Social Innovation in Industry 4.0
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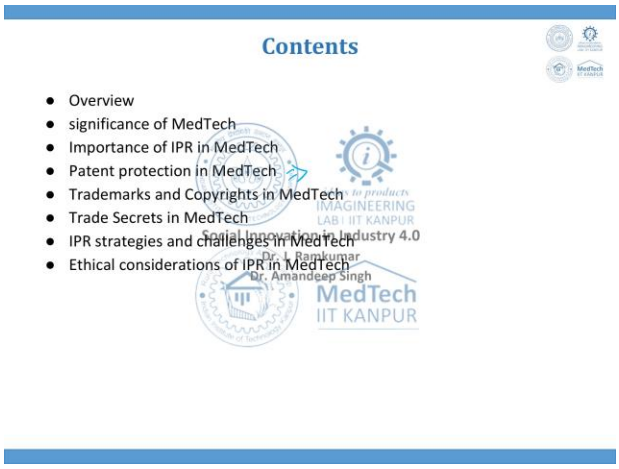
Lecture 33
IPR in Social Innovation, MedTech

Welcome to the next lecture on IPR in Social Innovation and I am more focusing towards Medical Technology. Why is it Medical Technology? Today, healthcare has become a need of the hour. So, people who are aging or newborn baby, they need lot of healthcare, and the healthcare has become pretty expensive across the globe. In fact, country like India has now become a tourist spot for hospital or healthcare. So, there is a new jargon which we talk about healthcare tour or healthcare tourism. So, people from abroad from developed countries come to India for medical care and go back.

Why? Because, it is expensive in their own countries and insurance many a times does not cover certain special type of diseases. Only for those reasons they come and that booms the economy of this country or several developing countries. So, this is for people who are there in developed countries coming to developing country. So, in developing country and underdeveloped countries, there are many many challenges.

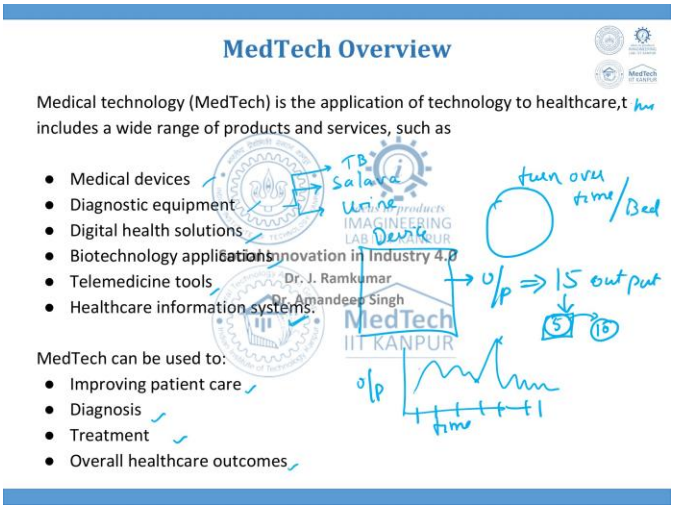
So, healthcare is one big industry where Social Innovation is always look forward to give high quality, better medicines and at an economical price. If somebody could do Social Innovation for the bottom of the pyramid, he is going to be a rich person in the near future. So, now there is lot of need focus in the Social Innovation.



So, the Content we try to look into the Overview, then significance of MedTech, Importance of IPR in MedTech, Patent Protection in MedTech, this is almost the same repeat, but you will have much more challenges here. Because in earlier engineering innovation, you do not have to worry so much about quality.

For example, if you are going to release a product in the market they will test for endurance, they will test for repeatability, they will test for service impact and pollution impact and other things. But when you get into this medical devices, it has to undergo animal trials, then it will undergo human trials, and then only it will be released. Suppose, you are trying to work on some drug, it might take a longer time. If you are working on non-invasive devices, maybe a shorter time, it can be done. So, people are now trying to look for several non-invasive device development and diagnostic devices.

Trademark and copyright, it is the same, but the process of getting clearance from the ethical committee clearance, plus the medical board is always a challenge. Trade Secrets in MedTech, IPR Strategies and Challenges, and Ethical Consideration of IPR.



Medical technology is the application of technology to healthcare. This includes a wide range of products and services, such as medical devices, diagnostic equipment, so that people are working on, can we use saliva for detecting diabetics. People are working on, can I use urine for diagnosing the health of kidney, can I use saliva for tuber close detection.

So, diagnostic devices are improvising, they are trying to reduce the cost of it. When we try to look at Social Innovation, it is more and more of turnover time per bed. This turnover time per bed, every hospital would like to have, that means to say, day one somebody gets admitted in the hospital. Day two, day three, all the major expenditure,

major critical care will be done, and then afterwards, it is slowly slowly tapering down the treatment, and going towards oral medication. So, what they are looking at is, turnaround time per bed.

