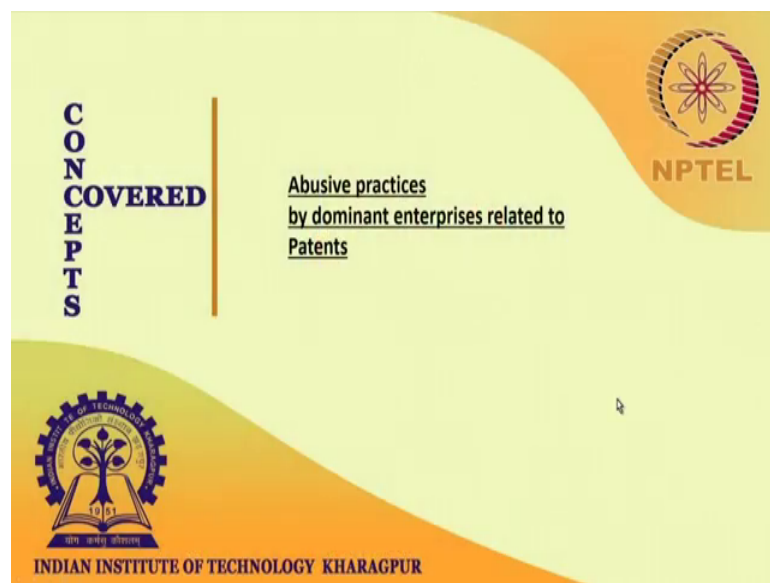


**Intellectual Property Rights, And Competition Law**  
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**Rajiv Gandhi School of Intellectual Property Law**  
**Indian Institute of Technology, Kharagpur**

**Lecture – 39**  
**Patent and Competition Law**

Hello all. Welcome to this session on Patent and Competition Law.

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So far we have studied various provisions mentioned in the European Union as well as in India regarding the competition aspect. And we have seen Article 101, 102 which specifically talks about various anti-competitive practices and the abuse of dominant position and the conditions under which the practices or the methods adopted by the firms may be regarded as anti-competitive in nature.

Similarly, in India we also dealt with various provisions for abuse of dominance and also anti-competitive agreements and we read about the exceptions provided in the Indian Competition Act relating to the IP rights conferred and the restrictions placed in the dealings of IP provisions which cannot be considered as competitive per se. But it does not mean that any restriction placed by a patent holder or IP holder would be immune from the provisions of the competition law.

So, we have in detail dealt with all these discussions. But in today's module we would focus in a summarised manner on how the behaviour of an enterprise or a firm particularly a patent owner can lead to monopolistic behaviour or anti-competitive behaviour. So, basically we would in this session cover the abusive practices by the dominant enterprises relating to patents.

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**Practices by Patent Holders Amounting to Abuse of Market Power**

- Refusal to license,
- Unfair or discriminatory licensing,
- Anticompetitive use of SEPs;
- Abuse of dominance via
  - Delaying market entry of competitors via misuse of patent/regulatory process (supplementary protection certificates(SPCs)),
  - Excessive pricing,
  - Concluding anticompetitive agreements(patent settlement agreements (PSAs)).

The slide features two logos at the bottom: the Indian Institute of Technology (IIT) logo on the left and the NPTEL logo on the right.

So, among the various important forms of intellectual property rights such as patents, trademarks and copyright patent is one of the most studied form of intellectual property right. So, there are many ways by which a patent owner can misuse his power conferred by a patent right. So, among these processes are the refusal to license, unfair or discriminate discriminatory licensing practices;

Then anti-competitive use of the standard essential patents which may lead to abuse of dominant position via delaying the market entry of competitor's product where the patent owner is trying to misuse the regulatory processes through various supplementary protection certificates or the patent extending mechanism available in specific countries.

Or by placing excessive price for the product, for the technology licensed and by entering into the anti-competitive agreements with other competitor such as the generic manufacture or other downstream processing companies.

