INTELLECTUAL PROPERTY AND PATENTING

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INTRODUCTION

A patent is a legal document that grants protection rights to an invention. Under this protection, it is guaranteed that no one but the patent owner can use the invention unless they authorize it through a license. Hence, a patent represents an exclusive right to use, commercialize, share or exploit an invention for certain purposes.

Being aware of what a patent is and how to obtain it is crucial for the creation and implementation of a project, either a product, process, design, or service. The development of patents incites technological development by encouraging more inventors to protect their ideas and keep innovating, and it also avoids unfair competition. Therefore, the purpose of the following document is to present a brief introduction to intellectual property and how it is related to biotechnology. Besides, a perspective on the laws on intellectual property and the procedure to obtain patents in different countries will be approached.

INTELLECTUAL PROPERTY

Intellectual property generally refers to the type of properties that emerge from creations of the mind (1). Thus, a natural or legal person protecting their goods is preventing others from stealing their creations and obtaining profits obtaining benefits that don't belong to them legally. Still, certain things cannot be patented, such as scientific theories, organisms, commercial methods, among others that vary from country to country, due to the fact that they do not strictly comply with the novel, inventive, and with industrial application requirements. With this in mind, the intellectual property encompasses the following categories (1):

- Literary, artistic, and scientific work, such as, songs, paintings, books, articles, among others, to which legislative protection is conferred under laws relative to Copyright.
- Interpretations and performances, radio broadcasts covering events such as concerts.

- Inventions. This generally encompasses a new device or method, which is related to protection through patents.
- Industrial drawings and models, such as the shape of day-to-day products, which could be protected through different laws.
- Trademarks, names and trade names, logos, geographic origin, among others.
- Protection against unfair competition, such as misleading customers with names or logos similar to other companies, misused geographic origin labels, among others.

As well, it is worth mentioning that the scope of the protection, description of the patented invention, and validity time of the patent must be specified on the document, and the criteria that must be met on each of the specifications can change depending on the country and on the nature of the patent. Yet, most of the laws and guidelines governing intellectual property internationally are subject to those proposed by the World Intellectual Property Organization (WIPO), which emerged in a post-war context to gather economic and Intellectual Property proposals (2).

BIOTECHNOLOGY AND INTELLECTUAL PROPERTY

Due to the nature of the project and of the community, the main area of discussion within the document will be biotechnology. First, a definition of biotechnology and historical background must be set in order to comprehend the legal implications. Then, the relationship between intellectual property and biotechnology will be described.

Defining biotechnology and its inventions within a legal framework can be problematic, therefore, there can be problems when dealing with what legislatures are referring to when talking about biotechnology. For example, the Convention on Biological Diversity (CBD) has a more traditional approach where it defines it as any application involving biological systems to generate a product or a process (3). On the other hand, the Cartagena Protocol structures a more specific definition of

modern biotechnology, rather than biotechnology as a whole, in which it highlights the use of new techniques involving, for example, nucleic acid manipulation (4).

Biotechnology has established itself and has exponentially expanded in the past few decades, proof of it is the continuous development of new iGEM projects which adjust to contemporary problems and use new technologies that come up as time passes. Hence, the scientific community has witnessed new techniques arise, as well as the generation of new products, which has inevitably given origin to different discussions and new problems.

First of all, when it comes to talking about patenting biological materials, some international agreements and precedents oversee the requirements and statutes governing the process. Among them stand out the Cartagena Protocol and the Nagoya Protocol. Both of them focus on the protection of biodiversity and revision of safety considerations to be taken into account when working with biotechnology and GMOs (4,5). Besides, some other treaties have established a framework for intellectual property and biological materials, such as the Budapest Treaty, which deals with the patenting of microorganisms and the recognition by the depositing of the biological material with any international depositary authority (6), and the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is a multilateral agreement where certain requirements are needed to set protection through intellectual property rights (7).

Knowing this, now some of the issues that arise from patenting biotechnology products or developments will be discussed. One of the main restrictions for patenting inventions generated through knowledge on the field is the protection of "*ordre public* and morality" or natural biological processes that are not of innovative application and do not come from microorganisms. When talking about *ordre public*, it refers to guaranteeing the protection of human, animal, and plant life or health; thus some of the "creations" that would be excluded for intellectual property rights would be, for example, human cloning (8). According to a report by Lesser in coordination with the WIPO (9), exclusion from patentability was one of

the problems that researchers faced, but those related to the processing of the patent application were the most common.

