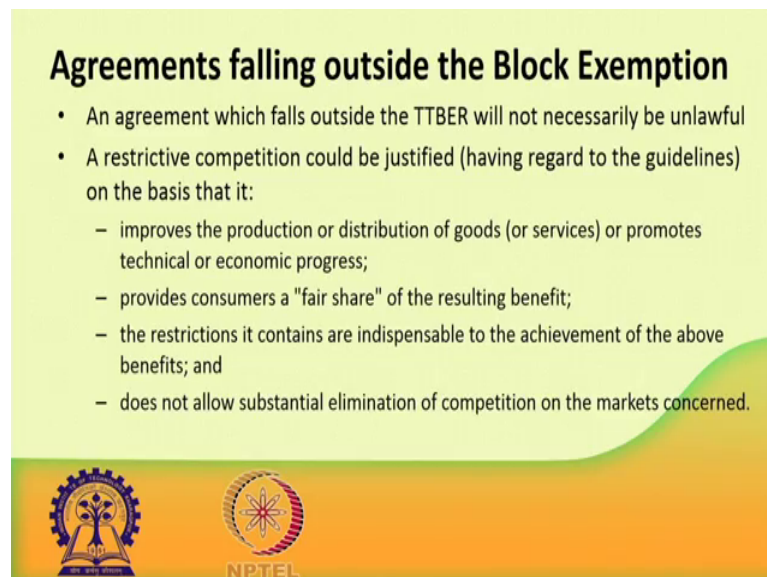


Intellectual Property Rights, And Competition Law
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Lecture -30
TTBER and Safe Harbour Provisions



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

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Agreements falling outside the Block Exemption

- An agreement which falls outside the TTBER will not necessarily be unlawful
- A restrictive competition could be justified (having regard to the guidelines) on the basis that it:
 - improves the production or distribution of goods (or services) or promotes technical or economic progress;
 - provides consumers a "fair share" of the resulting benefit;
 - the restrictions it contains are indispensable to the achievement of the above benefits; and
 - does not allow substantial elimination of competition on the markets concerned.


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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Assessment outside TTBER

- The Commission takes the view that outside the area of hardcore restrictions, 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 may be substitutable for the licensed technology at a comparable cost to the user.
- In assessing whether the technologies are sufficiently substitutable the relative commercial strength of the technologies in question must be taken into account.



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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Agreement between the competitors must be analyzed for the following factors:

- Nature of agreement
- Market position of parties
- Market position of competitors
- Market position of buyers of licensed product
- Existence and extent of any entry barrier
- Maturity of the market

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 subsection (1) or not.

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Negative effects of restrictive licence agreements

- The negative effects on competition on the market that may result from restrictive technology transfer agreements include:
 - 1. reduction of inter-technology competition between the companies operating on a technology market or on a market for products incorporating the technologies in question, including facilitation of collusion, both explicit and tacit;
 - 2. foreclosure of competitors by raising their costs, restricting their access to essential inputs or otherwise raising barriers to entry; and
 - 3. reduction of intra-technology competition between undertakings that produce products on the basis of the same technology.



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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- Obligations in licence agreements that are generally not restrictive of competition within the meaning of Article 101(1).
 - (a) confidentiality obligations;
 - (b) obligations on licensees not to sub-license;
 - (c) obligations not to use the licensed technology after the expiry of the agreement, provided that the licensed technology remains valid and in force;
 - (d) obligations to assist the licensor in enforcing the licensed intellectual property rights;
 - (e) obligations to pay minimum royalties or to produce a minimum quantity of products incorporating the licensed technology; and
 - (f) obligations to use the licensor's trade mark or indicate the name of the licensor on the product.



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 licensor'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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Assessment outside TTBER

- Restrictions in Licensing agreement
 - Royalty and non-compete agreement
- Exclusive licensing and sales Restriction
 - Field of use restriction
 - Captive use restriction
 - Tying agreement
 - Settlement agreement and

patent pools



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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Specific Guidance on Settlement Agreements

- Settlement agreements are specific measures to resolve dispute and licensing issues
- Per se are not anti competitive; Individual terms may be caught under Art 101(1)
- Technology transfer guideline addresses three issues:
 - Pay for delay restrictions
 - Cross licensing
 - Non challenge clause

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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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Settlement Agreements

- The Commission's considers that so-called "**pay-for-delay**" type settlement agreements often do not involve the transfer of technology rights, but are based on a value transfer from one party in return for a limitation on the entry and/or expansion on the market of the other party and therefore may be caught by Article 101(1).
- The guidelines also note that, if the parties to such a settlement agreement are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing.

