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Patents and Intellectual Property

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Abstract

To enable the creation of new ideas and products at the right time, as well as to protect existing drugs, the term "Life Cycle Management (LCM)" was coined for the pharmaceutical industry. LCM aims to maximize profits for any drug at any stage in its life cycle, from the very beginning of its creation until it is withdrawn from the market. Thus, this brings advantages with respect to intellectual rights and laws, as well as in food and drug regulations, since LCM is used as a tool for defense and attack against current or future competitors of the company. (Ponnusamy & Christopher, 2018)

Keywords: Chemists; Pharmacologists; Formulators; Regulatory scientists

Introduction

The 21st century has been dubbed the "Century of Knowledge". However, knowledge needs protection and also needs to generate profit, so that the economy and high-tech businesses can survive and generate new business [1]. Thus, the pharmaceutical industry too, along with all other existing industries and businesses, needs innovative ideas and to generate new products. Over the past few decades, research productivity has gone into gradual decline, leading to a skyrocketing of the cost to obtain a new market candidate drug to $800 million or more [1].

Pharmaceutical teams for LCM laws can be divided into three main types of professionals:

- Scientists from various fields, from chemists, pharmacologists, formulators, regulatory scientists, and others
- Legal professionals, ranging from corporate lawyers, patent attorneys, food and drug lawyers, and others
- Senior management, such as senior managers

Only in this way, through good administration and management, is the success of the pharmaceutical and biotechnology business possible, as well as the conversion of an idea into a marketable product [1].

This required the implementation of intellectual property (IP) laws and also food and drug laws, providing protection for the pharmaceutical industry and the area of biotechnology. These types of laws cover a wide range of areas of implementation, from books, films, musical compositions, computer programs, and many others. Basically IP laws are the protection of copyright (protection of original ideas), and there is a wide diversity of laws for protection in various areas [2].

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The pharmaceutical industry relies on four main types of IP, namely trade secrets, copyrights, trademarks and patents. Despite the great importance of all these types of protection for this industry, patent protection is considered to be the most important protection, and also the one that currently is most widely used. Every patent starts with an innovative scientific idea. However, applying for and acquiring one is a real race against time, since it sometimes takes a long time to acquire it because of all the bureaucracy involved. In this context, time is crucial due to all the competing companies [1].

Historical Background

Historically, in most developing countries patenting of pharmaceutical products was not allowed, although there were patents in place for other types of products such as machinery, electronics and many others. Because of this problem, there was a significant cost-benefit gap, i.e. the costs of having private exclusion rights over new innovations outweighed the benefits [3].

At the end of the 20th century, global IP policy had an important and fundamental reform: The WTO (World Trade Organization's World Trade Organization) made the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), in which it was defined that pharmaceutical patents would be mandatory for all WTO members. Thus, by the year 2005, pharmaceutical patents were universally available except for the poorest countries [3].

Due to the implementation of patents, competition between companies in the pharmaceutical industry has decreased. This has caused some fear due to the possibility of rising drug prices in developing countries. Should this happen, public health budgets would come under a lot of pressure and the population would be left without access to essential medicines. These concerns were most notorious in the 1990s and also in the early 2000s due to the HIV pandemic, which reflected a very high price on the medicines needed to stop this disease. Because of all these events, at that time several trade agreements were enacted between developing countries in Asia, Africa and Latin America, as well as the United States and the European Union [3].

Intellectual property basics

IP, as already mentioned, provides protection for innovative ideas, designs, and forms of expression in order to promote scientific and technological advancement. This protection begins through a governmental process, and is regulated by regulatory laws that require a long time to be able to be implemented [1].

Trade secrets

As noted earlier, IP laws have four main types, including trade secrets. These confer a business advantage if the secret is kept and should not be patentable. An example of a trade secret is a customer list protected by a computer password; then there is a formula that allows data to be disclosed only to a restricted group of individuals [1].

