05-17-05-9, 2006, p. 27.
[37] Case No. 14113/05-17-05-9, 2006, p. 29.
[38] Paris Convention for the Protection of Industrial Property, Stockholm (September 28, 1979), art 4 bis.
[39] Pires, 2005, p. 74; Goldstein, 2008, p. 353.
[40] See Mahne, 2012, p. 170; Oddi, 1987, p. 860; Abbott *et al.*,2007, p. 173.
[41] This question has also been recognized, or rather taken for granted, in American case law, see *Voda v. Cordis* 476 F.3d 887 (Fed. Cir. 2007), pp. 898-899.
[42] Correa, 2007, p. 44.

legislator from complying with the principles established by the several international treaties regulating patents. [43]

I am referring especially to the principle of national treatment, the principle of independence, and the minimum term of protection established by the TRIPS Agreement, and incorporated into Article 23 of the Industrial Property Act. If the Mexican Congress has determined to protect inventions by means of an invention patent, then it has to protect them under the terms established by both, international treaties and by national law. The foregoing prevents the term of protection of a national patent from being subject to that term of protection, which was granted in the country of origin. Otherwise, nationals of the country of origin would obtain a lesser term of protection than Mexican applicants. The current law has caused great uncertainty and an abundance of litigation, including what happened in the present dispute.

Regarding the national treatment principle, if a member state grants a certain right or term of protection of any legal form of intellectual property to its nationals, that same right or term must also be granted to the nationals of the other member states of the Paris Convention or the TRIPS agreement. Therefore, if the Mexican inventors, who filed their patent applications on the same date as Takeda did in Mexico, received a term of protection of 20 years after that filing date, and Takeda was not granted the same term, we are facing a violation to the principle of national treatment. The foregoing would even include any exception or benefit received by the foreign holder by Transitory Article Twelve of the Industrial Property Act.

All of the above legal developments pose a strong problem in the Mexican legal system since, according to Article 133 of the Mexican Constitution, international treaties are hierarchically superior to any national statute.[44] So, if a specific statutory provision contradicts an international treaty, as a matter of legal interpretation, then what should prevail are the provisions established by the international treaty.[45]

3.1 Preliminary Injunction at IMPI

The description below shows how TRIPS enforcement provisions have been incorporated into the Mexican legal system.[46]

It is important to point out that resolutions issued by IMPI can be appealed, optionally, to the division superior in hierarchy at the IMPI itself, or directly before the FCAJ who can declare the nullity of the appealed resolution and order for the IMPI to issue a new resolution in the terms established by the FCAJ itself, as happened in the previous section. Moreover, the resolution of the FCAJ can be fought through the procedure called *amparo*.

On June 15, 2006, Takeda filed a petition for provisional measures against Rimsa. This request was based on Article 199 bis of the Industrial Property Act. This statutory provision was issued by Mexican Congress to incorporate TRIPS Article 50 into the Mexican legal system, thereby establishing preliminary measures without hearing the opposing party, or *inaudita altera parte* measures. However, this request was not admitted, because the IMPI

[43] Ersling and Strove, 2015, p. 513.
[44] Mexican Supreme Court of Justice, Case No. P. LXXVII/99, Federal Judiciary Gazette, Ninth Time, volume X, November 1999, p. 46.
[45] Second Chamber, Mexican Supreme Court of Justice, Case No. IV.2o.A.76 K (10a.), Federal Judiciary Gazette, Tenth Time, book 12, November 2014, volume IV, p. 2918.
[46] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech (April 15, 1994), arts. 41 - 60.

held that the term of protection of the alleged infringed patent was being brought into question in another litigation.[47]

The other litigation was the one described before, including appeals and *amparos* promoted by Rimsa. As a result of those proceedings, on February 9, 2006, the IMPI had published in the Industrial Property Gazette that the patent was in force by a preliminary court order since its term of protection was in litigation. Against this publication, as well as the resolutions that previously led to the extension of the term of the patent, Rimsa promoted several *amparo* lawsuits, seeking to reverse this extension. However, it did not succeed in any of them.

Consequently, on July 26, 2006, the IMPI issued the requested preliminary measures, consisting of suspending the manufacture, offer for sale, sale, and distribution of the drug called *Diaberil*, whose active component was *Pioglitazone*. Furthermore, the IMPI was also ordered the drug in question to be withdrawn from circulation or distribution, and secured. Finally, the IMPI ordered the defendant to refrain from manufacturing and marketing any product that contained the active ingredient in question.

Article 199 bis 1 of the Industrial Property Act establishes the requirements that a plaintiff must demonstrate in order to obtain a preliminary measure. The first one is ownership of the right. To demonstrate this, Takeda produced a certified copy of the original title of the patent number 181354, whose original expiration date was January 15, 2006. However, it did not produce or mention the decree issued by the IMPI on July 20, 2006, in which it implemented the ruling of the FCAJ extending the patent term of protection until January 9, 2011. It is questionable that said decree was issued after the date in which the plaintiff presented its initial motion requesting the preliminary measures, that is to say on June 15, 2006. The foregoing causes doubt because the IMPI based the preliminary measures on a right that technically did not exist when said measures were requested; thus the law was applied retroactively.

