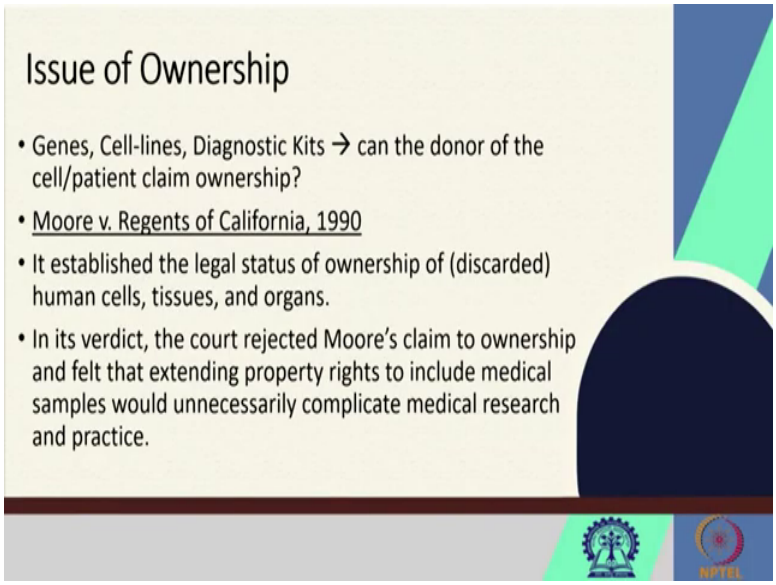
Legal and Regulatory Issues in Biotechnology
Prof. Niharika Sahoo Bhattacharya
Rajiv Gandhi School of Intellectual Property Law
Indian Institute of Technology, Kharagpur

Module - 02
Intellectual Property Rights and Biotech Inventions
Lecture - 09
Patenting issues in biotechnology (Continued)

Hello again. So, we are in this lecture 9. Today, we will be continuing our discussion regarding the Patenting issue with respect to the biotechnology. So, in earlier lectures, we discussed about the patenting issues with respect to patenting a gene segment or cell line.

So, the problems whether it is modified gene or how to distinguish between the discovery or invention related to a gene is a critical questions which is asked many a time during the patent application.

(Refer Slide Time: 01:07)



So, there are not only the issue with respect to whether or not a gene which is similar to the existing DNA or RNA structure or the complementary DNA which is made from the existing structure- how novel is that; what are the industrial applicability or the usefulness of those kind of inventions, are generally determined before they are granted patent.

So, we have discussed extensively regarding those issues. So, today, one of the associated issues with respect to patenting of those genes or the cell line is the question of 'the ownership'. So, generally, what happens in a patent document, an applicant is the person who applies for the patent. So, there are if you see a patent document, you can see many of the categories like applicant, inventors, assignees.

So, inventors are the scientist who basically work or who have worked in the area of that invention and brought out that invention and applicant. The inventors themselves may be applicant if they have done the whole experiment by themselves without taking support from any other organization, but many a times, what happens that the scientist or the inventors work under certain organization may be a public institution or a private institution using the resource of the institution, they have done the experiments. So, in those cases, the institution becomes the assignee of the application. And if they have transferred the rights to some any some other company.

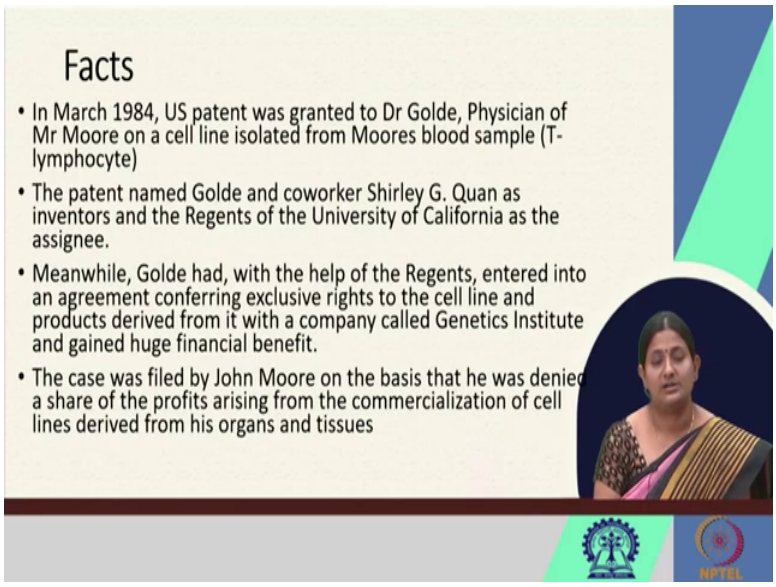
So, in those cases, the second company or any other organization to whom the rights with respect to that patents has been sold or given would be the assignee. So, one is the assignee, one is the applicant, and one is the inventor. So, many a times, what happens we particularly with respect to the biotechnology applications and in general with respect to the animal or human tissue cell lines so, those cell lines or the cells or the genes are isolated from a patient, or it is taken from a donor.

So, now, in a patent application, once the patent is granted, can the donor of the cell or the cell lines or the patient from whose body the parts were taken, or the cells have been isolated, can they claim ownership with respect to the patent? Or, can they claim benefit out of the profits which the patent has acquired?

So, this is a question which initiated we may say from the time when we have started discovering the cell lines or isolating the cells or the genes. So, one of the landmark decisions in this regard was the case in the United States, Moore versus the Regents of the California .

So, this is one of the case were it may be theoretically first time established that the legal status of the ownership of human cells or the tissue or the organs which is basically discarded or taken out of a patient body, allies with the institution who have carried out the experiments or done the treatment.

(Refer Slide Time: 04:42)



So, if we go to details of this case Moore versus California Regents so, here, Mister Moore was a patient who was being treated in one of the hospitals in California UCLA and the doctor or the physician is Dr. Golde. So, it is a kind of a cancer which Mister Moore has developed.

