Intellectual Property Rights, And Competition Law
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Lecture -30
TTBER and Safe Harbour Provisions

Hello. Let us take forward our discussion regarding TTBER principles and the Safe Harbour Provisions for various technology transfer agreements.

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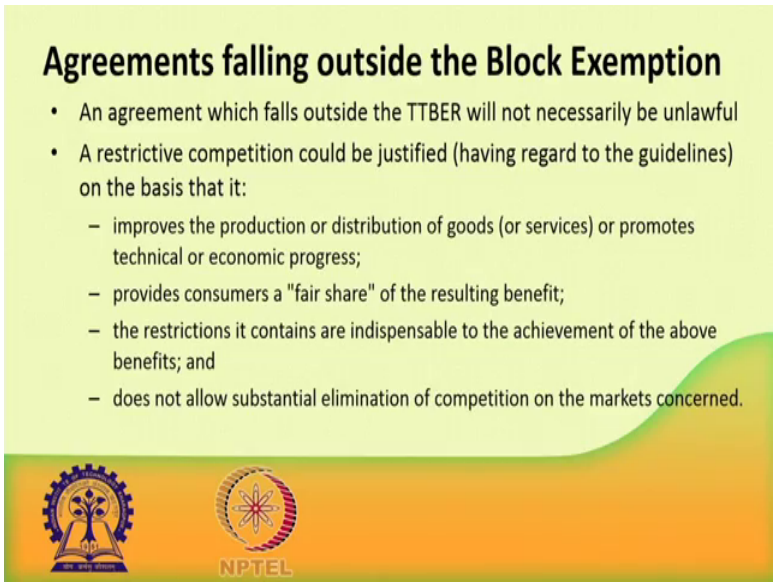

Let us discuss about the agreements that fall outside the block exemption. As we discussed, the TTBER provisions are applicable for technology transfer agreements particularly for intellectual property related technologies if the market shares is less than 20 percent for the competitive companies or less than 30 percent for non-competitors companies.

But what if there are certain agreements which do not fall under the criteria of the safe harbour or the TTBER block exemptions? Those kind of agreements, where either parties have a larger market share or when the agreement is between more than two parties, the TTBER principles are not directly applicable. However, the technology transfer guidelines provide various guidelines for those agreements.

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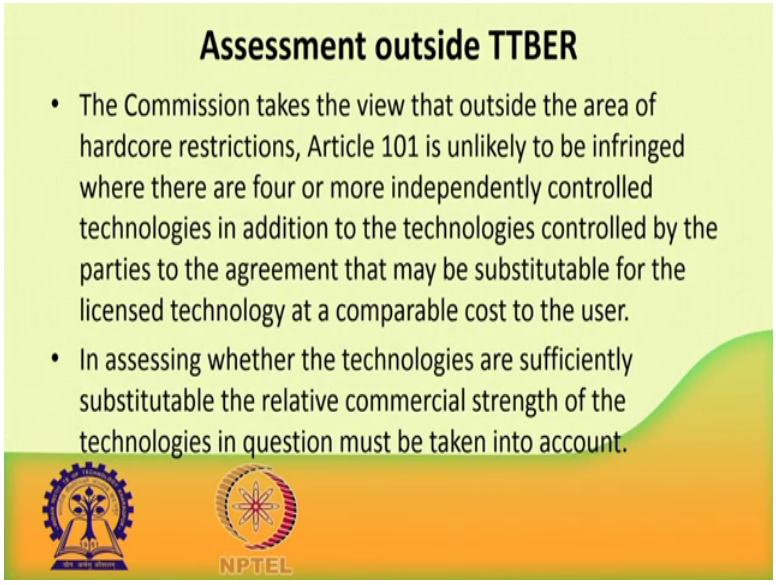

When an agreement is between two or more non-competing entities, then the European Commission looks into various anti-competitive effects for those agreements. But, when an agreement is between competitors, i.e. those companies which are involved in producing similar products or technologies and have similar IP in the same technology then there are chances that the anti-competitive factor can be raised.

In the technology transfer guideline, it is directly stated that the Article 101 is unlikely to be infringed, where there are four or more independently controlled technologies in addition to the technologies controlled by the parties to the agreement that maybe substitutable for the licensed technology at a comparable cost to other users, i.e. when there is an agreement between two or more parties and the parties are in control of four or more independent technologies, then it is less likely that there will be an anti-competitive effect.

The term “substitutable license technology” means, the competitors have certain technologies which maybe substitutable by any other related technologies. So, there is a less chance that the agreement will lead to anti-competitive effect. Further, while assessing the technologies it should be taken into account whether the technologies are sufficiently substitutable.

The relative commercial strength of the technology in question must be taken into account, i.e. while looking into the agreement, the European Commission assesses the strength of the technology, i.e. Is the technology really substitutable by related or alternative available for that technology or not? If certain alternatives are available then there is a less chance of anti-competitive effects.

