

# European Competition Law: Recent Developments in the Pharma Sector

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# Agenda

## I. Enforcement Environment

## II. Late Life Cycle Management

A. Product Denigration

B. Agreements with Competitors

## III. Pricing

A. Excessive

B. Rebates/Discounts

# **I. Enforcement Environment**

# Enforcement Environment

- **Focus on 2 main areas:**
  - Late life cycle management. Strategies used by companies to address generic entry
  - Pricing. Rebates/discount schemes and excessive pricing by dominant companies
- **Less focus on parallel trade**
- **Much more enforcement at national level, particularly UK, Italy and France**

## **II. Late Life Cycle Management**

# A. Product Denigration

# Recent Cases on Product Denigration

## ***Sanofi-Aventis***

- Decision in May 2013 imposing a fine of €40.6 million
- Upheld by Paris Court of Appeal in December 2014

## ***Schering-Plough***

- Decision in December 2013 imposing a fine of €15.4 million

## Key Points for Competition Authorities

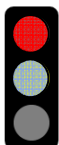
- Doctors are risk averse and sceptical about new drugs or generic versions of new drugs; they do not understand pharmacology or laws on generic marketing approvals and intellectual property
- Detailing visits are a key source of information for doctors
- Information should be “objective, complete and reliable”



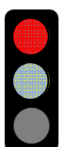
## Sanofi - Facts

- Plavix (clopidogrel) – blood thinner used to prevent blood clots and heart attacks
- Sanofi had patent on a salt that extended beyond basic patent, so generic had to use a different salt
- Sanofi had a patent on use in combination with aspirin to treat acute coronary syndrome (ACS)

## Sanofi - What Can You Say?



**Generic has different salt.**



**Generic has different salt and does not have indication for ACS.**



**Generic has different salt because we have a patent on our salt.**



**Generic has different salt, but the health authority has found that this difference does not affect the efficacy or safety profile of the generic.**

# Golden Rules

## Practical Guidance

- Statements should be objective, complete and reliable; they should not be incorrect or misleading.
- Do not suggest problem with safety or efficacy of generic without supporting evidence.
- If contradictory evidence exists (such as a finding of bioequivalence), this should be mentioned.

## **B. Agreements with Generics**

## Recent Cases - Agreements with Generics

Year	Companies	Investigated Practice	Country	Fines
On-going	Actavis / Concordia	Illegal market sharing agreement, where Concordia agreed to distribute Actavis's product instead of competing	UK	On-going
2016	GSK & Generics	Illegal patent settlement agreements	UK	£45 million
2014	Servier & Generics	Illegal patent settlement agreements and illegal acquisition of a competing technology	EU	€427.7 million
2013	Lundbeck & Generics	Illegal patent settlement agreements	EU	€146 million
2013	J&J / Sandoz	Illegal market sharing agreement, where Sandoz agreed to co-promote J&J's product instead of competing	EU	€16 million

## The Easy Cases

- Illegal market sharing agreements, where an originator and generic agree to cooperate instead of compete, and the originator's IP rights have expired
- Patent settlements exceeding the scope of the originator's patent (geographic or material scope, duration) - e.g., Generic may not sell any products that compete with Originator's product (not just the product that infringes the patent)
- Patent settlements where there is evidence that patent was obtained by fraud or is objectively baseless

