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Yours,

David Postolski

Welcome to our IAG May 2017 Newsletter

Inside this issue:

ECUADOR Orphan Drug Approval Route in Ecuadorian Legislation

ISRAEL Israel Court Recognizes Copyright and Moral Rights in the Format of a TV Show

CANADA How to Effectively Implement a Co-branding Strategy

CHILE Forms of Intellectual Property Protection

ISRAEL Smash

CANADA Not in My Backyard: Blocking Infringement at the Real and Virtual Border

ISRAEL Unipharm Requests Accelerated Examination of Pending Novartis Patent Application
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Orphan Drug Approval Route in Ecuadorian Legislation

"Orphan drugs" are intended for the diagnosis, prevention, and treatment of life-threatening diseases, serious illnesses or rare disorders in the population.

Rare diseases represent socio-health problems that are detected in a small number of people and require orphan drugs as part of their treatment. A rare disease is defined as a disease with a low occurrence rate in the population, a rate that is so minimal that often there are no treatments for the disease in hand or when the disease is extremely difficult to diagnose because of its low occurrence and the reduced research that is done by practicing physicians. In Europe, for example, a disorder or rare disease is one that affects 1 in every 2,000 citizens.

It is important to understand that the role of orphan drugs in the pharmaceutical industry is peculiar given that there is little interest in researching and developing orphan drugs because there is a limited market for them, which means that the cost of developing them is unlikely to be offset by selling them. Consequently, the development of an orphan drug, can be a financial risk that a pharmaceutical company is not willing to take. Thus it is important for legislatures to create some sort of incentive that will stimulate pharmaceuticals in the development of orphan drugs.

Many countries, including the United States, South Korea and members of the European Union, have created approval and marketing standards that are easier and faster to comply with, than those for common drugs. These standards have acted as financial incentives for the encouragement of the development of orphan drugs, which would otherwise lack the lucrative incentive for development. For these countries, having a less complicated and accelerated approval route, is a matter of public policy in the sense that medical advances are being generated that otherwise would not be achieved due to the high costs in research and development.

Orphan drugs generally follow the same regulatory development path as any other pharmaceutical product; ie it is intended that the medicine before leaving the market is stable, safe and effective. This is achieved in various clinical trials and the greater the number of patients in the test, the more control you have over the risk of the drug. However, given that orphan drugs are for rare diseases, countries have eased clinical trials, especially because it becomes impractical. For example, a clinical trial in phase III which usually has 1000 patients, would only be required to have 100 patients given that it is improbable to find 1000 patients with a rare disease (as defined above) and thus reducing clinical trials cost and accelerating the approval process.

Thanks to this flexible route of approval and commercialization due to practicality and public policy which serves as an impetus for the development of cures for rare diseases, orphan drugs can be placed in the market faster and at a lower cost, than a common drug. Without this flexibility, pharmaceutical costs would be too high and there would be no motivation for the research and development of them, causing many people unattended with difficult diseases to diagnose and treat in their bodies.

Currently, there are groups consisting of pharmaceuticals, doctors and lawyers who oppose the approval of orphan drugs by a fast and flexible route. Their position states that clinical trials are not complete, usually due to the lack of patients available for testing and thus these medicines carry a high risk when placed in the market, due to their complexity. This could lead to repercussions in terms of quality, efficacy and safety.

These groups, who oppose the approval of orphan drugs, are owners and marketers of orphan drugs themselves. They own orphan drugs that were approved years ago and thus have achieved a greater number of patients in their clinical
trials, while maintaining its orphan drug status. Thus, leading new developers to believe that opposition to the approval of an orphan drug, is motivated by a desire to stay on the market with little or minimal competition, and maintain monopoly power. Therefore, allowing them to continue to generate high sales given the lack of options for patients.

Currently, our legislation does not have regulations for the approval of orphan drugs. The only path available for approval is that of general and common drugs. This means that there is no differentiation by our laws between orphan drugs and common drugs, and therefore there is no fast approval route. Therefore, our current laws do not take into account the urgency of placing orphan drugs in the market for the treatment of rare and serious diseases among Ecuadorians.

There is a way in our legislation that may serve as a faster path of approval for orphan drugs. However, it is unclear whether this path may eventually exclude orphan drugs from its benefits. Article 30 of the Regulations Code for purposes of obtaining Sanitary Registration, Control and Surveillance of Biological Medicines for Human Use and Consumption (hereinafter "Regulations for the Registration of Biological Drug"), issued by Ministerial Agreement No. 3344 on May 17 Of 2013, published in the Official Gazette No. 21 on June 24, 2013, regarding the granting of Sanitary Registrations via Homologation, provides the following:

Art. 30. - The National Health Authority, through the ARCSA, or who exercises its powers, shall grant the Certificate of Health Registration for imported biological medicinal products for human use and consumption through Homologation...

Article 31 continues to state:

Art. 31.- For purposes of Health Registry of these drugs, approval shall mean the official recognition of Sanitary Registration issued by health authorities of the countries whose drug regulatory agencies have been qualified by the Pan American Health Organization (PAHO) / World Health Organization (WHO) Authorities Regional Reference, as well as those Sanitary registrations issued by health authorities in the United States, Canada, Australia, Japan, for the centralized registration of the European Medicines Agency process (EMA) and the Ministry of Food and Drug Safety of the Republic of Korea.

Approval shall also include the official recognition of Sanitary Registrations issued by countries whose biological drugs, exclusively vaccines, that have been prequalified by the Pan American Health Organization (PAHO) / World Health Organization (WHO).

also stating in Article 32

Art. 32.- Health Registration approvals will be granted to all biological medicines for human use and consumption, which have been registered by the countries mentioned in the previous article, provided they have specific regulations for this effect.

