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The current status of plant-related IP Rights in Brazil

How to reap the fruits of the protection culture in the agribusiness field

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ABSTRACT

Brazil is recognized as having an important economic market and, also due to its biodiversity, provides countless opportunities for technological developments in several fields. In the Industrial Property arena, it may be reaching its most favorable period, since the Brazilian PTO Patent and Trade Mark Office (INPI) has developed measures to overcome the backlog of examination of patent applications and could be placed soon together with the countries that have already achieved a mature protection culture. In the agribusiness field, Brazil stands out in level of importance worldwide, and the correspondent increasing technological development has started to be accompanied by its due protection. Specifically, regarding plant-related IP rights in Brazil, plant-related technology may be protected by patent and plant varieties (or cultivars) by plant variety protection certificate. However, in order to take advantage of all the opportunities and achieve the best protection – duly reaping the fruits of the protection culture in the country, being of particular relevance to the Agribusiness field –, one must have in mind that the Brazilian IP legal framework has particularities when it comes to this matter, as well as it may be more restrictive than the legal framework observed in other jurisdictions. Thus, without the intention to exhaust each theme, the present article presents an overview on the main topics concerning plant-related IP rights in Brazil.

1. INTRODUCTION

"Brazil is not for beginners", once said Tom Jobim[1], the famous poet, compositor, and singer of "Garota de Ipanema" in about 1960 to a foreign friend, when the country was going through a historical period marked by several contradictions. Until today, this phrase is still used in many different contexts to highlight its complexity.

In the present context, it fits perfectly to illustrate the dichotomy that may be the biggest (and true) cliché assertion about Brazil, a country known for the richest biodiversity, majestic landscapes, hospitable people and soccer, as well as for its social inequality, politics corruption and developing economy. From the general intellectual property (IP) perspective, the same reasoning applies. Brazil can be considered as a pioneer, being one of the 14 signatory countries of the first Paris Convention in 1883 and having already had industrial property rights provisions in its first Constitution in 1824, leading afterwards to the Industrial Property Law in Brazil, which was reformulated a few times into the current one. Despite of that fact, a still delayed IP rights culture, especially within the field of patents, by the society, can be seen in several technological fields.

However, in the Agribusiness sector, this reasoning is rapidly becoming distant from true. Brazil has a vast territory, favorable contour terrains and climate, and a big consumer market, which, in turn, made it possible for the agrobusiness-based economy to grow, putting the country as an important agri-player worldwide. Brazil became in 2018 the 3rd biggest agricultural exporter (under only the United States and the European Union[2]), and until 2019 has been within the 10 biggest economies worldwide according to the Austin Rating[3]. It is undeniable that this cannot be achieved without increased technological development that has started to be accompanied by its due protection.

Regardless of the technology field, although the vast majority of the patent protection in Brazil is still requested by non-residents – only about 17% (annual mean number) of the patents filed between 2008 and 2018 before the Brazilian Patent and Trademark Office (INPI) were filed by residents[4] - over the last few years it has been reported a growing number of applications filed by Brazilian Universities alone or together with companies, and also start-up companies. Also, the increase seen in the productivity of grains has been attributed to the development and the protection of new plant varieties in Brazil[5].

Residents or non-residents, that is, independently of the origin of the technology, all users of the protection systems in Brazil – the Brazilian PTO in particular –, are experiencing one of the most favorable periods of all times. That is because the Brazilian PTO has implemented direct measures to deal with the backlog of examination of patent applications, already reducing and aiming to

solve the issue soon. Also, the Institute is constantly publishing new measures – there are several expedited examination procedures in force, including the one directed to "green technologies" – that represent good opportunities for the Applicants to accelerate the examination of patent applications, if it is the case.

Taken together, what is needed for one to able to take advantage of the opportunities given by the Brazilian important economic market and vast biodiversity – that may represent the feedstock to the development of technologies in all fields, and could be of particular importance to the Agribusiness – is to get to know a little bit better the Brazilian IP legal framework regarding plant-related IP rights, for there are particularities that may be more restrictive than those observed in other jurisdictions' legal framework. Thus, without the intention to exhaust each theme, the present article presents an overview on the main topics concerning this matter in Brazil.

