

Biodiversity Protection, Farmers and Breeders Right

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Lecture 24 : Patents based on bioresources - Recent Trends and Developments

Welcome to the lecture on 24 on Patents on Bioresources, Recent Trends and Developments. In this lecture, we will take up the aspects of the relevance of the patent legislation and the biodiversity legislation when it comes to patenting. From the Indian context, we will understand what are the requirements in relation to the Patents Act 1970 under the Biological Diversity Act 2002, some representative cases. In order to look at the implementation of IP with respect to patenting, we need to also understand the interlinked aspect of ABS when it comes to the Biological Diversity Act. Some of the recent trends and developments will also be discussed. These are the keywords for the lecture.

So, when we look at the context of inventions coming out from the area of bioresources, there are provisions under the law which are relevant to this particular area more specifically. So, today we will also take up the aspect of the context of Patent Act from the point of view of where ineligible subject matter is concerned when it comes to bioresources, patentability criteria, what are the disclosure norms applicable. There are separate guidelines for this particular area, guidelines for biotechnological products and guidelines for TK. Now, this particular area is also specific because there is also a possibility of submission of sequences, nucleotide sequences, protein sequences.

So, therefore, understanding these are important. So, we now move to the context of looking at what are not inventions when it come to the area of bioresources under the Patents Act 1970. So, as you can see in this illustration, section 3B is relevant where invention with its primary function or the intended use among other things can seriously prejudice human, animal or plant life and health or to the environment. Then we come to section 3J which is particularly applicable to plants and animals as a whole or in part are not subject matter of patents. And also those processes essential to the propagation of plants and animals are also not subject matter.

In addition, we also have a specific section, section 3P under the Patents Act 1970 where inventions which are poorly traditional knowledge or which are per se traditional knowledge are not eligible under the law. So, those derived out of traditional knowledge subject to the criteria could be eligible. We now come to the aspect of looking at patentability criteria. So, for this let us look at the definition of invention under section 2(j) of the Patents Act, where invention means a new product or a process which involves an inventive step and is capable of industrial application. So, when we look at the three important criteria of novelty, inventive step and utility as we see from industrial

application, there are also norms with respect to how the area of bio resources are also looked at.

When it comes to patentability criteria, this is a very simple illustration to indicate to you how novelty is checked and how inventive step is checked. When we look at novelty, we look at a one to one correlation that is if you look at a complete one single prior art in this case overlapping with the invention, then we say identity is met. So, that is how we look at a complete overlap. So, for this we take only one aspect of the prior art either it is one single publication, one single patent document, one public use. But when it comes to the inventive step understanding, a particular invention may have met novelty, but it may not meet the inventive step that is it may be novel, but if you really bring together a set of prior art, still you are able to achieve the invention in which case we say the invention lacks inventive step.

So, this is where we are looking at the combination of the prior art yet you are coming up to the invention. Now, when we come to the area of by resources, we are looking at the imprints in the prior art in the form of the use of prior resources, what are the function of that particular by resource, if it is the same function that is being captured or if it is traditional knowledge associated with the resource. So, as we move on we will take up some of that. So, this is how we see in the animation. Then we come to the context of disclosure norms, when we look at the interpretation of patentability criteria we are looking at it from the point of view of reading that from the basic disclosure that is the complete specification in the case of patents.

Now, the complete specification has two parts the claims and the written document. Now, the written document has the description, the working of the invention and also what is the optimal or what are the preferred ways which we call the best mode. So, written description, enablement that is the several working ways and best mode are relevant when it comes to. So, in the area of biotechnology especially in the area of by resources patenting, those differences can be differences in the pH, differences in temperature, differences in how the invention is implemented. So, disclosure norms vary in different jurisdictions.

If you look at the Indian Patent Act, it is under section 10 4 where we are reading specific aspects that are again relevant not only to the general areas, but more specifically also to the area of by resources. Particularly I would like to draw your attention on this particular aspect of where the source of the biological material needs to be mentioned as per compliance under the Budapest treaty when it comes to patenting in India. Not only that disclosing the source and origin of the biological material in the specification is necessary. So, there is a requirement of compliance. So, with that we come to the understanding now

of where is the interface of the patent legislation and the biodiversity legislation when it comes to patenting on by resources.

For instance, if you are looking at the Indian Patent Act, applicants who are filing patents based on by resources in India derived from India will need a no objection clearance from the NBA. So, this is a very very important step. So, what happens? Let us say that this filing of the patent application has happened, simultaneously you have also filed the application for no objection clearance at the NBA. Until the NBA has cleared and you have obtained an NOC, even if the patent is examined and put in order of that it is gone through the steps or the verification as per the patentability criteria and all of it, still it will not be put in the order of grant because the NOC is still not obtained. So, therefore, before the sealing of the patent at least you must get the NOC from the NBA, this is a critical requirement.

