Patents and free economic competition: A perspective from the COVID-19 vaccines.

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Summary

Patents are elements that are frequently associated with monopolies that hinder market competition. This discussion is much more relevant in health, especially in the current context of the COVID-19 pandemic. This study aims to participate in this debate to demonstrate that the relationship between patents and competition law is not conflicting in nature. On the contrary, it can be argued that they share common objectives, e.g., that consumers have freedom of choice based on the quality and price of products and services. Moreover, the response to COVID-19 is a telling example of how the industrial property system is a fundamental enabler of innovation, production of new knowledge, generation of partnerships, and free competition.

The traditional approach to patents as monopolies has, in our opinion, three main sources:

- The first is due to their historical and semantic origin. Patents arose in the Middle Ages as incentives to attract merchants to specific territories, whereby monarchs granted them privileges to ensure that they stayed within their territories. Later, in England, the Statute of Monopolies was enacted, which incorporated the patentability requirements we know today to limit this discretionary or arbitrary power, thus turning patents into a recognition of new products to be applied in the practical arts (Dent, 2009).
- As a consequence of the first, the second is found in economic literature, which claims that monopoly revenues can be extracted from patents. This leads to the generation of headlines and arguments that liken patents to monopolistic behavior, interpreting them as instruments that limit competition or the capacity for innovation (Langinier & Moschini, 2002).
- The third is found in the repeated qualification of intellectual property rights as monopolies issued by judges.

In response to the first source, we must reply that patents, as we know them today, are part of a system that recognizes efforts and rewards the initiative of inventors for providing innovative solutions to various problems. Thus, the temporary exclusivity granted by a patent serves as an incentive with different positive effects. In this sense, this system is recognized as a social contract. The investor acquires the right to exclusively exploit the invention (patent) and recover the investment to achieve it. This leads to society, understood as consumers, industries, and researchers, benefiting from a new product that satisfies a need or is incorporated into a production process to improve it.

Concerning the second source, we must clarify that the legal framework for economic competition does not penalize or blame the existence of monopolies or a dominant market position. This is because, in a free enterprise economy, it is possible to achieve such a position due to a loyal and honest industrial effort. In fact, under the competition regime, a monopoly is not anti-competitive per se. From an economic and social point of view, its existence may serve as a stimulus to the entry of new agents who increase the supply of the good or service, attracted by the revenues that are being extracted from the market in which the monopoly exists. According to the above, the existence and permanence of the monopoly is temporary, and such temporality will depend on the industrial capacity of the competition to equal or improve the good or service.

From the previous, it could be understood where the assertions that a patented product can become a monopoly. But this, in turn, makes it valid to assert that any new product can be a monopoly, by the simple fact of being the first to enter a market or by being that which creates the market itself. Thus, a product with a high technological content (know-how), or an innovative product, which may contain a trade secret, may constitute a monopoly until the other agents manage, on their own merits, to equal it, improve it or offer alternatives.

Another factor may be the temporary exclusivity granted by the patent, which according to the Law, is 20 years from the date of application before the corresponding National Authority. However, for the same reasons stated above (attraction of revenues), market agents may try to create other products that improve the patented one or incorporate an equivalent offer through different technologies. Therefore, this period cannot be likened to creating a monopoly and restriction of competition; on the contrary, it can stimulate it.

The competition law applicable in Colombia considers that research activity and technical developments are pro-competitive, without excluding those protected by patents. Numeral 6 of article 47 of Decree 2153

of 1992, considers any agreement that has as its object, or as its effect, the limitation of technical developments as anticompetitive.

Based on the above, we assert that even if the concept that patents are monopolies was accepted, this would not necessarily imply an anticompetitive situation from an economic theory standpoint.

Finally, concerning the third source, we must consider that jurisprudence has traditionally qualified patents as monopolies, given the abovementioned historical reasons. However, today intellectual property rights, including patents, are defined as exclusive rights. Indeed, the World Intellectual Property Organization (2021) defines Intellectual Property as the exclusive rights resulting from creations of the mind: inventions, literary and artistic works, and symbols, names, and images used in business.

Thus, we must approach patents as rights resulting from providing intellectual solutions to technical problems. In this sense, the industrial property system encourages competition in generating novel solutions and provides technological advances, thus promoting innovation, competition, and benefiting society.

Along these lines, the patent system also strengthens knowledge and innovation, as it has become the most significant technological dossier of public information in the world. Indeed, all patent applications that reach a substantive decision on their grant (regardless of whether they have been granted or not) must be published in the Industrial Property registers. Now, according to the WIPO Statistics Center (2021), 3.22 million patent applications were filed worldwide in 2019, 3.32 million in 2018, and 3.17 million in 2017.

This repository allows anyone interested in technology to shorten the search processes for state-of-the-art, detect the technological paths in which different organizations (patent applicants) are profiled, and even geographical research dynamics. For example, the Superintendence of Industry and Commerce periodically publishes technological bulletins based on the information contained in the world patent system. As a result, the patent system facilitates transactions between those interested in undertaking a research project or exploiting an invention since it is possible to determine the ownership with certainty and, based thereon, the legal and economic delimitation of these activities.

