ENTREPRENEURSHIP AND SCIENTIFIC RESEARCH IN THE NUTRACEUTICAL INDUSTRY.THE CONCENTRATION AND DISPERSION INTELLECTUAL PROPERTY

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Abstract- This article analyzes the nutraceutical industry worldwide through the number of companies in this category. Intellectual property is measured by counting the patents have been generated worldwide and the number of publications produced by so-called, scientific stars of the most important countries. The involvement of business and academia is essential to the development and success of this industry, but not least, the protection of intellectual generated to maintain the level of innovation necessary for growth of the nutraceutical industry inventions.
This article shows the importance of the nutraceutical industry in the field of healthy foods, emphasizing the trend and profile companies and academics to protect their creations and inventions through intellectual property. It is analyzing the regulations of different countries, companies involved in this industry, the theory of entrepreneurship, knowledge and intellectual property.

Index Terms- Entrepreneurship, Intellectual Property, Nutraceuticals, Scientific Research.

I. INTRODUCTION

The nutrients obtained from adequate foods are vital to maintaining the functionality of the human body. With recent advances in medicine and nutrition, the benefits of food have received wide attention from health professionals and the population. New concepts have appeared with this trend, such as functional foods, nutraceuticals, nutritional therapy, among many others (1). In this way, Stephen De Felice, in 1989 coined the term "nutraceutical" like a natural product or substance that is a food or a part of food with biological active properties, with health benefits and disease prevention capacity and/or therapeutic effects. One of the major difficulties in the classification of nutraceuticals, is knowing exactly what the parameters established by each country to know what products may or may not be considered as such are nutraceuticals. This is due to the large number of products and derivatives that can be used to make a nutraceutical.

In contrast to the natural herbs used by the Asian traditionalists folk medicine, nutraceutical products is a modern approach, with a very strict scientific basis in food, pharma and biotechnology components, to follow patterns of modern medicine and nutrition and to use genetic engineering to obtain surprising results in the field healthy foods.
The frontier between healthy food, nutraceuticals and medicines is very close. From this, is important to uniformized the legislation through public policies, both for developed and developing countries, as important issues of nutrition and health are present in such products.
According to the Association of American Food Control Official (AAFCO) in 1996, two segments constitute the nutraceutical word, one is "nutrient" and the other segment is "pharmaceutical or biopharmaceutical". "Nutrient" means any substance contained in foods that cannot be created in the body, which aims to provide energy, amino acids or essential elements, while "pharmaceutical" or "biopharmaceutical", means the properties and actions of natural or synthetic substances in living organisms (conformed by small and/or big molecules manipulated by the human).

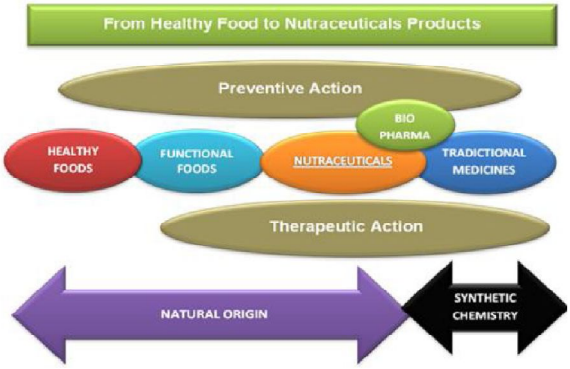
Then the joining of the two words gives "nutraceutical", that is any non-toxic food component that has been scientifically proven the health benefits, including prevention and treatment of disease.

A more comprehensivedefinition is developed by Agriculture and agri-food Canada (2) in which nutraceuticals are *"…products purified from foods that are generally sold in medicinal forms, such as powders, tablets or capsules, demonstrated to have physiological benefits or to provide protection against chronic disease. Nutraceuticals can be derived from plants (e.g., antioxidants, Echinacea, fenugreek, etc.), from animals and microorganisms (e.g. elk velvet, essential fatty acids, enzymes, etc.) and from marine sources (e.g., glucosamine, chitosan, fish oils, etc.)".*

By Health Canada, nutraceutical is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.

(2).These natural products are located on the border between food and medicine themselves (Table 1).

