Biodiversity Protection, Farmers and Breeders Right

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Lecture 25 : Disclosure requirements in Patent - A comparative perspective

Welcome to lecture 25 on the disclosure requirements in patents a comparative perspective. Now in the earlier lecture we have taken up the aspect of patenting in relation to buy resources where we discussed the general aspects of how the patenting activity is also linked with the implementation of biodiversity legislation. So that benefit sharing is a critical component that is realized. Now in this lecture we will take up the following concepts. More specifically the disclosure norms in relation to patents and buy resources, how do we see applicants submitting that information. From the TRIPS agreement how do we see patent disclosure, some representative examples of a cross country context of patent disclosure norms.

Disclosure norms in the case of India, how do we see the context of non-compliance, is the applicant more burdened with disclosure norms getting more elaborated and what are the consequences of non-disclosure. These are the keywords for the lecture. So, let us begin with the basic understanding of why is disclosure important in patents. Claims that define the monopoly in relation to an invention are read in light of the specification.

The complete specification gives us the entire view of the reading of the claims from a more elaborate context. That is if the invention is a product or a process we get to know the details of the product and the process in terms of a description, in terms of a figure. How that product and process is made is known from the context of looking at the several working ways of the invention, what are the different embodiments. We also get to understand from the complete specification the optimal or the preferred working. Therefore, this is a very important bargain that is private reward of a patent right in exchange of public disclosure that is complete clear and concise details of the invention need to be given.

So, patent disclosure enhances transparency and fairness in the patent system, this is one objective. Now by disclosing the inventions, inventors are able to build on the existing knowledge and this therefore, promotes the area of science and technology. When it comes to disclosure pertaining to genetic resources and TK, what is it that we are looking at? We are looking at the context of where inventions are based on biological resources, the information or the use of it and also the traditional knowledge associated with it. Here we need to appreciate the fact that legal principles are involved, the nature of the obligation placed on the applicant needs to be considered. Because you do not know the origin of the

resource, what are the consequences of failure to comply, how does the patent office implement verify and monitor compliance in itself and how about the context of the patent office in relation to the other offices as is required under certain laws.

So, I would like to bring your attention to the TRIPS agreement which mandates conditions on patent applicants that whenever an invention is disclosed in a patent application, it needs to be given in such a manner that it is sufficiently clear and complete. So, that a person skilled in the art may be able to carry it out and also indicate the best mode for carrying out the invention. Disclosure is also applicable in another sense, if you are filing abroad the national patent office will need to know such information. So, that is another aspect of disclosure, we are not going into the detail of it which is in the case of India it comes under the purview of section 8, our interest is to look at the context of bio resources. So, generally speaking the disclosure norms in relation to bio resources and TK vary in different jurisdictions.

In some cases there is no formal requirement, whereas in many others there are formal substantive as well as procedural requirements. And in many other cases there is a lot of evidence that is to be given as part of the documentation. And in many cases patent offices do have database resources wherein examiners will need to specifically also examine this area for prior art. So, some examples of how the implementation of the source of origin or the details of bio resources and TK has been implemented let us look at that. If you look at the Andean community agreement decision 486, there are common provisions available for industrial property.

In that if you look at article 26, it is a requirement for patent applicant to provide a copy of the contract for access and also where applicable a document that certifies the license or authorization of use of traditional knowledge of indigenous or local communities has to be provided. If the applicant fails to provide this information, this becomes a very important ground for invalidation of a patent. So, such a requirement mandates, so therefore, there is a mandatory requirement part of it, whereas in many other countries there is also voluntary disclosure. Warranty disclosure is a case where the applicant is not obliged, but in the case of a mandatory disclosure applicant is obliged to provide the information as stipulated under the law. Another case of where the Patents Act of 2013 of New Zealand takes into consideration that those patents which are essentially going to be offensive and in this context which are against public order and morality, the advice of the Maori Advisory Committee is considered.