If you do not get an NOC then yes, your grant will be on hold. So, therefore, we have the twin application of the Patents Act and the Biological Diversity Act in this particular case. So, the NBA's role in relation to IP is specifically under section 6 of the act. So, when the applicant applies to the NBA, then the procedures that are outlined under section 6 from the substantive end of what is examined and how the application must be submitted to how the clearance is given is there under the Biological Diversity Act. This is critical for the linkage between ABS and IP.

To ensure that those who are appropriating by resources for patenting activity need to do benefit sharing, we have an ABS mechanism. So, the procedure to seek NOC from the NBA is also need to be understood. It is not that all IP is a for which we need to take a NOC, there are exemptions. So, we will understand that. Let us take a one by one each of these.

So, the NBA's role is carved out under section 6 as you can see in this illustration. The permission of the NBA must be obtained and is a critical requirement. By granting approval, the NBA will impose a benefit sharing or a royalty or both conditions such that benefit sharing is available to the people who have actually provided the resource or the traditional knowledge associated with the resource. So, then we look at the procedure. For the procedure, there is a specific form.

Form 3 needs to be filled by the applicant giving the details of the resource and to what period of time the resource needs to be and for what purpose the resource is being utilized, what kind of activities are undertaken and there is a specific timeline for the disposition. So, after the approval is given by written agreement, the ABS form is also submitted and subject to commercialization the application of ABS comes into picture. So, this is the

form 3 as you can see details of the biological resource and associated knowledge, geographical location, if there is a traditional knowledge associated that needs to be disclosed as well and what are the research and developmental activities carried out in relation to the bias. So, NBA is having a monitoring role so far as even IP or even actual IP or even potential IP that you would be deriving from bio resources. So, rule 18 is applicable and rule 20 and there are specific procedures which are applicable in relation to the filling of the forms and the submission.

Rule 19 outlines the specific aspect of how the procedural aspects of taking the NOC are required. So, this is applicable to Indians as well as non-Indians who are using bio resources from India. So, an application and then the process of notifying as well as the grants are affected. Now, this is the procedure for on how after the applicant submits the NBA has a specific expert committee on ABS which will screen and if necessary further inputs may be necessary from the applicant those will be looked at and ultimately the NBA may clear the applicant or may not clear the applicant for want of more information. And so, you have two conditions in which the NBA may give the approval or may not grant the approval and this will be published on the NBA website.

In the case of plant variety protection such an exemption is there where for plant variety protection one need not approach the NBA. This is so, particularly for more of patents. So, for plant varieties since there is a separate law plant variety protection farmer rights act 2001, it does not come under the purview of the biological diversity act 2002. An important component of the ABS is actually the criteria for equitable benefit sharing. So, rule 20 is applicable where while granting the approval to any person for access or for the transfer of research results or in this particular place as we are discussing the application for patent, then NBA would impose terms wherein monetary or non-monetary or both may be applied to the applicant in relation to the access to the resource.

For which we have an elaborate guideline notified under section 21(4), the ABS guidelines 2014. Regulations 8, 9 and 10 are relevant when it comes to the purposes of IP rights. So, here regulation 8 is more of looking at the general procedural formalities whereas, regulation 9 stipulates two different conditions in which the access and benefit sharing is looked at. Where applicant himself is commercializing and in another case where applicant is assigning or licensing out. So, two different mechanisms are identified.

Then it is also part of the regulation where regulation 10 is applicable where with respect to the sharing of the benefits, the state boards are also notified. Now what you see in this is the general status of the ABS applications when it comes to form 3. So, we see increased number of applications which have been filed in relation to bio resources and IP. Some examples of the representative examples where the context of benefit sharing has been

identified. So, prior to the biological diversity act 2002, a very notable example is the case of the Aarogyappacha, the scientific name of the plant being *trichopus zeylanicus*.

The Kani tribe would stave off hunger by eating the leaves of this particular plant. So, scientists who were looking at identifying important germ plasm who were going with the Kani tribe members from the TBGRI found that this is a very important plant to work on. Later on with development this led to the development of the Jeevani drug. So, for the resource and the information on the resource, the Kani tribe people received benefit sharing and this is one example where we look at prior to the biological diversity act which is has been applicable. So, this is how we see that the tribes which are sharing the information are also receiving benefits out of the information that has been taken from them.