How much time a serious patient spends on the bed, is the matter. Every hospital is looking for several innovations to happen, such that the turnaround time is becoming very very low, such that they can have maximum patients. And, vice versa for a patient also, they are also looking forward, how quickly I can get out of the hospital. So, here this turnaround time is going to reduce the cost. So, people are looking for diagnostic devices.

Today, a new concept called as hospital at home or clinic at home is being very much promoted by corporate hospitals. The first three days, the corporate hospital takes the patient, works on the patient, and tries to stabilize the patient health, and then onwards they shift them to the house, keep various monitoring devices at home. From there they try to communicate through Wi-Fi, they try to communicate to the hospitals on a screen, then they try to promote telemedicine. So, diagnostic devices are today looking forward for how cost effective it can be. May be, in the earlier days there used to be a device where in which it tries to give output, maybe 15 outputs.

Different types of parameter outputs it tries to give, but out of which, there are 5 which are very critical, and the other 10 are secondary importance. By taking a ratio amongst the secondary, they also can use it for detecting some major diseases. But primary 5 are now on focus. Now, there are several devices which are developed exclusively and selectively, only for the 5 measuring outputs. And, use and pro-concepts have come up in a big way.

So, diagnostic devices are now becoming smaller, are getting smarter, and they are able to communicate to promote telemedicine and promptly taking care. Digital health solution. Today, there are several companies which has come up with smart watches. So, these smart watches measures your or blood pressure, it measures your pulse rate, it measures your body temperature, it tries to tell about a sleep pattern, heart functioning, all these things. Why all these things could happen today? There is IoT, there is a sensor which can exactly predict these things, and communicate with your watch, and from a watch to a smart phone.

Let me tell you a very recent experience I had. One of my colleague had a heart attack, and what we could quickly do, when the doctor asked him, is it the first shock he had or what was his response in the last 2-3 days, or something like that. Then, immediately, we could pull out some data from the smart phone watch, which got communicated to a smart phone from a watch to a phone. And, that was you, that was displayed in front of the doctor. The doctor could quickly figure out that yes, there is a cyclic pattern, and then he started giving medication, we were able to save him in a big way.

So, we are trying to look at digital health solutions, biotechnology applications, then telemedicine tools which I have already talked about, then healthcare information systems. The healthcare information system is very very important, when there is a change over of doctors, when there is a change over of nurse or a paramedic. So, then what happen,s there is lot of information which are communicated orally, and many of them are communicated in a written fashion. But when you write it or when you orally communicate, we try to add certain noise to the signal which might digress the importance of certain communication. So, at that point of view, if we could have a pad and Digi pad.

In that Digi pad, if the paramedic or the doctor is able to communicate few keywords which are getting recorded, then the next doctor or the next paramedic who comes into the shift, So, they look into those information and start updating or taking care of the patients. Healthcare information systems is becoming more and more important. So, now there is an app which has come into existence, where in which if you try to give a PDF version of your healthcare report, it tries to convert it into a dynamic word or dynamic file. And, from the dynamic file, it extracts information. And then, it plots the output with respect to time.

For example, if you have done blood report test every month, and then you would like to see your heartbeat whatever it is, it fluctuates, it goes like this and this. This will try to help us in finding out what made these values to go high or low and what the activities did we do. So, healthcare information is used for recording and diagnosing, when it is required. So, these are some of the green pasture area where lot of Social Innovation can happen. Today there are lot of new devices getting added to the outpatient inspection.

For example, as soon as a patient goes to the doctor the paramedic takes the temperature, BP, body weight, then maybe some other oxygen SPO 2 level, so many things are doing. In a similar way, they are also trying to add blood whatever it is, he has come. So, the blood, everything and maintain a standard data and this standard data is also communicated to the pharmacist. And, the pharmacist tries to keep the medicine or record what is the duration of the next replenishment have to happen. So, all these things are happening today in the healthcare information systems.

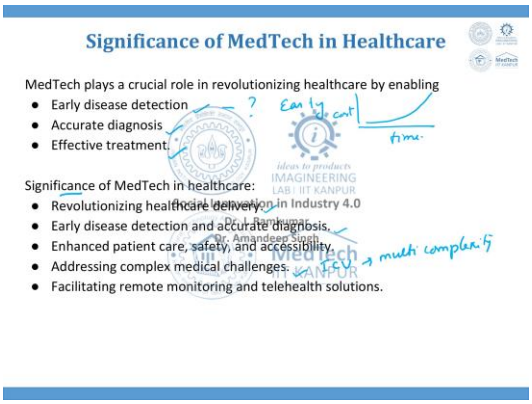
In fact, the data is also shared today with the insurance company. So, the loop is completely closed. So, healthcare information systems, here also, we are looking for innovation, And, apart from that, even today, the greener pasture is, how do you disperse. The urine pads of elderly people, per day consumption is almost 4 pads, and if they stay in an ICU for a week, intensive care unit for a week, they use 30 pads. Now, dispersing this big pads is a problem.