This means that Ecuador accepts and acknowledges the approval of drugs in the countries and organizations mentioned in Article 31 as are: The World Health Organization (WHO), United States, Japan, South Korea through its Ministry of Food and drug Safety, etc., without placing any condition that they should be approved via the traditional route or flexible route. In this sense it can be interpreted in that if the United States or the Republic of Korea, have approved an orphan drug, then according to Ecuadorian law, it can be approved in Ecuador via homologation, and as such, reach patients suffering from rare diseases across the country faster.
In addition, the rule, correctly, also requires a Post registration control in Article 34 numeral 10 which provides the following:

10. Once the Certificate of Sanitary Registration of biological medicines for human use and consumption has been issued through Homologation, the dossier with all the documentation will be sent automatically to the Unit responsible for carrying out the post registration control of medicines, so that it is included within its planning for this effect.

Thus it is clear that the risk of a drug, whether orphan or traditional, in the Ecuadorian market by requiring adequate drug control would be reduced in a timely manner.

If this is not the case, I invite our judges to draft jurisprudence to clarify the approval or non-approval of orphan medicinal products via the existing Homologation Regulation. Their intervention would solidify or clarify this incentive in order for international pharmacists and laboratories to introduce orphan medicinal products for rare diseases in our market and allow Ecuadorians access to them.

If our judges agree that homologation is not the right way, then I invite legislators to take into consideration the importance of creating a regulation that would make it easier to introduce orphan drugs into our country. New legislation would could serve as an incentive for laboratories to develop these drugs, without being forced to deal with the economic weight. Hence, contributing to a fair and democratic access to health for all Ecuadorians, regardless of the disease they face.

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BIBLIOGRAPHY


Israel Court Recognizes Copyright and Moral Rights in the Format of a TV Show

Background

Copyright protection is available for films, TV programs and other creative endeavors. The problem with TV formats is that ideas and concepts are not protected. The embodiment of the idea is, but a format that is 'copied' abroad will inevitably be re-shot and the content will change. A game show is scripted by its players. A quiz could conceivably have the same questions in different jurisdictions but the participants will answer differently. Much of the viewability of a TV program is related to the characters of the participants themselves. Different competitors in a song competition will sing differently. In a cookery program, the participants will cook differently. Different people look and act differently in game-show survival situations.

Until this ruling, it was not clear that formats of TV shows are copyright protected. The fact that they are bought and sold does not mean a court would recognize a rip-off program as being copyright infringing.

Upgrade

Armoza Productions Israel makes formats of TV programs that are successful abroad. Saar Brodsky and two partners created a format called "Upgrade" that was not successful in Israel, but which Armoza Productions managed to market abroad in 30 countries. In a groundbreaking ruling, the Israel District Court recognized copyright as subsiding in the format and thus ruled that the creators moral and financial copyright was infringed. It will be noted that the court could have ruled damages under the catch all tort of Unjust Enrichment.

Upgrade is a game show that goes into people's homes and offers them a chance to upgrade their personal items for brand new ones! Each home can wager their belongings against their trivia skills. If they answer correctly, their homes will be upgraded… but there's a catch! Wrong answers mean the items they own will be taken away. Are you ready to be left without a dishwasher, TV, or bedroom set?

In each episode the 'Upgrade' team will enter 2 households and play the game with them. It can be with a group of young bachelors or a big family in the middle of having their dinner – but no matter what, it is always by surprise and unexpected. Now on air in over 15 territories!

A link to the format that was posted on you tube may be found here.

Saar Brodsky, Rodrigo Gonzales and Gili Golan created the format in 2008 and made a pilot episode for Israel's Channel 10 that was eventually scrapped without being broadcast.
The 'rights' to the format were sold to 'Tanin Productions' which is owned by Golan (Tanin is a crocodile) and these were then transferred to Armoza Productions with a request that the three creators be credited with the concept.

Brodsky claimed that despite the significant worldwide success of the format his name was deleted from the credits in an attempt to prevent him benefiting from the copyright and profits. Judge Avnieli ruled that Armoza acted intentionally in bad faith despite knowing about his contribution to the format. Since Armoza Productions is a limited company with a single owner, the owner is personally responsible in this instance.

Judge Avnieli noted that Armoza claimed that Brodsky merely thought up the idea and discussed it with friends and did nothing to develop it further. She rejects this defense. The entertainment is the result of work by Brodsky, Gonzales and Golan which was embodied in a storyboard and presentation that was prepared for the filming of the pilot program, that was the result of deep contemplation regarding the details, the structure of the episodes, directions to the actors, choice of competitors, preparation of questions, activities and anchors that resulted in the specific end product.

The Judge noted that under cross-examination Armoza was asked to identify the creators of the format and whether the plaintiff was one of them, and Armoza's response was that they didn't know and that it wasn't relevant. This was not compatible with the evidence submitted that clearly showed that Brodsky was the producer of the pilot. Judge Avnieli considers that each time Armoza claimed to be the creators of the format without attributing Brodsky and his partners, they were infringing Brodsky's moral rights. The Judge ruled that Brodsky and partners should be credited in each episode, that Armoza should refrain from describing themselves as the creators and fined Armoza 30,000 Shekels in legal expenses. There is a parallel ongoing case for financial damages of 1.5 million shekels.

Armoza have vowed to appeal the decision.

COMMENT

It is almost embarrassing that Israel is developing a reputation for such programs.

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How to Effectively Implement a Co-branding Strategy

There have been relatively few cases which have considered situations involving co-branding although co-branding is fairly common. In the United States, there is some authority for the proposition that a product may be associated with multiple marks owned by different firms. A common example is a familiar manufacturer's mark and a merchant's mark appearing at the same time on a product, with one mark identifying the manufacturer and the other mark identifying the retail merchant. The use of multiple marks is appropriate so long as the separate identifying function of each mark is made apparent to consumers.

