

DISCUSSION PAPER

International Regime on Access and Benefit-Sharing (ABS): Exploring New Options for Achieving CBD-Related ABS Objectives

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Overall Vision

The need for continuing exchange of information between the CBD and WIPO and the need for mutual supportiveness of these organizations in pursuance of matters of common interest in relation to access and benefit-sharing (ABS) (concerning disclosure of the origin of genetic resources and related traditional knowledge in applications for intellectual property rights, including those raised by a proposed certificate of origin, source, and its legal providence) are emphasized. Kenya wholeheartedly approves of the cooperation between the CBD and WIPO in addressing the issue regarding the interrelation of access to genetic resources and disclosure requirements in IP documents.

Kenya has no specific regulatory regime on ABS in place. Although a potential regulatory structure has been put in place, it is yet to be developed into a substantive regime. There is a range of statutory, regulatory and policy provisions regulating access to genetic resources. The primary document in this case is the National Biodiversity Strategy Action Plan that stipulates National Policy on Biodiversity and Trade in Genetic Resource based products and processes.

Section 4.11 of the strategy states that Kenya will develop and implement policies and legislation to articulate and regulate the rights of access to, and benefit sharing of National Genetic Resources. It will strengthen the capacity of Kenyans to carry out bioprospecting activities.

Action 19 provides that Kenya will facilitate access to genetic resources and transfer of technology, and that Kenya Wild life Services (KWS), National Museums of Kenya (NMK), the National Council for Science and Technology (NCST), and Universities are the lead agencies. Action 21.4 provides that it will explore options and modalities for access and benefit sharing in the National Context and the lead agencies are, NMK, NCST, Universities, national research institutions and NGOs.

National Access Laws, Challenges, Monitoring And Enforcement Issues

Kenya has had a series of laws and regulations dealing with access for many years. Prior to the CBD, they were embedded within rules on research, collecting and export. They remain in different spheres, though CBD-related developments have begun to plug some holes and bring together the national actors. Issues of benefit sharing are only now being examined with some rigor.

¹ This paper reflects the view of the author and is not an official statement of the Kenyan Government.

Environment Management and Co-Ordination Act (EMCA-1999)

EMCA-1999 is Kenya's framework legislation, co-coordinating all environmental management activities in the country and constitutes one primary implementing legislation for the Convention on Biological Diversity (CBD). Section 53 of the Act mandates the National Environment Management Authority (NEMA) to issue guidelines and prescribe measures for sustainable management and utilization of genetic resources of Kenya for the benefit of the people of Kenya.

The guidelines specify appropriate arrangements for access to genetic resources of Kenya including the issue of licenses and fees to be paid for access, and measures for regulating the import and export of germplasm.

The sharing of benefits derived from Kenya's genetic resources, bio-safety measures necessary to regulate biotechnology, measures necessary to regulate the development, access to, and transfer of biotechnology as stipulated, in the context of Articles 15 and 16 of the CBD, are also considered.

Requirements and Process for Foreign Parties Accessing Genetic Material

To undertake research of any kind within Kenya, the Office of the President (OP) and the National Council for Science and Technology (NCST) are key agencies in granting permits for research programs, including that to access genetic resources. The OP grants, based upon advice from the NCST, act as authorization of for all research permits in Kenya, whether for Kenyans or foreigners. The granting of research permits is necessary but does not constitute fully complete authorization for access to genetic resources.

For foreign researchers, they need to identify those benefits that their research and program brings to Kenya, including training and resources provided to their Kenyan counterparts.

The OP/NCST Process has the ability to get a provisional permit from the OP, or more often from the Ministry of Education, on behalf of the OP. Requirements for a provisional permit include the submission of a research proposal, payment of administrative fee and the identification of a Kenyan partner, institution or sponsor. Provisional permit holders are allowed to conduct research pending issuance of final permits. Once a provisional permit has been given, the application is forwarded to NSCT for review. NCST gives the final approval. Provisional permits raise a question on the possibility of creating a loophole where collecting and exporting genetic resources could occur under a provisional permit that was not going to be given final approval.

Once a researcher has the permit from the OP, if the project includes collecting genetic resources from certain areas or collections, additional authorizations from other agencies may be required. For example, for any collection in protected areas, there is an additional obligation to get a permit from the Kenya Wildlife Service. This obligation and most of the others, pre-dated CBD. KWS's exclusive authority over protected areas dates back to the post-independence Wildlife Department and its stewardship of Kenyan genetic resources in these areas was reiterated in the 1999 EMCA Law.

Finally, even with the research permit and the collecting permit, a researcher also needs an export permit for specimens.

Local Counterparts

The main institutions dealing with genetic resources at the domestic level are the institutions that make up the National Research System, the universities, the National Museum of Kenya, and the many government research institutes. Kenya also houses a

number of important international research organizations such as ICIPE and IPRI. One of these institutions is the Kenyan Agricultural Research Institute (KARI). While KARI has developed some products based on the collection of germplasm from Kenya, it has also made extensive use of the collection of the International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). In turn, Kenya has made its national collection of germplasm openly available to CGIAR and other countries. Ownership of this germplasm, and in particular developed and improved genetic resource-based products and processes, requires intervention. The best intervention in this case will be an internationally binding disclosure requirement, which will ensure access and benefit sharing arrangement including a technology transfer mechanism.

