

Pharmaceutical patent in El Salvador

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Abstract

In this first submission of general studies on the Pharmaceutical Patents in El Salvador, the approach is its regulation within the Intellectual Property Act recently approved in El Salvador (year 2024). In a second submission its regulation at an international level will be approached and with its implications on Salvadoran territory. It must be clear that a legal framework will be addressed and it will continue being developed through subsequent research submissions which will be published. The regulation of patents in El Salvador establishes protection on this special property, which is a tool in product marketing and invented procedures. The legal regime of the patent applies to any other type of invention, including the ones within the pharmaceutical field. The patent grants an exclusive right of exploiting the pharmaceutical invention on Salvadoran soil. El Salvador acknowledges the legal entitlement of patents to an inventor, whether national or foreign, natural or legal. Also, this acknowledgement applies to the inventor's inheritors. The legal regulation of patents in this new law, is supplementary to other regulations which weigh on the market, such as the regulation in the Competition Law and Investments. Finally, the right to patent constitutes an instrument to market important medicines for society and patent investors.

Key Words: Patent, Invention, Expiry, expiration, full right, in their own right, Public domain, Territoriality

Introduction

First, general concepts on patents will be encompassed, which are the basis for its application within pharmaceutical patents, its legal definition plus others related and established within the law such as invention, novelty, state-of-the-art of technique, inventive level. Second, the approach to the patent term according to the recently approved legislation for intellectual property and the object of protection for a pharmaceutical patent and the holder's rights in El Salvador in accordance with the national law on the matter. The relation between patents and medicines. The applicable legal regime to the Intellectual Property Act, such as property law and other aspects related to patent law, hereinafter the Intellectual Property Law of El Salvador will be abbreviated as LPI for its acronym in Spanish.

Definition of patent in the Intellectual Property Law of El Salvador

In this section, the legal definition of patent will be explained. Article 3 has a section titled "Patent Definitions", written in numerals 44 to 61.

This way, article 3.44 in the LPI defines patent as follows: "Title through which an exclusive right is granted over an invention, utility model, or industrial design during the defined patent term established within this act, which expiration implies the entry in full right of said invention or utility model to the public domain".

The legal definition contains many concepts which should be highlighted: title, exclusive rights, invention,

utility model, design, legally established patent term, expiration -of the patent term- and "entry of full right of said invention or utility model to public domain". Each and every term will be explained to contribute to a better understanding of the definitions.

About the term: "title", in this new Intellectual Property Act a proper definition is not given which is why the Panhispanic Legal Dictionary in Spanish is needed and defines "title" as "the document that reflects the entitlement to a right" and it points to "enabling" (Panhispanic Legal Dictionary in Spanish 2024). From the above, it is possible to state that conferred enabling is to exploit the invention in exclusivity conditions within a defined territoriality, in case of El Salvador, it corresponds to the salvadoran territory.

The expression: "exclusive right" means that only the right holder, in this case the patent holder, will privately and uniquely have the faculties to exploit the right, without requesting authorization to do so.

In section 44 in article 3 of the LPI, the Salvadoran legislator defines "invention" as "every idea" a creation from the human intellect with an industrial application that complies with the patentability conditions the LPI establishes, and also, that solves a specific technical issue; meaning the invention complies with known requirements: (1) human creation, (2) industrial application, (3) the LPI's established requirements on invention patentability, (4) that it solves a determined technical issue.

The legal term from article 3.44 in the LPI contains two more which in the doctrine (law studies) and foreign legislation have their own identity, these are: "utility model" and "design". The article 3.46 in the LPI establishes that "utility model" is "all ways, configuration or disposition of elements of an artifact, tool, instrument, mechanism or other object, or any part of an object that allows a better or different functionality, usage or manufacturing of said object or part, or that it brings some function, advantage or technical aspect that it did not possess before." On the other hand, "industrial design" is "any bidimensional or tridimensional shape that, built into a useful product, provides a special appearance, and makes it apt to be a type or model for its manufacture". It is worth noting that the utility model and design have a conceptual entity that differs from a patent.

Also, article 3.44 in the LPI has the terms: "legally established patent term", which means that the legislator is acknowledged as a competent authority to establish within the law, a time in which the patent right will be recognized for its existence and legal protection meaning a "legal life".

