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The current negotiations for the Trans-Pacific Partnership (TPP) provide Mexico with a not-to-be-missed opportunity to review the country's intellectual property system. The partner of the life science practice of the most important IP law firm in Mexico discusses the challenges clients from the sector face in the market place and the possible measures to improve IP protection in Mexico.

Olivares began as an intellectual property (IP) boutique in 1969 and is today the most frequently awarded IP practice in Mexico, with a special focus on life science. Could you please introduce our readers to the firm and its most important recent milestones?

Olivares was founded by Sergio Olivares, who started the law firm with two attorneys and two technical experts. Fifteen years ago we started realizing that an increasing number of clients from the pharmaceutical industry were approaching us to help them enforce their patents. Olivares quickly became the first law firm in Mexico to start a life science practice with specialized human resources dedicated full-time to fulfill the needs of our clients in the sector. Today we have a staff of technical experts, who prosecute pharmaceutical patents along with litigators with a high degree of specialization in administrative proceedings, and expended our services into regulatory advice, administrative actions and legal litigations.

What started as a small IP boutique, is now a consolidated 160-staff one-stop-shop where it's not only about IP, but about developing a complete strategy to secure exclusivity for our clients on many fronts –within the regulatory environment, for their commercial strategy and even to create intelligence. And this 360-degree dedication has been Olivares' key differentiator over local competitors.

Mexico ranks seventh in Latin American and the Caribbean –behind Chile and Brazil— and 54th worldwide in the 2014 International Property Rights Index. How would you assess IP enforcement within the life science and pharmaceutical industry?

Mexico's IP law has not undergone relevant changes since 1994, when it was amended for the implementation of the North-American Free Trade Agreement (NAFTA). Whereas over this time we have experienced dramatic changes in the way we live and do business – from globalization to digital revolution passing through technological innovation – our IP law simply has not. Today we have the opportunity to update it, as Mexico is involved in the negotiations for the Trans-Pacific Partnership (TPP) with countries throughout the Asia-Pacific region, which imply important issues with regard to IP protection.

As IP experts, we have been hired by the Mexican Association of Pharmaceutical Research Industries (AMIIF) to represent them in the negotiation and over the past two years I have personally participated in all rounds. The three most important items in the spotlight are data package exclusivity for clinical trials, patent linkage and patent term restoration. So far it has been a very rewarding experience because my activities are very different from my usual routine – it's more about negotiation, government affairs and lobbying, as well as about providing our feedback to the Mexican representatives about the level of IP protection desirable for the country.

The TPP is expected to be signed by mid of 2015, so Mexico has now the opportunity to review its complete IP system to fulfill the obligations derived from the partnership, which we knew were going to be higher than the ones required by the NAFTA and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Besides the inevitable discussions, I strongly believe the current negotiations provide Mexico with the unique opportunity to overcome the current pitfalls of the IP legislation, improve the law and make it both more effective and efficient.

What is the most important challenge companies of the sector face in Mexico nowadays?

Today in case of patent infringement the most important challenge is the length of a cause of action. The first step of an infringement action implies presenting it before the Mexican Institute of

Industrial Property (IMPI), which – paradoxically – is also the institution that in Mexico issues the patents. Only few countries in the world have one and the same authority to issue and review a patent, and Mexico sadly is among them. In other countries, a court of law enforces patent law.

Also, the current legislative environment does nor provide a clear and established proceeding to exhaust all the options which arise during a patent infringement procedure; this means we often need to refer to other bodies, which, though, are not enacted to solve patent contentions. Last but not least, the patent holder is not entitled to claim damages until a final decision about the infringement is made, which can imply up to four stages of litigation. After this, three further stages can follow to claim damages. Hence, we are talking about twelve years of litigation – an eternity –, which, obviously, also require a long list of formal requirements to be fulfilled. Indeed, the infringer knows the times of justice in Mexico, so usually delays as much as possible the administrative procedure to avoid the civil one. This results in the patent holder most of the time either giving up or opting for a settlement.

What would be the ideal scenario?

The period of time would not be that bad, if the payment injunction against the infringer would be eventually fully effective or he out of the market. Albeit, in Mexico neither the one nor the other happens today. And the damages for our clients —especially if we are dealing with a blockbuster product –are immense. We propose to exonerate IMPI from the jurisdiction to solve contentious for patents: a civil or administrative court of law should decide their validity and enforcement, as the current system is unsustainable.

A further important milestone in the pharma industry has been the approval of the standard NOM 257 in December 2014, which regulates biotech and biosimilars. How do you assess the regulatory framework now in place?

I think the recently approved NOM 257 and the overall regulation in place for biotech drugs in Mexico is very solid. Both innovators as well as biosimilar producers welcomed it. Indeed, there are criticisms, but it was a good achievement, which places Mexico as a leader in the region in this field. It may be argued that there is still a lot of discretion, as drugs are reviewed on a case-by-case basis and this is something that should be avoided. Now the next step is its implementation; time will tell us if it is working.

What are some of the challenges clients from the healthcare and life sciences sector face you with?

Securing exclusivity is one of the most important issues we deal with. In the past health authorities granted marketing authorizations for pharmaceuticals when the applicant complied with the regulatory requirements, without reviewing possible violations of patent rights. As a result, more than 20 patented compounds were being infringed by different companies. We have successfully contested the non-publication of formulation and have obtained decisions from the courts ordering IMPI to include patents covering formulations and medical uses in the Linkage Gazette, which is published and updated every six months – and it has proven to be an effective tool. The amount of infringements almost plunged to zero.

For the future we have two important priorities. First, enforce the value of innovation and make IMPI distinguish between compounds and formulations, which is not the case today. Second, limit the amount of a patented drug imported under the so-called Roche-Bolar exemption. This provision allows applicants to import an amount of a patented drug to begin safety and efficacy and interchangeability tests to enter the market as soon as the patent expires. However, we often see that the product entering Mexico exceeds by far the amount required for approval. We exhort Cofepris and IMPI to implement clear guidelines and review each application on a case-by-case basis.

Looking ahead, where would you like to expand the services you provide within the life science practice in the future?

So far most of our clients are big pharma. We would like to expand our practice to mid-and-small sized innovative life science companies interested in entering or partnering up in Mexico. We are currently helping new companies establishing in the market providing them with advisory for their corporate structure, compliance, IP matters, legal responsibility and employment policies, amongst others.

The Mexican pharmaceutical industry is changing: in the past only international companies were innovators, while local companies focused on generic drugs. Today innovators are diversifying into generics, with new international players in the segment, as well as distinctive innovative local players. That being said, authorities are doing their best efforts to set a regulatory framework, which can create a balance and attract investment – and it’s definitely not an easy task. We believe the TPP provides a not-to-be-missed opportunity to review our entire law system to establish a ‘healthy’ IP system. I’m positive that better times and better opportunities are coming for Mexico, also thanks to the structural reforms the government has implemented.

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