Legal and Regulatory Issues in Biotechnology
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Module - 04
Technology transfer in biotech sector
Lecture - 17
Technology transfer agreements and patents

Welcome to the course again. So, in this lecture today, we will be discussing about the nature of the biotechnological license and how it is interrelated with the intellectual property particularly patents.

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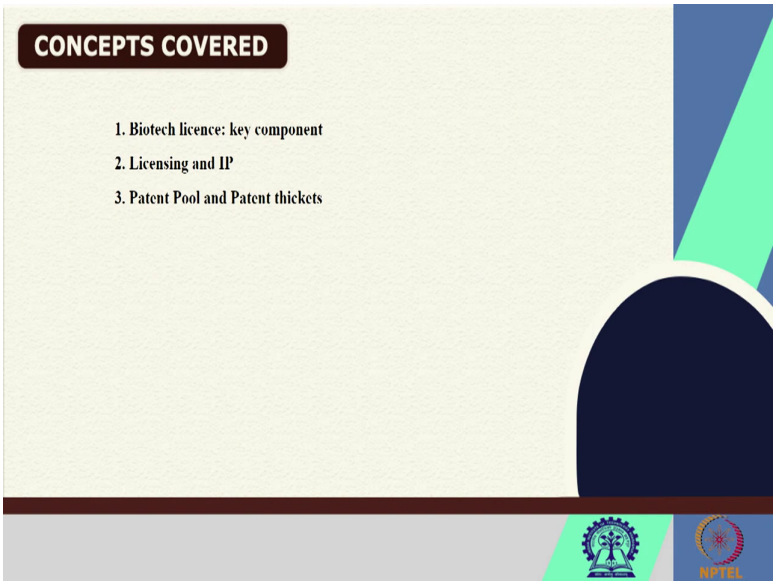

So, here, we would explore about the biotech license. What are the key components of this licensing process? Also, we would see the various aspect of the licensing and how it is interrelated with the intellectual property. And we will also have certain discussion about some popular concept or important concepts of patent pooling and patent thickets.

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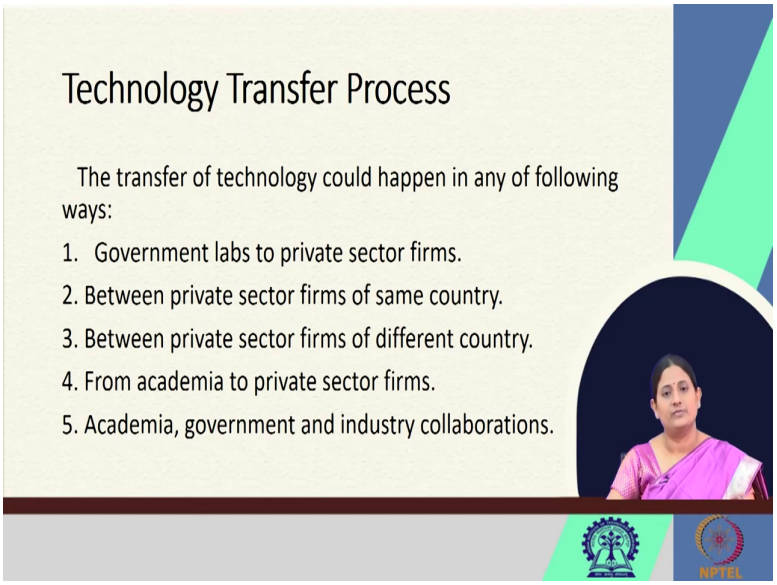

So, as we have been discussing, the technology transfer process means; the transfer of the technology from one party to the another can happen in many of the way like, the technologies may be developed by the government labs and can be transferred to the private entities or it can be transferred between the private sectors of the same country or between the private sector firms of the different country or it may be transferred from the academia to the public sector firm or academia government or industry collaboration may have certain technology, but all of them can benefit.

So, from technology transfer process is basically, a technology when it is given to some other entity.

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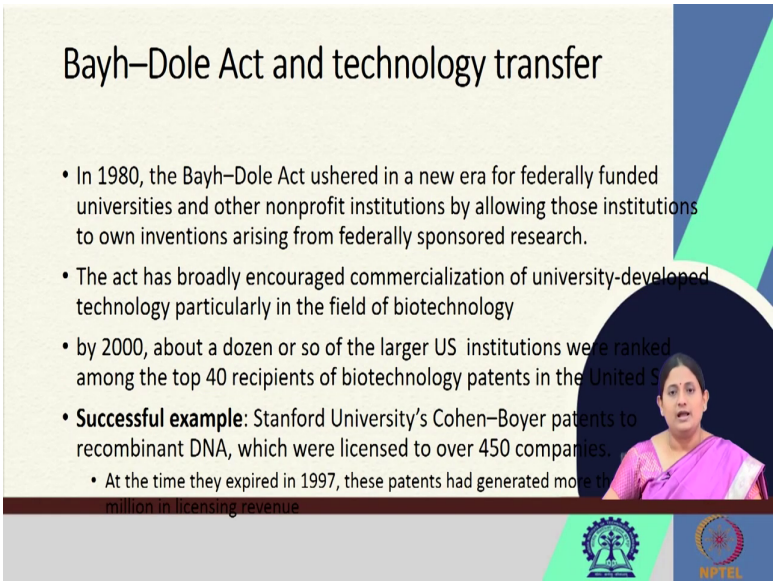

And this technology transfer processes gained importance particularly after 1984. So, basically when this Bayh-Dole Act came into force and it allowed the universities to commercialize their inventions, because those research which has been carried out by the federally funded federal funds. Now, the universities or the researchers were allowed to give those technologies to other institutions or other parties and commercialize those technology.

So, that lead to more and more filing of the patents or like other intellectual properties and also attempt to commercialize those technology. So, because you know this biotechnological research is a big like complicated research and that is why it needed lot of funding.