2. PLANTS IP RIGHTS IN BRAZIL

2.1. Patents

2.1.1. Matter excluded from patent protection in view of the Brazilian IP Law

The Brazilian Industrial Property Law (Brazilian IP Law, Law No. 9,279/96[6]) expressly excludes from patent protection plants and parts thereof. This is addressed in two particular items of two different articles (10-IX and 18-III). Article 10 sets out what cannot be considered as an invention (or utility model) in Brazil: "IX - the whole or part of natural living beings and biological materials as found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes"; and article 18 sets out what cannot be patented by legal proviso in Brazil: "III – the whole or part of living beings, except transgenic microorganisms[7] that satisfy the three requirements of patentability - novelty, inventive activity and industrial applicability - provided for in article 8[8] and which are not mere discoveries[9].".

Therefore, in practice, the claims directed to the whole or part of plants or seeds, including plant cells, even if transgenic, are not patentable in Brazil for not being considered as an invention or due to simple exclusion from Law by legal proviso.

The same interpretation applies to claims intended to protect extracts as found in nature (enriched extracts, on the other hand, can be protected in some cases[10]), biological sequences (even if obtained in a synthetic form, if they cannot be distinguished from their natural counterpart) and general compositions if characterized solely by comprising a single natural component, such as a plant ex-

1 Antonio Carlos Jobim.

2 MF Magazine, 'Terceiro maior exportador de produtos agrícolas do mundo, Brasil segue como o maior vendedor de soja em 2018', available at: https://blog.mfrural.com.br/terceiro-maior-exportador-agricola-do-mundo-brasil-segue-como-o-maior-vendedor-de-soja-em-2018/

3 Por Darlan Alvarenga, 'Brasil sai de lista das 10 maiores economias do mundo e cai para a 12ª posição, aponta ranking' (G1, 3 March 2021), available at: https://g1.globo.com/economia/noticia/2021/03/03/brasil-sai-de-lista-das-10-maiores-economias-do-mundo-e-cai-para-a-12a-posicao-aponta-ranking.ghtml

4 Information taken from INPI, Indicadores de Propriedade Industrial 2019: O uso do sistema de propriedade industrial no Brasil, April 2020.

5 ABPI, 'A proteção de cultivares e o sucesso do agronegócio', available at: https://abpi.org.br/noticias/a-protecao-de-cultivares-e-o-sucesso-do-agronegocio/

6 Industrial Property Law)

7 The generic term "microorganism" is used for bacteria, archaea, fungi, unicellular algae not classified as plants and protozoa. Thus, among the whole or part of living beings, natural or transgenic, the Brazilian IP Law only allows the patenting of transgenic microorganisms.

8 "Art. 8 - An invention is patentable if it satisfies the requirements of novelty, inventive activity, and industrial applicability."

9 Sole paragraph of article 13: "For the purposes of this Law, transgenic microorganisms are organisms, except the whole or part of plants or animals, which express, through direct human intervention in their genetic composition, a characteristic that is normally not attainable by the species under natural conditions."

10 According to item 4.2.1.1.3 of the Brazilian Guidelines of Examination of Patent Applications in the Field of Biotechnology of April 2020, the extract differentiated from its natural counterpart for being enriched in some of its components, will only be subject to protection when presenting characteristics not normally attainable by the species and resulting from direct human intervention, such as by means of genetic manipulation.

11 INPI, Revista da Propriedade Industrial, (No. 2604 1 December 2020), available at: https://www.gov.br/inpi/pt-br/servicos/patentes/legislacao/legislacao/InstrucaoNormativa118_DIRPABiotecnologia_01122020.pdf

tract. In this later case, the understanding applied, according to the Brazilian Guidelines of Examination of Patent Applications in the Field of Biotechnology of April 2020[11], is that it would confer protection to the non-patentable product itself. In order to circumvent this issue, it is possible to amend the claim so as to add components, parameters or characteristics so as to leave it clear that it actually refers to a composition (a mere diluent may not be accepted).

2.1.2. Biological sequences

On the other hand, there is plenty of plant-related technology that may be protected by patents.

Firstly, it is crucial to highlight the interpretation, as disposed in the Brazilian Biotech Guidelines as mentioned above, when it comes to biological sequences. That is because an important number of patents in the field of plant biotechnology is intended to protect a genetically modified sequence, such as a transgene genetic sequence (nucleotide sequence) that confers to a plant a given characteristic of interest, such as resistance to pathogens, resistance to insects, resistance to herbicides, resistance to drought, improved yield, etc.

As mentioned, in case the sequence, and in particular, the nucleotide sequence, is identical as one as found in nature, even if present in a different organism or has a different role, may fall under the restrictions of the Brazilian IP Law as discussed above.

