Legal and Regulatory Issues in Biotechnology
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Module - 02
Intellectual property Rights and Biotech inventions
Lecture - 07
Patenting issues in biotechnology

Hello all. So, in today's session, we will start with module 2, which is basically the Intellectual property Rights and the Biotechnology Invention. And in this particular session, I would discuss I would be discussing certain aspects of the Patenting issues with respect to biotechnology.

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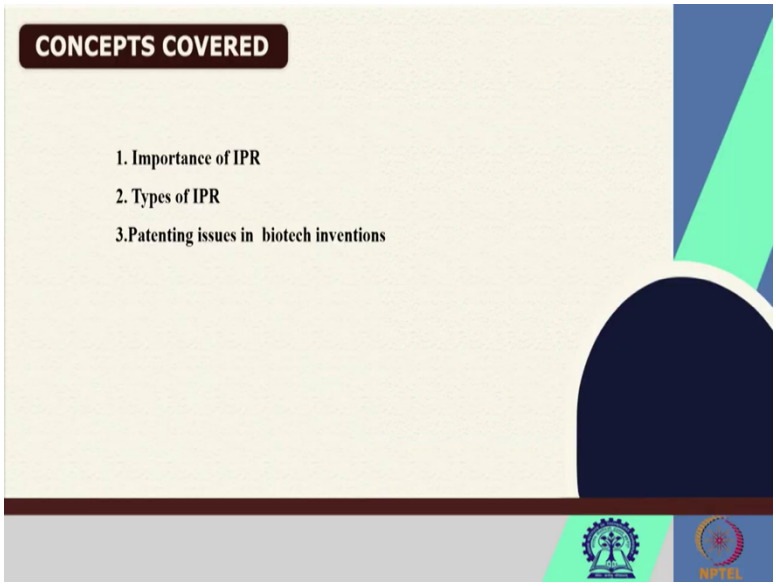

So, basically we will cover the concept of intellectual property rights in purview of biotechnological research and various types of intellectual property rights that may be applicable to different varieties of biotechnology research. And we will also discuss in detail, what are the challenges with respect to patenting for the biotechnology invention.

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So, now coming to intellectual property rights, which is known as the IPR, it is one of the important thing with respect to biotech research, maybe in any other research also; but particularly in case of biotech, the importance of IPR is quite high, because you know as we have already discussed in the earlier classes as well, the biotechnological research is a highly cost intensive research.

And it needs high investment, if you compare with respect to other pharmaceutical or chemical inventions; it is estimated that more than 50 percent of the revenue is generally invested again for research and development purpose, whereas in other sector it may stands from 5 to 15 percent.

So, in this case a need of high investment, but in many case the results are uncertain; but if somebody gets a clear idea or successful notion or invention, then it may give them millions of dollars of profit. Particularly you may see in the bio-pharmaceutical like this COVID vaccine as we are going through now this corona pandemic.

So, the bio pharmaceutical industry or any other related biotechnology industry is a high investment industry, which needs lot of investment as well as there is a need of highly skilled personnel's. So, all this makes the biotechnology research into a costly affair, as well as the product development cycle in the biotechnology research is also quite long. So, when somebody is taking a risk of investing lot of money as well as the time, and uncertain about the results which they might get; in that case some kind of protection

mechanism ensures the manufacturer or the researcher that their invention will be protected.

So, in this scenario the intellectual property rights which basically a bundle of right which is given to the inventor or the innovator or any creator of any intellectual work; so that gives a security to them that, their invention or their rights with respect to their work would be protected.

And in the biotechnological research, since there is lot of competition; so the manufacturers are also sometimes in need of certain kinds of exclusive marketing rights, so that they will reap the benefit which out of the investment which they have made in the whole R&D process as well as the long term protection of the innovation could happen due to the intellectual property right.

So, in bio-pharmaceuticals or particularly in a biotechnology research, the intellectual property right is very critical and it is known to not only protect the innovation or the invention; but it is also serving the function of further motivating the other researchers to carry out new inventions.