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When the agreement is between non-competitors; unless there is a specific query; the European Commission does not look into it. But when the agreement is between competitors, the EC looks into the agreement and the following factors.

It looks into the nature of the agreement and what is the market position of the parties involved, what is the market position of the competitor; even though they might not be directly involved in the technology transfer agreement, what is the market position of other competitors, what is the market position of the buyers of the product, whether there is any existence of or the extent of entry barrier for new technologies, how mature is the market.

These individual factors are looked into at greater detail to understand the anti-competitive effects of the agreement. For example, the nature of the agreement: whether it is an exclusive agreement, whether any reciprocal clauses are involved, whether there

is any non-compete clause associated with the development of a new technology which may further inhibit the development or which will may lead to price fixation of the product, market position of the parties, i.e. if the parties involved have a greater share or are having a larger market share then there is a higher chance that it would lead to competitiveness. Market position of the buyer's means, the buyers are willing to pay such amount of money to buy the technologies. It depends on the buyer's purchasing power or the acceptability of the technology from buyers end.

Whether there is any entry barrier or not, if there is any reciprocal arrangement by which the new technology is not being taken outside or the innovation is being hampered. The maturity of the market means, whether the technology is such that the people are really not willing to give up the old technology or is there any acceptability for the newer technology in that domain. Greater the maturity of the market, greater would be the market share of the competitors.

All these factors are taken into account to look into the technology transfer agreements, to find out whether it is abusive or whether it is against the provisions of Article 101 sub-section (1) or not.

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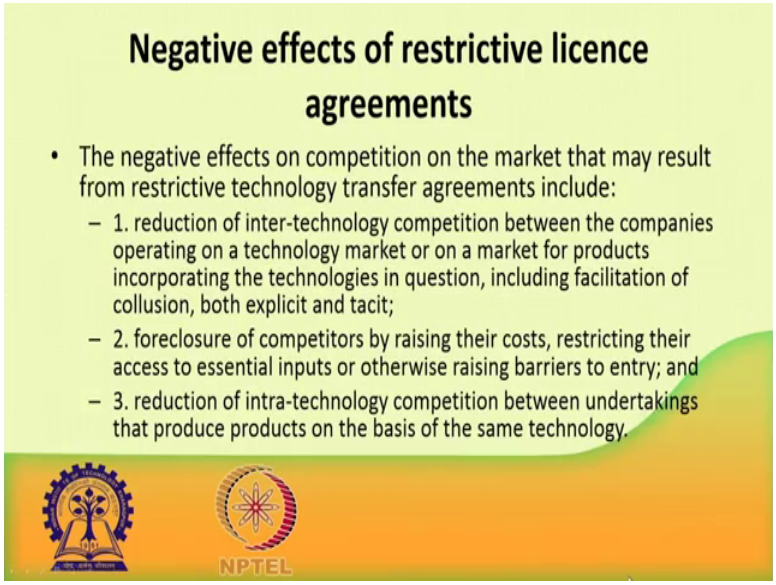

There are certain negative effects of restrictive license agreements. The negative effects on the competition or on the market resulting from restrictive technology transfer agreement may include: the reduction of inter-technology competitiveness between the companies operating on a technology market or on a market for the products incorporating those technologies in question. This may lead to facilitation of collusion, both explicit and tacit, i.e., if there are already certain restrictive provisions mentioned in the agreement, no new product or no new technology can come to the market, there is already a barrier. If the licensee has put a clause, where the licensor cannot perform R&D on the licensed technology, in that case it reduces the inter-technology competitiveness.

Only the IP which is associated in the technology licensing agreement is being given priority. It may lead to foreclosure of competitors by raising their cost, restricting their access to essential inputs or otherwise raising the barriers to entry. These kind of restrictions in the agreement may lead to foreclosure of competition.

It may lead to price fixation and increase in cost, since third party licensing is also not allowed. There are high chances that the product price may increase. And it may lead to lack of access to essential input because no third party is involved. If Sub-licensing or involvement of other parties is not allowed as per the agreement clause; then, it is a restriction on the essential inputs and may lead to raising the barriers to entry.

It is possible that the technology may not be accessible to other relevant product market, relevant geographical location. It may lead to reduction of intra-technology competition between the undertakings that produce the product on the basis of the same technology.

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These are the primary negative effects which may exist as a result of restriction in the agreement. In technology transfer agreement, particularly dealing with the IP, there are certain restrictive provisions always present. There are guidelines that lists out certain restrictive conditions generally found in the technology transfer agreement which are as follows. First: the confidentiality obligations-In most of the IP related licensing agreements, the confidentiality clause is one of the very important clause where the licensee, licensor are not allowed to disclose or talk about the technology which they are licensing.

Second: the obligations on the licensee not to sub-license. So, without the permission of the licensor, the licensee cannot sub-license the technologies associated with the agreement.