In the COVID-19 pandemic, patents have not hindered the availability of vaccines and treatments from fighting the disease caused by the SARS-CoV-2 virus. In fact, in just ten months, it was possible to identify the virus causing the health crisis and generate a range of vaccines and drugs that would have been very difficult to obtain without the incentives generated by the patent system. By May 2021, slightly more than

a year after the detection of the pandemic, 15 vaccines were introduced into the market using four different technologies and for which 13 manufacturers worldwide are responsible.

Thus, we consider that stating that a patent is a monopoly is somewhat simplistic, since the nature of patents is to offer solutions to a technical problem in the form of different products and processes that could be available in the market, as is the case of the various options we found for COVID-19 vaccines.

Key words

Patents, coronavirus, health, intellectual property, vaccines.

Introduction

This study is motivated by the need to demonstrate that patents are not monopolies per se, nor are they anti-competitive based on conceptual precision and examples. Therefore, they do not restrict consumers' access to the products protected by them.

Given their origin, there is a deeply rooted approach to patents as monopolies. In the Middle Ages, they were used to attract merchants to certain territories where monarchs granted privileges to ensure that these stayed within their territories. Later, in England, the Statute of Monopolies was enacted, which incorporated the patentability requirements that we know today, whose objective was to limit this discretionary or arbitrary power, thus turning patents into recognition of new products to be applied in the practical arts (Dent, 2009).

However, this conception of monopolies continued to be supported by economic literature (Langinier & Moschini, 2002), since it states that patents can be used to extract monopoly revenues and, consequently, are instruments that are either anti-competitive or limit the capacity for innovation. This approach is also supported by judges, who have stated that patents can be considered a monopoly in various rulings.

Given the above, the purpose of this paper is to provide conceptual clarifications of the patent system and the economic competition regime. It will allow us to reach two conclusions:

a. Patents do not equate to monopolies
b. On the contrary, they promote competition

In addition, based on the case of COVID-19 vaccines, we will demonstrate how the industrial property system promotes the generation of new knowledge and, therefore, innovation and competition.

The methodology used was based on three elements:

a. The analysis of the patent system's legal structure and the requirements for an invention to be patentable.
b. The study of the concepts of relevant market, dominant position and approach of the Competition Law regarding monopolies, in order to review the limits created by the free competition legal framework.
c. The review of the common points and disparities between the Patent System and the Free Competition System to establish whether patents are monopolies or whether they are restrictive of competition to the detriment of consumers.

Structure of the study:

Based on the above methodology, the study is divided into two large sections. The first, which is carried out in the abstract, begin by sharing the basic concepts of the Intellectual Property System. Reference is made to patents, their technical and legal requirements, and the right's scope. Once these initial concepts are addressed, a reflection is made on the relationship between patents and monopoly and intellectual property and anticompetitive conducts. This exercise seeks to answer the questions: Are patents a monopoly? Do patents restrict free competition?

The second section refers to a particular case, as it seeks to analyze the previous concepts and reflections in the light of COVID-19. We aim to determine whether the patent system:

- Has hindered the research or production of treatments against COVID-19
- Has allowed the output of a single solution to prove the existence of a monopoly
- Has served to produce several solutions to the problem

OVERVIEW

We are in the age of knowledge. Knowledge drives corporate competitiveness, especially for those companies that compete in markets where quality and/or technological advancement of products are at the industry's core. Thus, it is natural for companies to guard their knowledge against their competitors. Therefore, the first natural action of any agent in the market that believes it has found, invented, or

discovered a technical advance that can give it a competitive advantage is keeping it a secret. Thus, it is said that a trade or industrial secret is information that has commercial value (Landes & Posner, 1991). However, a trade secret does not grant a right of exclusivity since any person can reach that same technical advance through its means, without the person who first got it being able to exercise any action to prevent its exploitation.

On the other hand, there is the social contract offered by the patent system. In effect, this system provides the person who first arrived at the technical advance (after fulfilling the requirements) a mechanism that prevents third parties from copying it. This is in exchange for the disclosure of the information necessary to reach the technical advance so that all competitors can have access to the knowledge, which will allow them (the competitors) to try to surpass it or produce their goods differently, in order not to incur in the infringing conduct.

Having clarified the above, it is also necessary to point out that both systems entail externalities (like all property). The secret implies that the company takes all kinds of measures to safeguard it. At the same time, the patent has the externality of obtaining it, which means taking administrative steps in as many jurisdictions as necessary. In addition to this, there is the duty of maintenance and oversight vis-à-vis third parties.

Thus, from a cost perspective, the best option could be the trade secret, which demonstrates that the decision to request a patent is not automatic, simple, or free. Thus, it can be stated that an investor could choose to protect his invention using a trade secret, if he believes that patent protection has a higher cost than the value of his invention, his invention is not patentable, or the term of the patent does not fit his expectations 13.

Whatever the decision is taken, in the case of patents, there is a duty to disclose the technical information so that other people can use it and create new developments, produce new knowledge, or duplicate research efforts in a particular area. This specialized knowledge could have remained secret, and its holder could have benefited from maintaining the exclusivity of the technology. It is precisely on this point that the economic importance of the patent system is based. If inventions were kept secret and not presented and protected in this way, society would likely not have access to state-of-the-art technology with the same ease and speed.