If you see in general, the public funding institutions are the major stakeholders or major research areas where lot of research in different fields of biological research has been carry carried out. So, if you see by the year 2000, about 12 or dozen or more of the US institutes where the top patent holding in the United States like all the top 20 or top 40 positions are held by the research institutions.

For example, we have very successful example of this Cohen-Boyer patents which were for the recombinant DNA technology and this Stanford Universities this patent was licensed to 450 companies. So, by the time this patent expired in the year 1997, it had generated more than 250 million Dollar revenue.

So, you can understand the potential of the technology. So, there might be certain revolutionary technology, which may establish itself as a big success in the commercial world. So, with that intention like lot of public as well as private entities are being involved in this thing.

But what happens, even though the public research institutes have developed certain Nobel inventions or breakthrough research, but many a times they are unable to successfully commercialize the product. For example, if some institute developed some gene for a particular indication or a gene which may be helpful in transfer converting a plant into a more productive one.

So, in that case, it may not be possible for that research body or the institution to commercialize the product. For that, it needed the support of some other agencies or maybe a private body or a any other a business entity, which may carry out or commercialize that process. For that purpose, it is essential that those technology can be transferred to the other agency.

But again, like material transfer agreement the transfer of the technology must be bound by certain terms and conditions so that in future there will not be any dispute about the financial consideration or intellectual property consideration. So, that has to be kept in mind.

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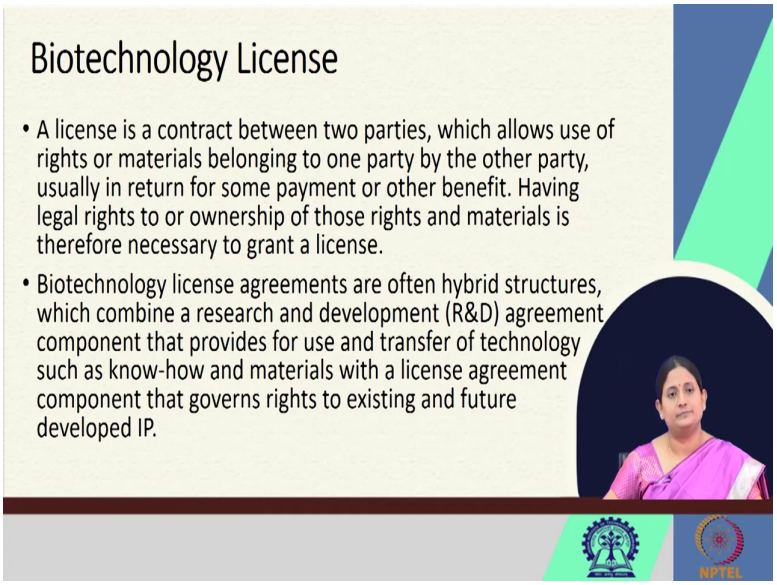

So, if we see the biotechnological license. So, in general, a license is a contract between the two parties, and it allows the use with respect to the rights of the materials belonging to one party to be used by the others. And for that use, the other party is giving some form of consideration or some compensation or some payment. And this legal right of the ownership regarding this material or using the technology is now given to the other party. So, this is about the general licence.

But if you come to biotechnological license. These biotechnological licenses are many a time referred to as hybrid structures. Hybrid structure in the sense; it is not only about the concept of R and D or the product which is being transferred, but again the associated know-hows and the potential role of intellectual property is also, looked into while generating or drafting a biotechnological license.

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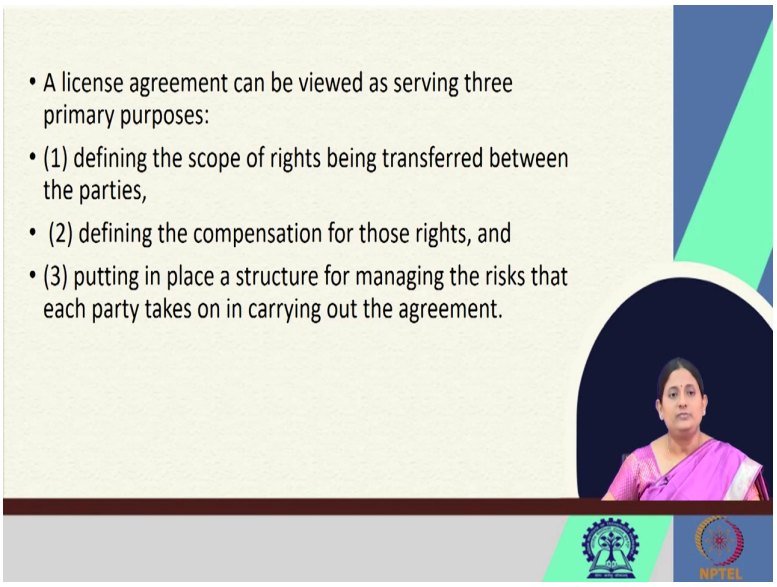

So, if you see the license agreement in general can be helpful for three reasons. 1st, it defines the scope of the rights being transferred between the parties like, what kind of right the parties will enjoy. Then, it defines the compensation for those rights means; what will be the compensation in terms of money or any other service or any other good. So, the company or the benefit sharing.

So, those compensations are properly spelled out in the licensing agreement. And it helps in putting in place the structure of managing the risk that each party takes in carrying out the agreement. So, the risk management what liability would be shared by whom that is also, generally put in a licensing agreement.