Why is that a problem? Because the pad is filled with urine. So, incinerating it is also a challenge and 30 pads incinerating you will have pollution norms. So, now, people are looking for devices which can start doing that. Second thing is, when you are looking for general hospitals, where the outpatient footfall is close to 500 patients per shift of 8 hours, then the beds many a times gets soggy. So, now, the bed sheet has to be replaced.

The bed sheet replacement is a costly affair because it has to be washed, it has to be dried, it is a costly affair. Now, people are looking for can we come up with some biodegradable material, which is economical, which can be laid on top of the bed where in which it is patient friendly, innovation is look forward. And, diagnosing, many of the vaginal cancers at outpatient facility, that is another diagnostic thing which is coming up. People suffering from oral cancer trying to develop devices which can be used for diagnosing and for therapy. For example, if your lower jaw is affected, assume, that there is a upper jaw and a lower jaw, between these two, you have muscles and that muscles have got stiffened.

So, your lower jaw cannot be moved. Moment your lower jaw cannot be moved, the biggest problem is you cannot eat, your body loses weight and other vital elements. So now, how do you open your lower jaw? It is not that you can beat it, break the teeth and push something inside, It is, you have to use ice cream sticks or you have to use some other small devices to open your lower jaw so that it can be used for diagnostics. India is one country, in the northern part of India we have lot of oral cancers. For them, they are also looking forward for devices, which can be developed under Social Innovation.

So, these are some of the things which there is green pasture open, there lot many people have started working for doing innovation, you have to do empathy study properly. Next, MedTech can be used to improve patient care, then diagnostic treatment, and the overall healthcare outcome.



So, what is the Significance of MedTech in Healthcare? So, MedTech plays a crucial role in revolutionizing healthcare by enabling early disease detection. Why is this important? Because early detection, when you try to put cost versus time, the cost which spent is very low, as and when the time progresses, it is going to be exponentially costly. Early detection is, what now lot of people are focusing, company is focusing and innovation can happen.

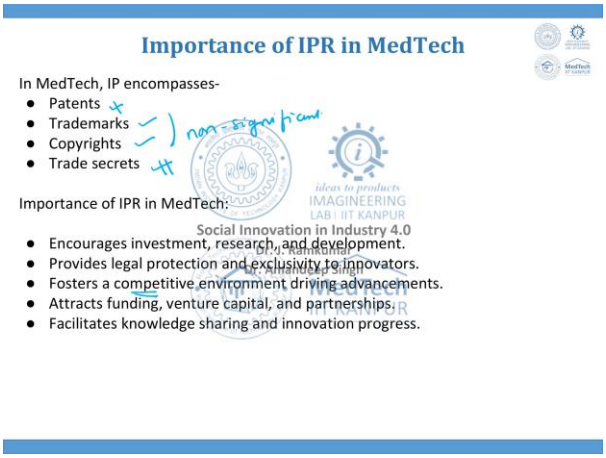
Accurate diagnosis, you cannot take a chance because healthcare is an emotional based industry, you cannot take a chance. So, you have to be as accurate as possible. Effective treatment, I have been under a medication for a skin disease allergy for the last 15 years. The first doctor I went, he started with some medication. So, I continued it for 2 years, then after 2 years I did not see any improvement.

So, I took the prescription, went to another doctor, he said undo all the medicines and start the next session. So, when I started continuing this operation 3, 4 doctors and 5 doctors now it has been 15 years. Still the disease or the allergy continues, and they have not done effective treatment. I have lost money, I have lost my confidence, and now I have started living with that allergy, trying to protect myself. The effective treatment was not given properly.

Since it is skin it is ok, if it is something else it will be very very difficult, and if you keep continuing with the same disease for a longer time, the mutation of the source of the disease keeps on happening. So, we will never be able to find out what is the root cause for the allergy. Symptoms are majorly people looking forward, but root cause people never look forward. So, effective treatment starts from identifying the root cause, from a symptom going towards a root cause. Significance of MedTech in Healthcare is revolutionizing healthcare delivery, early disease detection and accurate diagnosis, enhanced patient care, safety, and accessibility, addressing complex medical challenges.

