

# The genetic resources and benefit sharing law international essay

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Legal Brief' International Legal Framework In Access To Genetic Resources and Benefit Sharing'Aniefiok ITEILP 1553, Nigeria178 Dorrington RoadLancaster LA1 4TDLancashireUnited Kingdomaniefiokite@yahoo. co. uk

## **Summary**

The question of accessing genetic resources in gene-rich developing countries such as Macindon and equitable sharing of the benefits thereof has been a recurring problem despite numerous international agreements to overcome this challenge. Under the Convention on Biological Diversity (CBD) countries have sovereign rights over their genetic resources. This legal biref discussed the current international legal framework for accessing and sharing genetic resources in Macindon with the context of the Access and Benefits Sharing (ABS). It further discussed numerous entry requirements imposed by the regulation and other obligations imposed on a permit holder including the obligations to conduct environmental impact assessment and quantitative and qualitative sharing of the benefits with the indigenous communities and Macindon people. The international legal framework in ABS within the context of CBD is, in fact, articulated around multilateral agreements of World Intellectual Property Organization (WIPO) and Intellectual Property Rights (TRIPS) from World Trade Organization (WTO). Although the CBD provides the general legal framework within which ABS mechanisms operate, the actual implementation of agreements governing the access to these resources and the sharing of the benefits arising from their use is largely dependent on the national legislation established between involved parties.

## Introduction

Genetic resources have remained important raw materials in agriculture, development of medicine for the past decades and most communities depend on plants for substantial part of their livelihood including for food, domestic and medicinal purposes. A greater percentage of the world's population relies on plant-based traditional medicine for their primary healthcare. Macindon is a tropical developing country known for its rich biodiversity and the indigenous people have used the root of the Kita Tree to treat a wide variety of ailments for the past centuries. Biotechnology has opened a new frontier[1] in the recent years and for example, a western pharmaceutical company, Adarmis, obtained samples of the plant in Macindon and tested its therapeutic power. Adarmis identified the kitarix as one of the active ingredients in the Kita Tree root, developed a powerful analgesic and obtained patents on this new medicine in several developed countries. In light of the commercial success of the new medicine, other pharmaceutical companies also want to obtain samples of other genetic resources and study the ancestral traditions of the Macindon's indigenous peoples. Advances in science and biotechnological development has increased the potential uses of genetic resources and economic value, prompting a high demand of these resources and stimulating their trade. Therefore, a new and potentially serious threat to the use of genetic resource has recently become apparent. The genetic resource were considered to be the ' heritage of mankind'[2] prior to the 1992 Convention on Biological Diversity (CBD) and the past decade has witnessed a growing international attention to establish legal regimes to regulate access to

genetic resources. The entry into force of the CBD[3],[4] contains rules that clarify the rights and responsibilities of parties accessing biological resources from member nations. The objectives of the CBD are the conservation of biological diversity, the sustainable utilisation of its components and the fair and equitable sharing of benefits arising from such utilisation. Under the CBD,[5] Macindon have sovereign rights over the genetic resources within its boundaries and the responsibility for implementing agreements governing access to genetic resources and sharing of benefits arising from their use between the parties involved. The legal issues arising from the collection of Kita plant sample from Macindon include: The conservation and sustainable use of genetic resources to avoid overexploitation and destruction to Macindon biodiversity; and The conflict between the obligation of CBD on fair and equitable sharing of benefit arising from the utilisation of genetic resources on mutually acceptable terms and restricted access (patent right) granted to the Adamis pharmaceutical company under the Trade and Intellectual Property Rights (TRIPS).