Thus, if the patent system did not exist, there would be no incentive to publish technical information, which would lead to duplication of efforts and additional investments to develop the technology that is being kept secret.

The concept of patents

The above explanation is required to understand the legal concept and, therefore, the legal elements of patents. Thus, strictly speaking, a patent is: "*an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, must disclose technical information about the invention to the public in a patent application." (WIPO, 2021).* In other words, it is a technical rule that is applied to overcome obstacles that some products have to make them work better, or even the absence of products to solve a technical problem.

This does not mean that the developments surrounding a problem stop or end with a single invention. On the contrary, what usually occurs is that research and technological developments lead to different solutions (in the form of products and procedures) to the same technical problem, or the problem can be solved in different ways. Therefore, the purpose of the patent system is to identify the technical problem and to study whether the solution proposed is novel, represents a technological advance, and can be applied by the industry.

This shows us that the patent system and the legal analysis of inventions are devoid of political, circumstantial, or economic approaches or criteria since that has been its desired evolution. At this point, it is worth mentioning that, at some point in history, patents were considered privileges granted by monarchs in a discretionary manner to their close friends, without having to demonstrate any merit whatsoever (Nachbar, 2005). In other cases, they were also granted in recognition of an economic investment that required recovery (Cordova & Chavez, 2020). However, with the evolution of the patent system, this is no longer the case, and today there are clear rules on what can and cannot be patented.

For patenting purposes, technical problems have no limits and, therefore, there are different types of inventions. For example, in the past, to sterilize dairy foods, these were heated over long periods. However, this caused the product to deteriorate quickly. Over the years, high-temperature processes were developed, requiring short periods, and eliminating the pathogens while increasing the dairy product's shelf life (FDA, 2021).

By the above, there are several possibilities or areas in which a patent is warranted:

- The creation of a new product, which did not exist in nature, or in the "state of the art", and which emerges as useful in solving a specific technical problem.
- The joining of already existing, known elements to arrive to a new product, when such joining was the problem to overcome.
- The presentation of a product in a form different from the traditional or natural one, when this new presentation was considered impossible for the product to fulfill its function (for example, when a pharmaceutical product for oral consumption could not have been obtained before in an injectable presentation).
- The creation of different and technically better procedures (steps) to obtain the same product.

In this manner, patents are granted as an exclusive right for the commercial exploitation of a particular invention in any technological field: agriculture, ICTs, health, etc. Strictly speaking, they are (immaterial) property rights granted by the State to the inventor or his successor as recognition for making available to the public a new technology that is materialized in a product or process.

Patentability requirements and scope of the right

Bearing in mind that a patent is a solution to a technical problem, the law establishes three main requirements: if not identical, very similar in all countries, and respond to scientific methods and not to political, subjective, or economic reasons. Thus, the solution (invention) must be new (novelty), must evidence technical progress (inventive step), and must be able to be used by industry (industrial application).

Its political objective is that through the State, society recognizes and rewards the inventor's technological contribution, since the invention will consist of a new good that contributes to industrial progress, to knowledge and, consequently, will benefit society.

Indeed, in most cases, a patent application is preceded by a lengthy and costly research and development process. In the specific field of medical and pharmaceutical inventions, a development requires significant investments that are only possible insofar as there is a legal system that provides certainty of ownership over the research product.17 Since medical research does not offer the assurance of arriving at a specific product, nor a fixed time frame for arriving at that new product. It is considered high risk. Therefore, the patent system allows the investor and researcher the certainty that the investment can be recovered through a right of exclusivity, if and when the legal requirements are met.

In this sense, it must recognize that the patent regime has a built-in first line of contention. The purpose is that the invention patent is granted when the technical and intellectual merits sufficient to be worthy of such protection are demonstrated. Thus, patents are granted after due effort. Their richness lies in their intellectual content and not in random, hereditary, occasional, or regulatory circumstances.

Legal and technical requirements for patent eligibility

Intellectual property rules are generally international and originate, in most cases, in international treaties that are subsequently negotiated by countries in forums such as the WIPO, the World Trade Organization (WTO), or at the regional level in the Andean Community of Nations (CAN). The legal patent regime contemplates the requirements for its granting, the rights and obligations granted to its holder, as well as the limitations and exceptions thereto.

In the specific field of patent law, Andean Decision 486 of 2000, which arises within the Andean Community of Nations (CAN) framework, can be highlighted. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Patent Cooperation Treaty (PCT) are also.

The first safety control filter that must exercise for preventing the protection of inventions that do not have sufficient merit is exercised by the patent authorities through the rigorous observance of patentability requirements and their strict application in each case. As mentioned above, the three fundamental requirements for granting a patent are novelty, inventive step, and industrial application. Each of them will be explained below:

- **Novelty**

According to Article 16 of the Decision 486 of the CAN, to obtain patent protection, the invention must be new, and for that reason, it cannot have been disclosed in state of the art. The latter is the body of knowledge revealed to the public and accessible through supporting documents or audio, text, image, or video materials, in physical or digital repositories.