Third: obligations not to use the licensed technology after the expiry of the agreement provided that the licensed technology remains valid and in force. As you know, patent rights or other intellectual property rights are of limited durations. Hence, the IP agreements are also for a limited period of time. There are obligations on the party to not to use the licensed intellectual property after certain period of time. But when these clause extends to not to use or not to further improve upon, this may lead to anti-

competitiveness. But, per se, the obligation not to use the IP after the duration mentioned in the technology transfer agreement, is not restrictive in nature.

There are obligations to assist the licensor in enforcing the licensed intellectual property rights which are also not restrictive in nature.

There are obligations to pay minimum royalties or to produce minimum quantity of products incorporating the licensed technology. Sometimes, the licensor puts forward an obligation, where the licensee can only produce a limited quantity of the product in question for a limited geographical location. In case of high end technology it becomes somewhat essential to restrict the technology in a time frame or in a geographical location. Depending on the merits of the case, it is not considered as restrictive in nature.

There are also obligations to use the licenser's trademark or to indicate the name of the licensor on the product. As the licensor is giving his technology to the licensee, it becomes desirable on the part of the licensor to expect his trademark or name or logo to be put on the product which is being manufactured. In majority of the cases it may happen, unless and until, the licensor does not have the capability to produce the product or the infrastructure to produce the product involving those IP. Except for situations where (Say) a scientist or a researcher has developed certain technology which he may give to some company where it may not be necessary. But, when big companies are in possession of certain intellectual property rights, they generally insist that their trademark or name should be put on the product.

These six conditions, in general are not considered as restrictive in nature, unless extended to other related clauses.

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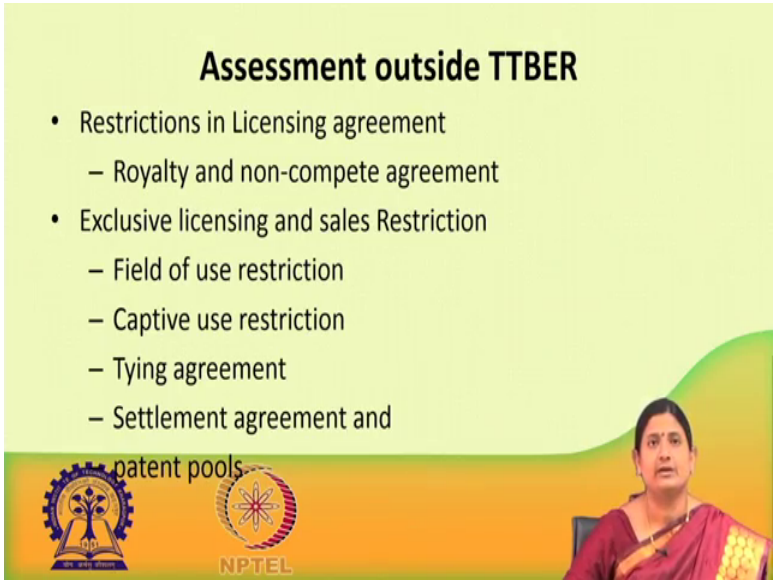

The technology transfer guidelines have specified various restrictive clauses which may exist in a technology transfer agreement. For example, the restrictions in a licensing agreement, the royalty or a non-compete agreement. In general, in the IP related technology transfer agreements, the royalty is decided by the licensor, either in the form of lump sum payment or instalments.

These do not attract the European commission's attention. But, when it extends to other non-compete agreements, for example, restrictions on not to use any third party technology along with their technology, restrictions on R&D for certain period of time.

These clauses raise the question of violating Article 101. Other clauses related to exclusive licensing, sales restrictions, the field of use restriction, captive use restriction, the tying agreement, settlement agreement and patent pools are generally assessed.

Field of use restriction means if there is a technology which may be used in manufacturing of two or more than two products, which product would be manufactured. For example, if there is a mold which may design a glass bottle and may also design a plastic bottle. In a technology transfer agreement, the licensee can only prepare a plastic bottle and not the glass bottle. Here, the technology can be used only for one particular product. This is known as the field of use or technical field of use restriction.

Sometimes if such a technology is crucial for the development of other products and the licensor has not allowed the licensee to use the technology which the licensee is already producing then it may raise the question of violation of Article 101.

Captive use restriction means that the licensor gives certain timeline within which the licensee can prepare or provides the geographical location only for which the product can be prepared or he list outs the customer to which the product can be sold. These are captive use restriction and in these cases the European Commission looks into the details to find out whether it is an abuse or in violation of Article 101 or not.

A tying agreement: when the licensor is in a strong position and has high market share, it is possible that they may bundle technologies when somebody asks for a license to a single technology. The licensor may tie up certain related products along with it. It is mostly seen when the licensor is having a high market share and there is no alternative is available. In such cases, it may lead to anti-competitive practices.

