Patent Law for Engineers and Scientists
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Lecture – 62
Compulsory Licensing
Compulsory Licenses

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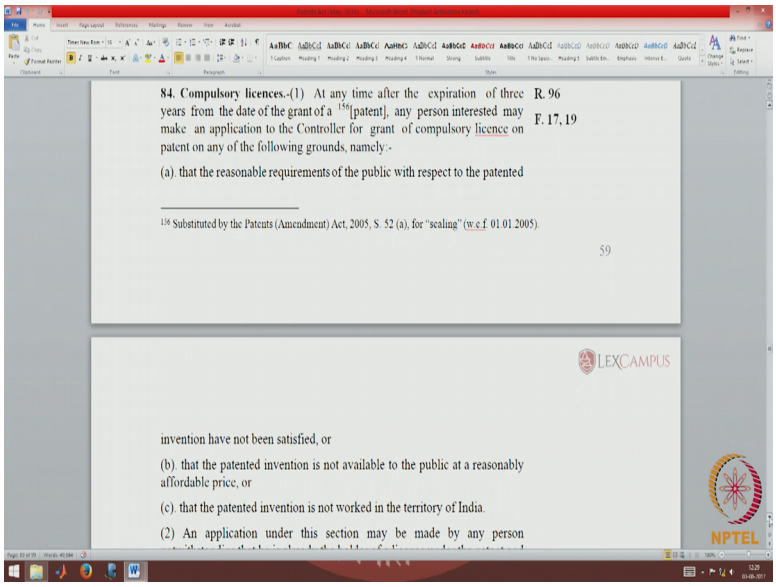

Now 84 as I said is the default method or the default root for getting a compulsory license. And 84 is what is normally intended when we refer to a compulsory license. When we talk about a compulsory license the in it is simplest form when we referring to 84. All the other 3 cases 91 92 and 92 a are special forms of compulsory licenses, which can be used in certain cases. But this is the default compulsory license. At any time after the expiration of 3 years from the date of grant of patent, any person interested may make an application for the grant of the compulsory license on the following grounds.

So, the first requirement in seeking a compulsory license is that the patent should have been granted and since the grant 3 year should have elapsed. So, you cannot make a request for a compulsory license, soon after the patent has granted, you have to wait for 3 years after the grant. Now compulsory license under section 84 can be made if 3 grounds are satisfied. Now it can be made by a person interested a person who has some interest in the patent as defined in section 2 the 3 grounds on which the compulsory license can

be sort for are a, the reasonable requirements of the public with regard to the patented invention has not been satisfied. Now this is from the public's view point. The reasonable requirement has not been satisfied.

Say if there is a drug that can cure type of cancer. And if the drug is not available in large quantities, and assume that the prevalence of that kind of cancer in India is huge lakhs of people or even crores of people who are effected by that type of cancer. And if the drug is patented and it is not manufactured in India. Rather the company which patented the drug only import few thousands of doses of the drug into the Indian market. Then that could be a case where the reasonable requirements of the public with regard to the patented invention have not been satisfied, because a few thousand copies of the drug cannot address the demand of larger population which may require the drug in greater number. So, reasonable requirement of a public can be understood a all these things have to be understood by the particular facts of a particular case. Now in this scenario which I would explain it could qualify that the fact that there is a great number needed and yet the number is not supplied could amount to be ground on which the reasonal requirement of the public is not satisfied.

B the patented invention is not available to the public at a reasonably affordable price. Now the first a was with regard to access the demand was greater than the supply. So, the ground a was with regard to access. Ground b is not on access, but it is on affordability. So, called drug may be available in every look and corner of the country, but it is highly priced and it is not available at an affordable price.

So, the second part or the ground b pertains to affordability, where as ground a was on access. So, b tells us that if the patented invention is not available at an affordable price. What is an affordable price? In India what is what amount affordable price in India could be different another jurisdiction? So, all these factors will have to be considered and in the only decision that we have of the compulsory license granted for bias patented drug nexavar, would show that the controller went through all these requirements before he came up with this order.

C the patented invention is not worked in the territory of India, it was not locally worked. Now working as I said is type 2 certain other provisions of the act there is a requirement that statements of working have to be a regularly filed before the patent office form 27 is

the form that is used for filing a statements on working whether the patented invention is worked on a commercial scale. So, we will we will look at the working requirement and we will see whether the working requirement is satisfied, but one of the grounds for seeking a compulsory license is that if the invention is not worked on a commercial scale in India it could be a ground for getting a compulsory license.