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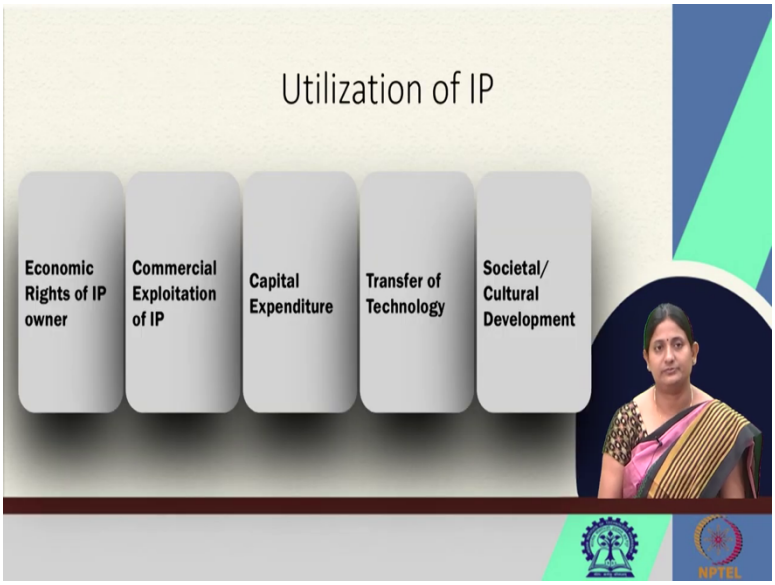

So, if we see broadly, the intellectual property rights gives many advantage to the owner or the inventor often any invention. For example, the intellectual property rights gives the economic rights, any product or any process which the company or the any

organization is developing; so all the economic rights generally is vested with the owner because of this intellectual property right is protected, so that nobody or no outsider can use that invention without the permission of the real owner.

And it allows the owner or the inventor to exploit the invention as per their whims; they are free to give the licenses or free to utilize that invention for any other purpose, any other tool. Basically the marketing rights remains with the inventor, the owner. So, the commercial exploitation of the IP is also vested in the owner of the intellectual property.

Then since it is a risky business as we have as I was mentioning, the capital needed for this kind of research is quite high. So, if some company has any sort of intellectual property that gives them advantage or leverage in getting funding opportunities or even venture capital funding; so the funding opportunity becomes high in case where some kind of intellectual property is associated.

Then there is transfer of technology, that liberty also remains with the owner of the IP in case it is protected through the intellectual property rights. And as a whole, it leads to the societal and cultural development. So, it has many fold functions, intellectual property rights in any industry whether it is biotech or chemical or any other industry you may say.

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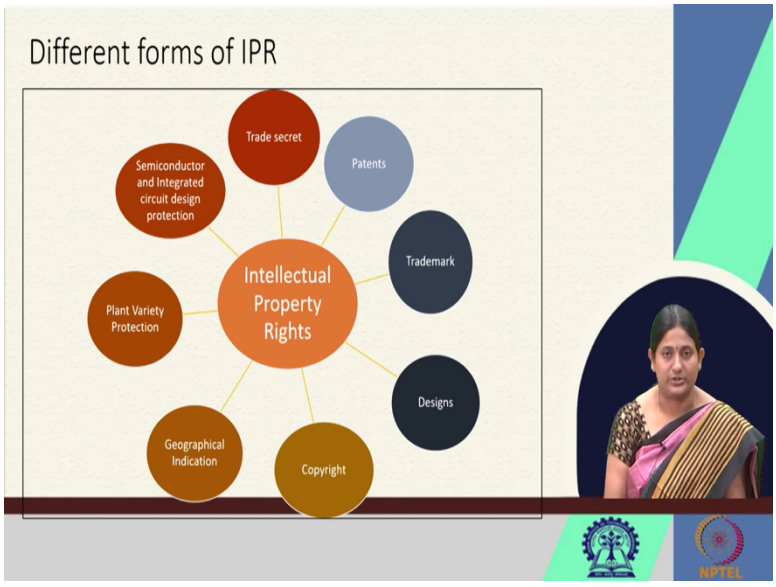

So, if we see the intellectual property right as I mentioned is a bundle of rights and there are different forms of the intellectual property right. Generally we as a scientist or the inventor are quite conversion to the term patent, but patent is one of the important forms of IPR definitely; but apart from patents, there are many other forms of the intellectual property rights. So, the World Intellectual Property Organization or the WIPO has defined the intellectual property rights into various categories.