Thus, in theory, any given modification in the sequence that may confer distinction from natural ones, may be acceptable to circumvent the restrictions regarding protection. This includes unmodified nucleotide substitutions, insertions or deletions in the sequence, provided that the resulting sequence is also not naturally occurring and, in case of deletions, provided that the deletion is not at the ends of the sequence (for then, the resulting sequence would be identical to part of the naturally occurring sequence, thus not being patentable). For this reason, claiming a transgene sequence together with the flanking sequences of the host organism (insertions at the ends of the sequence) may be sufficient to render the resulting sequence as modified, being liable to patent protection.

Another common patentable object of protection in this field of technology refers to cDNA (complementary DNA), which is a DNA sequence produced from RNA as a template. The understanding applied, according to the Biotech Examination Guidelines as mentioned is the following: in case of cDNA produced from messenger RNA (mRNA), if the originating gene has introns (non-coding sequences), the cDNA will be different from the corresponding gene, since cDNA sequence would only comprise the exons (coding sequence), thus being liable to patent protection. On the other hand, in case the cDNA is derived from a mRNA whose originating gene is only composed by exons, the cDNA would be identical to the corresponding DNA, thus not being patentable due to infringing article 10-IX of the Brazilian IP Law.

2.1.3. Processes for generating plants

The same reasoning as explained above directed to products applies to claims related to processes, in that the protection of biological processes considered as natural – that is, processes that may naturally occur in nature – are not liable to patent protection for fitting within the definition of article 10-IX of the Brazilian IP Law (natural biological processes are not considered invention).

Considering that said article could be interpreted as broad for not clearly and precisely defining what could be interpreted as a "natural biological process", once again the Biotech Examination Guidelines tried to better clarify the matter.

According to the Guidelines, "natural biological process" means any process that does not use technical means to obtain biological products or that, even when using technical means, it would be likely to occur in nature without human intervention, consisting entirely of a natural phenomena.

Thus, conventional methods of plant production based on the general steps of selection, breeding and propagation, for instance, are considered natural biological processes. In these cases, the understanding is that although there may be human interference for selecting specific plants of interest for breeding, it is not essential for the process to occur, only accelerating or limiting what could occur in nature. On the other hand, when the plants used for breeding are considered as "unnatural", such as transgenic plants with a heterologous gene, the process could be subject to patent protection. In this case, the human intervention is direct in the genetic composition of plants and has a permanent character.

2.1.4. Matter excluded from patent protection in view of the Biosafety Law

Some technologies are excluded from patent protection, not in view of the Brazilian IP Law, but in view of the Brazilian Biosafety Law (Biosafety Law, Law No. 11,105/05[12]), which expressly rules about this matter. According to article 6-VII of said Law: "6 - it is prohibited: (...) VII - the use, commercialization, registration, patenting and licensing of genetic use restriction technologies.". According to the single paragraph of this item: "For the purposes of this Law, genetic use restriction technologies are understood as any human intervention process for generating or multiplying genetically modified plants to produce sterile

[12] Law No. 11,105 of March 24, 2005 (Law on Biosafety).

[13] Resolution No. 093/2013 of June 10, 2013 ("Guidelines on the applicability of article 32 of Law 9279/96 in patent applications, within the scope of the INPI").

[14] Plant Variety Protection Law, Law No. 9,456/97, of April 25, 1997.

[15] Decree No. 2,366, of November 5, 1997.

reproductive structures, as well as any form of genetic manipulation aimed at the activation or deactivation of plant fertility-related genes by external chemical inducers.".

Thus, any methods leading to plants that are sterile are not patentable. To better clarify that matter, the Biotech Examination Guidelines further elaborated on this understating by stating that the processes and/or genetic manipulation that produce sterile reproductive structures (pollen, ovule, stigma, anther, fruit, and tissues thereof), or that aim at the activation or deactivation of genes related to the fertility of plants by external chemical inducers, fall within the prohibitions of article 6-VII of the Biosafety Law.

Nonetheless, claims directed to products such as vectors, constructs and expression cassettes, as well as processes for restoring the fertility based on the activation/deactivation of genes (provided that they do not involve the use of external chemical inducers) are duly subject to patent protection.

