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Community-based access and benefit-sharing platform and its role in biodiversity, culture and intellectual property rights

S S Atsali

Traditional Knowledge and Genetic Resources Unit, Kenya Industrial Property Institute, Weights and Measures Premises, Nairobi's South 'C', Popo Rd., Off Mombasa Rd., Kenya

E-mail: stanleyatsali@gmail.com

Abstract. The world is experiencing a paradigm shift towards new technical uses of genetic resources (GR), which is likely to have a significant impact on communities across the world. These new technologies comprise genome sequencing, gene editing, computational biology, nanotechnology among others, yet the technological innovation driving this shift is occurring only among a few elite, high-tech innovation actors, high-end universities, companies and research institutions. Kenya is a member of the World Trade Organizations (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights-TRIPS and party to the Convention on Biological Diversity (CBD) and its Cartagena and Nagoya Protocols. This survey interrogated constitutional provisions concerning Biodiversity, Culture and Intellectual (BCI) property rights, with a view of promoting community-based Access and Benefit-Sharing (ABS) platform. It highlights provisions of Articles 11, 40.5 and 69 of the constitution and interrogates the Protection of Traditional Knowledge and Cultural Expressions Act of 2016 that aims at ensuring compliance with these constitutional provision and aims at building trust between users and providers of traditional knowledge, associated GR and traditional cultural expressions and creating a sui generis mechanism for the protection of traditional knowledge and cultural expressions. In this survey, GR are defined as microorganisms, plants and animal materials, including indigenous seeds, genetic plant varieties and traditional animal breeds.

Keywords: biodiversity, intellectual property right, genetic resources.

1. Introduction

The world is experiencing a paradigm shift towards new technical uses of genetic resources (GR), which is likely to have a massive impact on communities across the world. These new technologies comprise genome sequencing, gene editing, computational biology, nanotechnology among others, yet the technological innovation driving this shift is occurring only among a few elite, high-tech innovation actors, high-end universities, companies and research institutions.

However, farmers and local communities are being left behind entirely, pausing a risk, since there is no capacity and language to understand the sophisticated technology and articulate their needs concerning the scientific, legal and policy developments caused by the shift. Major challenges are:

- 1) Translating the advanced technological progress to make it accessible and understandable to farmers and local communities.
- 2) Identifying and analyzing the needs of farmers and local communities concerning the new technologies and transformations in the use of GR.

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- 3) Articulating the needs of farmers about the new GR technologies in the advanced technical language of the high-end innovation actors.
- 4) Relaying those needs to the high-end innovation actors and relevant policy-making institutions.
- 5) The shift from genetic material to data as critical inputs for GR-based innovation is accompanied by a movement from Access and Benefit-Sharing (ABS) into the IP system as the primary regulatory frameworks. Kenya is a member of the World Trade Organizations (WTO) Agreement on Trade-Related aspects of Intellectual Property Rights [1]—TRIPS and party to the Convention on Biological Diversity (CBD) and its Cartagena and Nagoya Protocols [2].

The CBD of 1992 comprises the international legal framework for access to GR, traditional knowledge (TK) and benefit-sharing (ABS). The relevant provisions on ABS are concretized in and made internationally binding through Nagoya protocol to the Convention. This has fundamentally changed the terrain of working with GR in research and development, and national laws have to be reviewed to ensure compliance with its obligations.

Articles 11, 40.5 and 69 of the constitution and the Protection of Traditional Knowledge and Cultural Expressions Act [3] aim at ensuring compliance with these obligations and build trust between users and providers of TK, associated GR and traditional cultural expressions (TCEs). The Traditional Knowledge and Cultural Expressions Act of 2016 aims at creating a *sui generis* mechanism for the protection of TK and cultural expressions. An exciting aspect of this act is that it defines GR as microorganism, plant and animal material, including indigenous seeds, genetic plant varieties and traditional animal breeds.

Numerous challenges are still standing in the way before this can be achieved. This survey examined some of the outstanding issues identified based on a pilot case study of selected counties and national regulatory institutions and interrogated how they are coping with resulting challenges. Could disclosure of the source of origin of GR and associated TK in Intellectual Property Rights (IPR) applications help in enforcing ABS requirement at the community level.

