SARGENT & KRAHN®

PROPIEDAD INTELECTUAL DESDE 1889

IP Newsletter

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FIRM OF THE YEAR 2017

Our firm was the recipient for the second consecutive year, and for the seventh time in 11 years of the **"Firm of the Year 2017"** award, granted by the prestigious English publication Managing Intellectual Property (MIP). The ceremony was held at The Savoy Hotel in London on March 9. This award recognizes the best IP firms around the world in connection with outstanding achievements in the past year including successful IP cases with innovative practices and client satisfaction.

We want to thank our clients for their loyalty and for entrusting our firm with the protection of their intellectual property in Chile and abroad.

ANTITRUST - CELECOXIB

On June of last year, the Chilean National Economic Prosecutor's Office (Fiscalia Nacional Economica, or "FNE" hereinafter) lodged an antitrust action against G.D. Searle for alleged antitrust acts intended to restrict and obstruct the entry of competitors into the marketplace of pharmaceutical products containing Celecoxib, the active principle in the well-known anti-inflammatory Celebra®.

The FNE argued that the respondent had delayed the grant of a second patent application over a composition containing Celecoxib in order to use that "second patent" to block entry of competitors of Celebra® once the "first patent" had expired. G.D. Searle filed for the "first patent" claiming Celecoxib itself in 1998 which was granted in 2003 and was valid until 2014, and for the second claiming a composition containing Celecoxib in 1999, but this one was only granted in 2014 with a validity term until 2029. This latter patent has been the object of a cancelation action that is currently pending (the action was accepted by INAPI for lack of inventive step but is pending of an appeal recourse).

The FNE argued that G.D. Searle had incurred in the following reproachable acts:

- The prosecution of this "second patent" was much longer than usual and was evidence of the intent of the holder to obtain fresh patent protection for Celebra®, on top of the first patent (evergreening). The FNE argued that G.D. Searle delayed on purpose the prosecution of the application to its own benefit, as the validity term for patents stemming from applications lodged before 2005 is of 15 years from grant.

- G.D. Searle´s Celebra® is the same product that was covered with the "first patent" currently expired and now by the "second patent" and this was evidenced by the fact that the product continues to use the same sanitary registration. The FNE reasoned that if the products were different then G.D. Searle would have required a different sanitary registration.

- During prosecution of the "second patent" G.D. Searle would have withheld information about the cancellation of an EP counterpart and about a piece of prior art that would have rendered it obvious.

- Shortly before expiry of the first patent G.D. Searle sent Cease and Desist letters to 14 different parties asking to refrain in sales and commercialization of pharmaceutical products containing Celecoxib.

- G.D. Searle even filed an unfair competition and patent infringement action against Synthon Chile Limitada grounded on the "second patent".

According to the FNE these actions evidenced G.D. Searle's anti-competitive behavior and requested the Antitrust Court to order its immediate cessation along with the imposition of a fine of US$ 15.5 million.

Notwithstanding G.D. Searle denied any wrong, it agreed to execute a conciliatory agreement, already accepted by the Antitrust Court, along the following lines,

- The conciliatory agreement does not entail an acknowledgement by G.D. Searle that it incurred in any type of antitrust violations.
- Nevertheless, G.D. Searle grants a non-exclusive, irrevocable, free license to any current or eventual competitor to use, manufacture, sell, offer to sell, distribute and import the composition protected by the "second patent". The license also allows to sublicense and exports to countries where the composition is not protected with patents.
- G.D. Searle undertakes not to incur or participate in any manner, in any act or agreement that may impede or restrict free competition regarding the "second patent".
- G.D. Searle will withdraw its unfair competition and patent infringement action against Synthon Chile Limitada and will not file any further judicial or administrative actions grounded on the "second patent".
- G.D. Searle will not continue with promotional activities with medical professionals regarding CELECOXIB secondary brands, such as VALDYNE ® and CAPSURE ® for a period of time of 2 years.
- G.D. Searle will have to publish in two different local newspapers the terms and conditions of this conciliatory agreement.

This litigation is a clear indication of how much closer is the scrutiny of the Chilean Antitrust Authorities over the pharmaceutical market and in particular the intellectual property related issues.

DATA EXCLUSIVITY AND DATA PROTECTION

On September 22, 2015, invoking the rules of the Chilean Transparency Law, a private individual requested from the Agricultural Service, (SAG), a complete copy of the dossier of registration N° 4185, SMARTFRESH SMARTTABS, an agro-chemical product manufactured by the Rhom and Haas. The SAG eventually rejected the petition in view of a timely opposition filed by Rohm and Haas on the grounds that the dossier included trade secrets of commercial and economic value.

