11. CHALLENGES AND OPPORTUNITIES FOR THE GENERIC PHARMACEUTICAL INDUSTRY IN THE USMCA

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ABSTRACT

Recently (August 27, 2018), Mexico renewed the North American Free Trade Agreement, now renamed the United States, Mexico and Canada Agreement (USMCA) with the final text approved by the Senate on 19 June 2019. In it, commitments were made to adapt legislation on intellectual property that will have a great impact on trade among the three countries. One of the industries being impacted the most is the pharmaceutical industry. Some of the most

C. EVERGREENING

There are countries where patents that do not offer significant advancement to the technique, or that are superficial (or sometimes sequential) modifications with the sole purpose of obtaining protection on the same product, are expressly prohibited.[9] It is true that on many occasions,

Notwithstanding the foregoing, pharmaceutical companies maintain that any improvement in medicines implies costly investment in additional research and development efforts that deserve patent protection.[16] In fact, protecting innovation is the main objective of the patent system. It is important to understand that, although secondary patents are certainly related to issues such as health care and the blocking access to generic drugs in the market, they are not the only important factors. Matters of economic competition, regulatory linkage system or market itself need-1.84 T4 heiss t coentard (t)-31 (e)0.7 (e)-s-7.7 (dd(e)-12.7 (d0.7 (gu)1

institutions. It is also important that the legal framework regulating the sector maintain a balance between the parties involved.

3. USMCA COMMITMENTS ON PATENT TERM EXTENSION

A. ADJUSTMENT OF THE DURATION OF THE PATENT BY UNREASONABLE DELAYS BY THE GRANTING AUTHORITY

In the current Mexican legislation, patents are granted for a non-extendable period of 20 years from the date of the application.[25] However, with the commitments under the new treaty USMCA, this will have to change. Patents may now enjoy an extraordinary period of term extension.

It has been established in the USMCA, if there are unreasonable delays in granting the patent, the patent holder can request compensation on the term of the patent to be adjusted for such delays. An unreasonable delay includes a delay in the granting of a patent for more than five years from

It is a reality that obtaining a patent and not using it can be considered as inequitable conduct or unfair behavio because it violates the very essence of industrial property law and economic competition law.

A limit, such as the one described above, would establish a balance between protection afforded to innovative companies through both patents and marketing approval, and avoid clinical data protection from becoming an instrument for blocking trade and the entry of generic pharmaceuticals products into the market.

5. USMCA COMMITMENT: LINKAGE

The linkage is the relationship between the marketing approval that an app.2s Tw -11.0.7 (i)-16 (t)-2.4 th aceut6ingnt prst8.7 (k)-3 3.3 (i)-2.7treutio iivelc coA lra prentla6(a)-5 (ii)-3 (t)-161

authority having heard arguments from any party that could obviously benefit or be affected from that decision. As a consequence, an applicant cannot obtain the marketing approval, even if the product does not infringe the patent, specially a product related to processes or drug formulation, pharmaceutical compositions, polymorphs, Markush type, doses, metabolites, etc (mentioned before) whose infringement mainly is based on the interpretation of claims.

A process where concerned parties are not involved and where there is no legal certainty as to how the IMPI and COFEPRIS interpret whether an application infringes a patent or not, is considered very biased and without a balanced legal basis.

B. FINDING BALANCE

In the current system, the concerned parties in the marketing approval process are not heard by neither IMPI nor COFEPRIS. Therefore, the only existing beneficiary of the linkage system is the patent holder, because once his patent is entered in the gazette, no one can obtain a marketing approval for a pharmaceutical product related to that patent.

Moreover, until now, there is no opposition system in Mexico before the granting patent authority, whereby the patentability of an invention can be questioned. Hence, the applicant of a marketing approval fo3.7 (d.)-ae9..tng ar57 (o)-11.3 (f) -1.snSl ( )-13 (t)-3.3]TJ -0. -ae9...6 (o)1.9 (0)-5.9BapTp37

Products with Therapeutic Equivalent Evaluation', also known as the 'Orange Book'.[40]

However, the FDA, for the marketing approval of a drug, does not analyze whether the patent is valid or not, nor does it interpret claims or consult with the United States Patent and Trademarks Office (USPTO). It is constrained to be an administrative authority in the assessment of the safety and efficacy of medicines.

Unlike the current Mexican system, in the US, there is no interpretation by authorities without intervention from the parties, leaving it in the hands of patent holders to act or not on a potential patent infringement of their pharmaceutical product.

The Hatch-Waxman Amendment establishes four possibilities when requesting a marketing approval. One of them, known as ´certification under paragraph IV' or also as ANDA IV[41], the applicant must notify the owner of the patent involved so that he can oppose the request for such marketing approval, and if after 45 days, a patent infringement trial has not been initiated, the marketing approval will be granted.

On the other hand, if there is opposition to the marketing approval, the potential granting of the generic authorization process will freeze for 30 months or the duration of the trial (whichever is shorter). With this system, a marketing approval can be requested at any tim.7h eqayste.7h ag aoteimt19.4 (ny)-5.3 ( )-6 2(y)-

- Encourage research, either from the government, such as project financing or private initiative with the collaborative research model, in order to take advantage of patentability reforms in their favour, as part of a process to move from imitative model to the innovative model.
- Efficient processes both in the granting of patents and in the process of marketing approval to avoid the granting of compensation for the term extension of patents, whose economic consequence falls on the public health system, as well as on the patients themselves who ultimately absorb the monopoly market costs.
- Establish temporary limits for the beginni

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patent could be lost, in such a way that

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