So, there are many ways by which anti-competitive behaviour may arise during the transaction of a patent or a technology. So, in general we have seen from the earlier cases that when somebody refuses to transfer a technology particularly a patent it may act as a hindrance in the development of a new product in the downstream market. And if in some cases it acts as an essential facility, then the practices or the restrictions placed by the IP owner may be regarded as anti-competitive in nature.

So, in all these processes through which patent owner can abuse its position generally the anti-competitive behaviour arises when the patent owner is in dominant position. Now, we have seen what may constitute a dominant position for a particular firm i.e. the amount of market share it is holding, the substitutability of the technology it is having. So, there are various factors that are used to determine the dominant position of a firm. So, when the firm is in a dominant position and the behaviour; listed in this slide; may lead to an anti-competitive effect.

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**Refusal to License and Seeking Injunctive Relief by SEPs**

- SSOs bring equilibrium in the compulsory licensing of SEP by implementing licensing of SEPs by owners on FRAND terms
- SEP infringement cases:
  - Samsung case
  - Motorola case

The slide features a green and yellow background with a woman's video feed in the bottom right corner. At the bottom, there are logos for the Indian Institute of Technology (IIT) and NPTEL.

In general, in today's world, the development of standard essential patents which are basically the technology which are essential for the development of a new product and the technology itself acts as a standard in these cases and denying or refusal to license by the patent owner for the standard essential patents may lead to anti-competitive effect in the market.

What the standard setting organisations or the SSOs have done is that they have tried to maintain an equilibrium by issuing, by maintaining a provision of compulsory licensing of SEP by the patent owner on the basis of FRAND terms which we know as fair, reasonable and non-discriminatory terms.

In the earlier classes we have seen how these denial or refusal of the license to the standard essential patents by Samsung as well as by Motorola to Apple lead to anti-competitive behaviour. The European Commission determined that these kind of practices may be considered as anti-competitive behaviour and abuse of dominant position.

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- **Motorola case:**
- Motorola violated the EU competition law (Article 102 of the Treaty on Functioning of the EU (TFEU) which prohibits abuse of dominance) by seeking injunction in court against a willing licensee, Apple, on the basis of Motorola's SEP on 2G technology.
- The EC also found it anticompetitive that Motorola insisted Apple to give up its right to challenge the validity or infringement of Motorola's SEP.
- EC exercised its discretion (and exceptionally) did not impose a fine because of the divergent decisions of the EU Member States and the absence of the EU case law.

Particularly in the Motorola case, we have seen that Motorola violated Article 102 of the treaty of the Functioning of the European Union which tells about the abuse of dominant position by seeking injunction against a willing licensee i.e. Apple incorporation and the technology in question was the standard essential patent on 2G technology.

The European Commission found that it was an anti-competitive behaviour on the part of Motorola, and they insisted that Apple should not challenge the standard essential patent i.e. 2G technology if they entered into the licensing agreement. However, the European Commission did not impose a fine on Motorola because at that time there were no

particular case laws regarding the standard essential patents. So, European Commission exercised its discretionary power.

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- **Samsung Case:**
- EC accepted legally binding commitments offered by Samsung not to seek injunctions in relation to any of its present and future SEPs (e.g. Universal Mobile Telecommunications System (UMTS)) for mobile devices for a period of five years against any potential licensee that agrees to accept a particular licensing framework for the determination of FRAND terms.
- 12 months of negotiation period or
- Third party FRAND determination by a court or arbitrator

Similarly, in the Samsung case the European Commission accepted that the legally binding commitment offered by Samsung not to seek injunction in relation to any of its present or future SEPs particularly which were related to the UMTS technology for the mobile devices for a period of 5 years or more and against any potential licensee i.e. those who are willing to enter into a negotiation under the FRAND terms.

