BRAZIL´S POSITION ON DSI (Notification 2019-012)

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One of the 17 megadiverse countries (SHI, SINGH, KANT, ZHU, & WALLER, 2005), Brazil is often considered the most biologically diverse country in the world. Brazil's biodiversity is an essential resource for its people, not only directly because of the environmental services it provides, but also due to the development opportunities that these represent. Since the past decade, Brazil made impressive progress in fighting threats to biodiversity in various fronts, particularly in establishing protected areas, in the fight against deforestation and in regulating sectors that either threaten the country's biodiversity endowment or propose to use it in a sustainable way across the country's various landscapes.

So far, 117,289 species of animals are known to Brazil, their clear majority being arthropods (about 85%, almost 94,000 species) and chordates representing 10% of fauna species (Ministério da Ciência, Tecnologia e Inovações e Comunicações e Ministério do Meio Ambiente, 2018).

At this moment, 46,506 species are recognized for the Brazilian flora: 4,754 of Algae, 33,109 of Angiosperms, 1,564 of Bryophytes, 5,718 of Fungi, 30 of Gymnosperms and 1,331 of ferns and Lyophytes (Jardim Botânico do Rio de Janeiro, 2018).

The Convention on Biological Diversity - CBD explicitly recognized the authority of States to determine access to genetic resources as part of their sovereign rights over natural resources under their jurisdiction. Furthermore, it obliges all contracting parties to take legislative, administrative or policy measures, to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources.

For almost 20 years now, Brazil has put in place an ABS System and albeit the first national legislation (Provisional Act nº 2.186-16), from 2000, was revoked by the new Biodiversity Bill, (Law nº 13,123, enacted in 2015 and regulated by Decree nº 8,772, established in 2016 and in force since November 2017), the National ABS Competent Authority, the Genetic Heritage Management Council (CGEN), was maintained in charge of the coordination, development and implementation of Policies regarding access to genetic heritage (genetic resources - GR) and associated traditional knowledge - ATK and benefit sharing.

(a) To clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources;

Since the year 2000 Brazil has an established legislation on access to genetic resources, traditional knowledge and benefit-sharing in accordance with the Convention on Biological Diversity.

The Provisional Act No 2,186-16/2001 regulated articles 1, 8, 15 and 16 of the Convention and established a governance system for access to genetic resources and to associated traditional knowledge. It created the Genetic Heritage Management Council – CGen - and devised an administrative procedure for obtaining access authorization, prior informed consent and mutually agreed terms.

The Provisional Act interpreted and matched the expression used in the Convention on Biological Diversity – CBD - “genetic resources” as the term “genetic heritage”, used in Brazil’s 1988 National Constitution. Genetic Heritage was defined by the Provisional Act as the **information of genetic origin**, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from in situ conditions, including domesticated, or kept in ex situ collections, if collected from in situ conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone.

Thus, Brazil regulates the use of genetic information, even if disengaged from the physical sample since its first legal framework on ABS.

During the 15 years that the Provisional Act was in force, CGen granted over 2600 access authorizations and established 295 Benefit-sharing agreements (Ministério do Meio Ambiente, 2018). Including in those are some cases that have used exclusively digital sequence information.

This understanding has been maintained by the new legal framework on access and benefit sharing: Law No 13,123/2015 (Presidência da República, 2015) defines genetic heritage as the genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms.

Decree No. 8,772/2016, that regulates the mentioned Law, also required the identification of the genetic resources and its origin, including a geo-referenced coordinate of the location where the physical sample was collected *in situ*, even if obtained from *ex situ* or *in silico* sources. Therefore, Law 13123/2015 and its decree already include in its scope the use of digital genetic information, and users are subject to the need for registration and sharing of benefits from economic exploitation of products or reproductive material arising from it.