Another issue comes when taking into consideration specific biological material. One of the clearest examples is the patenting of whole organisms, which involves different considerations depending on the region where the patent is being issued. This was clearly seen in the Diamond v. Chakrabarty case (10), where the Supreme Court of the United States finally granted a patent to protect a GMO that helped degrade hydrocarbons after a long discussion of whether it was possible to patent or not. Some of the other issues that arise involve the concept of who owns the cell lines or biotechnological products and enforcement of punishment for patent protection violation since it is more difficult to protect biotech products (11).

Although there seem to be more problems that hinder the protection of biotechnological inventions through intellectual property rights, a patent can still be obtained with new products or processes developed in the field. Still, we must remember that the material or process subject to patenting must be an invention rather than a discovery and must not be contrary to the *ordre* public, besides displaying the traditional characteristics of a technological matter subject to patenting: novelty, inventive nature, and industrial application (11).

INTELLECTUAL PROPERTY PROTECTION

The process to protect intellectual property, although subjected to the WIPO's recommendations, is usually determined by the different legislations among several countries. Therefore, brief descriptions of the law and the corresponding procedure to register a piece of intellectual property in several Latin American countries are described in the following sections.

MEXICO

Mexico is one of the more than 190 countries that form part of the World Intellectual Property Organization. The country joined in 1975 (12), even though this country had already a background in assuring the protection of intellectual property rights before that year (13). Yet, laws established at the time are clearly

outdated, and now there are three main laws in force as of the moment of writing this document: the Federal Law on Plant Varieties (FLPV) updated in 2012, the Federal Law on Copyright (FLC), and the Federal Law on Industrial Property Protection (FLIPP), which were both updated and published, respectively, in 2020.

In the first place, the Federal Law on Plant Varieties. Initially published in 1996, its last update was published in 2012, and the law's goal is to set the guidelines and regulations for the protection of breeders' rights on plant varieties, which are considered a "subdivision of a species that includes a group of individuals with similar characteristics and that is considered stable and uniform" (14). The FLPV denominates the Ministry of Agriculture, Breeding, Rural Development, Fishing, and Agriculture as the institution responsible for overseeing its application, and it states that protection for 18 years to perennial crops and 15 years to other types of crops should be granted if applicable (14).

Next, the Federal Law on Copyright is another legal cornerstone for intellectual property protection within Mexican territory. This law mainly focuses on the protection of those products related to, but not limited to, the arts. Literary works, radio broadcasts, sculptures, architecture works, computer programs, among others, are the areas that stand out. Considering some exceptions established within the FLC, it protects authors' rights during their lives and 100 years posterior to their death. The main institution supervising the fulfillment of the law is the decentralized National Institute on Copyright, which was established in 1996 (15).

A third important law, which will be described in better detail since it strongly relates to biotechnology, is the Federal Law on Industrial Property Protection. As its name implies, one of the main objectives of this law is to protect industrial property -such as industrial designs, inventions, geographic origins, among others- in the form of patents that would last 20 years. In addition to this, other goals the FLIPP intends to achieve are the protection of industrial secrets, prevention and punishment against any act that harms the integrity of the intellectual property, promotion of inventive activity, and accessibility to the technical knowledge in the country (16).

Even though a special law on industrial property was set in 1942, it was not until 1991 that the Mexican Institute of Industrial Property (IMPI, for its acronym in Spanish) was created. The institutional body still persists nowadays, and it functions as a decentralized, judicial entity that would have the legal authority to help the Ministry of Economy in the administration of the correct protection of industrial property (17).

When considering potential biotechnological or biological product patenting, a sample must be deposited in addition to the patent request. As well, the law further specifies that new details in regards to this matter. Certain procedures and the products derived from them, where an organism is genetically modified and poses a danger to itself or to the human population cannot be patentable. In the same fashion, it states that biological material as it is found in nature, along with plant varieties or animal breeds and the essentially biological procedures to obtain them and their products, cannot be patented either. On the other hand, the FLIPP states that the patentability of "microbiological processes or any other technical procedure or product obtained from these procedures" shall not be affected (16). Further clarification of the loopholes is needed in the case of GM plants and animals.