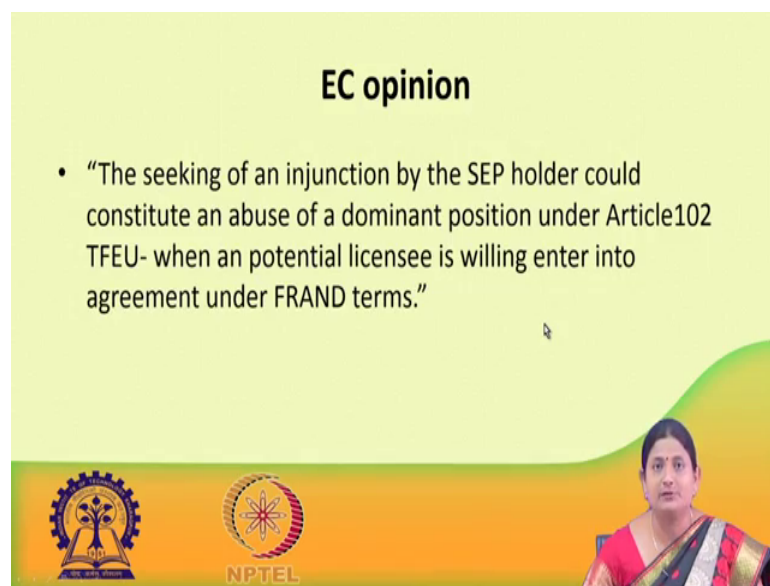
European Commission ordered that Samsung cannot deny to give the license to any of this potential licensee for a period of 5 years. And it was given a time period of 12 months for the negotiations with potential licensees and if some in cases where both the parties could not reach any settlement then there will be a third party determination of the FRAND terms by a court or by an arbitrator.

So, both of these cases show that refusal of license in case of the standard essential patent can be considered as anti-competitive behaviour. Because when a patent is given a status of the standard essential patent as per the standard setting organization say ETSI or any of such standard setting organization, all these holder of SEPs commit to a clause

where they cannot deny the licensing of patents on a fair, reasonable and non-discriminatory terms.

If they do so, they have to show the justification. Just by saying that you are infringing my rights by using the standard essential patents is not allowed per se and that is why he cannot ask for injunction.

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### EC opinion

- “The seeking of an injunction by the SEP holder could constitute an abuse of a dominant position under Article 102 TFEU- when a potential licensee is willing to enter into agreement under FRAND terms.”

IIT Bombay NPTEL

So, as per the European Commission seeking an injunction by the SEP holder would constitute an abuse of dominant position under Article 102 of the treaty of functioning of European Union when a potential licensee is willing to enter into the agreement under FRAND terms. So, if the licensee is not willing or not ready for negotiation then, obviously, as a patent right holder the SEP holder also has a right to ask for injunction. But when licensee is agreeing for some kind of negotiation under FRAND terms then in those cases asking for an injunction would be a violation of Article 102.

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- In 'Huawei Technologies Co. v ZTE', CJEU confirmed the same. The court stated:
  - "Article 102 TFEU must be interpreted as meaning that the proprietor of a SEP to a standard established by a standardisation body, which has given an irrevocable undertaking to that body to grant a licence to third parties on FRAND' terms, does not abuse its dominant position, within the meaning of that article, by bringing an action for infringement seeking an injunction prohibiting the infringement of its patent or seeking the recall of products for the manufacture of which that patent has been used, as long as:

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This decision of the European Commission was also affirmed in the Huawei technology case, Huawei versus ZTE, where the court stated that the Article 102 of TFEU must be interpreted as meaning that the proprietor of a SEP or a standard established by a standardisation body, has given an irrevocable undertaking to the body to grant license to third parties on FRAND terms, does not abuse the dominant position within the meaning of that article.