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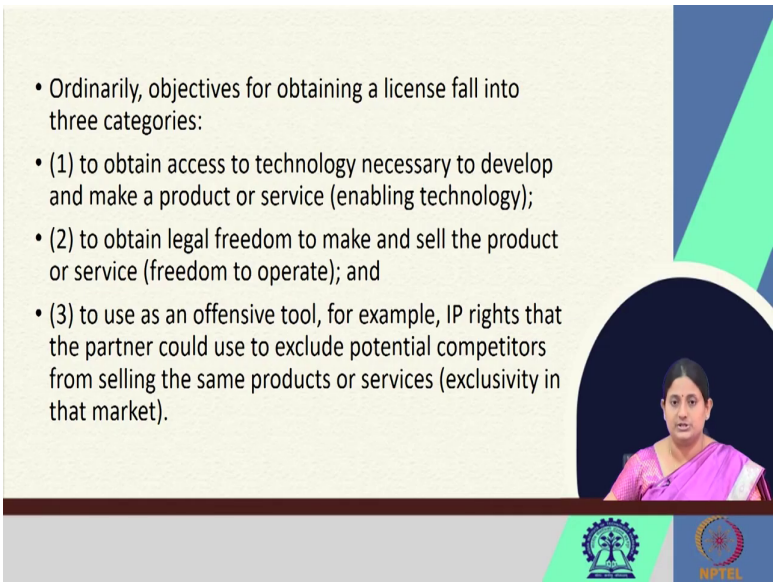

So, if you see, the objective of having a license falls into three major categories. 1st, someone would like to obtain the access to the technology, which is necessary to develop or develop a particular product or the service. So, which is a kind of an enabling technology. So, you need that readily available technology to develop certain product and then, commercialize that.

And then, you want to have this legal freedom to make and sell the product or the service, that you wanted to have the freedom to operate in that domain and you want to have the right to sell the product which you have developed through this license and agreement.

And sometimes people do license technologies, which is used as an offensive tool, for example, many patent right or intellectual property rights are there, which can be acquired by potential competitors to prevent the other party from selling the same kind of the product. So, in order to establish the exclusivity in the market also, sometimes the licensing negotiations are carried out. So, with this intention generally, the parties enter into the licensing negotiation.

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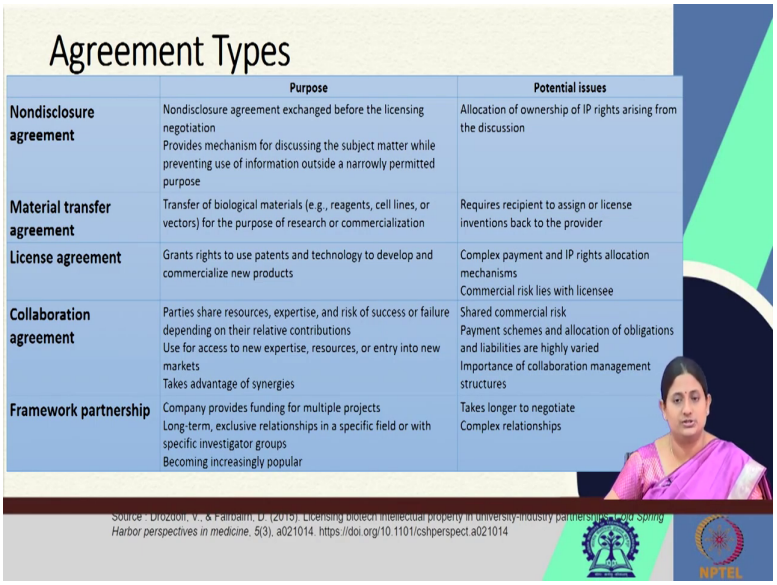

So, this is just a brief over we regarding different type of agreements which are carried out in terms of biotechnological research. So, if you see, like the different agreements which is pertinent for biotechnological research are the nondisclosure agreement, the material transfer agreements, licensing agreements, collaboration agreement and framework partnership.

So, let us have a little bit information about this thing like, nondisclosure agreement it is basically, when the research is just starting. So, it is exchanged before the licensing negotiation. So, you might have just exploding the possibility of having a licensing negotiation. You want certain technology and you want to have a what you called a good discussion before to ascertain, whether or not this kind of technology or you have you should licensing or not.

So, this nondisclosure agreement happens before the actual licensing agreements regarding the technology takes place and you there discuss the whole subject matter like regard related to your invention or your need or your technology. And this kind of an agreement basically helps to keep those information between the two parties only.

So, the nondisclosure agreement is a kind of an agreement, where the information can be kept as a trade secret sometime or secret between the parties. However, sometimes there might be certain issues like ownership of the IP, if the discussion lay leads to the development of

certain other intellectual property or certain some other ideas who will have the ownership about this. So, it may arise.

Then, material transfer agreement. We have already in the earlier class, have discussed like many of the things regarding the material transfer agreement where basically, the transfer of the biological material, whether it is a gene or a reagent or a cell line or any vector for the process of the research and the commercialization takes place.

So, now, that is also have certain issues. We have also discussed that in the earlier class and it requires the recipient to assign or license the invention back to the provider. So, if MTA is associated with certain IP development. So, you might have to give certain rights to the resource provider.

Then, other licensing agreements like the core technology license agreement. It basically grants rights to use certain patents or the technology to develop enter commercialize the product. And here, the potential issues mean, what are the terms and conditions in which the both the party are agreeing to be bound by that license. And sometimes, because the technology might not have been proved in the market. So, the commercial risks are also associated with this licensing agreement.

Then, what is a collaboration agreement. So, the collaboration agreement basically, they are the more than one party come together and they share the resources, expertise and risk of the success or the failures and they try to develop certain new product or the new process.

So, here, there is also a certain commercial risk, but again this risk is shared among the collaborators. Then, IP issues might arise, but again that has to be resolved as per the structure of the agreement. Then, another type of agreement, which is known as framework partnership. So, here the company basically provides the funding for the multiple projects, which is basically long-term and exclusive relationship in specific field or specific investigators are associated.

And now these are like gradually becoming very popular and it is a kind of a complex negotiation, because multiple projects are being funded and worked out together. So, it is a

little bit complex process to negotiate. So, these are basic types of the agreement, we generally take place in the biotech domain.

