Legal and Regulatory Issues in Biotechnology
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Module – 02
Intellectual property Rights and Biotech Inventions
Lecture - 10
IPR issues in Plant biotechnology

Hello all welcome back to our session in the Module 2. So, in today's discussion we would be dealing with some aspects of the Plant Biotechnology in particular and IPR issues with respect to plant biotechnologically derived product.

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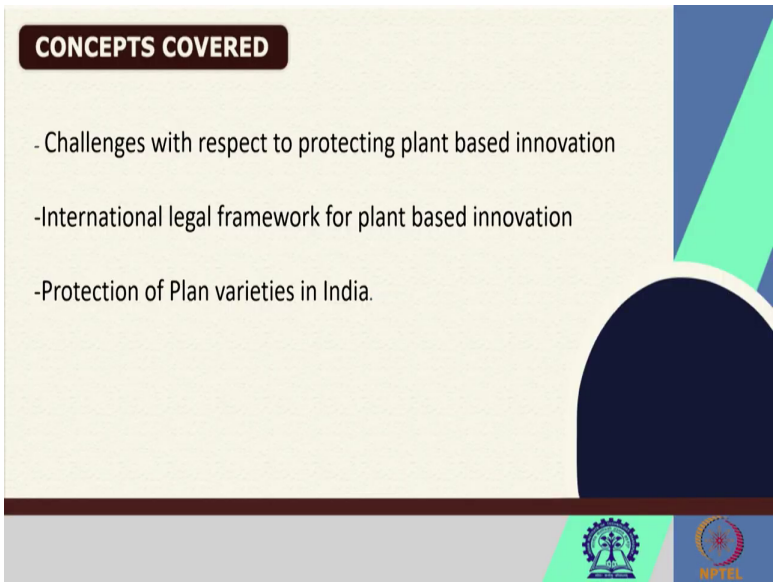

So, in earlier classes we discussed about the various IPR challenges particularly with respect to patents, and how the various products or components of these plants or animal cells, when it is isolated or when it exist in different forms, its issues from the legal perspective, the ethical perspective as well as certain technical aspects from the angle of patent.

But when it comes to plant biotechnology, the plant biotechnology may be utilized for the production of new varieties of the plants as well as certain metabolites or even pharmaceuticals which may have been derived from any plant extract or any plant component.

So, there are various products which may be generated from the plant biotechnological process like the animal one. The inventions with respect to the animal components using the biotechnological product has been majorly protected by the patent in the intellectual property arena. In case of the plant based innovations patent is not the single option, we have other options as well through which the plant biotechnological product particularly new variety of the plants may be protected.

So, that is a complicated circle of issues which needs to be understood from a general perspective. So, in today's class I would be basically covering some challenges with respect to protecting the plant based innovations and what are the existing international legal regulations to protect plant based innovations and why those regulations are required and finally we will come the current status for the protection of the plant varieties in India.

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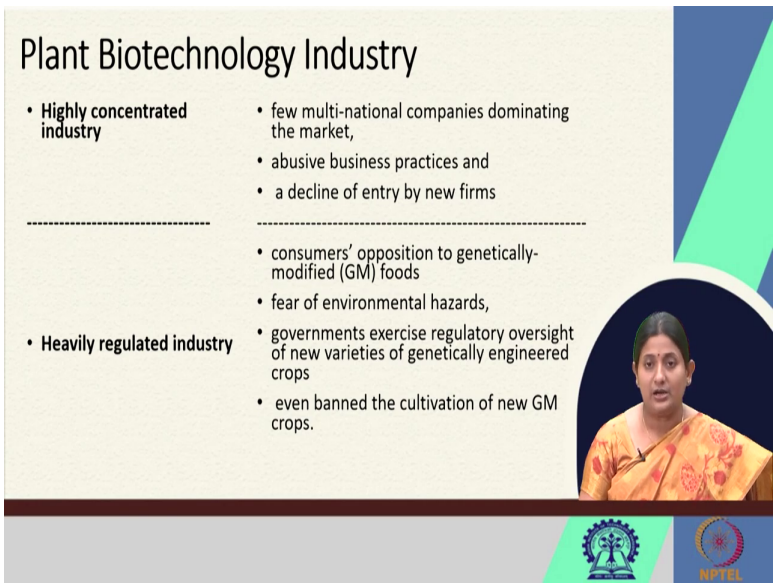

So, if we have a look into the plant biotechnological industry there are majorly two challenges, first one the plant biotech industry is highly concentrated industry. If you will search you will find a very handpicked number of plant biotechnological based companies that are into the domain of development or the new plant development compared to the other sector of the biotechnology.

So, there are few multinational companies like Monsanto, DuPont, dominating the market and in majority of the instances it has been seen that since there are few dominant

players. Many a times they indulge in the abusive business practices or in anti-competitive practices. And somehow the companies keep on merging with each other or entering into some sort of the agreements within each other. And that is also a reason, why there is a decline in the entry of new firms into this industry.

The second challenge which is from the regulatory point of view, is that the plant biotech industry is highly regulated industry. There are ethical concerns like the consumers' opposition towards the genetically modified food.

So, depending on the country of the origin if you see there are many instances where in the European Union (EU) the genetically modified crops are not allowed to be produced. So far, in India we only have one genetically modified plant that is the BT cotton which has been given approval for commercialization.

So, there are lots of oppositions and challenges to it, because there are fear for the environmental hazards, the unknown effects of the genetically modified plants with respect to our environment or the other ecological factors which are associated with plants.

And then the government also sometimes adopt stringent regulatory mechanisms to control these genetically engineered crops, in order to mitigate all the safety or other concerns. So, definitely it is the government's prerogative to control these things. Thereby in certain instances the GM crops have also been banned.

So, under these kind of circumstances there are industry dimension as well as the regulatory dimension. We again come back to the concept where we need the protection for the innovation in this domain and for that people or stakeholders have adopted the different IP measures.

So, in this case different forms of IPR also relevant like patents. Yes, if it is a new product or a process which is derived through the plant biotechnological process it may definitely be a patented. If it meets the required quality or the criteria of novelty, non obviousness and industrial applicability.

But again in many countries the new plant varieties cannot be protected through the patent mechanism because the whole plants or animals are not allowed to be protected

through patents, for example in the India and Europe and there are other countries as well. So, in those cases there we have other option called the plant variety protection, it is also another form of the intellectual property right.

