

SOCIOECONOMIC AND INTELLECTUAL PROPERTY ANALYSIS IN PHARMACEUTICAL NATURAL PRODUCTS

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SUMMARY

The absence of a consolidated definition of the term “natural product” is a problem to establish a relationship between this concept and intellectual property. The intellectual property includes many different categories, such as distinctive signs, invention patents, author rights, plant variety rights and other categories not recognize by all entities and countries denominated *sui generis*, for example, test data, traditional knowledge and the access to genetic and biologic resources. The objective of this study is to analyze with a diagnostic approach the added value that natural products have received through different types of intellectual property. Methods: The present study is a diagnostic and descriptive analysis of the relationships between natural products and the different types of intellectual property. A search using the World Health Organizations databases about intellectual property and the web pages of the world most important offices of intellectual property was used. Finally, a triangulation of the consulted information was carried out. Results and Conclusions: An increase of protected natural products was detected. The intellectual property identified categories were invention patents, plant variety rights, and distinctive signs. It is in consequence to the increase in national laws related to intellectual property that responds to the trades treaties present in some regions, for example, Latin America. However, there are two phenomena related to natural products. In first place, the natural products with some type of protection are concentrated in developed countries and multinational corporations, and in second place, a lot of natural products in Latin America do not have intellectual protection, usually due to the absence of the most beneficial categories of intellectual protection in the trades treaties or because these categories are not recognized by the States or international organizations.

KEYWORDS: brand name, intellectual property, natural products, patent.

INTRODUCTION

The intellectual property refers to a series of exclusive rights awards to the creative persons and the owners of intangible assets, which results in its legitimate possession. This initial approach may be clearer when analyzing the following definition: The intellectual property (IP) refers to the patents, brand names, copyright, industrial designs, and other kinds of intellectual goods that are generated in the creation of the mind, and in a broader sense, do not have a physical form (Organización Mundial de la Propiedad Intelectual, 2007, p. 6). When says that “in a broader sense, do not have a physical form” refers that despite they are intangible, these products could be physical matter, like a product, a book, a bottle, among other products and services (Madrigal Redondo G.L, 2010).



Figure. 1: Examples of natural products based on aliphatic primary alcohols isolated from sugar cane that has different kinds of intellectual property, like patents and brand names.

The main issue to establish a relationship between natural products and intellectual property is the delimitation of “natural product” definition. Usually, natural products are the processed, industrialized, and labeled products with medicinal properties that contain in their formulation ingredients obtained from plants, animals, minerals or mixes. They also could contain excipients besides the natural material (Costa Rica Procuraduría General de la República, 2013, p.1).

The preparations based on the resources obtained from natural raw material through fractionation, extraction with solvents, distillation, purification, fermentation, concentration or some different physic or biologic process are also considered as natural products (Costa Rica Procuraduría General de la República, 2013, p.1).

Intellectual property importance in society lies in the fact that, like any given property, it awards to its creator exclusive patrimonial rights, which could be commercially useful. (Cabanellas de las Cuevas, G., 2004). In addition, the protected goods give to its creator rights related to moral, confirming that the protection and implementation of property rights stimulate human inventiveness, and promote and accelerate the new ideas creation (Organización Mundial de la Propiedad Intelectual, 2007, p. 7).



Figure. 2: Natural product example that combines the traditional knowledge, designation of origin and a traditional brand from the tobacco plant.

The industrial property scope could frame in distinct immaterial goods categories that are used in industry, understanding the industry in its broader sense. WIPO in the document “Comprendiendo a la Propiedad Industrial” defines the term industry but the broad application of the term industry is established in the Paris Convention for the Protection of Industrial Property (Article 1(3)): The industrial property should be understood in its widest sense, and must apply not only in industry and commerce but also in agriculture, industries of any denomination, all types of natural products manufacture, like wines, grains, tobacco, fruits, minerals, mineral waters, beers, flowers and flavors (Organización Mundial de la Propiedad Intelectual, 2008; p.2).

It could be confirmed that the “Paris Convention” objective is to protect the immaterial goods that are

useful in industry and commerce, such as brand names, designation of origin, emblems, invention patents, industrial designs, among other categories (Unión de París. Procuraduría General de la República, Sistema Costarricense de Información Jurídica. 1886, p1).



Figure. 3: Example of a natural product that combined a plant traditional use, a biologic resource extraction and, a commercial brand name from *Quassia amara*.