Subsequently, the petitioner lodged an appeal, which was rejected by the Transparency Council (on the same grounds as the SAG), against which the petitioner filed illegality recourse before the Court of Appeals. The recourse argued that the Council failed to properly apply Industrial Property Legislation (essentially Data Protection and Data Exclusivity rules). Petitioner asserted that Data Exclusivity protection over SMARTFRESH SMARTTABS would have expired, and thus, in rejecting his request SAG would be unduly extending said protection in violation of Data Protection and Data Exclusivity rules as well as his right of access to public information.

On September 30, 2016, the Court of Appeals rejected the illegality recourse, affirming the decision of the Transparency Council. The Court first noted that the report drafted by the SAG stated that the information to which access was required was of considerable scientific value. The Court then explained that the information referred to a manufacturing strategy, and as such, eligible for protection as a trade secret.

In order to establish whether the information included in the agrochemical dossier could be protected as such the Court inquired whether: (i) the information was, or not, generally known or easily accessible by persons of said industry; (ii) the information was subject of reasonable efforts to keep it secret; and (iii) the secrecy provided the holder with an improvement or a competitive advantage. The first inquiry was proven by the study and scientific research that would have allowed Rohm and Hass to discover a specific molecule. This required a highly technical procedure, which was neither known nor easily accessible. The second inquiry was proven by the fact that the information was not voluntarily released to the SAG, but in compliance of a legal obligation. Additionally, the intention to keep it secret is also proven by the timely opposition to the access of information request. Finally, the company had invested a large amount of funds to meet the regulatory standards required by both national and international authorities. The Court also mentioned that the information is linked to a property right protected in the Constitution and that allowing its disclosure would essentially amount to an expropriation.

For all of these reasons the Court of Appeals rejected the illegality recourse and even ordered the defeated petitioner to cover all procedural expenses, which is not that common.

The case can be considered as a victory for the research based industry because it expressly recognizes that the information in agro-chemical dossiers submitted to SAG may be subject of both, Data Exclusivity and Trade Secret protection.

PATENT ADJUSTMENTS

In last months several interesting decisions have been rendered by the Industrial Property Court regarding Patent Adjustments.

In a first case, the Court modified its previous criteria and ruled that in order for a patent to be susceptible of adjustment, said patent had to still be in force at the time of filing the request. In the Case File N° 222-2016, the Court resolved that the patent upon which the request was filed had to be in force at the time of filing since if the patent had lapsed it had thus entered into the public domain.

In another relevant decision, (Case File N° 3070-2015) the Court also modified its previous criteria and ruled that a patent application which prosecution had lasted over three years from the examiner's request until grant but which full prosecution had not lasted five full years was indeed susceptible of adjustment. This decision explains that the literal text of the law allows for this possibility. The decision was not unanimous and had a vigorous dissent vote.

In another relevant decision, (Case File N° 2304-2016) the Court ruled that a third party cannot file a procedural annulment recourse against an adjustment already granted as it was not a part to the prosecution of the application nor during the prosecution of the Patent Adjustment request.

Finally, in a couple of recent cases the Court has ruled that Patent Adjustment requests for revalidation patents and for those with 15 years validity term, the adjustment granted must be shortened in half. The reasons for this have depended on the specific ruling and cases. In some cases the reason has been on equity grounds, in a revalidation patent, it was considered that the extension would imply a "rebirth" of the patent and thus the adjustment term had to be more limited since the term of that patent will go beyond that of its foreign counterpart, while in other cases it has been grounded on the fact that patents with a validity term of 15 years from grant, have an assured validity term which is not affected by the length of the prosecution.

PATENT PROSECUTION HIGHWAY

In recent months Chile has executed agreements with Peru, Colombia, Mexico, Canada and PROSUR establishing a Patent Prosecution Highway pilot program with those countries. These pilot programs will last for three years and can be extended after that time.

In general, the requirements to request this expedited prosecution are the following: (i) the application has the same initial dates (filing or priority) in Chile and the previous examination country or PCT application (only in case specific offices have acted as ISA/IPEA), (ii) the corresponding application in the previous examination country (or the corresponding ISA/IPEA if applicable) must have received a report that ruling that at least one or more claims are patentable (the application does not have to have been granted yet), (iii) the claims being prosecuted in Chile must correspond to one or more of the claims that were deemed patentable by the previous examination country, (iv) the application must have been published in Chile and (v) the Examiner must not have been appointed yet in Chile.

The procedure itself requires a form to be filed before INAPI requesting the expedited procedure and the following documents in support of the request: (i) the corresponding reports rendered by the previous examination country (or in the international PCT application), (ii) the claims that have been considered patentable by the previous examining country (or by the ISA/IPEA), (iii) a comparative table of the claims and (iv) copies of the prior art cited by the previous examination country (or by the ISA/IPEA).