And basically if you see there are two broad categories; one is known as the industrial property right- which is basically the any kind of intellectual property which is directly or somehow related to the industry, such as the patents or the trademarks or the designs and other is known as the rights with respect to the literary work or the artistic work, which is basically protected through the copyright.

So, apart from this industrial right and copyright, there are certain allied forms of the intellectual property rights which are known as the other forms of the intellectual property rights; that involves the trade secret, plant variety protection, geographical indication, then semiconductor and integrated circuit protection.

So, there are many types of the intellectual property rights and depending on the nature of the invention or the nature of the work, you have to choose the appropriate form to protect your invention or the work. For example, when we talk about patents; patent is something which is more technical in nature and it is a kind of intellectual property right which is given for an invention.

Trademark, you might be knowing trademarks are the name or the sign or the logo which is generally attached to a product, so that it acts as a source indicator; or in the marketing terms it is very essential, so in order to popularize a product or marketing or for advertisement, the trademark is an essential component.

And designs are a kind of an intellectual property, which is basically on the aspects of the external shape or the appearance of the product. Sometimes certain component irrespective of their technicality or the inventive concept in the product, the people are attracted by its exterior outlook or the design. So, the design protects the external shape or appearance of the product.

And copyright as we describe it is more about the literary or the artistic work; suppose some scientist are doing certain work, as a researcher we publish many papers, we write articles in journals, we write thesis all this literary or artistic work are protected through the copyright.

And if you come to the other forms of the intellectual property right, so we have the plant variety protection. Even though the patent protects some of the technical invention, but in many countries the plants are not allowed to be protected through the patents. In those case, we have a different *sui-generis* system known as the plant variety protection, which is particularly for the protection of the new variety of the plants or there are certain other varieties mention.

So, the plant variety protection is basically on the aspect of protection of the plants *per se*. And we have the geographical indication, geographical indication is a kind of intellectual property right, where it indicates that a kind of a product; it may be an agricultural or a manufactured or a natural product which has an inherent relationship with the geographical location from where it is produced, in terms of the quality or in terms of the reputation.

So, geographical indication gives the indication that the particular product is being produced in a particular area of a region or a nation. For example, the basmati rice or Darjeeling tea these are the popular examples for the geographical indication. Then we have semiconductor and integrated circuit design protection, which is more about the topography of the IC chips, which is protected through this kind of *sui generis* system.

And then interesting aspect of the intellectual property which is the trade secret, where any kind of the information which is basically commercially, which gives commercial advantage to the inventor, may be protected through the trade secret. There are certain conditions, if the information meets those requirements, it can be protected through the trade secret.

In some countries, we have defined trade secret acts or laws and in some countries like India, we have multiple provisions in different regulations or legislations, which gives the protection to the trade secret. So, overall we have a variety of options in the form of various intellectual property rights, which can be applicable to the biotechnological invention as well.

So, now the manufacturer or the inventor or the owner of any invention, they generally adopt the particular measure which is suitable for them and try to protect their innovation. So, once it is protected, it prevents the infringement or unauthorized copying of those kind of invention and it gives a marketing edge for the original owner.

So, that is why the profit from that invention is directly accrued by the owner and it further promotes the other invention as well for carryout new inventions in the area. So, that we are there is a continuous process of innovation. If there is no incentive for innovation then why anyone should go for any kind of invention, which is again highly risky as well as a costly affair.

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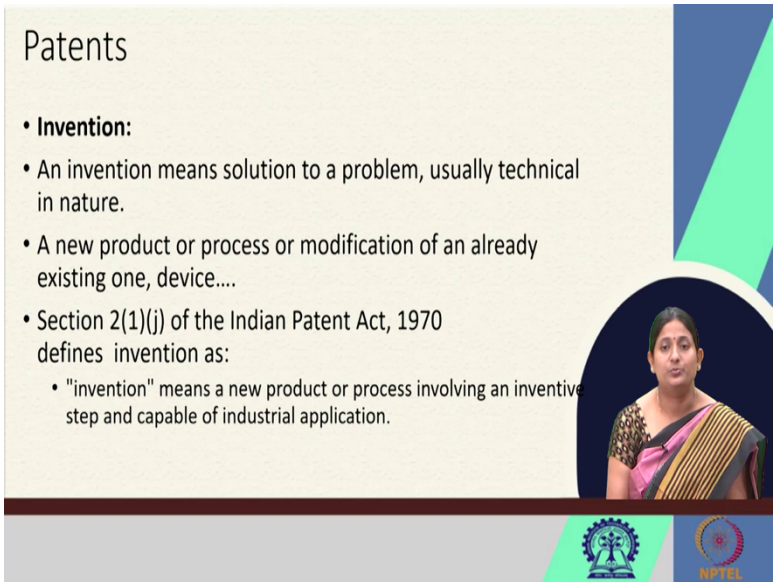