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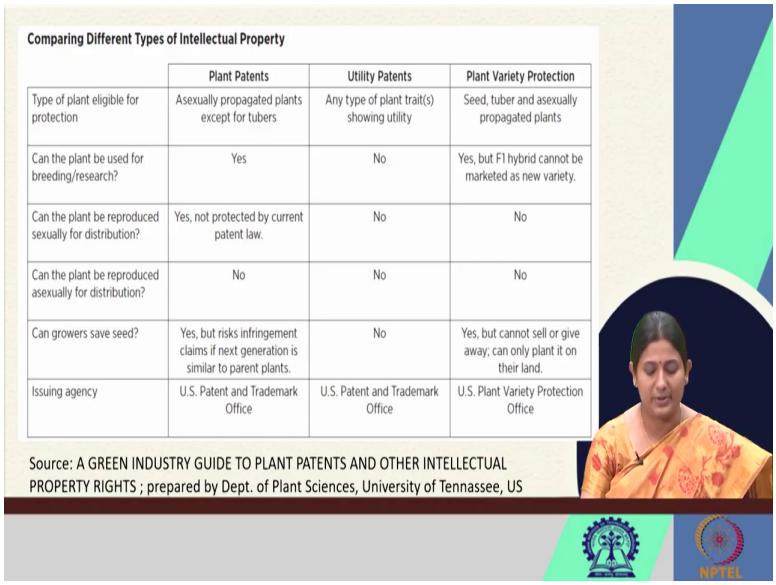

	Plant Patents	Utility Patents	Plant Variety Protection
Type of plant eligible for protection	Asexually propagated plants except for tubers	Any type of plant trait(s) showing utility	Seed, tuber and asexually propagated plants
Can the plant be used for breeding/research?	Yes	No	Yes, but F1 hybrid cannot be marketed as new variety.
Can the plant be reproduced sexually for distribution?	Yes, not protected by current patent law.	No	No
Can the plant be reproduced asexually for distribution?	No	No	No
Can growers save seed?	Yes, but risks infringement claims if next generation is similar to parent plants.	No	Yes, but cannot sell or give away; can only plant it on their land.
Issuing agency	U.S. Patent and Trademark Office	U.S. Patent and Trademark Office	U.S. Plant Variety Protection Office

And if you see the country like the United States (US) they have a different mechanisms for the plant patents, which is a patent system particularly for the plants. Also they have the normal patent system which is known as the utility patent system through which a plant biotechnology based invention can be protected or also we have this plant variety protection.

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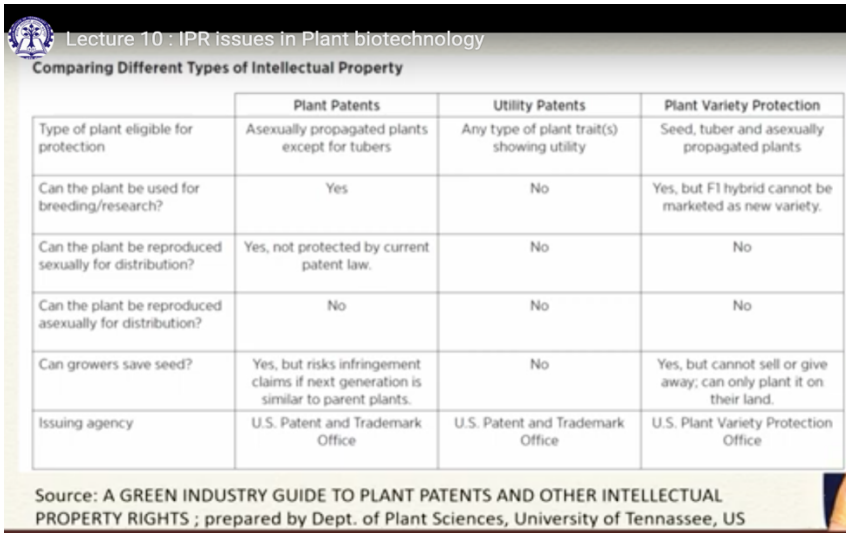

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So, this is a chart which I got from one of the guidance document from the University of Tennassee I thought of sharing this with you. So, there they have compared the different types of intellectual property protections and how they are different in case of the plant biotechnology.

So, for example, in case of the plant patents which is one of the earlier system for the protection of the plant varieties, in 1930s. Here, the domain of the protection remains constricted to the asexually propagated plants except the tubers. You have to understand like tubers like potatoes and other sweet potatoes variety those are the kind of a stipple food used in those countries as well.

So, those products are kept out of the purview of this plant patents. So, once the patent as the concept of patent is a monopoly right which is given for a defined period of time that is 20 years. Within that 20 years, generally the patented articles or patented products are not allowed to be used by the others.

But sometimes we have certain exemptions like - 'research exemption' where the other innovators can use that inventions for their research purposes or academic purposes, but in case of the plant patents again we do not really have the permission to use the patented plants into the breeding or the research program while developing a commercial variety. Till this research is ok, but if you are going to develop a variety or using the existing plant species that is not allowed.

And similarly, for the third point, can the plant be reproduced sexually for the distribution? If you have the right yes once you buy the plant then you have the right to again sexual reproduce that thing, but again for commercial purposes, if you want to sell that same variety in terms of brand in that same brand name or the same patent it may not be possible.

Then again, whether the grower can save the seed after the first generation has been grown? Yes, you can save the seed, but again there is a risk for the infringement if the next generation is similar to the parent plants and if they are because in many a times once the seed has been patented it is only used for the first generation or you cannot save and re sow the seed.

So, this is the issues with respect to plant patent. If it is a plant or the technology you cannot really use the technology for producing the other things without the permission of the patent holder. The plant variety protection is little bit different from the plant patents in terms, it includes all the new varieties of the plants or the seed tubers as well as the asexually propagated plants.

And here there are research exemptions, but you cannot market the F1 variety or the first generation of the new variety which has been produced by a cross of the genetically modified plant with the another plant. So, those F1 type varieties cannot be commercialized without the permission of the parent plant patent holder or plant variety protect the authorized registered user of that plant variety.

So, there are lot of variation between the three things. I will just give you some examples to just clarify it. For example there is a person who works in a particular nursery and he, by mistake or deliberately steals some kind of a new plant variety which is protected by a patent and then he tries to recultivate that plant or asexually propagate that plant or anyway by any method and then tries to sale that. If the company knows that the original patent holder knows that the person is now selling the same variety of the plant, as it may be examined scientifically and it can be proved that both the things are same, means the unauthorized selling of that thing of that real patented plant then in that case the person is liable for infringement.

And sometimes like if someone is buying tissue cultured derived plant and where there is no information of whether that plant is protected under the patent or any other intellectual property right.

And if someone again re propagates it or tries to develop seedlings from there or up shoots from there and tries to resell it, then it might be a problem. Even though you have utilized your labour and you did not know that information, but once you receive any objection from the parent company saying that you are not suppose to do this because this is covered under a patent or a plant variety protection, then as a consumer you may not be able to use that variety for commercial purposes.

Yes, if you have bought it for personal use then definitely you can use. So, in the last class we have discussed the case regarding this Monsanto where in one of the cases the person bought the seeds which are generally used for animal feed, but now he tried to use

that as a seed for growing plant and he claimed the exhaustion doctrine. But there the court also denied that in such cases and for these kinds of articles the exhaustion doctrine cannot be applicable.

So, like patents in case of technical inventions, the plant related inventions get patents, and are a strong deterrent. But the problem remains for the country where they do not recognize the patent system for the new varieties of the plants, like India.