Moreover, in what relates to need for clarification on the “concept, including relevant terminology and scope, of digital sequence information on genetic resources”, it must be stressed that a systemic reading of the CBD and The Plant Treaty strongly influenced the elaboration of Law 13,123/2015 and its Decree No. 8,772/2016. The CBD defines "genetic material" as any material of plant, animal, microbial or other origin containing functional units of heredity. Moreover, according to the Oxford Dictionary, the word "material" can be defined as "information or ideas for use in creating a book or other work". On the other hand, the definition of the word "matter" is "physical substance in general, as distinct from mind and spirit; (In physics) that occupies space and possesses rest mass, especially as distinct from energy". The term "material" should not be confused with the term "matter". The definition of the word "material" allows the interpretation of the term to include the set of information associated with the genetic resource, that is, the substrate information or working material.

Therefore, it is not only conceivable to understand the word "material" in the broader scope of its meaning, but it offers a more flexible and proper meaning. To restrict its understanding to match the meaning of the word “material” to the meaning of the word “matter” is jeopardize the obligation to share benefits, the sovereignty of the countries parties over their genetic resources, the Convention on Biological Diversity and the Plant Treaty.

Even if genetic information obtained digitally is to be considered as excluded from the concept of genetic material, a systemic interpretation of the Convention on Biological Diversity and the Nagoya Protocol leaves no doubt that the use of this information is subject to benefit sharing. The means of transmission of genetic information, whether in the form of matter from a DNA

sample or as information stored *in silico*, is irrelevant to the fulfillment of this obligation. Since there was a "utilization" of a physical sample to access this type of information, its application and subsequent commercialization should be shared in a fair and equitable way, in line with Article 5 of the Nagoya Protocol and article 10 of the Plant Treaty.

Therefore, the discussion of digital sequence information within the scope of international agreements ultimately does not impact the effective application of the CBD nor the Nagoya Protocol.

Furthermore, under the Pandemic Influenza Preparedness Framework, which one of its main objectives are access to vaccines and sharing of other benefits, there is already a clear definition of “Genetic sequences” which “means the order of nucleotides found in a molecule of DNA or RNA. They contain the **genetic information** that determines the biological characteristics of an organism or a virus.” In other chapter the PIP framework establishes the procedure for best practices relating to genetic sequence data (World Health Organization, 2011).

In this context, it’s easy to perceive that the object of discussion within the context of “digital sequence information” is not the word “digital”, which corresponds only to the medium in which information is transferred, and neither in the word “sequence” since it only signifies the order in which nucleotides are presented, but in its main core: the genetic information transmitted through digital media or any other media in a sequenced form or any other form. Thus, international fora discussing DSI or any other terminologies, such as "genetic sequence data", "dematerialized genetic resources", "*in silico* utilization", and "natural information", should converge in adopting “genetic information on genetic resources” as the proper terminology.

(b) On benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources.

The new ABS Legislation has been in place since November 2017, when the ABS electronic registration system “SisGen” started to operate. In general, there is no need for a prior authorization to start a research or development activity on genetic heritage. The prior authorization was substituted by a registry made with the SisGen, which must be concluded before some specific moments, as explained below.

The register is a declaratory, but mandatory instrument. The SisGen – The National System for Genetic Heritage and Associated Traditional Knowledge Management – https://sisgen.gov.br – is the electronic system maintained and operated by the Executive – Secretariat of CGEN, it is the “one stop shop” for the registration of ABS activities.

It manages the registry of access to genetic heritage or associated traditional knowledge; Notifications of finished product or reproductive material and benefit-sharing agreements. Additionally, the SisGen issues the Certificates of lawful access, that, to be granted, the access (research and development activity) registration must be carried out previously:

I – On the remittance of samples of genetic material;

II – On the application for any intellectual property rights;

III – On the commercialization of the intermediate product (by-products);

IV – On the disclosure of final or partial results in scientific or communication circles; or

V – On the notification of finished product or reproductive material developed as a result of the access.

Users are free to choose the best moment to do the registration as long it is before the above-mentioned triggering events. Moreover, since there is no need for a prior registration, if a given access activity doesn´t have any results, any intellectual property right applications, products or processes developed, that access activity doesn't have to be registered. The main idea is to promote and facilitate access and to only demand information when a concrete result has been achieved, moment in which the user must declare the access (research and technological development) and provide all the required information.