So, in this regard now let us go into the important form of an intellectual property right, which is the patents, which is highly crucial for the biotechnological invention. So, because you know patents are a kind of intellectual property right, which gives a protection to the inventions.

And when we are talking about biotechnological research or life sciences research, the core scientific process of developing a new product or a process or a product through a defined process, the protection of the same becomes very important. So, what is invention?

In scientific terms, we may define invention as the work which we do or the scientist does, but if you look into the legal definition of the invention, it is basically; if you come into Indian definition of the invention, so the Patent Act of 1970 defines the 'invention' as a new product or a process which involves an inventive step and which is capable of industrial application.

So, there are different aspects attached to a concept of invention that is it should be a new product and process. That the concept of novelty is attached with it. Involving an inventive step means, the concept of non-obviousness and capable of industrial application, then the concept of utility. So, everything is attached to the notion of the invention.

So, in a technical term, the invention may be a solution to a problem, basically which is technical in nature and which is solves may be through the generation of a new product or generation of a new process or modification of certain existing product or the process or the addition of something to a existing one. But in order to be patent eligible, that invention has to meet the legal definition as given in the Patents Act.

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So, the patent is basically a technology, which is protected through these patent rights and the requirements of the patents are also very much defined. So, as I was mentioning as the definition of the invention, the patent table invention must be new or novel; it

should involve an inventive step and it should be capable of industrial application or it should be useful to the society atlarge.

And all this three criteria of novelty, inventive step and utility is further confined to a defined set of the subject matter. Not all inventions or not all technical solutions to the problems are patent eligible subject matter. The Patent Act of different countries has defined plethora of things, which are non-patentable in nature. And why so? So, basically patent rights are a kind of a monopoly right.

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So, these rights are not permanent rights; if you see the patent rights, it was initially given for 14 years of time period, but later on worldwide now the patent term is extended to 20 years from the date of filing of the patent application. And one important thing with respect to patent is that, the patents are territorial rights or jurisdiction base type right.

So, if you apply a patent, you get the right in that particular country. So, if you want to have coverage in many countries, then you have to apply in those countries as well. So, what advantage do you get by this patent? So, you get 20 years of monopoly period, where apart from your permission, nobody is allowed to make or sell or use the product.

So, you have the very right to use the invention as per your requirement or as per the necessity and you can sell, you can mortgage, you can license, you can produce the product till the 20 years of the time. So, what is the purpose? why it is 20 years? The

patent rights are known as the kind of a right which is we know, we call this is a *quid pro quo* system; means you give something and then you get something. So, what the inventor is giving?

The inventor is has carried out the invention, so the inventor is giving the invention to the society or the public and that is why he is getting the 20 years of monopoly period. So, how it is given? So, the inventor is giving the invention in the form of this patent. Patent is basically a techno-legal document, which incorporates all the aspects of the invention, so that a person skilled in the art would be able to carry out the same invention by reading through that patent document without any difficulty.

So, till 20 years, the monopoly is given to the inventor; but after 20 years, the patent becomes free to the public. And then anyone who is interested in that invention can carry out the same invention. So, the inventor gets 20 years of the rights and after that the same invention become free to the public. So, the society also get something in terms of the new product or the new process and the inventor also gets the 20 years' time, where he can commercialize this invention.

So, it is a process where both the parties are getting benefited. So, the concept is like, monopoly is bad in any area; but again when someone has developed some product, in order to give them the benefit or because they have invested the time and money, so this concept of patent started, where for a definite period the inventor can use his invention for his own benefit.