So, here whenever it comes, when you move to intensive care unit, you will many a times have multiple complexity. So, that is, what is addressing complex medical

challenges and the other one is cost effective. Facilitating remote monitoring and telehealth solutions. So, all these things are Significance of MedTech in Healthcare.

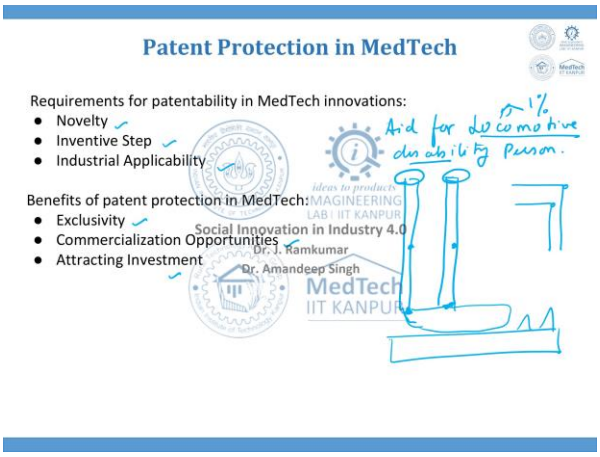


So, the IP encompasses of patents, trademarks, copyright and trade secrets. In pharma company, we go for trade secrets, and we have patents for process as well as design. Trademarks, of course, you have already seen company name, and then you also have copyrights with put a C, all those things. So, these two are non-significant. However, it is significant, but as compared to the other two, it is non-significant. Importance of IPR in medical encourages investment, research, and development.

If there is money, if there is a need, then there is an investment. So, it is all a chain reaction. So, encourage investments, research, and development. Then, provides legal protection and exclusivity to innovators. It is also a business, innovation is also business, but here, if you are trying to do it for a human cause or humanitarian grounds, then it will be at an economical price, or you will develop it free and allow it to put it in public domain.

Ask anybody who wants to use it, please use this recipe for developing the device and here are the outcome, or the benefits of the device, you can do it free also, no problem, many NGOs are doing it. So, if you want to make a profit, then provide legal protection and exclusivity to innovation. Foster a competitive environment driving advancement. Competitive environment is very very important.

This makes life moving. If there is no competition, people will become stagnant and wherever we are, we stay there. Attract funding, venture capital, and partnership. Facilitates knowledge sharing and innovation progress.

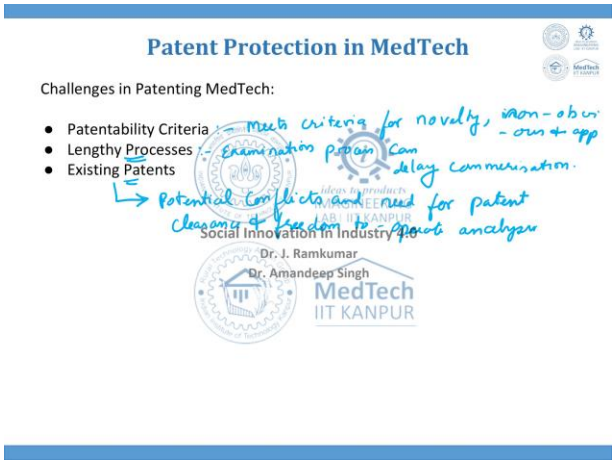


So, the requirements for patentability in medical innovation is novelty, inventive steps and industrial application. For example, when you are trying to develop aid for locomotive disability persons, we always make a support device which will be attached to the foot.

It will have a link here, and it will have a link here, and then you will have a clamp here and a clamp here. So, what will happen is, you will have sorry it is a big foot, but yeah, you will have a shoe, and then you will have two hinges here, which is attached to a shoe. Many a times people who have locomotive disability, when they wanted to bend their knees, this links has to be eased out. so that they can bend, the crutches or the supporting device can go like this. So, if they forget to disengage this, it hurts their knees.

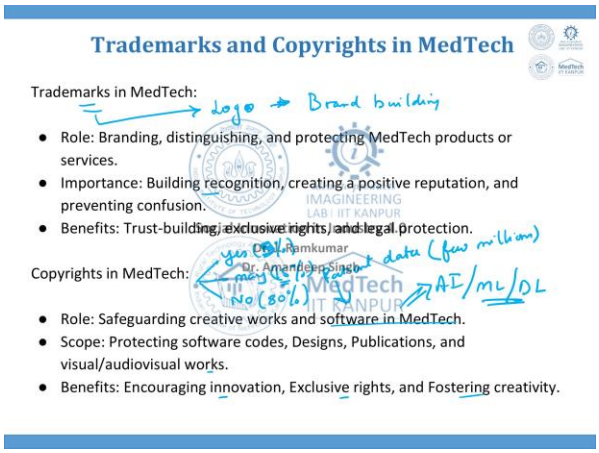
So, what we are supposed to do is, we are supposed to come up with an adaptive locking mechanism, where in which when there is a force or when there is a bend going to happen, it automatically releases, and then you start bending it. The same with here, when you are a walking on a flat, plane, or when you have an undulation, and when they keep it here, these links have to be removed. So, this is a painful act for the people with disability because if they forget, the entire load is shifted to their knees and foot. Many a times they cripple and they fall down. So, now, the innovative steps has to be figured out and industrial application also has to be figured out.