As most of the procedures set by the government, this law and the pertinent institutions frame the adequate steps to follow when requesting protection for intellectual property. Some of the procedures to follow are described below (18):

Steps for registering a patent			
Description	Cost	Other requirements	Time
1. File the patent to the IMPI. The patent's registry process is commenced by filling the application form on IMPI's website. The application forms' name	National patent (only in Mexican territory). $8,197 MXN (approximately	-Description -Summary -Drawings -Reivindication -Payment receipt	

is IMPI-OO-OO9. https://patenteenlinea.impi.gob.mx/Pages/Solicitud/Solicitudes.aspx?Id=HY9IV0zpnDbFqvCA1El5Cw%3d%3d	$403 USD) + taxes		
2. Patent application publication.		Three offices will be given, two of them are to rectify possible objections, and the last one would determine whether the patent is approved or not. If any of the offices are not answered, the patent application is withdrawn.	It takes approximately from 2 to 4 months
3. If the patent is approved, it is sent and published in the IMPI's Gazette, and a period of 18 months will begin for any other objection to occur.			18 months
4. Deep examination of the patent: when the objecting period is over, a thorough examination of the patent is performed in order to determine whether it complies with the requirements: -Novelty -Inventive activity -Industrial application		Four offices will be given, three of them to rectify and one to conduct the payment.	From 2 to 4 months
5. If the patent fulfills all			

of the requirements, an approval file is published for the patent to be granted.			
6. Title obtention: it is granted after the thorough examination and consequent judgment.	$3,099.84 MXN (~$152 USD)	The title is given with a validity of 20 years.	The term after the title obtention, once the proper examinations were passed, will hace a duration of 2 to 4 years..
7. Payment of fees for rights preservation: periodic payments should be done during the patent's 20 years of validity to preserve the rights.	- for the 1st to the 5th year, per year: $1.161.90 MXN (~$57 USD) - for the 6th to the 10th year, per year: $1,360.69 MXN (~$67 USD) - from the 10th to the 20th year, per year: $1,536.99 MXN (~$76 USD)		
TOTAL time: Approximately 3 to 5 years.	The costs involved during the overall procedure can surpass the quantity of $60,000 MXN (approximately $2,980 USD), when considering other studies or requests, such as certification expedition.		

BRAZIL

Brazil was one of fourteen countries to join in the Paris Convention (1883), the first-ever international treaty on Industrial Property, and the Berna Convention

(1886), which protects the works and rights of their authors. Also, Brazil joined the WIPO in 1975 (19). The Brazilian Industrial Property Institute (INPI, for its acronym in Portuguese) is the Brazilian Patent and Trademark Office, an autarchy linked to the Ministry of Development, Industry, and Commerce. The INPI is responsible for implementing rules regarding Industrial Property, which contains Intellectual Property Rights (IPRs). The IPRs consist of Copyright and Related Rights, Industrial Property, and ***sui generis*** IPRs. However, the latter two groups mainly defined the legal framework regulating the Brazilian biotechnology industry inventions (2020).

The Industrial Property is regulated by Federal Law No. 9.279/96 (LPI). It includes patents, trademarks, industrial designs, geographical indications, and non-patentable knowledge. The LPI describes a patentable invention that meets novelty, inventive step, descriptive sufficiency, and industrial application requirements. In other words, it is necessary not to be marketed, executed or used previously, and the deposited technology has advanced results than those well known by the person skilled in the art.

Furthermore, regarding living systems and biological products, the LPI presents some restrictions to the non-patentable matter as the following:

I. Therapeutic methods;
II. The whole or part of natural living beings, and biological materials found in nature, or even isolated from it, including the genome or germplasm of any natural living being and natural biological processes (except transgenic microorganisms that meet the three patentability requirements);
III. Spontaneous biological process without human intervention for final product/result;
IV. Natural biological products, whose containing only a natural extract;
V. Transgenic plants and their parts as well as the processes of obtaining plants by species crossing;

Although GM plants and GM animals are non-patentable in Brazil, their development is considered an invention. Transgenic microorganisms are the only

living being patentable invention under LPI interpretation or toolkits and methods for the development of general GMOs as gene constructs, recombinant proteins or composition of biological extracts (21). However, the invention must be produced or used in any industry, and biological sequences are involved only when the utility is clearly evidenced in its report (20).