So, there are patents which where the use of bio resources can mean that those bio resources sacred to the communities, they have cultural value, they have religious value. So, it may interfere therefore, with the rights of the community which consider it as a core aspect of

their religious belief. So, the functions of the Maori Advisory Committee have also been identified in this particular case. So, you see the inter linkage of the community when it comes to the role in the patenting activity where they become a watch for preventing the misappropriation of traditional knowledge and the resources which are inherent in there for their livelihoods. So, if one looks at the advisory committee, the advisory committee particularly looks at if the invention claimed in a patent application is derived from a Maori traditional knowledge or from the indigenous plants and animals, it has a say.

And if the commercial exploitation of the invention is likely to hinder or contrary to their values. So, therefore, we see this as another important context. In the case of a patent disclosure in Peru, the once the submission is received, it is checked through whether such claims which are related to by resources or the knowledge is it a part of the collective knowledge of any particular community which is already existing. In which case again the requirement for submitting a copy of a license or the access contract is a requirement. Now the failure to comply with such a thing will lead to the refusal.

So, here in this case as well you see a mandatory requirement which is stipulated. In case of France, the once the patent application is filed, the National Institute of Industrial Property sends it to the relevant authority only after assigning the file number, no examination is conducted. Once the user compliance is identified that is the user has been compliant with respect to access terms on taking the PIC or has an agreement with the community only in such cases the examination proceeds. So, this is again stipulated under the law. So, if you see many countries post the Nagoya protocol have implemented these measures into the individual laws.

In the case of Switzerland, we come to the federal act of patents for inventions. If any false information is given in relation to biological resources, it will attract a fine. Wherever applicable, if the applicant has taken information on by resources or the use of it or the traditional knowledge information, it is important to indicate the source. If the source is not mentioned, the applicant must specifically confirm in writing and that is a requirement. So, therefore, we see an elaboration of disclosure norms more specifically with respect to them.

When we come to the context of India, section 10 is applicable where on one end there is a compliance requirement in relation to the Budapest treaty, on the other end we are also looking at the compliance in relation to the if the information is collected from any indigenous communities or local communities such information should also be disclosed. Because that comes under the compliance and the NOC from the biological from the NBA under the biological diversity act 2002. This is just one example to illustrate to you in this particular patent application which is titled a topical formulation for chronic skin disease.

If you refer to the page 10 of the complete specification, a complete detail of not only the particular species that has been used, but also how the tribal population of Chhattisgarh region uses use the milky latex is also given. So, this is one example of that.

Now when it comes to India, we have specific guidelines for TK. So, these guidelines for TK are available at the Indian patent office website which inform the applicants on how the examiner is going to look at those applications which are related to traditional knowledge. To give you in brief what is the context of the guideline, all applications which are traditional knowledge based are further classified into subcategories at the patent office as either TK chemical, TK mechanical or TK biotechnology. And wherever examiner finds a citation matching with the traditional knowledge digital library, examiner notes that and specifically also notifies to the applicant. Now the examiner conducts a TKDL search to look at the search for anticipation.

So, whenever the claims are related to extracts which are already there as part of traditional knowledge, then also we can see the guidelines applicable. Sometimes combination of plants are used for developing an invention, but if there are known therapeutic effects then again the context of TK is strictly applied. There are also cases where traditionally many components are known to have specific disease elevating properties. In such a case if the applicant takes out only one of that particular ingredient and then comes up with a separate activity, even if that is the case if it is a known activity and these are known in traditional knowledge, then again the strict application of per se TK will apply. Sometimes additive effects are also given in applicants.

So, these are the different aspects with which the guideline deals with. So, it is also a pertinent to note at this stage that India has participated in the development of the traditional knowledge resource classification. Now what is this classification? This classification is based on the Indian system of medicine, it is based on the IPC and under the IPC the TKRC classification has also been recognized. Mainly divided into these four sections of Ayurveda, Unani, Siddha and Yoga. Under each you have several classes and this is what you see in this particular illustration.

So, the examiner will typically also when you are doing a IPC search also identify these classifications as relevant in the case of applications which are based on traditional knowledge. So, now, we come to the aspect of having understood the expansion of disclosure norms in countries where there is a requirement. How do we see non-compliance arising out? Where there are guidelines which are clearly stipulated more or less the applicant is aware. When there is no when there is incomplete disclosure then we see a case of where some description is missing. Sometimes it is inadequate because it is required that more information is given.