Then there are settlement agreements: these agreements are seen in generic pharmaceutical industries, where the pay for delay tactics or various co-promotional agreements, which delays the entry of a new product or generic product or a cheaper product to the market, exists. The innovator company retains its market exclusivity. It hampers the competition and the prices increase and may lead to anti-competitive behaviour.

Patent pools: Patent pools are a single platform where numerous technologies can be found or licensed. This is very essential and very helpful, but sometimes may lead to anti-competitive behaviour.

We would look into the two: settlement agreements and patent pools, in more details and how the guideline on the technology transfer agreements has emphasised on these two.

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The settlement agreements are a measure, by which two parties can resolve a dispute or licensing issue. Per se, settlement agreements are not-anti competitive because these are like out of court settlement. They are by mutual consent between two or more parties involved. Per-se these are not anti-competitive, but there are certain individual terms, which are covered under the sub-section 1 of Article 101. The technology transfer guideline addresses three major issues. First, the pay for delay restrictions; second, the cross licensing; third, the non-challenge clauses.

The pay for delay restrictions: In the case of generic pharmaceuticals, some payment or lump sum money is given to restrict the entry of a new product or a generic product into the market. By cross licensing it means that the two parties in questions should cross-license the technology with each other and no third party is allowed to receive the license of the technology or give the technology. This, in turn, is a limitation in the technology development. The innovation is hampered and hence is considered as anti-competitive behaviour.

The non-challenge clause: sometimes an IP in a technology transfer agreement is wrongfully given based on certain misleading facts. In such cases, the licensor generally puts a clause wherein the licensee cannot challenge that IP in question, which is against the European competition policy and is considered as anti-competitive behaviour.

These three: pay for delay restrictions, cross licensing and non-challenge clauses, have been dealt elaborately in the technology transfer guidelines.

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The Commission considers that, the so-called pay for delay type of settlement agreements, in general do not involve the transfer of technology, but these are based on value transfer from one party, in return for a limitation on the entry or expansion of the market of the other party. It is not the technology transfer of technology per se, but it is a payment method such as lump sum payment, which is made to stop the expansion of the market or entry of a product.

The guideline notes that, if the parties to such settlement agreement are actual or potential competitors and there is a significant value transfer from the licensor to the licensee, the commission will be particularly attentive to the risk of market allocation and market sharing.

The pay for delay tactics is more likely to come under scrutiny, when it is between two competitors, potential competitors i.e. when two parties are in a position of nearly similar technology, since it may create an anti-competitive effect or affect the market structure.

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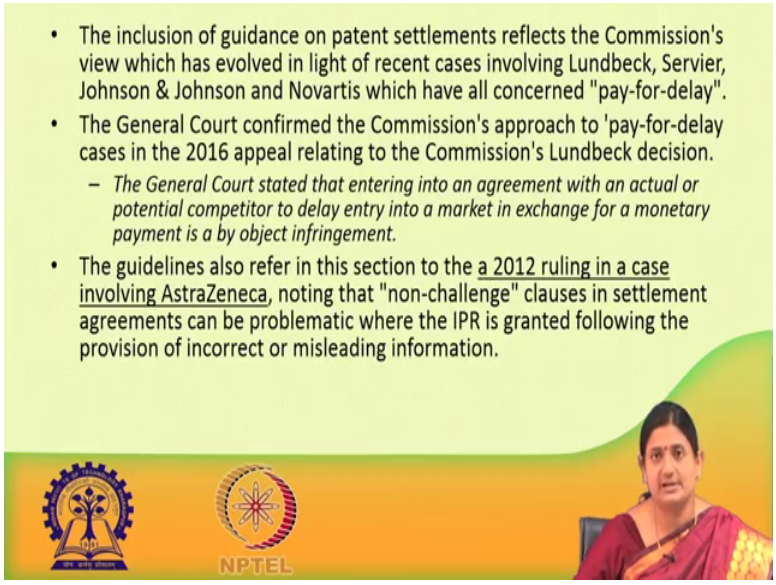

There are various cases, which lead to inclusion of these guidelines in the latest TTBER guideline, which we will be discussing one by one. These cases are, Lundbeck decision Servier, Johnson and Johnson and Novartis case. All of these cases raised the concern for pay for delay. Particularly, in the Lundbeck decision, the court has confirmed the commission's approach, in the year 2016. The court stated that entering into an agreement with an actual or potential competitor to delay entry into a market in exchange for a monetary payment is a *by object infringement*.

There can be two types of infringement: *by object* or *in effect*. *By object* means, if the object of the agreement is to stop the entry of a product or expansion of the market, then by object it will be considered to be an infringement of Article 101. Certain clauses may lead to certain results that affect market structure, such would be *in effect infringement*.

This guideline also refers to the 2012 ruling case of AstraZeneca; where it was noted that the non-challenge clauses in settlement agreement can be problematic where IPR is granted following the provision of incorrect or misleading information.