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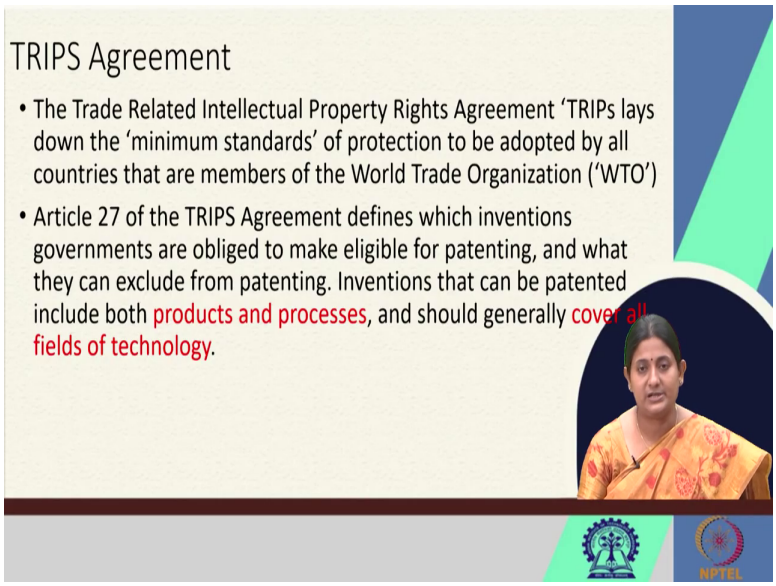

So, why there is so much of variations among the countries when it comes to the plant ?As you know any country's patent policy or IP policy is basically designed on the countries dynamic what will benefit to the country as a whole. So, we have our TRIPS agreement that is the Trade Related aspect of Intellectual Property System. So, the TRIPS agreement is rectified under this WTO. So, what is this TRIPS agreement?

The TRIPS agreement is a first of it is kind of international agreement where it lays down the basic 'minimum standards' for the protection of the intellectual property; different aspect of the intellectual property not only for patents, copyrights, trademarks, but all the forms of the intellectual property rights are covered under the TRIPS agreement.

So, in 1995 the TRIPS agreement came into existence and all the member countries of the World Trade Organization became party to this agreement. So, depending on the

nature of the country whether it is a developed or developing or under developed nations, the countries were given certain time period within which they have to change or modify their patent system as per the minimum standard.

So, even though there is a debate regarding whether these minimum standard should be there or not, but we are not going to that discussion, but anyway since India is also a member country to the WTO. So, India also signed this agreement in 1995 and it got 10 years of time period to modify or change it is the change its existing legislation on intellectual property right.

So, one of the provisions of this TRIPS agreement that is the Article 27. So, the Article 27 defines the invention or defines which kind of the inventions or what aspect of the inventions can be patented and what can be excluded from the patenting procedure. So, here it emphasize that the inventions that can be patented includes both the products and processes.

So, under the TRIPS agreement now every country have to give protection to both products as well as the processes and it should cover all the fields of the technology. So, it would imply that it should cover the plant technology as well. So, before this, India did not recognize the product patent after ratification of the TRIPS agreement India has to change its Patent law and in 2005, now we also recognize the product patents.

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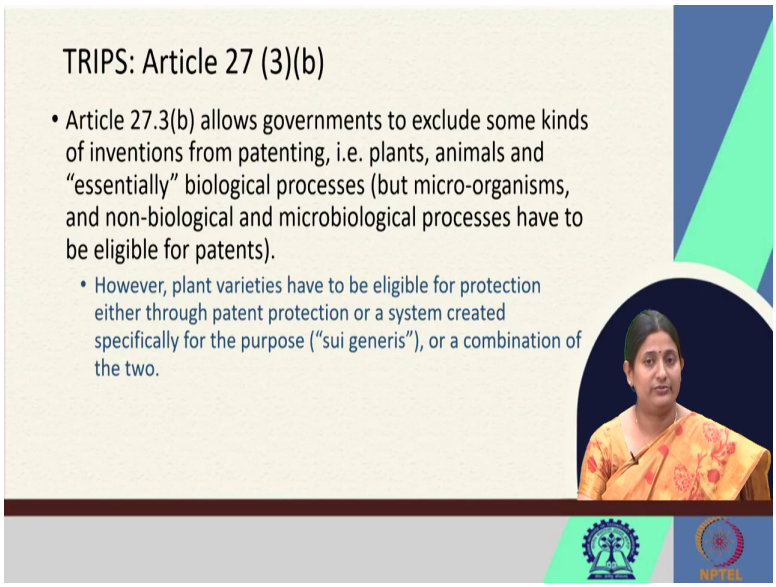

Particularly with respect to the plant patents the Article 27(3)(b) is the important one, where a under this provision it allowed the governments to exclude some kind of inventions from the patenting. For example, plants, animals and other "essential" biological processes excluding microorganisms or non-biological and microbiological processes can be excluded.

So, it is the countries' discretion, if they want, they may exclude. So, it was again up to the country if they want to exclude the plants, animals or essential biological process. However, it is mentioned as a provision that the plant varieties have to be eligible for the protection either through the patent system or a system which is specifically created for the protection of the same or a combination of the system.

So, the country if they want they can apply the current patent system for the protection of the plants or if they want they can create a completely new set of regulation or new system for the protection which is generally known as the *sui generis* system or both the ways also can also be protected can be adopted for the protection of the plant based innovation.

Now since the TRIPS gave the flexibility that it is up to the discretion of the member countries how they should go about the protection. So, now different countries have different standards.

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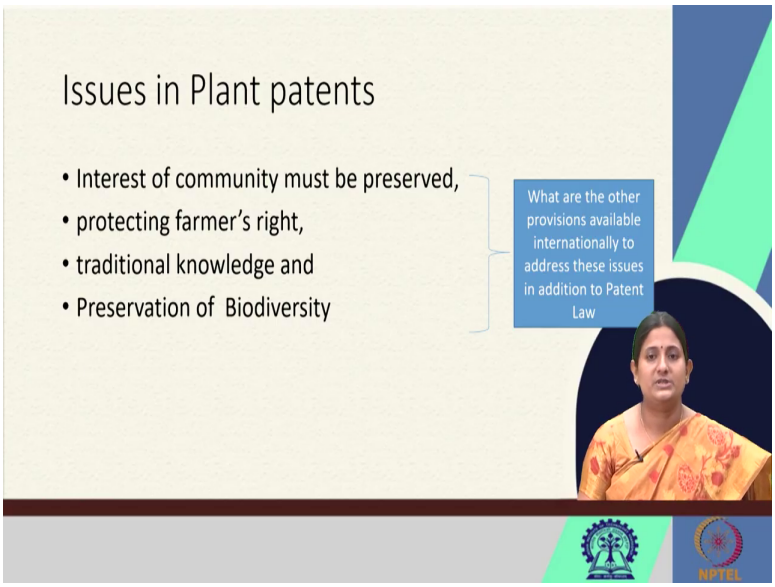

But again when we talk about the patents with respect to the plants then countries like India or other developed or underdeveloped countries face other challenges with respect to it. For example, how can we preserve the interest of the community if something has been patented for example, if some plants has been identified as a potential source for any biopharmaceutical substance.

And if a multinational company or a multi-billion industry takes a patent over that and they keep on producing without giving any benefit to the society or the community from where the product has originated then nothing can be done because it is patent protected.