To find the actual picture in the counties, and capacity of relevant institutions to enforce this requirement, this survey was carried out in three pilot counties of Kajiado, Busia and Vihiga with the aims of:

- 1) Finding the level of preparedness by the county governments to document TK and TCEs and establish county repositories as required by Section 4 of the Protection of Traditional Knowledge and Cultural Expressions Act of 2016.
- 2) Determining the existence of repositories and guidelines for documentation and access to TK, associated GR and TCEs as required by Sections 10, 18, 19, 20 and 25 of the Protection of Traditional Knowledge and Cultural Expressions Act of 2016.
- 3) Establish the existence of guidelines for examining biological inventions and suitability of the patent law to enforce the disclosure requirement.
- 4) Developing short- and long-term recommendations for implementation of the Protection of Traditional Knowledge and Cultural Expressions Act of 2016, and promotion of Community-based ABS Platforms (CABS Platform).

2. Policy framework

Protection of Traditional Knowledge and Cultural Expressions Act of 2016 is an Act of parliament that provides a framework for the protection and promotion of TK and TCEs. It gives effect to the Constitution of Kenya 2010 [4], article number 11, 40.5 and 69 of the Constitution of Kenya and recognizes GR, culture and protection of IPR.

Article 11 describes culture as the foundation of the nation and as the cumulative civilization of the people and the nation of Kenya. It calls for the state, through an act of parliament, to recognize ownership and the role of communities in the conservation and promotion of their scientific and indigenous technologies, and to provide for the protection of IPR of the people of Kenya. Nagoya Protocol, on the other hand, provides a transparent legal framework for the effective implementation

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of the third objective of the CBD. It applies to GR covered by CBD and to the benefits arising from its utilization. It also covers TK and TCE with GR held by indigenous and local communities.

The erosion of our cultures and the loss of Kenya's heritable (genetic) resources underscore the need for policies and legislation to conserve and regulate access to GR, protect TK and practices and facilitation of the equitable sharing of benefits arising from the use of such resources. This pilot project interrogated the implication of enforcing the disclosure of origin of biological resources and, or associated traditional knowledge in patent and utility model applications. It is believed that this framework with the disclosure requirement of the country of origin can facilitate contracts and licensing agreements for bioprospecting between communities, research and development institutions and other development partners.

In phase I, the survey attempted to establish the level of awareness by counties on Constitutional Provisions in Articles 11, 40.5 and 69, and determine existence of guidelines on documentation and access to TK, associated GR and TCEs in the county TK and TCEs as required by Sections 10, 18, 19, 20 and 25 of the Protection of Traditional Knowledge and Cultural Expressions Act of 2016.

In phase II, the TK and GR unit of Kenya Industrial Property Institute interrogated the suitability of IP regime in ensuring Returns on Community-based Assets (ROCBA), comprising Patents/Utility Models and breeder's rights, by requiring disclosure of the source of origin of TK and associated GR.

Phase I

Phase I activities attempted to establish the level of awareness by counties about Constitutional Provisions in Articles 11, 40.5 and 69, and determine existence of guidelines on documentation and access to TK, associated GR and TCEs as required by Sections 10, 18, 19, 20 and 25 of the Protection of Traditional Knowledge and Cultural Expressions Act of 2016.

Phase II

property assets.

Phase II interrogated the suitability of patent and utility model application procedures with the aim of intending to establish its suitability in ensuring ROCBA, by requiring disclosure of the source of origin of TK and associated GR in their application.

3. Finding of the survey in the pilot counties

The following ten questions were put to respondents in the pilot counties of Kajiado, Busia and Vihiga. Discussed herewith are the findings:

- 1) Does your county have designated county and sub-county culture, agriculture and livestock officers?
 - All the three counties have designated county and sub-county culture, agriculture and livestock officers.
- 2) Does your county have a Biodiversity, Culture and Intellectual (BCI) property policy? It was also established that the County Government of Busia has a draft of BCI property rights policy that was developed in the 2016/2017 financial year. However, the draft is yet to be debated at the county assembly. It is anticipated that once the draft is debated, it shall be enforced to ensure that communities in Busia County will enjoy returns on their biodiversity, culture and intellectual

It was established that county governments of Kajiado and Vihiga do not have a BCI property rights policy. However, there are community-based activities in the counties under the intangible cultural heritage and natural products initiative that could culminate in the development of a county BCI property rights policy.