Besides the registry of access, the notification on finished product derived from access to Genetic Heritage is also a declaratory instrument made with the SisGen. The Notification precedes the beginning of any activities of economic exploitation of a finished product.

It is through the notification that users of the Genetic Heritage declare to comply with the requirements of the Law and indicates the preferred modality of Benefit-Sharing to meet their legal obligations. The modality is up to the User to decide and are "monetary", through a payment to the National Fund, or "non-monetary", with the user directly funding a conservation project or activity, in accordance to the National Benefit Sharing Programme created by the Law nº 13.123/2015. In the non-monetary modality, a Benefit-Sharing Agreement must be signed, foreseen all the activities that the user declare to execute as benefit – sharing.

The Notification of a Finished Product equals to the celebration of mutually agreed terms, in accordance to the article 15 of the CBD, since the user agrees with the terms and conditions required by the national legislation. The Law predicts contract clauses, exemptions, sectoral treatment, and other terms and conditions that includes beneficiaries, users and providers rights; the types, duration and amounts due to pay as benefit sharing, as well as dispute resolution provisions and an appellate Council.

Also, in this sense, there is no different treatment or requirements regarding the notification of a finished product arising from research and technological development conducted on Digital Sequence Information. The required benefit-sharing arrangements include the economic exploitation of a finished product derived from a genetic heritage obtained from an *in-silico* source.

A finished product is defined by Law as a Product which is apt to be used by the final consumer, whether it is an individual or legal entity. Moreover, the Benefit sharing obligations applies only to a finished Product, that must be derived from access (research and technological development in the Brazilian Law), independently if it was produced in the country or abroad, and finally, the Genetic Heritage should be one of the main elements adding value to the product.

That means that in some cases there may be a finished product developed from a genetic resource that won't share benefits because the genetic resources presence in the finished product isn't "crucial to the existence of its functional features or its commercialization appeal".

According to the Law, it doesn´t matter who has conducted the access on DSI or who is commercially exploiting the finished product, it is the manufacturer of the finished product that must meet the Benefit-Sharing obligation.

After the registration and notification procedures, the user does not have to provide any further information, only if the Administrative verification procedure identifies any wrongdoing, which, according to the case, may be corrected directly in the System, or may demand more complex remedies, including the registry cancelation. It is the obligation of the user to provide all the true and correct information as demanded by the registration procedure and required in the Law and its regulations.

Since the Brazilian ABS model is declaratory, after the fulfillment and conclusion of the registration procedure, the SisGen provides a receipt of access registration, which constitutes a proper document to demonstrate that the user provided the information required, and has the following effects:

I – Allows for:

a) The application for any intellectual property right;

b) The commercialization of an intermediate product;

c) The disclosure of results, final or partial, of the research or technological development in scientific or media circles; and

d) The notification of a finished product or reproductive material developed as a result of access; and

II - Establishes the beginning of the Administrative Verification Procedure.

It must be stressed that the verification procedure is responsible for verifying irregularities, the user will not need to wait for the verification procedure to perform the activities mentioned above.

Finally, the CGEN issues the Certificate of Regularity, which declares the regularity of the activity up to the date of its issuing by the ABS National Authority and prevents the application of sanctions by the competent authorities in what regard to the activities carried out up to its date of issuing.

In the light of these considerations, it must be recalled that the conclusion of the registration of a Research activity by the user equals to the obtaining of a non-commercial access permit. Thereto, the registration of a Technological Development activity by the user, which in the Law is considered as a “systematic work on genetic heritage carried out with the objectives of developing new materials, products or devices, or improving or developing new processes, for economic exploitation”, equals to the obtaining of a commercial access permit. Finally, the conclusion of a Product Notification is the celebration of a Mutually Agreed Term between an User and the Ministry of Environment, which according to the Law, represents the Federal Government as the national genetic heritage provider in benefit-sharing negotiations.