So, while the treatment process is being initiated by the physician Doctor Golde, he suggested the removal of the spleen and it was carried out with the consent of the patient that is Mister Moore. However, once the spleen is removed, the cell lines where isolated from the spleen or particularly from the T-lymphocytes and it was used for various experimental purpose by the group of physicians at that UCLA.

And on that, they have applied a patent to the United States of Patent Office in 1983 and the patent was granted in 1984 to a particular cell line which was isolated from the T-lymphocytes from the patient's body and in that patent, the physicians, physician Doctor Golde and their co-worker which is Shirley G Quan were assigned as an inventor and the Regents of the University of the California was the assignee because the whole setup was carried out there itself.

And so, in between also like from 1970's onwards Mister Moore was associated with that physician and he has been in continuous treatment. So, Mister Moore was completely unaware about the various cell lines which are isolated from his body parts

and how the university has started commercializing those things so, he was completely unaware of the facts regarding that one.

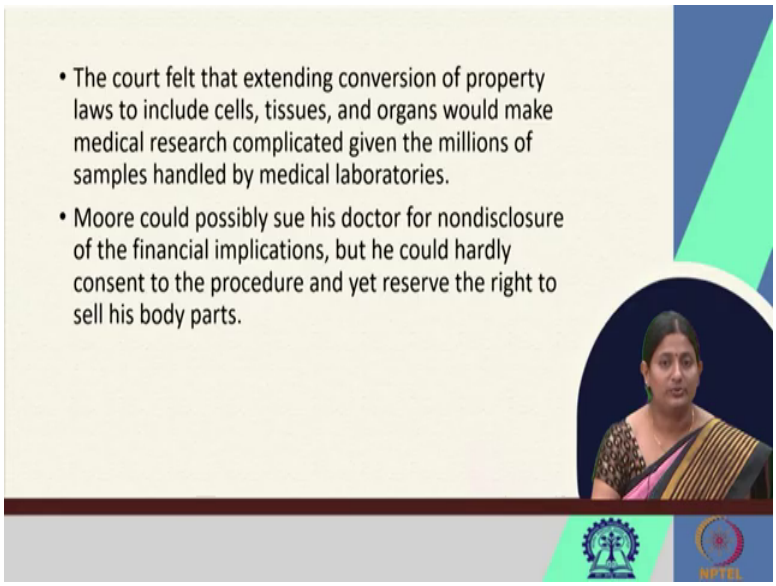
He came to know about all these things when a form or a when a deed was being asked to sign, where it is said that he is agreeing to grant all rights for any cell line of the body and so, then he did not sign these documents and he is thought of taking legal help.

So, later on it was revealed that the physician; Doctor Golde had entered into lot of commercial agreements with many company and Golde with the help of this California Regents have entered into an agreement which has given the exclusive rights to all the cell lines isolated from the patient's body Mister Moore and all the products derive from such cell lines to with a company called the Genetic Institution.

And it had gave him a lot of financial benefits like he was a shareholder of the company, and he has been assigned hundreds of thousands of dollars and even when the again there was second transfer of this rights to another company also that time also; he got a huge monetary benefit. So, when all these issues came into forefront, the patient John Moore filed a suit in the federal court.

So, initially the federal court agreed to share certain benefit, but later on that decision was reversed in the Supreme Court. So, the patient Mister John Moore filed the case on the basis that he was being denied of all the profits or a share of the profit which has been; which has been occurring by the commercialization of the cell lines which is derived from his body or his organs or the tissues.

(Refer Slide Time: 08:49)



So here the question was once the patient samples were taken out of the body of the patient, can the patient really claim over the ownership over the thing? So, the Supreme Court particularly felt that if the patients or the donors will start setting their rights over their organs or the tissue.

Then it would make the whole medical research process a very complicated one because you know there are thousands of patients, and the doctors are in process of learning many things and developing many things out of that.

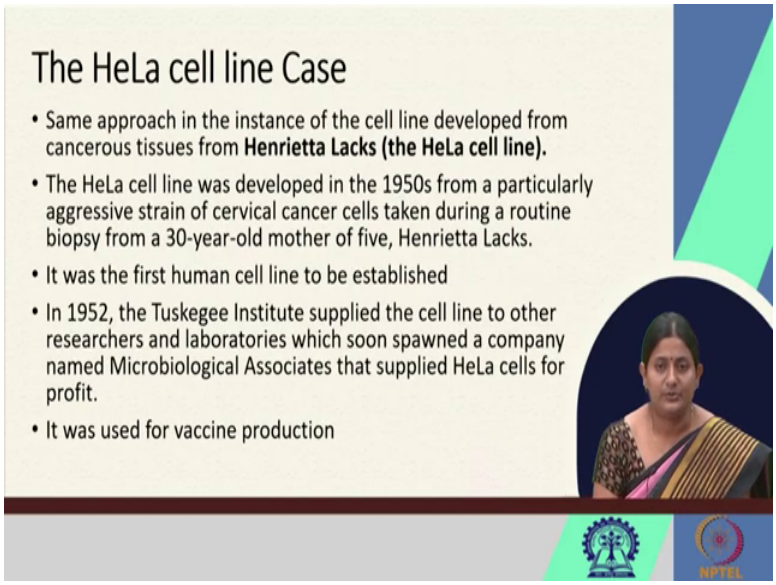
So, if each of the patient will start asking ownership or start asking benefit sharing, then it would be a complicated process and it would be difficult for the physicians to carry out the normal research process. So, in that case, the court denied any sort of financial or commercial benefit sharing with the patients.

However, it was felt that it is ethically wrong on the part of the physicians to keep in dark their patients regarding the future use of the cell lines of the tissue. So, Mister Moore could have probably sued his doctor for the non-disclosure of the financial implications.

But again, if he has given the consent to the treatment and his organs or tissue or any part of the body has been removed with his consent, he may not claim for any sort of financial benefit which is arising out of the use of those body parts.

So, this is one of the landmark decision in the history of the United States which first time clearly stated that the patients or the donors readily cannot claim any sort of benefit-sharing if which has been generated by the future use of those tissues .