For the invention to be considered new, it must not be found in state of the art, i.e., every one of its technical characteristics must be presented identically in said body of knowledge. In practice, the patentability examination is carried out by a patent examiner whose profile is that of a professional in the technological

sector in which the invention is classified. For example, for innovation in the pharmaceutical field, the examiner of the patent requirements will likely be a pharmaceutical chemist.

- **Inventive level**

The inventive level requirement establishes whether the solution proposed to the technical problem in the patent is obvious or evident to a person of the trade ordinarily skilled in the corresponding technical field, following Article 18, Decision 486 of the CAN. In other words, if the pharmaceutical chemist would not have needed to carry out research to reach the solution, the invention would not be patentable. Again, the prior state of the art plays a significant role. In this case, the patent examiner must use a method that allows an objective evaluation of whether the technical solution of the invention is self-evident.

- **Industrial Application**

The Industrial Application requirement refers to the fact that it may reproduce the object of the protected invention in some industries (Article 19, Decision 486 of the CAN). The invention is not required to be on the market or be applied in any type of industry at the time of the application. What is sought with the fulfillment of this requirement is that from the reading of the patent application, it can be inferred that the object has a potential for industrial application. This is usually the case of a patent application that deals with a possible drug, which has potential industrial application in that such drug can treat a disease, without this meaning that at the time of the evaluation by a patent examiner, the drug must be available in the market.

The technical problem that a patent intends to solve

There are other requirements under patent law that are not considered as substantial as the previous ones, but that must also be considered for a proper evaluation by a patent office. One of them is the statement of the technical problem that the invention intends to solve. For example, Article 28 of the Andean Decision 486 indicates that the description of the patent application must contain a description of the invention in terms that allow the understanding of the technical problem and of the solution provided by the invention, explaining the differences and possible advantages concerning the previous technology (Decision 486 of the Andean Community of Nations, Article 28). The above confirms that patents provide solutions to technical problems in any technological sector. They must comply with this requirement to determine whether they are eligible for the protections established by this Industrial Property figure.

Rights derived from a patent

Since patent rights are exclusive rights, i.e., the patent holder is the only one who can exploit the invention in the territory where the patent was granted. Therefore, the only one who can allow third parties to exploit it has been stated that patents are monopolies and restrict competition.

The legally enshrined rights prevent third parties who do not have the consent of the patent holder from performing any of the acts relating to the manufacturing or sale of the product. This also occurs when the patent claims a process, which prevents the use without the authorization of the patent holder.

In the same line, we find that one of the holder's main acts of commercial exploitation is the possibility of transferring or licensing its invention to a third party. Thus, the patent is not only a right of exclusion but an instrument that facilitates agreements. Indeed, the patent title allows third parties and parties interested in a project, an investment or a contract, to determine who owns each of the intangible assets to be used in a project or agreement.

The patent system also allows parties to a project that has yet to have a specific product to determine the share of the resulting property, including the possibility of deciding what each co-owner can do with it. Thus, it is expected that in agreements involving technology, the parties agree and recognize the intellectual property previously acquired by each party and that which will be jointly developed, which creates a new production unit that becomes an offer in a given market.

Example of a technical problem to be solved in the pharmaceutical field

The pharmaceutical sector is like any other sector in patents: society benefits from the fact that the private sector invests resources in the search for solutions to multiple health problems. Thus, companies make big bets by investing in research, development, and innovation, which they then protect through the different intellectual property systems to obtain a profit through their exploitation.

An example of this is the proton pump inhibitors used to produce drugs that alleviate the symptoms associated with gastric reflux. There are several active compounds to solve this problem: Omeprazole, Esomeprazole, Dexlansoprazole, and Rabeprazole. At first, different compounds and pharmaceutical compositions containing them were patented. Subsequently, developments, i.e. new patents, focused on:

- The improvement of pharmaceutical compositions so that their effect would be more prolonged and effective for a given period.
- The combination of different active ingredients to make them more effective.
- The reduction of the side effects derived from the use of this type of drugs.
- The improvement of their storage stability

Table 1. Different solutions to a same technical problem

Technical problem	Object of the technical solution	Product/Improvement	Patent Request/Patent	Applicant
Gastric Reflux	Proton pump inhibitor for suppression of gastric acid secretion	Omeprazol/inhibits	US4620008	HAESSLE AB
		Esomeprazol/ inhibits, higher bioavailability	SE19939301830A	ASTRA AB
		Dexlansoprazol/ inhibits, higher bioavailability	JP29567/1986	TAKEDA CHEMICAL INDUSTRIES
		Rabeprazol/ inhibits more effectively as compared to omeprazole.	JP27053686	EISAI CO LTD

As a result, each product addressed a problem, expanding the offer for consumers who, for one reason or another, were able to purchase one product but not the other.

ARE PATENTS A MONOPOLY?

Patents are an exclusive right granted by the State (meaning society) under the conditions mentioned above. As mentioned above, this exclusive right means that the patent holder is the only one authorized to exploit the patented products or to use the patented process. However, it is essential to specify that the exclusive right granted by the patent does not necessarily imply the granting of a monopoly in the economic sense of the word.

