

Proposal: Legal Elements for the “Global Multilateral Benefit-sharing Mechanism” as contemplated in Article 10 of the 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

Version 1.0

Creative Commons License (CC) 2018. Manuel Ruiz Muller, Joseph Henry Vogel, Klaus Angerer

Preamble:

In recognition of genetic resources being, for the purpose of adding value through intellectual property, natural information disseminated and diffused over various taxa and often of a transboundary nature.

Recognizing that through the granting of intellectual property rights, especially patents over inventions, many economic sectors, including the biotechnological, the pharmaceutical and the agroindustrial, have used natural information in varied ways, generating income that is rarely shared as a monetary benefit with the countries from which the natural information is found *in situ*.

Similarly recognizing that Article 10 of the Nagoya Protocol envisions the possibility of establishing a Global Multilateral [Fair and Equitable] Benefit-sharing Mechanism, in cases where utilized genetic resources for Research and Development (R&D) are found in transboundary situations or where it is not feasible to obtain or grant prior informed consent.

Aware of the inefficiency and inequity inherent to one country alone assuming the right to consent access for utilization of natural information, which is of a transboundary or shared nature among several countries.

Also recognizing that with respect to R&D, science has firmly established, since the middle of the 20th Century, that genetic resources are essentially information and that this admittedly reductionist perspective allows sound management and practical applications in diverse fields.

Aware of the necessity to align adequately incentives so that the third objective the Convention on Biological Diversity (CBD) concerning the sharing of benefits, may reinforce the first and second objectives, those being, respectively, conservation and sustainable use of biological diversity.

Suggesting that it is possible by means of a fair and equitable sharing of benefits derived from the utilization of genetic resources, together with other measures adopted at the national level, to countervail the tendency to destroy habitats rich in biodiversity, genetic resources and natural information.

Recognizing that the definition established in the CBD of “genetic resources” as “material of real or potential value” and its widespread interpretation as tangible matter, undermine any expectation of fairness and equity in the sharing of benefits.

Also recognizing that the term “natural information” turns out ideal in capturing cases where natural information has been extracted through research from the biological medium.

Maintaining that the concept of “information” alone is insufficient and must be qualified with “natural” to be distinguished from “artificial information” that is expressed in innovations of varied sorts, such as computers, software, artistic recordings, literary creations and so on, all of which may be protected through different types of intellectual property.

Further maintaining that the concept of “natural information” becomes especially useful for technological applications in diverse industries and areas of human creativity, including biotechnology, biomimicry, pharmacology and pharmacognosy among many others, for which intellectual property-like protection constitutes an homology with the intellectual property rights of artificial information.

Recognizing that economic principles for the efficient regulation of goods and services which are information in character, have been rigorously developed over decades of academic research.

Aware that efficiency in a multilateral mechanism for the sharing of benefits and the development of national regulations to facilitate access to natural information, are requisite to generate benefits that derive from utilization and thus guarantee a fair and equitable sharing in said benefit,

Emphasizing that widespread utilization of natural information best assures that benefits rebound effectively on conservation in situ and the sustainable use of biodiversity,

Recognizing that over the twenty-five years since the ratification of the CBD as international law, the contracts and bilateral agreements concluded for access to genetic resources and the fair and equitable sharing of benefits (ABS) have not proven themselves operative, thereby making necessary a new approach to ABS, grounded in the economics of information.

Also concerned by the impossibility of achieving efficiency, fairness and equity in the sharing of benefits derived from the utilization of natural information by means of concluding bilateral contracts among countries and parties, private or public, for information dispersed and diffused among two or more countries in perpetual competition for the monetary benefit in exchange of access and utilization of the natural information.

Clarifying that this new approach to ABS by means of the Global Multilateral Benefit-sharing Mechanism is based upon ex post verification of access and successful commercial utilization of the natural information, by means of the intellectual-property system, that allows in turn an efficient sharing that is fair and equitable in monetary benefits.

