

# IP Newsletter

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## CONTENTS

1. - BIOSIMILARS IN CHILE,  
CURRENT STATUS

2. - DOMAIN NAMES - NEW  
REGULATIONS

3. - TRADEMARK INFRINGEMENT AND  
INDEMNITY FOR DAMAGES

4. - PROTECTION OF RIGHT OF  
PUBLICITY

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## BIOSIMILARS IN CHILE - CURRENT STATUS

- Last September 6th the Ministry of Health issued the long awaited Technical Rule on biotechnological pharmaceutical products. As of this date a path for the registration of biosimilars is available in Chile.

Until the new Sanitary Regulation, Health Decree N°3, came into effect in December 2011, the procedure for the registration of chemical and biological products in Chile was the same. Accordingly, generic biological products could be registered under an abbreviated procedure, essentially relying in the safety and efficacy data provided by the reference product.

The new Sanitary Regulation changed the state of affairs, expressly indicating that an abbreviated procedure is not available for the registration of biological products, until the Ministry of Health issues a Technical Rule for biosimilars. The Technical Rule 170, has just been issued, and is in force as of September 6, 2014. It regulates both, the requirements for the registration of new biotechnological products, and the conditions under which the information required to evidence the comparable safety and efficacy of biosimilars can be abbreviated.

The Technical Rule applies solely to biotechnological products, not other kind of biological products, and indicates that it will only be possible to use as a reference, another biotechnological product registered before as a new product with the Chilean Health Institute. The process of registration will be sequential, with the biosimilar first having to establish a comparable quality, and subsequently comparable safety and efficacy with the product of reference. If comparable quality is not adequately established the biosimilar registration process will be interrupted and will be transformed into an ordinary registration process.

Remarkably the Technical Rule expressly indicates that every biosimilar product registered with the Chilean Health Institute, will be considered as interchangeable with the product of reference.

Finally, a resolution of the Ministry of Health will establish the terms and conditions to adjust the data of those biotechnological products registered before Health Decree N°3 came into effect, in consistency with the requirements of this Technical Rule.

## DOMAIN NAMES - NEW REGULATIONS

- As of December 1, 2013, important changes were included by NIC CHILE regarding the registration and settlement of disputes concerning the domain names in the ccTLD .CL.

NIC Chile informed last year that it would amend the Domain Name regulations and include important changes to the registration process and procedures for the settlement of disputes concerning the domain names in the ccTLD .CL. These new rules are effective since December 1, 2013, and some of the most relevant changes are the following:

- The application and registration of domain names are now simultaneous. In other words, “pending” applications no longer exist and the domain is registered after payment of the corresponding fee. Once the domain is registered, NIC Chile publishes it in its web site and the domain can be used.

- As a result of the above, “oppositions” are no longer possible and only “revocation actions” are admitted. Revocations actions filed within the first 30 days of the registration term can be based on “preferential interest” or “better right” (as the former oppositions). After this 30 day term, the plaintiff must prove that the registration is abusive or made in bad faith.

- The mediation phase before NIC Chile was eliminated.
- Arbitrators’ fees were standardized.

Our firm took the necessary steps to adjust to these changes. Since December 1, 2013, our monitoring system is sending notices for possible revocation of registered domains, based on a better or preferential right, within 30 days after the registration, and based on the existence of prior rights on a trademark identical or confusingly similar to the domain name in question.

However, these new regulations have not substantially altered the management of our Domain Name Department and currently our office and the other Chilean local offices are still handling cases initiated before December 1, 2013 that are ruled and will be decided according to the former Regulations.

## TRADEMARK INFRINGEMENT AND INDEMNITY FOR DAMAGES

- A condemnatory decision was recently issued in a trademark infringement case and the Infringers were sentenced to pay approximately US\$50,000 as indemnity for damages.

In 2010, DISTRIBUIDORA PANAMÁ CITY and its owners (“the Infringers”) sold a rum with a label that clearly imitates the FLOR DE CAÑA label.



COMPAÑÍA LICORERA CENTROAMERICANA S.A (“the Trademark Owner”) filed a criminal complaint for the malicious use of its trademark and a lawsuit for unfair competition for taking advantage of the fame of the FLOR DE CAÑA rum. In both cases (criminal complaint and unfair competition) the Trademark Owner obtained favorable decisions and these decisions are final.