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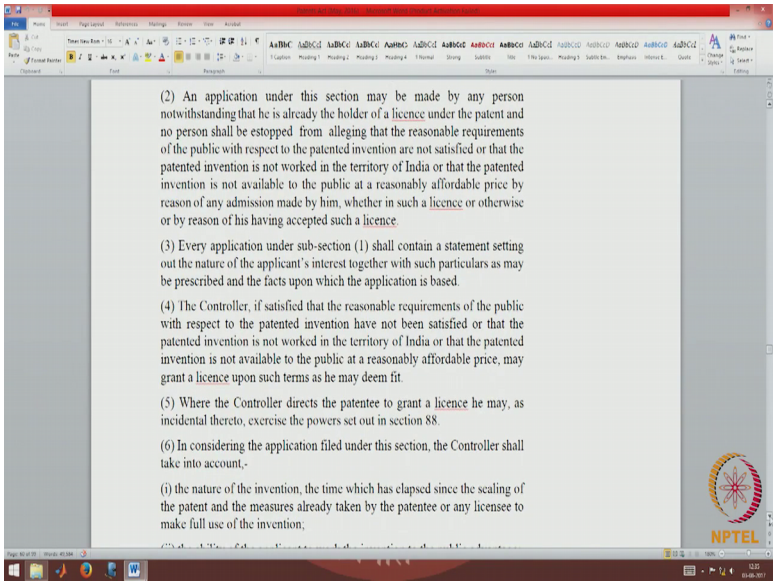

Now, what happens when the application is made subsection 2 tells us then an application is made by any person not withstanding that is already a holder of a license under the patent, and no person shall be estopped from alleging that the reasonable requirement of the public with respect to the patented inventions are not satisfied or that the patented invention is not worked in the territory of India. Or that the patented invention is not available to the public at an affordable price the 3 grounds which we just discussed. By reason of any admission made by them whether in such a license or otherwise or by reason of him having accepted that license.

Now, 2 envisages situation where the person seeking a compulsory license already has a volunteer license, a normal license. When we say a license it means a voluntary license. Now regardless of the condition mentioned in that license, the holder of the license could still approach with for an application for a compulsory license if these 3 grounds are satisfied. So, in the license even if the patentee had made a statement to which the holder of the license had agree that it will be available at an affordable price or it is being

worked in India, regardless of what the terms were a licensee was agreed on those terms can still pursue a compulsory license.

So, no person shall be a estopped from alleging. Now no person shall be estoped from alleging means that an interested person can still allege that the invention is not worked in India, even if there is an licensee for that patent. So, the 2 things we understand from this subsection is that, a licensee can make a licensee who is a voluntary licensee can make an application for a compulsory license though he has an arrangement with the patentee. And a person is not estopped by estopped we mean that a person is not precluded or a person is not prevented, from making the allegations under grounds a b and c of 84 1 by reason of such a person making an admission, whether in a license or by reason of having accepted a license. So, the fact that a person makes an admission with regard to any of these 3 grounds will not stop him from raising these ground or from making an application.

So, the fact that you are a licensee will not stop you from making a application for a compulsorily license, and the fact that you have made an admission that the drug is available at a reasonable price or it is being worked within the territory of India, or the requirement of the public are being met, even if you made such admission either in a license or in some other way form, still you can make an application for a compulsory license raising those very admissions which you said in the license or in another document or in some other form. And the reason a person accepts a license again will not be a ground for precluding him from making a compulsory license.

So, from this we understand that a compulsory license and application for a compulsory license can be applied for even if you hold a voluntary license. And the 3 grounds that it does not satisfy the reasonable requirement of the public, that it is not available at an affordable price and the patentee is not being worked within the territory of India, you could raise those very grounds even if you had admitted otherwise in a license or in any other form. Even if you made an admission that yes it is reasonably worked in India or it is available at a reasonable price still you will be able to take an application for a compulsory relations. In effect regardless of what statement you have made your statements will not hold you back from making a compulsory license.

3, an application under 84 1 shall contain a statements setting out the nature of the applicants interest together with such particulars as may be prescribe. And the facts upon which they application is based. So, a person interested will have to demonstrate his interest. So, the nature of an application applicant interest has to be demonstrated. And he has to set out the facts on which he is making the application.