Likewise recognizing that the multilateral system of sharing benefits for access and utilization of natural information can be implemented for holders of intellectual property in a stepwise fashion, beginning with the economic sectors and types of activities of greatest revenue.

Mindful that, as a general principle, the activities of biocommerce, biobusiness and other uses of biological diversity for which intellectual property rights are not sought over the value added to natural information, are guided by their own rules and principles, which are distinct from those in this Global Multilateral Mechanism.

Recognizing, in that regard, that a series of economic principles and legal instruments already in effect at a national level, regulate production and value chains related to components of biodiversity, such as environmental impact statements, management plans, collection permits and primary processing, sanitary permits, among others.

Aware, moreover, of the intensive and extensive use of natural information extracted and now independent from the biological medium in many industries, with global sales in the billions of US dollars.

Recognizing that countries, in the exercise of their sovereign rights, have the right to adopt and participate in the present Global Multilateral Mechanism.

The Ratified Parties to the Nagoya Protocol approve the following Global Multilateral Benefit-sharing Mechanism on the following terms:

Section 1. On definitions

Article 1. The applicable definitions for the mechanism are:

Access and Utilization: The process by which one obtains natural information of genetic resources or biological material and adds value.

Bounded openness: The conceptual foundation which stresses that natural information flows freely for R&D, until commercial success of an innovation at which time the innovation protected by intellectual property is obligated to share monetary benefits, the percentage of which has been defined according to the category of utilization that corresponds to the value added.

Determination of the royalty rate based upon a set of characteristics in the utilization of natural information: Several criteria will be taken into account by the Subsidiary Body on Technical and Technological Advice (SBSTTA) to fix the royalty for access and the utilization of natural information. Among the criteria are the type of intellectual property, the economic sector to which the value added corresponds and whether the use is direct or indirect, among others.¹

Commercial success: The moment in which an obligation to share benefits among country(ies) of origin arises due to having added value to natural information through an intellectual property right that generated significant economic benefits.

Natural information: An expression generated and extracted from matter that is living or was once alive, where “expression” refers to any distinction, non-uniformity or difference that was unintentional.

¹ In light of profitability, concerning the type of intellectual property, one may begin with patents and plant breeder’s rights, concerning economic sectors, with the pharmaceutical industry. Direct use is typical in cases of a principal agent of natural origin, for example, “paclitaxel” isolated from the Pacific Yew (*Taxus brevifolia*), which became the successful Taxol. Indirect use can be illustrated by the many derivatives of the first approved statin, Lovastatina, of microbial origin, or by cases where nature suggests a new mechanism for research, potentially lucrative, as exemplified by the alkaloid Epibatidine isolated from the poison dart frog (*Epipedobates anthonyii*).

Country of origin of natural information: Country(ies) in which one finds the biological media of the natural information in situ.

Provider of natural information: Country or institution from which one accesses the natural information in conditions in situ or ex situ, as is the case.

Technical mechanism to determine the distribution of natural information: A group of institutions with recognized technical and scientific capacity to contribute toward determining the taxonomic diffusion of natural information and geographic distribution of species of said taxa that convey the natural information, to the extent such determinations are possible.

Biological medium: The vehicle of biological origin that conveys natural information.

Sufficient commercial success: The amount of deposited royalties to justify the expense to determine the diffusion of natural information across taxa and the geographic distribution of species that carry said information.

User of natural information: A natural or artificial person who utilizes the natural information for the purpose of adding value through R&D and applies for and maintains an intellectual property right over said value.

Section 2. Objective

Article 2.- The objective of the global multilateral mechanism is to align incentives in a cost-efficient fashion for the conservation and sustainable use of biological diversity in situ, based on a fair and equitable sharing, among countries of origin, of the monetary benefits derived from access and the utilization of natural information.

Section 3. General principles

Article 3.-The multilateral mechanism is based upon the principle of bounded openness for access to and utilization of natural information.

Article 4.- Core to the mechanism are facilitated access, multilateralism, transparency and the generation and timely exchange of information to assure the achievement of the objective.