The leading case is *Yardman, Inc. v. Getz Exterminators Inc.*, 157 U.S.P.Q. 100 (TTAB 1968), where a lawnmower was manufactured by Yardman, Inc. and sold exclusively by Sears Roebucks & Co. The YARD-MAN trademark and the Sears trademark CRAFTSMAN were used on the mowers and their packaging. However, each machine bore a nameplate indicating that Yardman Inc. was the source of the mowers. This was accomplished by using the legend "Product of Yard-Man, Inc. ... for Sears, Roebuck & Co.".

There have been very few reported cases in Canada dealing with the issues associated with co-branding. Relying on the United States jurisprudence and principles established under the Canadian *Trademarks Act*, it appears that co-branding should not be objectionable by itself as long as the following steps are taken:

(a) Each participant should be licensed to use the trademarks which are used in the co-branded initiative. The licensing arrangements must satisfy the requirements of the *Trademarks Act* dealing with control of the character or quality of the goods or services. In addition, the licence should specify how the respective marks will be physically used, particularly in relation to each other; and

(b) The co-branded trademarks must be used in such a fashion as to maintain the distinctiveness of each mark. For example, if a manufacturer's and distributor's marks are used the manufacturer's mark must be identified with the manufacturer and the distributor's mark must be identified with the distributor. An appropriate trademark legend similar to that used in the Yardman case should be developed and used. The message to the public is vital.

There will, of course, be numerous other issues to consider for inclusion in the licences but the above represents the bare minimum from a trademark point of view.

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The main types of intellectual property protection in Chile are the following: patents, trademarks, utility models, industrial designs, new plant varieties and copyright. In addition, there is also legal protection for microorganisms, undisclosed information (in the pharmaceutical and agro-chemical fields), appellations of origin and trade secrets.

Patents are granted for products and for processes related to a product. Inventions applying for a patent can refer to any field of technology and are supposed to comply with the traditional patentability criteria of novelty, inventive step and industrial applicability. Patent applications are subject to examination as to substance which is a mandatory phase of the proceedings and they are also subject to the possibility of opposition after the publication of the application in the Official Gazette. Patents are granted for a 20-year term counted from the date of application. Extension of the protection term is possible in very specific cases.

Although patents may be granted for inventions in any field of technology, there are certain cases that Chilean law does not consider ‘inventions’ and therefore they cannot be patentable or, while having all the characteristics of an invention, the law does not allow the granting of a patent. The main cases of no patentability are the following:

a. discoveries, scientific theories, mathematical methods;
b. plants and animals, except microorganisms. However, it is to be noted that while plants cannot be the subject of a patent, they are nevertheless the subject of special protection under a special law on new plant varieties;
c. systems; methods; economic, financial, commercial or business principles or plans and those referred to purely mental or intellectual activities or gambling;
d. methods for surgical or therapeutic treatment for human beings or animals, as well as diagnosis methods for the human or animal body with the exception of products designed for implementing these methods; and

e. new uses; changes of shape, dimensions or proportions; changes of material of products. However, the new use of already known articles, objects or elements, can be the subject of patent protection when such new use may solve a technical problem, which did not have previously an equivalent solution, provided this new use may comply with all patentability requirements. In these cases, the new use is to be proved with experimental evidence included in the patent application.

The Patent Law provides for a special 12-month grace period in favour of novelty and inventive step, when a possible disclosure of the invention or elements of same results directly or has been authorised by applicant or when disclosure results from possible attempts of unfair competition infringement against applicant.

Trademarks are protected by Chilean law upon registration. Registration has a duration of 10 years and it can be renewed indefinitely.

Any sign can be registered as a trademark in Chile; provided it can be represented in a graphic form and it may able to distinguish products or services in the market. Chilean law provides also that marks can be applicable as a distinctive sign to commercial and industrial establishments.

Signs that can actually be registered as trademarks may consist of words, including names of people alive or dead, letters, numbers, figurative elements such as images, symbols, graphics, combinations of colours, slogans, sounds, as well as any combination of these.
Essential requirements for a mark to be registered in Chile are mainly originality and the capability of distinctiveness.

Moreover, there are signs that cannot be registered as trademarks. This is the case of the names of states, flags and other symbols of any state or international organisations; the name or portrait of a person without authorisation; expression or signs indicating gender, nature or origin of a given product; marks, which are identical or confusingly similar with marks already registered in Chile for the same goods or services, and, if registered abroad, when they enjoy fame and notoriety in the public sector that normally makes use of those products or services in the country of the original registration.

Chile has adopted the Nice International Classification of Goods and Services for the Registration of Trademarks.

Applications for the registration of trademarks may include several classes and will result in a single registration covering all classes, which are the subject of the grant of registration.

Chilean law does not provide for the protection of three-dimensional trademarks.

Chilean law also provides for the registration of collective and certification marks.

It is interesting to note that Chilean law does not provide for the mandatory use of registered trademarks. Therefore, there is no possibility of initiating a legal action against a registered trademark based upon this circumstance.

Utility models may consist of instruments, tools, devices, mechanisms, where the shape is instrumental and may thus be claimed either because of its external aspect or because of its working and provided this shape may be useful by providing a contribution to the function they are intended for or an advantage or new technical effect.

Utility models are subject to rules similar to patents although much simpler.

The law provides for a 10-year protection period from the date of file.

Industrial drawings and industrial designs

These two forms on industrial property protection is provided for two-dimensional and three-dimensional shapes, with or without colours, of any industrial article that may serve as a model for the manufacture of similar products, when their shape, geometry, ornamentation, or the combination of these, may produce a special appearance, resulting in a new physiognomy.

The law further provides that containers can be protected as an industrial design and cloth printing and stamping as industrial drawings.

Protection for these two figures will be granted for a term of 10 years from the date of filing.

Plant varieties

Plant varieties are not patentable in Chile. In fact, the Chilean Industrial Property Law especially provides among the clauses of 'non-patentability', the impossibility of obtaining a patent for a plant. However, the same provision of the Law makes reference to the rights provided for in the Plant Breeder’s Rights Law.