(Refer Slide Time: 10:49)



Similarly, if you see another older case, the HeLa cell line case, it follows the same principle of the Mister Moore case here, so, this HeLa cell line is one of the popular cell line and it was the first human cell line to be established in the medical history of the humans and here, this HeLa is basically is a short form from the name of the patient called Henrietta Lacks.

So, Henrietta Lack was a coloured woman and she was just 30 years old and she was suffering from cancer, cervical cancer and she was treated in a hospital where at the point of let during 1950's where the colour populations were kept in separate ward and they were given different treatments from the white population.

So when she developed this aggressive cervical cancer, she was treated and from her the routine biopsy, it was found that her cell lines were at kind of a different ability to grow where in general cases, at that point of time, it was very difficult to grow in any human cell lines in in-vitro.

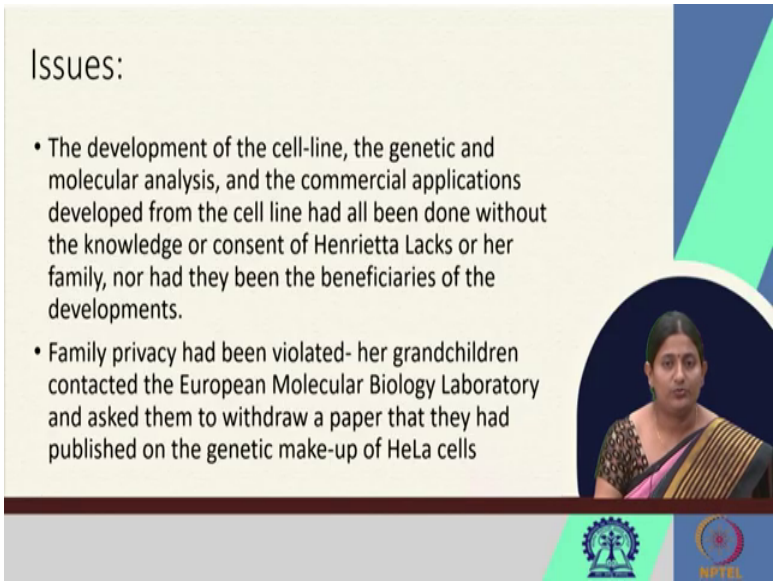
So, she was diagnosed with cancer in the year 1950 and at the 30; at 31 years of age, the patient died and like just after one year, in 1952, the Tuskegee Institute supplied her cell

line to the other researchers and the laboratories. Her cell line which is now given the name HeLa cell line has a unique ability to grow because she not only had cancer, she was also suffering from syphilis and with multiple disorders which somehow suppressed her immune system and it was able to grow very well.

So, the medical institute supplied the cell line to the other companies and from them to many researchers and companies and they formed a company called the Microbiological Associate, which is now became profit occurring company and they supplied the HeLa cell lines to many of the researchers across. It was popularly used for the vaccine production like polio vaccines and others.

So, this process was going on. The patient Henrietta Lacks, was a mother of five kids so her family members were totally unaware about the isolation of any kind of cell lines or the use of the cell lines which has been used in commercial purpose as well .

(Refer Slide Time: 13:43)



So, the issue came into forefront when after nearly 20 years later, the medical representative and the persons from the medical institute, approached the family members of the Miss Henrietta Lacks to get certain information about their cell lines and other related information. At that point of time, the family members got to know that their mother's cell are still alive means in the terms of the culturing of those cells, but it is again a huge profit making substance for the institute.

So, that had led to two kinds of situations, first of all it is the religious belief of some family like if the cells are still alive, then she will have the immortality of the soul or those things were not ethically acceptable by the family members. Secondly, the family of Miss Henrietta was very poor family so, they do not have a sufficient resources to even buy their medical insurance and even to carry out their education.

So, even though the millions of dollar businesses is going out with their mother's cell line, they are still deprived of any profit and as mentioned in the first point, the ethical concern regarding their religious belief was also there. So, the family members denied to agree to any such kind of the information which was been asked by the medical institute.

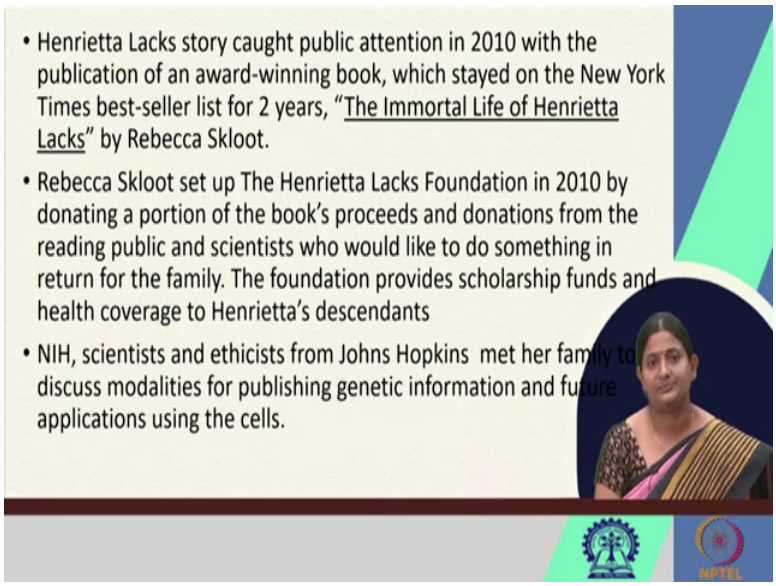
So, here, two issues were basically raised, first of all the development of the cell line or the genetic or the molecular analysis and the commercial applications which are developed from the cell line all were done without the knowledge or the consent of Miss Henrietta Lacks or their family members because no prior informed consent were taken from the patient or from their family members.

We have studied so far the various code of ethical conduct conducts, but at that time, there are two reasons, first they were colored populations and during 1950's the concept of informed consent were not prevalent as such and the black population particularly were treated as a guinea pigs where many experiments were performed. So, this is one of the issue.