A patent right is a property right, but not just any property, this is a special property since it has its own characteristics, having a legally established patent term, a matter which it governs, confers an exclusive right in the monopoly which constitutes this right as an industrial privilege and a legal protection in a territory determined by a State. Let it be known that the patent as a special type of law can only be delimited by a law issued by the El Salvador's Law-making Assembly, through the law-making process, this is known as "statutory law" or ordinary law.

The expression "expiration" - about the patent's legal life- is a concept which must be understood in relation to the "entry in full right of the invention or utility model to the public domain". Which is why the Salvadoran legislator confers the legal attribution to the state authority so at once it grants the patent rights, that is to say, the title to the inventor. This holder to the patent right will have the faculty to use this prerogative during an established timeframe, which when it is finished, will expire, meaning, it will cease said prerogative, in a way that, the exclusivity of the holder to exploit the invention will expire, from there, the holder will not be able to avoid others from exploiting said invention in the market. The expiration of the patent right means the ending of legal effects of this right, in simple words, "it dies" and it goes to the "public domain cloud", where all exclusive rights' remains go to "rest" and will become a part of society's legacy.

The expiration of the patent right and its entry to the public domain bring about the collective pact theory which supposedly exists between inventor and the society organized as a State, through which the patent right is authorized during a determined timeframe so that the inventor exploits it exclusively, profits privately and recovers the intellectual and economic investment used for the pharmaceutical invention, which once it expires, the society which granted protection to that right can harvest even more benefits from said invention through its open exploitation, without the restriction placed by exclusivity which supposed a concession of patent rights, except by the limits legally established.

In the same way, the concept of “novelty” should be highlighted, taken from the article 3.48 of the LPI, which is legally defined as “The condition that implies that the invention or utility model did not previously exist within the state of the art technique to the date of the patent request”. This definition of novelty brings about another relevant expression: “State-of-the-art technique”, which the article 3.49 from the LPI defines as: “Everything that has been disclosed or made accessible to the public, anywhere in the world, through a tangible publication, oral disclosure, sale or commercialization, use, or by any other means, before the patent application filing date in the country or, where applicable, before the filing date of the foreign application whose priority will be claimed, including the content of a patent application pending before the Institute, whose filing date or, where applicable, priority date, was earlier than that of the application being examined, but only to the extent that such content is included in the earlier application when it is published.”

On this subject, within the “menu” of the legal lexicon in patent matters, salvadoran lawyers collected another equally important expression: “inventive level”, which is the level or standard from an invention that is not obvious for a person specialized in the matter related to the invention, so for an expert in medicines or pharmaceutical products. Besides in the “inventive level” it is said as well that the invention had not been a product or evidently obtained using the pertinent state of the art technique, for which case, of the technique used within the pharmaceutical field.

About “industrial usage”, this is defined by the legislators as an attribute of an invention or procedure to employ in any type of industrial or productive activity, such as agriculture, livestock farming, mining, fishing, construction, and services, article 3.51 of the LPI.

Pharmaceutical patent validity in the Salvadoran legislation

Article 205 of the Intellectual Property Act of El Salvador (LPI) establishes that the patent will have a non-renewable duration of twenty years, which are counted from the date the application was presented in El Salvador.

It is worth noting that article 205, section two, of the LPI stipulates that the twenty-year patent term for a patent can be extended “only” if the Intellectual Property Institute delays granting the patent for more than five years from the date the patent application was presented, or if the institute delays granting the

patent for more than three years from the date the request for substantive examination was filed. In addition, this extension can be requested, if the entity responsible for granting the marketing authorization for pharmaceutical products delays granting this authorization for more than five years, from the date this request was presented. It is worth adding that this will apply assuming the product patent is already registered in El Salvador and its protection period is still in effect.

These exceptions, especially the last one, can be considered reasonable given that a patent holder would have no reason or justification to endure delays from the Salvadoran state entities in carrying out their activities. In other words, it would be unfair to deprive a patent holder of a twenty-year or longer patent protection and validity period when they have not taken any action that would cause the delay in its granting.

In this case, extending the patent term in these scenarios can be seen as a factor of promoting national and international investment, provided that the investment involves obtaining a patent for exploitation in El Salvador. In other words, the legal extension of these aspects would constitute a legal offer of reinforced protection for investments made in this area. It is worth adding that an investment can encompass those made in the field of industrial and intellectual property, specifically in this case, pharmaceutical patents.

The concept of investment is found in the Investment Law and also in the Bilateral Investment Treaties and the Free Trade Agreements to which El Salvador is a party and obligated to uphold. Specifically, article 3, item h) of the Investment Law, which establishes that the assets or resources considered as investment include, among other things, the intellectual property rights.