The Plant Breeder’s Rights Law (Law No. 19.342) provides a sui generis kind of protection, plant variety protection, which consists of the registration of the protected plant in the National Register of Protected Varieties, administered by the Seeds Department of the Ministry of Agriculture.

Chile is a member of the UPOV, and adopted the 1978 Act in 5 January 1996, but has not yet acceded to UPOV 1991.

As a member of the UPOV 1978 Act, Chile has adopted all its provisions regarding priority rights (12-month term), novelty (no offer for sale in Chile for more than 12 months, and no offer for sale abroad for more than six years for tree and vine species and for more than four years for other species), term of protection (minimum of 18 years for vines and trees and 15 years for other species), and scope of protection (restricted to the reproductive material of the variety).

Copyright

Copyright in Chile is governed by Law No. 17.336, originally enacted in 1970, which has been successively amended. The last amendment was made in 2010 and this is the text actually in force.

The law protects those rights, which, by the sole fact of the creation of a particular work, are acquired by their authors in the field of literature, art or science, regardless of their form or expression. According to the Berne Convention, no formalities are required to obtain protection.

Copyright covers moral and economic rights that protect ownership, exploitation and the integrity of a particular work.

The law covers the rights of Chilean authors, performers and producers as well as those of foreign nationals residing in Chile. Foreign nationals not residing in Chile have their protection recognised by the treaties Chile is a party to. These are, among others, the Berne Convention for the Protection of Literary and Artistic Works, the Universal Copyright Convention (UCC), the Inter-American Convention on Copyright and the International Convention for the

The law especially protects books, leaflets, periodicals, reviews, articles and writings; lectures, speeches, lessons or similar works, either written or recorded versions; dramatic and musical works; paintings, drawings, photographs, engravings; architectural projects, sculptures and works of figurative arts, adaptations, translations; video and slide shows, and software, among others.

The protection of copyright in Chile lasts for the author's life and 70 years thereafter.

The law provides for some limitations and exceptions to copyright for institutions of higher education, high schools and schools, in respect of courses taught in any form, provided they are not partially or wholly published without the authorisation of their authors. The same is applied for the reproduction of architectural works through photography, cinema, television or other similar process, as well as for the publication of the corresponding photographs in newspapers, periodicals, reviews, books and texts intended for educational purposes.

In Chile there is an official Copyright Registry, where rights and connected rights may be registered, although actual protection is granted without need of registration.

The owner of copyrights or related rights is entitled to file civil or criminal judicial actions in case of infringement and request the ceasing of the infringer’s unlawful activity, as well compensation for the economic and moral damage suffered. Infringers may be condemned to fines and in certain cases even to imprisonment.

Microorganisms
Chile is a member of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977, since the publication of Decree No. 81 from the Ministry of Foreign Affairs on 18 November 2011.

According to the provisions of the Budapest Treaty, on 26 March 2012, the Chilean Collection of Microbial Genetic Resources operative unit of the Agricultural Research Institute acquired the status of International Depositary Authority (IDA), being the first one in Latin America.

The Budapest Treaty ensures that an applicant for a patent need not deposit the biological material in all countries where patent protection is sought. The applicant needs only to deposit the biological material at one recognised institution, and this deposit will be recognised in all countries party to the Budapest Treaty.

Having accepted a microorganism for deposit, tested its viability and issued the receipt and viability statement, the IDA is obliged to maintain the microorganism according to the provisions of Rule 9, which states:

Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

Undisclosed information
The important discussion in the past 10 years mainly on pharmaceutical and agro-chemical inventions and their protection, led to include provisions for the protection of undisclosed information in the Industrial Property Law and its several amendments.

This was also the result of more serious and detailed examination for issuing marketing authorisations for new pharmaceutical and agrochemical products by the government authorities in charge, such as the National Health Institute – depending of the Health Ministry – for pharmaceuticals and the similar service for agrochemical products depending of the Ministry of Agriculture. Submission of new products to marketing authorisation implies the filing of sometimes complex, voluminous and expensive scientific or clinical information, normally containing highly sensitive and confidential information, which is essential for the production of the products to be sold. Moreover, this information refers to aspects of a particular product that are not normally disclosed and whose knowledge provides their owners with a competitive advantage that often exceeds the product for which authorisation is requested and may extend to similar products as well.

The law provides several definitions and rules the normal conducts in these cases and, in particular, eventual misconducts.

Probably the most important aspect of these provisions is that they provide for the obligation to the authorities of not disclosing the information filed in the context of the authorisation proceeding for a particular product, during five years for pharmaceutical products and 10 years for agrochemical products.
Appellations of origin

Appellations of origin and geographical indications are subject to special protection. In both cases the law protects a name that identifies a particular product as originating in a country, region, territory, when the quality, reputation or other characteristics of the product can be linked to the geographical origin of same.

The Industrial Property Law has included these two figures in the last amendments of the same and has provided a very similar definition for each without elaborating on the differences or rather, on the rather very special characteristics of each.

Although appellations of origin can be considered an old form of industrial property protection originating mainly in European countries (France, Germany, Italy, Spain, Portugal, etc.) and used mainly for wines, although also for other agricultural products, it was a subject of international discussion at the TRIPS negotiations where it was accepted by some countries but not by others. The compromise seems to have resulted in an attempt to protect geographical indications and to avoid any conflict or confusion with the protection afforded to trademarks.

The international discussion has not yet been concluded.

Chilean law has thus maintained both legal figures, which have been useful in particular for registering a number of new local appellations of origin, as well as for the recognition of well-known foreign appellations of origin and besides, to permit to lawfully deny their registration in Chile as local trademarks.

Trade secrets

Trade secrets were included for the first time in Chile in Industrial Property Law 19.039, and called ‘enterprise secrets’. A trade secret is any knowledge of products or industrial processes that when maintained a secret, gives its holder a competitive advantage.

There are few other provisions directed mainly at the violation of the secret and the unlawful acquisition of the same.