Article 5.- To assure the generation of significant benefits and the subsequent fair and equitable sharing of benefits among the country(ies) of origin, the Ratified Parties will be guided by national legal and regulatory systems that facilitate access of genetic resources for the purposes of utilization of the natural information with the possibility to add value, as foreseen in Article 15(2) of the CDB. This implies that national regimes of access to genetic resources, as biological media or vehicles of this natural information, be simple and clear.

Section 4. On the fair and equitable sharing of benefits

Article 6.- The sharing of monetary benefits derived from access and utilization of natural information among countries of origin will be realized when the innovations or product that contains natural information and is protected by intellectual property achieves commercial success.

Said sharing will be proportional to the habitats conserved of the species from which one could extract the natural information, whenever such determination is possible and when not,

proportional to a substantiated proxy made by the technical mechanism of the determination of the natural information.²

Article 7.- Access and utilization of natural information can occur in conditions *in situ* or *ex situ*. Whichever is the case, benefits will be distributed proportional to habitats, as stipulated in Article 6. In the event of species extinct *in situ*, the benefits will be channeled to the institution(s) which maintain(s) the specimens of said species *ex situ* for conservation, restoration and other purposes.

Article 8.- The Ratified Parties of the multilateral mechanism will adapt their policies and regulations about intellectual property to require that an applicant for intellectual property disclose in a simple fashion whether natural information was utilized or not.

Article 9.- If the species for which natural information was accessed is known at the moment of filing an application for an intellectual property, the User will maintain confidential said information until such time of verified commercial success of the innovation which triggers the obligation to disclose said information to the mechanism.

If the species are unknown at the moment of applying for the intellectual property, identification will be performed by the technical mechanism of determination of the distribution of natural information upon commercial success of the protected creation or innovation, sufficient to pay the associated costs of the identification incurred.

Article 10.- The income generated by the fixed royalty established by the SBSTTA and applied to the net revenue of the commercialized good or service, will be deposited at the end of the tax period applicable to the User who commercializes the good or service that contains the natural information, in a fund of sharing benefits according to that established in Article 21 of the system.³

Incumbent upon the User of the natural information who has begun to commercialize the good or service that enjoys intellectual-property protection, is to inform the ABS Clearing-House Mechanism of the amount of net sales from the good or service. Non-disclosure entrains penalties and sanctions to be determined by the national competent authority in matters of access to genetic resources.

Article 11. The country(ies) of origin of the natural information will receive a percentage of the monetary benefits generated by the commercialization of the good or service resulting from the process of adding value to said natural information, proportional to the calculation of the

²In cases where the determination of the habitat is not feasible with any acceptable level of confidence, the diffusion may be substituted with the mere presence of the species, weighted by the geographic size of the country, where the substitution is subject to updating in the light of technological improvements and scientific knowledge.

³ This fund may be integrated or separated from already established funds and will have the fiduciary character of escrow.

habitats in which are found species that contain said information, as long as said calculation is cost efficient.⁴

Article 12.- When significant errors have been detected in the determination of the distribution of natural information made by the technical mechanism, procedures for review and re-calculation of the distribution of benefits will be executed, based upon the date of filing said information.

Article 13.- In the case of non-monetary benefits and scientific institutional collaboration, the Ratified Parties will be able to maintain their policies and regulations about access and use of the components of biodiversity, including genetic resources, by means of institutional agreements, contracts, memoranda of understanding or other instruments to effects which may be defined internally and which conform to the principles of the CBD and the Nagoya Protocol.

Section 5. On the technical mechanism for the determination of the distribution of natural information

Article 14.- The technical mechanism of the determination of the distribution of the natural information is designed to identify, as precisely as possible, the country(ies) of origin of the species from which said information could have been extracted. Identification includes the geography of the habitats, deploying the technology available at the time of commercial success to calculate said distribution, so that the percentage of benefits will be shared fairly and equitably.⁵

Article 15.- In cases where the expected costs to ascertain the distribution of species is greater than the monetary benefits to be shared, the benefits which accumulated annually up to the expiry of the granted intellectual property, will be used to defray the costs for developing and maintaining the capacities and infrastructure of the technical mechanism for the determination of the distribution of the natural information.