This county BCI property rights policies aim at providing guidelines on documentation and access to TK, associated GR and TCEs of communities in the counties. The policies are expected to provide guidelines on enforcement of Annex 1 of Nagoya Protocol, in the context of granting of Prior Informed Consent (PIC) and drafting of mutually agreed terms on accessed TK, associated GR, and TCEs.

3) Are you aware of the Constitutional Provisions in Articles 11, 40.5 and 69?

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All respondents in the pilot counties answered that they are aware of Constitutional Provisions in articles 11, 40.5 and 69, whose substantive issues related to biodiversity, culture and intellectual property rights.

4) Are you aware of "The Protection of Traditional Knowledge and Cultural Expressions Act of 2016"?

It was established that the three counties are not aware of The Protection of Traditional Knowledge and Cultural Expressions Act of 2016, an Act of parliament that aims at creating a *sui generis* mechanism for the protection of TK and cultural expressions in Kenya and gives effect to enforcement of Articles 11, 40 and 69 (1) (c) of the constitution. This lack of awareness is at institutional and individual levels.

Section 4 of The Protection of Traditional Knowledge and Cultural Expressions Act of 2016, sets out responsibilities of county governments that include initial registration, preservation and conservation, facilitation of access and sharing of information and allocation of financial resources for TK and TCEs.

5) How is the county government planning to enforce provisions of Section 4?

It was established that all the three counties plan to enforce provisions of Section 4 through the county implementation activities in the Integrated Plan (CIP) of 2018–2022. This plan has aspects of documenting intangible cultural heritage and the generation, protection and commercialization of community-based natural products.

It has envisaged that the CIPs and the county BCI policies will provide a framework and guidelines on documentation and development of sub-county repositories, for the purpose to collect and compile information including documentation, storage, preservation and conservation, protection and promotion and facilitation of collaboration on access to, or sharing of information and data relating to TK, associated GR and TCEs.

Under Section 10 of the Act, communities are empowered to promote their TK, associated GR and TCEs, and to control its use and share in benefit from its commercial exploitation, where communities are to adopt their own rules and procedures for authorization of use by third parties.

6) How is the county government planning to enforce provisions of Section 10?

It was established that the three counties plan to enforce provisions of Section 10 through the CIP of 2018–2022. An emerging issue from Kajiado county respondents was concerning the absence of an intellectual property protection regime for animal breeds (gap identified in IP protection), [see Use of Livestock Resources for Food Security in Light of Climate Change policy brief of April 2017–breeding program and infrastructure—the case of Red Maasai sheep in Kenya. This was mainly about the definition of GR in the Traditional Knowledge and Cultural Expressions Act of 2016, which is defined as a microorganism, plant and animal material, including indigenous seeds, genetic plant varieties and traditional animal breeds.

It was the opinion of respondents from Kajiado County that animal breeders deserve an animal breeder's rights regime, just like plant breeders enjoy plant varieties protection and all benefits that are derived from obligations under Art. 9 of the FAOs ITPGRFA. They argue that, just like the plant breeders have plant breeder's rights, animal breeders also need an animal breeder's rights regime.

This argument is in line with Article 1(3) of the Paris Convention for protection of industrial property, which states that, industrial property shall apply not only to industry and commerce proper, but likewise to agricultural, and extractive industries, and all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour.

7) Protection against unlawful acts under Section 18 of the Act is modelled along with the conventional Intellectual Property Rights by conferring positive protection subject to exceptions and limitations under Section 19. How is the county government planning to enforce provisions of Sections 18 and 19?

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It was established that the county governments, in consultation with the national government, shall set up mechanisms to prevent misappropriation, misuse or unlawful access and exploitation of TK, associated GR and cultural expressions, where any user shall be required to obtain prior informed consent from the community holding the knowledge and use of the knowledge and associated GR shall be compatible with fair practice, relevant customary laws, protocols and practices and acknowledges the moral rights of communities, to ensure that communities realize returns on their assets.