This legal institution is still too new in Chile and evaluation looks premature.

II  RECENT DEVELOPMENTS

In the last 10 years, intellectual property policy and administration has reached a good professional level in Chile. Decisions and policies when in line with the obligations of the TRIPS Agreement and thereafter with the several negotiations Chile has undertaken in the framework, in particular of new free trade agreements, has certainly resulted in an important modernisation of the country’s intellectual property system in every respect.

This can be noticed in amendments to legislation, in the strengthening and improvement of the administration, in the incorporation of the customs authorities in the struggle against counterfeiting, and in the creation of special branches of the national police to address counterfeiting. These measures have certainly contributed to create better knowledge at the national level of intellectual property and its importance for development, trade and have provoked a broader public discussion on the main intellectual property issues.

On the improvements of the administration of intellectual property, it is interesting to point out two significant facts.

Chile acceded to the PCT in March 2009. On 4 October 2012, the Chilean Patent and Trademark Office was designated as International Searching Authority of Patents and International Preliminary Examining Authority of Patents by the Treaty’s General Assembly in Geneva.

When Chile acceded to the Budapest Treaty for the Protection of Microorganisms, the operative unit of the Ministry of Agriculture in charge of the Chilean Collection of Microbial Genetic Resources acquired the status of IDA, being the first in Latin America to be entrusted with these responsibilities.

The above two facts have and are certainly contributing to the further improvement of the country’s administration and also to the improvement of the general atmosphere for the respect of intellectual property.

III  OBTAINING PROTECTION

As explained in the section on patents, Chilean law provides for the protection of inventions in all fields of technology, with the exception of cases where the law does not consider the subject matter an invention or does not consider the subject matter as patentable.

Moreover, in connection with certain specific matters where sometimes laws may differ, we can perhaps add the following.

Genetic material and notably isolated DNA sequences are normally patentable in Chile provided they have a function or they are associate to a function.

Genetically altered cells are patentable in Chile since they are considered similar to living beings.
Methods of production in cells, plants animals are normally patentable except in cases when they are essentially biological.

Business methods are not patentable.

Computer software is not patentable in Chile, although it can be protected through copyright.

Methods for treating patients are not patentable.

Patents of use (Swiss-style claims) are accepted and normally used in Chile for protecting ‘use’ claims in patent applications comprising chemical or agro-chemical compounds, compositions or formulations.

IV  ENFORCEMENT

One of the most important innovations of the last amendment of the Industrial Property Law was the inclusion for the first time of the possibility to file civil actions in case of breach of rights protected by the Industrial Property Law. In effect, the last two laws on industrial property, the first dating back to 1931, only established the possibility of filing criminal proceedings that proved to be ineffective for the type of problems arising from the field of industrial property. This happened in part as a result of the drafting of the legal provision as well as of the lack of interest and sophistication of the courts in dealing with these cases. The provisions on the matter were further weakened by the modification introduced by Law 19,039 of 1991 that imposed on the claimant the obligation to prove the breach itself and also the fraud incurred by the defendant, which unnecessarily hindered the possibility of an effective proceeding.

If these matters were less important in the 1930s, when the above first law was promulgated, the development of the industrial and commercial activities in recent years urgently required more efficient legal provisions for the enforcement of industrial property rights.

The provisions of the new law represent evident progress in this field and the practical application thereof should result in the more effective protection of industrial property rights in relation to the increased number of infringements.

The legal framework established by the new law is discussed below.

i  Civil actions

In case of infringements to industrial property law rights, according to Article 106 of the new law, holders of these rights shall be entitled to file a civil complaint requesting:

a  cessation of the acts that breach their rights;

b  recovery of damages; and

c  the adoption of necessary measures to avoid the continuance of the breach.

The legislator included a complete array of measures to provide a solution to the problems resulting from a breach. In this respect, the possibility to claim damages is established, which in the past was impossible unless the defendant had first been convicted or at least indicted after a long criminal proceeding.

In order to improve the effectiveness of these actions, in Article 107 of the new law the legislator provided that these actions will follow the rules of a ‘summary proceeding’ stipulated in the Code of Civil Procedure that is submitted to substantially shorter terms than those of an ordinary proceeding, and whereby results would be obtained within a reasonable time. This aspect is especially relevant when considering that breaches are normally related to economic or commercial activities, when a late decision, even if it is favourable, can become completely useless.

Regarding compensation of damages, Article 108 of the new law entitles the claimant to elect one out of three possible systems for determining its amount, namely:

a  the profits that the claimant has ceased to receive as a consequence of the breach;

b  the profits obtained by the infringing party as a consequence of the breach; or

c  the price that the infringing party would have had to pay to the holder of the right by the granting of a licence, considering the commercial value of the infringed right and the contractual licences that could already have been granted.

The new law also contemplates the possibility of obtaining all kinds of precautionary measures in these proceedings; this involves a clear signal regarding the importance the legislator attaches to this matter that should serve as a support to the courts. The law especially refers to five precautionary measures:

a  order for the immediate cessation of the acts constituting the alleged breach;

b  seizure of the product that is the object of the alleged breach and the materials and means used to commit it. In the case of trademarks, this measure would comprise the seizure of packaging, labels and advertising material containing the trademark that is the object of the alleged breach;

c  appointment of one or more auditors;

d  prohibition to advertise or promote the products that are the cause of the alleged breach in any manner; and

e  retention by a loan institution or a third party designated by the court of the assets, funds or securities originating in the sale or marketing of the products that are the cause of the alleged breach.
The precautionary measures can be required within the framework of the same breach proceeding or as prejudicial measures; in addition, with the same character and by express decision of the law the measures set forth in the Code of Civil Procedure can be applied for.

This set of provisions, which is entirely new in the industrial property legislation, constitutes a sound basis for ensuring the observance of rights regulated by this law and its practical application is expected to demonstrate its effectiveness.