The Indemnity case was filed by COMPAÑÍA LICORERA CENTROAMERICANA S.A, two years ago and was based on the favorable trademark infringement decision issued by the Criminal Court. It must be noted that according to Chile’s Criminal Procedure Code it is not possible to claim damages in a criminal case thus, it was necessary to file a civil action.

The Industrial Property Law grants the plaintiff three alternatives to calculate damages for trademark infringement:

- 1) *The profits the Trademark Owner lost as a result of the infringement;*
- 2) *The profits the Infringer earned as a result of the infringement;*
- 3) *The royalty the Infringer should have paid for the use of the trademark.*

In this case the Trademark Owner grounded the case on the second alternative, i.e., **the profits the Infringer earned as a result of the infringement.** The Court determined these profits on the basis of the invoices that were issued; the depositions of the Infringers and an expert accounting report.

This decision is not final and can be appealed before the Appeal Court. However, the grounds are solid and hopefully it should be confirmed.

This case sets an important precedent, because in our country there are few decisions that have granted Indemnity for Damages caused by Trademark Infringement. Furthermore, it provides the Trademark Owner an additional legal alternative to attack the sale of products using a label that imitates its registered trademark.

## PROTECTION OF RIGHT OF PUBLICITY

- If a person can be recognized, then the use of his or her image must be authorized beforehand.

In 2007 the Chilean Labor Code was amended to protect publicity rights of professional athletes. Article 152 bis F of Law No. 20.178, that included this amendment, provides that the employer can only use, without authorization, the identity of its professional athletes and of other employees that work in activities associated to sports, if this use refers to the main object of the labor contract. All other uses of the identity of the professional athletes and of other employees that work in activities associated to sports, must be authorized by them. The Law uses the term “express authorization for each use”.

Although our Congress has not passed a Law to protect in general terms the right of publicity, our Courts of Appeals and the Supreme Court have defended personal identity ruling in favor of the plaintiffs that have filed a constitutional action named “Recurso de Protección”. The general jurisprudence considers that every human being is the owner of his or her identity. **Therefore, the use of the right of publicity of a person that can be clearly identified, without his or her authorization, infringes his or her property that includes tangible and non-tangible assets.**

It must be noted that for our Courts the plaintiff must be clearly identified. An interesting case regarding this requirement is “Cohen Sabah vs. La Tercera”.

In 1999, Mr. Salvador Cohen Sabah filed before the Court of Appeals of Santiago a constitutional action against newspaper “La Tercera”. Mr. Cohen claimed that the newspaper had published an article about overweight Chileans that included a photograph of a group of overweight people and he was one of them. He further argued that he had not authorized the publication of this photograph, and now he was made the laughingstock, especially at the gym, because the photograph was placed in the bulletin board to promote physical activity. He concluded that the property of his right of publicity had been infringed by the newspaper, requesting the seizure and destruction of the negative of the photograph and an order to the newspaper to refrain from publishing and selling the photograph.

“La Tercera” contested the action and requested its rejection, because the article about overweight Chileans only included one photograph of a group of ten people sitting in a public place that could not be distinguished one from the other, because the quality of photograph was not good and the group was not facing the photographer. The newspaper also addressed the

use of the photograph in the gym and explained that this situation was beyond their control. In their opinion the action should be rejected, because the publication of the photograph had not infringed Mr. Cohen’s right of publicity.

The Court of Appeals of Santiago ruled that the right of publicity of a plaintiff can only be infringed if he or she can be recognized, i.e., that it is possible to identify the person without any doubt. In the end the Court rejected the recourse, ruling that since the group in the photograph is not mentioned by name in the article and the faces cannot be identified by looking at the photograph, the right of publicity of Cohen had not been infringed.

Based on the above, we can draw as a conclusion that the right of publicity is protected in Chile and that although the photographer is the owner of the author rights of the photograph, these rights do not entitle him or her to use the identity or image of a person, that can be clearly identified, without his or her authorization. Additionally, it must be noted that this is also applicable to the uploading of a photograph in a social network or in internet. The upload does not imply an authorization to use right of publicity of an individual. Using the same terms of Article 152 bis f of Law No. 20.178, there must be an “express authorization for each use”.