So, what is the way out for that? What about the farmers right? Many a times it has been seen that the patenting has laid to the increase in the pricing. I just discussed the Monsanto example in India where the BT cotton seeds were sold at a high price to the other seed companies because the licenses were given by Monsanto to other seed companies for the BT cotton.

So, apart from that licensing fee they also charged certain trade fee for each packet of the seeds which you sell. You have to give certain percentage of that as a trade fee, means the new character which they have developed through the patented invention and for that Monsanto in India was charging around 1200 to 1400 rupees per packet.

So, there was an issue and it was checked by the competition commission of the India, whether or not the Monsanto is adopting any unfair means or is it coming under the purview of abuse of the dominance? So, those things has been seen in general patenting with the price hike as well as the inaccessibility by the farmers. The farmers cannot give such high amount to buy the seeds and carry out their normal farming procedure.

And, what about the traditional knowledge? if somebody misappropriates the traditional knowledge so what can be done and how can we preserve the biodiversity? If something has been patented that may be over exploit and there may be over exploitation of the resources. So, all these issues came up when the TRIPS agreement proposed that the plant related invention can also be protected through the patent mechanism.

There were lot of deliberation upon the that clause, but finally, country like India and other developed nations thought of creating *sui generis* mechanism through which (as

India is a season agricultural based country) the interest of the farmers, interest of the other community and biodiversity can be protected.

So, before enacting any *sui generis* legislation it was essential to understand what were the other existing system for the protection of such plant varieties. So, for that reason it the other system of the protection was studied to decide what kind of sui generis system can be adopted in context of India.

So, that everyone benefits. Because you have to promote the industry also, you have to preserve the biodiversity also and you have to keep the interest of the farmers as well.

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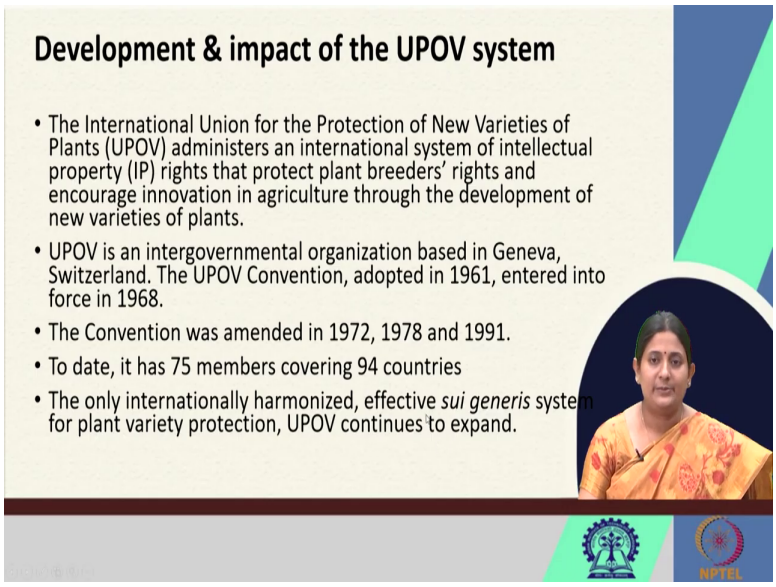

So, we needed a sustainable way through which each of this stakeholder can be benefited. So, at that time another system of protection was available which is known as the UPOV system, 'The Union for Protection of the Plant Variety' in the Europe system. So, basically it is an international system for the protection of the IP rights for the plant breeder and it encourages the innovation through the development of the new variety of the plants.

So, UPOV is an international organization based in Geneva and it was adopted in the year 1961 which entered into force in 1968 and it has been amended three times or so far and there are more around 94 member countries to it and it is now regarded as one of the

harmonized *sui generis* system for the protection of the plant varieties and many like gradually many countries are trying to be part of the system.

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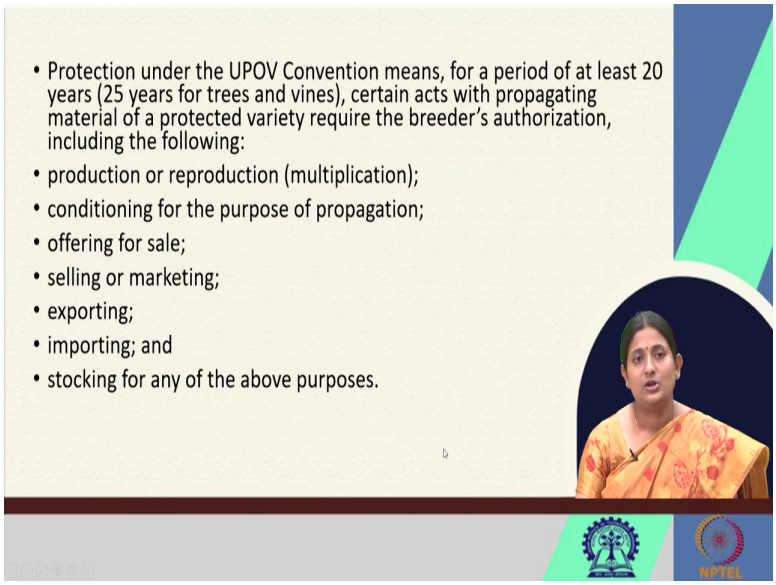

So, under this UPOV certain protection like patent for 20 years, similarly so the protection for the new or specific right for developing a new variety was given to the inventor or the plant breeder. So, at least 20 years or 25 years for the trees and vines were given and it gave certain powers to the breeder or authorized breeder who has produce the seeds.

Means without the permission the plant breeder no one would be able to reproduce those plants or no one is allowed to condition the plants for the propagation or they can sale the plants or market the plant or exporting and importing or stocking is was not per allowed without the permission of the authorized plant breeder.

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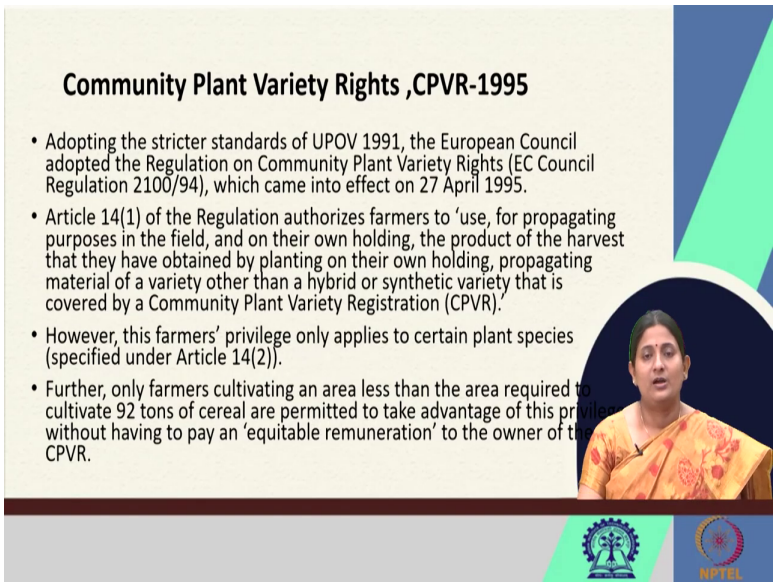

So, that was one of the system which is widely acclaimed and widely adopted in the European Union and after that, in 1995 the European Union again adopted certain stricter standards based on that same UPOV template and this is known as the Community Plant Variety right.