In view of the extremely positive preceding picture, it is difficult to understand the need for the inclusion in the new law of a provision such as its Article 109, which stipulates: ‘Without prejudice to the other actions contemplated in this title, the persons having marketed products that infringe an industrial property right shall not respond for damages, unless the same persons has manufactured or marketed the products being duly aware that they were committing a breach of an industrial property right.’

In effect, in the modern business world it seems incredible that a person is able to infringe a patent, trademark or any other industrial property right, without knowing exactly what he or she is doing.

Criminal actions
Following the model of the previous laws, the new law also provides rules for a criminal action in case of infringement of property law rights.

As in Law 19,039, the application of these provisions requires in most cases the existence of fraud or the intention to defraud on the part of the assumed infringing party as a circumstance that the holder of the infringed right should first prove, in addition to the breach itself.

As has been mentioned, it is difficult to imagine cases of infringement of industrial property rights, especially patents and trademarks, wherein the assumed transgressor is not clearly aware that his or her action constitutes a breach of a third party’s right.

In addition to the above situation, it is pertinent to state that the fines being contemplated, which can be between approximately US$1,700 to US$57,000, are virtually symbolic in the business and industrial world, even if the court applies the highest stipulated bracket.

Notwithstanding the foregoing, the new law includes some additional provisions that improve those previously existing and that, in view of their strictness, the absence of exceptions and material consequences could have some dissuasive effect in these cases. There is an express provision in the hypothesis of a breach of patents, whereby the objects illegally produced shall be destroyed and, assuming infringement of a trademark, the objects bearing the forged trademark shall also be destroyed.

However, as already pointed out, the introduction of the possibility to file a civil action and an immediate claim of damages in cases of breaches of industrial property rights are likely to limit the application of the above-described penal actions to cases of a criminal nature.

V  TRENDS AND OUTLOOK
Chilean intellectual property law is undergoing major revision. In fact, on 26 April 2013, the government submitted a new draft Law on Industrial Property to Congress, covering every aspect of the law and introducing several entirely new matters. Discussion on this new draft has taken place mainly during 2014 and 2015, but it is still uncertain when it will be completed.

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Smash

Talber Pop LTD owns Israel trademark number 240598 “SMASH” for Notebooks, stationery, diaries, binders; gift wrapping paper, paper gift wrapping bows, paper cake decorations, paper party bags, loot bags, cello bags, paper party decorations, paper party hats, paper tables cloths, paper napkins, banner made of paper and/or cardboards; all included in class 16, and Backpacks, sidepacks, back bags, side bags, sport bags, tote bags, book bags, school bags, food bags, pencil cases sold empty, wallets, waist packs, briefcases, bike bags, toiletry cases sold empty, fanny packs, suitcases, umbrellas, umbrella covers; all included in class 18. They also own a second Israel trademark number 241238 for SMASH in class 14 covering watches, chronometers and their parts.

On 30 December 2017, Smash Enterprises Pty LTD submitted a request to cancel the marks or to allow their marks to be co-registered. On 2 March 2016, Talber Pop responded with their Counter-Statement of Case.

The request for cancellation followed an attempt by Smash Enterprises Pty LTD to register their Israel Trademark Application 274301. After various extensions were authorized, on 26 January 2017 the parties submitted a joint request for coexistence based on a civil court ruling under which they undertook to differentiate their services and goods.

Smash Enterprises Pty LTD’s mark was in class 21 and covered containers for household or kitchen use; household or kitchen utensils; containers for beverages; containers for food; heat insulated containers for beverages; heat retaining containers for food and drink; insulated containers; lunch boxes; isothermic bags; bottles including water bottles (containers); beverage coolers (containers); drinking containers; portable coolers; ice containers; ice packs; plastic containers (household utensils); lids for household or kitchen containers; tableware, including plates, dishes, drinking glasses, bowls, cups, saucers, mugs and jugs, all being of plastic materials; cooking utensils for use with domestic barbecues; storage boxes, baskets and containers for household use; household rubbish containers (bins); glassware for domestic use; ceramic tableware; baking trays; storage jars; cooler bags; thermally insulated bags for food and drink.

Essentially, the two parties are interested in co-registration of Israel TM 274301 to Smash Enterprises together with those registered by Talber Pop LTD. (Smash Enterprises did have a second application in class 18, but seem to have abandoned that, as to allow the same mark for similar goods in the same class is particularly difficult).

The Commissioner can allow co-registration under Section 30a for identical or similar marks for identical or similar goods if the application to do is filed in good faith or if there are extenuating circumstances that allows coexistence.

The wording of Section 30(a) is as follows:
Where it appears to the Registrar that there is honest concurrent use, or where there are other special circumstances which in his opinion justify the registration of identical or similar trade marks for the same goods or description of goods by more than one proprietor, the Registrar may permit such registration subject to such conditions and limitations, if any as he may think fit. (b) A decision of the Registrar under subsection (a) shall be subject to appeal to the Supreme Court. The appeal shall be filled within thirty days from the date of the decision of the Registrar. In the appeal, the Court shall have all the powers conferred upon the Registrar under subsection (a).

The Applicant for coexistence has to prove that he is acting in good faith. Furthermore, he has to establish that despite the marks being identical or apparently similar to those registered, there is no practical risk that the consumer will confuse between the marks. In this regard, in the 87779/04 Yotvata vs. Tnuva ruling it is stated that:

In rulings [based on Section 30a of the Ordinance] the emphasis will be on the equitable behavior of the parties adopting the mark and on the need to protect the public from similar marks that might create misleading or unfair competition (Friedman p. 431).

See also 48827-03-14 Biosensors Europe SA vs. Commissioner of Patents from 22 February 2015: The burden of proof that there is no likelihood of confusion falls on the two companies interested in the co-registration, and they have to prove that for many years they used the marks in Israel without the public being confused.