2.1.5. Awareness about Article 32 of the Brazilian IP Law: limitations regarding amendments

When dealing with patent protection, there is a particular understanding applied for Article 32 of the Brazilian IP Law – regarding amendments in the set of claims after the examination is requested – that must be mentioned. This is because, as can be seen from the overview above, there are some restrictions in the Brazilian IP Law that may require adequate analysis of the scope of protection claimed and the performance of eventual amendments in the set of claims in order to obtain the maximum protection possible for each technological development.

Article 32 of the Brazilian IP Law itself states: "In order to better clarify or define the patent application, the applicant may perform amendments until the examination is requested, provided that these are limited to the matter initially disclosed in the application.". However, the understanding applied for such article, as disposed on Resolution No. 093/2013[13], is that after the Examination is requested, amendments in the set of claims can only be performed in order to better define or to limit the scope of protection of the set of claims for which examination was requested. Thus, amendments that broaden or change its scope of protection (for instance, adding a new category of claim, or a new independent claim, even if based on the specification) cannot be performed after the examination request. Such limitation also applies for divisional applications. The scope of protection of the set of claims of the divisional application shall be limited to the scope of protection of the set of claims for which examination was requested.

In view of that, differently from other jurisdictions, it is usually advisable to wait until closer to the deadline date of the examination request, when the applicant usually had the chance to have the application already examined elsewhere, and to properly evaluate the scope of protection of interest, to perform amendments in the set of claims just before requesting the examination without incurring the limitations imposed by the understanding of article 32 as mentioned.

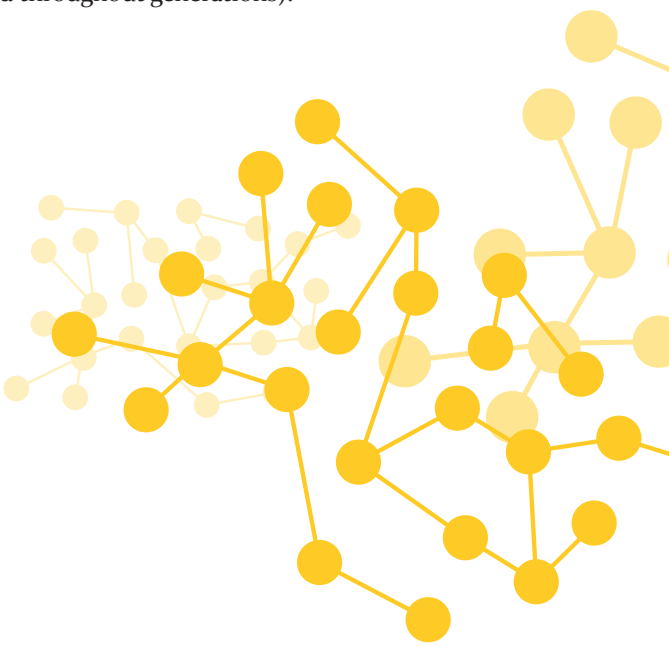
2.2 Plant Variety Protection

As mentioned, the Brazilian IP Law (Law No. 9,279/96) expressly excludes from patent protection plants and parts thereof. However, the protection of plant varieties (or cultivars), as disposed in the Brazilian Plant Variety Protection Law, Law No. 9,456/97[14], regulated Decree No. 2,366/97[15], may be obtained by the Plant Variety Protection Certificate issued by the National Cultivar Protection Service (SNPC) of the Ministry of Agriculture, Livestock and Food Supply in Brazil (MAPA). This is a sui generis type of protection originated from the intergovernmental organization UPOV – the International Union for the Protection of New Varieties of Plants – of which Brazil is a member.

The plant variety protection can be interpreted as complementary to the patent protection, in that the objects of protection conferred by both types of rights (patent protection and plant variety protection) do not overlap. Actually, if possible, in case the technological development allows it, both types of protection are advisable.

As imagined, whereas the patent can indirectly protect the plant produced by or comprising technology protectable by patent, the protection conferred by a cultivar will directly fall on the reproductive material or vegetative multiplication of the entire plant. Also, the certificate guarantees its owner, with a few exceptions, the right to commercial reproduction in the Brazilian territory, being forbidden to third parties, during the term of protection, production for commercial purposes, offering for sale or commercialization, of the propagating material of the cultivar, without the owner's permission.

By general definition based on the understating of the Law in question, a cultivar, which may be produced by any technique (traditional or genetic engineered), is the variety of a plant species that is clearly distinguishable from other cultivars by minimum margin of descriptors, that is, features (morphological, physiological, biochemical or molecular inheritable characteristics) of interest. In order to be protectable, the cultivar as to the descriptors must be distinct (from others of the same species), homogeneous (uniform if planted in commercial scale) and stable (preserved throughout generations).



