Expert Contributor
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The Future of the Linkage System in Mexico

Less than a month after the new Federal Law on the Protection of Industrial Property (LFPPI) was published in the Federal Official Gazette on Nov. 5, 2020, two proposals for amendments to the recently approved law were presented with the direct purpose of strengthening the linkage system of pharmaceutical patents in our country.

Specifically, the following proposals were presented:

- Initiative by Deputy Silvia Lorena Villavicencio Ayala and Deputy Porfirio Muñoz Ledo.
- The Draft Decree presented by Deputy Soraya Pérez Munguía and various Deputies of the Parliamentary Group of the Institutional Revolutionary Party (PRI).

It is not surprising that a few days after the publication of a law, proposals to reform it are presented, and what most caught my attention is that the deputies who presented these early proposals for amendments are the same ones who discussed, analyzed, and passed that same law.

In summary, both proposals sought the following:

1. to remove the patentability of new uses of known products
2. to limit the linkage system to active ingredients
3. to limit the linkage system to patents for pharmaceutical products approved by the Federal Commission for Protection against Health Risks (COFEPRIS)
4. to limit the linkage system to new chemical molecules, eliminating biotechnological products

On previous occasions, I have written and analyzed the linkage system in depth, so, on this occasion, I will limit myself to defining it generally as the system to avoid the granting of sanitary registrations in violation of current patents that protect pharmaceutical products, namely: active ingredients, formulations (by jurisprudence of the Supreme Court of Justice) and indications (by analogy with the jurisprudence of the Supreme Court of Justice); only process patents are excluded from the system for practical reasons (because the comparative analysis of processes would be endless), but not because they are patents of a lesser category.

I believe that what is proposed in these reforms violates the principle of Non-Discrimination of Patents, contravenes the guarantee enshrined in the Constitution regarding the rights of inventors and improvers over their inventions as well as general principles of patent law contemplated in the LFPPI itself, and the daily practice of the Mexican Institute of Industrial Property (IMPI).

No one doubts the value, relevance, and supremacy of economic, social and cultural rights, nor of the Human Rights recognized by international treaties and our Magna Carta, where the right to health and access to it stands out. However, in the case at hand, the proposed reforms do not suggest any adjective or substantive structure or method for greater or better access to health for Mexicans. Their only justification is the "limitation" of the rights of third parties in a system of legality that prevents the violation of exclusive rights, and all of this under the unfounded excuse that the current linkage system is a barrier to the entry of generic drugs.

Additionally, their corresponding preambles and background statements are based on false premises. The entire preamble is based on the fallacy that the linkage system is a barrier to generic drugs and that it has led to the abuse of patent holders. In this regard, it is mentioned that the linkage system only has the purpose of avoiding the granting of marketing authorizations in violation of current patents, which is why they are only a barrier for drugs that infringe or that violate third-party patents.

The only people or companies that could oppose the correct and proper functioning of a linkage system are those that intend or attempt to violate current patents, or circumvent the validity period of patents, since the system only serves to avoid this violation of exclusive rights. If the drug subject to approval does NOT violate the listed patent or does not fall within its scope, the generic drug marketing authorization must be granted.

Another false premise from which the reform proposals arise is that many of the listed patents are "secondary" patents of poor quality, ignoring, a priori and without any foundation, the patentability examination carried out by the IMPI. Such an allegation would have to be supported by decisions of administrative declaration of invalidity of patents. A patent is valid and is presumed valid according

to the applicable law, until proven otherwise. In this reckless and frivolous reform proposal, the patents granted by IMPI are accused of invalidity.

The National Supreme Court of Justice is accused of having erroneously interpreted articles 167 Bis of the General Health Law Regulations and 47 Bis of the Industrial Property Law Regulations in the jurisprudence for contradiction of thesis No. 389/2009 and it is intended to reiterate the same problem already overcome precisely by the interpretation of our highest court.

In other words, what is proposed is that, if the jurisprudence of the Supreme Court of Justice establishes that a regulatory precept is unconstitutional if it does not include formulation patents, the solution established by the proposals is to issue a law in which the unconstitutionality already declared by our Supreme Court of Justice prevails. In other words, the proposal insists on issuing norms already declared unconstitutional.

In the same way, I consider that the proposed reform would be unconstitutional for contravening the text of the TIPAT/CPTPP that establishes a linkage system intended to protect the patents of approved pharmaceutical products, since the topic of what pharmaceutical product — due to its nature, technical and legal definition — cannot be limited to the active ingredient has already been studied in law, not only in the aforementioned jurisprudence of the Supreme Court of Justice, and the many judicial precedents, but in the definition established in the General Health Law and international treaties signed by Mexico.

Therefore, the limitation sought by the law proposal, regarding limiting the linkage system to a patent of active principle, would be in violation of international treaties and various federal provisions of the General Health Law and the Industrial Property Law.

The definition and interpretation of a pharmaceutical product and its patents is not an arbitrariness of the Supreme Court of Justice, as the reform proposal disrespectfully suggests, but derives from definitions established in various international treaties, federal laws and the Mexican pharmacopoeia itself.

The proposed reforms would violate the rights acquired by all the patents that have been included in the allopathic medicines gazette of motu proprio by IMPI and at the request of their holders.

There will be no doubt for the reader that the undersigned is against said legislative reform proposals. Although it is now forgotten, similar proposals arise from time to time, especially as the discussion and promulgation of the regulation of the LFPPI is approaching, since the fifth transitory article of the LFPPI itself establishes that the IMPI, together with COFEPRIS, will participate in the establishment of the corresponding technical collaboration mechanism for inventions in the field of allopathic

medicines and this mechanism will become effective 120 business days after the publication of the Law.

This term has already been fulfilled for a long time and the draft regulation circulated by the previous administration of IMPI was left unfinished, it was said, due to the issue of the linkage system. The new administration of IMPI, now led by José Sánchez Pérez, is taking up the issue, so there is no doubt that proposals or voices similar to those criticized in this article will reappear again to influence the mood of the new administration in the elaboration and promulgation of the new regulation. However, as can be seen from this article, in my opinion, these proposals only seek to destroy what has been built over more than 20 years since the establishment of the linkage system in Mexico.