So, it is like in UK, the Monopolies Act was the first where the patent rights were given; the patent were given in the forms of the letters Patent and gradually different countries have developed different criterias.

Then we had TRIPS agreement, that is the Trade Related Aspects of Intellectual Property Right under the World Trade Organization, which defined a kind of an international standard which each member country must follow to develop their own regulation or patentability criteria.

So, it is being developed since early 19th century and, today in India we follow the Patent Acts of 1970, which has been amended many times and then we have the current provision of the Patent Act.

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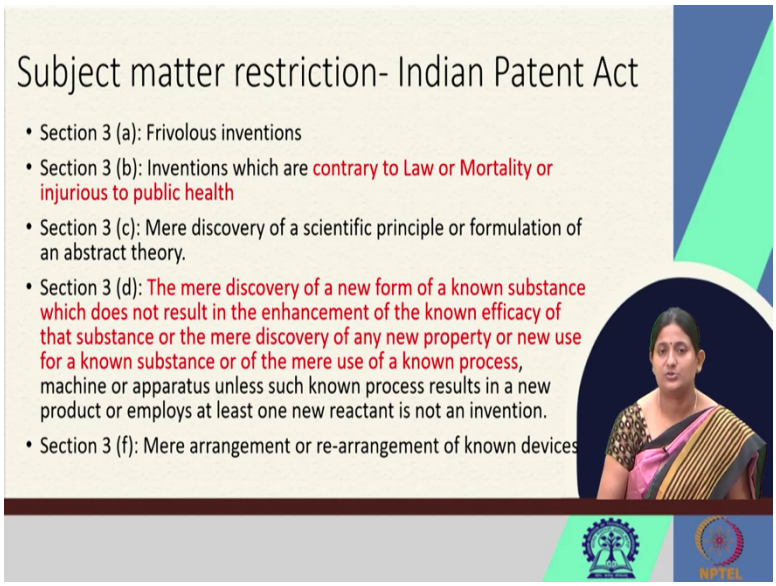

Now, coming again to the Indian Patent Act, particularly. As, I was mentioning not all inventions are patent eligible. So, even though you have a new product or new process; but that has to be checked whether it is meeting the criteria of the subject matter or not first.

Then the other three criteria's are checked to consider an invention to be a patentable invention or not. So, as we see our Indian Patent Act has defined a number of inventions, which are not patent eligible. The section 3 of the Indian Patent Act particularly defines all those or gives all those inventions which cannot be patented in India.

I will just briefly go through the provisions and to just make you all understand, what cannot be patented in general and in particularly for the biotechnological field. For example, section 3(a) talks about the frivolous inventions, where these kind of inventions cannot be patented.

The frivolous inventions are those; like, if an invention talks that it is an hundred percent efficient invention, there is no energy loss, which is not be possible in any way or somebody talks about a time machine, where it can teleport you or transport you. So, those kind of inventions will basically come under this category and they are not allowed to be or they are not considered as an patent eligible subject matter.

Then section 3(b) talks that, the invention which are contrary to the law or morality or injurious to public health. So, here any invention which is contrary to the current concept of public order or morality is not allowed and invention which is injurious to public health; for example, let us take the case of the corona pandemic.

So, development of a virus, which can be considered or which can be made as an bio-weapon would be very much, will be very much injurious to the public, so that kind of invention cannot be allowed. Or if you consider a machine where you can produce fake currencies, so which is against the public order and morality. So that is also not patentable.

Those categories of the invention which is harmful to the public or the society at large is not considered for patenting. Then section 3(c) talks about mere discovery of a scientific principle or formulation of an abstract theory. So, mere theories or scientific principle like the gravitational force or the other principles which are there in the nature, $E = mc^2$ or the energy laws, so those things cannot be considered for the patenting.

Section 3(d) is about the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of the substance or, mere discovery of any new product or the new use of a known substance. So, if there is already an invention and you are just modifying that invention to get a little bit more what you called a ‘new use’ of the product or you are just increasing the efficacy of that whole process, it cannot be generally patented.