According to the preliminary measures decree, the plaintiff demonstrated all the elements established by Article 199 bis 1 of the Industrial Property Act. Takeda demonstrated the actual and imminent violation of its rights, as well as the possible irreparable damage, in addition to providing necessary information for the identification of the infringing products and the place where the infringement was being committed. Moreover, the IMPI accepted a bail bond for the amount of twenty million pesos presented by the plaintiff in order to guarantee reparation for possible damages that the measure could cause the defendant.

According to second paragraph of Article 199 bis 1 of the Industrial Property Act, the person against whom preliminary measures have been issued may obtain their removal by means of a sufficient counter bail bond to respond for damages. Based on the foregoing, the defendant filed a counter-security policy for twenty-four million pesos, in order to obtain said benefit. On September 13, 2006, the IMPI accepted the counter-guarantee and ordered the withdrawal of the preliminary measures.

The plaintiff prevailed in the main infringement action; therefore, IMPI put the counter-security presented by the defendant at its disposal, which illustrates the risk faced by defendants who evade preliminary measures through this counter-guarantee.

This discussion has shown how preliminary measures without hearing from the opposing party are established, and illustrates how Article 50 of the TRIPS Agreement works within the Mexican legal system.

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[47] *Takeda v. Rimsa* (IMPI 2013) p. 3

3.2 Infringement Action at IMPI

Now let's look at the patent infringement action, all within the same docket record of the preliminary measures. On August 23, 2006, Takeda filed a complaint for the administrative declaration of infringement based on the causes established by fractions XI, XII and XXVII of Article 213 of the Industrial Property Act. After all stages of the proceedings were exhausted, on February 27, 2009, the IMPI issued a resolution in which it declared the administrative infringement of each of the causes of action.

The resolution began analyzing the defenses filed by Rimsa. One of them was that according to its original title, the alleged infringed patent expired on January 15, 2006. Therefore, the plaintiff had no right to sue for infringement since the medicine was in the public domain. In addition, Rimsa argued the absence of any legal provision that empowered the IMPI to extend the term of protection for a patent. The IMPI ruled the exception inadmissible, maintaining that by means of a decree issued on July 20, 2006, it had complied with what was ordered by the FCAJ, thus extending the term of protection of the patent until January 9, 2011. The IMPI did not miss the opportunity to recall that the decision of said court came precisely from an appeal filed by Takeda against a resolution in which the IMPI itself had originally refused to extend the term of protection of said patent.

After this, the IMPI analyzed and ruled about the evidence presented. I will briefly describe the most important pieces of evidence.

The first evidence was a certified copy of the alleged infringed patent title, to which IMPI gave full probative value to the ownership rights of the plaintiff. The foregoing took place notwithstanding the fact that, according to this title, the patent had expired on January 15, 2006. The plaintiff also presented as evidence, a certified copy of the cover page and page 53 of the IMPI Gazette published on March 9 and a certified copy of the Gazette published on February 2006. While the IMPI gave full probative value to these publications, the IMPI did not establish what the plaintiff had intended to demonstrate with them.

The plaintiff also exhibited a sample of the product marketed by the defendant, called *Diaberil*, which for procedural purposes in Mexico was considered a private documentary. Takeda also submitted a statement of facts raised on June 12, 2006 by a notary public who went to a specific pharmacy, attesting that a drug called *Diaberil*, containing *Pioglitazone*, was offered for sale there. To verify the above, the notary public asked the manager of the establishment for the medication in all its presentations; the manager assured him that although there were two presentations, he only had one of them. The notary public then proceeded to purchase the medication and requested an invoice at the time. Both, the medication and the invoice were added to the notarization of facts, with the medication in a sealed plastic bag to which a label was affixed indicating how it was acquired.

The plaintiff also presented as evidence, an admission which revealed that the defendant had marketed the product as *Diaberil*. This argued confession made by Rimsa consisted in the packing label that stated that the product had been "made in Mexico" by the defendant Rimsa.[48] Another important piece of evidence was the result of an inspection carried out by the IMPI on March 27, 2006 to an address identified on the record itself as property of the defendant, where pharmaceutical products were manufactured, stored, and conditioned, including *Diaberil*. This finding was documented in the respective statement of facts made by IMPI as a result of the inspection visit.

[48] *Takeda v. Rimsa* (2013) p. 45.

The plaintiff also presented evidence from another inspection carried out on July 5, 2006 by a notary public which corroborated in a public document, the commercial launch of the product *Diaberil*, as carried out by the defendant in a hotel in Mexico City. There were also parts of a speech made by the CEO of the defendant company, who according to the record stated: "the validity of the patent has expired and Takeda requested an extension of the same, a situation that is not considered in the law ... the product is safe because it complies with the active component ... it has a sanitary registry ... Rimsa ... has the legal arguments to defend itself ...."[49] Said notary also recorded the receipt of a brochure with the description of the medication, which was annexed to the record, as well as two medical samples of the product subject to the controversy. It is worth mentioning that the plaintiff verified another inspection like the previous one, but this time by a notary public in Guadalajara, at another hotel, at another presentation of the medication, which took place on July 4, 2006.

Furthermore, the plaintiff provided evidence of the inspection made on July 27, 2007 by IMPI staff to an address indicated by the plaintiff as the place where defendant Rimsa manufactured the infringing product. There the inspector certified several facts formulated by the IMPI itself through a decree ordering such a visit, including the manufacture of the drug subject to the controversy. Moreover, other facts were certified regarding the identity of the establishment, manufacture, and storage of infringing products. At the end of the inspection, the inspector secured the alleged infringing merchandise.