If a basic research on a genetic heritage, even if obtained from *in silico* origin, becomes a Technological Development, the user doesn´t have any further obligation besides updating his registry in the SisGen, what must be done once a year when better suit to the user.

Beyond, after one year and a half since SisGen started its operations, almost **800** Legal Persons (60% companies) and more than **25 thousand** natural persons concluded their registrations and are providing information on their research and development activities arising from genetic heritage (including from *in silico* origin) and ATK in the SisGen.

By May 2019, there were over **47 thousand** access (research and technological development) activities registered in SisGen, from which 16% (3,747) with declared commercial intention since were registered as technological development activities. Likewise, by May 28, there were **1,500** Finished Products Notifications in the SisGen.

Therefore, there are over 47 thousand access activities in conformity with the legislation, which means the same number of permits of access "granted" and 1,500 Mutually Agreed Terms celebrated under the new ABS Law. In addition, according to the Executive-Secretariat of the CGEN, by now, 400 Certificate of Regularity were requested by users, which are to be approved by the CGEN.

Comparing the former ABS Act, which issued 2,600 permits and more than 295 ABS Agreements/ Contracts in 15 years, to the new Legal framework on ABS, the current model obtained over 200 times more regular activities and over 75 times more contracts than the old model in the same one period.

Once there is no different treatment for a genetic heritage obtained from an *in situ*, *ex situ* or *in silico* source, been subject to the same obligations and rights, the SisGen registry has specific fields in which the user can inform the origin of its genetic heritage from *in silico* origin. The SisGen allows the user to inform the name of the data base, the genetic heritage code of access from that data base and a link to the information provided regarding the genetic heritage and the data base from which it was obtained.

Out of the almost 47.000 registered access activities in the SisGen by now, **449** declared *in silico* origin, from which **64** declared commercial intention activities, through the registration of Technological Development activities arising from the utilization of digital sequence information/genetic information on Genetic Resources.

Ergo, out of those 449 registrations, 385 are equivalent to "**benefit-sharing arrangements from non-commercial use of digital sequence information on genetic resources**" as much as those 64 Technological Development registries are **"benefit-sharing arrangements from commercial use of digital sequence information on genetic resources**".

It must be recalled that, in light with what states the Law nº 13,123/2015, an access with commercial intention (Technological Development) or non commercial intention (research) doesn´t have to share benefits, although they are subject to the terms and conditions of the Law, which foresees benefit sharing arrangements and exemptions, with which the user and the provider mutually agreed upon, once the user concludes the access activity registration in the SisGen.

In order to provide concrete examples on the ""**benefit-sharing arrangements from commercial use of digital sequence information on genetic resources",** one could refer to a Technological Development activity registered in the SisGen, which proposes the use of informatics techniques to find pharmacological receptors (proteins), deposited in the Protein Data Bank PDB, of natural products from the Brazilian Biodiversity. It also declares the databases of molecules with biological activity ZINC and SEA as source of the *in-silico* origin.

Another development activity registered in the SisGen informing the data bank from which the DSI/Genetic information on genetic resource was obtained is one which aims to develop a prototype kit for confirmatory diagnosis as a complementary technique for the detection and

identification of a given parasite. This technological development declared a Public Funded Antibody Platform as source of the genetic heritage.

Moreover, a third example out of 64 cases of DSI utilization is an invention that comprises the use of peptides synthetic derivatives of the toxins of a Brazilian Invertebrate for the treatment of ocular diseases. The source of the DSI utilized was “http://www.uniprot.org”. The UniProt Knowledgebase (UniProtKB) is “the central hub for the collection of functional information on proteins, with accurate, consistent and rich annotation”. UniProtKB mission is “to provide the scientific community with a comprehensive, high-quality and freely accessible resource of protein sequence and functional information”.

On a quick search in the UniProtKB website with the term “Brazil”, it showed almost 225,000 entries. Each entry, according to UniProtKB, captures the core data on a specific DSI, “mainly amino acid sequence, protein name or description, taxonomic data and citation information), as much annotation information as possible is added”, offering freely accessible resource of Digital Sequence Information.