So, by bringing an action for infringement, seeking an injunction, prohibiting the infringement of its patent, seeking the recall of products in which that patent has been used as long as three conditions are also specified there

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**Conditions:**

- prior to bringing that action, the proprietor has,
  - first, alerted the alleged infringer of the infringement complained about by designating that patent and specifying the way in which it has been infringed, and,
  - secondly, after the alleged infringer has expressed its willingness to conclude a licensing agreement on FRAND terms, presented to that infringer a specific, written offer for a licence on such terms, specifying, in particular, the royalty and the way in which it is to be calculated,



Prior to bringing an action for infringement, the proprietor has to, first: should have alerted the alleged infringer of the infringement complained about, by designating the patents, such and such have been infringed and specify the way in which they have been infringed. So, the first condition laid by the European Union court was that before bringing an action of infringement the licensee must alert the alleged infringer about the nature of the infringement, which patent has been infringed and the manner in which the patent was infringed. So, the alleged infringer must be aware about his practices that he is infringing the patents of the licensee or the SEP holder.

Secondly, after the alleged infringer has expressed his willingness to conclude a licensing agreement under the FRAND terms, which has been presented in a specific written offer or the conditions are suitable to both of them, which are calculated.

So, suppose the alleged infringer is willing to enter into a license, so only verbal willingness will not help. There must be certain written agreement between the two parties, under what terms and conditions both the parties will enter into the agreement and license the technology in question.



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**Contd.**

– where the alleged infringer continues to use the patent in question, the alleged infringer has not diligently responded to that offer, in accordance with recognised commercial practices in the field and in good faith, this being a matter which must be established on the basis of objective factors and which implies, in particular, that there are no delaying tactics.



And third condition is, when the alleged infringer continues to use the patent in question, the alleged infringer has not diligently responded to that offer, in accordance with the recognised commercial practices in the field, in good faith, this must be established on the basis of objective factors which implies that there are no delaying tactics.

So, once the potential licensor has been made aware of the terms and conditions of the FRAND terms and also knows the fact that he is infringing the SEP holder's patent in those cases if the potential licensee deliberately try to delay the licensing negotiation or deliberately does not respond to the offer made by the licensor, In those circumstances asking for injunction will not be abuse of dominant position.

So, the three conditions, first: the potential or the alleged infringer should be made aware of the infringing behaviour, conduct. And second: the licensor should have communicated the terms and conditions to the potential licensee. In the condition, where the potential licensee is not responding to the licensor's condition deliberately and is playing delayed tactics, in all those circumstances asking for injunction would not be a violation of the Article 103.

These three cases were landmark in terms of dealing of the SEPs as well as licensing and abuse of dominant position. In our last discussion, in the Indian Competition Law, we

have seen in the Micromax and Ericsson case, how Ericsson refused to share the details of the patents which were allegedly infringed by Micromax and asked for NDA, non-disclosure agreement before revealing any terms and conditions for the FRAND terms or before revealing the details of the patents which were said to be infringed by Micromax. So, all these behaviour are also dealt as anti-competitive behaviour by the Indian Competition Commission.

So, we may see that both, European Union as well as the Indian Competition Commission, foresee that these kind of behaviour by the dominant players in the SEP areas, or abuse of dominant position will be considered as anti-competitive behaviour.

SEPs are hot topic these days. Non-SEPs, particularly patents, for example, the unlocking pattern of the smart phones in the mobile phones, to swipe the screen so that it unlocks. So, this is not a kind of standard essential patents, but it is covered under certain patent, but not standard essential patents.

So, the standard essential patents are related to various audio visuals and wireless technologies, mobile GPRS technologies, 3G, 4G, 5G technologies, which have become essential and all the companies, all the firms need to only follow those patents to produce their product. So, these are very much essential for the companies operating in the downstream market to take the SEP, so that they can give rise to a new product. So, that becomes an essential facility per se.

So, denying any kind of right for those essential patents may lead to abuse of dominant position as well as anti-competitive practices.

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**Misuse of Regulatory Procedures**

- IP holders abusing their right to the SPCs and abusing the regulatory procedures in relation to it.

Example:

- **AstraZeneca-Losec case:**
- AstraZeneca was found guilty of delaying the market entry of competing generic products by:
  - (a) deliberately making misleading representations before the patent offices and/or courts and inducing them to grant extended patent protection for Losec in the form of SPCs to which the product was not entitled; and
  - (b) preventing parallel imports by deregistration of Losec's marketing authorisations.