The LPI, enacted in 1993 and later repealed by the current Intellectual Property Law, stated in its articles 109 and 109-A that the duration of a patent validity was for twenty years. However, this term can be extended for the same reasons outlined in literals a), b) and c) of article 205 of the new LPI. This extension of the patent’s validity period was a deliberate decision by the legislature when those articles of the old law were modified. Initially, the 1993 LPI (without modifications) established in article 109, section one, that the patent validity was granted for a non-renewable twenty-year term. However, in section two, it was stipulated that “invention patents for medicines” would have

a non-renewable validity period of fifteen years, from the date the application was submitted in the National Registration Center. In essence, there has been a progressive extension of the validity period for pharmaceutical patents in El Salvador.

With the new Intellectual Property Law (LPI), the legislator in El Salvador has reaffirmed its policy of strengthening patent protection for twenty years. This term, however, can be extended under reasonable grounds. Thus, the legislator exhaustively prescribes the grounds for extending the term, meaning no other circumstances can be included to broaden it. In doing so, the legislator tempers the strictness of the "non-renewable" nature of the patent's twenty-year term.

According to the new LPI, the Intellectual Property Institute is responsible for determining the length of a patent's term extension. Article 205, section four, of the LPI outlines the parameters for calculating this extension. This provision limits the Intellectual Property Institute from extending a patent's validity for more than five hundred and fifty days. The request for such an extension must be submitted to the hierarchical superior of the assistant registrar who granted the patent. The request for such an extension must be submitted to the hierarchical superior of the assistant registrar who decided on the patent's grant. This literal interpretation of the provision suggests that an applicant would first need to present and obtain the patent grant and then subsequently file a separate petition for an extension. This petition would require arguing and providing evidence of the delays in either the patent's grant or the marketing authorization for the pharmaceutical product.

If the "patent petitioner-inventor" obtains a denial of the request for the patent term extension under the legally prescribed conditions, the petitioner has the right of appeal to the competent judge.

The patent term extension is considered a key strategy for increasing the patent's strength over time, a significant interest for pharmaceutical innovators, among others (Morla, p. 56). It is worth mentioning that, in Europe, this interest is also evident through the recognition of Supplementary Protection Certificates (SPCs). These certificates, regulated at both national and European level, complement the patent protection and given their importance, SPCs warrant a more detailed discussion beyond these lines. These certificates have been subject of study for other international authors (Bercovitz, p. 480), in addition to the author of this article.

Notwithstanding all of the above, article 209 of the LPI stipulates a restriction on the patent right known as the Bolar exception. This exception limits the enjoyment and exercise of patent rights that are nearing to expiration. It allows a non-patent holder to submit an application for marketing authorization of a pharmaceutical product to the Sanitary Regulation Superintendency (SRS) or an equivalent entity. Also, to obtain necessary information about the patented pharmaceutical substance without difficulty, even though they do not hold the patent rights. In conclusion, the Bolar exception is a legal and conventional means of limiting the strength of a patent right at national, regional, and international levels (Tobar Rodríguez, 2014, p. 708).

It is crucial to understand that a patent holder can lose the right if the annual fee is not paid on time to keep it in force or to maintain a pending patent application. If the fee is not paid, the patent or patent application lapses by operation of law. This lapsing by operation of law means the provision is self-executing. In simpler terms, once the predetermined time for paying the annual fee passes and if the payment is not made, the patent or patent application's validity "will expire" without any need for a declaration from the Institute, as per Article 206 of the LPI in El Salvador. However, the Institute will still issue a declaration of the patent's lapse, in accordance with Article 272 of the LPI.

What does pharmaceutical patent protect?

La The patent protects two aspects: the product and the procedure to obtain the subject product protected by the patent, according to the article 196 of the LPI.

The patent protects the product itself, without the process used to obtain it being protected by the patent, although it could be protected.

Furthermore, the patent protects the procedure used for obtaining a product.

In addition, the patent "may only consist of one invention", however it is possible to grant one patent regarding a group of interrelated inventions based on a single inventive concept, article 196 section two of the LPI.

On the other hand, the patent constitutes a legal instrument to protect an invention and the medicine represents an invention which, in order to obtain it, requires -usually- an investor to inject capital and human resource.

