

At the midway of the current administration of Mexico, the Mexican government was living its best moment in decades; qualified voices around the globe were assuring and cheering the financial, trade and politic reforms, which were announced by President Peña Nieto since the very beginning of his mandate, namely: eleven structural reforms needed to transform Mexico.

Nowadays, there are some voices of criticism that rapidly forgotten that during these last three years, Mexico achieved reforms that were unthinkable and some of them were even consider taboos in the past. Nevertheless, Mexico passed and is implementing structural reforms that fluctuate from energy to transparency; from telecommunications to criminal proceedings; from labor to education, from taxes to antitrust.

In addition to the obvious complexity of the internal undertakings to pass those reforms, the Mexican government also has the difficult task to adequate those new policies and bodies of laws with the present and coming international commitments of Mexico reflected in international treaties.

As the subject matter of this article is focused to innovation and intellectual property, I will refer only to the energy reform and coming international obligations that will impact towards intellectual property and transfer of technology.

The opportunity for the oil and gas industry.

On August 12, 2014, several legislations and regulations governing the energy constitutional reform were enacted, allowing, inter alia, foreign and private investment in the oil and gas sector, leaving behind 76 years of state monopoly.

This energy reform will certainly have a positive influence on Mexico's economic growth by allowing competition in the country's largest sectors, implying implementation and transfer of new technologies.

These new technologies will definitively have an impact on the amount of patents and related intellectual property rights filed in our country. Currently, the approximate number of patent applications filed in Mexico oscillates between 14,000 and 15,000 per year, most of them filed by foreign companies,

but it is not a matter of coincidence but due to the relevance of the gas and oils sector in Mexico, that precisely one of the largest amount of patents filed by nationals belong to the Mexican Petroleum Institute (PEMEX's R&D arm).

One of the most important purposes of the energy reform is to provide Mexico with the required technology and experience to exploit its natural resources, which will translate into a reactivation of technology-transfer not only with the Mexican Petroleum Institute but with other relevant related sectors.

Therefore, the reform will give a rise to intellectual property, which is one of the essential elements of influence in driving technology development and innovation that reflects in the modernization of enterprises and the competitiveness of a country's economy. For this purpose, Mexico also requires changes to the domestic Intellectual Property Laws and Regulations to properly fulfill the modernization of Mexico intended with this energy reform and others already implemented.

The opportunity for the intellectual property scheme.

Regarding, the Intellectual Property scenario, the current Industrial Property Law in Mexico was enacted back in 1991 and it was substantially modified in 1994. The Mexican statutory law for copyright was published in the Mexican Official Gazette in December 1996. Since then, there have been few amendments and reforms to the intellectual property laws and its regulations, as well, the very few changes in the Institutions have barely impacted the Intellectual Property System in Mexico. Needless to say these laws derived directly from the negotiations of the North American Free Agreement with the U.S. and Canada (NAFTA) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

There is no doubt that when NAFTA was negotiated and subscribed by Mexico, the internet was incipient, the value and impact of the internet for commerce and business was full of speculations; at that point in time the digital age, the biotechnology and nanotechnology started to be considered as a near future, but the implications and impact to the life of millions of people and the revolution to the manner to run businesses and commerce around the world were at that point in time only in the imagination of some visionaries, but not in

the drafters of NAFTA neither in the lawmakers in Mexico, that prepared the laws in Mexico to comply with the requirements of NAFTA and TRIPS at the time.

If the impact of the internet, the digital age and the new technologies were not accurate and seriously contemplated in the negotiations of NAFTA, much less there were considerations regarding the implementation of rules to govern the new relationships derived from the internet, the digital age, the new technologies and the vanish of the geographical borders for the increasing phenomenon of the globalization and the non-stoppable international commerce.

In short, after 1991 the few changes implemented in the framework of the IP are listed herein as follows:

- 1994 amendments to the IP law. (Preliminary injunctions introduced in the system).
- 1993 the Mexican Institute of Intellectual Property is created.
- 1994 NAFTA entered in force.
- 1995 TRIPS entered in force.
- 1997 and 1999 reforms to the Copyright Law
- 2001 amendments to the Federal Law for Administrative Proceedings provided original jurisdiction to the Federal Court for Tax and Administrative Affairs (FCTA) to review the decisions issued by IMPI.
- 2002 it is published the Decree on the Promulgation of the WIPO Performances and Phonograms Treaty
- 2009 the FCTA created the IP Specialized Bench (SEPI).
- 2010 and 2011 discussions for adopting the Anti-Counterfeiting Trade Agreement (ACTA).

- 2011 Online proceedings before the SEPI.
- 2012 Gratuitous Application of Justice in the copyright arena.
- 2013 The Madrid Protocol Agreement entered into force.
- 2013 Discussions to adopt the Trans Pacific Partnership.

In conclusion, the statutory law for Industrial Property and Copyright and its Regulations and even the Institutions devoted to IP in Mexico complied already with their objectives to fulfill the commercial, trade and technology needs of the country when they were enacted, however, there is no doubt that nowadays, the system requires an urgent review, when claiming damages derived from the violation of industrial property rights.

The factor of international treaties, the Transpacific Partnership TPP.

In November 2011 during the APEC meeting, Mexico manifested its interest to initiate consults to participate in the Transpacific Partnership (TPP). On June 18, 2012 during the G20 in Los Cabos, México, the countries participating in the TPP decided to invite Mexico to participate.

The TPP countries originally are: Brunei, Chile, New Zealand and Singapore, since 2009 the negotiations included U.S.A, Australia, Vietnam, Malaysia and, Peru. Mexico, Canada and Japan to be part of TPP.