4, if the controller satisfied that the reasonable requirement of the public and respect of the patented invention have not been satisfied, or the patented invention is not worked or a patented invention is not available to the public at a reasonable price, may grant a license upon such terms as he deems fit. So, if any of the it is not that all these conditions have to be satisfied, it is if any one of these conditions are satisfied the controller can grant a license. And the controller will decide the terms of the license. Unlike a normal license or a voluntary license where the parties will decide the term.

5, where a controller directs the patentee to grant a license he may as incidental there to exercise the powers set out section 88. The controller has certain powers in granting compulsory licenses and they have mentioned in section 88, will soon look at it.

6, in considering the application file under this section the controller shall take into account. Now the grounds are what the applicant will plead and he will plead facts and he will try to make a case based on those 3 grounds. Now the controller if he has to grand or reject the application the controller will take into a account the following things.

1, the nature of the invention the time which has elapsed since the sealing of the patent. The sealing of the patent is redundant because it was an earlier practice where the patents before they have granted they were sealed it was a separate. Administrative action sealing, but it is been removed in every other part of the patents act except this place. So, the word sealing of the patent still appears here. It is an appendage that just still hangs over it does not make any sense, because in an earlier amendment we removed sealing as an administrative step, there is no sealing of patent as it was done earlier.

So, this is an remanent of the past which as existed there and hopefully in the next amendment probably this would be set right, since the grant of a patent because sealing is now replaced by grant. The time which is allows since the grant of the patent and the measures already taken by the patentee or any licensee to make full use of the invention. So, these are the factors he will consider. The ability of the applicant to work the

invention to the public advantage. So, if the person interested is a person who as only a research interest and if in another case is the person interested is a competitor who has manufacturing capacity, those 2 things will be differently in considering whether a patent should be put on compulsory licenses.

So, the ability of the applicant to work the invention to the public advantage is important. The capacity of the applicant to undertake the risk and providing capital and working the invention if the application were granted. If the controller allows the applicant to manufacture or allows the applicant the right to manufacture and sell the drug. Then the applicant should have the capacity to do that, and especially when the applicant raises a ground and says that the reasonable requirement of the public is not being met, which means the applicant should have the ability to supply that patented invention throughout the length and breadth of India to all So, it is big people. So, it is big requirement that the applicant will have to satisfy

4, as to whether the applicant has made effort to obtain the license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period the control made deem fit.

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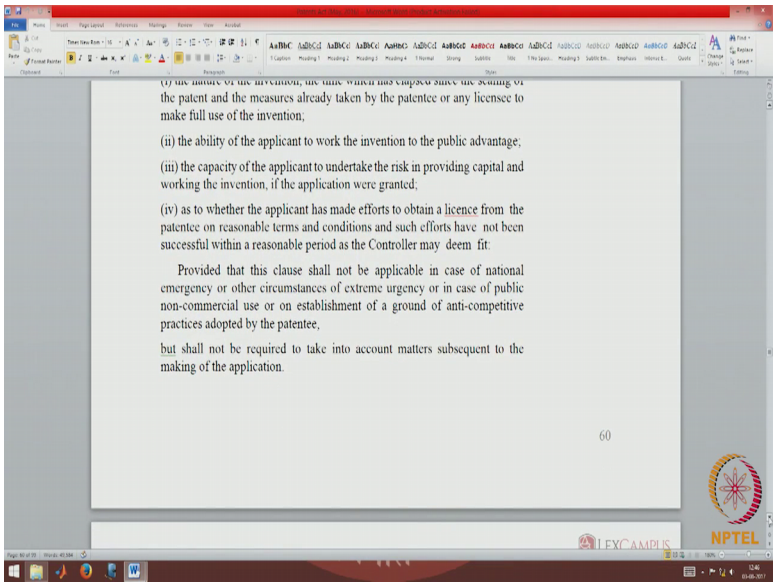

So, whether the they were any efforts to voluntarily get the license, provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency, or in any case of public non commercial use or on a establishment of a

ground of anti competitor practices adopted by the patentee. So, in these circumstances the controller need not look at one 2 3 and 4, but shall not be require to take into account matters subsequent to the making of the application. So, once in a application is made the controller will not look at any change in circumstances after the application is be rather he look at the events before making the application.

