Interview: Sergio Olivares – Managing Director, Olivares, Mexico

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Sergio Olivares, managing director at Olivares, explains the TPP's impact on the Mexican pharmaceutical industry's dynamism and Olivares' business proposal as a one-stop shop solution to fulfill all its current and future clients' intellectual property needs.

Olivares began as an intellectual property (IP) boutique in 1969 and is today the most frequently awarded IP practice in Mexico. Could you please give to our international audience an update about the operations of the firm since we met you two years ago?

My father founded Olivares in 1969 with two attorneys and two technical experts. The firm has been steadily growing since its inception and now it is composed by nine partners.

We have been developing and adapting our offering according to our clients' needs. In this sense, 15 years ago, we realized that an increasing number of customers from the pharmaceutical industry were approaching us to help them enforce their patents. More recently, we have expanded our offering into the corporate area taking advantage of the existing synergies with IP. As an example of these new services Olivares is currently working on a couple of initiatives to help its clients to monetize IP rights, particularly patents; Mexico has a lot of potential in this approach because a lot of national technology is not protected by patents due to the poor knowledge surrounding the need for IP rights.

We are diversifying and enlarging our operations to fulfill the needs of our clients and to keep up the pace with the latest industry trends in our business. Such success in our diversification strategy has been based on the existing synergies in terms of knowledge and procedures of our different divisions. As a consequence, Olivares is perceived as a disruptive firm that is fully capable of offering an integral and one-stop shop solution to its clients.

What have been the main accomplishments of Olivares during the last few years?

Since 2008, because of the global crisis, the world has drastically changed from an economic, social and political standpoint. As a consequence, IP practices have also had to adapt to such dynamism and Olivares has been highly creative in finding new ways to run its operations, being lawyers but also business people.

Some services provided by IP law firms have started to be considered, to a certain extent, as a commodity, especially in areas such as trademark filing, which is a relatively straightforward process. Therefore, we have found ways to add value by being innovative and proactive in our operations as we are changing the services and the way they are delivered. It is a reality that, if you are not able to keep pace with the industry trends, you are in danger of disappearing. So, our biggest accomplishment has been to ensure that our business model changes to remain in line with the latest industry trends and clients' demands.

Olivares quickly became the first law firm in Mexico to start a life science practice with specialized human resources dedicated full-time to fulfilling the needs of clients in the sector. How strategically important is the healthcare and life sciences industry within your entire business in comparison to the rest of the industry groups that you are serving such as IT, media and sports & entertainment?

Olivares has moved to different industries, creating one-stop shop solutions in all the areas in which we are active. We have been able to disrupt the classic legal firms approach and this strategy has been reflected in our operations. We have focused our efforts on promoting our new diversified and co-related areas.

With this being said, healthcare and life sciences are highly related to IP services, which is our historical business line. Indeed, our healthcare and life sciences division represents around 50 percent of our total revenues with a particularly strong demand for patents, regulatory and litigation services. Note that in pharma, chemicals, agribusiness, medical devices and other life sciences we estimate to make up around 30 percent of all patents. These sectors, and primarily the pharma sector, makes up 50 percent of all patent litigation in the country, and we are true experts

in both patent related litigation and also, importantly, administrative litigation, which is of course an ever-evolving area of law.

What is your footprint in the pharma and medtech industry?

We represent the world's leading innovator companies and have helped them establish stronger IP rights in Mexico than any other law firm or consulting firm has done. This is of course a big statement, but we can easily back it up with the successful initiatives that we have undertaken over the past decade. Two examples are our highly successful litigation strategies, that have taken literally a decade to come to fruition, that established patent linkage regulations in Mexico and that are in line with the provisions laid out in international treaties such as the NAFTA agreement. Furthermore, we have worked tirelessly to gain legal precedent to extend the terms for data exclusivity rights. We are registered lobbyists with the Mexican congress (the only IP firm in Mexico to be so) and we represent AMIIF (the Mexican Association of Pharmaceutical Research Industries), the lobbying group for innovator pharma companies doing business in Mexico. They trust us enough to have Alejandro Luna represent them in the many rounds of the TPP negotiations.

We believe we have done more than any other firm in Mexico for this industry, and are proud to serve a large number of the innovator companies in their fight against regulations and the generics market.

Mexico ranks 7th in Latin American and the Caribbean –behind Chile and Brazil— and 54th worldwide in the 2014 International Property Rights Index. As an expert in this area, what are the major challenges that you and your clients are currently facing from an IP perspective?

The path of development to continue enhancing the Mexican intellectual property framework is to maximize the standards of IP protection. Furthermore, Mexico is currently in the process of entering the Trans-Pacific Partnership (TPP) and, referring to IP protection, it will create some new challenges because the standards requested are higher. It is perceived that Mexico will sign individual agreements that are copies of the TPP agreement, with various countries that were involved in the TPP negotiations, regardless of whether the United States signs or not. This in turn will put more pressure on the government to modify IP related regulations so that Mexico meets its obligations to provide a regulatory system that meets the standards of these provisions.

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). Today Mexico has the opportunity to update it, as it belongs to the Trans-Pacific Partnership

(TPP) with countries throughout the Asia-Pacific region, which imply important issues in regard to the IP protection. As the leading law firm in this area in Mexico, what are your conclusions on that and how does it affect your operations?