3. IP RIGHTS INVOLVING COMPONENTS OF THE BRAZILIAN GENETIC ASSET AND ITS ASSOCIATED TRADITIONAL KNOWLEDGE

3.1. Brief historical context

As one may know, biodiversity is one of the main resources of the world, and it is fading away quickly. Many countries have started in the near past conservation measures in large scale in order to try to reverse the damages caused by human lifestyle. Brazil is, of course, an important player in this scenario, for it is considered to be the most biodiverse country in the world, having many different biomes and with a climate that favors the development of many different species.

Therefore, in this context of protection and conservation of the biodiversity worldwide, it is pertinent to mention the Convention of the Biological Diversity (CBD), established in 1992 during ECO-92 in Rio de Janeiro, which was the legal milestone that ultimately led to the current Biodiversity Law in Brazil (Law No. 13,123/15[16]), regulated by Decree 8,772/16[17].

The CBD is an international multilateral treaty of the United Nations which establishes norms and general principles for the protection and use of biological diversity by the signatory countries, respecting the sovereignty of each nation over the patrimony existing in its territory. The general and basic principles of the CBD[18] are: (i) the conservation of biological diversity; (ii) sustainable use of its components; and (iii) fair and equitable sharing of the benefits derived from the economic exploitation of genetic resources.

Historically, the legal dispositions of the CBD were internally incorporated in the Brazilian legal system by means of a Provisional Measure No. 2,186-16/2001[19], which was the legal framework in force in Brazil until the current Law came into force, in 2015.

The Provisional Measure was innocuous because it was almost impossible to be complied with. Among its dispositions, it established that in order for one to perform any research or technological development over a sample of the Brazilian genetic asset, it was necessary to request previous authorization to the Genetic Heritage Management Council (CGEN). it used to take years years for the authorization to be granted. Thus, the users used to either give up using samples of the Brazilian genetic asset or used to access them in disagreement with the Provisional Measure. Also, apart from the Brazilian biodiversity species that were considered endemic, no one could really know at that time what would constitute a sample of the Brazilian biodiversity, and the simplified understanding applied to using the Brazilian traditional knowledge was mainly literally obtaining the knowledge in loco from the indigenous populations, traditional communities or farmers.

So when the new Law came into force, correcting many of the former legal deficiencies, it was a milestone. It simplified a lot the proceedings predicted by the old Provisional Measure and established many definitions that were lacking. One of the main innovations brought by the new Law is that, for the majority of activities of access, no previous authorization by CGEN is needed. The new Law established an electronic registration system (SisGen), and a self-declaratory registration of the activities is sufficient for most of the cases of access.

In summary, the new Law and Decree address:

- the access to the genetic assets, access to the associated traditional knowledge;
- access to technology and technology transfer;
- economic exploitation of finished product or reproductive material;
- sharing of the benefits derived from access and remittance abroad of components of genetic assets.

In case one is to perform any of these activities, one must be aware that there are dispositions to be complied with.

The legal framework may lead to additional administrative and regulatory bureaucracy, especially for researchers (companies and individuals), but in the end, it is only intended to achieve, in practice, the three basic principles of the CBD as mentioned.

3.2. The link between Brazilian biodiversity and the patent system

But what does all of this have to do with patents? In general terms, both the former Provisional Measure and the new Biodiversity Law somehow conditioned the granting of IP rights to comply with the terms of the biodiversity legal framework in force. This ended up with the Brazilian PTO becoming a "checkpoint" for verifying this matter in Brazil. Currently, to comply with the provisions of the Biodiversity Law, the user, at the moment of requesting the intellectual property right, must inform whether there was access to Brazilian genetic assets or its associated traditional knowledge, as well as if there is an access registration. Thus, in summary, it is not possible to file a patent without this information in hands.

It is important to state that the Brazilian Biodiversity Law, which in turn influences the research and technological developments with Brazilian biodiversity and the possible IP rights derived from it, rules the country as a provider of the biodiversity resources. In this sense, exotic species (and its use as biological resources) are not subject to this Law. But this does not mean that that the use of exotic species is not subject to equivalent laws in their countries of origin.