Nevertheless, since there is in general no prior authorization to use Genetic Heritage from Brazil, anyone using that proteins sequences would have to register they results or notify products only when there is a concrete result and before some triggering events, such as the publication of a Scientific Paper, a Patent Application, a By Product commercialization, a finished Product Notification etc. That is why is paramount that databases require and provide the origin of the genetic information that they store and offer.

In other words, Brazilian genetic heritage can be freely accessed, but the results and products of its utilization must be regularized by a registration or notification procedure, in the proper moment and according to each case. Its paramount for Brazil to foster research and development arising from its genetic diversity and, having in mind the evolution of the techniques available to do so, it is the national understanding that access, including through the utilization of genetic resources from an *in-silico* origin, must be facilitated to generate the benefits that will fund biodiversity conservation and sustainable use. But to do so, the regulation must focus on results other than procedures.

Finally, in what relates to the verification of those registries and the information provided by the Users, done by the Administrative Verification Procedure, the total number of arrangements with possible use of digital sequence information on technological developments, as well as the information regarding the finished products developed by the utilization of DSI, may change.

Since the verification procedure review the registries to identify wrongdoing and mistakes, such as the utilization of Genetic Heritage that does not belong to the Brazilian sovereignty, some activities declared will be reclassified or corrected, with possible inclusion and withdraw of registries considered as arrangements with possible use of digital sequence information on technological developments instead of use on non-commercial research.

Albeit the numbers may change, it is expected to raise, and, in short time, more information, including on Benefit sharing arising from the economic exploitation of finished products derived from DSI utilization, will be shared through the ABS Clearing house.

Considering the foregoing and notwithstanding the fact that the DSI subject may still cause some confusion, due to its unclear scope and different point of views, some solutions of the ABS Law

No. 13,123 of 2015 could be considered for the implementation of the use of genetic information in the CBD and its Protocols, as possible ways to deal with DSI challenges.

In this sense, Brazil has adopted:

- A facilitated mechanism for access to genetic resources, with a change in the focus of regulation, previously focused on the control of access to genetic resources, now shifted towards control of the economic exploitation of products or reproductive materials arising from access;
- The development of an online registration system to trace, track and oversee access to genetic resources and associated traditional knowledge activities. The SisGen electronic system is declaratory, as opposed to the old *modus operandi* of the Provisional Act in which a procedure for validation of documents was in place;
- The registration must only be carried out prior to specific moments such as shipment, request for intellectual property rights, publication of results and commercialization. Research and development activities that do not result in any of the above-mentioned activities are not demanded to register;
- Registration is not needed prior to access (research and development) itself when only the genetic resources are accessed, without access to traditional knowledge: these activities are not restrained by any prior administrative procedure for granting access;
- Prior informed consent for access to genetic resources was granted by the National Congress: there is no administrative procedure for access to genetic resources; Prior Informed Consent for access to TK is mandatory and should be obtained directly with the ILCs;
- Economic exploitation of a finished product or reproductive material was established as the single point of incidence of benefit-sharing obligations: this is the link of the value chain with the highest value added, discharging any research and development activity: economic benefits are to be shared when they do exist;
- Because of the single point of incidence, the economic exploitation of any intermediate product is exempt from benefit sharing obligations;
- The percentage of monetary benefit sharing from products or reproductive material derived from the use of genetic resources is established as 1% of net revenues from the product or reproductive material sales: there is no speculation of values and no surprises for genetic resources users. It gives predictability and legal certainty to invest in Bio-based products arising from access;
- The clearly established point of incidence combined with a defined percentage of benefit-sharing to be valued under a specific concept such as “net revenue” make the monitoring of compliance feasible, since they are based on fiscal and accounting principles and rules;
- When the user chooses to share the benefits through non-monetary means, such as a conservation or social project, benefit-sharing is equivalent to seventy-five percent of the predicted value for the monetary modality. This concession considers expenses the user might have in implementing the project and encourages the non-monetary modality;
- Licensing, transferring or permitting any use of intellectual property rights does not require benefit sharing. Benefit sharing obligations exist only when a finished product or reproductive material using the licensed intellectual property is commercialized to the final consumer;