So, Article 14 of this Community Plant Variety right, authorises the farmers to use, for propagating purposes in the field and on their own holdings the product of the harvest that they have obtained by planting their own material. And like even though the plants are protected under this Community Variety Registration (CPVR) System, but still the farmers are allowed to use and save the seeds for the next generation of the cultivation.

But again there is a limitation or the condition applied to this provision, which is that, only those species which are specified under this provision of the Community Plant Variety Rights were allowed to be propagated in the next generation.

And the farmers who were cultivating the area which results in 92 tons of the serials where permitted to take this provision and they do not have to pay any equitable remuneration to the owner of the CPVR. So, it is a first time, certain exemptions where given to the farmers while using a registered variety or a new variety.

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Apart from this, there were other international system like we have a convention of biobiological diversity and we have this international treaty on the plant genetic resources for food and agriculture or which is popularly known as the International Seed Treaty.

So, this seed treaty is basically an international agreement which is based on the Convention of Biological Diversity (CBD) which aims at guarantying the food security through the conservation, exchange and sustainable use of the world's plant genetic resources for the production of the food and agricultural purposes and it also aims at fair and equitable benefit sharing arising out of its use.

So, these conditions were again available internationally. So, these things has to be taken into consideration before any country like India legislates in legislates its own *sui generis* system.

And this Seed Treaty also recognized the farmers rights. Anyway the farmers' rights are always subjected to the national laws and it also recognizes the protection of the traditional knowledge and the need for equitable participation in the case of benefit sharing and utilization of the plant genetic resources.

And also the right to participate in the decision making processes at the national level and related to other matters which are very much important for the conservation or the

sustainable use of the plant genetic material. So, these are the few international regulation available at that period of time which has to be taken into consideration before defining whether or not the plant patent system is useful or will have negative impact on the farmers right or the other stakeholders.

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This seed treaty also established a multilateral system for the excess benefit sharing, to facilitate the plant germplasm exchanges and the benefit sharing through the standard material agreements, so that the different biological resources or germplasm can be transferred from one country to another for the exploitation for research or art or commercial purposes.

But again keeping a track of the things that from where the material is originated; how it has been used, so, that the benefit sharing or that processes can be properly streamlined. So, these were the few provisions and patent raised some concern because if you do not mandate the provision of identification of the resource or identification of the origin that may later lead to a problem while the benefit sharing.

But anyway the many countries believe that patenting system is something different. It has not should not be read in the conjection with those because patent is just through the novelty and inventive step or utility of the invention. So, whether the benefit has been shared or not so that is the again that will come under the different aspect of the national

law and the country is free to take other aspect other measures for that but that should not hamper the patent system.

So, a lot of debate has happened in the WTO itself regarding the clause that whether or not pay plants can be patented or what are the other provisions. So, next we will be discussing about the plant variety protection in India.

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So, having said the, international regulations or existing provisions for the protection of the plant, India thought of enacting a *sui generis* legislation after it rectified the TRIPs agreement. So, in 2001 India enacted the Protection of the Plant Varieties and Farmers Right Act. So, if you mark it carefully, this is not only called as protection of the plant variety, but also Farmer's Rights Act because it also emphasized on the rights of the farmers.

So, the basic objective of this legislation is to develop an effective system of protection, where the investment for the research and development purposes from both the public as well as the private sectors can be maximized. And the development of the new plant varieties can be promoted as well, which will give appropriate returns to both, the investors as well as the consumers and the stakeholders.

And it aimed at facilitating the growth of the seed industry in the country through the domestic as well as the foreign investment which will ensure the availability of the high quality seeds and planting material to the Indian farmers.

Because you know if you do not give a mechanism for protection, the foreign companies might not be willing to come here and invest money unless they are secured about their invention. If anyone can freely use the protected inventions without any legal remedies for the rightful owner, then it would be problem for the company and they will not want to come to India and invest here.

And this act for the first time in India recognized the role of farmers as the cultivars and conservers in the contribution of the traditional rural or the tribal communities in the country and it tried to reward the people who have played a part in conserving the biodiversity . It also enacted the provision of the benefit sharing and the traditional rights of the farmers are protected under this legislation.

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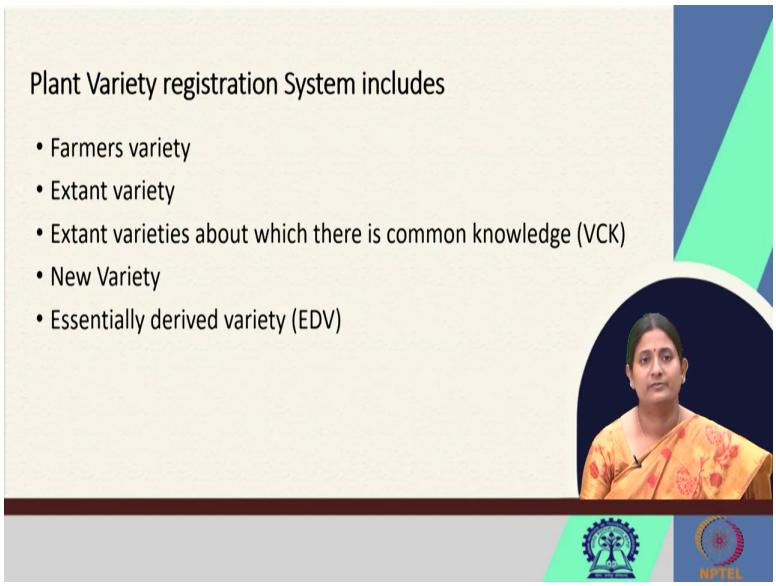

So, if we go deep into the plant variety registration system, we will see there are different varieties, with the nomenclature of the different varieties which are generally defined and protectable under this legislation. For example, we will hear about the farmers variety; extant variety; verity of which there is a common knowledge ; there are new varieties of the plant and essentially derived plants.

So, first three varieties like farmers variety, extant variety and varieties with common knowledge are generally those which are already existing and when you talk about the new variety or essential derived variety it has new varieties which may be developed through the intervention of the biotechnological process.