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In the Lundbeck decision, the Lundbeck subsidiary company was a pharmaceutical company in Netherlands. Proceedings against the company were initiated in 2010. Certain unilateral practices and the agreement with the object or effect of preventing the entry of generic citalopram into the market, particularly European market, was in question. It was suspected that the agreement or this practice is infringement of Article 101 and Article 102. And it infringes Article 53 and 54 of the European Economic Area (EEA) Agreement.

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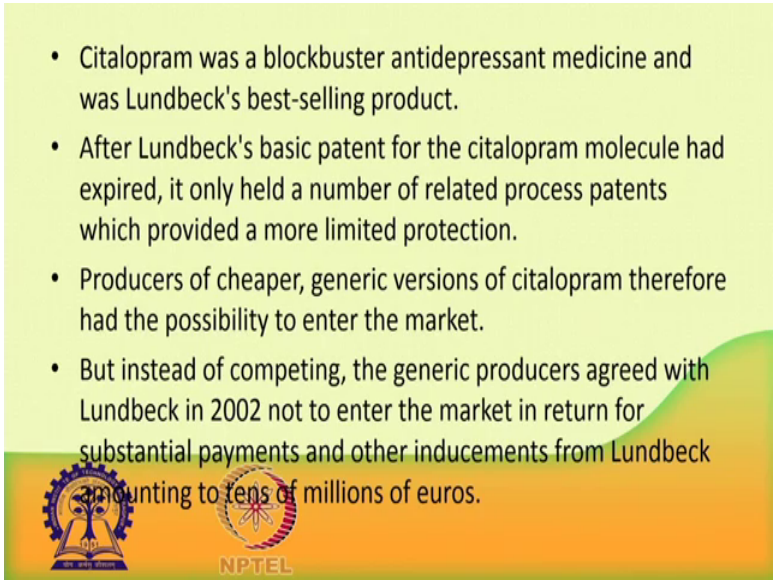

Citalopram was a blockbuster anti-depressant medicine and it was the Lundbeck's best selling product. Lundbeck had a number of patents on citalopram anti-depressant medicine but when the main patent on citalopram expired Lundbeck only had a few ancillary patents. One of the patents was regarding the preparation of crystallized salt form of this medicine.

These ancillary patents were not effective in holding the market or for holding stronger position for Lundbeck. It was becoming difficult for Lundbeck to stop other generic manufacturers to produce generic citalopram, which will be available at cheaper cost.

During that time, Lundbeck approached other potential generic competitors. And the generic competitors agreed to enter into an agreement with Lundbeck in 2002, for not entering into the market, in return for a substantial payment from Lundbeck. It means that Lundbeck gave certain lump sum amount of money (in millions of Euros) to other potential generic manufacturers and stopped them from entering into the generic segment of citalopram.

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Lundbeck also offered guaranteed profits in distribution agreements. Lundbeck also bought back all stocks of these genetics citalopram from the generic manufacturer and destroyed it.

In both the way, by destroying generic medicine as well by stopping generic manufacturer from directly entering into the market by paying lump sum amount; Lundbeck successfully retained its market position. It came to the radar of the European Commission and the European Commission imposed a fine of 93.8 millions on the Danish pharmaceutical company and other generic pharmaceutical companies were also fined nearly 52 million Euros.

The notable generic companies were *Alpharma, Merck, Generics UK, Arrow* and *Ranbaxy*. All these companies i.e. both the parties were fined because both the parties readily agreed to enter into anti-competitive agreements.

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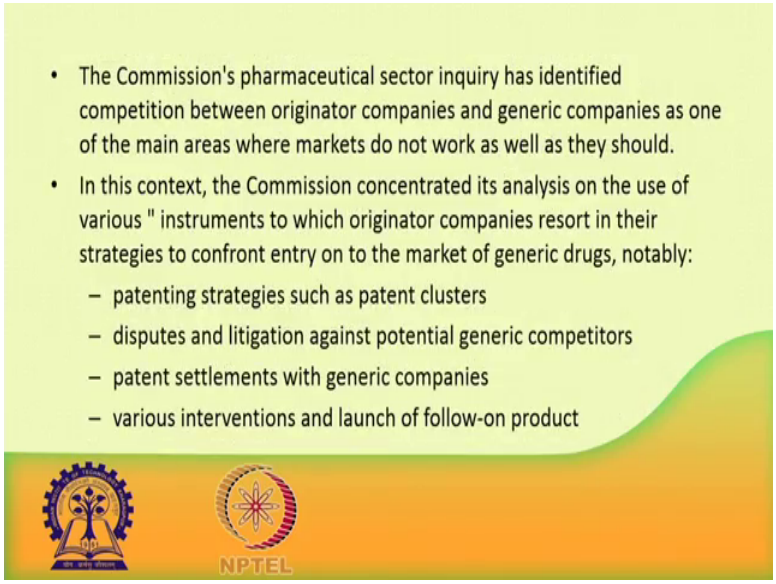

The European Commission has different departments, which look into various cases belonging to different technology. The Commission's pharmaceutical sector enquiry has identified that the competition between the originator company and the generic company is not a very simple and straight-forward.

