

Biodiversity Protection, Farmers and Breeders Right

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Lecture 33 : Compliance Procedure and Linkage with IPR

Welcome to the course on Biodiversity Protection, Farmers and Breeders Right. This lecture will be about compliance procedures and linkage with intellectual property rights. The concepts covered in this lecture are misappropriation of genetic resources and traditional knowledge, genetic resources and intellectual property rights, defensive protection of traditional knowledge, disclosure requirements with regard to traditional knowledge and genetic resources, the regulatory approval requirement, WIPO intergovernmental committee on intellectual property rights, genetic resources, traditional knowledge and folklore, the diplomatic conference 2024. The keywords for this lecture are misappropriation, traditional knowledge, intellectual property, defensive protection of traditional knowledge, disclosure requirements. Misappropriation of genetic resources and traditional knowledge which is usually called as biopiracy in popular literature. Biopiracy is commonly used to refer to obtaining access to genetic resource without the authority.

Misappropriation happens when bio based innovations are patented without complying with the ABS regulatory requirements. It also may be defined more broadly to involve unauthorized commercialization resulting from access, derivation of unjustified benefits or failure to provide for equitable benefits sharing. Biopiracy allegation has been raised against many industries and developed countries. Biopiracy or misappropriation generally means that a user of bio resource has access the resource without complying with the access and benefit sharing regulations of the provider country.

The CBD, the Nagoya protocol and the national legislations with regard to access and benefit sharing requires the users of bio resource to follow some rules and regulations which will include commitment with regard to benefit sharing. But many times users will access the resource without taking the prior approval as required in the national legislation and will develop inventions which will be patented by them. This will constitute misappropriation of bio resource or the associated traditional knowledge. Traditional knowledge and intellectual property rights is having a close interface. The traditional knowledge is knowledge, know how, skills and practices that are developed, sustained and passed on from generation to generation within a community and often forming parts of the communities cultural and spiritual identity.

Traditional knowledge can be found in wide variety of context including agricultural, scientific, technical, ecological, medicinal knowledge as well as biodiversity related

knowledge. Recognising traditional forms of creativity and innovation as protectable intellectual property may enable indigenous and local communities as well as governments to have a say over their use by others. This may make it possible for example, to protect traditional remedies artworks or even music against misappropriation and enable communities to control and benefit collectively from the commercial exploitation of such resources. The modern form of intellectual property law is developed to cover only modern forms of innovations like inventions or in case of copyright it is artistic works or literary works which are newly developed. But traditional knowledge is a knowledge, know how or skill which has been practiced, sustained and passed on from generation to generation within a community.

So it may have a history of 200 or 300 years. So protecting such traditional knowledge is not coming within the scope of modern intellectual property legislations. So there have been demand to reconstruct the intellectual property framework which is existing now in order to recognize traditional forms of creativity and innovations which exist in the form of traditional knowledge, traditional cultural expressions and folklore. Innovations that are based on traditional knowledge may benefit from patent, trademark and geographical indication protection or be protected as a trade secret or confidential information. How a traditional knowledge as such that is knowledge that has ancient roots and is often oral is not protected by the conventional intellectual property systems.

So if a traditional knowledge is accessed from a community and then based on that knowledge and innovation is developed that innovation could be protected under patent or other forms of intellectual property rights. But the traditional knowledge per say cannot be protected under the conventional intellectual property systems. Similarly, the traditional knowledge may become subject matter of some artistic work or creative work or a trademark or geographical indication. In such cases they could be protected under the corresponding intellectual property laws. But traditional knowledge per say is not afforded any form of protection under the conventional intellectual property systems.

So this allows users of traditional knowledge from accessing the traditional knowledge and then developing innovations based on it and once the innovation is developed that could be protected under the conventional intellectual property framework. While the policy issues concerning traditional knowledge are broad and diverse the IP issues breaks down to mainly two key themes. One is with regard to defensive protection of traditional knowledge and second is with regard to positive framework for protection of traditional knowledge. So the entire discussion or the negotiations that are happening at international level could be separated into these two parts. The arguments in favor of defensive protection of traditional knowledge and the arguments in favor of positive protection of traditional knowledge.