## Agreement When IP Rights Have Expired: J&J / Novartis

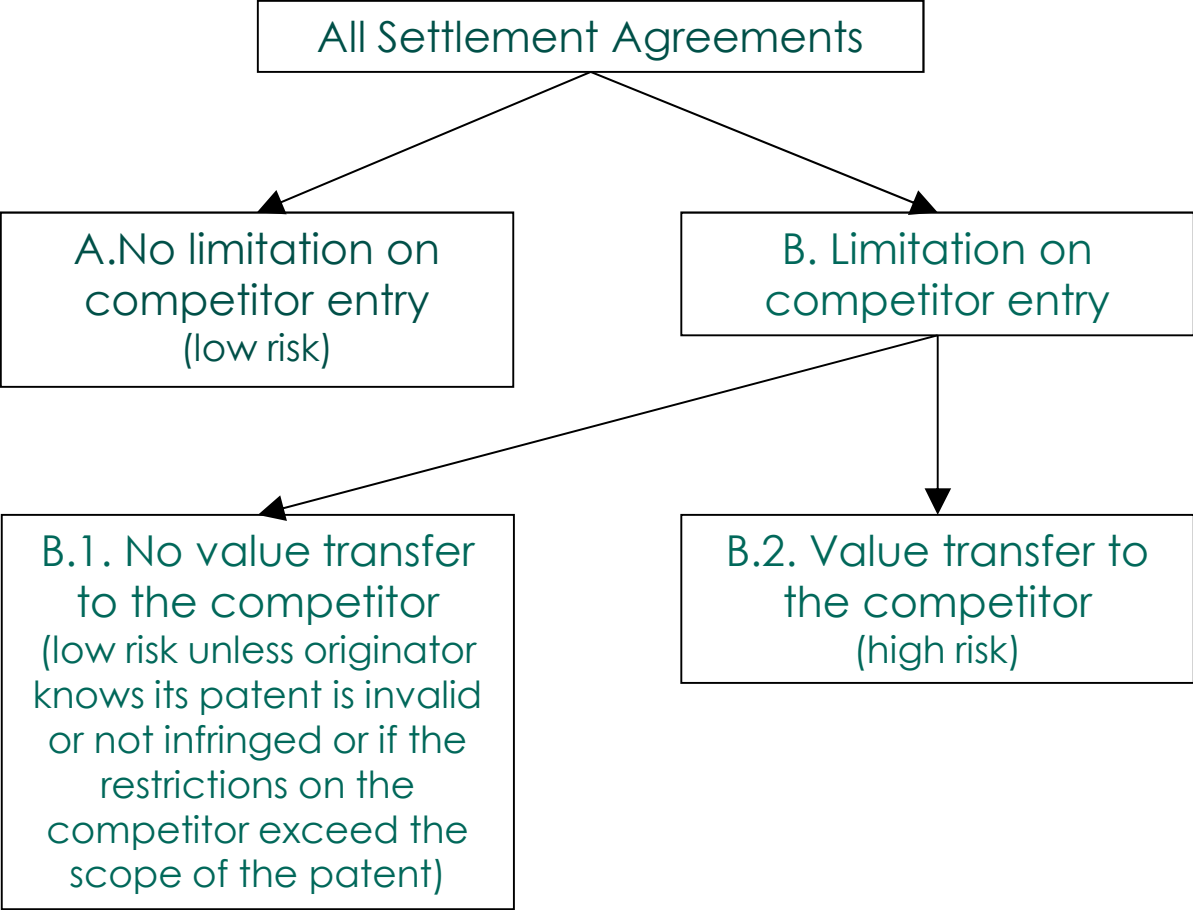
- J&J's pain-killer, fentanyl, went off patent in the Netherlands in 2005.
- Sandoz (Novartis sub) getting ready to launch a generic version.
- In July 2005, Dutch subs of the parties concluded co-promotion agreement where Sandoz would get paid a monthly fee in return for agreement not to launch generic.
- Agreement came to an end in December 2006 when a 3d party launched generic.