In the past, monopoly rights were granted to certain citizens (close to the king or government) to exploit certain products exclusively in some geographical regions, such as sugar or salt. However, patent law differs substantially from this type of monopoly insofar as it consists of a reward to the inventor for making available to the public something that did not exist before and that was obtained after an intellectual effort.

In other words, the inventor enjoys the public benefit of exploiting this invention for a limited period. In return, society benefits from having said invention in the form of a new product or process.

Given that intellectual property rules grant this exclusivity right, on the one hand, and, on the other, free competition protection rules advocate keeping markets open and competitive, it could be argued that there is dissent between the two disciplines (Wish & Bailey, 2015). However, in our opinion, this position is inadequate, as it disregards that both regulations have the purpose of procuring the welfare of consumers. On the contrary, when correctly applied, both regimes are complementary and can generate a virtuous circle for companies and society as a whole rather than being conflicting.

In this regard, the European Community [1] noted the following in the Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union about technology transfer agreements:

"Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to develop new or improved products and processes. So does competition by putting pressure on undertakings to innovate"[1]

In this sense, both regimes should be perceived as complementary to achieve the common good materialized in consumer welfare through more innovation, more goods, and services with better quality, at a better price, and better customer service.

The Organization for Economic Cooperation and Development (1997) has also recognized this complementarity, adding that, to identify a positive relationship between intellectual property rights and market competition, competition authorities play a significant role by ensuring they hold a dynamic and long-term vision and an understanding that new technologies and innovations can play a fundamental role in competitive processes.

This long-term vision stems from the assumption that technological progress contributes to increased social welfare by eliminating locational inefficiencies in markets with low levels of competition. At the same time,

[1] European Union, COMMUNICATION FROM THE COMMISSION, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014/C 89/03), Paragraph 7.

in some scenarios, it is valid to allow restrictions on competition today, via intellectual property rights, to obtain new or better goods, services and processes tomorrow (Gallini & Trebilock, 2021).

In this scenario, it should be recalled that the patent system is based on the social contract of recognizing an exclusive right to the inventor. At the same time, society receives as consideration the disclosure of the invention by the inventor. This is represented by the fact that, once the term of protection has expired, any person may exploit it or, even before, use it in research and development activities.

However, it cannot be ignored that in markets where intellectual property rights exist, there is a need to establish whether their possession generates or increases the market power of the agents that participate in it and if, therefore, they may be suitable instruments to restrict competition in markets where they are essential.

In this regard, it should be borne in mind that the competition rules do not penalize or condemn that a company has market power or even a dominant position in the market. What does constitute a violation of the competition rules is the abuse of that market power, through the materialization of different anticompetitive practices.

However, it should be noted that the existence of a patent does not imply per se the existence of market power. In this regard, competition authorities must make a case-by-case analysis, considering other circumstances that may counterbalance the presence of the exclusive right (OECD, 1997).

In the United States, for example, the courts refer to the existence of a patent as a patent monopoly [1]. At the same time, in Europe, the Court of Justice of the European Union has specified that the holding of an intellectual property right does not necessarily confer a dominant position in a market [2]. In the latter case, the Court suggests that an analysis should be conducted as to whether there are substitutes that may limit market power by the holder of such right.

Competition authorities such as the European Commission and the Superintendence of Industry and Commerce (2018), define relevant markets by considering additional elements to the existence of intellectual property rights, such as the characteristics and uses of products that may become substitutes, albeit imperfect, of products protected by a patent.

In the case of Colombia, and for pharmaceutical products, in particular, the Superintendence of Industry and Commerce (2015) has indicated that the definition of the relevant market is established using the ATC[1] classification of drugs by levels, up to level 3, according to the organ or system on which they act, their pharmacological effect and their therapeutic indications.

However, the authority complements the market definition exercise by analyzing the characteristics and uses of the drugs, including a study on the active ingredients present in the medicines, concluding in some cases which categories of medicines in ATC level 3 can be grouped, provided that these, despite belonging to different therapeutic groups, can be considered as substitutes by consumers (SIC, 2019).

Considering the above, a drug with an active patent may belong to the same relevant market as other drugs, so it cannot necessarily be said that it is a monopoly and that, in addition, it has a dominant position in the relevant market. The SIC established, in a particular case, that *"despite having lower prices, generic drugs for the systemic management of pain compete effectively in the market, which is why they will be included for the respective analysis of competition conditions"* (SIC, 2019).

INTELLECTUAL PROPERTY RIGHTS AND ANTICOMPETITIVE BEHAVIOR

There are different commercial practices related to intellectual property that has been subject to investigation by competition authorities worldwide. However, there is a certain consensus among competition authorities in recent years in recognizing the pro-competitive effects of intellectual property rights.

This means that the exercise of rights by patent holders, through different commercial practices, should not be approached from a prohibitive standpoint. Instead, the events that may constitute an anti-competitive practice should be analyzed on a case-by-case basis. This is the trend in jurisdictions such as the United States, Europe, Canada, Japan, and Korea (OECD, 2019).