On another hand, the Law of Crop Protection No. 9.456/97, based on ***sui generis*** rights, allows intellectual property to cultivars. The cultivar must be new, homogeneous and stable across generations, distinctive, and be useful. Additionally, a new cultivar or an essentially derived cultivar are modalities subject to protection, which establishes that "the protection of the cultivar will fall on the reproduction or vegetative multiplication material of the whole plant" (22).

The patents in the biotechnology field require additional steps to registration. Biological products, i.e., proteins or polynucleotides, have a sequence that is essential to describe them. Therefore, a Nucleotide or/and Amino Acid Sequence Listing shall be submitted (preferentially, XML format) to give more details about the product. As well, biological inventions that might contain fundamental parts that make possible its description must be deposited in an institution authorized by the INPI (23).

Moreover, Brazil has a national law on Access to Genetic Resources No 13.123/2015, which allows the granting of intellectual property based on access to genetic resources or associated traditional knowledge only after registration or authorization (in SisGen - National System of Genetic Resource Management and Associated Traditional Knowledge) previously to the patent application (24).

For more information about biotechnology patents in Brazil:

Portuguese (INPI official file)

English (Biotechnology Innovative Organization comments)

Steps for registering a patent			
Description	Cost	Other requirements	Time
1. File the patent to the INPI. Registration on the e-INPI system, select the service (i.e. patent deposit), and generate the bill for payment for the chosen service. Once completed, deposit in the e-patent system	National patent (only in Brazilian territory). $260,00* BR (approximately $49,24 USD) *This fee is reduced by 60% if the international application is filed by a natural person, a small or medium-sized enterprise, a cooperative, an academic institution, a non-profit-making entity, or a public institution.	-Description report -Claims -Biological Sequence Listings (if necessary) -Drawings - Abstract -Payment receipt	-
2. Patent application publication.	After 24 months and each subsequent year, the annual fees of the patent application have a fixed value, regardless of the filing date, until its grant. Ordinary period: $295,00 BR (approximately $56,48 USD) Extraordinary period (late): $590,00 BR (approximately $112,96 USD) .	When the application fill the requirements of the LPI and other provisions, the INPI will approve your invention as a patent application. If some documents are missing (other than claims and descriptive reports), the applicant has 30 calendar days to submit.	

3. If the patent is approved, a period of 18 months (from the deposit date) of confidentiality will begin. After that, it is sent and published in the Intellectual Property Magazine (INPI's publications).		As established by the LPI, the applicant may make voluntary changes until the request for a Deep Examination. This Examination must be required until 36 months from the deposit date	From 18 to 36 months (from the deposit date)
4. Deep examination of the patent: when the objecting period is over, a thorough examination of the patent is performed in order to determine whether it complies with the requirements: -Novelty -Inventive activity -Industrial application	Requesting examination and patent application with no more than ten claims: $590,00 BR(approximately $112,96 USD) Check here for more than ten claims or via PCT.	After payment of the examination application and not being filed for any reason, a Patent Examiner will analyze the Patent Application. Check here how to request for prioritized examination or possible conclusions from the Examiner.	Relative
5. Even if the patent fulfills all of the requirements, the applicant must request the issuance of the patent letter within 60 days (ordinary period) from the approval publication in the Magazine.	Ordinary period: $235,00 BR (approximately $45 USD) Extraordinary period (late): $475,00 BR (approximately $91 USD)		
6. Title obtention: it is granted after the thorough examination, consequent judgment			

and publication of the Patent Letter.			
7. Payment of fees for rights preservation: periodic payments should be done during the patent's 20 years of validity to preserve the rights.	- for the 1th to the 2nd year, per year: $295 BR ($56 USD)* - for the 3th to the 6th year, per year: $780 BR ($149 USD)* - for the 7th to the 10th year, per year: $1,120 BR ($214 USD)* - for the 11th to the 15th year, per year: $1,645 BR ($314 USD)* - for the 16th to the 20th year, per year: $2,005 BR ($383 USD)* * without Certificate of Addition. Check here for more details.		
8. Effective patent exploration: Within 3 (three) years, after the Patent is granted, the holder must begin the exploration or commercialization of the product. If this does not happen, in order not to lose his rights, he/she will have to grant an "exploitation license to any person or company that is interested."			
TOTAL time: Approximately 6 to 7 years.	The costs involved during the overall procedure can be approximately $2,265 BR ($433 USD).		