Olivares has helped the government to establish the proper IP regulatory framework of the healthcare industry for a long time. Indeed, the Mexican Association of Pharmaceutical Research Industries (AMIIF) requested our services to represent them in the negotiation process to enter the TPP. We represented AMIIF in negotiation, lobbing and political activities; we have been involved in such process for more than two years. Even though the entrance of Mexico to the TPP is highly crucial for the country, it is not 100 percent sure that such economical agreement is going to be finally a reality. Thus, we need to be forward-looking forecasting both possible scenarios.

On one hand, if the TPP actually becomes a reality for Mexico, the country will benefit from the hard work that has been done during all the negotiation process to meet the TPP standards. Referring to the intellectual property chapter, it will be highly positive since IP protection standards will be maximized.

On the other hand, if the TPP does not finally happen for Mexico, we should take advantage of all the work that has been done alongside such process to improve its laws in terms of better IP protection for instance.

I would like to highlight that Olivares is actively participating and helping the government to advance in this direction and to take advantage of the situation, regardless of the final outcome regarding the entrance of Mexico to the TPP.

We have perceived an epidemiologic transition in Mexico with more focus on chronic diseases. Such diseases can be only properly targeted through biotech or biosimilars treatments and an important milestone in the pharma industry has been the approval of the standard NOM 257 in December 2014, which regulates this area. How do you assess the regulatory framework in this area?

The first time that the biotechnological products were officially recognized in the applicable legislation, General Health Law was on June 2009, defining a “biologic/biotechnological product” as any substance that: has been manufactured by molecular biotechnology; has therapeutic, preventive or rehabilitative effects;

On October 2011, the Health Law Regulations were amended to establish the requirements to approve biologics and biocomparables, an area which was previously poorly regulated. After over 5

years of development, within the legal framework which included an emergency NOM, in 2014 the Mexican Official Standard Rule (NOM) NOM-257-SSA1-2014 regarding biotechnological products entered in force on February 2015.

The Health Law Regulations (Chapter VIII, Biotechnological products, Article 81) determines that recombinant proteins, monoclonal antibodies, synthetic peptides, nucleic acids synthetic or from plasmids are to be considered as biopharmaceuticals and biomedicaments.

Mexican Standard NOM-257-SSA1-2014 is supported by at least seven NOMs which are considered as the basis of technical and scientific evaluation presented during the medicament registration, such that it allows the Committee for New Molecules (CMN) and the subcommittee for evaluation of biotechnological products (SEPB) to issue an opinion related to:

New biotechnological medicaments during their research and/or development stage;

New biotechnological medicaments with their research and / or development stages completed;

Biotechnological medicaments biocomparable both in development stage and completed studies;

Biotechnological medicaments that already have a marketing authorization and are in the process of extension;

Classification of biotechnological medicaments as innovative or biocomparable, and

Definition ofreference medicaments.

Although the efficiency of the regulation is under test due to its recent enactment, there are few cases of strong criticism in the impact on the safety, efficacy and quality standards in biologics and biocomparables, until now, the main complaints have been due to the inobservance of exclusive rights, namely: patents and data package exclusivity.

Given the complexity of a biotechnological product, a central part is the follow-up of the behavior of the same in the population, so that the implementation of a pharmacovigilance program that allows the detection, identification, quantification, assessment and prevention of possible risks derived from the use of medicaments in humans, in other words is has to be prepared in accordance with Mexican Official Standard Rule NOM-220-SSA1-2012. This matter is now in vogue in Mexico due to a recent scandal in the acquisition of lower standard products in the State of Veracruz, where the State Ministry of Health has been accused to provide lower standard products to children with leukemia.

There are some issues unaddressed that are equally important for the industry, although, we trust that the authorities are working in having high and competitive standards for these types of products.

How is Olivares innovating to improve its service in terms of response times, cost efficiency and constantly developing its knowledge of client needs?

We have been highly successful in updating and innovating our operations to expand our business' umbrella but we have also heavily invested in enhancing our IT systems to improve the delivering of our services. Thus, we have not just been able to fulfill the dynamic needs of our clients but also to improve our efficiency ratios based on IT capabilities and synergies between our broad divisions. Innovation has permitted us to offer integral, efficient and effective solutions.

What are the key competitive advantages that make you the provider of choice both for the industry and the public institutions?

One of our main competitive advantage is clearly the unmatched knowledge within our teams, which can be argued are formed by the best attorneys and engineers in the country, but moreover, our people get to work on the most complex cases in the country and thus are always at the cutting edge of legal and business knowledge.

Our flexibility in terms of how we have reacted and adapted our operations to the national challenges have also been a key differentiator; as aforementioned, Olivares has disrupted the classic legal firm's business model creating one-stop shop solution as well as lowering costs through synergies and IT capabilities.

What are the key objectives that you would like to achieve in the upcoming three years?

As managing director of the firm, ensuring that we are always providing the best solution to our customers is one of my main priorities; I want to position Olivares as the legal partner of choice of all current and future clients. In this sense, we continue developing our strategy to add more value to our operations both in terms of quality and efficiency. Such a business model allows Olivares to enjoy a healthy but steady growth supported by its high performing teams.

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