Legal and Regulatory Issues in Biotechnology
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Module - 01
Regulation of Biotechnology Research
Lecture - 02
Biotechnology product development cycle and critical issues (continued)

So, we so far discussed about the genetically modified plants and the challenges therein. So, now, let us come to another important aspect of this Biotechnology development which is the in the area of human health.

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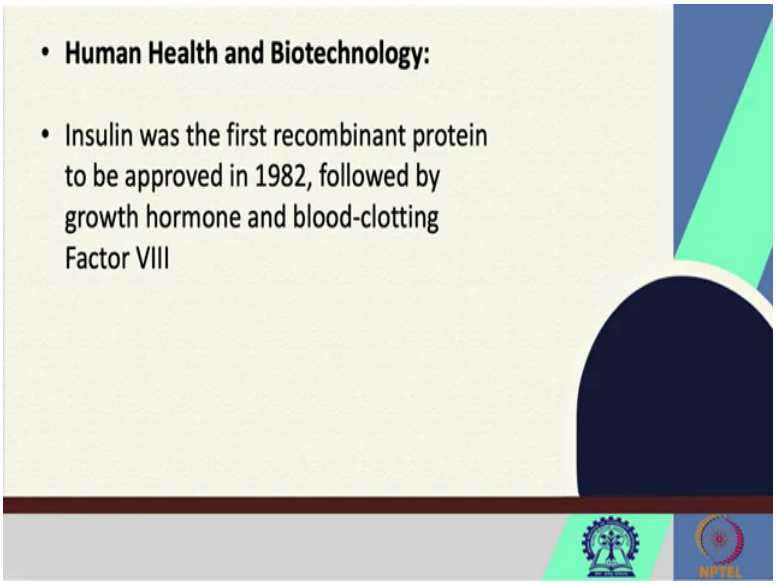

So, now as you know with day by day the humans are being infected with number of diseases whether communicable or non communicable diseases. Though chemical drugs are there for the treatments of various diseases, but the biotechnological process have really gave an arsenal to fight with the non communicable and many other diseases.

So, with the help of the biotechnological process we have now developed number of protein molecules, monoclonal antibodies, vaccines molecules and other like with the hybridoma technology and number of technologies are there by which we have been able to develop

medications or pharmaceuticals which are helpful in treating the human beings from different kinds of the diseases.

So, if you look back to the history of the biopharmaceutical. So, insulin was the first recombinant protein which has been produced and approved in the year 1982. So, if you look back to the history of the biopharmaceutical development, the human insulin which is used for the treatment of the diabetes.

The insulin was the first recombinant protein which was approved in way back 1982 and after that other protein molecules like human growth hormones, blood clotting factors etcetera has been in development since then, like till 2000 more than nearly 150 biopharmaceutical products has been developed and many of them are under pipeline.

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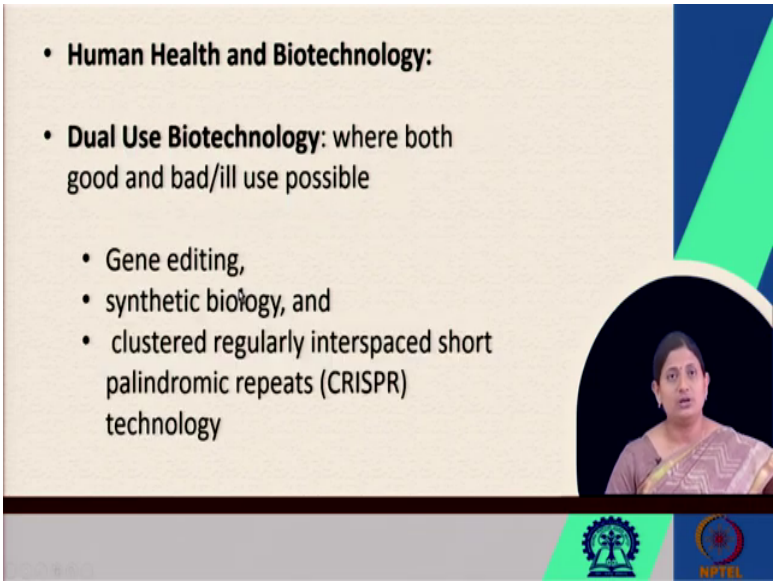

So, this technology has like changed the way how the science of treating people or basically medical science has been dealing with the different diseases. Now, initially what have used to happen is like the various compounds which are necessary for the treatment are like are isolated or extracted from the animals.

