Biodiversity Protection, Farmers and Breeders Right

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Lecture 23 : Challenges related to biopiracy - case studies

Welcome to the lecture 23 on the challenges in relation to biopiracy. We will examine certain case studies. In this lecture, we will cover the following concepts, definition, nature and scope of biopiracy, how we increasingly now use the term misappropriation, challenges to biopiracy, what are the different ways in which biopiracy can be addressed nationally as well as internationally. And we will recall the current discussions that are happening at the International fora on the need to look at ABS and its effective implementation. These are the keywords for the lecture. So, we begin with the basic aspects of what is biopiracy.

While there is no standard or uniform definition of biopiracy, in general it means obtaining access to biological resources or its information without the authority. So, today we increasingly use the word misappropriation. And here in the context of genetic resources, it means the violation of access conditions or deriving benefits without equitable benefit sharing. In this context, we need to remind ourselves that traditional communities have been facing the threat of misappropriation of their knowledge on the uses of bio resources for various purposes.

There is increased appropriation of IP. Predominantly the concerns on patents are there internationally. So, when we look at biopiracy, we are looking at the context of the entire bioresource itself or part of the bioresource, information relation to bioresource, and with the advances of technology today genomes are being sequenced day by day. So, the wealth of information in terms of the digital sequence information also has a lot of value in terms of looking at commercialization. So, the entire context of where we are looking at commercialization in relation to the use of bio resources, we see that the context of biopiracy is relevant.

When we look at TK and biopiracy, a lot of attention has been focused on traditional knowledge. Today, significant number of medicines that are used in the world are developed because of traditional medicinal knowledge. So, TK has been very susceptible to misappropriation. Not only that, when we look at the context of biopiracy and the appropriation of IP, a whole lot of patents are filed based on traditional knowledge. TK piracy is not limited only to patents, other aspects, other forms of IP are also relevant.

We do see traditional symbols being violated, indigenous communities use certain

traditional where these aspects have become a lot of design piracy is being observed. So, it is just not patents, but other forms of IP are also relevant when we discuss the context of the piracy in relation to the traditional knowledge. In the earlier weeks, we have looked at the potential of biotrade. It is important to recall that in the context of looking at which are the main routes for trade in relation to bio resources, for that will give us a clue on whether access to bio resources to these countries is happening on the terms spelled out under the ABS framework. So, here you see an illustration from the UNCTAD website information on what are the different types of bio resource based materials, whether it is extractives or whether it is products.

What is the nature of the imports and the exports for some of the major countries? So, this information is important to identify how the source in relation to bio resources is being looked at and also the commercialization and the entire supply chain. We come now to the discussion in relation to some biopiracy cases. In the case of the African tribes, the San tribes, they depend on a cactus called hoodia to stave off hunger and thirst. This traditional knowledge associated with the use of this particular cactus has been appropriated in form of patents. Products have been developed, but the community had not received the benefit sharing.

So, as a response, the South African Science Council brought a challenge and eventually benefit sharing was reached. So, this is one example which is very well noted. Another example of the how indigenous tribe information has been utilized for development of products is the case of the Ayahuasca, where the bark of the plant has been used for development of a ceremonial drink. This is part of the shaman tribes traditional knowledge and is also considered very sacred. Patents have been filed on the use of these.

Much later on, realizing that monopoly rights can exclude even the tribe to use the plant if in that territory you have patent rights asserted. The coordinating body of the indigenous organizations came together and filed for a re-examination of the patent at the USPTO. Based on the prior art that was available, the patent was revoked. We have another example of kawa, which is a plant whose roots are used in preparation of a drink, and this is native to the northern regions of Australia. The indigenous people use this for medicinal as well as antiseptic properties.

Several patents have been filed in relation to this particular plant, where the method of extraction, the use of it for treating bladder, urinary tract cancers, and even cosmetic companies which prepare cosmetic products are also looking at this in terms of value, patents being filed in relation to reduced hair loss and how hair growth can be stimulated. Now, this information on the use of kawa roots is a part of the traditional knowledge of the community, the Mirar community, and they have been using this traditional knowledge

from several centuries. The documented information in relation to this has been helpful in the challenge in relation to this particular patent. There are several cases that are reported on the misappropriation of bio resources and associated traditional knowledge. In India, India being one of the mega diverse countries has also reported several cases of misappropriation on the use of traditional knowledge or bio resources for development of products at the detriment of the communities and at the detriment of the conservation of bio resources.

Several examples from the very initial cases of the turmeric, the properties of the use of turmeric for wound healing which are very well known for ages and generations as part of the traditional knowledge has been appropriated in the form of patents. At the time of the filing of this patent, India did not have a repository of information in relation to traditional knowledge. When documented information was identified to challenge this patent at the USPTO, the need for development of the traditional knowledge digital library was realized. Another case of the NEME patent where we see the properties of NEME, the pesticide properties of NEME taken as patents. So, filing of patents on based on NEME had not only happened at the USPTO, but also at the European Patent Office.