Sometimes there is a case of wrong disclosure which is a problem, it can also attract opposition of a patent. Then in many other cases there can be non-replicability that is we are suggesting something as a source of origin, but actually that is one cannot verify or that information. There could be issues of insufficiency that can arise and since best mode is a requirement sometimes the origin the particular the if the details of the source are not clearly mentioned or adequately mentioned implementation of the best mode may also be affected. In cases of TK there are three different aspects that we look at one which is a known TK, one where it is derived from TK, another where TK is specific to the knowledge holders. So, if you look at it from the patent applicants perspective the greater the elaboration of disclosure norms greater is the burden on providing information.

So, timelines can be quite discouraging and there is also requirement of specific submissions. In this context databases can be of very handy not only that interlinking administrative authorities would really help the patent office and also related agencies more effectively work on such kind of applications which are based on by resources and IP. If one takes the example of Indian patent office how do we look at it from the PTO perspective? Determining the ambit of disclosure under section 10 of the Indian patent act becomes relevant. How much is adequate depends on how much needs to be disclosed and how much it is derived from TK. So, a practice guidance in the form of guide guidelines for biotechnology and TK are very useful.

Determining known information sometimes can be very difficult in certain context. Prior informed consent, customary law, these principles though not directly applicable as a requirement, but post grant they become relevant. What could be the consequences of non-disclosure? Refusal of grant, loss of rights, third party opposition can be initiated, patent revocation under the Indian patent act we have section 64 clearly also mentions this. So, how do you really reconcile with the context of on the end of the patent applicants, how do we look at it on the nature and scope of disclosure? The other context is the joint application of the patent act and the biological diversity act. Therefore, we have compliance additionally which need to be.

So, it is a mandatory requirement and therefore, this cannot be avoided. It is important to carefully look through the information that needs to be submitted from the substantible also the procedural compliance that need to be met. What are the remedies available for non-disclosure? This is relevant obviously, for fundamentally those countries where it is a precondition. Case law provides us an important lead to understand to what extent disclosure norms have been read in this particular area as well. Consumer impacts the overall implementation particularly when you are also a member country to the CBD.

Licenses would not be able to practice the invention if they are not very clear on the details disclosed in relation to the bio resources, the use of it and the traditional knowledge. These would be affected because the knowledge has been appropriated from them, but they have not received any benefits. On the other end, assertion of monopoly claims can severely disadvantage them. So, one looks at the patent systems, it is relevant to understand at some stage determining the nature and scope of disclosure becomes the first critical step. Equitable, inequitable conduct can arise.

So, this illustration just gives you an indication of the shifting of the pendulum. Where do we balance on one end the respecting the knowledge provided by the traditional knowledge holders, access to bio resources and the benefit sharing paradigm from the point of view of ABS on one end and on the other end looking at patent applicants to what extent we mandate disclosure. So, when we look at bio innovations and the area of commercialization coming out from the area of bio resources, we need to look at this particular creating the balance between both of these. In conclusion, disclosure norms are key to understand the claims in relation to an invention. Ensuring transparency and fairness in the patent systems has been an important context where you see the elaboration of disclosure norms.

International compliance from the point of view of the Budapest treaty for the geographical source of origin and on the other end implementation of the biodiversity legislations to those countries which are member countries to the CBD and further on the implementation of the Nagoya protocol where PIC, the MAT, the monitoring of the entire ABS part, understanding of the user and provider measures, all of this becomes relevant even for the applicants who are looking at patenting. Companies that have implemented laws and regulations governing the use of bio resources have relooked at their patent systems and have adjusted their patent systems accordingly. And as we see going forward, there is a greater compliance that is coming up as part of the legislations which are dealing with IP more particularly patent legislation. Consensus of non-disclosure of bio resources can be many. And in many patent systems depending on whether they are mandatory or have an optional or an optional system, these can be quite varied.

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