And the second one is that the family privacy was violated and because in one of the journals, they have again deduced the genetic codes of the cell line and it was published in the European Molecular Biology Laboratory association publications.

So, the family members of Henrietta Lacks, they contacted the European Molecular Biology Laboratory and ask them to withdraw that paper which they have published regarding the genetic makeup of the Henrietta Lacks cell lines. So, these two issues were raised.

(Refer Slide Time: 16:55)

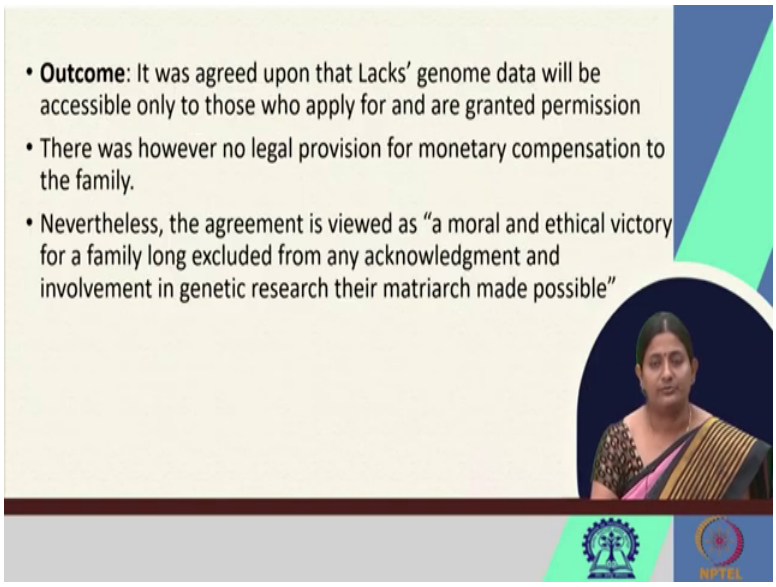


And you might have heard about that this whole story, it got public attention late in 2010 where one of the author Rebecca Skloot, she wrote a book on the whole story of Henrietta Lacks in the form of a book called The Immortal Life of the Henrietta Lacks and it was a best seller which remained on the top chart for 2 years and the author.

Then she set up another foundation ;the Henrietta Lacks Foundation' in the year 2010 by donating the profits she occurred by the publishing of that book and so, whatever so, this foundation basically helped the family members to provide these scholarship funds and other health coverage to her families descendants.

Finally, when these things got so much of attention in the news; may news or publication media, the family members of Henrietta Lack, met with the then director of the National Institute of the Health and other scientist and ethicists from the John Hopkins Institute and discussed the various modalities regarding the publication of the genetic information and the future application using; a future applications which may come up using that cells.

(Refer Slide Time: 18:23)



So, though it was late, but still they got certain good results. So, it was agreed that the Henrietta Lacks genome data will be accessible only to those who will apply for, and it will be reviewed by one committee where family members of Henrietta Lacks would be there and once they allow it or they will grant the permission, then only the genome data will be shared.

However, they were not provided with any kind of monetary compensation regarding the whole issue or the profit which the institute has generated for such a long year, but still it is considered as a kind of a moral and ethical victory for a family which has been fighting long back and they were excluded from any kind of acknowledgement or basically any kind of acknowledgement involving the genetic research and which has substantially laid to the progress of the science.

So, these are the two important cases which basically asserted the problem of ownership and even though, the donors or the patients are the one from which the cell lines are or genes are extracted or isolated, but still it is for the development of the science and there is no financial benefit per se given to the patient.

But yes, after this case, the concept of informed consent regarding not only mere fact that what kind of treatment, but the future use or application of the cell lines or the genes which has been isolated from the body that got certain attention. So, this kind of problem generally happens in the area of the biotechnological research.

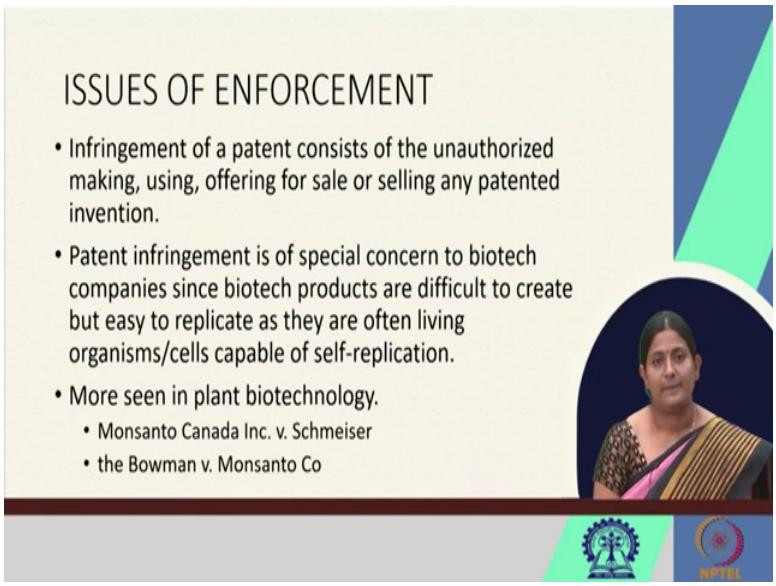
So, now, the patent filing in some countries for the cells or the gene so, what we have to do is whenever you are filing for a patent, one of the requirement in the patent application is that if you are a supplying or if you are seeking a patent on a genetic code or any other protein code or any other thing related to genetic material, you have to give the details of the codes of the genetic material or if it's microorganism, their identification and ATCC culture, every number has to be provided.

So, this is a part of the complete specification. In case of the plant varieties or in case of any other living plant resources or any other animal resources, if it is used in the patent application, the patent application should also give the or get the permission from the biodiversity authority so that in case of benefit sharing if some problem arises, then the resources could be traced back to the point of the origin.

So, these kind of issues are generally seen with respect to the biotech patent, the issues of ownership who owns the material.