This is where the Nagoya Protocol[20] comes in, aiming precisely to regulate the relationship between resource provider countries and user countries, by ensuring the reciprocity of obligations and rights between them. Brazil recently ratified this agreement on March 4th 2021 as a supplementary agreement to the CBD, ruling about one of its pillars, namely the fair and equitable sharing of benefits derived from access to the genetic assets.

In view of that, Brazil should soon establish legal rules to ensure that the laws of the countries providing international resources are also complied with in the national territory. Naturally, this reciprocity will also be demanded by Brazil, when other countries use Brazilian resources.

3.2.1 As to the definitions

To know if one is performing any of the activities predicted for in the Brazilian Biodiversity Law and Decree, it is important to understand how these dispositions define the activities.

Access to the Brazilian genetic asset, to begin with, is the research or the technological development carried out on a sample of Brazilian genetic assets. Thus, for instance, sequencing the genome of a species considered as derived from the Brazilian genetic asset would fall under the definition of access. However, contrary to the wording, access does not necessarily mean that the genome must be part of the research.

As to the species which are considered as derived from the Brazilian genetic asset, it is important to point out that this is still a complex topic. In a simplified manner, the Brazilian genetic assets are understood as the ones as follows:

- The Brazilian endemic species, as found on national territory, on the continental shelf, in the territorial sea and in the exclusive economic zone;
- Native species, as found in in situ conditions in the Brazilian territory, regardless of their collection site (e.g. transboundary species);
- Domesticated or cultivated species, given that they have acquired distinctive characteristics of their own in the Brazilian territory;
- The same species as above, even if in ex situ conditions (for instance from collections);
- As to microorganisms, the new Law brought a new understanding: any micro-organism isolated in the national territory, on the continental shelf, in the territorial sea and in the exclusive economic zone will be considered as Brazilian genetic asset.

The complexity mainly lays on the fact that it is not clear which species have acquired distinctive characteristics of their own in the Brazilian territory. Nonetheless, this an ongoing discussion with new understandings being constantly published on this matter and particular experts' consultation may be needed.

As to the access to the associated traditional knowledge, the new dispositions define it as the research or technological development carried out on traditional knowledge associated with genetic asset that enables or facilitates access to genetic asset, even if obtained from secondary sources such as fairs, publications, inventories, films, scientific articles, registers and other forms of systematization and registration of associated traditional knowledge.

It is important to keep in mind that the new dispositions brought another new understanding due to the aforementioned definition, it being possible to access the associated traditional knowledge without even leaving the lab.

Traditional knowledge associated with genetic assets is the information or practice of indigenous population, traditional community or traditional farmer on the properties or direct or indirect uses associated with genetic assets. The associated traditional knowledge can be of identifiable origin, when it is possible to find or link the origin of an associated traditional knowledge to at least one indigenous population, traditional community or traditional farmer. It can also be of non-identifiable origin, when it is not possible to find or link the origin of an associated traditional knowledge to at least one indigenous population, traditional community or traditional farmer.

The access to the associated traditional knowledge of identifiable origin is conditioned to the obtainment of prior informed consent from such communities or populations or farmers. Many communities, populations or farmers could be considered as the holders of the knowledge, but the prior informed consent must be celebrated with at least one of them, which is then considered as the provider of the knowledge.

3.2.2. As to the registration

According to the new dispositions, the following activities should be registered:

- Access to genetic assets or associated traditional knowledge within the country performed by a natural person or national legal entity, public or private. The access by a foreign natural person is forbidden by Law.
- Access to genetic assets or associated traditional knowledge by legal entities based abroad, associated with national institutions for scientific and technological research, public or private. This is important, for a foreign institution to perform access, it must be associated with a national institution for scientific and technological research.
- Access to genetic assets or associated traditional knowledge performed abroad by a natural person or national legal entity, public or private.
- Remittance of samples of genetic assets abroad with the purpose of access, in the two cases just above.
- Sending of samples containing the genetic asset by a national legal entity, public or private, for performing services abroad as a part of research or technological development.

It is important to point out that the registration must be carried out prior to the shipment, or to the requirement of any intellectual property right, or to the marketing of the intermediate product, or to the disclosure of the final or partial results, in scientific or communication means, or to the notification of finished product or reproductive material developed as a result of access.