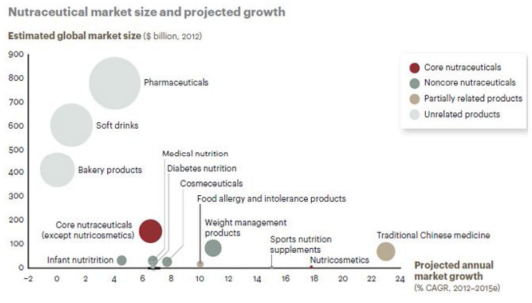
Table 1: From Healthy Food to Nutraceuticals Products



Source: Author elaboration

A KPMG study (3) indicates that the global market for nutraceuticals US dominates with 30%, follow Japan with 22%; Europe 14%, while the rest of the world is left with the remaining 34%. According to Shinde et al. (4), nutraceutical (including core, partially related and nutricosmetic) US market for 2014 was about 250 billion US. Each year, about 1,000 new products are launched on the market. Table 2 shows the globally market size and the projected growth by 2015, where we can see that the potential of the nutraceutical market throughout the world, outweigh the cosmetics, medical nutrition, infant nutrition, diabetics nutrition, weight management products, traditional Chinese medicine and is surpassed only by bakery products, soft drink and pharmaceutical sector.

Table 2: Estimated Global Market vs Projected Annual Market Growth on the Time



Source: ATKearney, (5)

Given the importance that is taking the nutraceutical industry in the world, is that becomes important to analyze the entrepreneurship generated by this industry, measuring the amount of intellectual property like patents worldwide, as well as related to scientific and academic production by major publications generated by scientific stars of the most important countries. The involvement of entrepreneurs and academics is essential for the development and success of this industry, but it is no less crucial, intellectual protection of inventions generated to maintain the level of innovation necessary for growth of the nutraceutical sector. Intellectual property (like a patents and scientific publications) can protect an active ingredient extracted from a living organism and adapting or reforming this original product with a new biopharmaceutical entity and obtain an original component with a different and innovative structure called nutraceutical healthy food.

This article attempts to show the importance of nutraceutical industry in the field of healthy foods worldwide, emphasizing on the trend and profile of firms and academics to protect their creations and inventions through intellectual property. It seeks to analyze regulations of different countries, companies involved in this industry, theory of entrepreneurship, knowledge and intellectual property.

II. THEORY AND ENTREPRENEURSHIP

The entrepreneurship term began to take shape as we interpret it today from the evolutionary studies on innovation made by Joseph Schumpeter (6), who proposed the concept of “creative destruction” and “entrepreneurship”. For him, the entrepreneurship notion is not a close concept, because this covers numerous variables involving both internal and external components from the company, in relation to productivity, growth, investment, risk, governance, culture. It is an ecosystem (7) that is in constant evolution and interaction between the parties and therefore far from a stipulated stability. For its part, innovation is the only business activity is closely related to economic growth. Schumpeter (6) launches that what is known as a process of "creative destruction" through which companies that do not adopt new technologies and innovate tend to disappear. In this sense, for Schumpeter, the entrepreneur is primarily generating innovation. However, many economists do not consider the importance and influence of the entrepreneur in the early stages of economic development, but rather in the later stages of development, where economic growth is driven by knowledge and competence (8). For Soriano and Huarng (9), the role of employers is crucial in the creation of new economic activities that contribute to generating wealth, jobs and growth, as well as to ensure the welfare of society.

On the other hand, “neoclassical theory” from the perspective of "Marshall" tries to explain the equilibrium conditions in the markets under the assumptions of the preexistence of knowledge and free information. Perfect competition, uniformity in the existence of goods and the free entry and exit, make this theory somewhat anachronistic versus the evolutionary theory, where it is analyzed from an opposite point of view from J. Schumpeter's theory. The principles of "Marshall" attempts to show that markets operate under certain assumptions of perfect competition, in which there is no chance of excess profits and therefore there is no exploitation of labor in the production process. Marshall suggests that

large-scale production is essential to economic progress and economic innovation (10), while postulated that the equilibrium is obtained through the many different players in the market, competition, therefore, it occurs in a non-monopolistic market and perfect balance. His theories consider the establishment of the balance of supply and demand in the market for goods and services. While Schumpeter considered "creative-destruction", no balance, changing markets, skills and resources as hubs of innovation.