So, suppose if a plant is native to particular region, or it is like only found in a particular region, and if some medicinal compound is been generated, which is patented so, can that particular region or can that village or the area, can they get certain benefit out of it or not? So, that point has been debated under the patent law as well and now, the disclosure of the facts related to the this origin of the resource is one of the requirement in the patent application.

(Refer Slide Time: 22:15)



So, now, one criteria for the patent that we dealt with- the novelty, the inventive concept or the industrial applicability. When it is the gene sequence, what kind of use is it giving to us? Well, if it is a gene for gene therapy, will be it considered as an industrial use?, which is a highly individualized medicine treatment

Can a modified DNA be used for the diagnostic kit or an EST sequence? Does it has high potential of utility? So, all these are generally considered in the patent and in some cases like it generates millions of dollars profit to the company or the organization who has filed the patent or who has the invention.

So, that's why in the biotech arena, people prefer to go for patenting their invention because that gives some kinds of security, that their invention is protected and nobody can use the invention or take benefit of their invention without taking their permission, it is a monopoly right for 20 years.

So, now, the whole crux of the patent is, that your inventory is getting certain monopoly, but sometimes, infringement of those rights happened, that leads to patent infringement. So, what is a patent infringement?

So, patent infringement is, using the invention to create the product or to use that process without the permission of the inventor and gaining commercial benefit or if there is an unauthorized making or using or offering of the sales or importation of the product patented invention, then also it amounts to in infringement. So, once you have a patent right and somebody infringes on your right so, you have the option to bring that person to the court of law and get the damages or the losses which you have suffered.

While this occurs in every field, there are chances that patents in all the fields of the invention might be copied or might be used by someone else, but the patent infringement in the biotech domain is again a special concern particularly because in biotech, the product are very difficult to invent or create for the first time.

But once the product or the technique is already invented, it becomes very easy to replicate the process because many a times, living organisms are involved and they are capable of self-replication and when I mention so, it is particularly more prevalent in the case of the plant biotechnology.

In animal cell culture, yes, you need a setup. If it is a biopharmaceutical industry or an Agrichemi the Agro-product industry, you need some kind of a setup or some kind of invention to carry out the process, but if you have made a genetically modified plant and you have the seed, those seed may replicate into itself.

And it is very difficult to stop such kind of the infringement and that is why the plant patent is another debatable area whether or not the invention in the area of the plant can be protected.

So, plant related inventions are protected, but plant patents or patent on a plant variety or patent on an animal variety is generally not allowed in all the countries. The United States is an exceptions where they provide the plant patents, means you if you have created a genetically modified plant, you can apply for a patent there and if you meet the defined criteria, you may get a plant patent.

So, this issue have two dimension, one in the developed countries and one in the developing countries. So, there are many landmark decisions in the area. So, as you know Monsanto, Dupont are the main seed producing company or leading Agri-biotech companies.

So, there are two landmark decisions which talked about the infringement with respect to the patents related to the plants. Monsanto Canada versus Schmeiser and the Bowman versus Monsanto corporation, these are the two landmark decisions which talked about the infringement with respect to the patents related to the plants.

(Refer Slide Time: 26:51)

So, just to give you the facts of the case, Monsanto Canada versus Schmeiser, the Monsanto developed a variety of a soya plant called the roundup ready canola, that is resistant to a certain kind of the herbicide.

So, here, one of the farmer named Schmeiser, he somewhere discovered or identified few canola plants that were resistant to the herbicides and then, he started propagating those plants and again, repropagated it year by year. So, he just grew over 1000 acres of his land with those resistant variety of the corn and those resistant variety of the corns were patented by Monsanto.

So, when Monsanto came to know about this activity by the farmer, they filed a case of infringement where the farmer has not taken the permission to recultivate. So, generally what happens when there is a plant patent or patent on a genetically modified plant, the farmers are not supposed to recultivate those seeds.

The company use certain technology known GURT technology or the gene-terminator technology, so that the plant will not be able to breed in this next generation. So, even if it is not there, but still the farmers were suppose to buy the seeds every time when they plant the material.

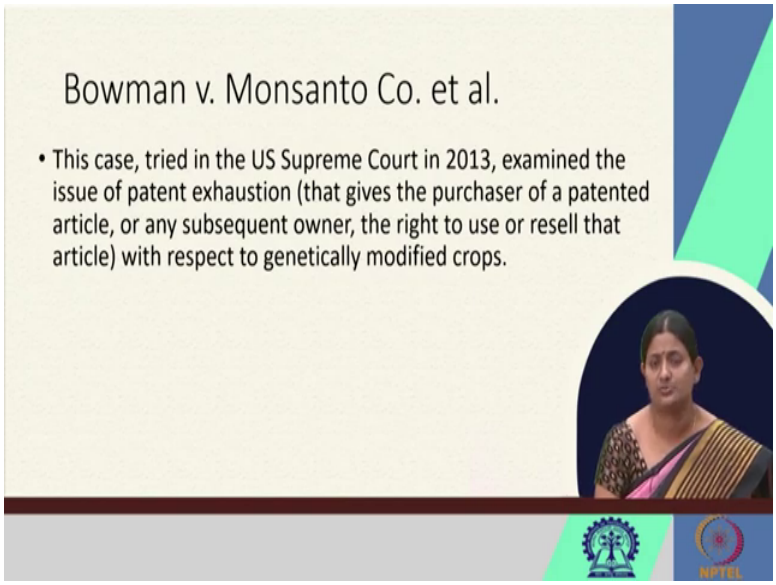
So, when Monsanto came to know about the conditions that the Schmeiser either knew or ought to have known the varieties which he is cultivating, as he again cultivated and

got such profit. So, finally, in this case, the Supreme Court ruled in favour of Monsanto and dismiss the arguments over the use of the patented genes or the cells where it is applied only in the context of the isolated firm.

Schmeiser to his defence argued that if it is some herbicide resistant gene or herbicide resistant cell technology so, it would be applicable when we are talking about a cell in gene in the isolated condition, but not about the plant itself, but that argument was not taken by the court and the person was found guilty of infringing the patent of Monsanto.