From a competition law perspective, one of the conducts that have received the most attention is the licensing of intellectual property as a mechanism to enable the dissemination of knowledge. However, there are also concerns regarding unilateral practices stemming from licensing agreements, essential patents, patents or standardization technologies, or royalties. These practices include but are not limited to exclusivity clauses, specific pricing mechanisms or quantity restrictions, cross-licensing, patent pools, and refusals to grant licenses.

In this line, the guidance issued by the competition authorities and the Courts in different jurisdictions has been to penalize certain conducts that may harm competition in the markets. However, the starting point is always the need to establish an appropriate balance between intellectual property protection and competition.

Thus, when the patent holder imposes unreasonable conditions from the point of view of competition, it may give rise to the configuration of anti-competitive behavior. Another practice that has come under scrutiny by competition authorities is excessive pricing by holders of patents and other rights. However, most authorities are opposed to intervening in these cases, as their mission is not to regulate the market. To that extent, they only interfere when regulatory failures in the market and a company's solid and permanent dominant position.

In any case, in competition regimes such as the United States, which are entirely opposed to such intervention, the Courts have indicated that monopolists can set prices as high as the market can accept, suggesting that any price level should be considered a business practice of the companies. This is the same case in Australia, Canada, and Mexico, where excessive prices are not considered a violation of the competition protection regime (Jenny, 2016).

In the specific case of pharmaceutical markets, some jurisdictions have investigated cases on price formation dynamics. However, there seems to be a consensus that these investigations should only deal with drugs without active patents (OECD, 2018). This is to the extent that "monopoly prices" are the incentive that drives companies to patent the drug. Thus, a failure to apply competition laws should not discourage innovation in the sector (Fletcher & Jardine, 2006).

COVID -19

Now, we will approach COVID-19 as a technical problem that requires a solution and, consequently, look at it from a patent system viewpoint, based on the elements that characterize it. These are identifying the technical problem, the invention as a solution, and, subsequently, whether it meets the requirements of novelty, inventive level, and industrial application to be patentable. All this is in light of the different solutions known so far in state of the art.

COVID-19 as a technical problem that requires a solution from a patent standpoint

The pandemic caused by COVID-19 has had a global impact since December 2019, not only on healthcare systems but also on the economy and the fact that it has modified people's social interaction and behavior.

Pharmaceutical companies have been in the spotlight during this pandemic, mainly because much of the hopes for emerging from the health crisis have rested on their ability to research, develop and produce a vaccine to fight this disease (Al-japairai & Mahmood, 2020).

There is consensus that the vaccines that have been developed so far were achieved in record time, and, in part, these results are due to the existence of instruments such as Industrial Property (Hanney; Wooding & Sussex, 2020). Indeed, this system helped to:

- The rapid identification of technologies that showed significant potential to be used in a possible treatment or vaccine.
- The identification of companies or individuals who either owned such technologies or had the know-how to develop them.
- Ensure legal certainty so that contracts, agreements, and understandings could be negotiated and developed among the actors that had to come together to produce a treatment for COVID-19.

It is undeniable that the sustainability of pharmaceutical companies engaged in research, development, and innovation relies on the existence, recognition, and respect of intellectual property rights. Likewise, it cannot be refuted that the response deployed by the entire scientific community and the pharmaceutical sector to face COVID-19 is unprecedented in our history.

Normally, the way to address a problem through the research and development process of the product until such a time it’s ready to enters the market involves a feasibility study, which implies an analysis of the existence of methods, products, or other actors that would compete with the product to be developed.

Once a project has been approved, including the necessary resources for its development, between the initial research stages. Preclinical and clinical studies are carried out when the final product is obtained across all phases (I to IV). This includes steps such as the review of the quality of the product, its inability to generate danger to humans, its efficacy and other data related to the physicochemical characteristics, and its quantitative and qualitative composition. This can take more than ten years (Strovel; Sittampalam, 2012),

so patent protection of 20 years seems appropriate, considering the process described above and the amount of time it takes.

With the COVID-19 pandemic, these steps had to be completed in record time. In other words, to obtain vaccines capable of providing the necessary immunity against the virus, a significantly more significant amount of clinical data had to be collected over a short period. This was required to achieve efficiency in terms of time and simultaneously comply with health approvals to ensure safety and efficacy.

Once the SARS-CoV-2 virus (coronavirus) was identified using a technical process, it was possible to determine the cause of the disease, understand the virus and thus identify potential therapeutic and preventive strategies to address it.

This effort would have been impossible, or at least would have taken much longer, if it had not been possible to rely on global knowledge, since it was using patented and non-patented technologies that it was possible to obtain its genetic information. Thanks to the patent system, today, there are six main technologies used to develop vaccines. Some of these are currently patented, and others are not. This means that in addition to the holders of the patented technology, their competitors could obtain this information using other technologies which, not being patented, are freely available.

The vaccines (the invention) as a solution to the problem

It is important to remember that a vaccine is a biological preparation that provides immunity against a pathogenic agent. The agent contained in the vaccine causes the body's immune system to recognize it as a threat, fight and control it, and more importantly, fight the microorganism effectively in the future without the aggravating effects of contagion. To obtain the relevant vaccine, the virus responsible for the disease must be identified and its genetic sequence must be determined.