The first cause of the action filed was the one established by fraction XI of Article 213 of the Industrial Property Act, whose description of an infringement is "to manufacture products covered by a patent or by a registration of a utility model or design industrial, without the consent of the owner or without the respective license." In order to set this cause of the action, the IMPI established two hypothetical elements to be demonstrated: the first one, the existence of a patent, property of a person; the second element was to demonstrate the manufacture or processing of products covered by that patent, without having the consent or license of the owner of the same.[50]

It is here where the case seems incongruous, since, to hold the first element, which is the existence of a valid patent right, the IMPI only considered the patent title, without offering a reason or making further analysis of the extension of its term of protection. That is to say, it only mentioned a title whose expiration date was January 15, 2006, five months before the plaintiff filed its infringement complaint, thus omitting to mention the resolution issued by the IMPI itself on July 20, 2006 where, in compliance with what was ordered by the FCAJ, the term of protection of the patent was extended to January 9, 2011. Likewise, the IMPI did not mention any publication in the Gazette regarding the extension of the term of protection. The foregoing is very important, because although one may infer from the record that the new term of protection derived from the extension of the same, in a well-founded and reasoned resolution,[51] this issue should have been clearly established.

The second element of the cause of the action, related to the manufacture or elaboration of the patented product without authorization or license of the patent holder, was upheld by the IMPI only because of the evidence resulting from the inspection of the premises of defendant Rimsa, which were carried out by IMPI staff on July 27, 2006.

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[49] *Takeda v. Rimsa* (2013) p. 53.

[50] *Takeda v. Rimsa* (2013) p. 107.

[51] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech (April 15, 1994), art 41(3), establishes that decisions declaring infringement must be "reasoned."

The doctrine has established that the most difficult element for demonstrating a patent infringement, is if the infringing product or process violated the claims of the patent base of the action.[52] That is, the offending product is compared to the claims of the original patent title. Here this did not happen, since the defendant openly manufactured and marketed a product that invaded the patent of the plaintiff, with the expectation that it would be in the public domain.

As the second cause of the action, the plaintiff filed the infringement as established in fraction XII of Article 213 of the Industrial Property Act, consisting of: "... offering for sale or putting into circulation products covered by a patent ... knowingly that were manufactured or made without the owner's consent ...."

The first element, the ownership of a valid patent, was held to be proven with the analysis of the first cause of the action. Then, the IMPI relied on two notarized inspection visits presented by plaintiff to demonstrate the presentation of the *Diaberil* product by Rimsa, one made in a hotel in Guadalajara, and the other made in a hotel in Mexico City. As described above, in the latter, the notary public stated that the CEO of Rimsa had indicated that the patent object of litigation had already expired and that the plaintiff had requested the extension of its term of protection. With this, the IMPI held that Rimsa, manufactured and sold the product knowing about the patent basis of the action.[53]

The last cause of the action filed by the plaintiff contained in the residual fraction XVII of Article 213 of the Industrial Property Act establishes as an infringement: "the other violations of the provisions of this Act that do not constitute crimes ...." This fraction was related to the exclusive rights granted to the owners of the patents by the fraction I of Article 25 of the same statute, consisting of the "right to prevent other persons from manufacturing, using, selling, offering for sale, or importing the patented product, without owners' consent...." The IMPI ruled on this infringement because of the defendant's unauthorized manufacturing of the product called *Diaberil*, which contained the substance protected by the patent base of the action.

Finally, the IMPI sentenced defendant Rimsa to pay a fine for the amount of twenty thousand days of minimum wage, the usual unit to set fines in Mexico.[54] In addition, it ordered the defendant to "refrain from manufacturing or elaborating, as well as offering for sale, or putting into circulation products that invade ... the patent 181354 ...."[55] In this regard, the IMPI determined to make definitive the preliminary measures imposed on the defendant, ordering the bail bond presented when requesting said measures to be placed at the disposition of the plaintiff. In addition, it ordered the counter bail bond presented by the defendant in order to lift the preliminary measures and amounted to twenty-four million pesos to be put at the plaintiff's disposition. [56]

### 3.3 Review of IMPI Infringement Ruling by FCAJ

Defendant Rimsa filed a trial of nullity before the FCAJ against the infringement judgment of the IMPI. I would summarize the motives for challenge this way: First, Rimsa argued that there was no statutory provision authorizing the extension of the term of protection of a patent; second, Rimsa argued that it had not been heard in the aforementioned

[52] McJohn, 2003, p. 173.
[53] *Takeda v. Rimsa* (IMPI 2013) p. 109.
[54] Around eighty thousand American dollars, at the exchange rate of 20 Mexican pesos per dollar.
[55] *Takeda v. Rimsa* (IMPI 2013) p. 113.
[56] Around one million two hundred thousand US dollars, at the exchange rate of 20 Mexican pesos per dollar.

extension proceeding since it was not part of it, which violated its opportunity to be heard or due process;[57] and finally Rimsa argued that such extension in the term of protection was not applicable, since the term had not been published in the Intellectual Property Gazette. Therefore, contrary to what was established by the IMPI resolution, there was no infringement.