And however, the farmer was saved from paying the damages because he did not spray the crop with the herbicides and had not therefore profited from the invention. So, the crux of the matter is that when the invention is within a living organism like plant or in plants, it would be very difficult to stop the reproduction of those kind of the organism even though it is patented. So, that issue is also faced in case of the biotech patent.

(Refer Slide Time: 30:13)



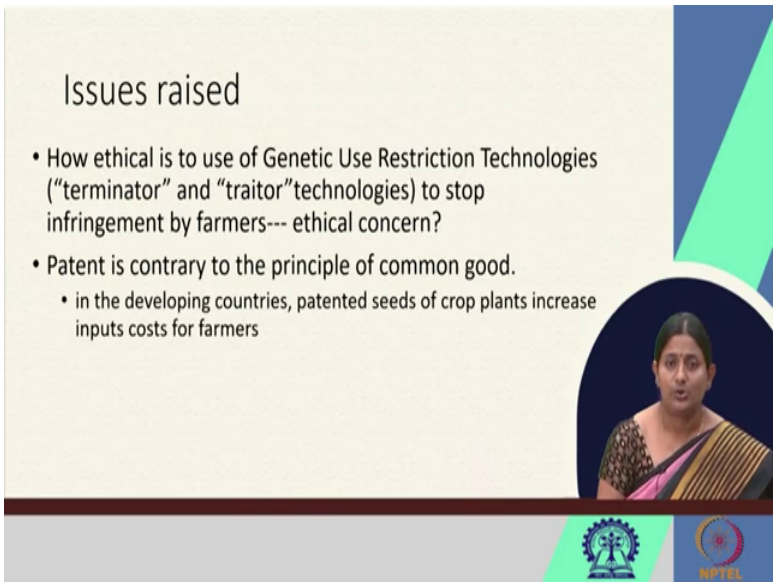
Similarly, in the Bowman versus Monsanto, again the Supreme Court took the issue of the infringement where patent has been violated and here, to his defence Mister Bowman he gave the concept of the patent exhaustion where means once you have bought a patented article, you have the whole right with respect to the article. So, if you want to reproduce it again, then you may do it.

So, here the farmer argued that by cultivating, he had created a new article by using that patented thing, but here, the court again did not take that argument and it did not consider the theory of patent exhaustion which gave the purchaser or the purchaser of a patented article or any subsequent ownership or the right to use or resell that article and this was in the case of the genetically modified crops.

So, if you see in the developed nations like the United States or in Canada, there are more than 200 cases filed by the Monsanto itself for infringement, where their patents have been violated. DuPont also filed and they have hired companies to find out whether or not people or farmers are cultivating their genetically modified plants without their permission.

So, because you know this is because for every acre of profit, the farmer has to give certain benefit to the main company itself. So, that is a big issue in the developed nations.

(Refer Slide Time: 31:50)



And if we see the concept of technology with respect to the plant which has been patented and if it is available in developing nations, then again, the dimensions of how we look into the problem is little bit different.

As, you know, in India we do not allow patents on the plant, but if there is a patent on the related technology and if the company is prohibiting the farmer from recultivating their

seeds in general it will hamper their interest. As, in traditional cultivation method, the farmers save their seeds so that they can re cultivate in the next generation.

And if by any use of the technology for example, this Genetic Use Restriction Technology- 'GURT,' which is the terminator or the traitor gene technology. If it is applied, then it will be ethically wrong. As, to gain profit, they cannot really use this kind of the technology which is harmful for the farmers.

So, the standard or the farmers in a developing nation like ours are completely different from the farmers in the developed nations. Our landholdings are very less. So, the farmers need to save the seeds for the future cultivation, and they cannot buy those seeds generation after generation.

Because again these patented seeds were are highly costly and there has been instances where in India particularly, Monsanto, they have tried to sell their seed at high prices and that is again a different part where the competition issues come in. The competition commission of India have taken cognizance in the matter where the seed companies were selling at high prices.

So, you really cannot try to establish a monopoly or create an anticompetitive environment, where no other seed company can sell their seeds and because you are a leading company, you have a patent, you will keep on selling it at higher price. There should be a balance.

The inventor should also get certain profits as well as the end users also should also be allowed to carry out his profession as he was doing, here in case of the farmers. And overall many a group also argue that the patent with respect to the plants are highly unethical and it is contrary to the principle of the common good.

So, because of the patent the price of seeds increases that raises the cost. like you must have heard about the Bt cotton issues in the states of Maharashtra and other states. So, the price increases, it creates an additional burden on the farmers.

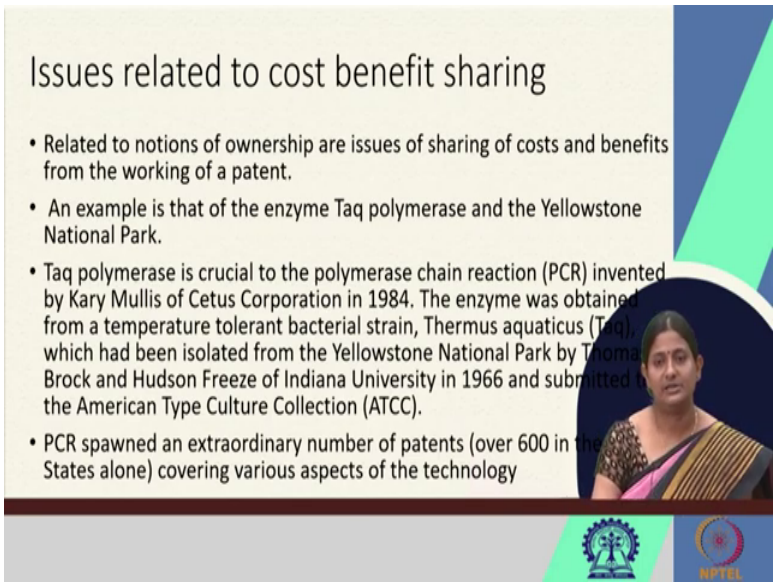
So, it is not the only issue where the infringement takes place by the recultivation of the plant, but issue also arises when the farmers are again deprived of their own right or their

overburden to pay high prices to use the good varieties of the seed. So, this is again another interesting issue which is related to plant biotechnology.