So, at that time there was a risk that some of the prior molecules or some of the other traits may pass on to the impurities may get mixed with the product and that may lead to some undesirable side effects, but with this recombinant DNA technology not only the

development of the drug could take place in a higher or in more amount or quantity, but in a shorter time period also.

So, after 1982 as I mentioned so, there has been number of drug molecule, which are being produced by the recombinant DNA technology. If you see the technology basically we can like can really categorise this biotechnology use into two ways like, that is the beauty or the challenge with the biotechnological thing is that now it can be used in both way in good way as well as in the bad way.

So, there are technique or the processes. For example, gene editing technology, synthetic biology then there is CRISPR technology. These are the things which can have very good effect at the same time if not properly used it may destroy the society it may have a very bad or the bad use which is really harmful for the society.

So, the terminology dual use technology is generally used in the case of the defence sectors, but here also in biotechnologically this has been now used more appropriately because of the affiliation or the fear of the potential misuse of the technology. So, like gene editing, what is gene editing? So, you are really able to edit or modify or delete certain gene.

So, now, if something is not working properly some gene is not working properly, not producing the desired protein or producing in less amount or whatever may be the way, you can change the gene and then treat that individual, but again if that technology is not used in a positive sense and it may again deliberately you edits the genes to get certain effect which is not desirable or to destroy something. So, then it may be a problem.

Synthetic biology, for example, the study of the viral particle for example, this Corona Virus it is so recent like after these SARS COVID. So, now, there has been lot of studies with respect to the viruses and again during that studies it is also possible to create new mutant strains of the virus which again may be very harmful to the society. So, that is one of the again negative implication of the science or technology.

Then, there is CRISPR technology, it is also a kind of a gene editing technology and this can be very helpful in generating number of biopharmaceuticals which can treat many of the

animal or the plant diseases, but at the same time the with the ill intension this technology can also be a problem. So, that is the issues with respect to the biotechnology.

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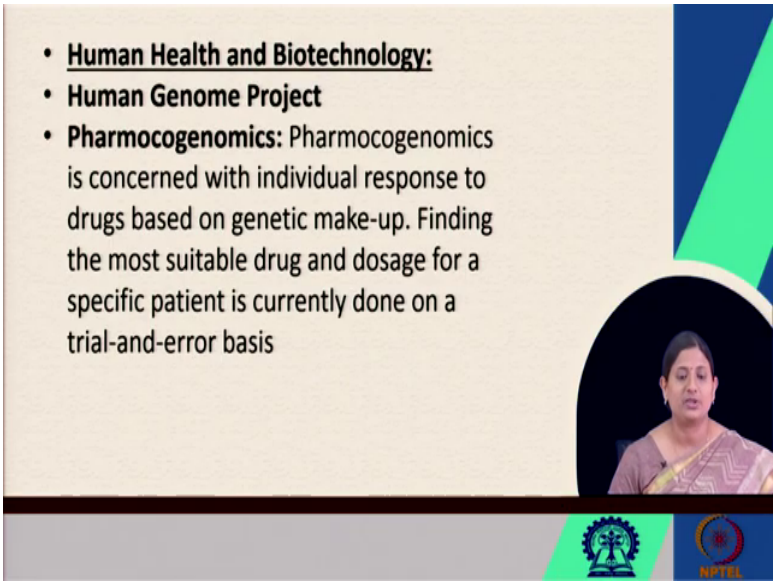

And particularly after the Human Genome Project now we have map of the human genome and scientists are getting to understand how the various genes are interacting and how they are responsible for the secretion of the defined protein. And how these again potentially be formed or how these genes can be a potential agent for development of the newer product or newer technology.

And after that we have this pharmacogenomics, where the individual responses to the drugs based on the genetic makeup or like how to find a suitable drug or the doses for a specific patient can be done in a trial and error basis. So, these are the technology which are now being developed and we have access to those which has help which has helped us in many way.