In this regard, the main thread running through the Ordinance is that identical or confusingly similar marks should not be registered if they will mislead the public. Thus in 10959/05 Delta Lingerie S.A.O.F vs Cachan Tea Board, India :7.12.06 :

Confusion and the risk of misleading is the living breath of the Ordinance. This is the main danger that we have to deal with. The various options of Section 11 that list marks that may not be registered reflect different types of confusion, and way to prevent them.

Where marks are more confusingly similar, the level of evidence that is required to show that there is no danger in their both being registered by Commissioner discretion under Section 30a is higher. See for example, the ruling concerning Israel TMs 24886 and 233056 Orbinka Investments LTD vs Now Securities Ohr Yehuda 1989 ltd., 24 July 2015 and 252115, 244719 Gaudi Trade SPA vs. Guess, Inc., 27 July 2016. Alternatively, the Commissioner has to consider whether there are other special considerations that allow identical or similar marks for identical or similar goods.

In this instance the parties have reached a coexistence agreement following arbitration before Adv. Gai-Ron, and the Arbitrator of IP prefers constructive discussion and compromise rather than judicial ruling that are all or nothing. Nevertheless, the mere fact that the parties are interested in co-existing is insufficient to allow it where the is a likelihood of confusion. The Commissioner has the sole authority and responsibility to ensure that the Israel public are not confused by such marks, and such agreements are no more than an indication
that must be weighed up with other considerations before allowing co-existence. See 1611/07 Micha Danziger vs. Shmuel Mor, 23 August 2012:

The desire of the parties that grow and market Gypsophila is one thing. The registration of confusingly similar marks is something else. Furthermore, and this is the important point – we are not relating to the parties’ consent, but to the balances in the law. The prohibition to register the requested mark is based on the need to protect consumers that were not party to the agreement between appellant and defender, (although such agreements may be indicative as part of a general analysis).

Thus it cannot be disputed that the Commissioner is not obliged to follow agreements between the parties. Nevertheless, in appropriate circumstances and where such agreements are valid, the Commissioner may allow co-existence based on such agreements – see 10105-05-16 Campalock ltd vs Commissioner of Patents, Trademarks and Designs 4/12/16.

In this instance, the parties submitted a two paragraph laconic request for co-existence stating that they had reached an agreement. However it is not enough to negotiate an agreement that serves the interests of the parties. A request to allow two pending applications to coexist or for a new application to be registered alongside an existing one must be justified by a detailed explanation showing why the public will not be confused.

There is no way to relate to whether the sides behaved equitably since the case should be closed before a hearing is conducted. The parties did not even address this issue in their request. The marks are identical for the word SMASH and there is certainly a similarity between schoolbags in class 18 and food bags and drink containers in Class 21 since these goods could be sold in the same retail outlets and there is therefore a room for confusion between goods in classes 18 and 21.

The Examiner reached a similar conclusion when she objected to the 2743011 mark under Section 11(9), and mere consent of the owner of a mark cited against a pending mark is insufficient to overcome a Section 11(9) objection.

The agreement does list the steps that the parties have undertaken to take, but this is insufficient. Firstly, the mark owner of the registered marks undertakes not to use a logo similar to that of the Applicant for cancellation, but the logo is not appended. An agreement not to use the same graphic is too narrow since the degree of similarity that is allowed is not related to. The registration would cause the register to be different from that happening in business.

Under the agreement, the side requesting cancellation would have the sole right to use the mark for boxes and containers for storing food and drink and the mark owner would be prohibited from so-doing. However, the mark owner’s registration 240598 (group 18) includes “food bags”. Food bags are essentially food storage bags. There is thus an overlap which creates confusion.

Thus the Arbitrator Ms Shoshani Caspi finds herself considering two identical marks for the word SMASH for two different entities that cover inter alia the same goods which creates a strong risk of confusion.
Consequently, as part of their joint submission, the parties should have provided a detailed explanation why TM 274301 in class 21 should be registerable together with TM 240598 in class 18. This wasn’t done, and the parties have provided no explanation as to how to avoid confusion. The request for coexistence is refused. The parties have until 1 June 2017 to inform whether they wish to conduct a cancellation proceeding.

Smash ruling, Ms Shoshani Caspi, 26 April 2017.

Comment

The ruling is solid and both parties were represented. The parties are interested in compromising. The Patent and Trademark Office have to consider the public interest and to prevent confusion, but nevertheless one wonders why the arbitrator did not simply request that the parties relate to a list of issues that their agreement does not address, rather than to refuse the request.

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Not in My Backyard: Blocking Infringement at the Real and Virtual Border

Presentations concerning the effective use of border enforcement mechanisms and blocking injunctions in the U.S., Canada, the U.K. and the EU were made at the 32nd Annual Intellectual Property Law Conference of the American Bar Association which took place in Arlington, VA on April 5th. A copy of a paper concerning developments in Canada that was presented may be found here.

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Unipharm Requests Accelerated Examination of Pending Novartis Patent Application

Israel Patent Application No. 249922 is a divisional application of 205208 that was filed on 3 January 2017, and which claims priority from USSN 60/985,668 filed on 6 November 2007. Under Section 16, the filing of the divisional application was published on 29 February 2017.

The ‘922 application relates to “DUAL-ACTING PHARMACEUTICAL COMPOSITIONS BASED ON SUPERSTRUCTURES OF ANGIOTENSIN RECEPTOR ANTAGONIST/BLOCKER (ARB) AND NEUTRAL ENDOPEPTIDASE (NEP) INHIBITOR”.

On 4 January 2017, the Applicant received a Notice Prior to Examination under Section 18 and regulation 36. Examination has not started.

Unipharm requested that the examination of the Application be accelerated under Section 19a of the Israel Patent Law. The request was supported by an Affidavit from Mr Zevulun Tomer, Unipharm’s CEO:

I affirm that if IL 249922 to Novartis AG is examined in due course, it will cause a delay in Unipharm’s development of a product that is a high priority. … Making the Examination special will prevent delays and costs and serves the public interest by making drugs more available at lower cost and by opening the market to competition.