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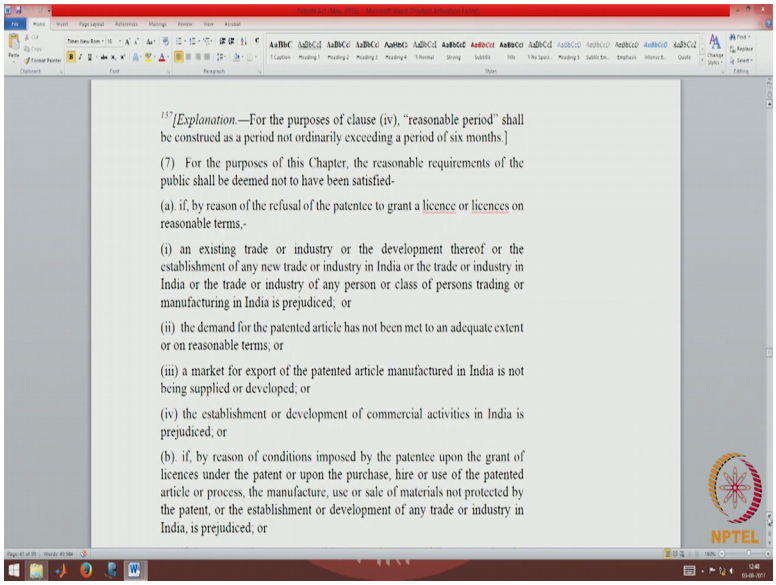

Has an explanation for the purpose of clause 4 reasonable period shall be construed as a period not ordinarily exceeding 6 months. So, the reasonable period under this section shall be understood as 6 months.

So, the licensing the effort to seek a license should not have been successful within a period of 6 months. 7, for the purpose of the chapter the reasonable requirements of the public shall be deemed not to have been satisfied. Now this is a explanation of ground a 84 1 a reasonable requirement now 7 describes what we understand as reasonable requirements of a public.

A, if by reason of refusal of the patentee to grant a license or licensee on reasonable terms. One, So the applicant approach the patentee for a license, and the patentee refuse the license on reasonable terms, as a consequence one an existing trade or industry or development there of or the establishment of any new trade or industry in India or trade or industry in India or trade or industry of any person or class of persons trading and manufacturing in India is prejudice. So, an existing trade or an industry is prejudist by

not granting that license. Your patentee if he does not grant license then an existing trade or industry in India or the development of that industry is affected. So, it is like what we can call a technology holder.

The patentee who has a technology is not giving it and because it is not given a trade or an industry is prejudist or is affected adversely. To the demand of the patented article has not been met to an adequate extent or on reasonable terms. There is a demand for a patented article say I will saving drug and it is not met to an adequate extent or on reasonable terms.

3, the market for export of the patented article manufactured in India is not being supplied or developed. So, compulsory licenses can be granted for export. So, the market for export of a the patented article manufactured in India is not been supplied or developed.

4, the establishment or development of commercial activities in India is prejudist. In one we saw that a trade or industry is prejudist here commercial activities establishment of development of commercial activities is prejudist. Now that is a, now b states that if the patentee refuses to grant a license if by reason of the conditions imposed by the patentee upon the grant of the license under a patent or upon the purchase hire or use of the patented article or process the manufacture use or sale of materials not protected by the patent or the establishment or development of any trade in India is prejudist.

So, by the patentee not granting a license the manufacture use or sale of materials not protected by patent. Say there is technology that is patented, and there are materials which are used in the technology which need not be patented. If those materials supply of those material is prejudist then again it can be condition whether reasonable requirement of the public is not met. For instance, there is a technology for making a mission which can create paper cups, of this machine uses only the machine and the technology patented. Now assume that this machine uses the special grade of paper in creating that those paper cups. And the owner of the machine which is patented insist that the paper material for making the cups has to be procured prime from him., which amounts to manufacture use or sale of materials not protected by the patent.

The patent in itself does not protect the quality of the paper that is used. But the patentee insist that you have to buy my machine an along with the machine you have to buy paper

from me. So, that is a condition that is added by the patentee for which he does not have a patent. He does not have a patent on the paper or on the materials used, but he clubs it along with the sale of the patented invention. In such a case we can say that this amounts to a condition that is imposed which effects the sale of materials not protected by the patent. And when that is prejudice it can be regarded as a ground that satisfies 84 1 a.