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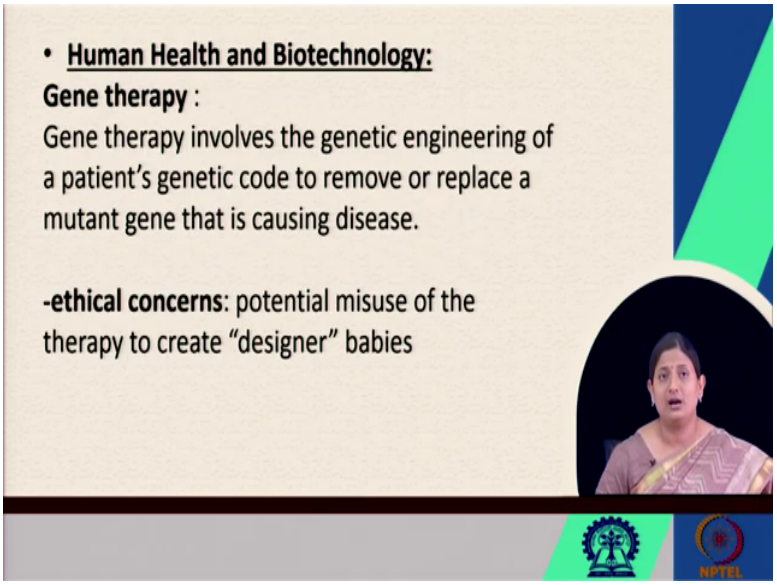

And the gene therapies as I mentioning so, it involves the genetic engineering of the patient where the patients genetic code is studied and defaulty genes are replaced by the good genes or the well coding genes so, that the disease causing agent is been removed from the body.

However, with the advent of the technology again there comes the ethical concern, how will you stop the potential misuse of the therapy. So, sometimes this technology or the therapy may be gene therapy may be CRISPR technology and other associated technology may be misused, for example, it can be misused for creating the "designer" baby.

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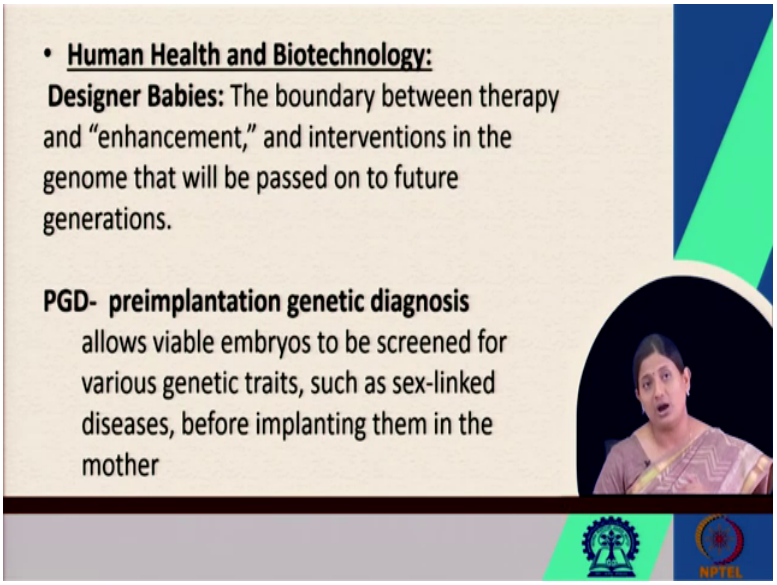

A designer baby wherein you are like trying to design a baby with respect to may be hair colour, may be skin colour, may be eye colour or any other trait ok. So, the boundary between the therapy and the "enhancement" and the interventions in the genome that will be passed on to the future generation is very blurred. How to decide or who is there to check, whether it is a therapy or whether it is an announcement procedure. So, that is the thing which has to be checked by the regulators.

So, the society, the people who are sceptical about this biotechnological process have this concern regarding this blood boundary between the potential good use or the bad use where which may if it is gone unchecked then it may create a serious problem to the society. There are definitely techniques which are helpful for many of the diseases which can be prevented in the children or the child.

