Santamarina y Steta Law Solutions – Alejandro Luna and José Alfredo Sedano, Lawyers – Mexico



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José Alfredo Sedano, lawyers at the leading legal firm of Santamarina y Steta, discuss the current legal challenges faced by companies in the pharmaceutical and healthcare sector in Mexico and urge for the amendment of the current regulatory framework.

How was the healthcare and life science practice started at Santamarina y Steta?

Alejandro Luna (AL): Santamarina y Steta's healthcare practice was established eighteen years ago. After the implementation of the North American Free Trade Agreement (NAFTA) in 1994, Mexico saw a lot of changes and many specialized regulations being implemented with regard to food, cosmetics pharmaceuticals, and medical technology. The firm started getting involved with an increasing number of regulatory cases, predominantly stemming from international trade customs, which made us realize the healthcare sector had a great potential and that we could provide a specialized legal service that no other firm was offering at the time. On matters related to health regulation, the majority of legal firms in Mexico have specialized in intellectual property (IP), rather than in the actual regulatory or legislative work.

Simultaneously, a trend could be noticed that moved from a traditionally regulated environment to a self-regulated one. This meant that further advice was demanded from different parties and, naturally, we began specializing and forming new talents. The process was initially challenging, as

for instance there was no real internal regulation within the regulatory authority, the Federal Commission for the Protection against Sanitary Risk (COFERPIS), which had previously been part of the Ministry of Health as a mere general directorate of this Ministry.

IP rights in Mexico are protected by a combination of national laws and international agreements. How well developed is this framework for the Mexican pharmaceutical and healthcare sector and what needs to be changed?

José Alfredo Sedano (JS): Current IP regulations are in definite need of amendments that can take into account technological advancement. For instance, it was not previously possible to produce molecules of minor dimensions as it is the case now. Yet, the regulations remained the same and this is causing major problems to the pharmaceutical industry, especially with patents. Technological advancement of this sort should be taken into consideration, however the timeframe can be expected to be rather extensive. Another main issue is that the Mexican Institute of Industrial Property (IMPI) is mainly focusing on the protection of active ingredients without taking the necessary actions in order to provide proper protection to processes, compounds and formulations. Furthermore, the lack of proper communication between IMPI and COFEPRIS with regard to the granting of new marketing authorizations and the possible infringement of IP rights continues to be an issue that is gradually being addressed, but at a pace which is insufficient to create a proper environment that can facilitate the launch of new products.

AL: The situation has gotten better in the past years, also because the IMPI and COFEPRIS jointly adopted the Orange Book process, called according to the FDA publication ‘Approved Drug Products with Therapeutic Equivalence Evaluations’, which identifies drug products approved on the basis of safety and effectiveness US under the Federal Food, Drug, and Cosmetic Act. However, both Cofepris and the IMPI are evidently underfunded and are lacking human resources. It will also be interesting to see how federal tribunals and administrative tribunals will evolve in the future, as five years ago they have created special sub-courts specifically dedicated to IP cases. Perhaps further specialized courts will or should soon be developed.

You work very closely with Cofepris on behalf of your clients to prepare and file the documentation required to obtain corresponding authorizations from health officials. What type of services does your firm offer and how would you assess the work of the Commission?

AL: Santamarina y Steta provides a wide range of services and advice across different areas. We advise on certifications for the entering of foreign pharmaceutical companies without the need of

establishing facilities in Mexico, good manufacturing practices (GMP) compliance, inspection visits and audits, administrative litigation, obtaining of import or export permits, as well as marketing authorizations, review of advertisement towards professionals and the general public, clinical trials and data privacy. In fact, as part of our participation with the International Pharmaceutical Privacy Consortium (IPPC), we have recently conducted a course on data privacy jointly with CANIFARMA (the National Chamber of the Pharmaceutical Industry) and CETIFARMA (the Council of Ethics and Transparency of the Mexican Pharmaceutical Industry).

Cofepris has evolved considerably throughout the years. They are now more efficient and are employing authorized third party consultants to relief their workload; they also work very closely with companies to promote both the industry as a whole and the specific products. All of this while keeping at heart their felt responsibility towards public health. As in all cases, there is always space for improvement but their timeframe for filings and other administrative processes has shortened drastically.

Since 2012, Mexico has been one of the first countries in Latin America to regulate biotech and biosimilar drugs and the Official Mexican Standard NOM 257 is currently under revision. How would you assess the current regulatory framework for the biotech and biosimilar sector?

AL: I do not believe the judicial authority is ready for this yet, as they have not developed the necessary expertise in the sector. The annual congress for the bar association has recently taken place in Puebla whereby Ministro José Ramón Cossío Díaz and various members of the Supreme Court of Justice concluded in a call for litigators to provide all the basic information and educate the Court, as they are currently lacking the competency to tackle this issue. Access to these specialty pharmaceuticals shall also become an issue for courts, especially since Mexico has strived to achieve universal coverage in its public health system and in providing the necessary medicine and pharmaceuticals, although it does have limited resources to acquire and offer such high-end pharmaceuticals.

Mexico is at a very interesting stage, as we are seeing the pharmaceutical sector shifting its efforts towards high specialty drugs. All of this has a lot to do with the change in demographics, which is altering the type of predominant diseases in the nation. Both genetic and infectious diseases are requiring the industry to adapt to patients’ needs and ensuring objectivity in these cases remains very important.

JS: The development in the biotechnology sector will be very interesting, as it is not possible to patent human or animal DNA which would eventually be required in the field.

What makes Santamarina y Steta the legal partner of choice for companies in the pharmaceutical and healthcare sector and what is your vision for the future?

AL: Santamarina y Steta should be the partner of choice for different reasons. First of all, we were one of the first firms to specialize in the health and life sciences sector, which made us witnesses of the different law alterations throughout the years. Secondly, our clientele encompasses areas in different yet relevant sectors – from biotechnology to medical devices, foodstuffs, transgenics, cosmetics, advertising and all types of health inputs. This enabled us to gather an expertise in the field that very few firms can offer. Additionally, we are able to provide a fully integrated team that is very well coordinated in related areas such as corporate, IP, litigation, customs and international trade, tax, among others.

JS: Most legal firms in Mexico focus on the practice of patents and do not specialize in legal advice for advertising or labeling, for example. It is understandably not very cost-efficient to seek advice from two separate legal entities for the same problem. Here at Santamarina y Steta we provide clients the exact solution that they need in all aspects and this represents a great advantage for clients.

AL: In the future, I aim to see the firm more specialized on intellectual property and biotechnology. It is a very competitive market but we are very ambitious. I also believe the firm can become more efficient with daily filings. We are currently handling one of the first class actions on transgenics and I am very curious to see how far we will get on the litigation side.

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