We have several examples of the twin application of the patent act and the biodiversity act when it comes to patent applications. So, in a case where the application has been filed based on a composition of lycopene and beta carotene, the patent claims were rejected on many other aspects including the aspect that the applicant has not sought a clearance from NBA. Now the applicant in the hearing mentioned that the source was China and Spain and since the permission is only for those materials which are taken from India section 6 of the biological diversity act should not be applicable to them. However, in the speaking order the controller mentioned that these are widely available, the extracts that had taken and those plant substances are also widely available in India and it seems very unlikely on how the availability of such a product would be there. So, if the product raw material is coming from some other country then it is reasonably available at affordable price is a question.

So, therefore, invoking section 83 the controller refused for a grant. Yet another example of where another formulation which again came under the purview of the biological diversity act, the requirement for the disclosure of the geographical origin and the biological material was a requirement. In this case also the NBA, NOC was not obtained and here again the controller has insisted that these are the plants which are widely available in India and used in traditional medicine and it is important that if these resources are again taken from other countries the when the product is really available in India it will be not at a reasonably a price that will be where you can use it for the Indian public. And in this context in this case also the controller refused to proceed with the application and mandated the applicant to seek NBA clearance. So, but there are many other cases where you see that they the controller has agreed to wherever clearly distinctly those resources are taken from other countries there is no requirement of a NOC.

So, we do see both the sides of the cases on both ends. There are also instances where

Indian agencies have filed for revocation of patents because the information has been sought from India. In this case the conventional breeding practice of where virus resistant melons were a part of the research this information was used to develop the variety of melons by genetically engineering them. So, since this information has been typically sought from the work that is done in India. So, in this case the EP patent was opposed, NBA had filed an observation for non-compliance where the applicant should have sought the clearance from the NBA under section 6.

So, when we look at the context of ABS and IP we discuss the context of section 6, but when we look at ABS regulation itself we see the relevance of the need to monitor access to resources for biosurvey, bio-utilization under section 3, intimation to the state board whenever activities are taken up in relation to research on bio resources from that particular state 21 from the point of view of looking at the core aspect of looking at benefit sharing as an important component of access. So, when we look at the overall picture we look at the context of the ABS and IP from this entire perspective as well. Some of the recent trends that we see that the duty to disclose is now varying in different jurisdictions some do not have a requirement for where there is a requirement you have elaborately either incorporation in the patent law or a separate legislation wherein the patent authority by way of submission has to also look at either the using of the database with respect to traditional knowledge or it has been the case of where the separate legislation where either the traditional knowledge holders need to be consulted for the clearance. So, when we look at the duty to disclose non-compliance could lead to rejection of patent applications this is one aspect of it. Today we know that intellectual property on bio resources is also very important area.

The WIPO has launched WIPO green in 2013 where one can actually search for patents which are which deal with sustainable solutions. One can also look at the platform where you can identify those who have provided technology into the WIPO green to those who are also seeking technology. So, this is a very interesting platform for one to look up and interact and also identify solutions. Most recently we looked at the context of the high seas treaties where again the area of marine bio resources and IP has also raised a important is also a very important context when it when you look at the international arena. So, what would be the context of looking at biodiversity appropriation from areas beyond national jurisdiction is one important thing which is there for the future for us to see.

And then of course, we see sustained efforts from the WIPO intergovernmental committee on genetic resources and TK since the time of 2004. And today we see the draft international legal instrument being discussed and we hope to see the finalization of it very soon. But this is also spelling out the clear context of what should be the glossary in relation to traditional knowledge, how TCEs are incorporated into it and what should be

the mechanism. On the other end we are also looking at the recent trends of how digital sequence information is being looked at from the multilateral perspective on looking at access and benefit sharing and what information and what how do we look at sharing of that information. The COP 15 decisions have been relevant not only that from the point of view of the Nagoya Protocol also their decisions which are also emerging to be important to look at the overall mechanism.

So, concluding we now begin to note that in many other countries we look at the application of the patent act where disclosure norms spell out clearly the need and requirement for the source of origin and also the use of bio resources if they are linked with traditional knowledge and a linkage with access and benefit sharing. Now access and benefit sharing guidelines determine how the benefit sharing need to be done. When we look at the Indian context we see an interesting set of cases in relation to the twin application of the biodiversity legislation as well as the patents act. Internationally we see several trends on the importance of the linkage between IP and bio resources and the potential and also the relevance of the biodiversity beyond national jurisdictions and the implementation of sustainable IP solutions.

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