For example, this Pre implantation Genetic Diagnosis or the PGD technology which allows the viable embryos to be screened for the various genetic traits such as the sex-linked diseases or other diseases. So, before it has been implanted into the mother, so those kind of risk has been assess so that the baby is born safe and sound.

So, that is helpful, but again how to assure that? So, that remains a challenge in the case of the animal or the health biotechnology.

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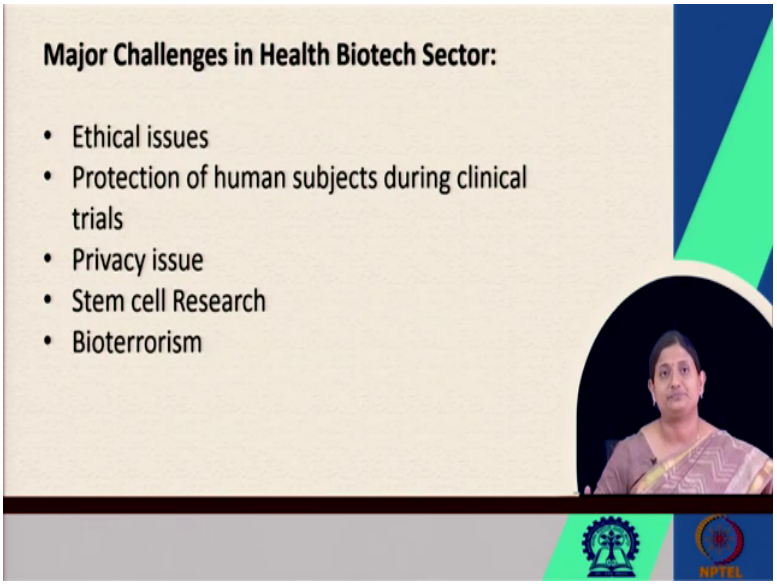

So, if we see the whole challenges in the health biotech sector is multifold, the major issue with respect to the animal or the human health biotechnology sector is the ethical issues. Ethics; what is good, what is bad? So, what is morally acceptable, what is not acceptable? So, those dilemma are there in the case of the health biotechnology sector.

Then the use of the human subjects or the animal subjects during the clinical trials, because whenever you are developing a therapeutic compound you have to assess the risk like the safety and efficacy study has to be done. So, you have to do it on do trials on the animals and the humans. So, how justified is it to carry out studies in the poor animals or even human subjects? Ok. So, those ethical questions or moral questions still remains a question mark in the case of the health biotech sector.

There are also privacy issue, when we are talking about personalized medicine or the gene therapy or the other aspect of the biotechnological process, we when we are studying individually the whole genome of an individual or how susceptible is he to a particular disease or his genetic makeup like those data which may be private to him when it is if it is exposed to outside, it may create an issue for the individual respected individual.

So, how well equipped are we to preserve that privacy issue privacy of that patient or the individual while undergoing this kind of process. Then, there are number of questions with

respect to the stem cell research, embryonic stem cells research like; at what stage can we really modify the embryo?

Or are we allowed to modify a embryo? At what stage it is till what stage it is allowed or not allowed? So, that is a question now in many of the countries not only with respect to India there are many other countries that is a question still evolving. Then the issue of bioterrorism, something which can be a potential destruction weapon like may be deadly virus may be any other technology which may eradicate the whole human race very easily.

So, those things are possible with respect to the biotechnology. So, these are the major challenges with respect to the health biotech sectors which has to be addressed before such technology comes to the consumers. So, that is one of the issue, which the regulators are trying to take care of.