ECUADOR

For the Ecuadorian State and according to the Ecuadorian Institute of Intellectual Property (IEPI), a patent is defined as a set of rights granted by the state, to an inventor or its assignee, in exchange for the disclosure of an invention (25).

With Decree 356 issued in April 3, 2018, President Lenín Moreno transformed the Ecuadorian Institute of Intellectual Property (IEPI) in the National Service of Intellectual Rights (SENADI for its acronym in Spanish), granting it new responsibilities and promoting the defense of intellectual rights. In this context,

SENADI is the only entity in Ecuador that guarantees the protection of property rights over an invention (26).

On the other hand, the intellectual property laws for the protection of inventions are included in the National Legislation of Ecuador, which mentions that the granting of patents for inventions or procedures must be based on the fact that they have been legally acquired (27).

Furthermore, in 2016 the Organic Code of the Social Economy of Knowledge, Creativity and Innovation (COESC) was issued, which replaced the 1998 Intellectual Property Law, to harmonize Ecuadorian legislation with international standards in the protection and management of knowledge. This new normative body standardizes the substantive and adjective rules for obtaining a patent (28).

In addition, the Ingenuities' Code states that all inventions can be patented, whether a product or procedure in all fields of technology, as long as it is new and has an inventive and industrial application. It is worth mentioning that discoveries, which do not fulfill inventive activity, in the framework of Andean legislation are not patentable; and when it comes to living matter or biological material, there are more restrictions related to whether it is patentable (30).

In addition, a utility modality can be patented, which refers to a new arrangement of elements of some artifact, tool, instrument, mechanism, or another object which allows a better or different operation that did not exist before (30). In this sense, the prohibition of obtaining second-use patents is adopted from Decision 486, which means that a second use of the same invention is not patentable.

In the Ecuadorian case, both genomic DNA and the genes of all living beings as they are in nature are excluded as objects of a patent. It is not enough to isolate a biological sample, but rather a modification is necessary for a further substantive examination to define whether it is patentable (31). Regarding the patentability of microorganisms, these must be evaluated according to the Andean Community protocols which will allow exceptions to the prohibitions of patentability of

biological material (32), given that, since they belong to nature, they are considered public goods and as such are governed by non-patentability.

SENADI is based on the "Andean Patent Manual" (32) which presents a harmonization of procedures at the regional level, the steps are (33-35):

Steps for registering a patent				
Description	Cost	Other requirements	Time	Considerations
Presentation of the application before the IEPI.	$136 USD	Payment of the maintenance fee for the first annuity ($ 12 USD). Invention data: • Name of the invention and its description •Plans and drawings that may be necessary	Starts any business days	
Form examination. Verifies that the application is clear and correctly presented.			Within 15 business days	If the formal requirements do not comply, a period of 2 months is given to correct the defects.

Publication		In the case of applications with biological material, proceed as indicated in article 281 of the COESC. which states that a biological sample must be deposited in the competent institution when a detailed description cannot be provided	Within 18 months from the date of application It is expected 6 months from the publication to pass the patentability examination	
Possibility of opposition. It has the purpose that third parties can know the request, and can present an opposition for once	$250 USD	Determine that the product/process to be patented is not legal, or already exists.	Since publication, a period of 60 days is opened for the opposition.	The patent applicant will have 60 days to answer the opposition
Patentability examination	$196-$596.49 USD	Request for patentability qualification. Proof of payment.	In case of no qualification, you have 60 days with a 30-day extension to correct the impediments	The Patent Management Unit examines whether the invention is patentable.

Background examination. The patentability of the invention is determined.	N/A			
Concession resolution	$136-$204 USD			In an approval case, the concession title of invention patents is granted
Total Time: 4 years Validity: 20 years from the application date				
Note: During the 20 validity years of the patent, annual payments must be made to maintain its rights, otherwise the expiration of the patent is declared and the rights over it are lost. In the case of biotechnology patents, most of this type of research is associated with a public or private research institution; in this case, the distribution of the profits is negotiated between the inventors and the institutions.				