And so, it has to be scrutinised very carefully to understand whether the behaviour is anti-competitive or not. In this context, the Commission has started looking into various instruments in which, the originator company or the innovator company resorts to their strategies to confront the entry of generic drugs.

Those strategies are: the patenting strategy such as patent clusters i.e. having more than one patent in a particular drug segment/drug molecule, dispute and litigation strategy against potential competitors by filing or by initiating disputes or litigation against the potential competitor thereby delaying the entry of generic product into the market. Patent settlement strategy with generic company.

All these four major tactics from innovator companies are looked into by the European Commission to check whether these behaviours are anti-competitive or not.

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The Commission found that the agreements by Lundbeck constituted restriction of competition *by object,* which were in breach of the prohibition on anti-competitive agreements under Article 101 of TFEU. The Commission gave a *theory of harm* and this theory of harm can be summarised in three points.

First: Lundbeck and generic undertakings were at least potential competitors i.e. Lundbeck had the technology and as the patent expired, generic manufacturers had the potential to enter into the same domain, hence, they were potential competitors.

Second: the generic undertakings committed in the agreement to limit, for the duration of the agreement; their independent efforts to enter one or more European Economic Area

market with their generic products. So, with that agreement, they agreed to not to enter into the market and stopped the introduction of cheaper products into those market.

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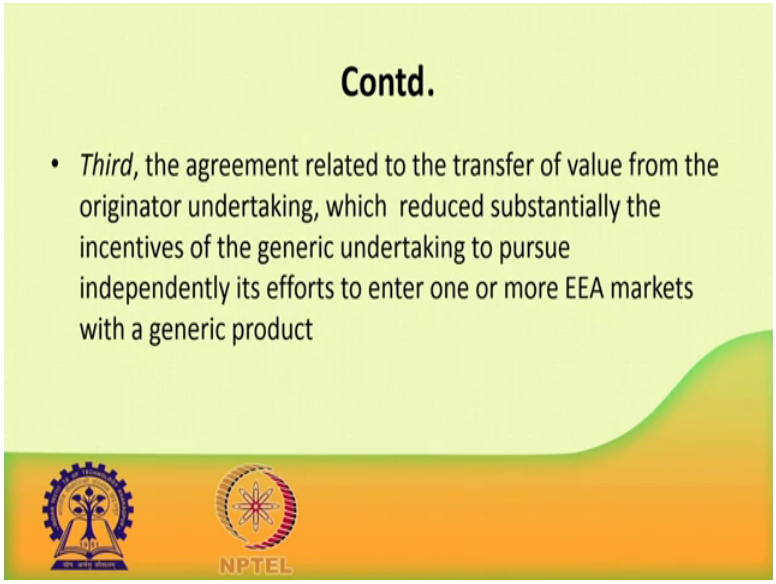

Third: the agreement related to the transfer of value from the originator undertaking reduced substantially the incentive of the generic undertakings to pursue independently their efforts to enter into the European market, with a generic product. Without supplying the product to the market, generic companies were receiving money. The generic companies did not make any independent effort to enter into the European market.

This is the theory of harm, which the European Commission came out with, in this decision. This is one of the landmark decision, where the pay for delay tactics was considered to be in violation of Article 101.

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Another important case in this direction is *Johnson and Johnson* and *Novartis* case. *Janssen Cilag*, which is a subsidiary of Johnson and Johnson was supplying a painkiller drug, known as fentanyl, in Netherlands and it concluded a co-promotion agreement with a generic competitor *Sandoz,* a Novartis subsidiary, in 2005.

In 2005, there were no regulatory barriers to develop generic versions of fentanyl patches. Therefore, Sandoz was free to enter into the Dutch market. However, *Janssen Cilag* offered certain monthly payments to Sandoz; so that no generic product of fentanyl patches can be launched by Sandoz in the Dutch market.

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Consequently, Sandoz abstained from entering into the market with generic fentanyl patches. The duration of the agreement was from June 2005 to July 2006. In December 2006, another third party was about to launch generic fentanyl. Sandoz raised objections and thence it came into the eyes of the European Commission.

The European Commission found that the co-promotional agreement between Johnson and Sandoz has delayed the entry of generic medicine for **17 months**. The price of the fentanyl patches was kept artificially high, in the markets of Netherland during this time from June 2005 to July 2006. Janssen Cilag paid approximately 5 million Euros to Sandoz, in monthly instalments for the un-defined agreement.