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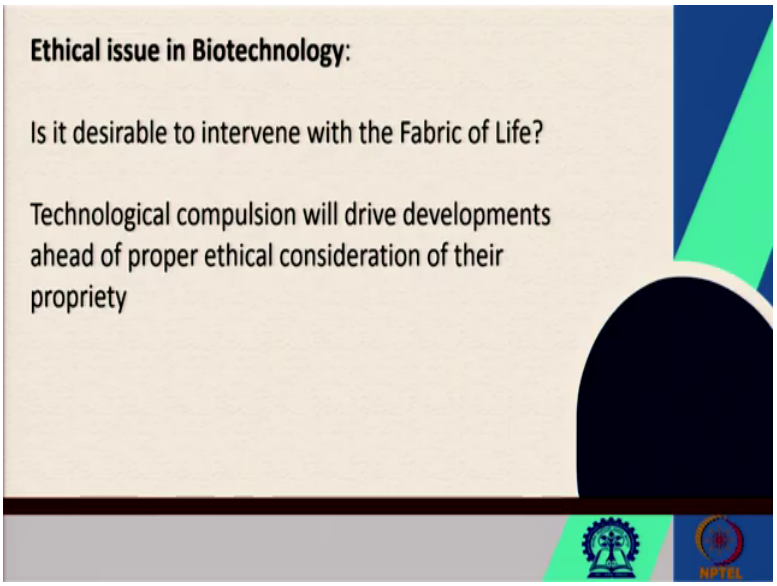

Because like the whole issue can be really intervene with the fabric of the life or is it really desirable to intervene with the fabric of the life? That is the bigger question with respect to the biotechnology and as and we are moving ahead with the technology this technology compulsion will drive the developments ahead of the proper ethical consideration of the propriety.

So, there is always a demand or always a need for going forward need more and more that kind of the technology, but again how do you balance those things, what kind of ethical consideration must be taken into account before developing or implementing those technologies is a big challenge in case of the human biotechnology.

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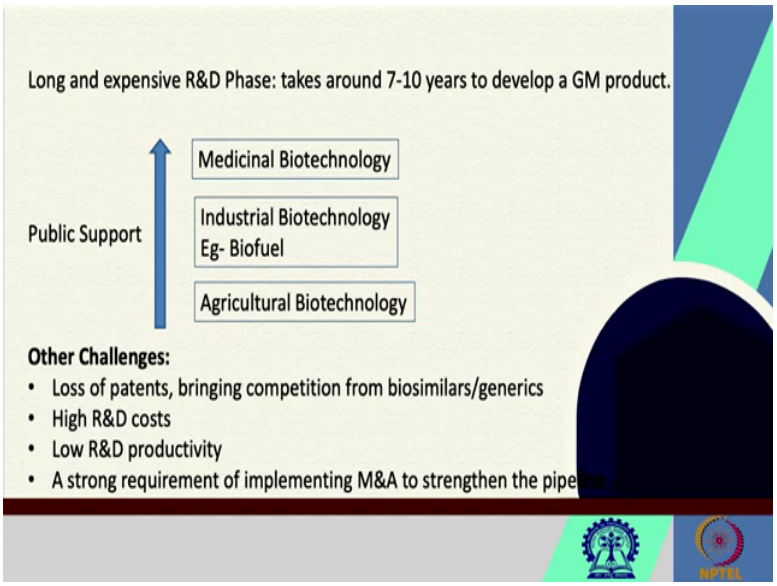

So, if you see the whole development of the biopharmaceuticals or biotechnological medicines. So, it is again as I mentioned all the biotechnological research is a very lengthy process, it is very expensive, it requires like 7 to 10 years to develop a genetically modified product.

So, now after doing such a long research investing millions of dollars in a particular product; obviously, the company or the proprietor would want a return in that sense. So, that is why he wants to make sure that his product is protected by various available legal means and also he would try to market their product so that maximum benefit can be achieved.

So, that is why in many a times the recombinant drug molecules are highly priced which is may be in like is not easily affordable by all class of the people. So, the high R and D cost particularly leads to high cost of the product and the protection of the technology through the intellectual property, regimes through patents and other forms of the intellectual property rights is somehow secures the proprietor.

But again the fear that after those rights are lapsed or are over then how to cope up with the competition. The competition with from the biosimilars or the biogenerics means when the patent is over the it is the technology is free to public. So, at that time what strategy can be adopted?

So, the how to enhance the R and D productivity, because this biotechnology is not only a single technology whenever you are developing a product you may need multiple technologies. So, the more the stronger need to more and more merger and acquisition or more and more collaboration is one of the challenges for the biotechnological product development.