## **International Legal Framework: Access and Benefit Sharing (ABS)**

### **Convention on Biological Diversity (CBD) in Access and Benefit Sharing (ABS)**

The CBD is an international legal framework that has sought to encourage the formation of mutually beneficial relationships between providers and users of genetic resources based on a concept of bilateral agreement. In order to prevent biopiracy and create a climate of mutual trust, the global community undertook to regulate the handling of genetic resources in the

CBD, which is a binding international agreement. Access to genetic resources is premised on three principles: (a) sovereignty over genetic resources, (b) prior informed consent and (c) a voluntary agreement on benefit sharing. These principles provide the legal basis for a quid pro quo between countries.[6]The CBD contains rules that clarify the rights and responsibilities of all of the contracting parties. The provision of Article 10 of CBD[7]provides the legal basis for parties to take administrative and policy measures to control harmful impacts of mainstream economic activities such as over exploitation of target species and the incidental taking of non-target species. However, it is important to note that access is possible only for ‘ environmentally sound uses’[8]and a providing country may deny access on the ground that access may harm its environment. Further, Article 14 of CBD[9]draw the attention of state parties to the need for assessing possible environmental impact of its programme and policies that may have significant adverse affect on biodiversity, including exchange of information and consultation, notification in case of imminent danger to affected parties as well as promote national arrangements for emergencies.[10]The major aspect of the CBD addresses the system that governs access to genetic resources and how the benefits arising from their use are shared: Access and Benefit Sharing (ABS). Access and Benefit Sharing (ABS) issues within the context of genetic resources comprise a substantial portion of the current debates regarding the formation and adoption of intellectual property regulatory frameworks. Access in this context refers to the ability of individuals to acquire, exchange, or use genetic resources for a multitude of purposes, not necessarily limited to commercial application. However,

benefit-sharing issues are explicitly within the context of commercialisation; financial incentives to access the genetic resources for commercialisation are substantial, particularly if there is sufficient demand for the resultant product. Access to Genetic resources is dealt with in Article 15 of CBD[11]and where the access is granted, Article 15 paragraphs 4 and 5 require that it must be on mutually agreed terms and subject to prior informed consent of the party providing such resources. The two paragraphs of Article 15 also address the return of benefits derived from subsequent use of genetic resources. The benefits include: Possible participation in scientific research based on the genetic resources of the supplied article.[12]The fair and equitable sharing of research and development results and commercial and other benefits arising from the use of the genetic resources.[13]Both these provisions are not obligations that a Party seeking access should mandatorily include in the agreement, but are desirable requirements that negotiating parties (i. e. Macindon government) should take note of. With regards to benefit sharing, it is the obligation of the state to take legislative, administrative or policy measures to share the benefits arising from the commercial and other utilisation of genetic resources on a mutually acceptable terms (MAT) with the contracting parties providing the resources. Access to genetic resource is further balanced by making it subject to ' Prior Informed Consent' (PIC).[14]PIC in the context of ABS can be broadly defined as a criterion that explicitly states that the original holders of the Plant Genetic Resource (PGR), the state, or landowners have agreed to allow the resource to be used by another party. That is, if resources are to be exchanged across boundaries, they will mobilise if and only if there exists an

agreement or statement that ensures that those originally holding the resource are indeed aware and in agreement that the resource can be provided to an outside party. It is, in essence, to recognise those original holders as the custodian of the resource by ensuring that their permission has been granted before any resources are taken (or provided) by them. More explicitly, PIC in the form of regulation may require that: National governments (of Macindon) establish an authority for PIC; Specific terms are provided to determine standards for what information must be given to the holders; Local community participation in PIC (i. e. individual holders, representatives of these individuals, entire communities, or in some cases, the state). Mutually Agreed Terms (MAT)[15]define the terms and conditions by which any agreement relating to the transfer of PGR from holders to those wishing to acquire them are to adhere to. They can include provisions on a number of issues: Continuing monetary benefits to the original holders; Technology transfer, training, or research; Requirements on reporting how the resources are being used by the parties who acquire the PGR; Defining what forms the Intellectual Property Rights (IPRs) will have over the resource; Recognition of where the resources came from, not only in terms of geography but also in terms of parental lineage (this is referred to as " full disclosure"); Defining what benefits the original holders will receive as a result of the transfer. The CBD entered into force (ratified and adopted) in 1993 and with this new legislation, a new world system for the use of biological matter now exists that has changed the nature of public and private sector Research and Development efforts. The CBD has evolved significantly through the work of its intergovernmental working group on ABS