So, number of issues are there with respect to the patenting. So, in one way patent gives a monopoly right, but again, is this monopoly good for everyone? Because, as I mentioned in the earlier class, intellectual property right is to balance both the ends.

One way the inventor should also be motivated or get certain incentive and the end-user and the public should also get certain benefits. So, how to balance, where to balance? It depends on different countries in the different contexts.

(Refer Slide Time: 35:38)



So, coming to the next issue, there are again issues related to the ‘cost benefit sharing’. Cost benefit sharing is, if you have taken a resource from somewhere, can we really acknowledge them? are we sharing the profit to them? So, there are again a few things which come up. For example, one of the important invention in the era of biotechnology was the discovery of the enzyme ‘Taq polymerase’.

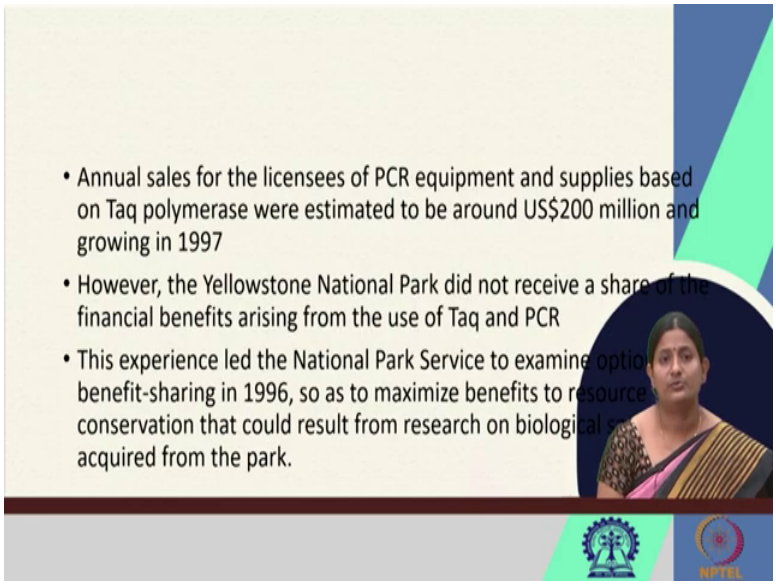
So, this ‘Taq polymerase’ is an enzyme which is isolated from the Thermus aquaticus bacteria and this is a highly temperature resistant variety and this Taq polymerase is very crucial for the polymerase chain reaction which is invented by Kary Mullis and Kary Mullis of Cetus Corporation in 1984.

So, this strain of the bacterium was first isolated in the Yellowstone National Park of the United States and like then, when once they isolated it, they were typified and then, it was like a deposited in the American Type Culture Collection because every microorganism has to be nomenclatured in a particular way.

So, the use of this enzyme laid the whole revolution in the area of the biotechnology through the PCR machine polymeric chain reaction. It is now crucial for every biotech research.

And now, you can see there are more than 600 patents related to the PCR and it is now been used in various aspects of the technology in the whole, whether it is for plant biotechnology or animal biotechnology, in different domains.

(Refer Slide Time: 37:38)



However, the concern was that Thermus aquaticus is an important part of the PCR and the technology related to the PCR and patents related to the PCRs have generated more than 200 millions of dollars. Now, as I am talking about the year 1997 and when the patent was alive, but remember it is a continuous profiting business. However, the place Yellowstone National Park, the authority there did not receive any share of the financial benefit, which was occurred from the use of the Thermus aquaticus bacteria or the PCR as such.

So, after knowing that bacterium strain has been discovered from that natural resource and it has become so successful. But because there was no agreement per se or there was nothing in written so, the Yellowstone National Park, did not have any profit sharing throughout the whole process. This bad experience have laid the National Park Services to examine their own policies related to the benefit sharing in the year 1996.

So, what they did? They thought of maximizing the benefit, which may occur from the conservation that could be useful in the research for any biological specimen which has been acquired from the park. So, they started forming a committee which would look into the cost benefit sharing mechanism once the materials were isolated from that park itself, but the problem was that, there was no IPR policy with them.

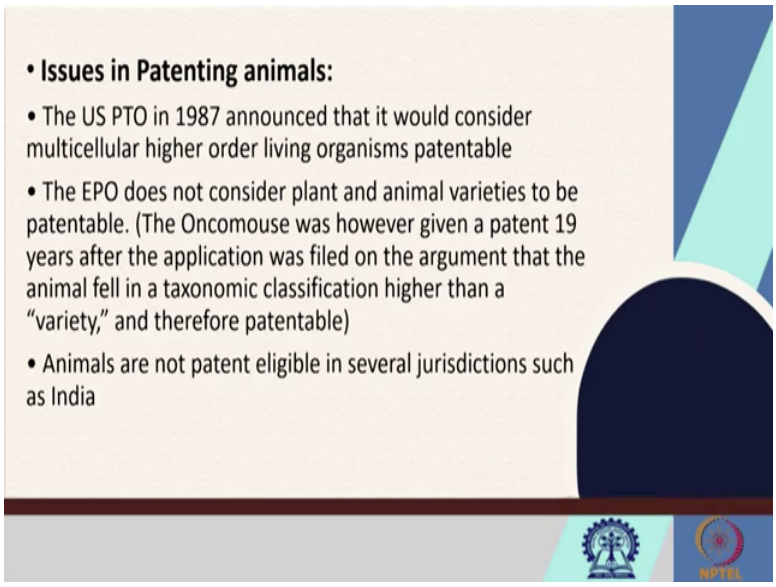
So, even though there were many instances where biological resources were been identified, but since there was no particular IPR mechanism, the cost benefit sharing aspect could not be very properly dealt with. But again, this is not only about the cost benefit sharing from a locality or a region where you are getting the organism.