State of the art, which includes current and expired patents, shows various technologies available for the production of vaccines. For example, some use microorganisms eliminated by chemical processes, heat transfer, or nuclear energy; vaccines containing parts of the microorganism have been cultivated and then eliminated to destroy their capacity to produce a particular disease in another living organism. Other processes use microorganisms still alive but have been weakened and cultured under conditions that deactivate their contagious properties.

In the case of COVID-19, these have been the technologies used for each of the vaccines that have been approved so far:

Table 2. Technologies used in COVID-19 vaccines.

Type of technology/possible alternatives	Clinical trials I-II	Clinical trials III-IV	Vaccines obtained and in use
ARNm	9	4	2
Inactivated or attenuated viruses	8	9	6
Viral vectors	21	5	5
Subunit protein	19	9	3
DNA	8	2	0
Virus-like particles	4	1	0

The vaccines that have already been approved by a regulatory agency are as follows:

- - The two vaccines that are based on messenger RNA (mRNA) [2] are: Pfizer-BioNTech[3] and Moderna.
- - The six vaccines that use inactivated microorganism-based procedures are: Sinopharm[4], Sinovac, Covaxin[5], WIBP-CorV, SinopharmCoviVac[6] and QazCovid-in.
- - The five vaccines using viral vectors are: Sputnik V, Sputnik Light, Oxford-AstraZeneca, Johnson & Johnson[7] and Convidecia.
- - The two vaccines that employ the technological solution known as "subunit" technology are: EpiVacCorona[8] and RBD-Dimer.

It is worth noting that, as of May 17, 2021, there are 319 vaccine candidates, of which 30 are in Phase III or IV clinical trials, which represent 9.4%[9]of the total vaccine candidate pool. This ratio indicates that there

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7744276/
[3]https://extranet.who.int/pqweb/sites/default/files/documents/TAG-EUL_PublicReport_BioNTech_DEC20.pdf
[4] https://www.bloomberg.com/news/articles/2020-12-09/uae-says-sinopharm-vaccine-has-86-efficacy-against-covid-19
[5] https://www.livemint.com/news/india/coronavirus-vaccine-in-india-these-states-have-started-phase-3-trials-of-bharat-biotech-covaxin-11606908773897.html
[6] https://www.dw.com/en/two-more-russian-vaccines-what-we-do-and-dont-know/a-56811025
[7] https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf
[8] https://rospatent.gov.ru/en/news/vektor-zapatentoval-vakcinu-sars-cov
[9] https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

are at least 30 vaccine candidates that could have a high chance of becoming an option to fight the COVID-19 pandemic.

Regarding the type of technology being used, the most widely used is the "subunit" technology, with 101 candidates representing 31.7% of the sample. The procedure based on viral vectors includes 64 candidates representing 20.1% and the (mRNA) technologies 38 vaccine candidates for a total of 11.9%.

Furthermore, it should be noted that potential vaccines using two other types of technology are currently being tested. The first of these is known as VLP (Virus-Like Particles) [10], of which there are 25 vaccine candidates for a total of 7.84%[11] of the sample. Another technology that is being worked on for candidate vaccines but has not yet been able to place any of them on the market is known as DNA technology (WHO, 2021). For the sample, 27 vaccine candidates use this method for a total of 8.46% of the total[12].

The intent of the preceding is to show that there are currently many vaccine candidates on the market geared towards fighting COVID-19. Therefore, it is clear that patents have not been an obstacle to generating vaccine options to counter COVID-19.

As a result, four technologies have generated 15 vaccines, with 13 different manufacturers, that have proven to be effective in fighting the virus. In this way, these vaccines seek to solve the technical problem, using other forms of administration, storage, and cooling. This implies that another one of the characteristics of the application of the patent system is fulfilled, i.e., there is a continuous improvement and diversity of technical solutions to obtain products that meet the proposed purposes.

In other words, there is a supply of products, as well as competition conditions for products and technologies that seek to satisfy a demand, and the patent system has not prevented them from being used to research, develop, and ultimately offer vaccines, therefore no monopoly or restrictions to competition exist.

Since there is such a wide variety of technologies offered, the following statements can be made from the perspective of the patent system:

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7090963/
[11] https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
[12] https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

- It is possible that the methodology created to obtain the vaccine against COVID-19 is not the object of the patents, either because the technology is not patented or it was already patented as a procedure to create vaccines.
- It is possible that the known methodologies to create vaccines were not effective for application in the creation of the vaccine against COVID-19. To that extent, only those that have been successful constitute a solution to this technical problem.
- It is possible that the technology for detecting the virus's genetic information is not patented or patented. It was the owner who used that technology to create the vaccine.
- Several vaccine candidates may have faced obstacles during the vaccine invention process. These obstacles are problems that researchers solved and may have been the subject of a patent.

Thus, the vaccine for COVID-19 can be the subject of a patent as a final product. However, as an invention, it must be analyzed considering the patentability requirements. In this sense, a review must be conducted as to whether the processes used are subject to patentability claims or the product intended to be patented. It may well be only the latter since the methodology may not be considered novel, or it would be evident that the vaccine could be obtained therefrom.