(WG-ABS) and the WG-ABS at its first meeting in Bonn, 2001 drafted a voluntary guideline to assist parties with the implementation of the ABS provision of CBD, this is technically referred to as Bonn Guidelines. The sixth meeting of the Conference of Parties to the CBD in April 2002 (COP 6) deliberated on the interpretation of Article 15 of CBD,[16]and arrived at Decision VI/24.[17]This decision brought forth " the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation". The Bonn Guidelines are voluntary, but do comprise the first widely accepted criteria for the licensing of access to genetic resources and they are expected to be influential in the formation of national legislature. Appendix I[18]of the Guidelines offers a detailed list of provisions that should be included in any Material Transfer Agreement (MTA), which is relevant considering one of the goals of the Guidelines is to facilitate a harmonisation of the way that MTAs are created. However, these rules are not exhaustive and when one considers the wide variety of circumstances that exist regarding how communities hold these resources and in identifying exactly who is the true holder, any set of guidelines must be considered as being suggestive.

## **Current International Legal Framework in Access and Benefit Sharing (ABS)**

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'[19]agreed in Nagoya at CBD COP10 further details the ABS provisions of the Convention. The Protocol establishes a clear and transparent framework on how researchers and companies will in the future



obtain access to genetic resources and to traditional knowledge associated with genetic resources for research and development and how benefits arising from the use of such material or knowledge will be shared. The Protocol also sets out a clear obligation for Parties to provide that users of genetic material under their jurisdiction respect the domestic regulatory frameworks of Parties where genetic material has been acquired.[20]The Nagoya Protocol is intended to ensure equitable benefit sharing in return for the use of genetic resources, acknowledging and respecting at the same time indigenous communities' rights over their traditional knowledge and genetic resources. The Nagoya Protocol is a treaty with legally binding effects that significantly expands the general ABS framework of the CBD, and it is expected to enter into force in 2014. Once operational, the Nagoya Protocol will generate significant benefits for biodiversity conservation in states that make available the genetic resources over which they hold sovereign rights. It will in particular: Establish more predictable conditions for access to genetic resources. Ensure benefit-sharing between users and providers of genetic resources. Ensure that only legally acquired genetic resources are used.

**The Nagoya Protocol[21] applies to genetic resources that are covered by the CBD, the benefits arising from their utilization and also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization. To facilitate the implementation of the obligation of CBD on access to genetic resources, Macindon authority has to designate and strengthen her national focal points as contained in the Article 13 of the Nagoya Protocol.[22] In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources. Under the nagoya Protocol, Macindon authority shall:**

Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements; and provide for fair and non-arbitrary rules and procedures on accessing genetic resources; Provide information on how to apply for prior informed consent; Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time; Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly; Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic

resources; and Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia: A dispute settlement clause; Terms on benefit-sharing, including in relation to intellectual property rights; Terms on subsequent third-party use, if any; and Terms on changes of intent, where applicable. With respect to monitoring and compliance, Macindon authority shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.[23] In addition, Macindon authority has the right to take appropriate measure to address non-compliance with the set standards even though paragraph 3 require parties to cooperate in cases of alleged violation of domestic access and benefit sharing legislation.