The negotiations on an international legal instrument is currently taking place in the world intellectual property organizations, India governmental committee on intellectual property genetic resource, traditional knowledge and folklore. In some countries sujanitry's legislation has also been developed specifically to address positive protection of traditional knowledge. In addition providers and users may also enter into contractual agreements regarding use of existing IP systems of protection. So this means that the main arguments that are raised at the international level could be either for defensive protection of TK or for positive protection of traditional knowledge. Defensive protection simply means that the misappropriation of traditional knowledge is prevented, but positive protection means that the holders of traditional knowledge will be recognized as the rightful owners of the traditional knowledge.

In some countries there are national legislations already existing which gives some form of positive protection to traditional knowledge. Genetic resources constitutes a unique subject matter for intellectual property protection ever since IP systems began to protect innovations in modern life sciences as early as mid 1970s. They include for example, patenting microorganisms, plant varieties, animal breeds, genetic sequences, nucleotides, amino acid sequence information, traits, molecular event, plasmids and vectors. So all these constitutes genetic resource which could be subject matter of an invention which could be patented under the conventional intellectual property framework. The genetic resource and the related life science innovations and the information cut across a number of branches of intellectual property law and practice including patents, trade secrets, copyright, technological protection measures as well as other branches of intellectual property law.

The IP issues associated with genetic resource therefore, need to be addressed in a customized cross cutting and practical manner. The advancements in the biotechnology fields has now allowed human beings to access microorganisms, plant varieties, animal breeds, genetic sequences, nucleotide and amino acid sequence information, traits, molecular events, plasmids and vectors and then doing research to develop innovations based on them. Now there is a huge demand for bio based innovations and also there is a feeling that all solutions to the problems that mankind is facing now is already existing in the nature. So this has accelerated research on different components of biodiversity. So this has resulted in advanced utilization of components of biodiversity like microorganism, plant varieties, animal breeds, other genetic resources etcetera for the purpose of research and development of innovations.

Once these innovations are developed they become patentable or protectable under intellectual property framework. In considering intellectual property issues associated

with genetic resource, the world intellectual property organizations work complements the framework of access and benefit sharing provided by the Convention on Biological Diversity and its Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization, the Pandemic Influenza Preparedness Framework or the PIP framework of the World Health Organization and other specialized access and benefit sharing frameworks. So, at present there exist at the international level different forms of specialized access and benefit sharing framework. So under the Convention on Biological Diversity and the Nagoya Protocol there is an internationally recognized legal framework for access and benefit sharing with regard to genetic resources which are existing within the national jurisdiction of a sovereign state. The International Treaty on Plant Genetic Resources related to Food and Agriculture which is under the FAO or the United Nations Food and Agriculture Organization.

So under this treaty it is specifically covering the resources which are required for food and agriculture purposes. So this can include resources which are within the national jurisdiction and outside the national jurisdiction as well. Similarly, there is a new legal framework which is formulated under the auspices of United Nations UNCLOS or the United Nations Convention on Law of the Seas for addressing the utilization of genetic resources which are existing in the marine environment which is outside the national jurisdiction. So for example, a genetic resource or a marine genetic resource which is accessed from the high seas or areas which are outside the national jurisdiction would come under this new legal framework. So that means, there are three different international legal frameworks existing in order to address access and benefit sharing with regard to genetic resources existing within the national jurisdiction, beyond national jurisdiction and even in the high seas.

Similar to that there are several regional and bilateral international legal frameworks for access and benefit sharing related to genetic resources. Inventions based on or developed using genetic resources which is associated with traditional knowledge or not may be patentable or protected by plant breeders right also. So similar to patent there is another form of intellectual property right which is the plant breeders right which recognized intellectual innovations related to development of new plant varieties. There are concerns about patents being granted over such inventions which do not fulfill the access and benefit sharing requirements. So many times the patent office or the intellectual property granting body will not look at whether the user has complied with the access and benefit sharing requirements of the country from where the genetic resource is accessed.