[16] Biodiversity Law, Law No. 13,123/15 of May 20, 2015.
[17] Decree No. 8,772/16 of May 11, 2016.
[18] The complete CBD text can be found at: https://www.cbd.int/convention/text/
[19] Provisional Measure No. 2,186-16/2001 of August 23, 2001.
[20] The complete Nagoya Protocol text can be found at: https://www.cbd.int/abs/text/

After the registrations just mentioned, it will go under an administrative verification process in order to guarantee that the registration was duly performed according to the Law. Also, the user may request the certificate of regularity of access. It is recommended that such certificates be requested before performing any of the activities mentioned above, for incorrect registration may lead to cancelation of registry and/or penalties.

3.2.3. As to the benefits sharing

Although the activities as previously observed require the registration in SisGen, not every research or technological development derived from access to Brazilian genetic assets or its associated tradition knowledge will be subjected to benefits sharing.

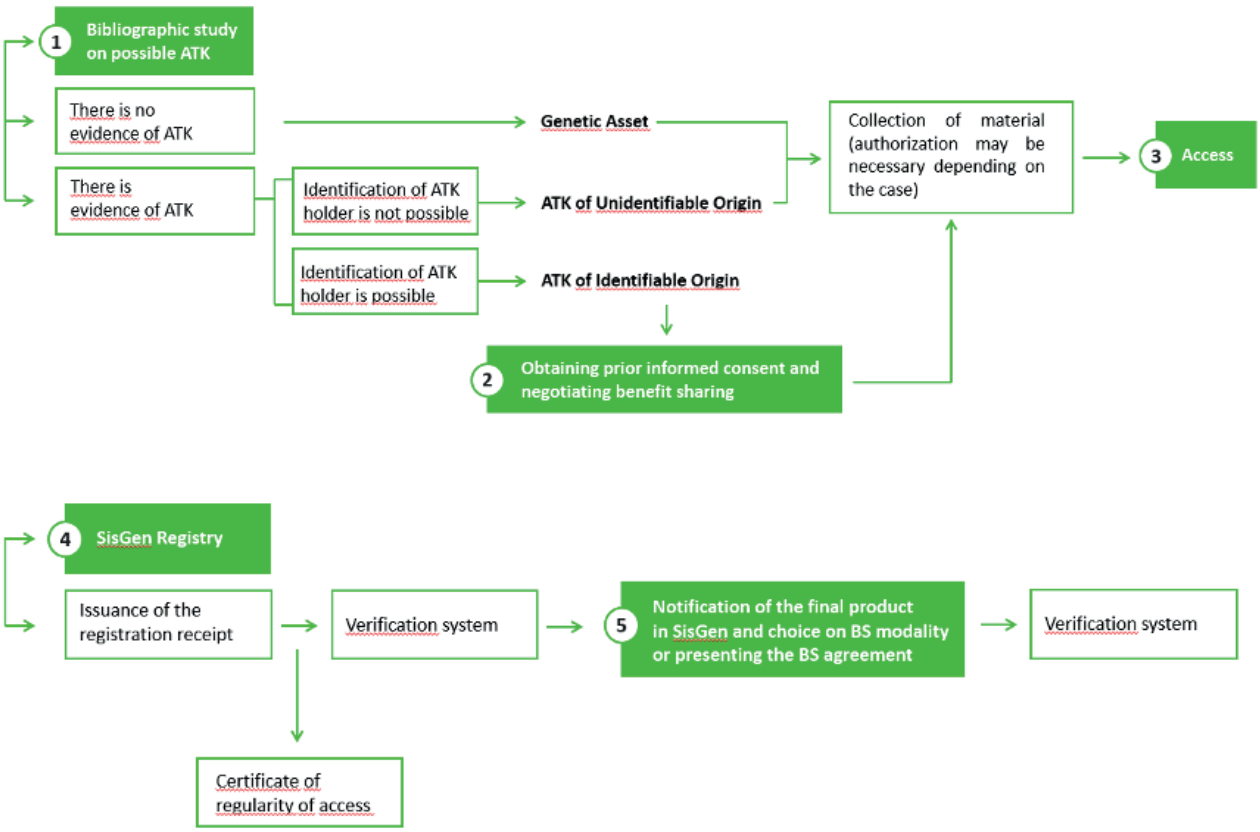
According to the new dispositions, only the following will share benefits derived from access:

- The producer of the finished product or the producer of the reproductive material derived from access to genetic asset or associated traditional knowledge, even if produced outside the country, regardless of who has previously made the access.
- In the case of a finished product the genetic asset or associated traditional knowledge component must be one of the main elements of added value (elements whose presence in the finished product is decisive for the existence of the functional characteristics or for the formation of the marketing appeal).