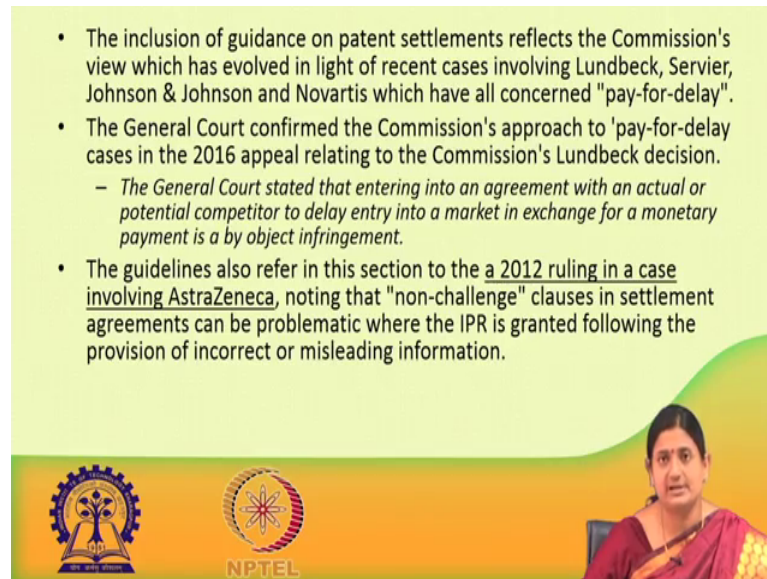
 

The Commission considers that, the so-called pay for delay type of settlement agreements, in general do not involve the transfer of technology, but these are based on value transfer from one party, in return for a limitation on the entry or expansion of the market of the other party. It is not the technology 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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The slide features a light green background with a yellow-to-green gradient at the bottom. It contains three bullet points. The first bullet point discusses the Commission's view on patent settlements, mentioning cases involving Lundbeck, Servier, Johnson & Johnson, and Novartis. The second bullet point states that the General Court confirmed the Commission's approach to 'pay-for-delay' cases in the 2016 appeal, with a sub-point quoting the court's decision on 'by object infringement'. The third bullet point refers to a 2012 ruling in the AstraZeneca case regarding 'non-challenge' clauses. At the bottom of the slide, there are three logos: the Indian Institute of Technology (IIT) logo on the left, the NPTEL logo in the center, and a portrait of a woman in a red sari on the right.

- The inclusion of guidance on patent settlements reflects the Commission's view which has evolved in light of recent cases involving Lundbeck, Servier, Johnson & Johnson and Novartis which have all concerned "pay-for-delay".
- The General Court confirmed the Commission's approach to 'pay-for-delay' cases in the 2016 appeal relating to the Commission's Lundbeck decision.
 - *The General 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.*
- The guidelines also refer in this section to the [a 2012 ruling in a case involving AstraZeneca](#), noting that "non-challenge" clauses in settlement agreements can be problematic where the IPR is granted following the provision of incorrect or misleading information.

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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The Lundbeck decision

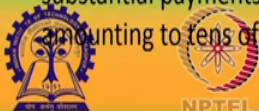
- On Jan 7, 2010- proceedings were opened against the pharmaceutical undertaking Lundbeck
- The facts concern unilateral practices and/or agreements with the object or effect of preventing or delaying entry of **generic citalopram** into the markets of citalopram in the European Economic Area (EEA).
- These suspected practices and/or agreements constitute possible infringements of Article 101 and/or Article 102 of the Treaty on the Functioning of the European Union and Article 53 and/or Article 54 of the EEA Agreement.



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 antidepressant medicine and was Lundbeck's best-selling product.
- After Lundbeck's basic patent for the citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection.
- Producers of cheaper, generic versions of citalopram therefore had the possibility to enter the market.
- But instead of competing, the generic producers agreed with Lundbeck in 2002 not to enter the market in return for substantial payments and other inducements from Lundbeck amounting to tens of millions of euros.