## **Trade Related Intellectual Property Rights (TRIPS) and Patent Over Genetic Resources**

The World Trade Organization (WTO) is an international organisation that deal with the global rules of trade between nations and in 1995, the WTO formulate the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The Agreement is comprehensive in scope and contains standards for protection of a number of Intellectual Property (IP) rights as well as rules on the enforcement of such rights.[24] The Agreement on TRIPS probably represents the most significant development in World Trade Law and intellectual property issues have become an integral part of the world

trading system. According to the Agreement on TRIPS,[25]products and processes related to the use of plant and animal species may be patentable including their genetic resources. The commercialisation of products derived from genetic resources also enjoy patent right, however, nothing in the text of the agreement makes reference to the source(s) of the genetic resources. The flexibility of TRIPS Article 27. 3(b) may allow member states to incorporate ABS - " friendly" provisions. The current formulation of TRIPS Article 27. 3 literature has its origin in the Patent Cooperation Treaty (PCT). [26]Furthermore, it closely links to the well-established traditional international system of the protection of intellectual property rights - the World Intellectual Property Organization (WIPO) and it adopts a comparative perspective in highlighting related and similar provisions and developments in other international and regional instruments. It is designed to meet the needs both of the WTO and the intellectual property community. Therefore, TRIPS is " legally" enforceable via the WTO dispute settlement mechanism. Considering the fact that Research and Development leading to production of Kitarix from kita root require a huge time and financial investment, it may be important for the pharmaceutical company to get IP protection in order to be able to recover its investment and profit. However, there was no recognition of the indigenous knowledge in this case and this brings in an issue of doubt over who really has the IP right over the Kitarix. Overall, indigenous knowledge contributed in no small way to the discovery about the efficacy of Kita root and such knowledge, however, does not qualify for patent since it is communal intellectual property. Under TRIPS Agreement Article 27 (Patentable Subject Matter) and Article 28 (Rights Conferred), full

implementation of IP right contradicts with the obligation of CBD on benefit sharing in a mutually acceptable terms, as the owner of the IP determines what part of the benefit is accessible to third party.[27]As such, the WG-ABS consider the inclusion of IPR as part of benefit arising from the utilisation of genetic resources and inclusion of disclosure and international certificate of origin initial application for IP and patent right.[28]According to the COP-6 guidelines, the IPR applications have to provide disclosure of the country of origin of genetic resources, the consent of the designated authority from the country of origin in order to promote MAT (mutually agreed terms) for access to genetic resources and the associated traditional knowledge and a certificate evidencing compliance with national legislation regarding PIC (prior informed consent). If these requirements are not fulfilled in the context of CBD, no patent will be granted and TRIPS Agreement is bound to be legally enforceable via WTO dispute settlement mechanism.

## **Conclusion**

The CBD provides the general legal framework within which ABS operate and in line with the obligation of state parties under the CBD, Macindon government must facilitate access to genetic resources on mutually agreed terms. There is need for simple, non-bureaucratic, and flexible regulation to control access to genetic resources. Access procedure must be clarified and a competent national authority designated to control access. The national authorities at Macindon must ensure participation of the indigenous people in the capacity building and knowledge transfer in benefit sharing. National law must be strengthened to establish and clarify the right of indigenous people to land resources in line with the provision of the CBD. Furthermore,

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government agency regulating access must ensure that the terms in access and benefit sharing agreement are unambiguous so that cooperating partners are clear of their right and responsibilities in benefit sharing. However, the benefit sharing negotiation must be open and flexible to accommodate the dissenting views and opinion of different benefit sharing partnerships, it must take particular care to facilitate the implementation of the three objectives of CBD. It must also take into account the protection offered by IPR and consider this as part of benefit sharing before granting approval of patent right to commercial partners. In the present case of Kita root, if the pharmaceutical company did not obtained the consent of Macindon authority prior to its application for patent right, the authority in Macindon has the right to file opposition to the patent right sought over her genetic resources, and may force its withdrawal pending further negotiation until both parties mutually agrees on the benefit sharing mechanisms. Although the CBD Convention has been ratified by most countries in the world, the opposition to patent application must be based on the relevant section of the current international regime on ABS and Macindon Government must critically negotiate the terms of benefit sharing taken into account her national priorities and the objective of the CBD.