Article 16.- The technical mechanism for the determination of the geographic distribution of natural information comprises those international institutions of recognized standing, working in activities of taxonomy, monitoring biodiversity, patterns of distribution, developing models of speciation and phylogeny and other activities to understand how and by what means marine and terrestrial biodiversity are distributed.

⁴ Genetic therapies which derive from the direct use of the naked mole rat (*Heterocephalus glaber*) could become an enormous commercial success. Inasmuch as the habitat is already well defined, the determination of geographic distribution would be cost efficient.

⁵ Execution of the technical mechanism for the distribution of natural information is sequential: To analyze through molecular biology the presence or absence of natural information in the populations, then in populations from the same species, species from the same genus, genera from the same family, families from the same order and so on, until no longer present; develop modeling of the species where there is the presence of the natural information; and in function of the analyses, weigh the possibility of carrying out verification in situ of the identified habitats based on the models.

Section 6. On the royalties for commercial or industrial successes

Article 17.- Depending on the commercial or industrial sector corresponding to the innovation or creation and the type of intellectual property solicited, among other relevant considerations, the Ratified Parties of the Global Multilateral Mechanism, by means of the SBSTTA, will fix a royalty percentage for approval by the Conference of the Parties (COP), that will be applied annually to the net sales generated for the good or service developed from the natural information and be effective over the lifetime of the right granted. Once the royalty is determined on basis of a set of characteristics, said percentage will be effective for a period of twenty years.

To encourage timeliness in reaching agreement about the royalty percentage, and only in the case where Parties prolong the negotiations, the percentage will be imposed in a random fashion, between upper and lower limits that are justified by the SBSTTA.

The Ratified Parties will review the royalty every five years since its establishment by the COP and can adjust it in conformity with technical and economic considerations that may have arisen.

Article 18.- To avoid stacking of royalties when a good or service has utilized multiple ensembles of natural information, the Ratified Parties will determine a ceiling of summed royalties to be paid, where the countries of origin receive royalty income according to the royalty percentage weighted by the number of distinct ensembles of natural information incorporated in said good or service, as is the case.⁶

Article 19.- The holder of an intellectual-property right will classify his good or service according to the categories established by the COP for determining which royalty is applicable for the value added to the natural information, upon having duly notified and informed the ABS Clearing-house Mechanism of the commercialization.

In the case of imprecise or erroneous classification and any resultant underpayment of royalties, the SBSTTA will calculate a compensatory amount and in the case of overpayment of royalties, a credit with interests.

Article 20. Natural information utilized in goods or services which are not protected by intellectual property right and lie in the public domain, are not subject to the principles and objectives of this multilateral system, inasmuch as they have not solicited nor obtained intellectual property rights.

⁶To avoid “stacking” of royalties for natural information in one good or service, the countries of origin of each ensemble of natural information will receive a percentage divided by the number of ensembles of natural information found in the good or service. For example, assume that the COP defines a royalty for patents in a sector at 15%; imagine the case of a product which utilizes 5 distinct ensembles of natural information; each ensemble will receive 3% royalty which sums to 15%, thereby avoiding a stacking which would result in a 75% royalty.

Section 7. On the fund for sharing the benefits from the utilization of natural information

Article 21. The Ratified Parties will establish an International Fund of Sharing and Distribution of the Benefits Derived from the Utilization of Natural Information.

Article 22.- The International Fund will be constituted as an escrow, either integrated or annexed to already existing international funds to distribute the monetary benefits in accordance with that established by the technical mechanism for the determination of the distribution of natural information.

Supplementary provisions

First.- The technical mechanism for the determination of the distribution of the natural information will be selected from among scientific international institutions of recognized standing. The mechanism will function with more than one institution to determine the distribution in accordance to specialization and strengths.