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 paid significant lump sums, purchased generics' stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement.
- The agreements gave Lundbeck the certainty that the generics producers would stay out of the market for the duration of the agreements without giving the generic producers any guarantee of market entry thereafter.
- The European Commission has imposed a **fine of € 93,8 million** on Danish pharmaceutical company Lundbeck and **finest totaling € 52,2 million** on several producers of generic medicines.
- These generic companies were notably **Alpharma (now part of Zoetis), Merck KGaA/Generics UK (Generics UK is now part of Mylan), Arrow (now part of Actavis), and Ranbaxy.**



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 Commission's pharmaceutical sector inquiry has identified competition between originator companies and generic companies as one of the main areas where markets do not work as well as they should.
- In this context, the Commission concentrated its analysis on the use of various " instruments to which originator companies resort in their strategies to confront entry on to the market of generic drugs, notably:
 - patenting strategies such as patent clusters
 - disputes and litigation against potential generic competitors
 - patent settlements with generic companies
 - various interventions and launch of follow-on product

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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Decision

- In its Decision of 19 June 2013, the Commission found that the agreements constituted restrictions of competition **by object**, in breach of the prohibition of anti-competitive agreements under Article 101 TFEU.
- The Commission's theory of harm can be summarised as follows:
 - *First*, Lundbeck and the generic undertakings were "at least" potential competitors.
 - *Second*, the generic undertakings committed in the agreements to limit, for the duration of the agreement, their independent efforts to enter one or more EEA markets with their generic products.

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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, which reduced substantially the incentives of the generic undertaking to pursue independently its efforts to enter one or more EEA markets with a generic product



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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Anti-trust: J&J and Novartis

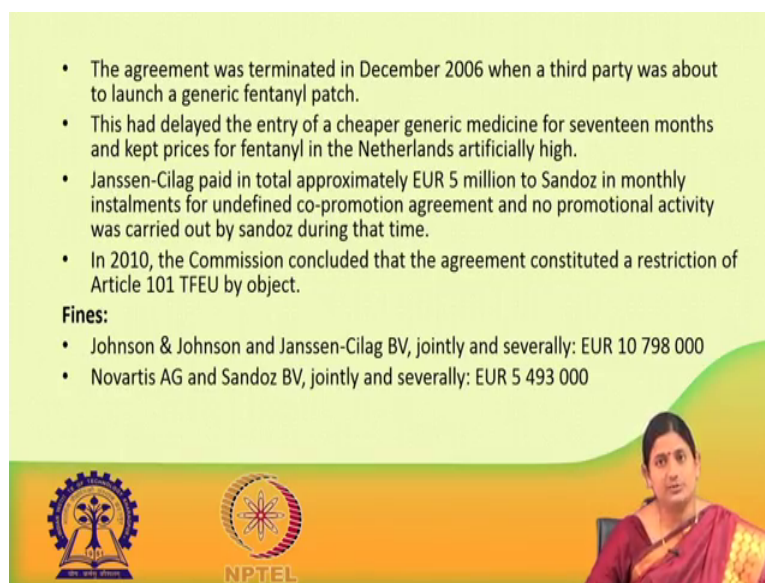
- **Janssen-Cilag**, the J&J subsidiary supplying the pain-killer fentanyl in the Netherlands, concluded a so-called "**co-promotion agreement**" with its close generic competitor **Sandoz**, a Novartis subsidiary, in July 2005.
- At the time there were no regulatory barriers to develop and market generic versions of the **fentanyl patches** and therefore for Sandoz to enter the Dutch market.
- The agreement foresaw monthly payments from Janssen-Cilag to Sandoz for as long as no generic product was launched in the Dutch market.
- Consequently, Sandoz abstained from entering the market with generic fentanyl patches for the duration of the agreement from July 2005 until December 2006.



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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- The agreement was terminated in December 2006 when a third party was about to launch a generic fentanyl patch.
- This had delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high.
- Janssen-Cilag paid in total approximately EUR 5 million to Sandoz in monthly instalments for undefined co-promotion agreement and no promotional activity was carried out by Sandoz during that time.
- In 2010, the Commission concluded that the agreement constituted a restriction of Article 101 TFEU by object.

Fines:

- Johnson & Johnson and Janssen-Cilag BV, jointly and severally: EUR 10 798 000
- Novartis AG and Sandoz BV, jointly and severally: EUR 5 493 000