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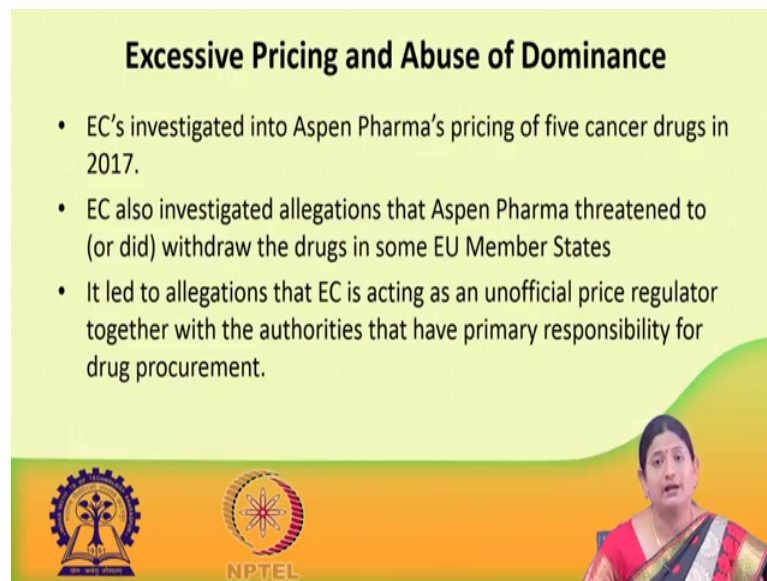
Then the second and most prominent way by which patent holders try to misuse the power, which they have by virtue of patent right, is by the misuse of regulatory procedures. This happens in case of pharmaceutical sector because as you know a drug development process takes a long time and it has to be approved by the corresponding medical authority to give license for the product to come to the market.

So, the licensing procedure takes place after nearly 5 to 7 years and the patent right is for 20 years so when the product manufacturer gets the license to market its product nearly half of the time period of the patent right has expired. So, in those cases, there are certain mechanism by which the patent owner can extend its right. So, one of the mechanism is SPC, Supplementary Protection Certificate for which extra 5 or 7 years time period is given to the innovator firm apart from the normal grant of 20 years.

Some cases, the pharmaceutical companies misuse this regulatory procedure and try to retain their market dominance power for additional period, even though they are not truly in a position to deserve that thing. One of the example which we have also discussed earlier is the AstraZeneca case or the Losec case, where AstraZeneca was found guilty of delaying the market entry of the competing generic products.

It has deliberately made misrepresentations to the patent offices as well as the regulatory authorities and induced them to grant SPCs, supplementary patent protection for the drug Losec. But the data was not valid and it was a misleading representation. So they tried to persuade them to grant SPC. Secondly, they also prevented the parallel imports by de-registration of Losec marketing authorization in many of the member states.

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**Excessive Pricing and Abuse of Dominance**

- EC's investigated into Aspen Pharma's pricing of five cancer drugs in 2017.
- EC also investigated allegations that Aspen Pharma threatened to (or did) withdraw the drugs in some EU Member States
- It led to allegations that EC is acting as an unofficial price regulator together with the authorities that have primary responsibility for drug procurement.

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These two behaviours were regarded as anti-competitive practices. The European Commission fined AstraZeneca heavily for these practices. And the third process by which the companies or the dominant firm try to abuse the dominant position is by excessive pricing. As you know patent owner has a definite new technology which has a good market potential.

One way by which they want to leverage their patent right is by pricing, excessively pricing that article. This is very much prevalent in the pharmaceutical industries, for example, European Commission's investigation into Aspen Pharmaceutical. There was a case against the Aspen Pharma, where it was alleged that Aspen Pharma has raised the price of five cancer drugs in 2017.