It is important to point out that when a finished product or reproductive material is the result of different accesses, they will not be considered cumulatively for the calculation of benefits sharing. Also, in case the finished product or the reproductive material has not been produced in Brazil, the importer, subsidiary, controlled, colligated, linked company or commercial representative of the foreign producer in the national territory, or in the territory of countries with which Brazil has an agreement to this end, responds jointly with the manufacturer of the finished product or the reproductive material for the benefit sharing.

Finally, there are two modalities predicted in the new dispositions for benefits sharing: monetary or non-monetary, depending on the case. When monetary, the payment will be to the Federal Government, by means of the National Benefit Sharing Fund (FNRP).

For instance, in the case of genetic assets, one can choose between the modalities – monetary or non-monetary. In case of monetary, the Brazilian Biodiversity Law determines that the amount in question is 1% of the yearly net income to the FNRP of the Federal Government, whereas in case it is non-monetary, it will be equivalent to 0,75% of the yearly net income, according to a benefits sharing project defined with the Federal Government (it must be among related ones) or 1% in the remaining cases (if the project is different from the related ones). In case of associated traditional knowledge, if identifiable, a part of the total amount is freely negotiated with the provider + another part is monetary: 0,5% of the yearly net income to the Fund of the Government. In case of associated traditional knowledge of non-identifiable origin, it is always monetary, and the amount in question is 1% of the yearly net income to the FNRP of the Federal Government.



3.2.4. Take home message

When performing research with Brazilian genetic asset, that may or may not lead to an intellectual property right, the simplified recommended steps (as illustrated and summarized in the chart below) should be followed.

Step 1 is performing a bibliographic study on possible traditional knowledge associated with the Brazilian genetic asset to be studied. In case there is no evidence of associated traditional knowledge (ATK), then, one is performing access to the genetic asset. In case there is evidence of associated traditional knowledge, one must determine if it is of identifiable or non-identifiable origin. In case of identification of origin, step 2 is obtaining prior informed consent and negotiating the benefits sharing.

Afterwards, for all the three modalities (access to genetic asset, access to the associated traditional knowledge of identifiable or non-identifiable origin) it is possible to collect the sample (authorization may be needed from particular Brazilian authorities, depending on the case) and to perform the access, which is step 3.

In case the research is fruitful, step 4 is performing the registration in SisGen system, as mentioned. It will automatically issue the registration receipt, which is sufficient to start performing the activities mentioned that must be preceded by registration. But since the registration will undergo verification procedure, it is recommended that the user actively requests the issuance of the certificate of regularity of access before performing the activities mentioned that must be preceded by registration, such as, for instance, requesting any intellectual property right.

Finally, step 5 concerns the production of a product. If a product is produced, one must notify the final product at the SisGen system and choose the benefits sharing (BS) modality or present the benefits sharing agreement, if it is the case. This notification will undergo the verification system as well.

4. CONCLUSION

In Brazil, the plant-related IP rights are conferred by patents or by plant variety protection, which protect distinct and complementary aspects of the technology.

Despite having particularities and some restrictions as to the protection of a few aspects related to plant technology by patents, there are transparent guidelines and possibilities to circumvent some of the restrictions.

However, knowing how to claim the protection is as important as when to do it. Considering the restriction of the Brazilian IP Law regarding amendments after the examination is requested (after the examination request, amendments in the set of claims are only allowed to better define or to limit the subject matter of the set of claims for which examination was requested), it is advisable that, in case of complex technology, which is almost always the case with biotechnology and particularly biotechnology within the agribusiness, a technical revision of the case is performed by a patent specialist so as to evaluate the scope of interest in view of the invention and if amendments that may not be allowed after, be performed before the examination request.

Finally, when it comes to performing research or technological development with components of the Brazilian biodiversity, it is important to have in mind that there is a Law in force and particular measures should be taken (including before the request of any intellectual property right) and could even lead to the necessity of benefits sharing in Brazil.

Isabella Katz Migliori

Isabella Katz Migliori is currently a senior patent specialist at Lobo de Rizzo Advogados. She has a Bachelor degree in Biological Sciences from Universidade Estadual Paulista (UNESP), a Master Degree and a PhD degree in Immunology from the University of São Paulo (USP), as well as a Post-Graduate Diploma in Health Care and Hospital Management from Fundação Getúlio Vargas. She has extensive experience in the fields of life sciences, biotechnology, immunology, chemical and agrochemical patent applications.