So, we do see that the appropriation of information in relation to bio resources finds its way in patents across the world. There are several such examples of those which we commonly know. For instance, we are looking at the controversy in relation to Basmati rice, where the long grain scented nature of it which is essential to the nature of Basmati was part of the independent claims of a patent filed by researchers in the US. In this case, the basic nature of the long grain nature and scented property, since it is known in the regions where Basmati is grown, those claims have been cancelled, while other claims in relation to the modification of genes for the introduction of these specific properties was allowed at the USPTO. We do have a lot of patents filed in relation to the properties of ginger and for diseases such as diabetes where generally the knowledge in relation to the use of blackberry, bitter gourd, the eggplant, these are well-known examples which people generally use to address the issues of diabetes.

Several patents have been filed, but unfortunately no reference of prior knowledge that exists in relation to the use of it has been recorded. We also have several patents in relation to Indian ginseng. So, wherever you see the traditional knowledge or the use of bio resources where patents have been filed, the opposition to those patents or revocation as the proceedings depending on the status of it have been initiated, and we do see a lot of revocation or non-grants happening. These are some of the other examples in relation to how different plants have been subject matter of the patents in terms of their use, and predominantly we see traditional knowledge information has been misappropriated. So, what does this point us out to? So, when we look at all of these examples, we realize that

several aspects of bio resources whether it is raw material, extracts, finished products, is somewhere through exchange at the end point are realized as a form of IP.

So, it is important to address the entire chain from the bio resource to the product or the filing of IP. We also see that over harvesting of bio resources is also a big problem. In the earlier examples that we mentioned on biopiracy, while at the initial point of time when the resource was just used by the indigenous people, it was available in plenty. Once the commercialization of products happened, there was over appropriation of the bio resources to the extent that it had to be listed under annexure 2 of the CITES agreement. So, what was not threatened is now listed as distinctly a threatened plant species.

Therefore, we are running the risk of losing species. Counterfeiting is a big issue. In most cases, we see no permission being sought by the relevant authorities, unauthorized plant collections, bio resource collections do lead in some cases to cases on biopiracy. Lack of benefit sharing, today we are looking at the context of intellectual property rights where exclusive rights are being sought on some of these, which means that these are going to be subject matter of property rights. And the very resource or the very knowledge that indigenous communities were using will be no longer be available for the communities to use, which means that their rights are being threatened, their livelihoods could be at a big risk.

With the increasing digital modes of recording information on one end, there is more access of information. Not only that, genome sequencing methods are so advanced that today the sequence of genomes or the grammar of the genomes is laid down, and with so many different genomes being sequenced, we have the entire genetic information, greater propensity to realize the value of it. With that, there is also a risk of what we call the digital area of biopiracy. So, digital sequence information safeguarding that is also important because it is not the resource, but the information on the sequence which is also valuable. So, addressing the issue of biopiracy becomes important thereby.

If we walk down through the international evolution of some of these aspects, we come to several regional as well as international initiatives that have been taken up. The Johannesburg declaration on biopiracy, biodiversity and community rights is relevant to understand the propositions that were laid down at that point of time on how the context of food and health security and environment needs to be given utmost importance, how prior informed consent should be a necessary part, the role of governments in relation to policy and legislation in relation to this area. The declaration also emphasized on the use of the African model law on community rights when it came to member countries of the African continent. The proposition also to carefully look at the implementation of the TRIPS agreement and to bring in sui generis systems for the protection of plant varieties.

How one should be very careful to exclude out life forms from the context of patents and looking at the role of GMOs when it comes to biodiversity.

Sustainable agriculture systems and their development is also vital. The like-minded group of mega biodiverse countries came up with a very important declaration at the Cusco declaration. This was a very important declaration, and that this meeting provided the impetus to move the mandate of the working group on 8(j) to take up the aspect of ABS and developing the framework. We are also looking at the how the emphasis on bond guidelines for access to genetic resources, which was announced at the COP 6 of the CBD, how that becomes the important background, and also affirming the context of the World Summit on Sustainable Development and thereby in particular the Johannesburg declaration on sustainable development. This Cusco declaration also gave importance to an emphasis to how sub-regional and regional instruments are important when we are looking at regulating the access to genetic resources.