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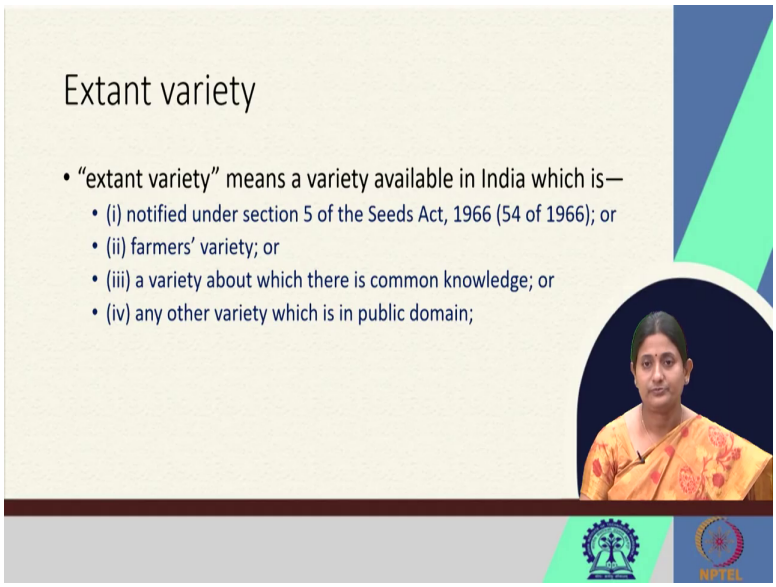

So, if we look into the definition of the "extant variety" so, it basically define the extant variety are defined as the varieties which are available in India and notified under the Section 5 of the Seeds Act. So, these are the notified varieties, already been notified under Seed Act.

And it includes the farmers variety, farmers variety means the varieties which the farmers have been cultivating in general. So, as our ancestors have been cultivating some kind of the variety which we generally use. So those are also the farmers variety.

And a variety about which there is common knowledge means maybe these are the wild race varieties which were in use at certain point of time, but gradually due to like better varieties those varieties are not in use for example, a rice variety that may take a long period of time to cook to cook.

As, because we do not have much time to cook these days. So, we may adopt a variety which will save our time. So, those kind of varieties are gradually not in use, but still

they exist in the nature. So, those varieties generally come under this provision variety about which there is a common knowledge, but may not be used that rampantly.

And any other variety which is in the public domain, are also protected through this varieties, for which there are many other varieties which are in public domain and can also come under the purview of the extant variety and may be protected through this Plant Variety Protection Act.

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Yes, as we have already discussed. The farmers variety may be wild relative or the land race of the variety about which the farmers possess the common knowledge. One of the beauty of this legislation is that the farmers varieties are exempted from the application or the registration fees and there are different provisions which are generally not applicable to the farmers variety.

So, now, here we have to understand the difference between the plant patent system. In patent the novelty is one of the critical aspects, means it has to be new. But when we talk about the extant variety or the farmers variety generally these are not new they are already existing in the nature. So, that novelty concept is not there, but we have to see that this plant variety protection system has a kind of a 'registration system'.

It is basically you are registering the varieties which either you have developed or either you are aware or you work on that as a farmer or as a breeder. So, this allows you to

register those varieties under the plant variety protection system and it is that novelty aspect it different from the patent.

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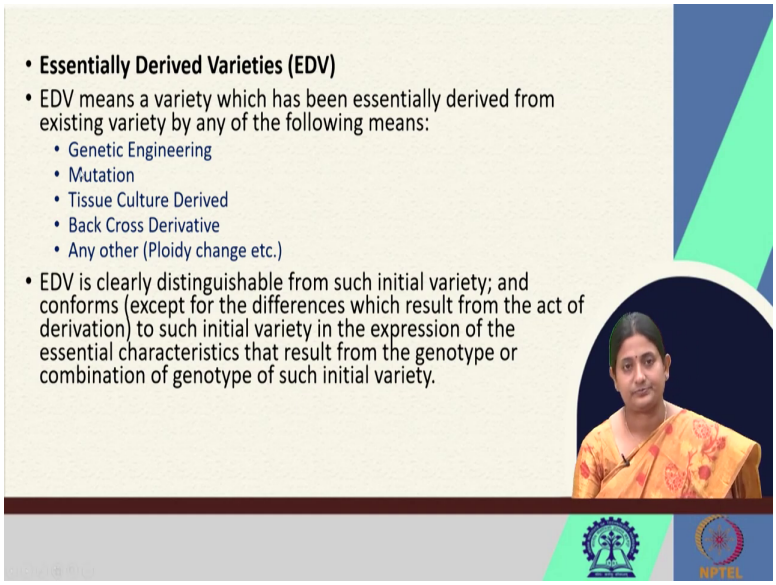

Now coming to the other categories of the plant variety which can be protected under the Plant Varieties Act is the 'Essentially Derived Varieties'. Now, the essentially derived varieties are the varieties which are generally derived from an existing variety by biotechnological interventions.

Like genetic engineering processes or by mutation or by tissue culture process or even by back cross or any other like ploidy changes. So, if someone is developing a new variety from an existing variety by changing one or more character so, that may come under the purview of the essentially derived variety.

And new variety is something new. So, any new variety of the plant like this BT cotton for example. So, it is a technology where the BT gene has been inserted, but the plant so, or the plant is a now because it becomes resistant. So, it is it kind of a trait which has been inserted into that plant.

So, similarly if it is a new trait or any new gene can be expressed in a plant that may also be new gene in the terms of some character which is making certain difference with the existing variety, those things can be considered as a new variety condition and it should meet with the other criteria as well.

So, the essential derived varieties are developed from an initial variety and it is clearly distinguishable from the initial variety and it conforms to the initial variety for the expression of the essential characteristics that result from the genotype or combination of the genotypes from such initial variety. So, it is same with the initial variety apart from the other new character which has been imparted to that by the biotechnological process.

So, these varieties can also be protected under the Plant Variety Protection Act. In India we can protect the technological part under the patent system. So, we should not be confused, no plant technology can be protected through patent, but the plant per se or a modified plant or a new plant cannot be protected under the patent for which this Plant Verity Protection Act is there in which we can protect the new plants.

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So, patent can be filed by anyone any inventor or in any applicant who possesses the technology. Similarly the plant variety can be registered by any person who claims to be the breeder of the variety, means any researcher who is working and who has developed a variety, plant breeder, so, they can apply. Any successor of the breeder or any person who is the assignee of the breeder in respect which he got the right, can apply for that.

Even the farmer or group of farmers or community of the farmers may claim as a breeder of the variety, means if certain variety of the rice or wheat are cultivated in some part or some village. So, those community can also come forward and register those variety or any person who are authorized to make application on the behalf of the farmers or even

any University or publicly funded organization can also be the breeder of the variety. So, basically register is that any person, any University, any private or any government form can apply for the plant registration.

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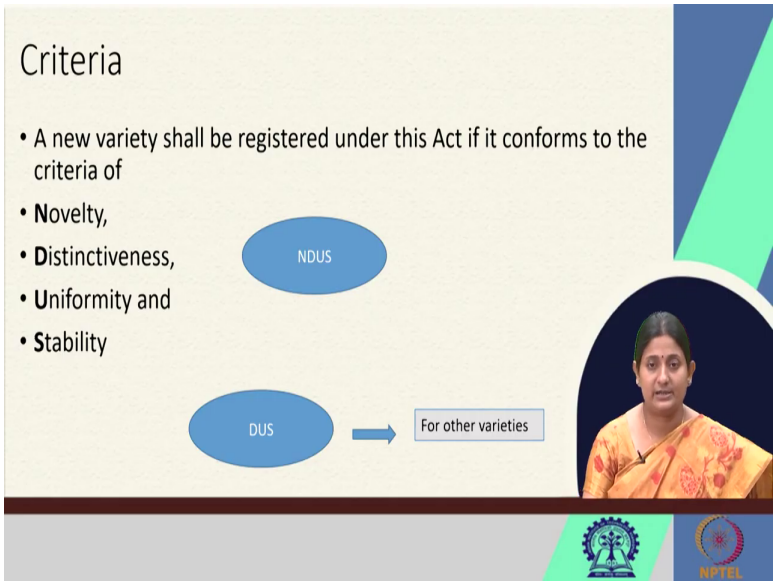

So, What is the criteria under which we can register a plant variety? So, for the patents we know by now that there are three major criteria; novelty, inventive step and industrial applicability. Obviously, it has to confer to the specified subject matter patentable subject matter.