Here there is a dispute about what can be considered as a mere enhancement of the known efficacy or the mere discovery. So, now, you have to prove that the efficacy has been substantially increased, which is again giving a lot of benefit to the potential users. So, it depends on the type of the invention. But simply discovering or simply modifing or just help talking about a new use of a known substance, may not allow the invention to be patentable.

Then mere arrangement or the rearrangement of the devices, where you cannot just mix two or three apparatus and can produce a new apparatus. So, unless and until there is substantive inventive step is involved, so those kind of things are also not patentable.

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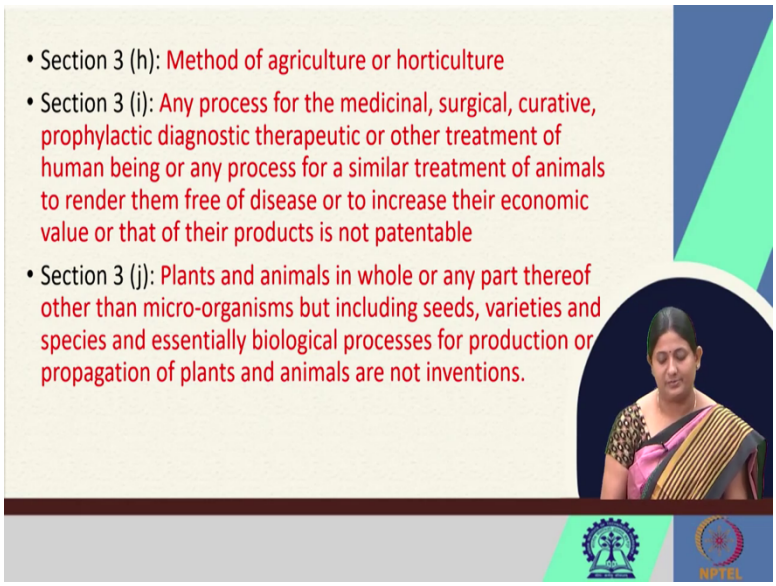

And method of agriculture or horticulture, like the cultivation method or soil enhancement method. So, in general which is more; because India is an agriculture based country, so anything which is majorly applicable for the cultivation of the lands or may be useful for the farmers in general, which is known are not allowed under the Patent Act of India.

Then the Patent Act of India further forbids any medicinal, surgical or the curative or the diagnostic or treatment of the human beings or the animals. And also very importantly the plants and animals in the whole or any part thereof other than the micro-organisms are not patent eligible subject matter. So, one cannot patent a whole plant or animal in India.

But the micro-organisms can be patent eligible, provided it is not a mere discovery of the micro-organism. And seeds and other varieties and species, essential biological processes; they are also not considered as an invention under the purview of the Indian Patent Act.

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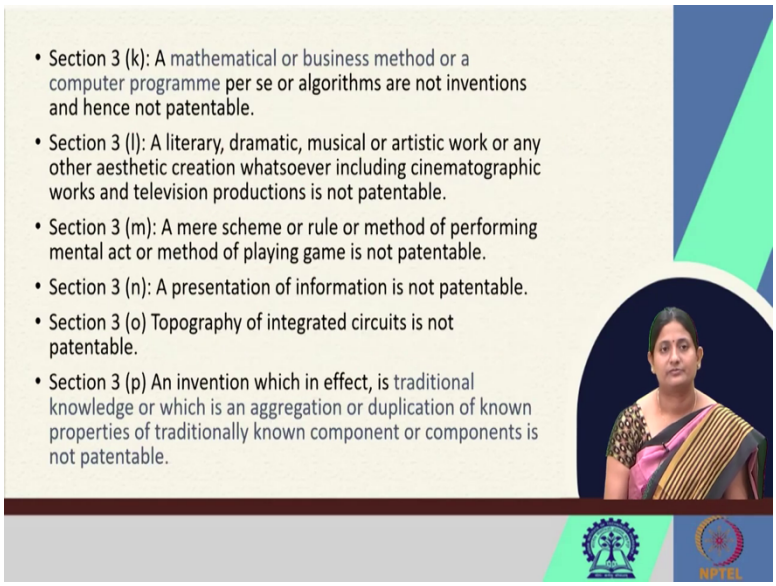

Further the Patent Act forbids the mathematical or the business method or computer programme per se; computer programmes can be protected under the copyright. The business method is a again a debatable area, where countries like United States sometimes allow the patents on the business method.