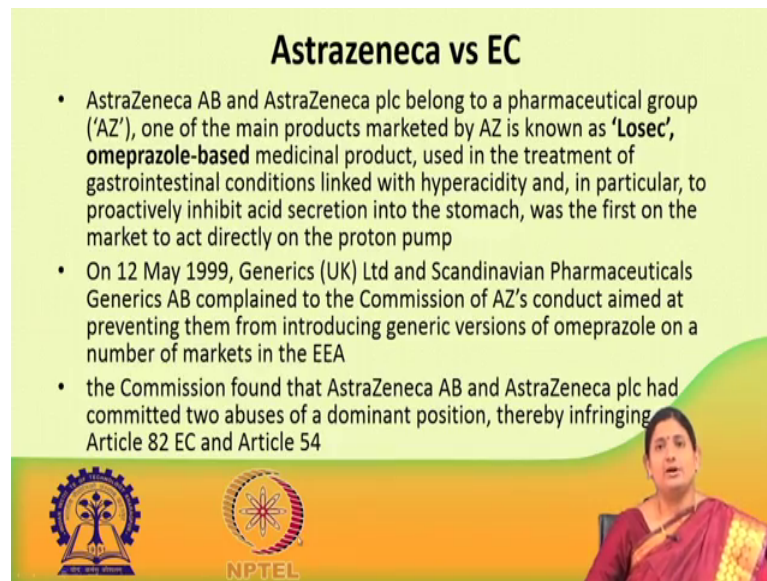


Consequently, Sandoz abstained from entering into the market with generic fentanyl patches. The duration of the agreement was from June 2005 to July 2006. In December 2006, another third party was about to launch generic fentanyl. Sandoz raised objections and thence it came into the eyes of the European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

- AstraZeneca AB and AstraZeneca plc belong to a pharmaceutical group ('AZ'), one of the main products marketed by AZ is known as '**Losec**', **omeprazole-based** medicinal product, used in the treatment of gastrointestinal conditions linked with hyperacidity and, in particular, to proactively inhibit acid secretion into the stomach, was the first on the market to act directly on the proton pump
- On 12 May 1999, Generics (UK) Ltd and Scandinavian Pharmaceuticals Generics AB complained to the Commission of AZ's conduct aimed at preventing them from introducing generic versions of omeprazole on a number of markets in the EEA
- the Commission found that AstraZeneca AB and AstraZeneca plc had committed two abuses of a dominant position, thereby infringing Article 82 EC and Article 54

The slide also features the logos of the Indian Institute of Technology (IIT) Bombay and NPTEL (National Programme on Technology Enhanced Learning) at the bottom left, and a small inset image of a woman in a red sari on the right side.

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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- The Commission distinguished two stages in first abuse,
 - the first of which concerned representations made when, on 7 June 1993, instructions were sent to the patent agents through whom SPC applications were filed in seven Member States, and
 - the second of which referred to representations subsequently made to several patent offices and before national courts.
- the second abuse consisted in the submission of requests for deregistration of the MAs for Losec capsules in Denmark, Sweden and Norway, combined with the withdrawal of Losec capsules from the market and the launch of Losec MUPS tablets ('Multiple Unit Pellet System'; a system of tablets with multiple microgranules) in those three countries.



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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- In the Commission's submission, those steps were taken in order to ensure that the abridged registration route would not be available to producers of generic omeprazole and they also had the consequence that parallel importers were likely to lose their parallel import licences.
- It took issue, in particular, with the appellants' strategic implementation of the regulatory framework in order to artificially protect from competition products that were no longer protected by a patent and for which the period of data exclusivity had expired.
- In respect of those two abuses, the Commission imposed on the appellants jointly and severally a fine of EUR 46 million and on AstraZeneca AB a separate fine of EUR 14 million.

The slide features a light green background with a yellow and green gradient at the bottom. On the left, there is a logo of a gear with a tree inside, and in the center, the NPTEL logo. On the right, a woman wearing a red sari with gold borders is visible, appearing to be speaking or presenting.

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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Technology pools and restrains

- TTBER applies to licence agreements concluded between the pool and third party licensees.
- In making its assessment the Commission will be guided by the following main principles:
 - 1. The stronger the market position of the pool the greater the risk of anti-competitive effects.
 - 2. Pools that hold a strong position on the market should be open and non-discriminatory.
 - 3. Pools should not unduly foreclose third party technologies or limit the creation of alternative pools.



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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Patent Pools


- Patent pools can give companies cheaper and easier access to necessary intellectual property rights, such as standard essential patents, by establishing a one-stop-shop.
- Recognising the often pro-competitive nature of patent pools, the creation of and licensing from patent pools now benefits from a safe harbour in the Guidelines.



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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- The Commission lists a number of factors which will be considered when assessing whether a patent pool can generally benefit from the safe harbour:
 - participation is open;
 - safeguards are in place to ensure only essential technologies are pooled;
 - pooled technologies are licensed into the pool on a non-exclusive basis;
 - pooled technology is licenced out of the pool on FRAND terms;
 - the parties contributing technology to the pool and the licensees are free to challenge the validity and the essentiality of the pooled technology;
 - the parties contributing technology to the pool and the licensees are free to develop competing technology; and
 - there are safeguards against the exchange of sensitive information.



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.