COMPARISON

In the following table, a comparison among the legal procedure to follow to specifically obtain a patent in each one of the three countries is summarized.

Comparison among the different countries			
Characteristic	Mexico	Brazil	Ecuador
Law	Federal Law on Protection of Industrial property (LFPPI)	Federal Law No. 9279/96 (LPI)	Organic Code of the Social Economy of Knowledge, Creativity and Innovation (COESC)
Institutions	Mexican Institute of Industrial Property (IMPI)	Brazilian Industrial property Institute (INPI)	Ecuadorian Institute of Intellectual Property
Time	Approximately 3 to 5 years	Approximately 6 to 7 years.	Approximately 4 years
Cost	Without the yearly fees, the cost can be approximately $555 USD. If a certification is issued, the cost might increase.	Without the yearly fees, the cost can be approximately $433 USD	Without the yearly fees, the cost can be approximately $718-$1,186.49 USD.

CONCLUSIONS

In conclusion, similarities among the nature and origin of the different regulations could be observed, which was expected since all of this countries are parties of important international organizations and treaties. Still, some slight differences in the costs and time needed to obtain a patent could be observed in all countries, being Brazil the country whose process is the less expensive (without considering yearly fees for patent preservation). Still, while developing the research it was noted that further clarifications are needed in the legislations to reduce the presence of loopholes.

REFERENCES

(1) WIPO. (2021). Módulo 1: Introducción a la propiedad intelectual. In WIPO, DL-101: Curso general de propiedad intelectual.

(2) Jungmann, D. & Bonetti, E. (2010). Inovação e Propriedade Intelectual: guia para o docente. Brasília: SENAI. https://www.gov.br/inpi/pt-br/composicao/arquivos/guia_docente_iel-senai-e-inpi.pdf

(3) CBD. (2006, November 2). ***Article 2. Use of Terms***. Convention on Biological Diversity. https://www.cbd.int/convention/articles/?a=cbd-02

(4) Secretariat of the Convention on Biological Diversity. (2000). ***CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY***. UN.

(5) Secretariat of the Convention on Biological Diversity. (2011). ***NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY***. UN.

(6) WIPO. (n.d.a.). ***Summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)***. World Intellectual Property Organization. https://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html

(7) USPTO. (2017, November 6). Trade related aspects of IP rights. ***United States Patent and Trademark Office***. https://www.uspto.gov/ip-policy/patent-policy/trade-related-aspects-ip-rights

(8) Barbosa, D. B., & Grau-Kuntz, K. (2010, January). ***3. Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights***. WORLD INTELLECTUAL PROPERTY ORGANIZATION. https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf

(9) Lesser, W. (2001). ROLE OF IPR IN BIOTECHNOLOGY TRANSFER - CORPORATE VIEWS. *WIPO*. Published. https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_lesser_biotech.pdf

(10) Skelton, C. (1980). *Diamond v. Chakrabarty, 447 U.S. 303* (1980). Justia Law. https://supreme.justia.com/cases/federal/us/447/303/

(11) Nambisan, P. (2017). *An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology*. Academic Press.

(12) WIPO. (2021). *Information by Country: Mexico.* World Intellectual Property Organization. https://www.wipo.int/members/en/details.jsp?country_id=123

(13) López Beltrán, M. A. (2012). *La propiedad intelectual en México* [Thesis]. Universidad Autónoma de Nuevo León. http://eprints.uanl.mx/3017/1/1080224580.pdf

(14) SAGARPA. (2012). *Ley Federal de Variedades Vegetales*. Ciudad de México, México: SAGARPA. Recuperado de: http://www.diputados.gob.mx/LeyesBiblio/pdf/120.pdf

(15) Instituto Nacional del Derecho de Autor. (2020). *Ley federal del derecho de autor*. Ciudad de México, México: Instituto Nacional del Derecho de Autor. Recuperado de: http://www.diputados.gob.mx/LeyesBiblio/pdf/122_010720.pdf