There are also demands for creating inbuilt mechanisms within the patent law framework to disqualify patent applications that do not comply with CBD obligations on prior informed

consent, mutually agreed terms, fair and equitable benefit sharing and disclosure of origin. So this demand essentially means that there has to be some complementary relationship between the requirements of the conventional biological diversity and the international legal framework related to intellectual property rights. So in case a patent application is received which is not complying with the access and benefit sharing requirements then the patent office should go forward to either disqualify the patent application or reject the patent application. So in such scenarios there would be compulsion on the users of biodiversity to comply with the access and benefit sharing regulations of the provider country and at the international level there is also a growing demand to include disclosure of origin as a mandatory requirement in case of intellectual property applications which are based on genetic resources or traditional knowledge. A number of countries have also enacted domestic legislation putting into effect these obligations and WIPO members are considering whether and to what extent intellectual property system should be used to support them.

Many WIPO members want to make it mandatory for patent applications to show the source or origin of genetic resource as well as evidence of prior informed consent and a benefit sharing agreement. So many of the member states have already made the demand that the disclosure of source or origin of the genetic resource shall be a mandatory requirement before the grant of the patent. Similarly, they also require that along with the patent application in case if the invention is based on a genetic resource or the traditional knowledge then the patent applicant shall also submit some evidence with regard to obtaining of prior informed consent or the execution of a benefit sharing agreement. So many countries are already demanding the submission of internationally recognised certificate of compliance or IRCC as a requirement for granting of various regulatory approvals. The defensive protection of traditional knowledge refers to strategies to ensure that third parties do not gain illegitimate or unfounded intellectual property rights over traditional knowledge.

These measures include amendment of the WIPO administered patent systems or the international classification system and the substantive examination procedures to identify similarities with prior art. So defensive protection means that the several strategies are adopted in order to ensure that a patent which is in effect traditional knowledge is not taken forward for the grant of intellectual property right. So this requires the minimum documentation that is regarding the existence of a prior art or the traditional knowledge and it also cause an obligation on the member states to adopt a system of substantive examination where in the similarity with existing traditional knowledge which is documented will also be considered before the grant of the intellectual property right. Some countries and communities are also developing traditional knowledge databases that may be used as evidence of prior art in order to defeat a claim to patent which is essentially

based on traditional knowledge. WIPO or the World Intellectual Property Organisation has also developed a toolkit which will provide practical assistance to the traditional knowledge holders in documenting the traditional knowledge.

The documentation of traditional knowledge and traditional cultural expressions is a process which TK and TCEs are identified, collected, organized and registered or recorded. So this is an elaborate process by which traditional knowledge or traditional cultural expressions are identified and then collected, then organized and then registered or recorded in a database. From an intellectual property perspective, a documentation exercise needs to be undertaken within a framework of sound objectives and principles and guided by clear assessment of risks and potential benefits particularly for indigenous people and local communities. This documentation may help traditional knowledge holders and the governments in defensive protection of traditional knowledge. So from an intellectual property perspective if you see the documentation of traditional knowledge has its own merits and demerits.

So if you look at the demerits, if a traditional knowledge is existing in the oral form it will never be commercialized unless the holders of traditional knowledge disclose it to a potential user. So as long as it is kept as a secret the traditional knowledge holder has an advantage with regard to protection of that traditional knowledge. But once it is documented it becomes part of a document or a database which may be secretly maintained by the government in certain cases. But in case it is not secretly maintained it may bring the traditional knowledge to the public domain or to the public knowledge which will in effect make the claim of the indigenous people or local community weaker. Similarly if there is a defensive protection regime which is constituted under the intellectual property system it has its own merits also.

So before the grant of the patent the patent office will do a substantive examination which will include searching in a database which is maintained at the international level in which the traditional knowledge and traditional cultural expression of different indigenous people and local communities are recorded. So this will in effect prevent the erroneous grant of patents which are actually per se traditional knowledge. The defensive protection stops people outside the community from acquiring intellectual property rights over traditional knowledge. India for example has compiled a searchable database known as traditional knowledge digital library. It contains documented information about traditional medicinal preparations that can be used as evidence of prior art by patent examiners when accessing patent applications.