Trade secrets are not registered with any government or other agency in order to keep their disclosure to a minimum. This process is the opposite of patenting, since patent protection requires disclosure.

However, it is necessary that the decision making for a patentable invention be kept as a trade secret, rather than becoming a patent right away. While there are many inventions that need to be patented for their protection, there are many others that do not need such patenting in order for their creators to benefit [1].

Trademarks

Through this law (also incorporated into the IP), symbols used on goods and services of all kinds are protected. That same symbol must be affixed to the product or be used when a certain service is being provided. In this way, the trademark owner is protected against possible copying or attempted misuse, and also avoids any possible confusion on the part of the consumer. In a way, this law allows the consumer to have greater confidence in the product and its quality. In the case of the pharmaceutical industry, the trade name of certain drugs must be registered as a trademark [1].

Copyrights

Copyright protects the original ideas that are acquired and approved, and protects the publications of the studies done. The pharmaceutical industry is no exception, as this law protects information provided by companies in this industry. Systematically, companies in this industry protect the copyright of their package leaflets. However, generic approval of a certain drug dictates that the package insert of that generic drug must be the "same" as the original that is already registered [1].

Patentability and freedom of operation

Patent protection is the most important IP protection in the pharmaceutical industry. Basically, a patent is a legal right that prevents third parties from using 6 or violate the original idea of a product/production [1]. Essentially they grant exclusive rights to inventions, but for a limited period in the territories where they are granted. Once a patent is acquired, it will last for twenty years after the date of its application. While the patent is in force in a particular country, the rights to produce and sell goods covered by the patent in that country belong exclusively to the patent owner [3].

For an invention to be considered patentable it needs to meet four basic requirements: it must be novel, have utility, be inventive, and there must be a written disclosure. If these requirements are not met, there will not be a substantiation for a patent application [1]. Despite the implementation of patents, patents do not prevent the original idea from being commercialized, especially when the product to be commercialized uses technologies belonging to other original ideas [1].

Because of this problem, two distinct but complementary concepts emerge: patentability assessment and freedom of operation assessment. Simply put, patentability is to assess whether the original idea qualifies for a patent application or not. On the other hand, freedom of operation is to determine whether a particular invention may violate another existing one [1].

Patents, because of the lucrative investment and development benefits they generate for firms, can create incentives for invention and innovation. While patents create knowledge, which is something that does not create rivalry in a private company with a single owner, the same instrument that encourages new inventions also restricts their diffusion and use. Basically, the idea of implementing a patent system is the prospect of a competitive price during the period in which it is in force in the company that implemented it. In this way, there will be a generation of investments, as well as a trade-off between dynamic benefits (incentives for innovation) and static costs (higher prices due to reduced access) [3].

Patent due diligence process

Due diligence is an exercise that must be done carefully before a deal is struck. Essentially, it is a process of investigating a business opportunity that the investor must agree to do, so that in this way he can assess the risks of the business he intends to execute [4]. Due diligence should be done during the transfer of technology and evaluation of the values of that technology. Only in this way will the technology covered by a particular patent, which was approved after going through this process, achieve a higher valuation [1].

Enabling technology and freedom of operation

In order for certain products to be developed, there are sometimes technologies or materials whose use becomes mandatory, otherwise product manufacturing becomes impossible. As a consequence of this problem, the potential licensee for the product will need to make considerations about commercializing the product, and must be able to acquire rights to the enabling technology or material [1].

The same is true of patent rights, since they only give their holders exclusivity so that third parties cannot perform the claimed invention. However, it does not give them positive rights to practice their own invention, i.e. they will also need to acquire rights to use enabling technology or material. In this succinct way, the owner of the invention may not be authorized to develop their own invention [1].

Local and international IP protection

As mentioned earlier, the owner of the technology may want to start its protection first in one location and only then go to other locations. This is because patent rights are geographical, so protection needs to go from one country to another. To make this transition of patents between countries possible, the patent applicant has 1 year to consider filing in other countries [1].