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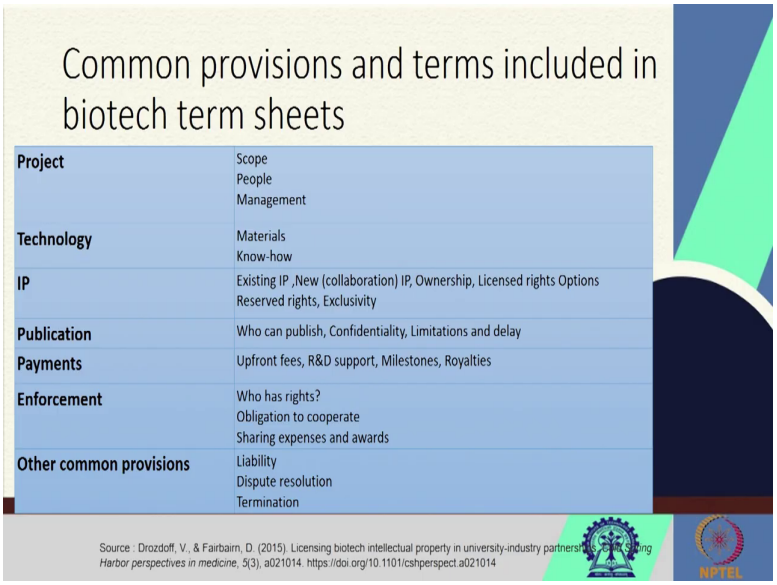

Now, coming to the different provisions, which must be taken into account while drafting the biotech licensing agreement, which is known as the terms and condition of the term sheet. So, because you again harping on the issue that biotech research is a very long and complex and cost intensive process. So, here, whenever there is a licensing negotiation, they there are certain key points which has to be taken into consideration.

First, the scope of the project means; what is this all about, who are the people involved with that and how the management is going to take care of that. So, before the negotiation takes place, you have to be clear about all this aspect. Then, what technology in terms. There might be more than one technology involves, what are the material involves and what kind of know-how's are associated with it. So, those has to be very clear and has to be mentioned in the term sheet.

Then, intellectual property again, a very important part of any of the biotech negotiations. So, you have to be careful about the existing IP, which is covered by patents or any other forms of intellectual property, with respect to the technology. And if some new IP develops then, the what will how you are going to resolve the ownership issue.

If there is a collaboration again, what would be the sharing cost sharing benefit sharing mechanism. Then, how are you going to plan for the licensing options and there are reserved rights or the exclusivity about the developed technology, as well as the intellectual property; that has to be again made clear from the beginning.

Then, publication process. Who can publish what should be the confidentiality norm, what kind of publication is allowed and what will be the limitation of the publication or do you have a clause that will be certain delays in the publication, then it is going to publish. So, that has to be also taken into consideration.

And most important, the payment conditions for the biotech license. So, what kind of payment mechanism would be chosen, whether you are going to pay the upfront fees. So, basically, if you see the what you called the payment mechanism can be of different types.

So, in some cases, it is upfront fees like before or when you are taking a license, depending on the valuation of the technology, you are giving a lump sum amount of money to the license or technology provider. So, that is called the upfront fees. Again, some risks are associated with that. Like, you never know how much potential is that. So, either it may prove to be highly potential sometimes, it may not work out. So, that has to take into account.

Then, for R and D support, what would be your allocation of the money. Then, there might be milestone payments, because sometimes what happened in the particularly in the pharmaceutical research like I mentioned there might be certain lead molecule. So, as in when you are progressing with your research, you are paying to the other party like, once your drug is successful in the phase one clinical trial or phase two clinical trial or you might get got an approved approval by the drug regulatory agencies.

So, each these steps are known as the milestones and for each of these steps, you might give the payment to the technology provider or there might be other consideration like royalties. So, royalties are either a fixed percentage of the profit which you will be acquiring or depending on the units of the product sold you may also ask for the royalties. So, the terms and condition for the payments has to be again made clear in the term sheet.

Then, for the enforcement. Since, the technology belong to one party and it is used by the other party then, who has the right to take enforcement measures. Suppose, there is an infringement issue happens who is the one who can sue the infringer then, what is the obligation to cooperate and if there is an expense related to litigation or any other thing then, who will be sharing the expenses or awards.

So, it might be both ways, either you are also infringing certain technologies or your technology is being infringe. In both the ways, it might be a problematic situation. So, those has to be also taken care of. Then, other common provisions and tours, the liability issues, the dispute resolution and under which terms and condition the licensing negotiation may be terminated. So, these are basic provisions which are generally present in each of the biotech licensing technology.

Again, the scope of the thing like again as I mentioned. A gene may be useful in under various circumstances, either you might develop a product you might use it as a research tool. So, in the licensing agreement, the scope of use of those technology has to be made clear.

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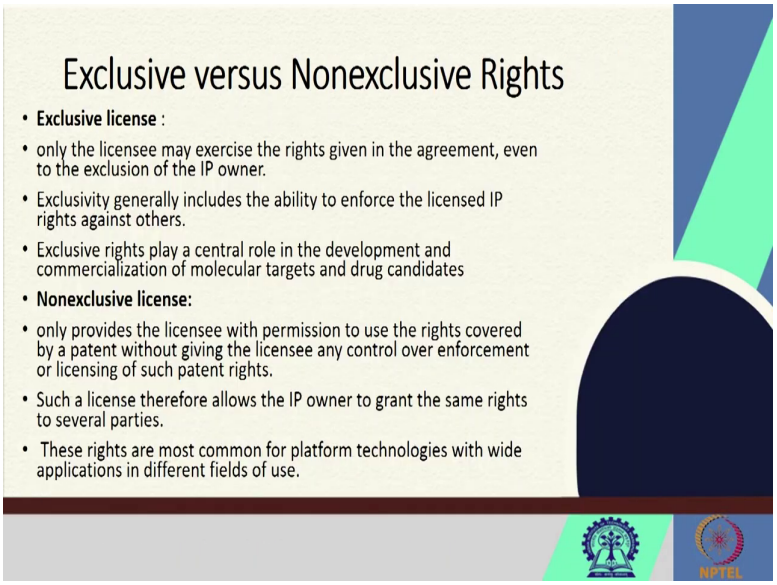

And again, if we see the whole biotech licensing maybe again majorly of two type exclusive license and nonexclusive license. So, in the exclusive license, there the license is given to one of the licensee and the licensee only exercise the rights given in the agreement. Again,

sometimes even the IP owner is excluded so, but the licensee is the only person who enforces whose uses this technology.