The traditional knowledge digital library was compiled by the council of scientific and industrial research under the government of India in order to counter biopiracy. The TKDL

or the traditional knowledge digital library contains information regarding the already documented traditional knowledge which was existing in Ayurvedic text, Unani text etc. So all these documented texts were converted into different foreign languages and has been compiled into a database form which is easily searchable. They have also adopted a classification system through which the traditional knowledge can be easily searched and identified. The traditional knowledge digital library is now made available to different patent offices across the world so that during the substantive examination they can search the traditional knowledge database and then find out whether there is a prior art already existing with regard to the invention for which patent application is newly filed.

This database was created following a well known case in the United States patent and trademark office which had granted a patent for the use of turmeric to treat wounds a property which is a well known traditional knowledge in India and documented in ancient Sanskrit text. defensive strategies must also be used to protect sacred cultural manifestations such as sacred symbols or words from being registered as trademarks by the third parties. India had faced some infamous biopiracy cases in the 1980s and 1990s like the turmeric case, the neem case etc. So in those cases the government understood the requirement of having a documentary proof with regard to the existence of traditional knowledge. In many countries only a document will be accepted as an evidence of prior art as per the national intellectual property framework.

So in case a counter allegation is made with regard to a patent that there is already a prior art existing in the form of a traditional knowledge the patent law may require that a documentary proof has to be submitted. So if the traditional knowledge is existing only in the oral form then defending such patents would not be possible. So in such cases the databases or the traditional knowledge libraries which are created for ensuring defensive protection of traditional knowledge becomes extremely important and relevant. A disclosure requirement with regard to traditional knowledge and genetic resource is also a demand among the developing countries in the international forums. The disclosure requirement may be derived from existing patent law or based in other legal systems.

In the first category the possibilities include the requirement of extending the disclosing the source and geographical origin of a biological resource used in the invention. This will enable the working of the invention by the legitimate user. The disclosure requirement with regard to patents that is describing the innovation in the complete specification is part of one of the mandatory requirements under the patent legal framework. So this will enable the invention to reach the public domain completely after the expiry of the patent. It will also contributes to the state of art because once the intellectual property application is filed the document which describes the innovation will be publicly available and it will be easily accessible for researchers or other industry competitors.

As part of this requirement there is a growing demand to add the disclosure of source and geographical origin as a mandatory requirement within the intellectual property framework. This requirement means that in case a patent applicant is using a biological resource for the development of their innovation then they have to disclose the source and geographical origin of that bio resource in the complete specification when a patent application is filed. So, this has two positive effects one is this will enable a competitor or a legitimate user to easily identify the bio resource which is used in the invention and it will help them in working the invention for legitimate purposes. Apart from that the disclosure of source and geographical origin will also help in assertion of benefit sharing obligations. So, once the source and geographical origin of a biological resource which is used in the invention is clearly mentioned in the specification then it becomes a documentary proof on which the provider country can build a sound case for sharing of benefits.

The disclosure requirement with regard to traditional knowledge and genetic resource is already existing in India's patent act. The disclosure of source and geographical origin of biological material used in the invention is a mandatory requirement under section 10.4 of the patent act 1970. So, in case a patent applicant who is filing a patent application in India has used a biological resource for the development of the innovation then the source and geographical origin of that biological resource has to be clearly mentioned in the complete specification. This is a mandatory requirement under section 10(4)(ii)(d) of the patent act 1970. Similarly, the incorrect and wrongful disclosure of source and geographical origin is a ground for pre grand opposition under section 25 clause 1 J. So, that means, if a patent applicant has incorrectly or wrongfully disclosed the source and geographical origin of a biological material then it becomes a ground for pre grand opposition of the patent. Similarly, incorrect or wrongful disclosure is also a ground for post grand opposition under section 25 clause 2 J and revocation of the patent under section 64 clause P. So, that means, a patent applicant has to be very very careful while disclosing the source and geographical origin of the biological resource used in the invention. So, once the patent application is filed and in the specification if the source and geographical origin of the biological material is not mentioned then the patent application need not be considered for the grant of the patent by the patent controller.