Once again, the FCAJ ruled against the defendant, dismissing all the arguments as *res judicata*.[58] The FCAJ held that the legality of the decree by which the IMPI complied with the order extending the term of protection of the patent had been confirmed previously. In this sense, it established that "a binding ruling had been made for the parties ... to consider otherwise would imply a violation of the principles of legal certainty and security."[59]

Thus, the FCAJ held that, since the extension of the patent term of protection until January 9, 2011, was already determined, it was inadmissible that the defendant Rimsa "sought to exempt herself from the infringements declared under the argument that the patent ... had lost its validity...." [60]

Although the FCAJ acknowledged that Rimsa could not intervene in the procedures to extend the term of protection of the patent, "since its intervention was not admitted ... it is not for the FCAJ in the present procedure to determine the legality of that determination."[61] Furthermore, it held that the lack of legal interest or standing would have been the main reason for the dismissal of the *amparo* lawsuits filed to combat the extension of the patent.

The above situation raises an important problem, since initially the defendant was not allowed to intervene in the proceedings to extend the term of patent protection, due to lack of legal interest or standing; and later in the infringement action, the issue was considered *res judicata*. The legal system disregarded a legitimate expectation resulting from a patent supposed to be in the public domain, especially for a laboratory planning to manufacture the medication once it had been in the public domain. This laboratory had, in fact, already made a monetary investment and obtained marketing approval from the health authorities. If all of these considerations were not considered of legal interest or standing, it was due to excessive and blinding formalism in those courts, a common situation in the Mexican legal system.

Rimsa finally argued that the infringement ruling could not be issued because it had been initiated before IMPI, a nullity procedure against the allegedly infringed patent. However, the FCAJ considered that Rimsa did not file such an action, because IMPI had dismissed it.[62] Therefore, the FCAJ disregarded the argument, holding that the decision of the IMPI denying the nullity of the patent had the presumption of legality.

### 3.4 The *Amparo* 245/2014.

In the Mexican legal system, a legal writ of protection called *amparo* is available against the violation of any constitutional right, among other things. However, most of the time, the constitutional infringed right is the correct application of the law, which is contained

[57] Amparo 245/2014 (2014) p. 28.
[58] Amparo 245/2014 (2014) p. 33.
[59] Amparo 245/2014 (2014) p. 34.
[60] Amparo 245/2014 (2014) p. 34.
[61] Amparo 245/2014 (2014) p. 36.
[62] Amparo 245/2014 (2014) p. 42.

in articles 14 and 16 of the Mexican Constitution.[63] While the use of *amparos* was historically criticized as converting a cassation or ordinary appeal into a constitutional action that would fill constitutional courts with ordinary appeal cases,[64] currently the extensiveness of the action of *amparo* is a hallmark of the Mexican legal system.[65] Against the resolution of the FCAJ just described above, Rimsa filed an *amparo* suit, with arguments primarily related to the correct application of the law and, in addition, some arguments related to due process of law and the constitutional right of no retroactivity.

Both the first and the second arguments referred again, to the extension of the term of protection of the patent basis of the infringement action. These were similar to the arguments presented before the FCAJ.

Another argument, was related to the fact that the infringement procedure should not be resolved until the resolution of a procedure of nullity filed against the alleged infringed patent became final. This is because in that nullity case, an *amparo* could still be initiated. In this sense, Rimsa argued that the FCAJ incorrectly upheld the presumption of legality of the ruling, denying the nullity of the patent. The Circuit Court only considered this last argument. It based its determination, mainly on Article 366 of the Federal Code of Civil Procedure, which establishes that a procedure will be suspended, until a resolution in a different procedure is pronounced, in order to avoid contradictory resolutions on related issues. Then, the Circuit Court vacated the resolution, ordering the FCAJ to issue a new resolution in order to determine whether the decision regarding the nullity of the patent, would remain final. The Circuit Court also ordered the FCAJ to determine "the consequences that such determination has in the infringement procedure…."[66]

On remand, the FCAJ declared that the only consequence of this was that the infringement procedure would be suspended, "until the administrative declaration of nullity procedure in which the patent is filed ... is definitively resolved."[67] So, it stayed the effects of the infringement judgement until the time to fill an Amparo in the nullity procedure had elapsed. Therefore, everything remained the same. Against this FCAJ ruling, Rimsa unsuccessfully attempted another appeal that reached the Supreme Court.

## 4. Mexican Experience on Patent Term Extensions and USMCA. What is next?

### 4.1 Lessons from the Case

The litigation described above illustrates at least two problems. The first is a poor legislative technique that, when drafting Transitory Article Twelve of the Industrial Property Act, the legislators ignored or rejected basic principles about patents established by both the Paris Convention and the TRIPS Agreement, specifically the principles of national treatment and independence of patents. The second problem is the liberal and activist interpretation that FCAJ judges have taken with respect to this statutory provision.

Moreover, the criterion that left the defendant out of the litigation extending the term of protection of the patent is unfortunate and excessively formalistic due to lack of legal interest or standing. If the expectation to exploit a patent that passes into public domain, together with the investment made to carry out such exploitation is not of legal interest, it is

[63] In this specific case, doctrine usually called this procedure Amparo Cassation, because of its similarity to the cassation appeal of French origin. Fix-Zamudio y Valencia, 2009, p. 924.
[64] Rabasa, 1955, pp. 75 y 103.
[65] Burgoa, 2009, p. 145.
[66] Amparo 245/2014 (2014) p. 76.
[67] Inconformidad 608/2015 (2015) p. 13.

worth asking what it is. In addition, during the infringement action, the defendant had no chance to defend himself against such extension with the argument of "*res judicata*." Therefore, this was not a fair or equitable procedure, as ordered by Articles and 41 (1), and 42 of the TRIPS Agreement. Moreover, there is a retroactivity issue, since we are dealing with a procedure that begins with a motion for preliminary measures filed on June 15, 2006, but the IMPI did not change the term of protection of the patent until July 20, 2006.