So, basically, this exclusive license allows the licensee to enforce the licensing the IP rights associated with this technology. And if you see, it is basically done in or used in the development or commercialization of the molecular targets for the drug candidate, where only one individual R is given the right to license right to develop the technology and that individual might have the capacity because by virtue of this licensing agreement to sublicense in some cases.

So, again that goes on depending on another situation. In an exclusive license, the licensing has all the rights as equivalent to the original technology original owner of that invention. Then, there is another concept called the nonexclusive license. So, in the nonexclusive license, it basically provides the licensee with the permission to use the rights covered by the patent without giving the licensing any control over the enforcement or licensing of such patent.

So, you are just like a user, where the technology is given to you and means the to the licensee and he can use the technology for the development of the product. Suppose, any infringement issue takes place or any he wants to cross license it, he is not allowed to do. So, only the original licenser can take place or can take out of the enforcement issues or further sharing of the technology.

So, by virtue of this nonexclusive license, the owner of the technology may give many numbers as many as number of nonexclusive licenses to many parties. So, at a time many producers can produce the same or can commercialize the same technology. And this kind of rights are generally found in the what you called in the area of the platform technologies basic technologies or development of the different tools. So, those kinds of license argument in those fields.

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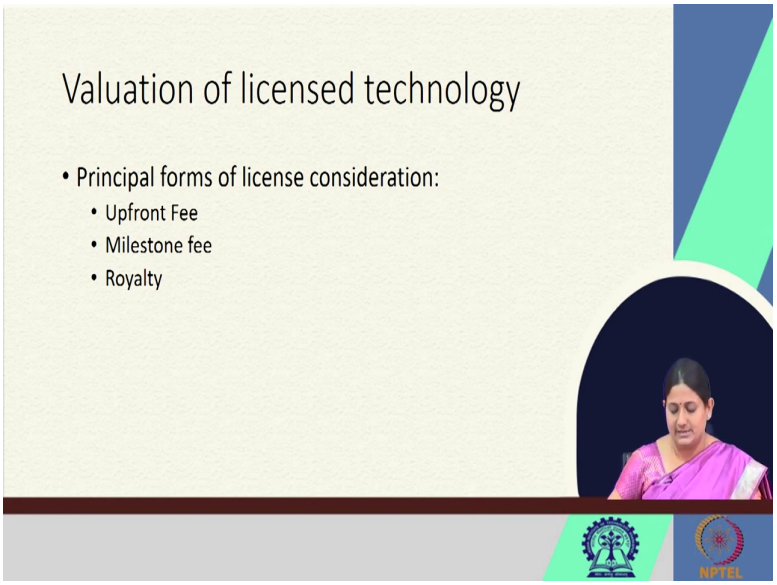

Now, again, the payment option I have already mentioned that. The valuation of the licensed technology is very important, because to determine what kind of payment consideration has to be done. So, you have to decide or you have to value the technology how valuable will be the technology. So, that assessment has to be done very carefully.

And then, depending like how you are going to pay the fee whether it is an upfront fee or milestone fee or the royalty. So, in pharmaceutical sector if you see, it is basically the milestone fee and then, it goes on as an end the drug progresses and then finally, the royalty is also given. So, valuation of the technology can be done in many ways and accordingly payment is decided.

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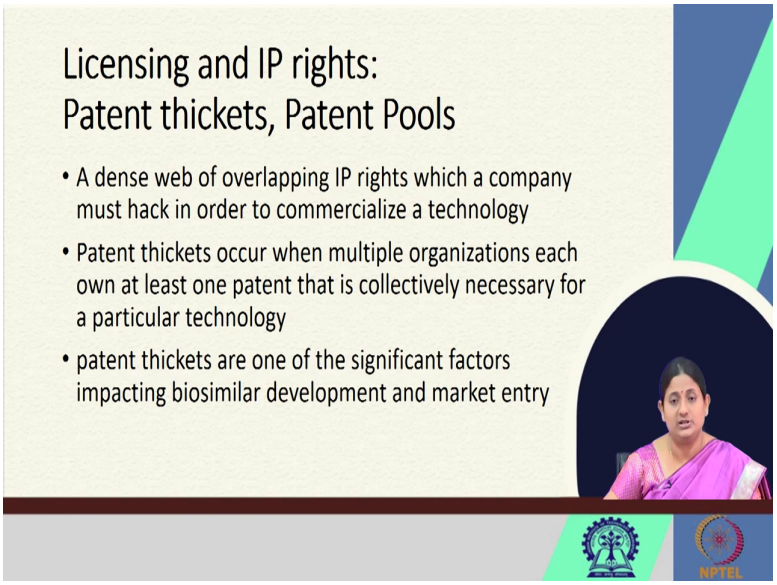

Now, any biotechnological development if you see, it is most of the time majority of the time it is associated with the intellectual property, because the developer wants to protect his rights and they generally filed the patents or thus basically, patent will the important form where we take when you take the case of the biotechnology.

So, here as I said the single product development, whether it pharmaceutical or any other product it involves lot of technology not a single technology. So, sometimes what happens, you are in position of one technology and you need 10 other technologists to make that product. So, what you do as a like you negotiate with each of these individual technology provider or patent owner and then license that and then finally, produce.

So, sometimes the concept of patent in respect to a biotechnological invention, becomes a problem for the product commercialization as well. So, there are two concept one is known as the patent pool another is know the patent thicket. So, let us discuss it one by one. So, in case of patent thickets, which is generally used in a negative connotation. So, the patent thicket is considered as a dense way of overlapping IP rights, which a company must hack in order to commercialize a technology.