However, the intellectual property rights are sometimes in conflict with other rights, for example, biologic material extraction rights and native populations rights. The term traditional knowledge is understood as a living entity of knowledge that passes down from one generation to the next in a community. Frequently, it forms part of the community cultural and spiritual identity. In the WIPO’s program about traditional knowledge, the genetic resources and the traditional cultural expressions are also covered (Organización Mundial de la Propiedad Intelectual, 2015).

The main objective of this study is to analyze with a diagnostic approach the added value that natural products have acquired through different kinds of intellectual property.

MATERIALS AND METHODS

This text is a diagnostic study about the relationship between intellectual property and natural products in Latin America during the period 2000 – May 2016. The study main variables are brand names, designs, plant variety rights, designations of origin, geographical indications, natural product protections, patent applications, granted patents, the main inventors, the main applicants and the major applications in the field. The objective was to correlate these variables with the state of the art and establish priorities or fields where the technology, as a scientific application, is used to the development and innovation of new products. The WIPO’s databases, for example, Patentscope®, were used in the variables analysis to quantify and classify the number of patent applications in this area, and to the correlation analysis between the state of art and the variables above-mentioned.

A randomized sampling was used to obtain a representative sample with 95% confidence and the total population of the patents applications was considered.

From this, the patents applications were classified according to the main fields of art. Also, a descriptive search using the web pages of America and WIPO's most important intellectual property offices was used. And finally, the obtained information was triangulated to develop a concept map.

RESULTS AND DISCUSSION

Establish a complete relationship between intellectual property and natural resources is not easy due to the

complexity of the interrelation. In the above figures, it is possible to observe that a natural product often combines different intellectual property categories. Also, there are intellectual property categories recognized by agreements and institutions, but not recognized by some countries. For example, the access to genetic and biologic resources and the traditional knowledge. Figure 4 shows the general interrelations between natural products and intellectual property.

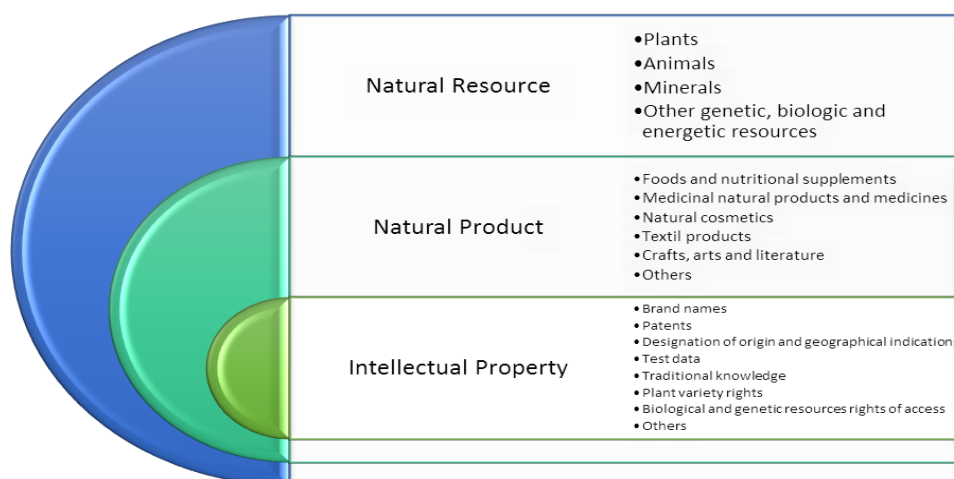


Figure. 4: Interrelation between intellectual property, natural products, and natural resources.

In 1996, the World Trade Organization (WTO), establish a treaty called Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). The objective was to “*reduce the international trade distortions and barriers, considering the requirement to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not become barriers to legitimate trade*” (Organización Mundial del Comercio 1996).

However, nowadays exist a large concentration of intellectual property rights in some sectors, including the natural products, which keep the trade distortions and barriers as shown in Figure 5 and Figure 6. In the pharmaceutical field, the products that are based or include natural products have created disputes related to the influence of the intellectual property rights, especially invention patents, in right to health and medicines access (Pan American Health Organization, 2004 y 2006).

Analyzing the invention patents, the evaluated aspects was the number of patents applications with natural products derived from medicinal plants, the main countries that patent natural products and, temporary distribution of the patent applications in the last 10 years.