Even if the case seems to suggest an apparent winner, in truth, there were no winners at all. Legislative misfortunes were not resolved at the jurisdictional sphere. The defendant, obviously lost the infringement litigation, but the winning party did not do well either, since the principles of independence of patents and national treatment were violated to its eventual detriment. At the end of the day, Takeda obtained a shorter term of protection than Mexican nationals who filed an application on the same day the plaintiff did.

This and other similar litigations could have been avoided from the beginning at the legislative level. If the intention was to protect those inventions which otherwise would not meet the novelty requirement, Congress should have granted them the 20 years established by Article 23 of the Industrial Property Act and not subject their term of protection to uncertainty. If that had been the case, there would be two winners in this case, not two litigants.

The lesson here is that statutory provisions allowing extensions, or interpreted so as to allow extensions on the term of protection of patents, create uncertainty and also add an unnecessary burden on patent offices. At the time of this litigation, IMPI had to create a new administrative division in order to deal with numerous motions to extend the term protection based on Transitory Article Twelve of the Industrial Property Act. The problem was finally solved by time. Today, there are no more patent term extensions in the Mexican legal system. Transitory Article Twelve was applicable only to patents filed in Mexico within a year after the Industrial Property Act came into force in 1991.

4.2 USMCA Patent Term Adjustments.

The Mexican legal system faces a greater problem that will not be resolved over time: the new USMCA intellectual property chapter. This chapter was copied almost verbatim from the intellectual property chapter of the Trans-Pacific Partnership Agreement (TPP).[68] Chapter 20 of the USMCA contains provisions establishing patent term "adjustments" in two not well-defined scenarios. The first one is when "there are unreasonable delays" in the issuance of a patent.[69] The second is for pharmaceutical products when there is an "unreasonable curtailment of the effective patent term as a result of the marketing approval process."[70] As the above litigation showed, both scenarios assure uncertain, complicated, and burdensome patent term adjustment procedures.[71]

While there is an argument that looser definitions in trade agreements can open several modes for implementation, the more than 60 pages of intellectual property Chapter 20 of the USMCA has been characterized in the opposite way, as defining in detail a broad range of domestic intellectual property standards.[72] Chapter 20 does not appear to be

[68] Hughes,2017, p. 493.
[69] USMCA, article 20.44 (3).
[70] USMCA, article 20.46 (2).
[71] Kilic, 2014, p. 44.
[72] Weatherall, 2016, p. 261.

regulating trade, but dictating domestic intellectual property law.[73] However, it is reasonable to assume that those patent extension provisions, were deliberate imprecisely to overcome political interest and trade negotiations.[74] Accordingly, if we take the first argument, on those patent extension vague terms, the door is open for the Mexican Congress to implement them narrowly in the Mexican Industrial Property Act. A good example is the U.S. Patent Act itself, which limit time extensions to five years in cases of marketing approval delays.[75] Those lengthy U.S. statutory provisions are very specific, unlike most statutory provisions in the Mexican Industrial Act. Nevertheless, those U.S. provisions are not implementing any international treaty, but creating the later exported extension of the patent term. Therefore, when drafting patent term extensions, it would be helpful for the Mexican Congress to look at the U.S. Patent Act. While the language may be imperfect, well-crafted statutory provisions, specific and restricted, give less deference to judges' interpretation.

Patent term extensions were the result of lobbying efforts by the U.S. pharmaceutical industry. The problem for them is that the Food and Drug Administration (FDA) requires marketing approval processes in order to assure safety and effectiveness of medications. This approval normally varies from eight to twelve years.[76] However, in order to protect the ideas and research behind new medications, pharmaceutical companies have to file applications for patent protection at the very beginning of the research, when they have not even started the marketing approval process. In addition, the 20 years term of protection established by article 33 of the TRIPS agreement, begins at the patent application filing date. Therefore, the argument for patent term extensions is to compensate such delays that would means shortening periods of exclusivity.

Obviously, the next step would be to incorporate patent term extensions in bilateral trade agreements, in the failed TPP, and now in the USMCA. That is perfectly understandable from the pharmaceuticals point of view. However, those patent term extensions as defined by USMCA do not include several safeguards existing in the U.S. legal system. When the U.S. Congress amended the Patent Act through a reform called the Hatch-Waxman Act, it tried to balance interests of brand pharmaceutical companies and generic producers.[77] That is why the U.S. Patent Act provisions are somehow more balanced than USMCA adjustment term provisions. The Hatch-Waxman Act establishes extensions on the patent term of protection in order to compensate for a portion of the term of protection lost when pharmaceuticals seek FDA marketing approval.[78] However, it also establishes the Abbreviated New Drug Application Procedure (ANDA), which allows generic medication producers to rely on original brand drugs safety and efficacy data after data exclusivity rights have elapsed.[79]

Like the USMCA, the Hatch-Waxman Act provides extensions on patent term of protection and data exclusivity of 5 years for safety and efficacy data for big brand pharmaceuticals. However, unlike the Hatch-Waxman Act, the USMCA does not guarantee to producers of generics the use of a brand's data once the exclusivity time has elapsed, nor does it offer any abbreviated marketing approval procedure. This lack of incentives to