So, now as I mentioned in the initial slides that this biotechnology has number of application, but if we see in general from the general prospective if we see the public support with respect to the different fields of the biotechnologically is varied. So, the public support with respect to the medicinal biotechnology particularly the pharmaceutical products because it is directly related to the human health is highly supported.

There has been incentives from the government side, there has been many studies and like people are more motivated to do research in this area. For example, this Corona pandemic is one of the best example where within a period of one year we have number of vaccines ready, but again we need more and more companies to come forward and produce the vaccine.

For that we need an environment where not only the policy is favouring them in terms of more and more financial support and like this what is called this push and pull mechanism, where basically you are pushing the companies to work more or develop new products by incentivising them in terms of grants or any other projects or money and then you are again trying or committing them that you are going to buy the products that is called the pull mechanism.

So, those kinds of incentives are being given in the field of the medicinal biotechnology and after that yes to some extent the industrial biotechnology. For example, this biofuel like where we are all dealing with the climate crisis climate change crisis. So, we are now going

moving towards the more renewal sources of energy. So, now they are also some kind of support some supports are given to develop more and more product in that area.

But, when it comes to agricultural biotechnology we have waste a lot of resistance worldwide, yes United States is one of the leading country where the resistance is less, but if you come to country like even India. So, far only one GM plant has been commercialized so far, this Bt cotton though many are under like under field trials and other things, but we have not been able to market anything after Bt cotton.

Why so? What is even though number of other countries have adopted them we have not been able to adopt them, because that risk perception that satisfaction that this product is going to be safe for the human as well as the animal as well as the ecosystem still remains a question. So, if you see this whole biotechnological domain is like surrounded by legal, political, economical, social and regulatory challenges.

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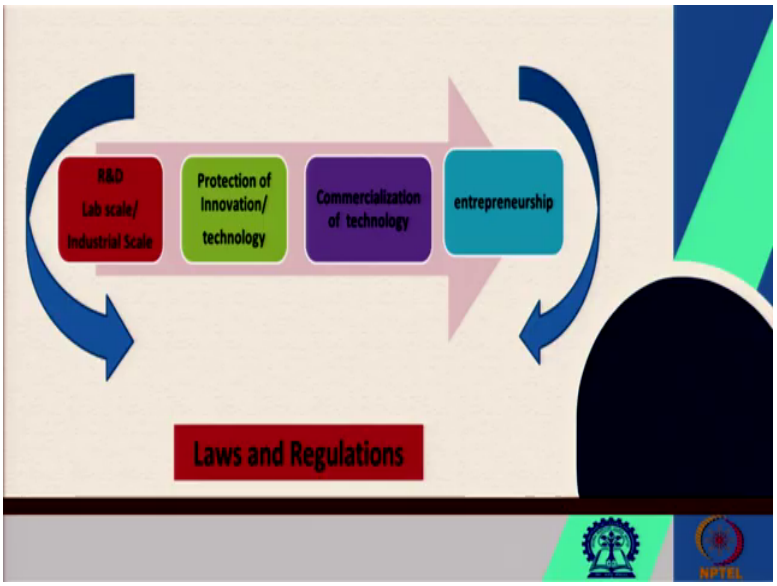

So, here like if you see the whole product development cycle, where biotechnological product development starts with the R and D like starting in the lab then where you take a gene and then start experimenting by inserting it in a particular target molecule or target individual or cells.

And then you start performing the experiment in the industrial scale which is again a very long process protecting them through the various IP laws and then trying to commercialize the product by adopting the various legal and the regulatories guidelines or provisions given in a particular country and then you are trying to market that product and then the cycle continues.

So, whole product development chain starting from R and D to the final commercialization or the marketing is guided by this various laws and regulations or directly or indirectly that shapes or regulates the whole biotechnological product in the society.

So, now in the coming classes we will see how in each of this steps are being regulated and why we need to know this laws and regulations, because without that we cannot go in a one way direction where we do not know where to go and where to reach. So, we have to understand the whole process in a synergistic way and this learning will help the biotechnologist and the regulators to properly evaluate and guide the product development process.

So, thank you all again for joining the session, looking forward to meet you in the next session.

Thank you.