So, requirements for patent is finding out the novelty, finding out the innovative step, how to bend it, and industrial application, because there are people who are going to buy it. And, this population in India itself is, approximately, 1 percent of our population which might go to 100,000 people. So, benefits of patent protection in Medtech are exclusivity, commercial opportunity and attractive investments. We have seen it in plenty. So, we keep moving.



What are the challenges in patenting a Medtech? The patentability criteria, it meets criteria for novelty, non-obviousness, and application. These are the things, which are the criteria. The lengthy processes are going to be examination process can delay commercialization. The lengthy process is there.

It is a very big challenge, very very big challenge. Suppose, a pharma company takes minimum 8 years to get into the market for starting and producing. Until and unless, it is a vital thing, there is a market pull emergency. Say for example, during COVID vaccinations, It was emergency, some relaxation was given in the process, and they could quickly go to the customers. Then, existing patents, there is always a potential, should be very very careful, potential conflicts and need for patent clearance and freedom to operate analysis. So, this is very very important, existing patent breach or potential conflict. So, you have to be very careful. These are the big challenges, and getting the novelty is not so easy.



So, trademark, we have said already. So, branding, distinguishing, and protecting Medtech products or services can be there. Importance is build recognition, for example, there are certain pharma companies, by looking at the logo itself, people will say, this is this company. So, build recognition is very very important, creating a positive reputation, and preventing confusion.

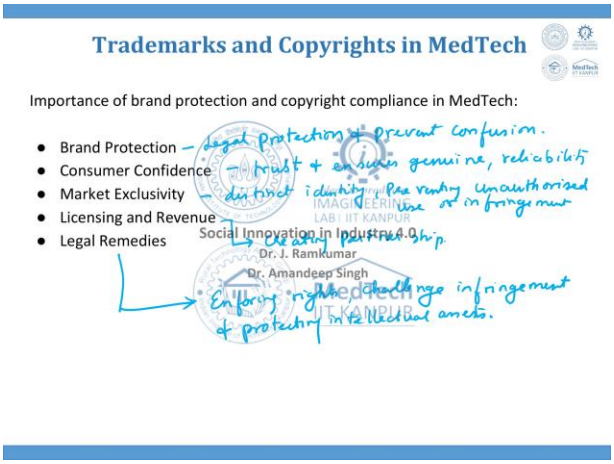
This building recognition is very very important, build factor is important. So, that is why, we always look at trademarks. The logo play a very important role in brand building, and lot of companies spend lot of time, money and effort in building up brand image. Because this brand image is that trust-building, exclusive rights, and legal protection. So, when we are talking about copyright in Medtech, it is safeguarding creative work and software in Medtech technology.

Scope is protecting software code. Say for example, today there is lot of AI, ML, DL based codes, which are available, where in which it tries to predict or it tries to analyze and tell you, these are all the possible diseases or these are all the places where you can expect a failure to happen. So, software are becoming more and more user-friendly. We are currently working on a low cost handheld x-ray device, where in which the software is being developed with the help of AI, ML and DL. So, here when I say AI, it is inclusive of ML and DL, and I am just trying to deep learning is a subset of machine learning. So, here the biggest challenge is, we need lot of patient data, that is a challenge, patient data.

So, maybe we need few millions of data to build and assess our software. This software says three things. It says yes, there is a presence, maybe there is a presence, then they say no, there is a presence. Majority of the time, 80 percent of the time, we always land up with no presence. Then, we will have 10 percent here, or maybe 5 percent here, and 15 percent it puts maybe.

And, this 15 percent is the only place where the doctors have to use their prudence and wisdom in pushing it whether to no or to yes. This is the place where there has to be multi signal processing has to happen. Look at 6 or 7 data, look at ratios, look at propositions, and then you try to put either in maybe, no, or yes. So, a software is being developed and lot of copyrights are going for the software.