The experts say that the eleven partners of the TPP will represent the 30 % of the world GDP, 19 % of the worldwide exports, 22 % of the worldwide importations and a market of 198 million of potential consumers without counting the U.S. population.

Since the very beginning, the leaders of the partners of the TPP expressed that said agreement will: *“be a model for ambition for other free trade agreements in the future, forging close linkages among economies, enhancing our competitiveness, befitting our consumers”*.

The implications of the TPP goes beyond the Mexican IP system, as it pretends

to support the creation of jobs, higher living standards and the reduction of poverty in the country members, but to those that are devoted to IP, as well as, the companies and individuals from the innovation and creativity economy, an efficient, enhanced, and improved IP system would be always welcome.

Regarding intellectual property, the original goal of partners of the TPP original was that copyrights, patents and trademarks will be effectively enforced and the perception was that the countries were negotiating an international agreement of last generation, in all aspects, including a higher standard of protection for the intellectual property than previous international agreements.

The terms, conditions and wording of the TPP remained confidential during more than two years; however, it is now public that the main topics regarding intellectual property are the following:

Non-traditional trademarks.

Madrid Protocol/International trademark applications.

Appellation of origin and geographic indications.

Efficient and prompt civil and criminal enforcement.

Effective customs measures

Pharmaceutical patents.

Agrochemical patents.

Copyrights and the digital era.

While writing this article, it was announced that on February 4, 2016, the eleven countries of TPP will sign the agreement in New Zealand, which will be the country in custody of the agreement. Therefore, the imminent integration of Mexico to the Trans-Pacific Partnership is a new and valuable opportunity to review and change its entire Intellectual Property System and adopt higher, and even more important, efficient standards of IP protection. In addition, the

impact in Mexico of this eventual international treaty is confirmed by precedents of the Mexican Supreme Court that place international treaties approved by the Mexican Senate in high value within the hierarchy of the domestic legal frame.

Chapter 18 of TPP hits the life science industry.

Although there are many implications in the IP arena derived from the TPP, negotiations, in this article, I will limit the comments to the impact to the life sciences industry. The Mexican Government just released a text of the final negotiations of the TPP and some specific issues such as regulatory data protection (RDP), patent linkage and patent term compensations will impact the Mexican legal system in connection with the life science industry.

I.- Patentability. Main issues of relevance for Mexico are the following concepts established in Chapter 18: “...each party shall make patents available for any invention, weather a product of process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application. “...each party that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new process of using a known product.” This wording and obligations established in TPP would help to shape the patent law in Mexico, to expressly recognize patentability of second uses of known products, as well as, to clarify patentability subject matter.

II.- RDP. The protection would be at least three years for new formulations, new indications or new methods of administration or at least five years for new chemicals. Parties may limit the period of protection for three and five years respectively. Currently, Mexico is granting “de facto” five years for chemicals, it will be interesting how the Mexican government will conciliate the possibility to limit to five years the term of protection while NAFTA states a minimum of five years of data protection for chemicals.

One of the most debated cases during the negotiations, the term of data protection for biologics; it was established for at least eight years or five years plus, consisting in “other” measures, recognizing the market circumstances also contribute to the effective market protection to deliver a comparable outcome

in the market.

Hopefully, in the case of biologics, Mexico will opt for the eight years period of protection instead of the five-plus scheme which has a wide range of discretion and interpretation. If this latter scheme of five “years plus” is adopted, unfortunately, we expect further litigation for the term of data protection for biologics.

An additional and positive inclusion within the treaty is that RDP protects against “similar products”, in this regard the treaty says that a pharmaceutical product is similar to a previously approved pharmaceutical product if the marketing approval, or, in the alternative, the applicant’s request for such approval, of that similar pharmaceutical product is based upon the undisclosed test or other data concerning the safety and efficacy of the previously approved pharmaceutical product or the prior approval of that previously approved product.

This will be the most difficult challenge for the implementation of the TPP, as practically our domestic law is silent about RDP, therefore, the implementation in the law will start from zero, and the range of discretion in deciding some particularities on the matter would make the difference in having an adequate protection or may trigger again litigation about interpretation of TPP, the eventual law or complaints about the inefficient application in the domestic law of the TPP’s obligations.

III.- Regarding the linkage regulation, the text allows Mexico to maintain their actual patent linkage which does not include use patents. Therefore, the Mexican Patent linkage will not be impacted very much by the TPP, although, there are positive issues such as the recognition of second uses as a subject matter patentability which obviously will help the entire enforcement of use patents and also would help to confirm the inclusion of these types of patents through court orders. However, it seems that the Mexican government prefers a patent linkage with the burdens addressed to the authorities (Mexican Patent Office and COFEPRIS) rather than to the patent holder and the applicant of the marketing authorization.

IV.- TPP contemplates patent term adjustments due to unreasonable delays in

the patent prosecution and unreasonable curtailment on the patent protection due to the regulatory processes; taking into consideration that our current law expressly limits the life term of a patent to 20 years as from the filing date, in this particular case, the Mexican IP and the Health Law should be amended as currently, the law expressly states that the patent term is non-extendable.

V.- There are transitional periods for some countries to be obligated to comply with the specifications of TPP, in the case of Mexico is five years for any case of RDP and four and a half for unreasonable curtailment in the life term of patent due to regulatory delays.

Finally, there is a multiparty scheme for the agreement to enter in force but in any event, the expectation is that TPP may be part of our legal system in Mexico within the next two years but notwithstanding the time, having in mind the hierarchy of international treaties in our legal structure, certainly TPP will shape the legal frame for the life science industry and entire IP Law in Mexico.