[73] Weatherall, 2016, p. 260.
[74] Walker, 2001, p. 203.
[75] 35 U.S.C. §§ 154 – 156.
[76] Moberg, 2014, p. 238.
[77] Cardenas-Navia, 2014, p. 1304.
[78] Cardenas-Navia, 2014, p. 1312. *See also* 35 U.S.C. § 156
[79] Lyengar, 2015, p. 668.

produce cheaper generic medications in the USMCA may create an imbalance not present in the U.S. legislation.[80] In the case of Mexico, even before the USMCA the situation has been quite different. Except for the litigation revisited in this article, the Mexican legislation does not provide for patent term extensions, nor does it provide for data exclusivity. However, pharmaceutical companies manage to sue producers of generic medications when they use their clinical data in order to get marketing approval. The legal base of those litigations is established on vague provisions of data protection and unfair competition contained in the TRIPS Agreement article 39(3) and NAFTA article 1711(5).[81] The Mexican Congress has not implemented those provisions in national legislation. Therefore, some judges apply those provisions directly because they consider international intellectual property treaties as self-executing. Unfair competition is a broad concept open to litigation. Again, it would be useful for the Mexican Congress to look at the U.S. Hatch-Waxman Act when implementing USMCA.

The balance is important in order to secure cheaper generic medications to the population. Local populations will have restricted access to medication and the Mexican government will have to increase the budget to provide such medications, in the best-case scenario.[82] However, this continues to be a legal matter, and the worries and pronouncements of developing countries, such as those reflected in the ambiguous and useless Doha Declaration on TRIPs and Public Health,[83] will not prevail over legal definitions and developments.

### 4.3 Striking Unbalances. Intellectual Property and Investor-State Arbitration

Adding more complexities, article 14.1(f) of the USMCA establishes intellectual property rights as covered investment. This expressly opens the door for right holders to initiate investor-state dispute settlement arbitration procedures. These investor-state arbitrations, when filed by intellectual property right holders, are often used to challenge domestic court decisions,[84] ranging from infringement, annulment or, as in this case, those denying patent term extensions. Even statutory provisions could be subject to review by these arbitral tribunals. Surprisingly, some of them have refrained themselves from having "appellate jurisdiction" over national courts, but others have not. Those arbitral awards have no binding force for subsequent cases, and thus cause uncertainty about the scope of their decisions. In this regard, pharmaceutical companies have been criticized for using these dispute settlement procedures in order to destabilize "existing explicit and implicit understandings…."[85]

This is a perfect cocktail for uncertainty in intellectual property litigation, especially regarding the term of protection of patents. If, as shown in this article, ordinary litigation can be uncertain, having investor-state dispute settlement procedures will bring even more uncertainty about USMCA principles for extending patent terms of protection. The result will be that any extension of a patent term will never be enough. Vague and overbroad principles, normally present in investor-state dispute settlement arbitration and terms like "fair and equitable treatment," "creeping expropriation concepts," "legitimate expectations," and

[80] Shepherd, 2016, p. 23.
[81] Lindner and Morante, 2018, p. 338.
[82] Weatherall, 2016, p. 265.
[83] Kilic, 2014, p. 31; Sell, 2011, p. 469-470.
[84] Gathil and Ho, 2017, p. 429.
[85] Gathil and Ho, 2017, p. 430.

others will mix with vague USMCA patent extension principles like "unreasonable delays," or "unreasonable curtailment" of expectations. The result could be the doubling of patent terms of protection as a legitimate expectation.

The dispute of *Ely Lilly v. Canada* is an example of how Canada has experienced this kind of intellectual property investor-state dispute settlement arbitrations. In this case, Ely Lilly challenged the invalidation by Canadian courts of two medication patents through the application of a rule called the promise utility doctrine. The arbitral tribunal ruled in favor of Canada. However, the ruling left the door open for arbitral tribunals to review judicial decisions:

> …the Tribunal emphasizes that a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of the national judiciary. It is not the task of a NAFTA Chapter Eleven tribunal to review the findings of national courts and considerable deference is to be accorded to the conduct and decisions of such courts. It will accordingly only be in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, that it will be appropriate for a NAFTA Chapter Eleven tribunal to assess such conduct against the obligations of the respondent State under NAFTA Article 1105(1).[86]

In recent years, pharmaceutical companies have triggered a new wave of investment arbitration procedures.[87] The characteristics of investment arbitration pose new problems not present in national litigation. There is a secrecy in these procedures,[88] arbitrators do not necessarily know the intellectual property law of the host country and are not accountable under any national law; and, when speaking of an arbitral procedure over a medication there is always a component of public health and access to medicines. Perhaps, the most striking problem is the unequal access to justice that generic producers are going to face. At least in the case of Mexico, these generic companies are usually national companies and not considered foreign investors.

Another issue is the standard of review. It comes from a principle present in all investment treatments, called fair and equitable treatment. This is an open concept and if a host country does not comply with the investor's legitimate expectations, it is in violation of this fair and equitable treatment. In this regard, there is an argument that establishes that the content of intellectual property in international agreements creates a legitimate expectation in the investor.[89] After all, if the host country is a member state, it is reasonable that the investor may assume the application of the principles of those international treaties. The problem is that those agreements are deliberately written in vague terms in order to provide member states room for maneuvering at implementation. This makes me think that the ambiguous way in which adjustment provisions in the USMCA are written may pose a huge problem under this argument.