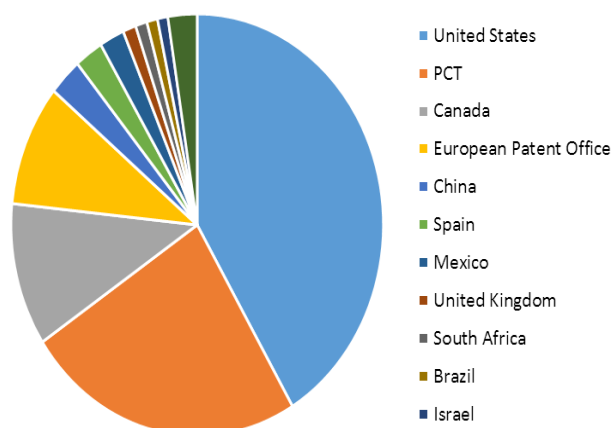


Figure. 5: Patents regional offices distribution per country with the term natural medicine in the database Patentscope®. Source: World Intellectual Property Organization, 2016.

The United States of America is the leader, with almost fifty percent of the patent applications. The second place is the WIPO's office through the Patent Cooperation Treaty (PCT) with approximately twenty percent, and the next is Canada and Europe through the European Patent Convention (EPC), each one with around ten percent of the total patent filed (World Intellectual Property Organization, 2016).

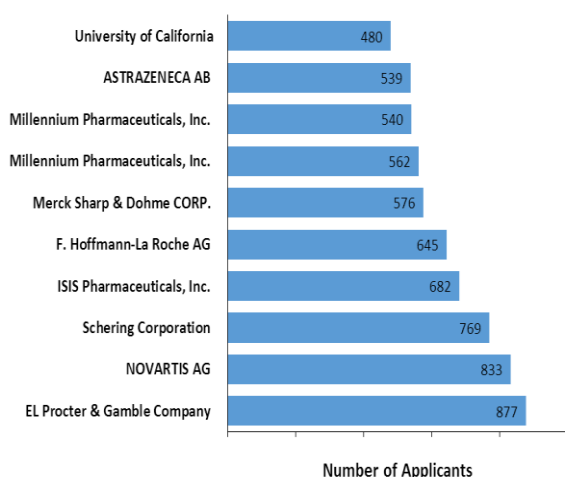


Figure. 6: Patents distribution per applicants with the term natural medicine in the database Patentscope®. Source: World Intellectual Property Organization, 2016.

As in the previous figure, the main applicants to the natural products derived from medicinal plants is restricted to a few ones, including Astra Zeneca, Glaxo Group Limited, Novartis, F Hoffman, La Roche, with almost a twelve percent of the total applications (World Intellectual Property Organization, 2016).

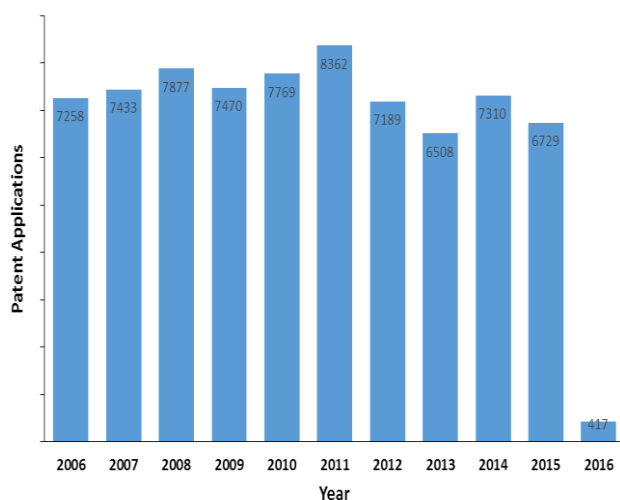


Figure. 7: Total patent applications distribution per year with the term natural medicine in the database Patentscope®. Source: World Intellectual Property Organization, 2016.

Based on Figure 7, there are increasing patenting activity cycles of natural products derived from medicinal plants. The cycles are five years, and the increase of each cycle is higher than the previous one. It is important to emphasize that patents are a simple solution to evaluate the natural products and intellectual property interrelation development. It is due to the patents describe the technical characteristics, for example, the origin or nature of materials. Although a patent does not necessarily imply the product commercialization, and a product marketed not necessarily had a patent, this study

establishes the degree of relation between natural products and intellectual property, mainly in developed countries. Some other studies in intellectual property do not allow the interrelation between the product characteristics and intellectual property, with the only exception of the designation of origin and geographical indications. Consequently, development and implementation of different study mechanisms is needed to quantify and analyze the mentioned relationship (World Intellectual Property Organization, 2016).