But again if you see, can we really establish a proprietorship or ownership over a natural product ? So, it is a national park, Yellowstone National Park is a natural place where the microorganisms are naturally found.

So, can the national park authority claim ownership over a product which is natural or quite common in that area? This is the question. So, if now everyone would try to assert certain ownership or the proprietorship over a product which is native to that region, then it would be really messy situation to go about, when we are exploring or using that product.

This is again another argument with respect to the cost benefit sharing, with respect to the biotechnological invention. So, ownership issues, cost benefit sharing issue, these are quite prevalent in this area.

(Refer Slide Time: 40:49)



We were talking about the different aspects of it, and we have seen in how in the Anand Mohan Chakravarthy case and then Myriad case the modified microorganisms were finally, allowed to be patented. Where a genetic material has to be substantially changed with lot of substantial utility to be patentable. But, there are instances where the multicellular organisms have been patented.

So, the main issue is with patenting the animals. So, the human stem cells or human embryos or even cloning procedures, are generally not allowed in many countries, and when it comes to multicellular organisms like a whole plant, modified plant or a whole animal it is generally prohibited.

The European Biotechnological Directive, prohibits the patent on plant or animal variety. In India also plants and animals or a part thereof or essential biological processes, are not patent eligible subject matter. However, in United States in 1987, they announced that they will consider the multicellular higher order living organism as a patentable article.

But this stand was not accepted by the European Authority, European Union and the landmark case here is the Oncomouse case. So, the Oncomouse is a kind of mouse which is generally used in the cancer research. So, when the scientist discovered this MYC gene, which is basically an onco cancer causing gene and then, what they did?

The scientist inserted that MYC gene into the the zygote of a mouse and then, they developed into a mouse which is prone to develop cancer or became a cancerogenic mouse. So, these mouse models were very much helpful in understanding the progress in the area of the basic physiology or different aspects of the cancer research, because it was in 1980's that time the cancer research or there was lot of research over the treatment for the cancer.

And it was not really feasible or possible to study the progress of the cancer in the human bodies because again, it is a high that technologies were not developed then, but after this development of the Oncomouse which may act as an model to study and understand how the cancer progresses in a body. So, that gave a very useful insight into the cancer research.

So, when the scientist developed this Oncomouse in the Harvard University, they applied for a patent in 1984. In the United State that patent was granted in the year 1988, within just 4 years United States they granted the patent because here, there was no problem multicellular higher organisms were allowed to be patent, were considered as a patentable item.

The same application was filed in different countries including Europe and in 1985. The Harvard Institute filed a patent in the European Union as well since the European Union article 53 did not do not considered any animal or plant variety to be patentable, the patent office rejected the patent application, then it was appealed in the appellate board.

So, in order to understand, whether the oncogenic mouse variety can be considered as a variety itself or it is something different. So, if you see so, the variety is in the taxonomy and the variety is sub species like it is smaller ranks or smaller than a species and since the mouse or the Oncomouse is a mouse which is a specie.

So, it is not a variety. So, under article 53, it was possible to give a patent. However, few argue that whether it is a variety or species or this taxonomy of the animal? Or, can we really give patent to something or this patent be particularly rejected on the grounds of the public order and morality?

As they are creating a mouse which is inherently cancerous or can develop cancer, by deliberately inserting the cancer-causing gene into a living organism. So, can this

proposition be ethically accepted? So, that was the issue, but again the cost benefit approach comes in where you have to see the risk or the pain given to a particular organism and the profit or the benefits which the society is getting.

Since cancer was highly prevalent non-communicable disease for which there was no research or there is very less study. We need to develop medicines for that and if this kind of deliberate insertion of the MYC gene to a mouse model would give you a model where the cancer study can progress then it would minimize the sufferings of the human beings and minimize the use of the different animal models or to on which the studies has been performed.

Then finally, it was accepted that this oncogenic mouse is very much helpful in the whole cancer research process. So, finally, after 19 years of debate, the application on this animal variety, that is Oncomouse was granted in the European Union on the condition that it is not a variety, it is a animal species and therefore, it is patentable.

So, this was a long battle and the Oncomouse is not only protected as a patent, the name as well – 'Oncomouse' was trademarked by the Harvard University. So, in the patent application, the Harvard University, the inventors, they also claimed the process of inducing cancer in all the mammalian species. So, there did not consider that claim and kept it restricted to this mouse model which is known as the Oncomouse.

So, in the area patenting animal, there is a lot of controversy. You cannot really patent cloned animal as such. In India, we strictly prohibit the patent on any animal variety or the plant variety. In United States, these stands are little bit flexible in many cases, they allow the patenting of the multicellular organisms as well.

So, again, this is another contested issue in the animal patenting. So, even when the first cloned animal, Dolly evolved, there were lot of controversy. Because when something is done by the cloning process there is suffering. The Dolly sheep have suffered from lot of diseases and its immunity was less, then the lifespan was also less. So, can we really deliberately give pain to somebody? Or what is the usefulness of those kind of inventions?

So, the whole patenting process or intellectual property process revolves round this issue of the ethical aspects as well as the utility aspects. We have the patentability standards to

be followed but it is very difficult to achieve. But these issues are most frequently encountered in the area of the biotechnology research.

So, this is with ownership; the cost benefit sharing and with respect to identifying invention versus discovery, then there are country specific issues also. For example, for India, I have shown you various non-patentable items under the section 3 of the patent Act, where, section 3(d) talks about the mere enhancement or mere efficacy of a product cannot be patented.

So, in the pharmaceutical domain, again it becomes a challenge to establish whether or not the efficiency of the process or the efficacy of a medicine can come under the purview of provision. Who will decide that? So, there are controversy in that domain too, we will deal it in a separate lecture. So, I hope this has given you a little bit understanding of the general issues which all of us may encounter in the area of biotechnology patenting.

So, thank you very much for attending the session. So, we will meet in the next session.

Thank you.