This could be a perverse mechanism incentivizing pharmaceuticals to re-litigate what they lose in domestic courts.[90] Considering this, Canada and the European Union excluded

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[86] ICSID, *Ely Lilly v. Canada*, Case No. UNCT/14/2 , March 16, 2017. Available at: http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf.
[87] Vadi, 2015, p. 25.
[88] Samples, 2019, p. 140.
[89] Vadi, 2015, p. 61.
[90] Gervais, 2019, pp. 290-291.

domestic intellectual property jurisdictional resolutions from investor-state dispute settlement arbitration procedures in the Comprehensive Economic and Trade Agreement (CETA).[91] This could be a very positive thing in the USMCA, but given the poor role of Mexican negotiators, perhaps they did not even realized the consequences of what they were accepting.

In fact, during negotiations for the USMCA, Canada withdrew entirely from the investor-state dispute settlement procedures. Perhaps this would also be a wise decision for Mexico. The expectation for Mexico was to attract foreign direct investment, but this is more about the retirement of intellectual property royalties. However, it seems that Mexico needs more foreign direct investment, and that is why it overlooked the analysis of the consequences of investor-state dispute settlement procedures and intellectual property.

The USMCA has already been signed, and at this stage of the process, in which the congresses of the countries involved are supposed to approve the treaty, the Mexican legislators should pay special attention to patent term extension provisions, to past Mexican experiences on the subject, and also to the possible intellectual property investor-state dispute settlement arbitrations. If the Mexican Congress agrees on the effects of such a mixture, then it should consider increasing the budget of the IMPI, and the FCAJ in order to deal with those patent term extensions. Moreover, it should consider the budget needed to provide affordable medicines for people and to the money needed to honor possible intellectual property dispute settlement arbitration awards.

## 5. Conclusions

Provisions extending patent term of protection can be burdensome and problematic to apply. In the case of Mexico, those expenses are imposed on the IMPI and also on the court system. Private actors also have disadvantages, starting with expenses related to litigation as well as the uncertainty about patent terms of protection.

Past experiences, like the application of Transitory Article Twelve of the Industrial Property Act have shown the uncertainty and the burden caused by these provisions. It would seem that although the people have given a temporary monopoly to inventors in order to encourage innovative activity, not having a clear period of time for such exclusive rights, unbalances the equation. After all, the Mexican Constitution has established intellectual property rights for "limited times."[92]

If the USMCA is approved by the Mexican Congress, patent term extensions and investor-state dispute settlement procedures are problems that have probably not been envisioned by Mexican negotiators. Therefore, the obligation is on the Congress to analyze and evaluate these contingencies. Obviously, the economic impact of USMCA on the Mexican economy is huge, so the treaty will undoubtedly be approved. Therefore, it is in the implementation phase when measures can be taken to counteract the negative effects. Perhaps, defining the implementing statutory provisions well is the answer. Specifying a reduced number of specific cases for patent term adjustments, establishing exactly the period of time to be added, increasing the burden for the applicant to those adjustments. Or perhaps, giving right holders what they do want would be a solution.

[91] Gervais, 2019, p. 294.
[92] Mexican Constitution, art. 28, p 10.

The important point for Congress, is to know what is about to happen and debate over it. It is my perception that negotiators do not realize what they signed, nor does Congress realize what is about to approve or implement. The subject should be on the table in order to deal with successful implementation into the Mexican legal system.

References


Abbott, Frederick *et al.* (2007): *International Intellectual Property in an Integrated World Economy* (Nueva York, Aspen Publishers).

Andrews, Damon (2011): "Why Patentees Litigate", *Columbia Science and Technology Law Review*, vol. 12, pp. 219 – 254.

Burgoa, Ignacio (2009): *El Juicio de Amparo* (México, Porrúa, forty-third edition).

Cardenas-Navia, Jaime (2014): "Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration", vol. 29, pp. 1301-1382.

Correa, Carlos (2007): *Trade Related Aspects of Intellectual Property Rights* (Oxford, Oxford University Press).

Ersling, Jay A. and STROVE, Frederik W. (2015): "A Framework for Patent Exhaustion from Foreign Sales", *Fordham Intellectual Property, Media & Entertainment Law Journal*, vol. 25, pp. 499 – 535.

Farrand, James R. (2006): "Territoriality and Incentives Under the Patent Laws", *Berkeley Technology Law Journal*, vol. 21, pp. 1215 – 1291.

Fix-Zamudio, Héctor and Valencia, Salvador (2009): *Derecho Constitucional Mexicano y Comparado* (México, Porrúa, sixth edition).

GATHIL, James and HO, Cynthia (2017): "Regime Shifting of IP Lawmaking and Enforcement from the WTO to the International Investment Regime," *Journal of Law Science & Technology*, vol. 18, pp. 427- 463.

GERVAIS, Daniel (2019): "Intellectual Property: A Beacon for Reform of Investor-State Dispute Settlement," *Michigan Journal of International Law*, vol. 40, pp. 289-325.

GOLDSTEIN, Paul (2008): *International Intellectual Property Law* (New York, Foundation Press, second edition).

HEMPHILL, C. Scott and LEMLEY, Mark (2011): "Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act," *Antitrust Law Journal*, vol. 77, pp. 947-989.