The United States has a system that makes patenting processes easier and faster. In this case, applicants for a patent (inventors) can write a kind of sketch of their idea, and thus they can project their idea to prove what they really want. In this way they demonstrate what they want before putting it into practice, bringing some advantages, such as a reduction of time to predict a final result (even if hypothetical) and also money. A major problem with this practice is the fact that many countries do not accept this type of projection model, so the first twelve months will be critical for experiments if foreign rights are taken into consideration [1].

Patent Cooperation Treaty (PCT)

The PCT was established in the 1980s and administered by the World Intellectual Property Organization. Currently, there are already more than 100 countries that have joined this PCT [1]. This Treaty gives the possibility for a given invention to acquire patent protection simultaneously in a large number of countries by filing an "international" patent application [5].

The application can be filed by any person who is a national or resident of the contracting state, and is usually filed with the national patent office of that contracting state, or with the International Bureau of WIPO in Geneva. After its filing, it is then submitted to an

"international search", which is carried out by the ISA (International Search Authority). This search results in an "international search report," that is, a set of references to published documents that could affect the patentability of the invention claimed in the international application. At the same time, the ISA prepares a written opinion on patentability [5].

Patent Cooperation Treaty in Portugal

In Portugal, this Treaty was approved in 1992. Its signing and implementation allowed:

1. Contribute to the development of science and technology;

2. Improve legal protection for inventions;

3. Making it simpler and more economical to obtain international protection for inventions;

4. Make it easy and quick for everyone to access technical information;

5. Stimulate and accelerate the economic progress of developing countries by adopting measures to increase the effectiveness of their legal systems for the protection of inventions [6].

Planning Ahead

As you have already seen, this whole process is quite complex, so it is necessary to plan well for the first twelve months after the first deposit. A great deal of work and effort is required during this period of time. Also in the laboratory more experiments must be performed and more research done, so that the invention claimed in the patent application is better supported [1].

One of the most important parameters in this process and one that should be given particular attention is the commercial side of the invention. For this, some parameters should be explored:

1. Identifying commercially viable products that are covered by patents;

2. Licensing potential;

3. Partnership for research to be sponsored;

4. Advice from competent personnel in the area of product marketing;

5. It is necessary to know who the target audience is.

All decisions should be made in advance in order to reduce costs and also avoid mistakes [1].

Example of a study

In the late 1990s/early 2000s a study was conducted in the United States to develop a product cycle model with endogenous innovation, imitation, and foreign direct investment (FDI). Through this model, the effect of strengthening southern intellectual property rights (IPR) protection on the imitation exposure of multinationals, relative to northern firms, the composition of international technology transfer, FDI, and innovation was determined [7].

The main focus was on the fact that FDI and imitation serve as channels for international technology transfer. However, the South's IPR protection excludes FDI and innovation. Thus, through the study conducted, it was proven that stronger IPR in the South does not make multinationals more protected from imitation when compared to Northern firms. Moreover, by increasing the price of imitation, IPR will force a higher expenditure of resources for a probability of imitation success [7].

In this way, resources will become scarcer in the South for production, causing investment to decrease, reducing employability. This scarcity will also be reflected in the North due to the decrease in investment, causing innovation to decrease. Thus, it can be seen that the stronger the protection exercised over a given product, the more difficult it is to imitate it due to its higher costs. However it has also been shown that it takes a great deal of research work to be able to carry out imitation, so there is no foreign investment (FDI) and therefore there will be a reduction in innovation [7].

Conclusion

Through what has been demonstrated throughout this paper, it can be concluded that IP laws are of extreme importance when it comes to both the pharmaceutical industry and also biotechnology. Thus, it is of utmost importance that all those working in the business of pharmaceutical development and innovation are aware of all the necessary processes so that their discoveries are protected as much as possible.

This is the only way to protect the discovery of new drugs that are so difficult to discover, as well as having high development and discovery costs. On the other hand, these laws also help in the competitiveness between companies.

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