Growth theories tend to recognize that knowledge generation and thus innovation that accompanies this play a crucial role in determining the trajectories of many of the national and regional economies (11; 12). The entrepreneurship, which is generated through the dynamics of innovation, with the development of new processes, products and organizational structures tends to concentrate in regions where knowledge is produced within an ecosystem where there is a continuous interaction between different crucial actors like a public and private firms, government agencies, financing agencies and universities. (13).

Entrepreneurship is based on the following assumptions: It requires the existence of opportunities; differences exist between people; the relationship to risk; it is a process that braids reports with innovation activities and organizing (14). Business functionality can be conceptualized as the discovery of opportunities and the subsequent creation of new economic activity, often through the creation of a new organization (15). However, innovation is framed in the dynamics of economic growth and competitiveness associated to knowledge based on one economic sector or region (16).

Entrepreneurship in the nutraceutical industry is very important and a net progress in many parts of the world where we have an interesting number of companies dedicated 100% to the industry, and the net dominator, the United States with 342 companies, followed very far by Canada with 15 companies and then comes a group formed by Japan, France and China with four companies, after India and Israel with three companies each country (17).

Whereas the United States as the leader in the world of nutraceuticals is important to note that a concentration of nutraceutical companies in certain states is observed. California leads with 63 companies of the 342, followed by New Jersey with 52, then New York, with 39 companies and the final concentration is 18 Florida nutraceutical companies. The rest of the companies are spread by all the country, but without a higher specific gravity.

III. INTELLECTUAL PROPERTY

The World Intellectual Property Organization (WIPO) provides a number of protections against the use of unauthorized third parties about a new product, created by human intelligence and has no obvious features (this must be tangible). Referring to the nutraceuticals for example, there is what is known as Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which seeks, among others, the protection of traditional medical knowledge of IP addressing issues that have to do with access and the sharing of benefits from genetic resources generated as novel thus avoiding misappropriation by unauthorized third parties, which have patented compounds derived from traditional medicines without the prior consent of the owners.

One of the features most used by the inventors of enterprise for protect their creations is the patent, but not unique. To obtain a patent, an invention must be new, original and industrially applicable. A patent grants a bundle of exclusive rights for a limited time, usually 20 years, which allows the inventor to prevent others from making, using, selling, offering for sale or importing the patented invention without permission. Another mechanism of protection is copyright, which protects literary works and in this case academic scientists who use them. In this sense, Fedhera et al. (18) evaluated the role of formal intellectual property rights (IPR) in the configuration of the downstream demand for knowledge that is given to initially know through scientific publication, in fields where research is generated and is used across different institutional bridges (comparatively between academia with industry). For scientific discoveries with potential commercial application, researchers may seek to establish a formal intellectual property protection to enable researchers to access knowledge described in a particular journal.

Lei et al. (19) estimate that a system of intellectual property (IP) can promote inventive skills in science and help to promote the transformation of research achievements in marketed products. But the restrictions associated with access can reduce the use of inventions by other scientists. It is well known that biological scientists report increasing difficulties associated with access to research tools, but only if the tools are built into the physical property controlled by others and not easily duplicated.

Intellectual property rights (IPR) have taken a vital importance for innovative businesses. One of the reasons for this is the weight of knowledge management in companies. Innovation processes depend largely on knowledge generation, why protect that power generation is essential. The intellectual property rights are used not only to protect innovation but also to defend a competitive and to search for new funding as effectively letter position (20)

The increased use of intellectual property rights (IPR) in scientific research has triggered a major academic

and political debate. On the one hand, it highlights the benefits of IPR, which is suggest that this can facilitate creativity, improve financing and the exchange of knowledge and skills that would otherwise remain secret. In fact, in the context of university research primarily with public funds, it has been suggested that DPI offers important incentives for the production and commercialization of discoveries (21).