This agreement stopped Sandoz from entering into the market as well as from carrying out any promotional activities. In 2010, the European Commission concluded that this agreement was a restriction under Article 101 and both Johnson and Johnson as well as Novartis were heavily fined. Around 10 million Euros fine was imposed on Johnson and nearly 5.5 millions Euros was fined on Sandoz.

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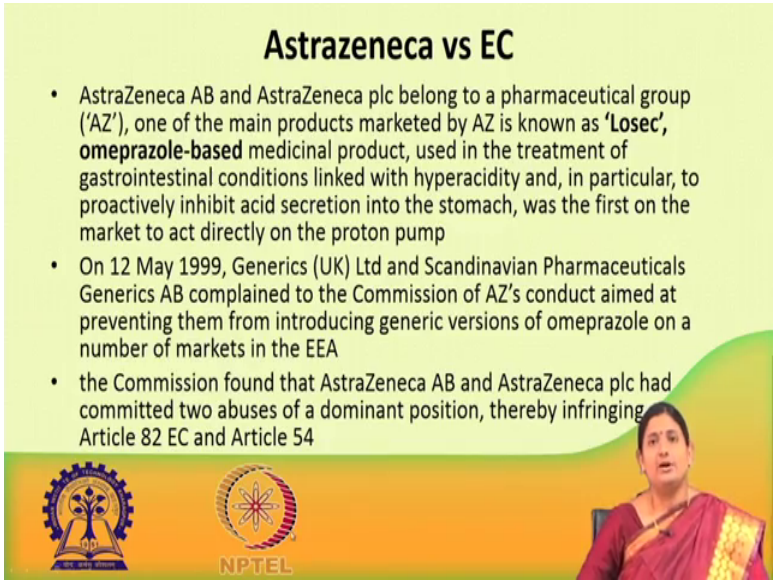

This is one of the important case where an innovator pharmaceutical company stops the entry of generic pharmaceutical companies. Another important case was AstraZeneca where not only the pay for delay tactics was used but non-challenge clause or misleading ground was also used by which IP rights were tried to be extended.

AstraZeneca had a blockbuster product called *Losec* which was an omeprazole based medicine used for the treatment of gastrointestinal conditions linked with hyper acidity. This was a new technology at that time which involved a proton pump.

In 1999, generic companies from UK and Scandinavian pharmaceutical generic AB complained to the Commission regarding AstraZeneca's conduct and they said that AstraZeneca's conduct is aimed at preventing generic manufacturers from introducing the generic version of omeprazole, in a number of markets, in the European economic area.

The commission found that, AstraZeneca's conduct was abuse of dominant position and was infringing Article 102, Article 82 and Article 54 of the European Commission.

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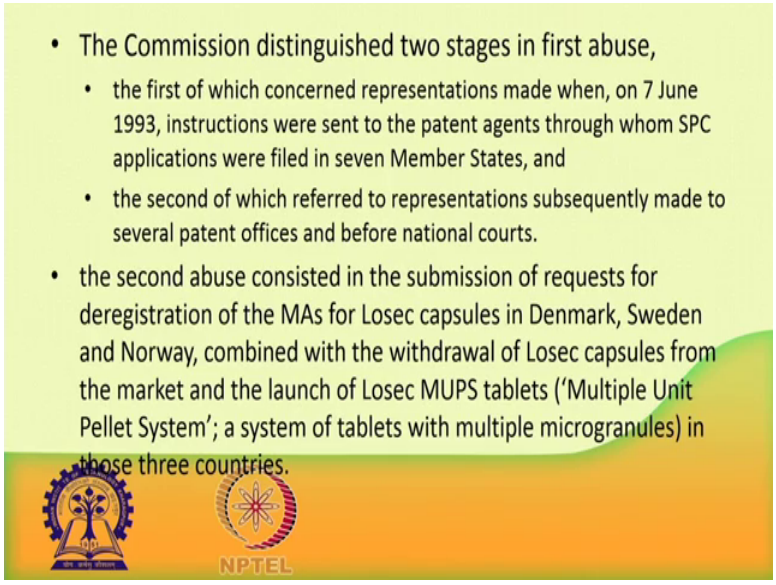

There were two abuse of dominant position. The first abuse is classified into two types. The first abuse was concerned with when AstraZeneca made representation, in 1993. Instructions were sent to the patent agents through whom *supplementary protection certificate application* were filed.

Supplementary Protection Certificate are provisions by which the patent term can be extended for 5 more years. In case of biologic drug molecules, getting marketing authorization takes a long period of time. To get effective benefit from the intellectual property laws, there are provisions by which patent rights can be extended to certain period of time and which can be achieved by supplementary protection certificate.

It was found that AstraZeneca made representations for getting supplementary protection certificate on misleading grounds. Subsequently, it made representations to various national patent offices and national courts.

The second abuse was regarding the submission of request for de-registration of marketing authorization of Losec capsules in Denmark, Sweden and Norway and the launch of Losec MUPS tablet, a new form of tablet where multiple micro-granules were released at a time. So, AstraZeneca tried to take away all the existing Losec capsules from the market and introduced a new tablet.