- 8) One of the main challenges faced in Kenya is the use of TK to create works that are protected under existing Intellectual Property Rights. This is addressed by Section 20(1), which requires written authorization of the use of such works for commercial purposes. How is the county government planning to enforce provisions of Section 20(1)?
 - The three-county governments indicated that they shall confer all the rights as stipulated in the Traditional Knowledge and Cultural Expressions Act of 2016, including the monetary and non-monetary rights (shared IPRs) as anticipated by NEMAs Environment and co-ordination (conservation of biological diversity and resources, access to GR and benefit-sharing) regulations of 2006 and Annex 1 of Nagoya Protocol.
- 9) Section 25 of the Act cover provisions on the authorization of use of TK and cultural expressions, or notification of agreements. How is the county government planning to enforce provisions of Section 25?

The county governments of Kajiado, Busia and Vihiga indicated that they should collaborate with the national IPR offices (Kenya Industrial Property Institute, Kenya Copyrights Board) to ensure that TK, associated GR and TCEs are protected against all acts of misappropriation, misuse, unlawful access or exploitation.

It is expected that the draft county culture, biodiversity and intellectual property rights policies (BCI) shall ensure those holders of TK, associated GR or cultural expressions shall grant access, authorizations, assignments or licenses in respect of protected TK or cultural expressions in writing and copy submitted to the cabinet secretary and the respective county executive committee member in charge of matters relating to TK and culture.

The Traditional Knowledge and Cultural Expressions Act of 2016 seeks to regulate the use of TK and cultural expressions and ensure that the communities or individuals holding the knowledge can control their access and use, benefit from commercial exploitation, protect against misuse and misappropriation and promote its use and preservation.

10) How is the county government planning to enforce these provisions?

In response to question 10 with Table 1 on cultural industries, it was established that all the listed cultural expressions 1–16 are found in the pilot counties of Kajiado, Busia and Vihiga, and that they shall be documented.

It is also envisaged that several products that have a particular appellation to any geographical location in the pilot counties shall be documented and appropriate community collective marks, geographical indications and appellations of origin registered.

The cultural industries listed in Table 1, such as architecture, music, art, visual arts and performances, to a certain extent involves the use of TK and TCEs. Songs, dances and culinary art of preparation, cooking and presentation of traditional food, is the main attraction of such cultural days and events.

In Busia County, it was established that all the listed cultural expressions 1–16 in Table 1 are found and shall be documented. The central communities in the county are Bakhayo, Banyala, Marachi, Samia, Teso and Luo. Marachi community has traditional mats that could qualify for a community collective mark that can be registered if the community forms and registers an association.

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Table 1. Relates to question 10.

Creative economic sub-sector	The protection of intellectual property
Architecture	Copyright
Advertising	Copyright
The fine arts antiquities	Copyright and traditional cultural expressions
Craft	Copyright, trademark and design industry
Design interior	Copyright and design industry
Design visual communication	Plant and design industry
Fashion	Copyright and design industry
Film, animation, and video	Copyright
Photography	Copyright
Application and games developer	Copyright
Music	Copyright
Performing arts	Copyright
Publishing	Copyright
Television and radio	Copyright
Culinary	Trademark and Geographical Indications (an indication of origin)

It was the opinion of the Busia county cultural officer that cultural products like Marachi baskets that could constitute have a unique appellation due to TK of the Marachi community and be protected by a community collective mark. The Marachi community has the potential for developing a collective mark for its products.

It was found that almost every community in the pilot counties had a unique product that can qualify for registration of community collective marks. This could leverage on the one village one product (OVOP) initiative by the Ministry of Industry Trade and Cooperatives, which aims at branding at least one product from each community in each county.

In Vihiga County, it was established that all the listed cultural expressions 1–16 in Table 1 are found. The County came out most active in this category, where it has an elaborate, annual cultural festivities calendar/week that features cultural expressions from Maragoli community on 26 December, Banyore community on 27 December, Tiriki community on 28 December, and Teriki/Nandi community on 30 December every year.