A special procedure for the natural products protection does not exist, but in some countries, the legislation is working on this issue. For example, in the United States of America, animals, plants and natural products can be protected, while in Costa Rica animals and plants cannot be protected, and natural products should be inventions, not discoveries, to receive the protection. In El Salvador, only plants can be protected and in Europe the wild animals (Costa Rica Procuraduría General de la República, 1983 b, 2000b, 2000c).

Some natural products are relevant at sanitary level due to the compulsory of a sanitary authorization. A sanitary authorization or health registration is a kind of intellectual property *sui generis*. However, the legislation between the countries is very different in requirements and product definitions. Examples of products categories are foods, dietary supplements, natural cosmetics, natural products derived from plants, and phytopharmaceuticals.

The registration of cosmetic products is not required in the United States of America, and internationally, there is not a standardized definition for natural cosmetics and organic cosmetics. Usually, that kind of products are classified by private certifying bodies through certification marks and in consequence, the requirements differ significantly between them.

On the other hand, medicines are linked to another type of intellectual property *sui generis*, specifically ADPIC PLUS. In these cases, the test data bring protection to clinical information during 5 – 10 years and it is needed for the medicinal product registration.

Microorganisms and genetic material protection have acquired relevance. In some countries, like Cuba, the patents laws clearly expresses the impossibility of patent human genetic material. However, in other countries, it is not clearly expressed. For example, Mexico allows it tacitly, and in the United States of America it is possible, but the regulations are very strict. The microorganisms and genetic material legislation forces to realize a material library to certify its date and origin, and to facilitate the material access and reproduction.

According to the legislative differences, the *sui generis* protection to new varieties of plants has increased. It is a protection type of genetic and biologic resources ruled by the International Union for the Protection of New

Varieties of Plants (UPOV). In Latin America, there have been registered a few cases of this new protection type, and it is due to the lack of legislation, in contrast to Europe that has experimented a strong development. Despite that, Latin America is characterized by a wide range of improving crops, such as potato, quinoa, corn, among others. These crops have a lot of varieties, demonstrating the great potential of establishing the interrelations between intellectual property and natural products (Rapela M., Schotz. G., 2006).

In Costa Rica, have been developed projects of plants improvement to the production of natural products with best commercial, organoleptic, resistance and productivity characteristics. For example, the "Perfect

Papaya", chili, and wild fruits like pejobaye and sour guava. But the challenge is to combine the next three variables: traditional and technical knowledge, intellectual property rights and, the production and added value.

This analysis studies the most useful mechanisms to provided added value to natural products through different kinds of intellectual property. Geographical indication, designation of origin, collective marks, certification marks and commercial marks, in that order, are very useful to provide a low – middle protection and added value to the natural products.

Table. 1: Definition comparison between the distinguishing signs categories and related examples.

Category	Definition	Examples
Designation of origin	Designation of origin is the name, expression, image or sign of a place, region, or country used to designate a product originating in that specific place, region, or country. The product quality and characteristics should be attributed exclusively to the geographical environment, and human and natural factors.	Tarrazú coffee Turrialba cheese Honduras coffee
Geographical indication	A geographical indication is a sign that identifies a product originally from a specific place, a region or a country. Its quality and reputation are attributed, essentially, to the place of origin. Any sign or signs could constitute a geographical indication.	Guatemala sugar Habano Mud from the Dead Sea
Brandname	Brandname is any sign or signs combination that allows the products or services distinction between different persons. It should be enough distinctive to identify the goods or services from others of the same class.	OKF® Tropical® Imperial® Abexol® Q-assia®
Collective mark	Collective marks are signs that distinguish a product or service of different enterprises. The owner is a collective entity that group authorized persons or enterprises to use the mark.	Esencial Costa Rica Ron de Cuba 100% Frijol de Costa Rica
Certification mark	Certification marks are signs that receive products or services with characteristics or quality parameters that have been controlled and certified by the mark owner.	Ecocert® ISO® USDA Organic®

Source: Costa Rica, Procuraduría General de la República, Sistema Costarricense de Información Jurídica. 1983 c.