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The basic intention for this was to prevent parallel importers from supplying Losec capsules. All these actions, taken together, the commission found that this was an abuse of dominant position and violation of Article 102. AstraZeneca strategically implemented the regulatory framework in order to artificially protect products from competition which were no longer protected by patent and for which the data exclusivity period had expired. This was taken into consideration by the European Commission and with respect to these two abuses, the Commission imposed a fine of nearly 46 million Euros on AstraZeneca AB and a separate fine of 14 millions.

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These were the major cases which lead to the incorporation of guidelines regarding settlement agreements or pay for delay tactics in the technology transfer guidelines.

One of the other important thing in this guideline is regarding technology pools and restraints. As you know, TTBER applies to licensing agreements concluded between the pool and third party licensees.

In those kind of assessment, the commission is guided by three main principles. First: it is of the belief that the stronger the market position of the pool, the greater will be the risk of anti-competitive effect. Second: the pools that hold a strong position on the market should be open and non-discriminatory. Third: the pools should not unduly foreclose third party technologies or limit the creation of alternative pools.

In assessing the technology pools, the Commission assess the position of the market, the position of the pool, what kind of technologies is being incorporated and how it is dealing with the third party technologies.

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One kind of technology pool is patent pool. Patent pools give the companies cheaper and easier access to necessary intellectual property rights; such as the standard essential patents. These are one stop shop for intellectual property licensee. By recognising the pro-competitive nature of patent pools, the creation and licensing from patent pools is given benefit in the safe harbour guidelines. This is a kind of arrangement where one can easily get many technologies at a go. So, it is generally given a safe harbour position in the guideline.

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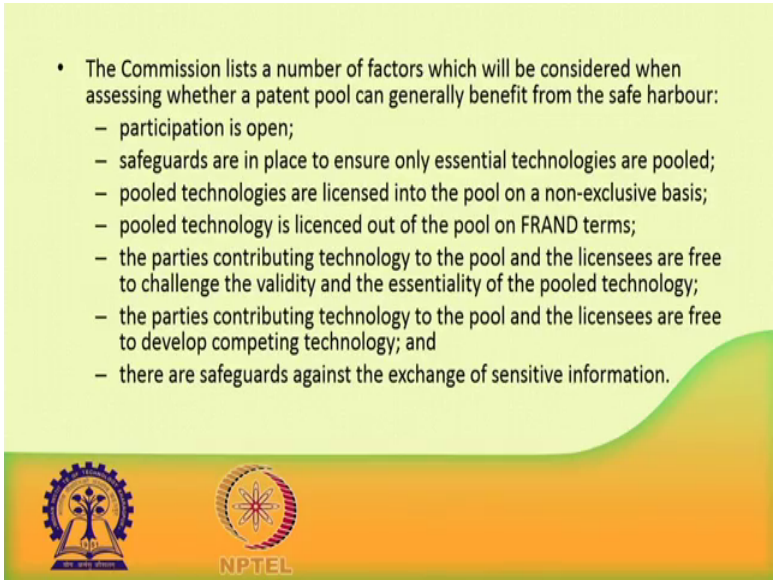

However, the commission also lists a number of factors which will be considered when they assess, whether a patent pool can generally benefit from safe harbour or not. They look into whether the participation is open for all or not, whether there is any restriction on the entry of firms or parties to the pool. They also look into what kind of safeguards are in place to ensure that only essential technologies are pooled.

The technology area is very complicated such as wireless communication or ICT. It becomes very difficult to assess what is essential and what is non-essential. Unless there is a strict scrutiny that the patent pool consists of only essential patents, one may end up paying more for less number of technology. There should always be safeguards to ensure that only essential technologies are pooled.

Third, the pooled technologies are licensed into the pool on a non-exclusive basis. The non-exclusivity of these pooled technology is also an essential factor in determining whether it can get a safe harbour or not. Also whether the pooled technology is licensed on *FRAND terms (fair, reasonable and non-discriminatory)* or not, which we will discuss in the later segments. The parties contributing technology to the pool and the licensee are free to challenge the validity and the essentiality of the pooled technology.

There should be no challenge clause associated with these kind of pools. And the parties contributing technology to the pool and the licensee are free to develop competing technologies. The participants should be free to develop further technology by using the pooled technology. There are safeguards against the exchange of sensitive information also.

These are the few criteria which the European Commission looks into before giving a safe harbour provision to such agreements. So far, we have discussed about technology transfer, block exemption regulation and safe harbour provisions; and how the European Commission looks into the technology transfer agreement involving intellectual property rights, safe harbour for different kind of agreements; the scope for the agreements which fall outside of TTBER. In subsequent modules, we will discuss about standard essential patents and how technology defines standard essential patents.

Thank you.