Similarly, in case of the plant variety protection, the plant variety must confer to certain standards and these standards are known as the four specified standards for a new variety which is known as the NDUS standard that is- novelty, distinctiveness, uniformity and stability. So, new plant variety can be protected under the plant variety registration system provided it meets the criteria of the novelty, distinctiveness, uniformity and stability.

So, what is novelty here? Like, patent novelty is something new which has not been there in the prior art so, which is existed for the first step. Similarly, here also novelty means the plant variety must not have been marketed before in India or in abroad.

So, 1 year grace period is given if it is marketed in abroad. But again novelty in the terms the plant should be very new to the society and it should not have been marketed before

then it would be considered as the novel. And as I mentioned so, if it is marketed abroad 1 year grace period is given, within which you can apply for the registration.

Distinctiveness- distinctiveness means there must be a character or there must be some character by which you are able to distinguish this variety with respect to some earlier existing variety. For example, if there is a black rose. So, black is a colour which is very uncommon to the rose, but now if by any process someone develops a black rose. So, that black colour of the petal should be a distinct character which makes it distinct from the other varieties of the flowers ok.

So, that is the distinctive character. So, there should be at least one distinct character which is making them different from the existing. So, if it is a fruit so, the sweetness of the fruit or if it is litchi, so, the pulp of the litchi- how thick it is, how sweet it is. So, all these are different characters which a plant may may express. So, it has to be distinct with respect to the existing variety.

Then, uniformity - so, uniformity is that the expression of that character that 'distinct character' should be uniform across the population. So, if I am planting the like 100 seeds of the new plant variety which claims to be distinct then all the 100 plants must be expressing those characters, like again depending on the environmental.

So, there might be some environmental effect by which the expression may be less or more, but excluding that at least all the plant should be able to express the character which is set to be distinct.

Then, stability- again it is not that only for one generation the plant will express the character. That character has to percolate in every generation. So, that is known as the stability of the character. So, if any plant variety meets this four criteria then it can be registered under the plant variety protection system. And for the other varieties like farmer variety which cannot be considered so novel because it is already been cultivated or the other extend varieties.

So, we do not have the novelty criteria for them the DUS standards applies, that is distinctiveness, uniformity and the stability. So, if a plant variety meets this specified character you can apply for the registration of the plants.

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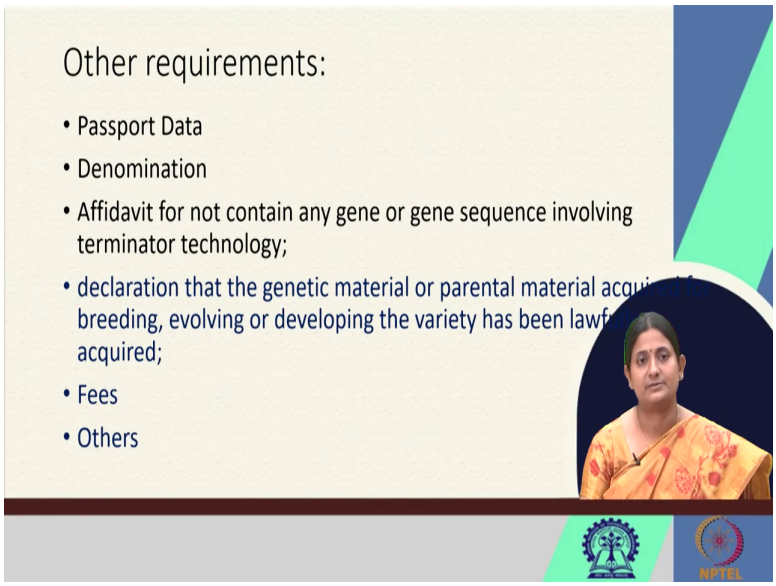

The other requirements related to the plant is that it is that- how you will decide or how you give the novelty or distinctiveness or stability data? So, in every application the applicant has to submit certain passport data regarding these characters which we have discussed so for. So, that has to be given.

And you have to name the plant variety by something which is known as the 'Denomination'. So, there should be a proper naming of the plant variety. So, if you have heard there may be rice varieties, like, 'pusa 1' some numbers like that. So, there is a denomination which is given. Again there are guidelines about how the plant should be named. So, denomination also forms an important part of the requirement.

Then another important part is that the applicant has to provide an affidavit which mentions that the plant variety do not contain any gene or any gene sequence which involves the terminator technology. So, we discussed about this GURT technology or the terminator gene which basically inhibits the plant to express the same character in the next generation.

So, if you are saving the seed for the next generation you might not get the same character as expressed in the previous generation. So, that is known as the 'terminator technology'. So, use of the terminator technology in these new varieties are not accepted. So, the applicant has to provide an affidavit for the same, also the applicant has to give a declaration that the genetic material or the parental material is acquired or developed.

So, these are the few essential criteria requirements that is needed for application of the plant variety. Apart from that you have to pay the fees and some other criteria as mentioned in the Plant Variety Protection Act.

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So, once you have apply for the plant variety the DUS data has to be given. So, you have to also deposit some amount of seed also and then it would be tested by the plant variety protection authority for the mentioned characteristics to check and to check whether or not those characters are being properly expressed .

So, depending on the nature of the seed or nature of the plant the testing criteria differs. So, they may be sent to few of the plant research centre where it would be grown and seen. So, it is again very depending on the plant variety. Once they satisfy, then the plant variety would be registered in the plant variety registry.

So, then the applicant would be issued a certificate for the variety under the Act and this gives the applicant the exclusive right to use those variety and nobody would be able to produce or sell or market or distribute or import or export the product without the permission of the plant breeder or the authorized registered owner of the plant variety.

And the duration of the plant variety is also varied for trees and vines. It is 18 years from the date of application, for other crops it is 15 years and for the extant varieties notified,

it is 15 years from the date of notification as per the Seeds Act. So, like patent you get some amount of exclusivity over that right over the variety.