On 2 April 2017, Novartis AG opposed the request. Their position was that the request was vague and did not fulfill the conditions of Section 19a(c). Novartis notes that Unipharm did not provide details regarding which drug they intended developing, and if their intent was to develop a generic version of ENTRESTO, Novartis noted that that product was protected by other patents, some of which were pending patent extensions, and so accelerating the examination of ‘922 would not have the allegedly desired consequences.

Novartis also noted that if an Opposition is eventually submitted against IL 205208 under Section 26 of the Israel Patent Law which published for opposition purposes on 31 January 2017, anyway under Commissioner Circulars 035/2017 and 020/2012, no extensions in the Examination of the ‘922 application would be allowed. The Commissioner noted that on 23 April 2017, the period for submitting an Opposition was still
open, so there was no need for him to address this theoretical issue. In response to Novartis’s counter-statement, Unipharm reiterated their claims.

Section 19a(c) provides the situations where a third-party can request acceleration of a pending application to another:

\[(c)\] A person other than the applicant, and who is not associated with the applicant or works on his behalf, may submit to the Commissioner a detailed request along with an affidavit supporting the facts, for an accelerated examination of an application that was published under section 16A, if one of the following occurs: (1) There is an established concern that the examination of the application of the patent according to the set order may cause the applicant of an accelerated examination application, who works in the field of the invention, a delay in the development or in the production of a product or a process claimed in the patent application under this subsection. (2) Time elapsed since the submission of the request is unreasonably long under section 15 or from the day the request entered the national stage under section 48D, and taking into consideration any significantly lengthy time since the lapsed date up to the beginning of the examination of other application of the same type. (3) Public interest; (4) Extenuating circumstances which provide justification.

As established re Israel Patent Application 221842 J. L. Glatt Lift ltd, 14 June 2016:

The possibility of accelerating examination under Section 19a is an exception to the general rule regarding examination that is given in Section 9 and regulation 34:

Applying the exception is likely to damage the principle of the first to file is to be awarded the patent and is likely to damage the general quality of patent examinations. For example, prior art that is not yet examined could be overlooked.

It is clear that accelerating examination under Section 19a is reserved for extreme cases where it is justified to deviate from the normal order. The burden of proof is on the Applicant for Accelerated Examination who is to detail his request and support it with evidence.

Unipharm’s request and Mr Tomer’s affidavit relate in general to Section 19a(c) but it appears that they intend part (1) which relates to ‘delays in developing or manufacturing a product’ that Unipharm intends to manufacture, and to part (3) that relates to the ‘public good’ that is served by greater accessibility to drugs, reduced costs and competition in the market.

Unipharm claims that under their work program, if a patent issues for the ‘922 application, this will prevent them developing and then manufacturing their product. Unipharm’s affidavit details the managerial program and preferences. The Commissioner Asa Kling does not see any reason not to accept an Affidavit from a CEO who may be presumed to know the company’s plans. There is no need to cross-examine under Section 163a of the Israel Patent Law 1967, and if it should transpire that Unipharm have lied, this Affidavit could be used against them. Therefore, it seems that Unipharm have provided the appropriate support for their request as required by Section 19a(c)(1) of the Law for accelerated examination.
This is not the case with respect to ‘public interest’ under Section 19a(c)(3) of the Law. As explained in the Glat Lift case, accelerated examination under Section 10 is reserved for extraordinary cases that are important to the State of Israel in general. The Application and Affidavit do not point to such a specific condition. It does not explain how accelerated examination will result in competition that will bring about a drop in prices. As Novartis noted, it doesn’t even explain which market sector will have enhanced access. The Section 19a(c)(3) justification is rejected.

However, due to the Section 19a(c)(1) justification, examination of pending application 249922 will be expedited on payment of the relevant fee. Suspension or extensions will be permitted only in accordance with Section 19(a)(1) of the Law. No costs are awarded.

COMMENT

In this instance, as we are dealing with a divisional application, there is no danger of earlier filed not published art being missed due to the patent being examined out of turn. The Commissioner Circulars 035/2017 and 020/2012 explain Patent Office policy to examine divisional applications of opposed applications as fast as possible. There is a real danger that applicants for pharmaceuticals that are opposed will file continuations and divisionals to keep the patent application alive in an attempt to evergreen. So on balance, it seems that the request is reasonable and the Commissioner was right to grant it. If Novartis are acting in good faith, they should be interested in having their patent application examined as fast as possible. They have not provided a justification for delaying, such as wanting to wait for examination of a corresponding application to be concluded so that they can request allowance under Section 17c or similar.

With a justification under Section 19a(c)(1) it does not matter that the Section 19a(c)(3) request was denied. However, I don’t fully understand the Commissioner’s reasoning. If he considers that one has to be facing a drug shortage within an epidemic, that is one thing. However, I don’t think that one should have to explain how allowing generic competition lowers drug prices for the common good. This is self-evident and true for all drugs, and the underlying logic of free markets and really dates back to Adam Smith’s Wealth of Nations. Still, the Law does seem to require something extraordinary.

We note that Unipharm successfully handled this request themselves, without professional representation. This is not the first time that Unipharm have successfully fought inter-partes proceedings at the Israel Patent Office without using an attorney. Nevertheless, others are strongly advised not to follow their example.

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International Action Group (IAG)

A hub for international associates affiliated with the ABA-IPL to participate in all areas of the Section, in order to communicate, network, and to work together to build global bridges.

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- Maintain your connection to U.S. and global trends in IP law with the Section’s bi-monthly Landslide® magazine;
- Network and participate in Section international programming and events with member colleagues: leaders, global law firms, and multi-national corporate counsel from over 75 countries; and
- Present proposals to speak, moderate, or organize a program at an ABA-IPL conference, teleconference or webinar in the United States.