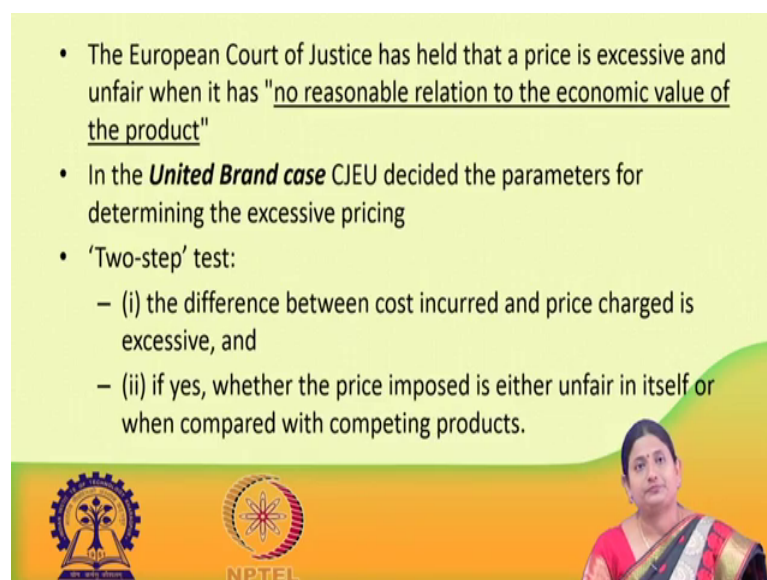
So, the European Commission also investigated one of the other allegation that Aspen Pharma threatened to withdraw cancer genetic drugs from some of EU member states. And in Italy, Aspen Pharma was heavily fined in 2017.

However, the European court of justice has not taken into consideration the Italian decision. They investigated the matter independently. It was alleged that the European Commission is unofficially acting as a price regulator together with other authorities which are the primary responsibility for drug procurement.

Sometimes investigating such cases where pricing is involved is not easy, because European Commission is the only authority to investigate anti-competitive behaviour of firms in the European economic area. So, when European Commission gives judgment or decision about pricing, how the pricing is high, how much percentage hike is there and how a company should try to regulate the pricing.

Then, it was alleged by the pharmaceutical companies that European Commission is over-riding it's boundary and it is acting as a price regulator. So this is one of the criticism which the European Commission gained during this time.

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- The European Court of Justice has held that a price is excessive and unfair when it has "no reasonable relation to the economic value of the product"
- In the **United Brand case** CJEU decided the parameters for determining the excessive pricing
- 'Two-step' test:
  - (i) the difference between cost incurred and price charged is excessive, and
  - (ii) if yes, whether the price imposed is either unfair in itself or when compared with competing products.

While deciding these cases European court of justice held that the price can be termed as excessive and unfair when it has no reasonable relation to the economic value of the

product. So when a company is having a monopoly, having a patent on a standard essential patent for a particular thing then it may charge little bit higher price. Most of the consumers are willing to pay a bit more price for branded item or when a patent is involved the price is generally higher than the other products. But when will it be termed as excessive, the definition of excessive is quite difficult to determine. So, in this case, the European court of justice held that the price is excessive and unfair when there is no reasonable relation to the economic value of the product.

In one of the earlier United Brand cases during the 1970s the court has come up with a procedure to determine the excessive pricing. The court gave a two-pronged test or the two steps test, where the first step that should be taken into consideration was to calculate the difference of cost incurred and the excessive price charged, how much price, amount is required to produce that product and how much the company is charging for that product.


And second, whether the price imposed is unfair in itself, when compared to the other similar products is the price very high, in those circumstances price is considered to be unfair. So, in the first step it is to be determined whether a price is excessive or not. The court said that one must calculate how much price is required or how much amount was incurred during the development of the product and how much the company is charging.

So, if the price comes to be excessive in the normal sense, the price will be considered unfair in itself compared to other available products in the similar technology or other competing products.

So, in 1978 this was the decision given in the United Brand case.