IV. REGULATIONS

A study by Meštrović (22), illustrate that the regulations related to nutraceuticals are not globally uniform. Each country sets its own definitions and rules, according to their needs and knowledge. In the US, the Food and Drug Administration (FDA) regulates nutraceuticals under a different set of rules for covering "conventional" foods and pharmaceuticals. The FDA is who authorized to act and seize any dangerous product that hits the market. Manufacturers have to ensure that the information on the label is truthful and not misleading, but are not required to register their products with the FDA or get FDA approval before producing or selling nutraceuticals. In the EU, the European Food Safety Authority (EFSA) is who regulates nutraceuticals products. This legislation focuses on "food supplements", defined as concentrated sources of nutrients (e.g., proteins, minerals and vitamins) and other substances with a beneficial nutritional effect. The main EU legislation on food supplements is Directive 2002/46 / EC. In Europe, development and quality requirements are extremely stringent. As a result, the European nutraceutical companies, which are generally considered to be leaders in innovation, enjoy a perception of producing high quality products. In Canada and Australia, nutraceuticals are regulated almost as if it were a drug. The Indian law does not attribute any specific legal status for nutraceuticals. The regulations for nutraceuticals, Government of India Act include the Food Safety and Standards (FSSA), which was adopted in 2006 but has not yet been implemented. In short, in most countries, nutraceuticals are regulated as a food category. In some regions or countries, there is an explicit set of rules for supplements (eg, United States, European Union, and the Association of Southeast Asian Nations) and nutraceutical (India, Canada and Australia), derived from a paradigm regulatory based foods. In Latin America, access requirements vary nutraceuticals market, with registration based approaches used in Colombia, Brazil and Argentina, and reporting approaches in Mexico and Chile. In countries like Brazil, China and Taiwan, regulators require clinical studies in animals and humans as a requirement for registration nutraceutical.

Table 3 shows some characteristics related to the different rules governing the definition and characteristics of nutraceuticals in the United States, European Union, India, Japan and China.

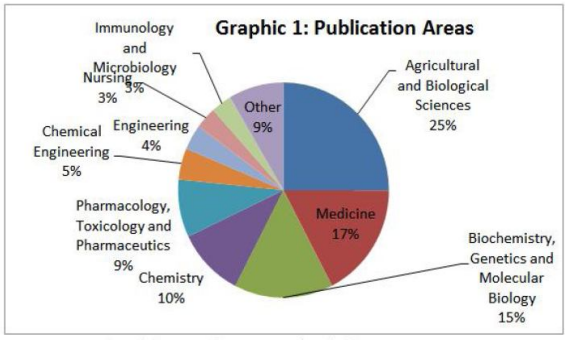
Table 3: Varying Definitions and Regulations for Nutraceuticals around the World

Country	Given Label	Definition	Regulating Body
United States of America	Dietary Supplements	Any of the following which have a beneficial nutritional effect • Vitamins • Minerals • Botanicals and their extracts • Amino Acids • Concentrates and Extract	Food and Drug Authority
European Union	Food Supplements	• Concentrated Sources of Nutrients • Other substances with a beneficial nutritional effect	European Food Safety Authority
India	Foods for special dietary use	• Plants/botanicals: Whole or extracts • Minerals, Vitamins, Amino Acids, Enzymes • Substances of animal origin	Food Safety and Standards Act
Japan	Foods for Specific Health Use	Any food that can provide and/or supplement any of the following • Nutrition • Sensory Satisfaction • Beneficial Physiological Effect	Japan Health and Nutrition Food Association
China	Health Foods	Any food that • should be suitable for specific group(s) of people • should also be able to adjust body functions and • should not aim at curing diseases or cause acute, sub acute or chronic harm to the body	State Food and Drug Administration

V. RESULTS

To analyze the nutraceutical industry, different databases with the intention of making a comprehensive diagnosis of the sector and its importance in generating companies, patents and publications are studied.

The graphic 1 show the publications by application areas in nutraceuticals industry and illustrate the intervention of a very varied field of action between which we have agricultural and biologicals sciences with 25% of total publications, followed with 17% by medicine; biochemistry, genetics and molecular biology has a 15%; chemistry 10% and pharmacology, toxicology and pharmaceutics with 9%. Other fields in the composition of the nutraceuticals publications area are more marginal, reaching 9% and 15% all together.

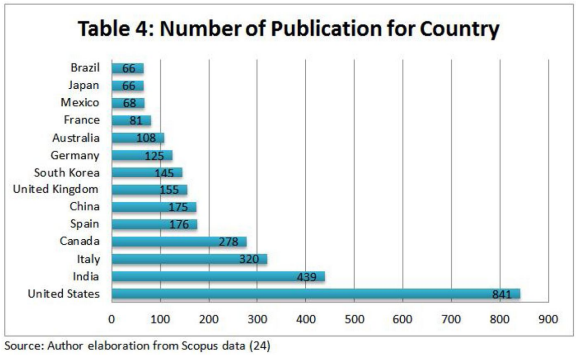


Source: Author elaboration from Scopus data (24)

The decision of a scientist in relation to developing an entrepreneurship and market the yields of their innovative activity, not less, as some academics, by either training or skills and different expertise, are more likely not only to publish their creations but also to market their findings depending on supply and demand that may be able to detect. However, this action is not only dependent on the scientist, but also comes to play the institutional, the scope of research funding, the culture of the university / department and the influence of colleagues who have been identified

as determinants in making the decision to transition to the scientific entrepreneurship (25; 26).