Analysis of findings from the three pilot counties of Kajiado, Busia and Vigiga

- 1) All respondents in the pilot counties of Kajiado, Busia and Vihiga were aware of the Constitutional Provisions of Articles 11, 40.5 and 69.
- 2) All respondents in the pilot counties of Kajiado, Busia and Vihiga lacked awareness of the existence of The Protection of Traditional Knowledge and Cultural Expressions Act of 2016, which is an Act of Parliament for actualizing Constitutional Provisions in Articles 11, 40.5 and 69.

As per the definition of GR provided for in The Protection of Traditional Knowledge and Cultural Expressions Act of 2016, there is lack of an appropriate regime for the protection of Animal Breeders Rights, which was identified as a gap.

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4. Finding for phase II

4.1. Kenya Copyrights Board

Kenya Copyrights Board was interrogated on issues related to the development of implementing regulations for the Traditional Knowledge and Cultural Expressions Act of 2016, and the establishment of the National Repository as required by Section 5.

Section 5 of the Traditional Knowledge and Cultural Expressions Act of 2016 requires the national government to:

- 1) Establish and maintain a repository at the Kenya Copyright Board.
- 2) Promote and conserve TK and cultural expressions of communities in Kenya.
- 3) Protect traditional knowledge and cultural expressions from misuse and misappropriation.
- 4) The facilitation of access to information and the sharing of information and data relating to TK and cultural expressions.

What is the Kenya Copyrights Board doing to ensure that the Protection of Traditional Knowledge and Cultural Expressions Act of 2016 is enforced?

Findings:

It was established that Kenya Copyright Board, the custodian of the Act, is developing draft implementation guidelines and regulations for the Traditional Knowledge and Cultural Expressions Act of 2016 and shall involve stakeholders. It is hoped that the guidelines and implementing regulations shall help National and County Governments to meet their obligations as required by Sections 4 and 5.

4.2. Kenya Industrial Property Institute

The survey sought to know how the institute proposes to enforce the disclosure requirement in patents and Utility model applications to ensure ABS on accessed and commercialized TK and associated GR. It also sought to establish how biological inventions, including biotechnological inventions, are examined.

The manager patent was requested to respond to the following questions, the County Governments of Kajiado, Busia and Vihiga indicated that they should collaborate with the national IPR offices (Kenya Industrial Property Institute [KIPI], Kenya Copyrights Board and Kenya Plant Health Inspectorate Service) to ensure that TK and associated GR and TCEs are protected against all acts of misappropriation, misuse, unlawful access, or exploitation.

- 1) What is KIPI doing to ensure that TK and associated GR of communities is not misappropriated, misused, unlawful accessed or exploited through patents and utility models?
- 2) Are there guidelines for examination of biological inventions, including biotechnology?

4.3. Analysis of Kecobo and KIPI

It was established that the Industrial Property Act (IPA) has provision for patent and utility model protection for microorganisms or other self-replicable material, products of GR and herbal products and nutritional formulations that give new effects.

The response from the manager patents was that a proposal had been made to the State law office to amend IPA to call for disclosure of the source of TK and associated GR in patent and utility model applications to ensure that communities benefited from their accessed TK and associated GR. Once the State law passes the amendments, KIPI shall have it enforced to ensure that communities realize returns on their assets.

It was further established that there are no guidelines on the examination of biological inventions, including biotechnology applications. It was found that the absence of the guidelines has caused a lack of clarity in the execution of biological-based inventions, including biotechnology.

Biological inventions are examined based on provisions of Section 29 of IPA 2001 and Regulation 11 of Implementing Regulations of 2002. It was found that neither of the designated depository institutions (KALRO and Kenya Medical Research Institute [KEMRI]) has guidelines on depositing and maintaining microorganisms for patent purposes.

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A case to note is KE/P/2013/001960, [PCT/JP2012/062935] that relates to and involves the use of a microorganism which is considered not to be available to the public. According to the requirements of Section 29 of the IPA [5], the applicant was required to deposit the culture of the microorganism with Kenya Agricultural Research Institute (KARI) or KEMRI. Although the nine claims have been examined substantively and found to be novel, inventive and industrially applicable, a patent cannot be granted because the depository requirement has not been met, hence, the application is considered as insufficiently disclosed.

