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Solution Lecture – 37 **Limitations of Patent Rights - Compulsory License**

Compulsory licenses are granted when there are situations which warrant a grant of a compulsory license.

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Types of CL

NPTE

- Third Party Initiated CL
- Special CL
- CL of Related Patents
- CL for Export of Pharmaceuticals

Under the Indian <u>patents_Patents_act_Act_</u>there are 4 types of compulsory licenses that can be granted, the first one is a third party initiated compulsory license of what we also refer to as a market initiated compulsory license. Then we have a special compulsory license which is issued in special circumstances, then we have the compulsory license of related patterns and we have a compulsory license for export of pharmaceuticals. These are the 4 types of compulsory licenses that can be granted under the act.

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NPTEL

Application for CL [S.84]

- Establish a prima facie case for S.84
- Who can apply: Any person interested after the expiration of 3 years from grant of patent
- Conditions:
 - Reasonable requirements of public not satisfied
 - Not available at reasonably affordable price
 - Not worked in India
- Other applications under SS. 91, 92 92A

Now, let us look at the first type which is the general type, it is an application for a compulsory license which can be done under section_Section_84.—; Now_now_this is a market initiated compulsory license. Now to warrant the issuance of a compulsory license the person who makes an application has to establish a prima facie case, he has to show that there is a case for the grant of a compulsory license. Now, who can apply? Any person interested can apply a person interested is defined as a person who has a research interest among other things and this can be done after 3 years of expiration of the grant of the patent.

It is should have been 3 years since the patent has been granted only then a compulsory license can be applied for. Now, what are the conditions for the grant of a compulsory license under section_Section_84 which deals with the general company license or the market initiated compulsory license_one_One_of the conditions for the grant is that the reasonable requirements of the public are not satisfied. So, if the reasonable requirements of the public are not satisfied with regard to a particular invention covered by a patent; then you can ask for a compulsory license for that patent.

Secondly, the invention which is covered by a patent is not available at reasonably affordable price. So, it is not available as an affordable price again you can file a compulsory license and the third reason why you can ask for a compulsory license under section—Section—84 is that the invention is not worked in India. The patent, the invention covered by the patent is not worked in India. Now as mentioned apart from these, this

type they could be applications under 91, 92 and 92 A; the 3 other types of compulsory licenses.

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Third Party Initiated [S.84]



- Procedure
 - Adjournment of applications, if time not enough to work the patent
 - Opposition of application
- Factors considered before grant [S.84(6)]
 - Nature of invention, steps taken to use invention
 - Ability to work invention for public advantage
 - Capacity of applicant to undertake risk
 - Failed in obtaining license

Now, the procedure is that the application has to be disposed of in a timely fashion, they can be opposition to the application somebody files an application for a compulsory license that can be opposed, there is a procedure for opposition and there are factors that the controller has to consider before the grant of a compulsory license.

The nature of the invention and steps taken to use the invention, the ability to work the invention for public advantage, capacity of the applicant to undertake the risk because the risk will involve manufacturing and supplying it in India and the fact that the applicant failed to obtain a license. Now these are the factors which will be considered before granting a compulsory license.

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Incidental Orders: Controller

- Granting Licences to Customers of the Applicant
- Cancelling or Amending Existing Licences
- Granting Licences for Other Patents
- Revision of Terms and Conditions

The controller can also make certain incidental orders, granting licenses to customers of the applicant and also the controller has the power to cancel and amend existing licenses. They can also be licenses can also be granted for other patents, which are necessary for implementing the compulsory license. The controller also has the power to revise the terms and conditions of a grant of a compulsory license.

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Licensing of Related Patents [S.91]

- **Who:** Any person, right to work any other invention as a patentee or licensee
- When: Prevented without such licence from working the other invention efficiently
- Conditions:
 - Willing to grant/procure, license of other invention
 - Substantial contribution, industrial activities

The second type of a compulsory license is a compulsory license which pertains to related patents; this is granted under <u>section Section 91</u>, who can apply? <u>any Any person</u> who has a right to work any invention as a patentee or licensee.; <u>Soso</u>, a person has a right to work an invention as a patentee or a licensee can apply for a grant.

Now, a reason why such an application should be made is that the person is prevented without such license from working the other invention effectively. So, when 2 patents are related the person has 1 patent, he owns the patent or his license, the patent he is not able to work his patent because of another patent which he needs to license. If he does not license that patent then it could amount to infringement, so when there are related patents in a way in which you cannot operate or use one without infringing the other then you can seek a license for a related patent. The conditions are that the person who seeks the patent should be willing to grant or procure license of the other invention.

Then they are asked the invention itself should make a substantial contribution to industrial activities. So, the technology should be something which is important for a license to be granted.

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Special Compulsory License [S.92]

- NPTEL
- · Compulsory licenses to work the invention
 - circumstances of national emergency
 - circumstances of extreme urgency
 - cases of public non-commercial use
- Includes public health crisis
- Notification by Central Govt.

The third type of license is this special compulsory license under section 92, now these are licenses granted to work the invention in circumstances of national emergency, in circumstances of extreme urgency or in cases of public non commercial use. Now, this includes public health crisis like HIV, aids and other health crisis, so in case where there is a need to issue a compulsory license in need in the case of a national emergency or extreme urgency then section 92 can be employed section 92 has not been employed so far.

Because there have been no instances requiring the issue of one such license. The procedure for granting special compulsory license is that the government, the central government has to issue a notification first, upon the notification the controller can grant a compulsory license.

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Compulsory License for Export [S.92A]

- Manufacture and export of pharma products
- To a country having insufficient manufacturing capacity
 - Address public health problems
 - Such country allows importation from India

The fourth type of compulsory license is the compulsory license for export of pharmaceutical products this is covered under section 92 A. Now this is an exclusive license for manufacturing within India and export of pharmaceutical products outside India.

So, the object of this license is to manufacture in India and to export outside India to a country having insufficient manufacturing capacity. Now, this is a special provision to address the needs of other countries, there could be countries which do not have adequate manufacturing capacities and which need the drug or pharmaceutical product to be imported into their country and this mechanism is to facilitate that need and it can be done by employing the local manufacturing capacity within India. It is to address public health problems and such countries allow importation from India their law should allow importation from India.

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NPTEL

Revocation [S.85]

- Revocation in cases of not working
- Who: Person interested, Central Govt
- When: 2 years after date of grant of CL
- Conditions:
 - Invention not been worked
 - Reasonable requirements of public not satisfied
 - Not available at affordable price

There is also a provision where a patent can be revoked after the grant of a compulsory license. Now these are revocation in cases of not working, the person any person interested or the central government can also move for a revocation, now the application for revocation can be moved only after 2 years of grant of the compulsory license.

So, we have already seen a compulsory license can only be granted after 3 years of the patent being granted and a compulsory license has been granted and it is been 2 years after the grant of the compulsory license, nothing has been done the patent has not been worked. So, the invention has not been worked reasonable requirements of the public not are, not being satisfied and the invention is not available at an affordable.

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Termination [S.94]



- Termination of application made under S.84
- Application made to the Controller by the patentee or interested person
- License holder has the right to object such termination
- Application to be made on F.21

Compulsory licenses granted can also be terminated an application that is been granted a compulsory license under section 84 can be terminated. The procedure is mentioned in section 94, application shall be made to the controller by the patentee or the interested person, because the patentee is the person who is affected by a compulsory license. So, it can be made by the patentee license holder has the right to object to such termination the person who is currently enjoying the benefit of a compulsory license can object to the termination and the form to be used is form twenty one for making an application for termination.