Suppose, there are ten patents for a product and nine of them are willing to give you license, but only one person not being able to negotiate properly. So, that delays the whole product

development process. So, as the number of patents increases with respect to a particular product, the complexity with respect to those product development or commercialization also increases.

So, generally, what happens in many cases since the research are in varied domain sometimes, it becomes very difficult to ascertain who are the patent holders and some persons deliberately file patents in different area just to block those technologies. So, these are known as the patent thickets.

So, the patent thickets occur when the multiple organization multiple organizations own at least one patent, which is collectively necessary for the particular technology development. And like it delays the market entry and it is highly significant particularly for the biosimilars or biopharmaceutical segment and it may potentially delay, as well as increase the price of the technology as well.

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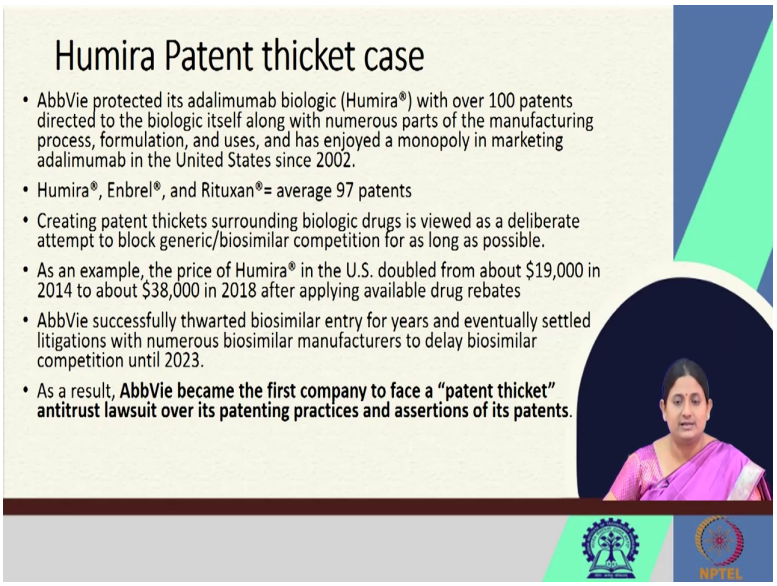

So, this connotation is like always used in the negative way. One of the greatest examples of this is the Humira case. So, Humira is one of the top selling drugs pharmaceutical substances in United States. So, the company AbbVie, which protects the the main ingredient adalimumab biologic, which is the main ingredient of Humira.

And you will be surprised to know that they have filed more than 200 patents to protect this compound and about out of which more than 100 patents were granted and they are directed to the biologic itself. And it involves different kinds of like starting from the formulation, the process, the delivery method and then, genes, plasmid different aspects were taken as a patent. And the patent for this Humira were granted in the year 2002.

So, 100 of patents. So, you may imagine like, if somebody wants to make a biosimilar for the same drug. So, they have to wait till all the patents expire. So, even though the first patent has expired in 2018, still the drug has is being as a top selling and the price of the drug is also doubled like, in 2014 the price was 19000 Dollars. Now, it has increased to 38000 Dollars.

So, this patent thicket was like considered as a deliberate effort to like stop the competitors to enter into that domain. So, this notion also what you called gives rise to the issue of the competition anticompetitive practices, which comes under the purview of the competition law means, when you are deliberately preventing somebody to enter into the market then this might be called as the anticompetitive behaviour.

So, this Humira against Humira potential anticompetitive like case was filed; however, many of the company have gone through out of court settlement, because they believed that the legal battle is again a long process. So, it may take further more real. So, till 2023 this Humira drug is secured.

So, there was a study basically, which compared the patent component for the biological drugs as well as the small or the chemically derived drugs. So, it was founded on the average, the biological drugs have 97 patents and for this small molecule drug, they are around 40 or 45. So, like Humira, Enbrel, Rituxan on the average like they have 97 patents surrounding each of the drug molecule.

So, you can see that this patent thicket is like a kind of a - If one company the developer innovator company has all the patents then, it is giving the monopoly to the company well beyond 20 years of time the patent time period, but again if it is held by different individuals then, again it becomes difficult for a producer to commercialize or produce that product. So, in both the ways it is an issue.

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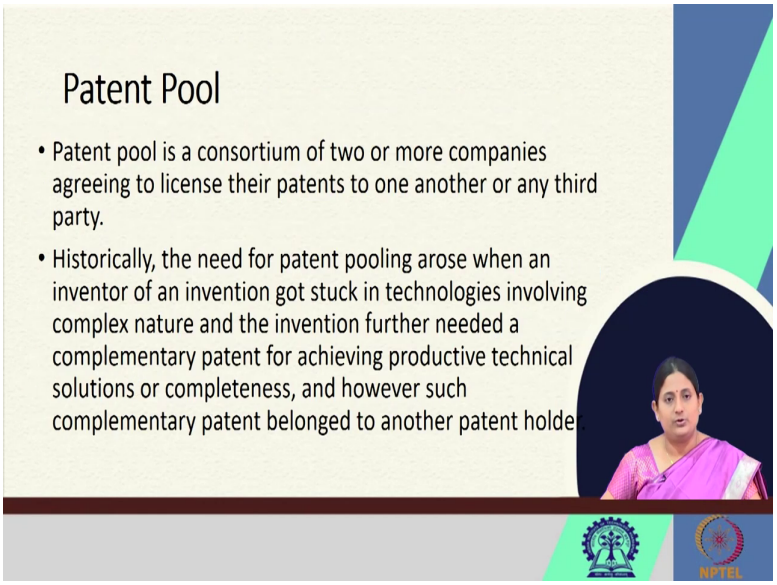

So, that is what about the patent thicket. Next coming to the concept of patent pooling. So, patent pooling is basically again, a positive, it is considered as a positive endeavour, where two or more companies they agree to license their patents to one another as well as to the third party.

So, as I said the biotechnological product might have different components and for which different entity might be having the IP rights. So, all of them when come together and give the pay to put the patents together. Now, anyone of the party, whether the party which have given the patents or any third party are allowed to license those technologies.