In America, the designation of origin and geographical indications are new intellectual property categories that have been little used due to the lack of legislation. In Europe, these kinds of protections are highly developed and are two of the protection types that recognize the traditional knowledge, origin, and access to the products. Cuba highlight in America due to the development of fifty denominations of origin or geographical indications, including the following products: propolis, honey, tobacco, cigars, sugar, coffee, and rum. On the other hand, in Mexico, products like liquors are important, for example, the tequila produced by the Agave Azul fermentation through traditional practices in specific regions.

Central America has been working in the implementation of the mentioned kinds of protection. Economic agreements with the European Union that require the recognition of origin and geographical indications was signed. The Turrialba cheese and Tarrazú coffee from Costa Rica, Honduras coffee, and Guatemala sugar, are the first products with the denomination of origin and geographical indication in the region. In South America, these intellectual property protections are in development, for example, Colombian coffees, Chilean and Peruvian pisco, or the Brazilian meet cuts, coffee, and the famous cachaza.

In Europe, this system has the highest development, there are thousands of origin denominations for natural products, for example, Valencia rice, Kalamata olives, Parmesan cheese, Rioja wine, champagne. However, most of the protections are for foods, an indication that

some other kinds of products are not protected by denominations of origin, except for cosmetics based on peloids, thermal waters and clays. For example, in Galicia have been developed different protection types like the collective marks and certification marks that are more flexible to protect products like crafts, textile products, cosmetics and natural products derived from plants.

Certain natural products companies have developed generic marks that are used as collective marks to its products but the considerations to registration are not fulfilled, for example, Herbalife®, Omnilife®, Tio Nacho®, Genoma Labs®, Ayurveda®, among others.

In addition, a subcategory of the mentioned protections is the “Country Trademarks”, which framework in the same context the origin, collective mark, and certification mark. An example is the country trademark Esencial Costa Rica®.

In the crafts, art and textiles fields, the copyrights, industrial models, and design models have an especial importance. The copyrights offer a low protection, but guarantees the authorship of a work, which in many times, are exclusive designs or produced with specific materials, especially in native communities. Copyrights protect the written, dramatic, and expressive creations, including artistic, musical, and dramatic works (Costa Rica, Procuraduría General de la República, Sistema Costarricense de Información Jurídica. 1983a).



Figure 8: Descriptive scheme of the main intellectual property categories related to natural products protection.

One of the main situations found in the present analysis is the fact that many natural products and derivatives are not protected due to the economic costs or the lack of legislation, either because of it still in development phases or because it has not been incorporated into current legislation. For example, the rights of access to genetic material and biodiversity have not been incorporated into intellectual property despite there are international conventions like the Cartagena convention. Costa Rica leads at world level the incorporation of the mentioned rights to intellectual property. There is a

special Biodiversity Law that correlates the rights of genetic material and biodiversity to intellectual property, specifically with the invention patents. In this case, it is necessary a previous revision by a technical entity before the patent concession and also, it is required the establishment of bioprospecting rules (Costa Rica, Procuraduría General de la República, Sistema Costarricense de Información Jurídica. 2000a).

The traditional rights of native communities are usually discussed. The “Traditional knowledge” is understood as a living entity of knowledge that passes down from one generation to the next in a community. Frequently, it forms part of the community cultural and spiritual identity. WIPO’s program about traditional knowledge also include the genetic resources and the traditional cultural expressions (Organización Mundial de la Propiedad Intelectual, 2015).

Both, the access to genetic resources and the traditional knowledge, are strongly associated. In Latin America, is imperative to legislate about these topics due to the important resources that native communities conserve and the important biodiversity that characterized the region. Some countries, such as Bolivia and Panama have been working in the implementation of the mentioned legislation.

One of the main principles of intellectual property is its non-exclusivity between different categories. Therefore, a combination of different categories gives a higher protection. However, the economic barrier, especially in developing countries or in low resources communities, is usually a limiting factor to apply this principle, which does not necessarily means the absence of intellectual property rights, but it has not been consolidated.

CONCLUSIONS

There is a clear tendency to protect, through different intellectual property categories, the natural products. Also, there are differences between the protection procedures for plants, animals, microorganisms and natural products accordingly with regions or countries. The intellectual property provides an added value to natural products. Despite the mentioned facts, there is a deficiency in the protection of intellectual property rights related to the traditional knowledge and natural resources. In addition, a lot of natural products property rights are not legally consolidated which do not allow data generation.

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