C, if the patentee imposes condition upon the grant of licenses under the patent to provide exclusive grant back prevention to challenges to the validity of patent or coercive package licensing. Now these are what we call restrictive trade practices or in today's language you can call them anti competitive practices. So, when a person insist on a exclusive grant back or agrees that he will not challenges the validity of a patent, or involves in cohesive package licensing package licensing is you cannot by single product you will have to buy package and the entire package will be licensed. There is no ability for the person pick and choose patents. The patents are given as a portfolio. Now in all these cases it can be deemed that the reasonable requirements of the public is not met. These are technically these are considered as a matters that come under competition law, but they also figured in the patents act.

D, if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practical. Again this is will be considered for understanding whether the patented invention was the requirements of the public were satisfied.

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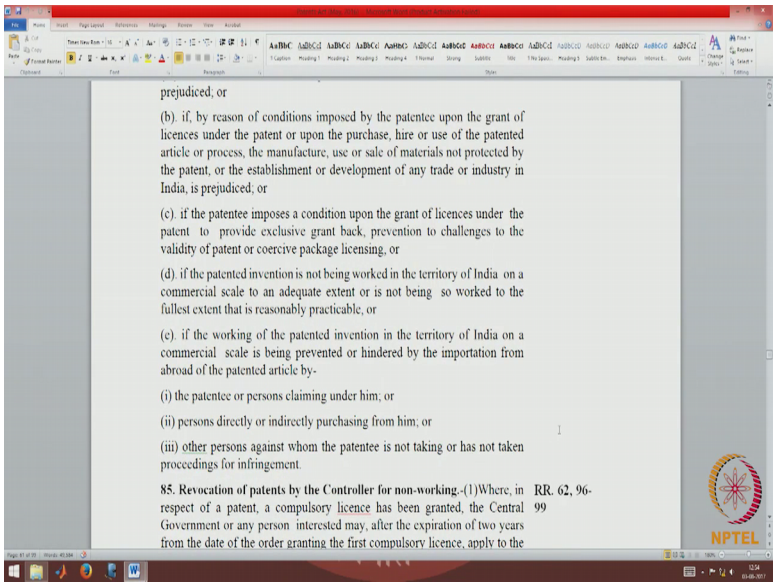

E, if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or a person directly or indirectly purchasing from him or other persons whom the patentee is not taking or not taken proceedings of infringement. Which means the patentee is not taking any action against certain people and importation by those people or by the patentee or by people purchasing from the patentee hinders the working of the patented invention in India.

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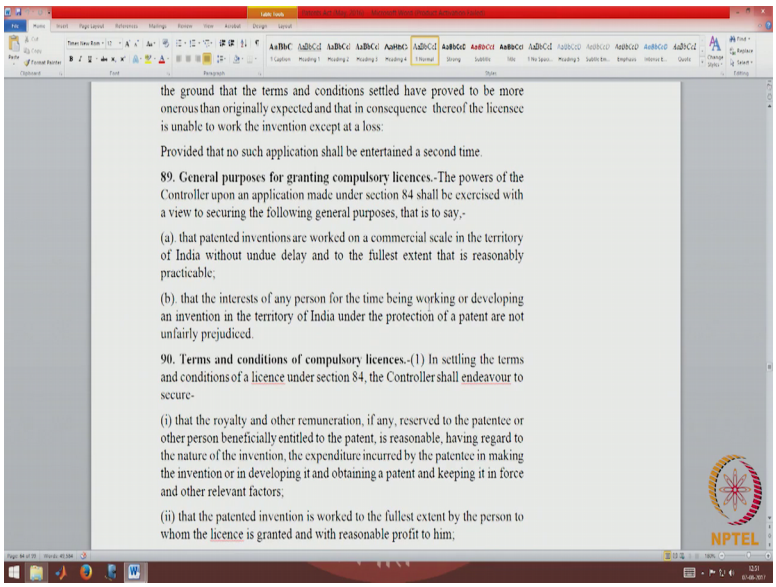

89 talks about general purposes for granting a compulsory licenses, the powers of the controller upon the application made under section 84 shall be a exercise with view of the securing the following general purposes.

A the patented invention have worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable. B at the interest of a any person for time being working or developing and invention the territory of India under the protection of a patent are not unfairly prejudiced. These are the 2 conditions that the controller shall look into in exercise in his powers under section 84. 90 terms and condition of compulsory licenses. Now in settling the terms of compulsory license the controller shall look into the following matters.