## Agreement When IP Rights Have Expired: J&J / Novartis

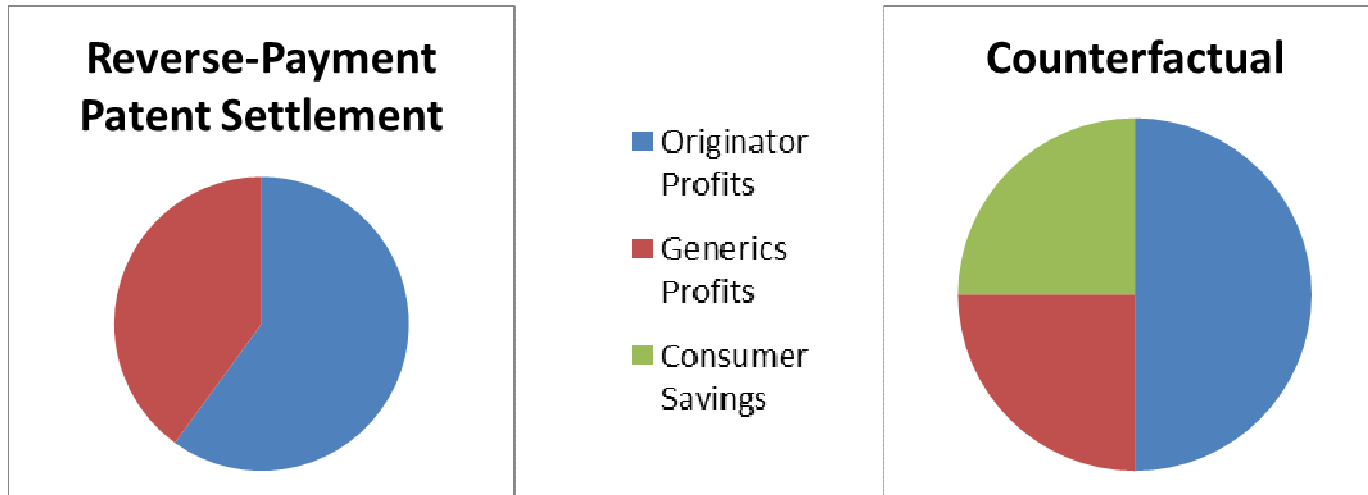
- EU Commission imposed fines: €10.7 million on J&J; €5.5 million on Novartis.
- Found that purpose of agreement was to delay launch of generic, causing prices to remain high.
- Bad emails in file: Sandoz agreed to deal in exchange for “part of the cake” and “to keep the current price high.”



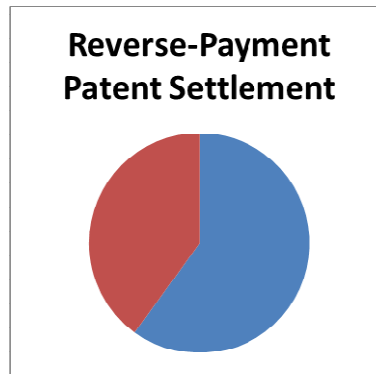
# Commission's Analytical Framework for Patent Settlements



# The Commission's Simplistic Analysis

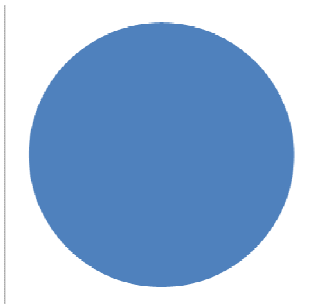


# Many Counterfactuals Are Possible

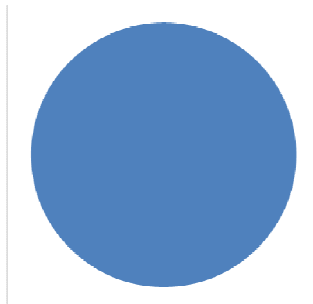


- Originator Profits
- Generics Profits
- Consumer Savings

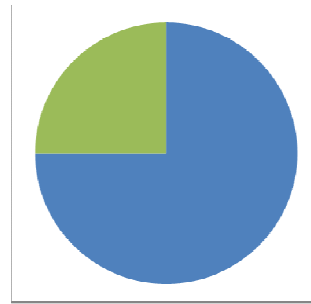
Originator Wins  
Injunction and  
on the Merits