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- **Comparator tests:**
- In AKKA/LAA, the Court held that other methods can be applied than the price-cost test specified in United Brands for determining whether a price is excessive.
- Building on previous cases dealing with copyright management organizations, the Court confirmed the methodology of a comparison of the prices charged by the dominant undertaking with prices charged for similar products or services in one or several other Member States.
- comparison that is being carried out should be based on comparators "selected in accordance with objective, appropriate and verifiable criteria" and that the comparison is "made on a consistent basis"

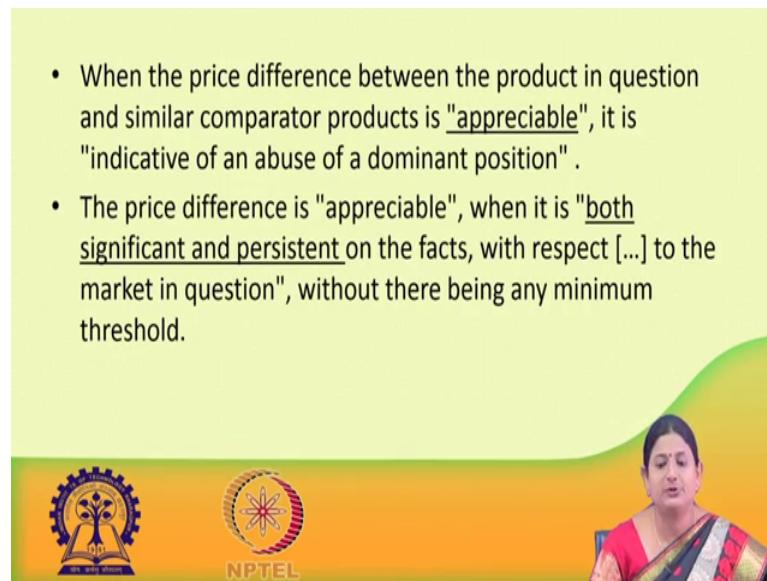


However, during the recent AKKA and LAA case in Germany, court held that apart from this two-pronged test there are other test available by which excessive pricing can be determined, on the basis of the comparisons with other existing product which is known as the comparator test.

Particularly in this case, building on the previous cases on copyright management organization, the court confirmed that the methodology of comparison of price charged by the dominant undertaking with the price charged for similar product or service in several members. The court tried to compare how much the dominant firm is charging in the questioned case and how similar companies with similar kind of rights are charging in other member states.

While this kind of comparison is made between different member state, the comparators must be *selected in accordance with the objective, appropriate and verifiable criteria*. And the comparison should be made on a consistent basis. So, you cannot compare an apple with an orange, but we need to know the nature of the product which is in question, the nature of the market. So, while making such comparison it is very much essential to determine the criteria of comparison.

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- When the price difference between the product in question and similar comparator products is "appreciable", it is "indicative of an abuse of a dominant position" .
- The price difference is "appreciable", when it is "both significant and persistent on the facts, with respect [...] to the market in question", without there being any minimum threshold.

The price difference between the product in question and the similar comparable product is appreciable then it will be indicative of abuse of dominant position. If some of the dominant player is charging very excessive price, very little price or had excessive price in certain member state while cheaper in other member state and the difference is appreciable i.e. it can be demarcated, this may indicate an abuse of the dominant position.

The price difference is appreciable when it is both significant and persistent on the facts with respect to the market in question. So, the nature of the comparable product, the condition in which the product is being sold or being used should be taken into comparison to determine whether the price difference is appreciable or not. So, if the price difference is appreciable then it is an indication of the abuse of the dominant position.