Additionally, INAPI has informed that this procedure will only be available for applications that have not faced any third party oppositions. INAPI expects that applications that are prosecuted via this expedited system should save around one year in prosecution time.

CHAMBER OF REPRESENTATIVES, RESOLUTION 798 ON COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS

On January 25 this year, the Chamber of Representatives of the Chilean Congress approved the Resolution 798, submitted by a group of seven representatives led by Dep. Giorgio Jackson, by 67 votes in favor, none against, and 32 abstentions.

I. FORMAL ASPECTS

From a formal stand point, the resolutions of the Chamber of Representatives originate in petitions formulated by a maximum number of ten representatives with the purpose of obtaining a general pronouncement of the Chamber in topics of general interest, either national or international. Therefore this is not a law project, not even a proposition to legislate, but

simply a concern of the Chamber about a topic connected with health policies that it shares with the Executive branch.

Since these resolutions are not manifestation of the control attributions of the Chamber, they do not oblige the Executive to provide a response. Nevertheless, in view of the interest that in recent times different state authorities have voiced in connection to the tension between industrial property and access to health (INAPI- National Economic Prosecutor), the likelihood is that this Resolution would be effectively responded by the Executive, within the terms that it deems more appropriate.

II. SUBSTANTIVE ASPECTS

From the substantive perspective, the Resolution is directed to the Ministry of Health requiring it to actively use the institution of compulsory licensing over pharmaceutical patents in order to stir competition and lower the price of medicines to be acquired by public and private health services, and the public in general; and likewise it ask this Ministry to prepare the guidelines and protocols that may serve to select the patented medicines with respect to which these licenses should be required.

Additionally and to the effects of facilitating the foregoing objective, it asks the Ministry of Economy to review and complement the statute of compulsory licensing so as to make its application by authorities and private parties simpler and easier, and also it asks this Ministry to prepare the guidelines and protocols that would serve to determine the price and other conditions of these licenses.

Finally, the Resolution establishes that these licenses should be required invoking public health and governmental non-commercial uses, both causes contemplated in Art. 51 2) of the Chilean Law on Industrial Property, which regulates compulsory licensing. (In this analysis it is understood that the phrase "governmental non-commercial uses" to be equivalent to "public non-commercial use", which is the language in the law).

III. LEGAL ASPECTS

a) Legal causes.

The Resolution establishes that the causes to require these licenses should be public health and governmental non-commercial uses, which avoid the burden of demonstrating the existence of an emergency situation, which moreover in health matters could only be possible in cases of contagious diseases. Therefore, in proposing the two legal causes under study, the Resolution release the Health Authority from the need of evidencing the existence of a situation of health emergency, and at the same time allows this authority to request a compulsory license over any kind of patented medicines, not only those ones directed to the treatment of contagious diseases.

b) Warnings and Doubts.

First, in order to grant a compulsory license under the legal cause of public non-commercial use, it is assumed that the medicines are given to the public free of charge or at least on a non-profit basis, conditions that hardly could be met in the cases of medicines that are acquired by private health services and individuals.

With respect to these groups it would not be justified to grant this kind of compulsory licenses.

Likewise, neither Trips nor the Law allow general guidelines and protocols to select the patented medicines to which these compulsory licenses should be required. Indeed this proposition is against the specific mandate that both impose in the sense that every compulsory license should be treated on its individual merits. (Art. 51 bis d) of the Law and 31 a) of Trips).

Moreover, a policy of compulsory licensing as the one proposed in the Resolution implies a significant discrimination with respect to the technical field of pharmaceuticals, which would be against Art. 27 of Trips that mandates that patents shall be available and enjoyable without discrimination in any field of technology. The Resolution also infringes the Free Trade Agreement between Chile and the United States, since this treaty establishes the obligation of respecting, among others, the rules of Trips, and moreover it expressly reiterates the obligation of non-discrimination regarding the fields of technology where patenting should be available.[1]

On other side, in the petition that is made to the Ministry of Economy the Resolution not only requires to update Art. 51 of the Law, but moreover, it requires that it prepares and publish administrative guidelines for the grant of these compulsory licenses, including parameters and other criteria to the effects of determining the royalty rate and other conditions of their grant.

Once again, the idea of a uniform analysis of the conditions under which a compulsory license should be granted is against the rules of Trips and the Law that have been cited before, which establish the obligation of reviewing the conditions for the grant of a compulsory license as well as for the calculation of its royalty rate, according to the individual merits of every case.

The matter is now in the hands of the Executive to decide whether simply take notice of the Chamber's concern, or go further and propose the regulatory and legal adjustments that the Resolution advocates for.

[1] Arts. 17.1:5. and 17.9:1 of the Free Trade Agreement Chile-US.