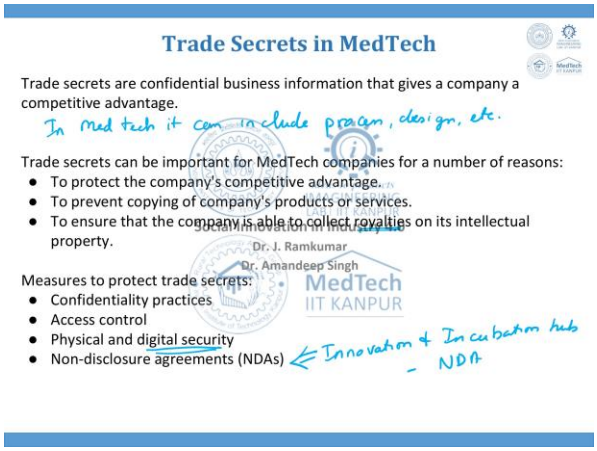
So, the design, publication, audio-video work is also done. So, the benefits are encouraging innovation, exclusive rights, and fostering creativity.



So, the importance of brand protection and copyright compliance. Band protection is, to ensure legal protection and prevent confusion, we always go for brand protection. Consumer conflict, it is trust and ensures genuineness, or you also talk about reliability of the medicine or whatever it is.

Market exclusiveness is to distinct identity. For example, in India nose inhaler, initially, a company called Vicks, brought it into the market. So, the brand name, that is now become so popular, brand name or the product name is. Now, they do not even call it as Vicks inhaler, they call it as can you have a Vicks. So, it has come to that level.

Distinct identity and preventing unauthorized use or infringement. Next, licensing and revenue, it is always used for creating partnership. And, legal remedies are enforcing rights, challenge infringement, and protecting intellectual assets. So, these are some of the things which are part of Copyrights and Trademarks in MedTech.

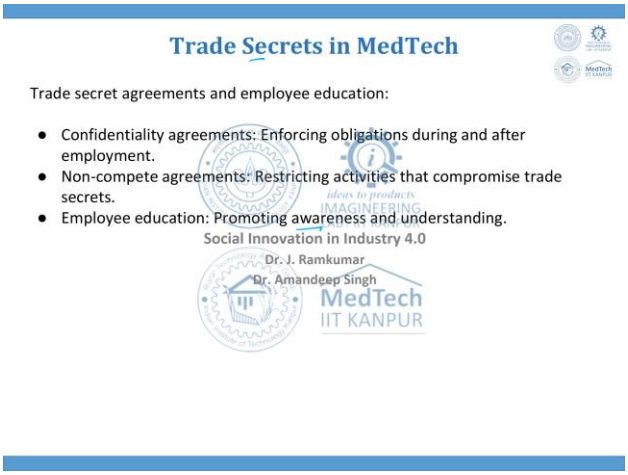


When we talk about trade secrets, trade secrets are confidential business information that gives a company a competitive advantage. See, when you are trying to apply for patent after 25 years or 50 years or 75 years, this gets into the public domain.

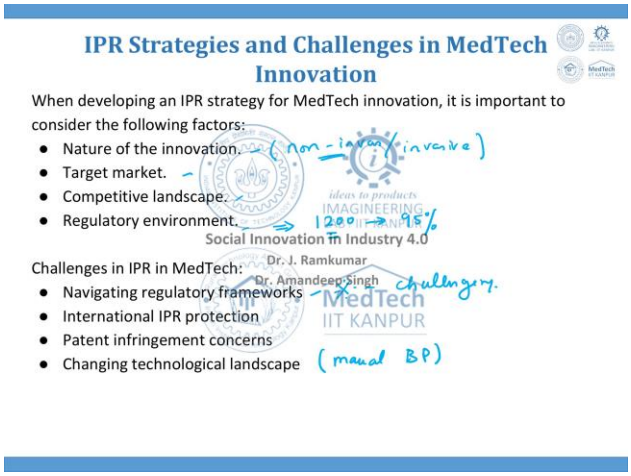
What the business world thinks of is, like, if you are developing a product, and if you are applying for a patent, I give you all rights to make money for the first 25 years or first 50 years. And after that, they say or they feel, you have made enough money. So, now, why do not you put it in the public domain because you have enjoyed the exclusivity for so long. So, in the same way, we also have trade secrets. So, trade secrets are confidential business information that gives a company a competitive advantage.

In MedTech, it can include process, design, etcetera. Trade secrets can be important for MedTech companies for a number of reasons. To protect the company's competitive advantage, to prevent copyrights to the company, to ensure that the company is able to collect royalty on its intellectual property. The measures to protect trade secrets are already we have discussed. Confidentiality practices, assess control, physical and digital security.

Now, today there is lot of push for digital security. Then, it is NDA, when you run innovation and incubation hub, you will always try to sign an NDA (Non-Disclosure Agreement) with people.



