Patent Law for Engineers and Scientiests
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Lecture - 67
Compulsory Licensing

Compulsory License for Export of Pharma Products

92 A is the fourth type, no 92 A is a special provision it was introduced by the amendment in 2005, a compulsory license for export of pharmaceutical product in certain exceptional circumstances.

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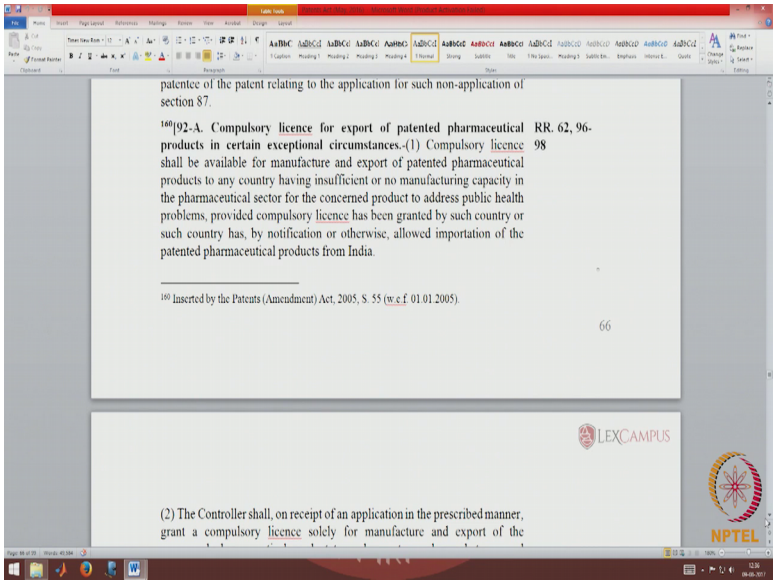

So, 92 A is understood as in license for the purpose of export. Now in all the other cases there was an local need the reasonable requirements of the public in India were not met, people in India could not get that invention at an affordable price, it was not locally worked in India the related patent in India was not available to the patentee, and it had made a substantial contribution to that industry, all these things are local conditions.

Now, 92 A and even we saw the national emergency and extreme urgency public noncommercial use, all these things we understand them as local requirement pertaining to the requirements in India. 92 A capital A pertains to export. There is no local need and its solely designed for export and this is actually a provision that keeps in mind that India

has a vibrant manufacturing sector in certain industries especially pharmaceuticals, and for pharmaceuticals alone because India has the ability to manufacture.

This provision is provided so, that countries which want to rely on Indies manufacturing capacity could utilize this provision and there would not be any bar in the patents act in India for allowing such an export because for export to happen there has to be local manufacture, and manufacturing is one of the protected acts under section 48. So, when manufacturing is protected as a right of the patentee, any person who involves in the manufacturing infringe the patent. So, to protect a person to manufacture because you can only export once you manufacture it here. So, the right to manufacture and export are covered in this erosion.

Now, let us look at this provision, subsection 1 compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country, the requirement is having insufficient or low manufacturing capacity in pharmaceutical sector.

So, you either have insufficient that country has insufficient or no manufacturing capacity in pharmaceutical sector, for the concern product to address public health problems. So, that country should have a public health problem they should have a national emergency or they should have a public health problem, in whatever way that country defines it provided compulsory license has been granted by such country or such country has by notification or otherwise allowed importation of pharmaceutical products from India. So, what is the requirement? There is a public health problem in that country, the country does not have capacity or it has insufficient capacity manufacturing capacity, and the country has issued a compulsory license or at least a notification allowing importation of patented pharmaceutical products from India.

Now, this provision is there to secure the rights of the Indian companies or any company that is having its manufacturing set up in India. It should not be that the company in India has manufactured everything, and then it realizes that it cannot supply to the foreign country because there is no the laws of the foreign country, do not allow importation of patented products.

So, the first requirement is that they should be a requirement in the form of a compulsory license or a notification, allowing for the pharmaceutical products that are manufactured

in India to be imported into that country it is a requirement. So, rather than proactively creating patented products, and then looking out for countries who may be in need this provision actually curbs that and states that there has to be a notification first either in the form of a compulsory license or a normal notification, allowing these products to enter. So, that is a it has been made a pre requirement.

2. The controller shall on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacturing manufacture and export of the concerned pharmaceutical product to such country, under such terms and conditions as may be specified and published by him.