But in India, per se business method or mathematical models are not allowed or not considered as a patent eligible subject matter. All the literary, dramatic, musical or the artistic work or any aesthetic creation is again not considered for patent; it is basically coming under the purview of the copyright. Mere scheme or rule or method of performing mental act or method of playing games are also not patentable.

Topography of integrated circuit is not patentable, it is considered under the Semiconductor and Integrated Circuit Protection Act. An invention which in effect is traditional knowledge and the traditionally known component or components or traditionally known properties of the various substances are also not are not protected.

So, you might have heard about the turmeric or the neem case or the basmati rice case. Where the wound healing properties of the turmeric; or the anti-infective property of the neem, were tried to be patented in other countries. Because it is traditionally known in India, those things are generally not are not patent eligible.

So, anything which is traditionally known comes under the purview of the traditional knowledge, and cannot be considered for patent.

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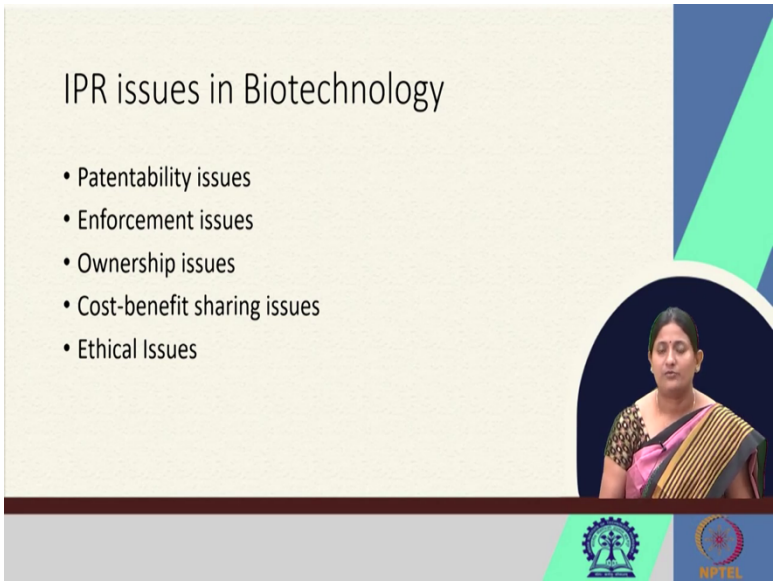

So, those are in general the non-patentable aspects of the invention. So, if you see the provisions laid in the section 3 of the Indian Patent Act, there are many provisions which is directly applicable to the biotechnological research. For example, patenting of the plants or the animal varieties or patenting of the micro-organism, patenting of the essential biological process or patenting of the traditional knowledge when we talk about that; so there are certain medicinal property of the plant.

So, how can we circumvent all those things? Or, what are the areas where patent can happen? and how the patenting in area of biotechnology is evolving or changing, is our next point of discussion. So, if we look into the intellectual property right issues in biotechnology, particularly with respect to the patents; the issues can be majorly of five types. First there are issues with respect to patenting of the different articles coming under the biotechnology arena.

There are enforcement issue, ownership issues with respect to the invention; then there have been instances of the cost benefits sharing issues, and overall we have a big debate over the ethical issues. So, now what will we do, we will go one by one into all this types of the issue and try to understand what are the definite challenges in the area of biotechnology.

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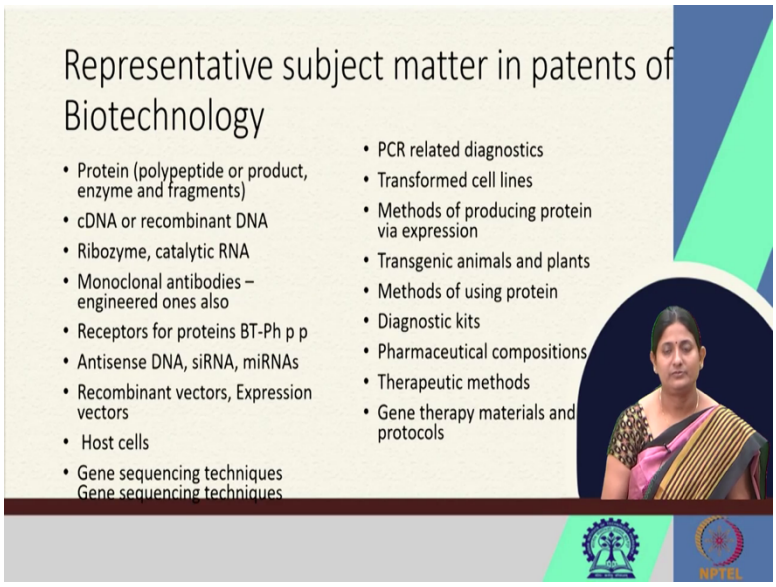