So, Trade Secrets in Medical or MedTech are, trade secrets are agreements and employee education. When we look at trade secret agreement and employee education, the confidentiality agreement is very important which is enforcing obligations during and after the employment. Next is non-compete agreement, restricting activities that compromise trade secrets. Then, employee education, promoting awareness and understanding about the product and trade secret is very important.



When developing an IPR strategy for MedTech innovation, it is important to consider the following factors. Nature of innovation, target market. Nature of innovation is very important, because are we going to do non-invasive or are we going to be invasive, are we going to be non-invasive or invasive, because this is very important. Then, it is target market, then competitive landscape, then regulatory environment, this is also very important.

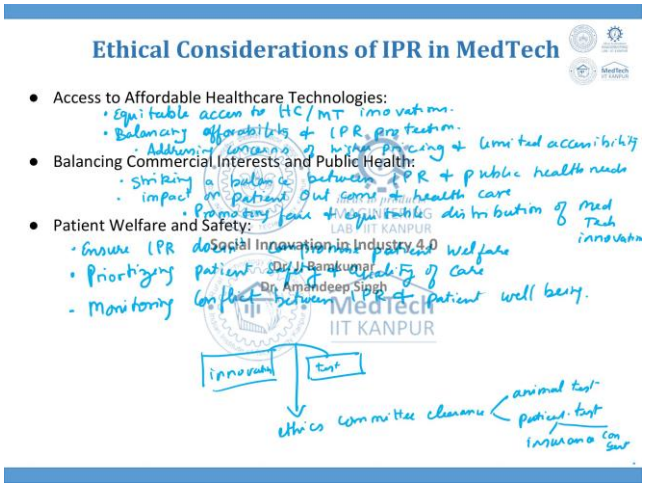
You decide and you also have to know what is the regulatory environment. For example, if you try to develop a non-invasive device. And, if you are trying to use it from saliva to predict the blood sugar level, just an example blood sugar level. Then, the regulatory environment says that at least try to do 1200 samples, and your confidence level of your equipment, or the success rate of the results prediction should be at least 95 percent. So, this is very important the regulatory environment, there are rules you have to understand. The rules, there are design of experiments given, follow the design of experiments, and then do it.

You have to also understand when you start identifying the nature of innovation. You also have to keep this in mind, do not push it later. Target market is very important from their innovation. Then, trying to find out who is competitive, what is the better of it. And then finally, if I have to go to market what is the regulatory environment required. The

challenges in IPR is, navigating through regulatory frameworks is extremely important and extremely challenging, very very challenging.

Then, international IPR protection is also required, then infringement concern, then changing technological landscape. So, for example, earlier we were all talking about manual BP measuring device. Now, it is all that became automatic BP measuring device. Now, earlier it was blood sugar taking, we used to go to a pathologist and get it done.

Today, it has all become like a one prick GULCO's assessment has been done. So, so many things are improving, according to which the technologies have to be developed.



Moving to the last topic of Ethical Consideration of IPR in MedTech. Assess of affordable healthcare technologies. It is equitable access to healthcare or MedTech innovation.

Then, it is balancing affordability and IPR protection. And, the third point is going to be addressing concern of higher pricing, and limited accessibility. And, every country has their own regulatory framework. For example, if some product is got in the Indian standards. If you want to move to the international standards, again there is an international approval has to be taken for the same.

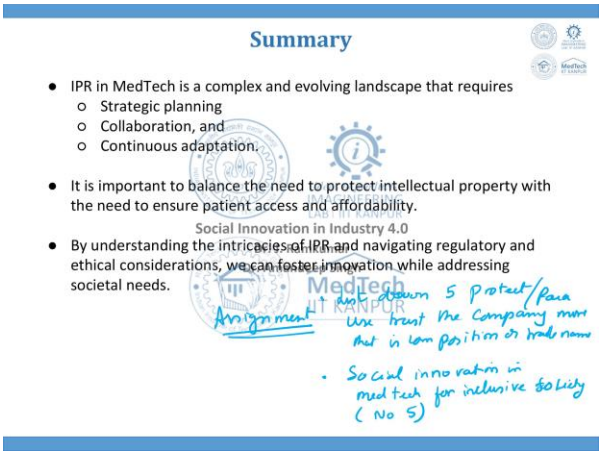
Then, balancing commercial interest and public healthcare. It is striking a balance between IPR and public health needs. Next is considering impact on patient outcome and healthcare. This is another important point. And, the third one is going to be promoting fair and equitable distribution of MedTech innovation.