Property Rights Issues

The IPR obligations are met through collaborative efforts of KIPI (for Industrial Property issues) and KEPHIS (which has a mandate including Plant Variety Protection and quarantine).

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National bio-safety committee, co-coordinated by the NSCT, with membership from KIPI, KEPHIS, and the National Agricultural Research Institutions among others, and in particular KARI, play a major role in environmental regulation with their mandates including matters of technology development and transfer.

Plant Variety Protection (UPOV -1978 / UPOV-1991)

Kenya enacted the Seeds and Plant Varieties Act Cap 326 in 1977, providing for the protection of plant breeders rights. The 1977 Act (reviewed in 1991) and the 1994 regulations, broadly comply with the provisions of UPOV 1978 convention. Kenya became a party to UPOV 1978 convention in April 2000. The parent legislation and the implementing regulations are both being revised. It is expected that these will include some features of UPOV 1991.

The Act has no specific provisions addressing the question of farmers' rights. The 2001 draft bill does not contain provisions reflecting those of UPOV 1991, however, as these provisions still prohibit the exchange of seed among farmers, and thus fall far short of the realization of farmers' rights (control of wheat seed and cut flowers case in Kenya is of relevance).

Kenya provides for protection of plant varieties by an effective sui-generis system under provisions of the UPOV convention. Microorganisms and microbiological processes and products, are all subject to patent protection. The current legislation is being reviewed to address issues and interests of indigenous communities and small-scale farmers as stipulated in UPOV 1991 and the domestication of the ITPGF/A, where farmers' rights are addressed. Amendment of Art. 29 of TRIPS, to demand for disclosure and production of certificates of origin in all IP application on products and processes based on genetic resources is recommended. This would be a solution for monitoring and the distribution of benefits, through royalties and other contractual benefits arrangements.

National Patent Legislation

The main challenges to address in the creation of an effective International Regime is in this paper's view, a legally-binding instrument necessary in order for States to codify sovereign rights over its genetic resources. Kenya has been a member of WTO since 1995, and has made its patent law TRIPS compliant. It supports the developing country position on the relationship between WIPO (IP Treaties) and the CBD, arguing that there are cross cutting issues that should be resolved. An interesting case of reference is the IP related ABS case involving *Extremophiles* in a patent protected technology in the detergent and textile industry.

Plant parts or bio-technological processes and products (micro-organisms and micro-biological processes and products) are patentable as provided for under Section 26 of Industrial Property Act -2001, but exclude plants from patent ability. The possible way plants and plant parts can be refused protection would be on grounds of public morality, public health and safety, or humanity and environmental conservation. In this case, a Patent and PVP system, with a role for trademarks, certification marks and appellation of origin, will be the most mutually beneficial approach. This makes it ideal to protect and provide evidence for benefit sharing, should IP documents disclose countries of origin.

Potential Solutions

R & D Institutions and IP Management

Genetic resource based R&D activities of public institutions in Kenya are carried out by the national research system, foreign research institutions and international research institutions. For them to access and develop Genetic Resource based processes and products, it is recommended that a legally binding sui-generis system for Genetic Resources (GR) and Traditional Knowledge (TK), where CBD and WIPO IP treaties are mutually supportive, be adopted. This will help to address bio-piracy that is due to National legislations missing complete and functioning elements because of an absence of a legally binding Disclosure of Country of Origin requirement in IP application. Disclosure of Country of Origin could fill the gap in the ABS system in IP applications and Amendment of TRIPS Art.29, to require the same.

Recommendations

Genetic resources acquired prior to CBD are to be given same IP disclosure requirements, similar to post CBD accessions. This should not be voluntary, but mandatory, for IPR purposes. Genetic material accessed for research purposes only should not be transferred to third parties, without safeguards to assure that the non-commercial nature of the original transfer is maintained. If this material is requested to be used for commercial research, it should not be transferred until there is an agreement of mutually agreed terms with the appropriate Kenyan authorities.

It is also recommended that processing of IPR applications be on condition of legally obtained GR, accompanied by any restrictions under which the material was obtained.

Conclusion

Kenya takes note of the report of the IGC and appreciates the work being done by the committee on WO/GA/31/8 matters concerning intellectual property and genetic resources traditional knowledge and folklore and invitation made by CBD-COP 7 and in particular Decision VII/19 because it touches on issues within WIPO mandate. The issues raised in the invitation are relevant to the work of the intergovernmental committee and several other WIPO processes.

On the methodology, it believes that the issues raised touches on the work of various processes and committees under WIPO including the IGC, CBD and WIPO secretariats, who, in collaboration with WTO, should identify the various processes and relevant committees to expedite the tasks anticipated by the invitation.