HUGHES, Kelly (2017): "Trans(parency) Pacific Partnership: The Downfall of the TPP?", *Colorado Technology Law Journal*, vol. 15, pp. 487- 510

ILARDI, Alfredo and BLAKENEY, Michael (2004): *International Encyclopedia of Intellectual Property Treaties* (Oxford, Oxford University Press).

KHOURY, Amir (2012): "The End of the National Patent Office", *The Intellectual Property Law Review*, vol. 52, pp. 197 – 240.

KILLIC, Burcu (2014): "Defending the Spirit of the Doha Declaration in Free Trade Agreements: Transpacific Partnership and Access to Affordable Medicines", *Loyola University of Chicago International Law Review*, vol. 12, pp 23.

LAPENNE, Juan (2010): "Patent Cooperation Treaty", *Journal of the Patent and Trademark Office Society*, vol. 92, pp. 192 -207.

LEMLEY, Mark A. and MOORE, Kimberly A. (2004): "Ending Abuse of Patent Continuations", *Boston University Law Review*, vol. 84, pp. 63-123.

LINDER Lopez, Hedwig and MORANTE Soria, Manuel (2018): *El Uso Estrategico de las Patentes Secundarias y otros Instrumentos en el Sector Farmaceutico: la Experiencia Mexicana* in BECERRA Ramirez, Manuel and MARTINEZ Olivera, Roberto (2018), *Industria Farmaceutica, Derecho a la Salud y Propiedad Intelectual: el Reto del Equilibrio* (Mexico City, UNAM).

IYENGAR, Vikram (2015): "Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?" *Journal of the Patent and Trademark Office Society,* vol. 97, pp. 663-690.

MCJOHN, Stephen M (2003): *Intellectual Property* (Nueva York, Aspen Publishers).

MAHNE, Kevin (2012): "A Unitary Patent and Unified Patent Court for the European Union: An Analysis of Europe's Long Standing Attempt to Create a Supranational Patent System", *Journal of the Patent and Trademark Office Society,* vol. 94, pp. 162 – 191.

MARKHAM, Wesley (2011): "Terminal Illness: Curing the Patent Term Using Empirical Analysis of the Patent Globalization", *New York University Intellectual Property & Entertainment Law Ledger,* vol. 2, pp. 121 - 130.

MIGLIORINI, Robert A. (2007): "Twelve Years Later: Provisional Patent Application Filing Revisited", *Journal of the Patent and Trademark Office Society,* vol. 89, pp. 437 – 455.

MOBERG, Katrina (2014), "Private Industry's Impact on U.S. Trade Law and International Intellectual Property Law: A Study of Post-TRIPS U.S. Bilateral Agreements and the Capture of the USTR," *Journal of the Patent and Trademark Office Society*, vol. 96, pp. 228- 256.

MUELLER, Janice M. (2009): *Patent Law* (Nueva York, Aspen Publishers, third edition)

ODDI, Samuel (1987): "The International Patent System and Third World Development: Reality or Myth?" *Duke Law Journal,* vol. 1987, pp. 831 – 877.

PIL, Sung (2014): "Harmonizing Public and Private International Law: Implications of the Apple v. Samsung IP Litigation", *Journal of East Asia & International Law,* vol. 7, pp. 351 – 378.

PIRES, Nuno (2005): *The TRIPs Regime of Patent Rights* (The Hague, Kluwer Law International, second edition).

RABASA, Emilio, (1955): *El Artículo 14. Estudio Constitucional y El Juicio Constitucional. Orígenes, Teoría y Extensión* (México, Porrúa, second edition).

SAMPLES, Tim R. (2019), "Winning and Losing in Investor-State Dispute Settlement," *American Business Law Journal*, vol. 56, pp. 115- 175.

SELL, Susan (2011), "TRIPs was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP", *Journal of Intellectual Property Law*, vol. 18, pp. 447- 472

SHEPHERD, Joanna (2016), "Disrupting the Balance: The Conflict between Hatch-Waxman and Inter Partes Review," *New York University Journal of Intellectual Property & Entertainment Law*, vol. 6, pp. 14 - 45.

SHINALL, Michael (2012): "Priority and Disclosure: Challenges and Protections to Small Investors in a First to File World", *Journal of the Patent and Trademark Office Society,* vol. 94, pp. 362 – 400.

SOLOVY, Eric M. and KRISHNAMURTHY, Pavan S. (2017): "TRIPs Agreement Flexibilities and their Limitations", *George Washington International Law Review,* vol. 50, pp. 69 – 124.

TOBIAS, Peter *et al*. (2009): *WTO Trade Related Aspects of Intellectual Property Rights* (Leiden, Martinus Nijhoff Publishers).

VADI, Valentina S. (2015): "Towards a New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments," *New York University Journal of Intellectual Property & Entertainment Law*, vol. 5, pp. 5-83.

WALKER, JR, John M. (2001): "Judicial Tendencies in Statutory Construction: Differing Views on the Role of the Judge." *New York University Annual Survey of American Law*, vol 58, pp. 203- 239.

WEATHERALL, Kimberlee (2016): "Intellectual Property in the TPP: Not the New TRIPs", *Melbourne Journal of International Law*, vol 17, pp 257- 289

WIPO (2018): "PCT The International Patent System". Disponible en: http://www.wipo.int/pct/en/. Accessed: August 27, 2018.