There may be different products resulting from different combinations and that act against the virus in different ways, but with the same result. Some vaccines may be cataloged as better than others by their characteristics. For example, some vaccines require a single dose. Others have been shown to be more effective in each sample or population (Yale, 2021). Other vaccines require shallow temperatures so that new ways of producing them for conservation in more favorable environmental conditions are already being considered (WHO, 2021). Some vaccines are more suitable for certain patients, given their pre-existing conditions.

For all the above reasons, patent offices will not, and should not, concentrate on the economic effect, wrongly called monopolistic or social, of the granting of patents submitted. They should focus on determining which meet the patentability requirements, as explained above. That is, if the solution presented is novel, inventive, and susceptible to industrial application.

Finally, this exercise demonstrates the non-existence of a monopoly in vaccines resulting from patents. On the contrary, it proves intense competition, in which different products are offered to satisfy the same need. In this way, a common goal of the competition and industrial property laws is achieved: to benefit the consumer.

Have patents promoted monopolies within the framework of the pandemic?

The specific case of COVID-19 vaccines is a clear example of how a patent right does not grant a market monopoly to its holder. For example, while it is true that no one can produce the Pfizer-BioNTech vaccine without the authorization of the patent holder, it is also true that, from the consumer's point of view, the consumer can choose between the one produced by Pfizer-BioNTech or opt for any of the 15 other options that were on the market by mid-May 2021.

Have intellectual property rights promoted anti-competitive behavior under COVID-19?

Free economic competition may be infringed through a series of practices that limit or prevent market competition. Colombian legislation establishes the following violations, among others (SIC, 2021):

- Agreements or arrangements that directly or indirectly aim to limit the production, supply, distribution or consumption of raw materials, products, merchandise or national or foreign services, and in general, all kinds of practices, procedures or systems tending to limit free competition and to maintain or determine inequitable prices (article 1 of Law 155 of 1959).
- Agreements between two or more companies prevent, restrict or distort competition (article 47 of Decree 2153 of 1992).
- Abusive dominant position behaviors (article 50 of Decree 2153 of 1992).
- Unilateral acts carried out by companies (article 48 of Decree 2153 of 1992), such as:
    - Infringing the rules on advertising contained in the consumer protection statute.
    - Influencing a company to increase the prices of its products or services or to desist from its intention to lower prices.
    - Refusing to sell or provide services to a company or discriminating against it when this could be understood as a retaliation to its pricing policy.

In the specific field of COVID-19, no conducts have been observed that merit actions by the competition authorities derived from anti-competitive practices. On the contrary, the task of fighting against COVID-19 has allowed pharmaceutical companies to enter an intense collaboration scheme by licensing their intellectual property and know-how for the development, production, and distribution of vaccines. Therefore, the proposal to liberalize patent rights would not, at least from a competitive point of view, positively impact achieving more vaccines in a shorter time and at a lower price.

Expert institutes such as Max Planck agree that even assuming that the release of patents on vaccines to

fight COVID-19 would be sufficient to allow third parties to participate in their production, it could generate the complete opposite effect (Hilty & Batista, 2021). Currently, the biggest challenge in the production of vaccines is the limitation in quality raw materials, components, syringes, supplies, among others.

Proposing patent liberalization may be a popular measure that shakes the political foundations of countries and is supported by a current discourse revolving around social dissatisfaction. But we should not lose sight of the fact that, if the objective of patent liberalization is to achieve a greater production of vaccines at a faster pace, it is very likely that, with the entry of new players into vaccine production because of such liberalization, there will be significant negative and collateral effects on the production of vaccines. Especially the negative impact it may have on the inputs needed for vaccine production.

Conclusions

There is a clear interdependent relationship between creation, innovation, and the intellectual property regime. The rights granted, for example, by a patent, are the means or the tool for the holder to obtain benefits derived from the exercise of that industrial property right. If this exclusivity right did not exist, there would probably not be sufficient incentives to invest resources, time, and personnel in developing a technology, nor would there be enough incentives to disseminate the information involved in the technical developments.

Although it is believed that the non-existence of the patent system would allow third parties to compete more quickly since the trade secret would not prevent them from duplicating the invention if they arrive at it honestly, in many cases, the time needed to access this knowledge could be longer than that offered by the patent system, slowing down the production of knowledge and generating economic inefficiencies.

On the contrary, with the incentive provided by the patent right, a virtuous circle is generated that results in more knowledge in a more efficient manner, benefiting society and, therefore, the consumer.

A patent cannot be considered a monopoly as it is contrary to the very meaning of what it represents, i.e., a protection granted by the State to a person who has solved a technical problem through an administrative procedure, reviewing formal and substantial objective requirements of the rules of patent law.

Nor can it be said that through patents, the supply of a product is reduced to a single seller because

competitors can, with their efforts and, based on the same patent information, come up with other solutions to the technical problem in the form of different products and processes that could become available in a market.

In the case of COVID-19, it is demonstrated that the incentives established by the patent system have worked, since only a year and a half after the detection of the pandemic, 15 vaccines have been introduced in the market using four different technologies and for which 13 manufacturers worldwide are responsible. In other words, to date, there are 15 solutions to fight the virus.

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