The invention patent constitutes an indicator of innovation. There is a relationship between the invention and the society's prosperity, since the patent of an invention of a medicine can help to boost the retailer's competitiveness and at the same time, facilitate the medicine's entry into the market. (Portillo, p.361)

In this regard, a new medicine invention represents a social event, now, a global one that can heal, save lives or relieve pain. Definitely, medicines can contribute to improving human being's quality of life. For this reason, it is important to consider the relationship between the right of the patent and the access to high-quality medicines in El Salvador.

As a form of comparative analysis, the pharmaceutical patent represents a tool to guarantee the right to access medicines. In Colombia, from the academy, it has been concluded that there is no conflict among the health rights, the access to medicines and the exclusive right of pharmaceutical patents. Nevertheless, the right to a patent ensures that its holder has the possibility to recover the high costs of research and development of a new product, which has a positive impact on consumers of medicines (Fenwarth and Lopez, 2016, p. 30). The same conclusion can be extrapolated for El Salvador.

What can a patent holder do?

The holder of the patent will have the right to its invention in accordance with the article 198 of the LPI. Whether various people are participating in the invention, jointly, they will be holders of the patent right and everyone should express the percentage of the right that corresponds to each one in their capacity as inventor.

The holder of a patent right must make use of the patent within the limits that the Intellectual Property Law establishes and this includes not to abuse the right. Abusing of the right means that a holder of a patent right uses it improperly, contrary or far from the patent's intentions and thereby causing damage that he will be obliged to repair (Castillo, p.159). Currently, a holder of a patent right can be limited to exercise the exploitation of the patent is subject to a code of ethics. In fact, it is considered that the issue of pharmaceutical patents must be focused on the relationship between ethics, health, research and marketing (Pourrieux y Ramal, p. 2). Entrepreneurs in the pharmaceutical field should have a code of ethics appropriate to their economic branch

A pharmaceutical patent holder, who has reasonably recovered his investment and obtained the expected profit, can also contribute to transferring technology to developing countries and improving access to medicines (Uribe and Martinez, p. 115).

What is the importance of respecting a patent in national hiring?

The patent holder recognized in El Salvador shall be protected from the power of the state. This protection will be conducted by various means. First, the acknowledgment that the Institute of Intellectual Property of the National Registration Center (CNR by its acronyms in Spanish) delivered by a patent certificate. The holder of this right will be able to request protection from the judges in the country to prohibit the exploitation of the patent without the holder's authorization to avoid manufacturing, marketing, importing, and exporting medicines or similar products with the active ingredient of the medicine which is protected by the patent (article 207, LPI). This right, since it is exclusive, grants the holder to oppose any economic use that could endanger their pharmaceutical invention.

What happens with pharmaceutical patents granted under the repealed law?

The patents granted based on the intellectual property law which has been repealed with the entry in force of The New Intellectual Property Law, will continue with their term validity, in accordance with the principle of non-retroactivity of the law, article 21 of The Constitution of the Republic.

Furthermore, The Intellectual Property Law represents a tool of economic policy and in that sense, has an impact on the attraction and preservation of investment. For this reason, the way to protect the rights of patent investors is to respect the patent term. It must be remembered that the patent is a property right and as such, must be respected by all.

What does an inventor in El Salvador require to obtain a pharmaceutical patent?

Based on article 201 of the LPI, an inventor can obtain protection for his/her invention, for which to obtain an invention patent is required which will need authorization. A patent of invention may be obtained in respect of any subject matter, except for those excluded by law, provided that it possesses novelty, inventive level and industrial application.

National company

National inventors, whether natural or legal persons, can obtain the registration of their patent rights and thereby protect their inventions and related investments.

Foreign Company

Article 4 of the IPL enshrines the principle of equal treatment of the national or foreign natural or legal person to acquire and enjoy the ownership of patent rights and any other right concerning the IPL. In this sense, this provision prescribes that nationality shall not constitute a condition to enjoy such rights.

Also, Article 13 of the Investment Law recognizes and guarantees to domestic and foreign investors the protection of property, including intellectual property. This provision, as well as the Intellectual Property Law, represents a development of the constitutional guarantee to the protection of intellectual property according to article 103, paragraph two of the Constitution of El Salvador.

Legal studies claim that the development of the population on a global level, regarding the technological and scientific field, is associated with the numbers of patent applications. In this sense, for example, new patented technologies in biological topics are concentrated in the most economically developed countries, as they have the installed capacity to research and exploit cutting-edge technologies (Montoya and Restrepo, 2018, p. 63). Also, the largest number of patents granted in developing countries have been applied for by non-residents (Montoya and Restrepo, 2018, 54).

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