Before that a broad overview of the patenting in the biotechnology area would give you an idea that the in major aspect of the biotechnology patent is not only granted for genes or the DNAs or the pharmaceutical combination; there are other aspect which are also patented across the world.

So, if you see, this is a list of representative subject matter; so, we have this various protein which includes the sequences of the polypeptide or sequences for the enzymes or different fragments that is patent eligible. Then we have various complimentary DNA products or the recombinant DNA products, plasmids which have been patented; we have ribozymes, we have mono nuclear monoclonal antibodies, receptor proteins, the antisense DNA, siRNA, miRNA.

Then we have recombinant vectors, expression vectors, host cell and gene sequencing techniques and PCR related diagnostic; then various cell lines, methods of producing proteins via various expression, transgenic animals and plants that has been patented in some area, diagnostic kits, pharmaceutical composition, various therapeutic methods all these like a variety of things has been have been patented across the globe.

So, the patent law might be different little bit here and there in different countries. But if you see, many aspects of the biotechnology have been patented over the years. So, now, let us try to analyze the problem with respect to the patenting provisions as well as the what is happening or what is the societal requirement or how is it perceived.

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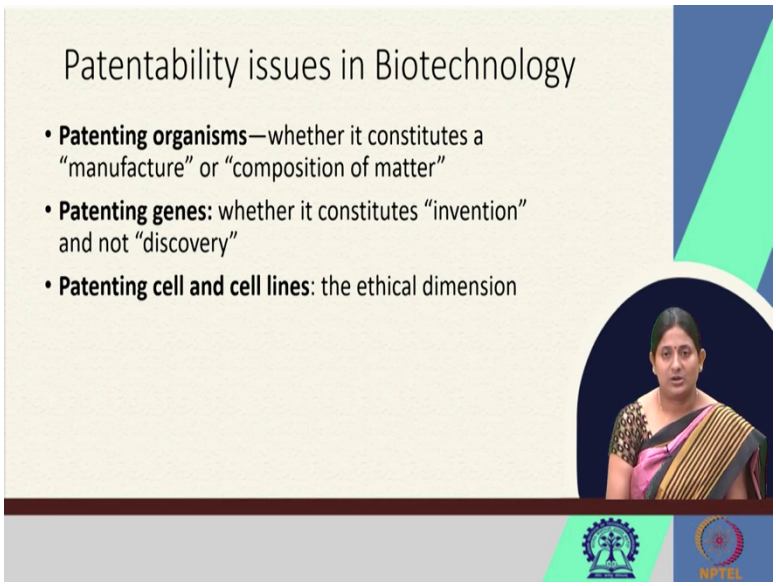

So, if we consider the patentability issues in biotechnology, so it may be again patenting issues with respect to patenting an organism as a whole or patenting the various genes found in the organism or patenting the cell or the cell lines. So, if you see, you may not find many instances of patenting over the whole organism; but there are instances where the whole virus or the bacteria or different organisms have been applied for the patent.

So, there the main question which arises is, whether the organism itself constitute an article of manufacture or it is an composition of the matter. And when you talk about an individual genes, the isolated genes would it be invention or if it is a naturally occurring or the gene sequences that is already been present; we shall consider it as discovery, because as per the patent law mere discoveries are not patentable.

So, you have to apply certain human interventions or technical interventions to make them patent eligible subject line. Then in case of the patenting cell or the cell lines, it is more about the ethical dimensions. So, this lecture would be continued and in the next lecture, I will be again be defining or describing in detail the various patentability issues in the biotechnology.

Thank you.