

Interview with Maximiliano Santa Cruz, National Director, National Institute of Industrial Property (INAPI)

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Could you tell us about the circumstances that lead Chile to create a regulatory body such as the INAPI back in 2008, which compared to your neighbouring countries like Argentina who created their IP regulatory body in 1996, was a very late start for Chile?

The institute is about to be two years old on January 1st 2011 and since its beginning it replaced a very old industrial property department that was employing around eighty people. The department was rather small and it was mostly dealing with the registration of patents and trademarks. Therefore in 2008 INAPI was created to be a registration board and also a tribunal, and the new law gave us several other mandates: getting involved in the policy issues giving advice to the President in IP matters, dealing with international affairs by recommending to the President on adhering or not to international treaties and also doing a strong work on technology transfer and dissemination of knowledge, so we now have a very important department for transferring knowledge. The draft of the legislation for the creation of the Institute was rather old - from the beginning of the 1990s - so it was a long awaited process. In my opinion it may have taken so long to approve because the government was busy negotiating Free Trade Agreements, among others, with the EU and USA and afterwards got involved in two implementation laws - one dealing with copyright enacted in last April and the other one in 2005 dealing with industrial property. That is in my view, why the institute was left behind for some years but fortunately it has been created and is now operating

with around 180 employees. INAPI is autonomous from the Ministry of Economy but it maintains a very close relationship with it and aligns itself with its policies. We are not self-financed, but we have our own budget which is part of our autonomy.

Since your appointment as Director for INAPI in October of 2009, what have been the main milestones and achievements of the institution?

The main milestone for INAPI has been the preparation of the national phase of PCT (Patent Cooperation Treaty) which we are actually executing at the moment, and also putting a lot of effort within our transfer of knowledge division that has had fantastic performance recently. Today we have three publications on dissemination of knowledge: in technology in the public domain, technology for the reconstruction after the earthquake and the tsunami and the third one on important Chilean productive sectors like horticulture, mining industry and aquaculture. We are also organizing seminars in intellectual property and dealing with patent databases and also reviewing the current legislation in the domain. Before that we worked on trademark guidelines that we published for comments last September on our website in a very transparent way very much appreciated by the public, and as a next step we are preparing the patent guidelines. In addition, we are preparing a compilation of IP legislation with more than twenty norms taken from the industrial property law and the copyright law together with the existing legislation for appellation of origins, agriculture and health. Thus we put all the legislation together and it will be published very soon. Another initiative I am very proud to present to you of is a book we launched several weeks ago made from historical documents dating back to 1840. We have launched it together with the Minister of Economy as to present to Chileans the history of industrial property in the country. Another transformation happening nowadays in INAPI is the renewal of the IT infrastructure with the change of platform to a new one called IPAS that is provided by WIPO.

Most of the international innovator companies mentioned the infringement of their patents of both products and processes as one the main obstacles for them to further invest and bring innovation to the country. In this context, what are your main priorities for strengthening the regulatory environment for patents? What is your plan of action to approach your main agenda?

INAPI is not an enforcement agency therefore all issues dealing with patent infringements should be dealt with in courts. Nevertheless, in 2005 some changes were made to the industrial property enforcement system deciding that patent infringement trials should have a faster procedure in the court, technically not lasting more than six months and special preliminary injunctions could be dictated.

Unfortunately I cannot give you numbers of lawsuits happening in the country or companies

involved in them but my impression is that companies are not using the system as much as they could. Specifically on pharmaceutical issues, the government is currently discussing improvements of the system through the creation of an inter-ministerial committee made of representatives from the Ministries of Foreign Affairs, Economy, and Health together with the ISP, INAPI and the General Directorate for International Economic Relations. The committee is dealing with implementation issues in the pharmaceutical sector and ways of improving them, being at the point of analysing the existing legislation, but with no concrete results yet.

Also on enforcement issues, we have a current agreement with the customs agency and we are planning to sign an agreement with the "IP brigade" - the unit in charge of IP enforcement inside the national police force. For that reason I think we can do a very good work in terms of education: offering news, statistics, and information about what to do when a patent is infringed and so on. In January of 2011 our webpage should have systematized information on enforcement issues.

What steps has the government taken to ensure respect of intellectual property? Has there been a shift from the previous administration to the current one?

The creation of INAPI was a major move in terms of educating on the importance of IP, including its protection and enforcement. The establishment a few years ago of the IP Brigade, within the national police force, was also a step in the right direction towards going from words to action. The current administration has also put up a working group on illegal trade which should analyze the problem, among others, from an IP perspective.

How can the linkage between the registration of pharmaceutical products and their commercialization be strengthened? Are you working together with other governmental institutions, such as the ISP, and ministries to improve this situation?

The inter-ministerial committee that we are part of is also looking into the issue of a possible linkage between the two stages of product lifecycle. In my opinion our responsibility today is to participate to the work of this committee the best we can and to find ways to improve the system. We are committed to ensure the best environment for the companies operating in Chile. Chile is part of the TRIPS agreement, a Free Trade Agreement with the US and an Association Agreement with the European Community, amongst many other international treaties. How have these treaties played a role in regulating the Chilean pharmaceutical industry? What is INAPI doing to make sure that the directives of these treaties are abided by?

We committed to several obligations in these treaties, many of them impacting directly on the pharmaceutical sector, such as extending the protection of patents in case of delays which we are already running in INAPI and ISP. Furthermore, the treaties with the US and EU influence to a great

extent the Chilean patent system, and on top of bringing to the country higher norms and standards, it also definitely brings transparency to the system while also improving procedures and processes.

Is INAPI planning to develop a list of pharmaceutical products that are currently under patents here in Chile, comparable to the Orange Book of the FDA in the US, in collaboration with the ISP as a means to improve the transparency of patented pharmaceutical products in the country?

According to what I know the Orange book is not an official list produced by FDA but directly fed by the owners of the patents themselves. They are given the option of introducing their patents into the book if they choose so. Anyhow, we do not have a plan of developing such a list of pharmaceutical patents in the Chilean market with the ISP; nevertheless we are aware of the concerns coming from the generics industry. At the moment we are analyzing data to assess the situation and we are in contact with all the important players in the industry as to get an unbiased opinion.

What is INAPI doing to improve the image of the country's pharmaceutical industry as a means to bring Chile the recognition it deserves as an innovation-based economy?

Today, as a young organization, we are focusing on providing information and knowledge about the system to actors such as SMEs, international companies, universities, researchers and the larger public in general. In addition, we are improving our procedures in order to become better, faster and cheaper. Thirdly, we are already working on our main legislation and some law guidelines. As a last point, the IT platform is going to be an important change for INAPI in terms of bringing us closer not only to Chilean readers but also to foreigners.

Overall in Chile the IP environment still needs improvements. Nevertheless, Chile is one of the countries where most trademarks are filed and with respect to patents the numbers are increasing every year.

What is your final message to the readers of Pharmaceutical Executive about the engagement of INAPI to ensure the highest standards of protection for intellectual property and therefore foster innovation in Chile?

Aside from what I already mentioned above, we are also working in collaboration with the Innovation Agency within the Ministry of Economy in order to make improvements on the innovation side. I can assure you that INAPI is going to be the best IP agency in Latin America in the future; some surveys made by IP magazines already rank us very high after less than two years of activity. Therefore, our physical infrastructure together with our new IT platform, the modern

legislation and new and better procedures and the quality of our people all appoint us as a leading agency in Latin America.

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