When we look at the overall context of the Convention on Biological Diversity, what you see in this illustration is the interplay of where we look at the article 8J, which emphasizes on respecting the needs and expectations of the indigenous communities, their innovations and their livelihood. We look at the context of article 15 on how the benefit sharing should be identified, and several guidances provided under the CBD, which you have already gone through in the earlier lectures. So, the international framework on ABS pretty much provides the outline on how one can address the issue of biopiracy by involving the context of the PIC, the material transfer agreements, identifying source. So, and that is where we see the value of it. There are independent efforts world over to create documented information which will serve as prior art when it comes to patents being filed in this area.

And this documented information in the form of libraries or databases whatsoever name are they are called by serve as defensive protection. What you see in this illustration is one such example of the TKDL, the Traditional Knowledge Digital Library, which houses as a single central repository of information on Indian system of medicine. And this has been successfully utilized to challenge patents. This is a very important contribution from India implemented as several different national patent offices in the examiner platform. So, when examiners are looking at applications which are based on TKDL and bio resources, the prior art in relation to those are accessed from the TKDL.

The updation of the TKDL is an ongoing process. And in this illustration, you see several examples of how successfully patents have been challenged based on the use of TKDL. So, when we look at the overall context of biopiracy and the ongoing use of bio resources and traditional knowledge, we need to look at how well the process of addressing those concerns have been identified. So, when we look at research and development, it is at that

stage we are looking at compliance in relation to attribution, the source information, ensuring that the terms of use are met. Today in publishing of academic manuscripts, we do see a need for biodiversity compliance, source of the herbaria from where the material has been accessed, all of this has to be clearly mentioned.

Then we look at the aspect of where information or exchange of bio resources happens, and that is where we look at material transfer agreements. They are variously called as bio resource agreements, SMTAs. These become important to understand access and use terms. It is not only between research institutions, but it is between research institutions and companies and many a time it is also between how country to country information or resource is being accessed. And at that stage from a country to country level, we look at compliance that comes from the international end.

The CBD from its implementation, and today in the post Nagoya period, we look at the Nagoya protocol for the guidance in relation to the international framework on how access and benefit sharing can be taken up. National authorities have several measures. For instance, custom measures at the customs policy in relation to identifying counterfeit is very important. One illustration is shown on this particular slide. So, several measures in cohort would help in bringing in compliance in relation to the access and also the use terms in relation to the bio resource as well as traditional knowledge.

So, the more and more information that is documented, and the compliance internationally in relation to the material transfer agreements and ABS, these things on the end of biopiracy will be more and more reduced. This is the post Nagoya part of it, where we look at the need for looking at PIC principles and MAT, wherever the utilization genetic resources concern. The need for internationally recognized certificates of compliance, India being the one with the largest number of them submitted at the ABS clearinghouse. Several countries are moving forward to also take up a role in relation to submitting internationally recognized certificates of compliance. National checkpoints are very important in this regard.

Building in better administrative measures and transparency in the entire process of access is very important. So, when we look at the Nagoya, in the earlier lectures you would have gone through the context of user measures and provider measures. Both are adequately important if we look at the context of exchange of germ plasm, the use of it for several purposes. So, today the area of bioprospecting, bio survey, bio utilization as such could be used for only research purposes, but you never know in future intellectual property claims could exist. Therefore, the entire dimension of ABS is applicable to all of it.

Under the CBD, under various decisions, several guidelines have been announced. These

are voluntary guidelines, but serve as a very important guidance for those who take up work with indigenous communities, with countries in relation to research in relation to bio resources, commercialization based on bio resources and TK. Beginning from the Akwe Kon guidelines which are on the sacred sites and water bodies and land associated with traditional dwellers, how do you look at the context of respecting the sites and being culturally sensitive. So, any study that is on based on assessment will need to look at these as a important guidance. We also have the code of conduct guideline announced under the specific where what are the ethical practices that one should take up as a part of the research design when we deal with indigenous communities or interact with them.

In order to prevent the unlawful appropriation of traditional knowledge, what are the different forms of consent principles are identified under the most coastal guidelines where we have the context of prior informed consent, free informed consent, approval and involvement. So, that definitional terms identified under this which can serve as an important guidance for the consent principles. And the most recent one identified in 2018 at the Sharm El Sheikh COP meeting, the guidelines in relation to repatriation of traditional knowledge, very important from the point of view of looking at a recovery, re-establishing traditional knowledge back to the community. So, guidelines have been also announced in relation to the repatriation of TK. So, all in all these guidelines serve as a very important guidance available for those who work with the context of research and development when it comes to the bio resources and traditional knowledge and the interaction with the communities in relation to that.

So, we come to the conclusion. Misappropriation of bio resources is an international problem. There are several challenges when it comes to biopiracy which today also includes digital information in relation to bio resources and digital sequence information. Addressing biopiracy is a multipurpose approach. Application of ABS terms and the use of guidelines can be very beneficial in this particular context.

These are a few references for the lecture. Thank you.