(16) Instituto Mexicano de Propiedad Industrial (2020). *Ley federal de protección a la propiedad industrial*. Ciudad de México, México: Instituto Mexicano de Propiedad Industrial. Recuperado de: http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPPI_010720.pdf

(17) Instituto Mexicano de la Propiedad Industrial. (2018, June 8). *Conoce el IMPI | ¿Qué es el IMPI?*. https://www.gob.mx/impi/acciones-y-programas/conoce-el-impi-que-es-el-impi

(18) Secretaría de Economía. (2021). ACUERDO POR EL QUE SE DA A CONOCER LA TARIFA POR LOS SERVICIOS QUE PRESTA EL INSTITUTO MEXICANO DE PROPIEDAD INDUSTRIAL. Diario Oficial de la Federación.

(19) WIPO. (n.d.b). ***Information by Country: Brazil.*** World Intellectual Property Organization. https://www.wipo.int/directory/en/details.jsp?country_code=BR

(20) Florêncio, M. N. S. ***et al***. (2020). The sectoral dynamics of protection of biotechnology in Brazil. World Patent Information.

(21) Figuereido, L. H. M. et al. (2019). An overview of intellectual property within agricultural biotechnology in Brazil. Biotechnology Research and Innovation.

(22) BRASIL. Lei n. 9.456/97, de 25 de abril de 1997. Lei de Proteção de Cultivares. (1997). http://www.planalto.gov.br/ccivil_03/leis/l9456.htm

(23) BRASIL. Lei n. 9.279 de 14 de maio de 1996. Lei da Propriedade Industrial. (1996). http://www.planalto.gov.br/ccivil_03/leis/l9279.htm

(24) BRASIL. Lei n 13.123/2015, de 20 de maio de 2015. Lei de Acesso ao Patrimônio Genético. (2015). http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2015/lei/l13123.htm

(25) Servicio Nacional de Derechos Intelectuales. (2019). ***Patentes***. Obtenido de https://www.derechosintelectuales.gob.ec/patentes-2/

(26) Gobierno de la República del Ecuador. (2018). ***El IEPI se transforma en SENADI***. Obtenido de https://www.derechosintelectuales.gob.ec/el-iepi-se-transforma-en-senadi/

(27) SICE. (2001). ***Derechos de Propiedad Intelectual***. Obtenido de http://www.sice.oas.org/int_prop/nat_leg/ecuador/l320e.asp

(28) Lotaip. (2016). ***Código Orgpanico de la Economía Social de los Conocimientos, Creatividad e Innovación***. Obtenido de https://lotaip.ikiam.edu.ec/ikiam2019/abril/anexos/Mat%20A2-Base_Legal/c

odigo_organico_de_la_economia%20social_de_los_conocimientos_creatividad_e_innovación.pdf

(29) Villagómez, I. (2018). *Criterios para la concesión de patentes de Biotecnología en Ecuador*. Obtenido de http://repositorio.puce.edu.ec/bitstream/handle/22000/15026/Tesis%20final%20Ismael%20Villag%c3%b3mez.pdf?sequence=1&isAllowed=y

(30) *FactureroMóvil* . (2017). Obtenido de Requisitos para el registro de una Patente de Invención en Ecuador: https://www.factureromovil.com/requisitos-para-registro-de-una-patente-de-invencin-en-ecuador

(31) Cheang, E. (2010). Patentes biotecnológicas. Derecho Ecuador: https://derechoecuador.com/patentes-biotecnologicas/

(32) WIPO. (2014). Manual para el examen de solicitudes de patentes de invención en las oficinas de los países de la Comunidad Andina. Quito: Abya Yala.

(33) GobEc. (2013). *Tarifas Propiedad Intelectual*. Obtenido de https://www.propiedadintelectual.gob.ec/wp-content/uploads/2013/08/tarifario-de-tasas-con-descuentos.pdf

(34) Protectia. (2019). *Registro de patentes en Ecuador – Patentar productos o inventos*. Obtenido de https://www.protectia.eu/registro-patentes/registro-de-patentes-internacional/registro-patentes-ecuador/

(35) SENADI. (2019). *RESOLUCIÓN No. 002-2019-DG-NT-SENADI*. Obtenido de http://derechosintelectuales.gob.ec/wp-content/uploads/2020/05/RESOLUCION_No.002-2019-DG-NT-SENADI.pdf