1, that the royalty and other remuneration if any reserved to the patentee or other persons beneficiary entitled to the patent is reasonable. So, he shall ensure that the royalty is reasonable having regard to a nature of invention they expenditure incurred by the patentee in making the invention what we call R and D expenditure or in developing it and obtaining a patent and keeping it in force and other relevant factors.

Now so, the royalty shall be determined by the controller the royalty that the compulsory licensee has to be pay to the patentee. And in determining the royalty, the royalty one has to be reasonable royalty it has to be reasonable the other factors the nature of the invention expenses R and D expenses how long the patent was kept alive by paying the fee and all these things shall be factored.

2, that the patented invention is work to the fullest extent by a person to whom the license is granted and with reasonable profit to him. So, once a license is granted it has to be ensure that it is work to the fullest extent, and it also brings to the person a profit, a reasonable profit.

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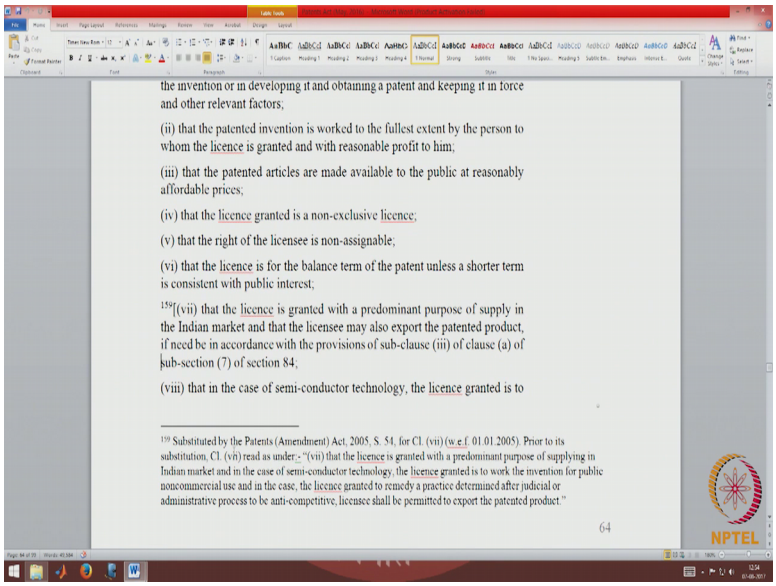

So, the terms of the license will be structured in such a way that the party who makes the patented invention who works the patented invention also on a profit.

3, that the patented articles are made available to the public at reasonable affordable prices. So, the price is something which the controller can fix in these proceedings.

4, that the licensee grated is non exclusive license. So, the compulsory license are non exclusive license. So, if others files similar compulsory licenses on the same invention the patentee can give further such non exclusive license. An exclusive licenses granted to just one person. So, they cannot be many exclusive licenses. So, the idea behind the scheme of the act is that if more people approach the patent controller the patent controller should be able to grant further licenses. So, in that sense it is non exclusive that the right of the licensee is non assignable the licensee cannot transfer or alienate is right or assign is right.

6, the license is granted for the balance term of the patent unless a short turn term is consistence with public interest, normally the when a license is granted it is granted for the remaining term of the patent whatever remains. Unless shorter period is agree. 7 that the license is granted with the predominant purpose of supply in the Indian market and that the licensee may also export the patented product if need be in accordance with the provisions of sub clause 3 of clause a of subsection 7 of section 84.

Now, that provides certain conditions on 3 the condition being a market for export of a patented article manufacture in India is not been supplied or developed. That could be one of the grounds for determining reasonable requirements of a public have not been met. So, in granting a license it is predominantly for the Indian market, but they could also be conditions of export that are considered.