- Micro-businesses, small businesses, micro individual entrepreneurs, traditional farmers and their cooperatives are exempt from benefit-sharing obligations;
- Another solution was the establishment of a National Benefit-Sharing Fund for centralization and subsequent redistribution of benefits arising from the use of genetic resources and associated traditional knowledge through a management committee for actions focused on research, development and conservation of genetic resources and protection of associated traditional knowledge;
- Once the due amount to be shared is given by law (1% of net revenues from the product or reproductive material sales), users can pay the benefits directly to the Fund, through an electronic voucher provided by SisGen, once the registration and notification requirements are fulfilled and when there are benefits to be shared. The need to sign the Benefit-Sharing Agreement (MAT) will occur only when users decides for the non-monetary modality.

Furthermore, many have pointed the difficulties in identification of both the genetic resource or its origin as an argument for preventing digital sequence information from being considered within the scope of both the CBD and the Plant Treaty. Brazilian Decree 8,772/2016 has already foreseen procedures to be adopted in cases of techniques which access microorganisms that are not isolated from a specific substrate and have not been identified, such as metagenomics.

Brazil also have positioned in favor of using the Global Multilateral Benefit-Sharing Mechanism to resolve issues of benefit sharing relating to situations in which prior informed consent cannot be obtained, such as lack of origin information, transboundary situations or products and reproductive material resulting from multiple access from different origins (Ministry of Foreign Affairs of Brazil, 2017).

Therefore, useful instruments are already in place to resolve issues for the use of digital sequence information within the framework of the CBD. There are viable regulating strategies and establishment of trigger points that will not impede the rapid share of information, crucial for our current scientific demands.

Final remarks

The use of genetic information in the context of access and benefit sharing is regulated by the Brazilian legislation since 2000.

In line with the definitions of the Brazilian Law, the object of international discussions should not focus on digital sequence data but in its core object: the genetic information contained by it.

There are several alternatives to regulate access to genetic information, including for food and agriculture, that is not by creating overly bureaucratic Sisyphean tasks. Mainly, countries should change the focus from regulating of processes/procedures towards regulating results. This shift relieves the bureaucratic burden of research and development and focuses on the end of the chain, the economic exploitation of products and reproductive material.

When national legislations focus on monitoring end-products, instead of monitoring the process to obtain those, more user-friendly ABS systems will come to exist, strengthening confidence in ABS international system.

For that countries should invest in the creation of simple, declaratory and transparent regulations, but at the same time invest in effective tracking and tracing tools that allows

monitoring of compliance. Additionally, it should provide changing of intention mechanisms (specially from non-agricultural research to agricultural research, and vice-versa), a clearly defined triggering event, quantifiable and non-speculative values for benefit-sharing, preferably based on fiscal and accounting principles and rules, and a strategy in which monetary benefit-sharing should be an obligation when there is a clear monetary benefit being obtained from the use of a genetic resource.

Predictable rules will allow users to foresee their costs and obligations, in the short and long term, and will provide legal clarity to users and thus encourage the use of genetic resources. Legal measures that facilitate and foster research and development will generate more benefits, which can be channeled to biodiversity conservation and sustainable use, fulfilling the objectives of the international agreements on ABS.

Lastly, Brazil firmly believes the concept of ABS is a useful and workable tool and that it represents a potentially substantive source of national funding for conservation in many countries. ABS is a powerful regulatory tool to promote synergies, cooperation, business and social development among countries, and societies moving towards a different sustainable, efficient and democratic model of economic development. It encodes a new understanding on how to do business, guided by environmentally-sound practices, respect and social responsibility, what allows the rational economic exploitation of biodiversity to finance its conservation and sustainable use.

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