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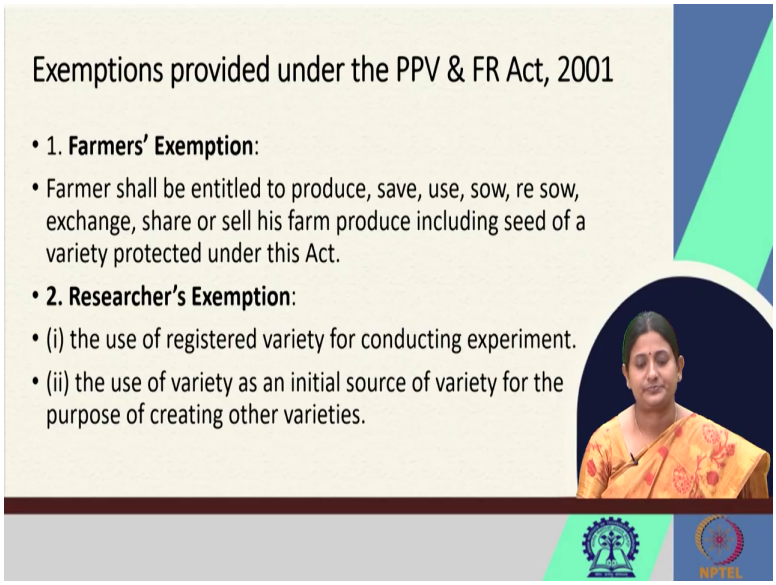

Now, this Act is called Protection of Plant Variety and Farmers Right Act. So, now, what is that farmer's right we are talking about. So, as we saw, since you are a breeder so you get the monopoly to use your thing without your permission now nobody is allowed to use that thing, but here the this legislation gives certain exemptions to the farmers as well as for the research purposes.

So, under the farmer's exemption the farmers are allowed to produce, to save, to use or sow or re sow the seeds or exchange or share or sale the form produce including the seed of the variety under this Act, But again the farmers are not allowed to sell the seed under the brand name. So, if they produce they can give it to some of their family members or other things or for commercial purpose as well, but not in that brand name.

And also, the legislation gives certain researchers' exemption, where the registered varieties can be used for conducting experiments and the use of this variety as a initial source of variety for the purpose of the creating other varieties is allowed. So, researchers can use the variety for developing the product.

But again for marketing of those or commercialization of the product, like if you have use that as an initial variety, you have to mention those thing in the application and then

if required you have to take the license from that person. Only if you are directly using that variety to get your own variety. So, those are the certain provisions which are mentioned in the Plant Variety Protection Act.

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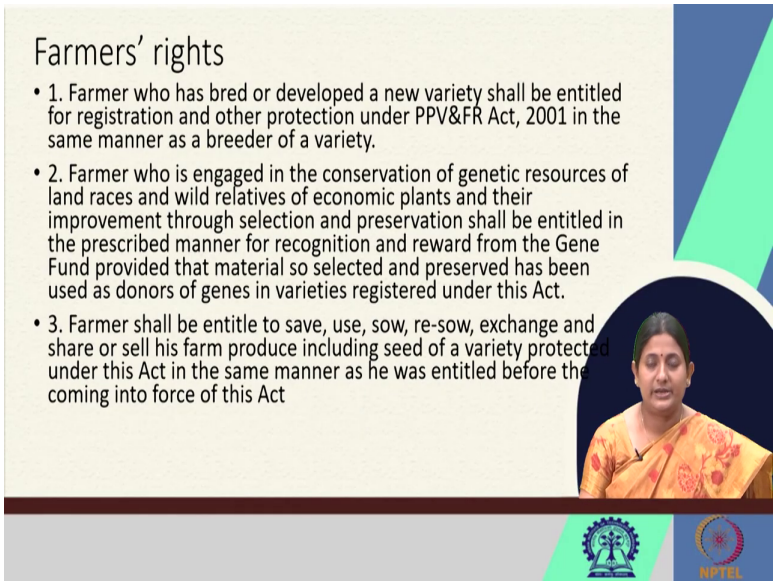

And it has also gives some extra rights to the farmers like they can sow re sow those things. Like anyone who has breded or developed a new varieties are entitled as a breeder or the farmer here.

So, farmer who are engaged in the conservation of the genetic resources or the land race or the wild relatives of the economic plants and or contributed in some way for the economic development or the preservation of those plants.

Now, they are also eligible to get some rewards under the gene fund which is a specific fund created under this Act. So, this is one of the unique features of this Act and then the rights with respect to the seeds which they have grown will also remains with the farmer.

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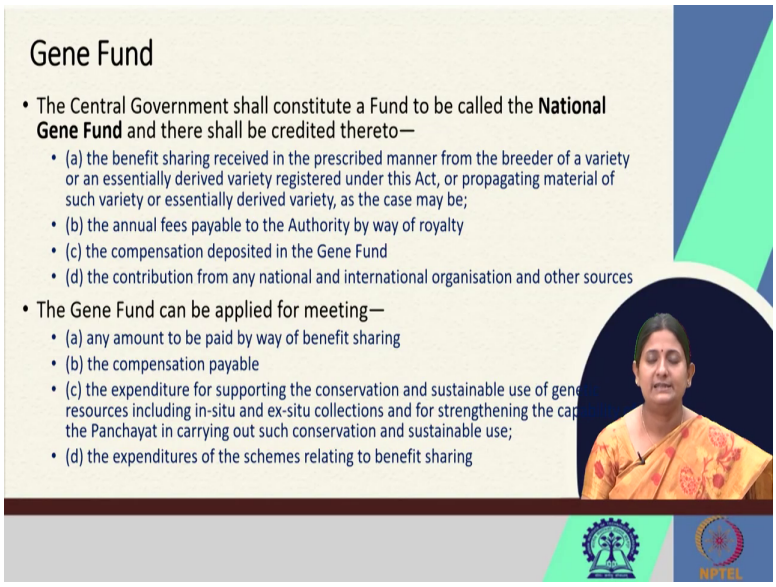

So, this gene fund is a special provision which is created by the central government and this is known as the 'National Gene Fund'. Basically this is fund where all the benefit sharing which are received in the prescribed manner by the breeder or the measure of the essential varieties are collected.

And whatever annual fees paid by the applicants to the authority by the way of royalty is also collected there. The compensations given by the various producers and the contribution from the national or any other international organizations are deposited here under the National Gene Fund.

And this money from the national gene fund are used for meeting the expenses related to other benefit sharing or some compensation, It is payable to some farmers or other persons and expenditure supporting the conservation or sustainable use of the genetic resources for *ex situ* as well as the *in situ* conservation and other schemes related to the benefit sharing are also incurred from this National Gene Fund.

And the Government of India has also initiated some different awards like the 'Germplasm Saviour award' and other things which is again given through this gene fund. So, this is the way through which the plant variety protection system in India has created a specific framework, in which not only the developer or the breeder can get benefit out of the provisions laid here in, but also the farmers and the other users can also use the seeds without being fearful about the patented thing and other thing.

So, this is a different aspect from the normal technology, of the biotechnology which we have been talking now. So, as a whole now we understand how the intellectual property related aspects are seen in context of the biotechnological research. So, whether you talk about patent! whether you talk about trademark!

Like in this plant inventions also trademark makes an important thing. How you name a plant that may be a issue, sometimes. Whether it is a generic name or how the plant has been popular made popular or like that. So, everything has to be taken and protected carefully so, that the innovator or the inventor gets maximum benefit out of it.

So, this is little bit about the intellectual property system with respect to the plant biotechnology. We did not deal much more. In this course this is the basic knowledge we all should have. So, that a while going forward to understand the regulatory challenges we can understand it in a better or simple manner. So, thank you for being with me and see you soon next.

Thank you.