So, if you see the need of patent pooling arose, when the inventor of an invention got stuck in technologies involving the complex nature and the invention and further needed a complementary patent for achieving the product and it wanted certain technical solution or other things. So, basically it is a cooperative mechanism where or complementary mechanism where you are getting certain help from the pool. So, that is known as the patent pool.

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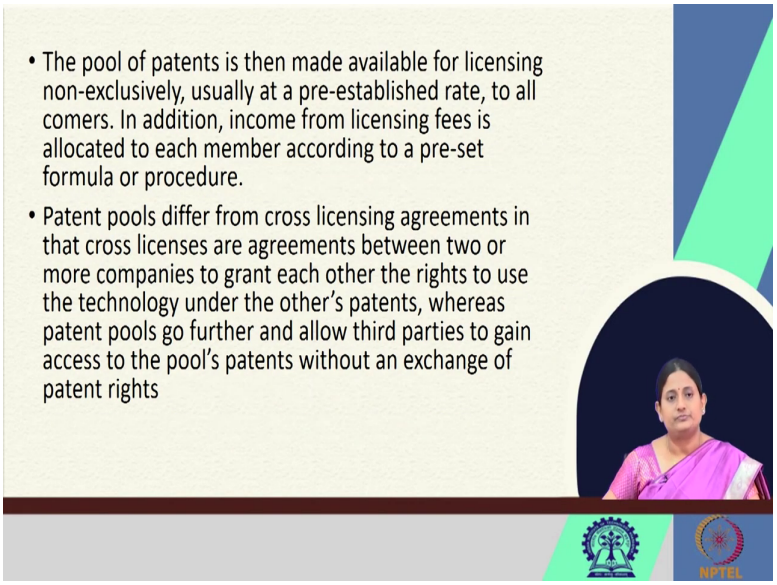

And generally, in the pool of the patents, it is available in the nonexclusive forms and the rate was also before established and for what whoever comes for licensing negotiation. And in addition to that, the income from the licensing fee is allocated to each member according to a preset formula or procedure. So, because it is a pool, whatever technology is being licensed, that profit is again being shared among the other members.

And this patent pool is different from the other licensing mechanism like the cross-licensing mechanism. So, what happens in cross-licensing, I license your technology and you license my technology. So, it is the exchange between the two parties, but in patent pooling, any third party can also participate and can license the technology. So, this is the basic difference between the patent pool and the cross-licensing mechanism.

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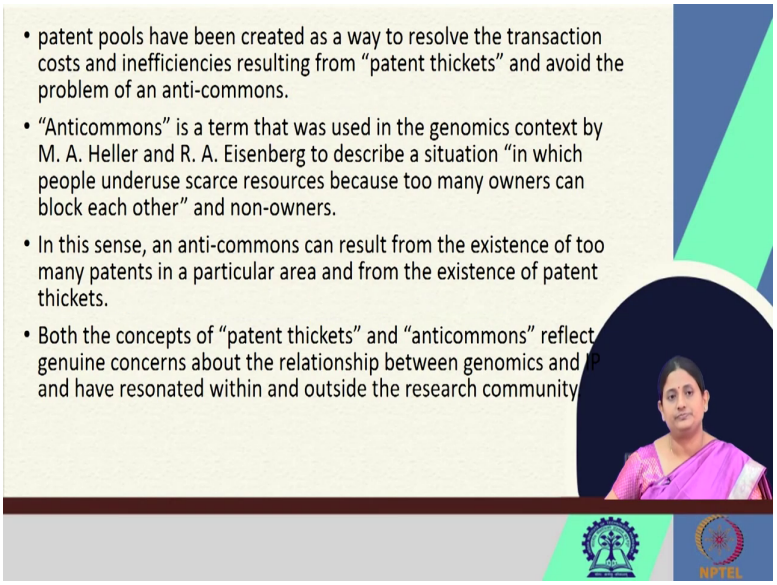

So, again, these mechanisms are basically created to resolve the issue with respect to patent thickets and what you call to avoid the problem of the anticommons. So, this term anticommon was used in the context of genomics by M. A. Heller and Eisenberg to describe a situation in which people underuse starts resource, because too many owners can block each other or the non-owners.

So, when there are what you called too many patents are there in a particular user and there may be chance of patent thickets so that may lead to anticommons. So, in the genomic research, where again many things are interrelated, this may become a problem and that for that to avoid or to circumvent that problem, this concept of patent pool has been developed.

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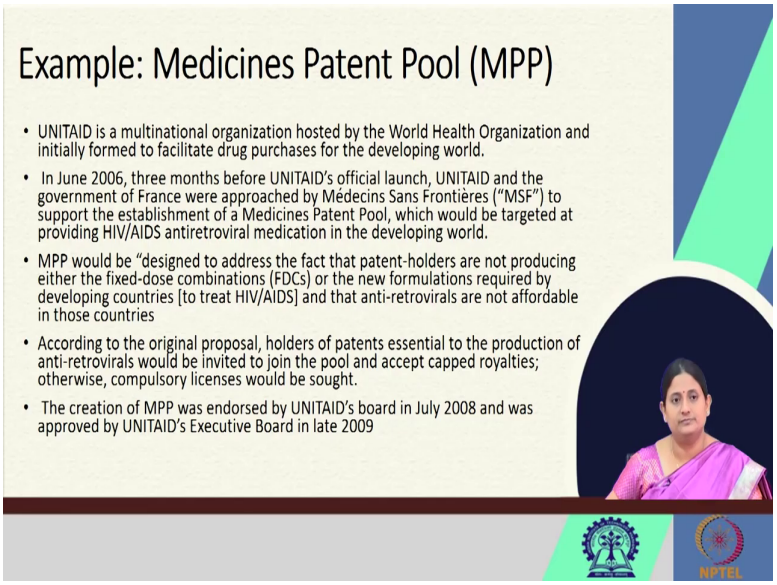

So, now, if we see the day-to-day thing. So, we have different what you called patent pool arrangements like, Medicine Patent Pool or MPP. So, under this UNITAID which is a multinational organization along with the WHO, they have tried to come up with a patent pool mechanism to facilitate the drug purchase around the developing world.