However, table 4 indicate it can be seen that the number of publications by country is quite different from that of the authors, since it places the United States leading with 841 publications, followed by India with 439, Italy with 320, Canada with 278 publications. While South Korea (in next Table), is in the eighth position and Saudi Arabia, not even on this list. This shows that there is a high concentration of researchers in certain countries such as South Korea and Saudi Arabia and on the contrary, a large spread in countries like USA, Canada, Italy, Portugal, Israel, which pays even more, the concept researchers stars for certain innovations.



Source: Author elaboration from Scopus data (24)

Table 5 show that Saudi Arabia have a only one researcher, but he monopolize the total scientific publications with 23.38% of the total, followed by South Korea with also only one research and a 18,40% of total publications. Further back are Canada, United States, Portugal, Italy and Israel. A particular case is the United States that reached 26.36% of the publications, but merging the three researchers who are in the top list. In the world of nutraceuticals, as in other areas of research, there is a core of researchers called "stars", are those that stand out above the norm, and repeating, hogging most of the findings in a certain area as explained in this table 5.

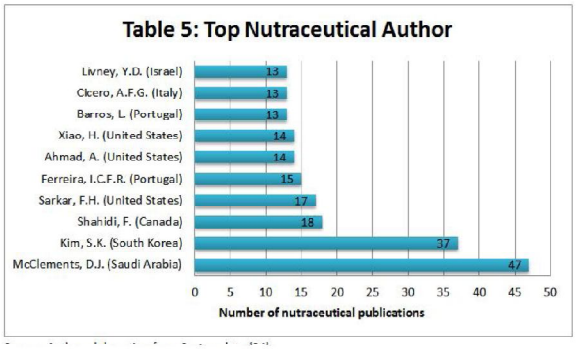
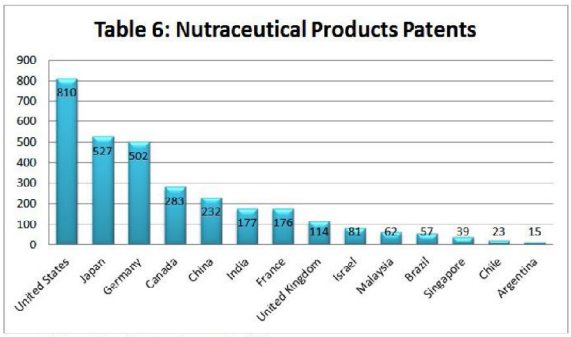


Table 6, shows that the developed countries dominate the scene where the United States once again focuses the dynamics of patents with over 810 patents, followed by Japan with 527, Germany with 502, Canada with 283, China 232. Developing countries begin to emerge albeit with less force particularly Asians and Latin America.



Source: Author elaboration from Scopus data (24)

CONCLUSION

There is no correlation between the number of patents by country and number of scientific publications, nor a correlation between the number of patents by country and nationality of the authors of publications, because we have a concentration and dispersion according to the case. The logic would be that there had been a correlation between the number of patents per country vs. number of publications by country of origin of the author, but this is not stated in this way, which could explain the degree of importance given to entrepreneurship and to a patent in certain countries vs the greater importance given to scientific publications by academics in other countries. Either way, it is important that entrepreneurship, academia and intellectual property in the nutraceutical industry is essential to their development and innovation. It is important for entrepreneurs and for academics, moves the wheel of innovation through intellectual protection.

Finally, there are a number of companies working very hard and producing innovations in the world of nutraceuticals. In parallel, many researchers do the same with their scientific research. Some create their own entrepreneurships and the researcher post their creations in major journals and books.

The nutraceutical industry is a sector in constant growth, with a strong upward trend in the next five years and beyond a simple fashion, to become an element of social and economic welfare.

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