Implications of this lack of clarity are that biotechnology applications are technically prohibited, which is contrary to the spirit of Article 16 of the CBD on sustainable application and adaptation of biotechnology.

Copyrights Board, who are custodians of The Protection of Traditional Knowledge and Cultural Expressions Act of 2016 should, in collaboration with Council of Governors, create awareness on obligations of all the 47 counties on matters related to biodiversity, culture and intellectual property rights.

To guarantee Returns on Community Based Assets (ROCBA), the disclosure of origin of biological resources and or associated traditional knowledge in intellectual property applications is required. This proposal for amendment has been submitted to the State Law Office. It stipulates that, where the subject matter of an IP application concerns, is derived from or developed with biological resources and, or associated TK of communities or individuals, the applicants should disclose the community or individual in the community providing the resources and, or associated TK and from whom they were obtained.

The applicants are also required to provide information including evidence of compliance with the Constitutional Provisions of Articles 11 and 69 among other legal requirements in the providing county for prior informed consent for access and fair and equitable benefit-sharing of benefits arising from the commercial or other utilization of such resources and, or associated TK.

As per the definition of GR provided in The Protection of Traditional Knowledge and Cultural Expressions Act of 2016 and lack of an appropriate regime for the protection of animal breeders rights, it is recommended that the identified gap be filled with and appropriate intellectual property regime.

Animal husbandry, a branch of agriculture concerned with animals that are raised for meat, fibre, milk, eggs, or other products and that include day-to-day care, selective breeding and the raising of livestock, was a significant concern of Kajiado County.

It can be observed that the Kyrgyz Republic has a law on the legal protection of selection achievement and governs economic and moral relations arising out of the creation [discovery, development], legal protection and use of selection achievements for which patents have been granted in the Kyrgyz Republic. Czech Republic has a law on the legal protection of new varieties of plants and breeds of animals and protects new plant and animal varieties [6,7].

These two regimes could provide possible options for addressing this gap to the selection and protection of traditional animal breeds. An animal breeder's regime shall ensure exclusive rights for the breeders and communities. This can help in recouping the investment in research and development of traditional animal breeds and grant opportunities for licensing. Communities will also increase their negotiation power and create a positive image for both researchers and communities. It is anticipated that this may prove useful for raising funds, finding business and add the market value of the traditional animal breeds.

Option one:

An animal breeder regime could be developed based on the Kyrgyz Republic Law on the legal protection of selection achievement of May 26,1998 governs economic and moral relations arising out of the creation [discovery, development], legal protection and use of selection achievements for which patents have been granted in the Kyrgyz Republic.

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Option two:

An animal breeders regime could be developed based on the Czech Law on the legal protection of new varieties of plants and breeds of animals protects new plant and animal varieties, [See Kyrgyz republic law on the legal protection of selection achievements and Czech law on the legal protection of new varieties of plants and breeds of animals].

5. Concluding remarks

It is highly recommended that Kenya develops an IPR regime for traditional animal breeds based on any of these two options. As per the absence of guidelines for examination of biological inventions, it is recommended that they are developed by KIPI.

The Biological Diversity Act, 2002 (starting now referred to as BD Act of India) provides a mechanism for access to the GR and benefit-sharing accrued from there. To facilitate this access and benefit-sharing and in order to prevent any unauthorized use of the biological resources of India, in 2005 suitable amendments were made in Section 10 of the Patents Act, 1970, wherein disclosure of the source and geographical origin of the biological material was made mandatory in an application for patent when the said material is used in an invention. Beside a declaration by the applicant regarding the required permission from the competent authority was inserted in Form 1 of the Patents Rules, 2003.

It is recommended that KIPI develops such guidelines for clarity and streamline examination of biological-based inventions. On the other hand, since KEMRI and KALRO lack capacity to handle deposited microorganisms for patent prosecution, Kenya should ascent to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for Patent Procedure. Lack of guidelines for examination of biological inventions, including biotechnology, was identified in the examination procedures of KIPI.

A look at case KE/P/2013/001960, [PCT/JP2012/062935] demonstrates effects of this lack of clarity on where to deposit microorganisms for patent examination purposes, that has technically prohibited KIPI from substantively examining and granting a patent to the applicant.

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