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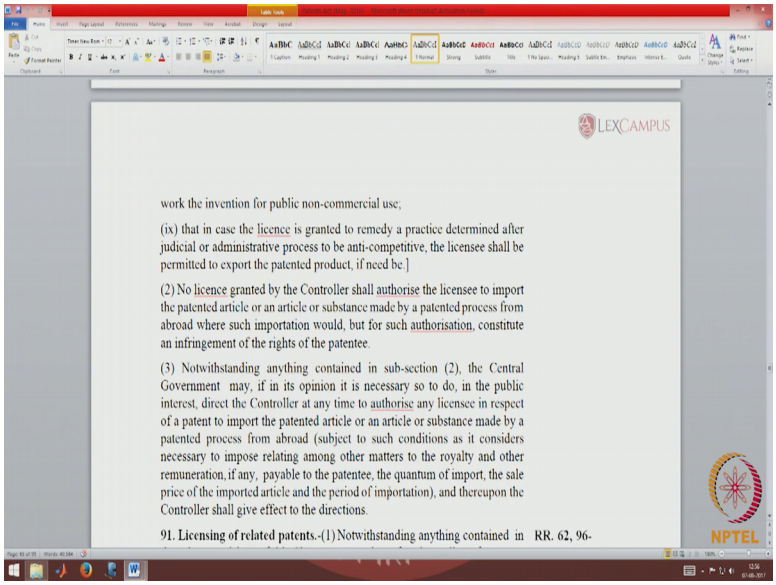

8, in the case of semi conducted technology license granted is to work the invention for public non commercial use. 9, that in the case of a license is granted to remedy a practice determined after judicial or administrative process to be anti competitive a licensee shall be permitted to export the product if need be.

Now, a license by the controller can also be granted. To remedy a practice determined after judicial or administrative process to be anti competitive. So, there is an administrative process which decides that a particular practices anti competitive compulsory license can be granted pursuant to that by the controller. Now in such case the license shall be permitted to export the patented product if there is a need. 2, no license granted by the controller shall authorize the licensee to import the patented article or an article or substances made by the patented forces from abroad where such importation would, but for such authorization constitute infringement of rights of a patentee.

The idea of the compulsory licenses local working is always tied to the grant of a compulsory license. So, even if compulsory license is granted for a reasonable requirement of public not being met or the invention is not available at an affordable price, still importation is not an option for the licensee. The licensee will have to manufacturing. So, in cases where importation would amount to infringement then the licensee would not be allowed to import.

Now, we know that under section 48 importation is one of the acts that constitutes infringement. It is one of the acts granted as an exclusive right to the patentee. So, the license is objective should not be import, but rather manufacture.

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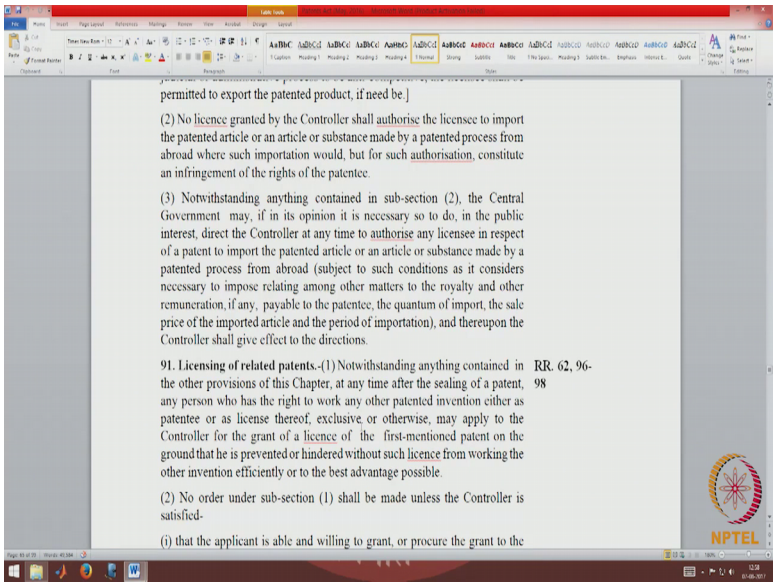

3, notwithstanding anything contained in subsection 2 the central government may if in it is opinion it is necessary to do so in the public interest. Direct the controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by the patented process from abroad. Subject to such conditions as it considers necessary and other remuneration if any payable to the patentee quantum of import sale of price of the imported article. And the period of importation these are the conditions that the controller shall take into constellation and there upon the controller shall give effect to the direction.

Now, there is an exception. In some cases the central government may say that allow parties to import. Now this could be where there is no local ability to manufacture or the

ability to manufacture locally far exceeds the demand for that particular product. For instance, if there is a outbreak of a bird flu virus, and there is a particular raw material which is not available in India, but it is manufactured elsewhere. And we find that it is not possible for the companies in India to match up manufacture and supply huge quantities of a particular drug within the short span of time, then the central government can use this provision in public interest and direct licensee to also import the patented article if necessary.