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- National competition authorities (NCAs) have adopted four infringement decisions related to unfair pricing in the pharmaceutical sector
  - 2001, UK NCA found that **Napp Pharmaceuticals (Napp)** abused its dominant position in the market for the supply of sustained release morphine tablets
  - 2016, the Italian NCA found that **Aspen** abused its dominant position in Italy by imposing unfair prices for four off-patent anti-cancer medicines (alkeran, leukeran, purinethol and tioguanine)
  - 2016, the UK NCA found that **Pfizer and the distributor Flynn** had each abused their respective dominant positions in the UK by charging unfair prices for phenytoin sodium capsules, an anti-epilepsy medicine manufactured by Pfizer
  - 2018, the Danish NCA found that **CD Pharma** abused its dominant position in Denmark by charging Amgros (a wholesale buyer for public hospitals) unfair prices for Syntocinon (which contains oxytocin) after a price increase of 2000%



European Commission as well as various national competition authorities have come up with four major cases related to unfair pricing in the pharmaceutical sectors. The first was in 2001 in United Kingdom where the national competition authority found that the NAPP pharmaceutical or NAPP abused its dominant position in the market for the supply of the sustained released formulation of morphine tablets. It was held that the high excessive price charged by NAPP was nearly 1500 percent rise in pricing. So, it was considered to be an abuse of the dominant position.

Similarly, later decisions were in 2016 and 2018. In 2016 Italian national competition authority found that the Aspen Pharma has abused its dominant position in Italy by imposing unfair prices for four of its off-patent generic anti-cancer medicines. In 2016, in United Kingdom, NCA found that Pfizer and its distributor company Flynn, had abused their dominant position by charging unfair prices for the phenytoin sodium capsules, an anti-epilepsy medicine manufactured by Pfizer.

Again in 2018, the Danish National Competition Authority found that the CD Pharma abused a dominant position in Denmark by charging Amgros, which is a wholesale buyer public hospital, unfair prices for syntocinon, an oxytocin based medicine used after childbirth for pregnant ladies. The price increase was nearly 2000 percent.

These cases are the recent development where abuse of dominant position is done via charging excessive pricing. These are just basics of how various methods can be adopted by various firms. In most of the cases these are dominant firms and may lead with abuse of monopoly or abuse of the dominant position.

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**Restricting Competitors' Entry  
to the Market or 'Paying off Competition**

- Patent settlement agreements-PSAs
- Originators in many instances enter into patent-related procedures/disputes/litigation in order to delay the entry of generics in the market→→→ PSA

Examples:

|   |                  |
|---|------------------|
| • Citalopram case- pay for delay        | Perindopril case |
| • Fentanyl case- co-promotion agreement | Modafinil case,  |



One of the prominent method by which dominant player tries to restrict competitor's entry into the market is by paying off the competition. It is known as patent settlement agreements. This is a normal tactics, that the patent holder will ask for injunction for the probable infringement or the said alleged infringement by the generic manufactures or they would try to enter into some kind of litigations, so that it will delay the entry of generic medicines into the market.

So, the other way is through the patent settlement agreements, they deliberately try to delay the entry of the generic manufacturers in the market. The prominent example which we have already discussed in the earlier classes is the citalopram case where the Lundbeck was fined heavily for delay tactics, it paid the generic companies to not to launch the product into market, delaying the production of the generic medicines in some of the member states of European Union for which it was heavily fined.

It procured generic medicines which had already been produced for the purpose of destruction. There was *fentanyl case* of the co-promotion agreement, where the companies tried to enter into settlement agreements, where none of them were producing generic drugs, generic medicines.

And for which they got heavy royalty, not to manufacture the generic medicines. The *perindopril case*, *the modafinil case*, these are the examples where payment was given to generic manufacturers to not to produce generic medicine. So, basically, the competition was hindered and the end consumer was not able to get cheaper medicines. All these were anti-competitive behaviour. Paying for delay tactics or the pay for delay tactics or patent settlement agreements are one of the ways by which competitors or the dominant players restrict the entry of competitors.

In this module so far we have discussed various ways by which dominant player or the SEP holder or a patent holder tries to harm the competition by delaying the market entry of the product or by stopping the development of new product or by raising the price high, by charging high prices for the product.

Please go through all these cases in detail by which you can get a complete overview of the processes and view point of various competition authority.

In the next module we will deal with trademark and copyright infringements and IP licensing related to trademarks and copyright and how they lead to anti-competitive behaviour. So, stay tuned for the next module.

Thank you.