And subsequently even if the source and geographical origin is mentioned and later it was found that the source and geographical origin is incorrect or wrongly disclosed then it is a ground for pre grand opposition and once the patent is granted this becomes ground for post grand opposition and even revocation of the patent under section 64 clause P. Regulatory approval requirement is another important demand raised by the developing countries and the mega biodiverse countries. The requirement of regulatory approval can

effectively link the patent legal framework with the access and beneficiary regulations. The regulatory approval will be mandatory for the grant or the commercialization of the patents. This will encourage patentee to comply with the access and beneficiary requirements under the convention on biological diversity Nagoya protocol and the national legislation.

Once this regulatory approval requirement is made mandatory then the patent office will have to check for compliance with the ABS procedures that is submission of internationally organized certificate of compliance IRCC, obtaining of the prior informed consent or PIC, execution of mutually agreed terms or MAT as part of the substantive examination of the patent application. So, regulatory approval requirement in essence means that the patent office also has to check whether the patent applicant has obtained the requisite regulatory approval under the access and beneficiary regulations of the provider country. If the patent applicant has already obtained the ABS approval then there is no problem, but if the patent applicant has not obtained the requisite access and beneficiary approval then the patent shall not be considered for grant. This requirement is there in patent legislation of only very few countries, but many of the countries have objected to having this requirement as part of international legal framework for intellectual property rights. But once this is made a mandatory requirement for the grant of the patent then every patent applicant whose invention is based on research on a genetic resource will have to submit the requisite regulatory approval in order to get his patent granted.

This will encourage the patent applicants to comply with the requirement under the conventional biological diversity Nagoya protocol and the national legislations. So, once this requirement is made part of the national or international legal framework then the patent officers will have this additional responsibility to check for compliance with ABS procedures. So, once a patent application is received and it is based on a genetic resource then the patent office will have to check whether the patent applicant has submitted the IRCC or the internationally recognized certificate of compliance or the evidence with regard to prior informed consent or evidence with regard to execution of mutually agreed terms without which the patent cannot be considered for grant. There are lot of developments happening at the international level with regard to creation of a legal framework to give effect to the disclosure requirements and the regulatory approval requirements. The WIPO Intergovernmental Committee on Intellectual Property, Genetic Resource, Traditional Knowledge and folklore or the IGC undertakes text based negotiation to finalize an agreement on the international legal instrument for protection of traditional knowledge, traditional cultural expression and genetic resources.

So, the international negotiations is mainly focused on having a defensive protection, having a positive protection, instituting the requirement of disclosures, instituting the

requirements of regulatory approval in the international legal framework related to intellectual property rights. So, these discussions are currently undergoing in the WIPO Intergovernmental Committee on Intellectual Property Rights, Traditional Knowledge, Traditional Cultural Expression and Genetic Resources. So, currently the text based negotiation is going on and the text proposes both defensive and positive protection for traditional knowledge, genetic resource and traditional cultural expressions. The special session of intergovernmental committee will take place from September 4 to 8, 2023. This session is expected to consider the document which is circulated which contains the text of the draft international legal instrument and any other contribution of member state with the aim to further close any existing gaps to a sufficient level.

The preparatory committee of the diplomatic conference to conclude an international legal instrument related to intellectual property, genetic resource and traditional knowledge associated with genetic resource will take place in September 2023 and will establish the necessary modalities for the diplomatic conference. On July 21, 2022 the WIPO General Assembly decided to convene a diplomatic conference to conclude an international legal instrument related to intellectual property, genetic resource, traditional knowledge associated with genetic resource and other aspects not later than 2024. The diplomatic conference will be preceded by a special session of the intergovernmental committee which is expected to take place in September 2023 and by a preparatory committee of the diplomatic conference which is also expected to take place in September 2023. To conclude the genetic resource and associated traditional knowledge have constituted a distinctive and unique category of subject matter for IP protection since the emergence of modern biotechnology and modern plant breeding. The world intellectual property organization has been addressing these issues for a long time.

The WIPO diplomatic conference 2024 is expected to result in the adoption of a legal framework that provides effective measures to address the misappropriation of genetic resource and traditional knowledge. The references of all this lecture can be seen here. Thank you very much for listening to the lecture. I hope you are enjoying the course.