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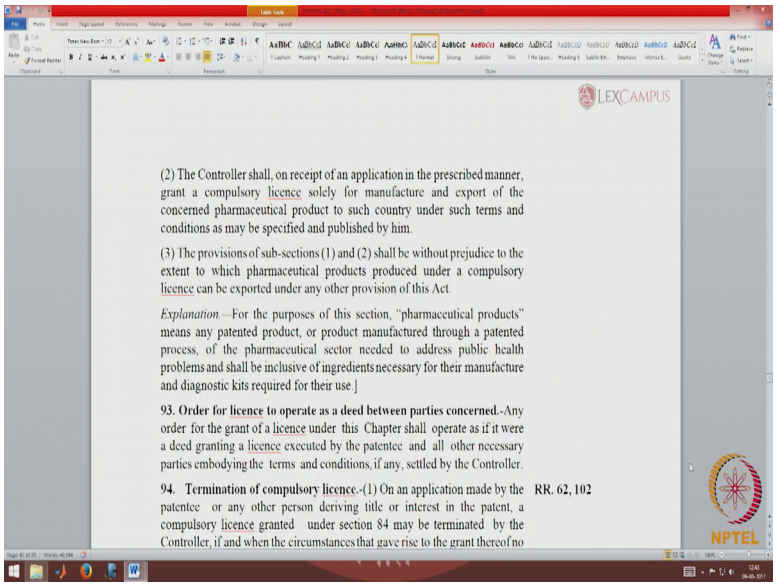

So, the compulsory license is granted solely for manufacture and export. So, whatever is manufactured will not be sold in India, it will just be for the purpose of export. 3 the provisions of the objection 1 and 2, shall that be without prejudice to the extent to which pharmaceutical products produced under compulsory license can be exported under any other portion of this act.

Now, this is it without prejudice means it is without exception to any other provision. In fact, we saw in determining the terms of the compulsory license. In 91 7 predominant purpose of the supply in the Indian market is one of the things that the controller can decide he shall endeavour to secure, that the license is granted with the predominant purpose of supply in the Indian market. Now this provision which I just now read from

section 90, will not affect subsection 3 of 92 capital A because it means it is without prejudice.

So, it this cannot operate by itself even in spite of any other provision explanation. For the purpose of this section pharmaceutical products may mean patented product or product manufactured through a patented process of a pharmaceutical sector, needed to address public health problems and shall be inclusive of ingredients necessary for such factual and diagnostic kits required for their use.

Now, pharmaceutical products is defined under this section, you will recollect that under section 2 there is a definition of a pharmaceutical substance, but that definition is not widely used, here is a in the explanation you find the definition of a pharmaceutical product.

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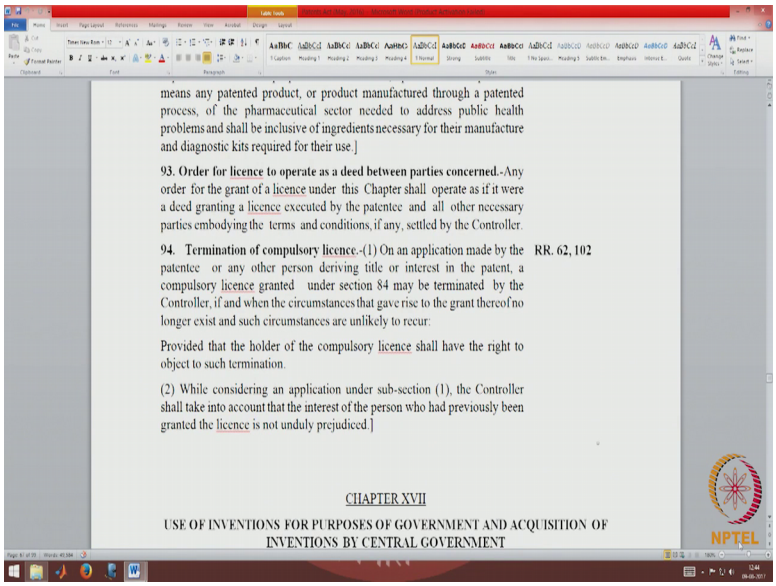
means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.]

93. Order for licence to operate as a deed between parties concerned.-Any order for the grant of a licence under this Chapter shall operate as if it were a deed granting a licence executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.

94. Termination of compulsory licence.-(1) On an application made by the patentee or any other person deriving title or interest in the patent, a compulsory licence granted under section 84 may be terminated by the Controller, if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur: RR. 62, 102

Provided that the holder of the compulsory licence shall have the right to object to such termination.

(2) While considering an application under sub-section (1), the Controller shall take into account that the interest of the person who had previously been granted the licence is not unduly prejudiced.]

CHAPTER XVII

USE OF INVENTIONS FOR PURPOSES OF GOVERNMENT AND ACQUISITION OF INVENTIONS BY CENTRAL GOVERNMENT

So, section 2 1t a defines a pharmaceutical substance, and 92 A explanation defines or explains what pharmaceutical products are. Now once a compulsory license is granted, 93 states that the order for license to operate as a deed between the parties. Now a normal license is a deed between the parties deed in the sense that it is an agreement, because its voluntary the normal license will be regarded as a contract or an agreement between parties. But in this case there is no consent between the parties either to grant or to receive, the cont the consent is simply not there. In fact, that is the way we call it a

compulsory it is an enforced license, the controller has imposed the license on the licensure or on the patentee.

So, 93 says that any order for the grant of a license under this chapter shall operate as if it were a deed granting a license executed by the patentee, and all other necessary parties embodying the terms and condition if any settled by the controller. So, this though the controller grants it will be regarded as a deed or an agreement executed by the patentee and the other parties.