These are innovation. Then, patient welfare and safety. Here, we ensure IPR does not

compromise patients welfare. For example, for your success or for your projection, do not reveal the patients name, photo, or other things. So, there is a ethics committee clearance and now you should also understand ethics committee, it is must. For example, you have an innovation, then this innovation you will have to test it on patients test.

So, here you have to get an ethics committee clearance. And, this ethics committee clearance gives for two things, one is for animal test, and the other one was a patient test. When you are doing this patient test, you are supposed to get insurance for all the patients to whom are you testing. And then, you should also get their consent form, the patient says that yes, I agree to be part of this. This is what ensure IPR does not compromise on patient welfare, and suppose, if it something happens, you have to give a coverage.

Then, prioritizing patient safety, and quality of care, this is important. And, the last one is going to be monitoring conflict between IPR and patient well-being, these are very very important.



So, moving to the summary of this lecture. IPR in MedTech is complex. It is not simple, like in engineering innovation, fintech innovation, that is all slightly much better, and reaching out, rolling out to the market is going to be easy and people accept it. For example, agricultural innovation developing a tool, it is easy developing a process, it is easy, but the only challenge is, how does it impact on the output like the fruit, vegetable, that is a challenge, but doing something to improve productivity is okay, developing a automatic setup is okay, using a drone for pesticides spraying is okay.

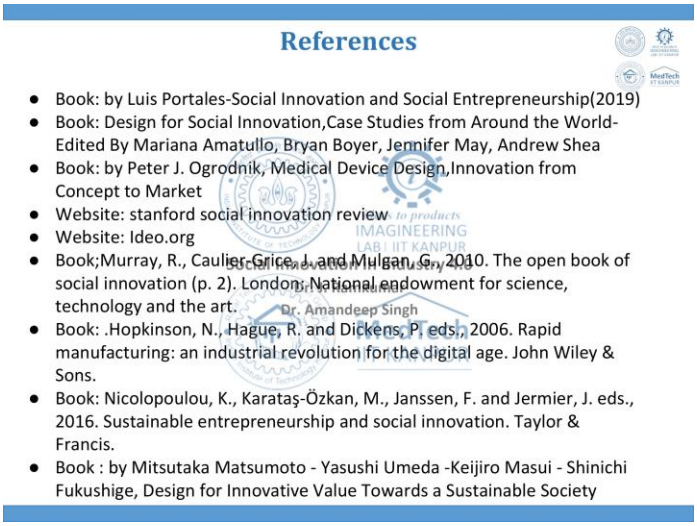
But, what is the influence of pesticide with respect to the fruit quality or for the human society, that is a challenge. Very recently what happened was, there was lot of peacocks which were trying to keep on be disturbing the farmer yield. So, a farmer out of frustration, he had some little bit of poison added to it, such that he could try to save his

yield, but unfortunately the peacocks went and had this poisonous maize, whatever is there, and then it all died. So, this is not acceptable. So, here what we do is, we try to look into processes, and try to see how we can protect the animal as well as keep the biodiversity balance and having an higher yield.

Here, there is nothing called as an innovation solution, it is only a brutal. So, that is what I said, IPR and well-being, IPR and balancing biodiversity is very important. In the same way, for IPR and MedTech also it is very complex, it involves landscape that requires strategic planning. Anything you do it in India, in Sri Lanka, if somebody wants to take it, they can take it, do it, and they can apply for a patent. Be very careful, with some modifications.

Strategic planning, collaboration and continuous adaptation has to be there. The steth which was thought of as a tool for medical profession, now that steth itself is converted into a Wi-Fi small stethoscopes where there is nothing to be placed in your ears. And, even in stethoscope, it is pretty interesting. When you get a very feeble signal, or if you get a non-consistent signal, it is very difficult for a human to intervene. So, now this Wi-Fi based stethoscopes are coming up in a big way.

By using AI tool in identifying the weak signals and noise in a signal and give you some interpretation. Now, Wi-Fi is an adaption of the stethoscope whatever was there, which we used to have manual and which used in the years. It is important to balance the need to protect intellectual property with the need to ensure patient assess and affordability. By understanding the intricacies of IPR and navigating through regulatory and ethical consideration, we can foster innovation while addressing societal needs.



These are the References. Before I could finish the lecture, I would like to give you a small assignment. Try to list down 5 products-pharma where in which you trust the company more than its composition or trade name, first assignment. Second assignment is look at some of the Social Innovations which has happened in the Medtech area for inclusive society, again here minimum 5 in numbers.

You will make an assignment and when you make an assignment you will see through the process how did the innovation happen and how did it reach out to the market, how are these companies, are they giants or are they small innovators who are into the market. With this, I would like to thank you for patient listening for this lecture. Thank you.