And like in June, 2006 the UNITAID and The Médecins Sans Frontieres or M S F organization like, they came together for the establishment of the patent pool and particularly it is targeted to providing the HIV or AIDS antiretroviral medication in the developing world.

And the MPP is designed in such a way, that the patent holders who are not producing either the fixed dose combinations or the new formulations they will give the technology. So, in for the developing countries. So, that the antiretroviral drugs can be things to as combinations can be produced at its affordable rate and the holders of the patent are like invited will be invited to join the pool and they will be accepting certain capped royalties.

And if they do not agree then compulsory licensing would be issued. And this medicine patent pool was endorsed in the year like 2009 and it has been helping for the development of the new different fixed dose combinations.

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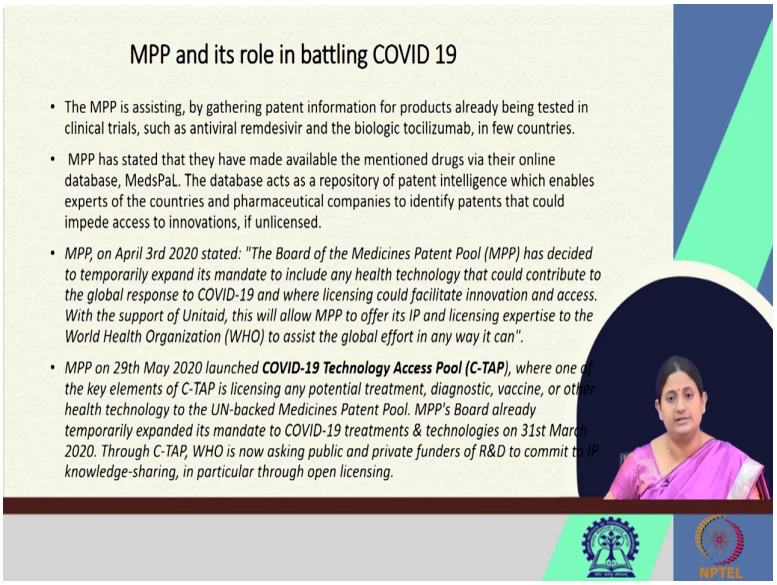

And in the recent times, this medicine patent pool is also helping in battling the COVID-19 virus pandemic. So, like they are trying to assist by gathering all the patent information related to the products which are already in the clinical trial or have been already been developed including, the antiviral remdesivir or any biologic like tocilizumab in few countries. So, all this informations are now gathered and the plan to develop a kind of a patent pool which would be accessible to everyone.

And so, the MPP already have made available the different drugs which are being already in certain phases of development in their database known as the MedsPaL. And it is a database which act as a repository for the patent intelligence which enables the expert of the countries and other pharmaceutical companies to identify patents that could be essential for the development or that may impede the development of the drug, if unlicensed.

So, on 29th of May 2020, they have launched these COVID-19 technology access pool where one of the key element of the C-TAP is licensing any potential treatment diagnosis diagnostics or vaccines or any other health technology to the UN backed medicine patent pool.

So, this is one of the again initiation initiative has been taken to like gather the information. So, that in future potential medications can be developed. So, this is a good sign that

everyone would be able to more and more drugs can be developed for battling against this COVID-19 disease.

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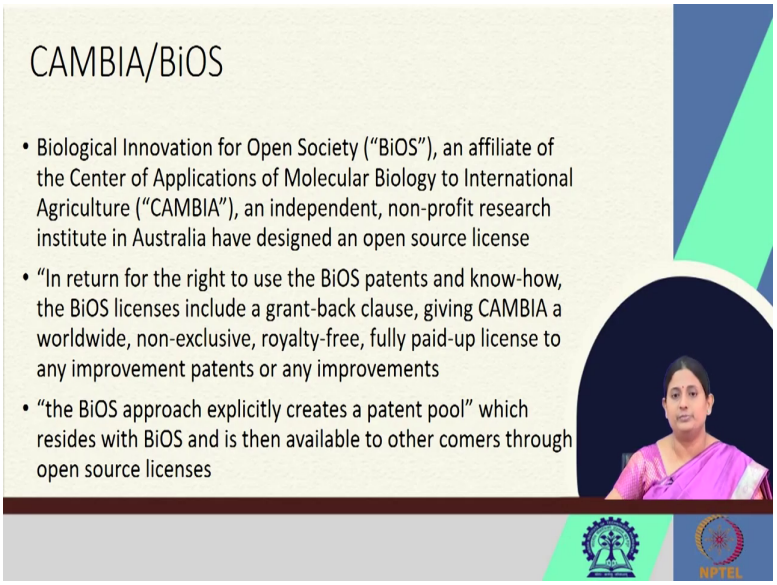

Apart from this, there are other patent pool like this CAMBIA or BiOS or biological innovation for open society. It is an affiliation of these centre for application for molecular biology to international agriculture or CAMBIA and it is an independent non-profit research institute in Australia and have designed an open source license.

So, "In return for the right to use the BiOS patents and the know-how's, the BiOS license include a grant-back clause, giving the CAMBIA a worldwide, non-exclusive, royalty-free, full paid-up license to any improvements patents or any improvements. So, that is once deposited.

So, now, improvement can be done without any these different clauses which I mentioned. So, this is also a kind of a patent pool which resides in the BiOS and it is available to the other comers through the open-source licensing. So, that new technologies can be developed. So, these are the few again, pool or a place where all the technologies can be has been gathered and that can be given to other parties. So, that more and more technology can be developed.

And as I mentioned in the biotechnological research, this becomes very important because we need a lot of technology in a collaborative way to develop different products which can be commercialized successfully. So, with this, we end this session on our biotech licensing negotiations. So, thank you for being with me. Hope this has been useful to you all.

Thank you.