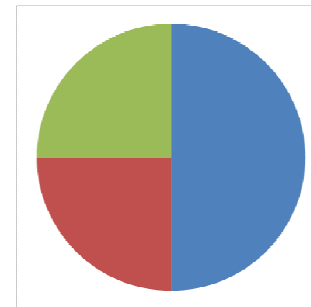
Generic Decides  
Not to Enter Due  
to Patent Risks



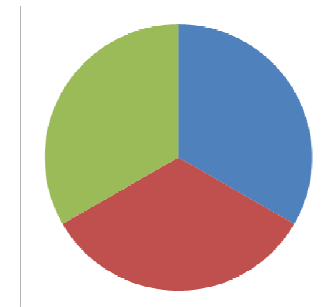
Generic Enters At  
Risk and Loses in  
Litigation



Split the Time  
Deal



Generic Enters  
and Wins  
Litigation



# Relevance of Reverse Payment

- Is the direction of the payment relevant?
- Commission: reverse payment is anti-competitive because it suggests that Originator must think that it is likely to lose in litigation, so it must make a payment to keep Generic off the market
- But direction of payment is a red herring – it is a function of the parties' relative bargaining positions and does not necessarily reflect the strength of the parties' claims.

# Relevance of Reverse Payment

- **Asymmetry of risk:**

Reverse payment by Originator to Generic simply reflects asymmetry of risk – even if Originator very likely to win, this asymmetry means that it may not want to take a chance of losing.



## Better Approach

- Assume that patent is valid and infringed unless compelling evidence that Originator would lose in patent litigation.
- Assumption that patent is valid is more consistent with patent system than an assumption that it is invalid.

# Patent Settlements - Summary

It may violate EU competition law if a patent holder pays a competitor to cease patent litigation and stay off of the market, even if the patent holder is not dominant

## High-Risk Activities:

Paying a competitor to stay off of the market (with cash or a favourable side deal), even in the context of a patent settlement

Entering into a settlement restricting entry by the competitor if Originator knows that its patent is not valid or not infringed

Entering into a settlement imposing restrictions on the competitor that go beyond the restrictions that Originator could impose by enforcing its patents

## Allowable/Low-Risk Activities:

Entering into a settlement with no restriction on the ability of the competitor to enter and compete on the market (even if there is a payment to the competitor)

Entering into a settlement restricting the competitor from entering, as long as there is no payment or value transfer to the competitor

## III. Pricing



# Recent Pricing Cases in the Pharmaceutical Sector

Year	Companies	Investigated Practice	Country	Fines
Ongoing	Aspen	Excessive price increases	EU	
Ongoing	MSD	Loyalty-inducing discount scheme	UK	
Ongoing	Actavis	Excessive price increases	UK	
2016	Flynn / Pfizer	Excessive price increases	UK	£89.4 million
2016	Aspen	Excessive price increases	Italy	€5.2 million
2015	Not Disclosed	Loyalty-inducing discount scheme	UK	None
2014	AstraZeneca	Hospital discounts	Netherlands	None
2013	Schering-Plough / Reckitt Benckiser	Fidelity rebates to pharmacies (and denigration)	France	€15.3 million

## **A. Excessive Pricing**

## Excessive Pricing: The Dilemma

- Excessive pricing is often seen as the quintessential evil of monopoly
- But recognition that high prices create incentives to innovate and invest and attract competition to the market. High prices also encourage companies to race to get their products to market first, which benefits patients.
- How do you distinguish between acceptably high prices and excessive prices?

## Legal Test for Excessive Pricing

- Article 102(a) provides that an abuse may consist of “*directly or indirectly imposing unfair purchase or selling prices ...*”
- In *United Brands* (1978), the Court of Justice said that charging a price which is excessive because “*it has no reasonable relation to the economic value of the product*” is abusive.
- Court of Justice set out a 2-pronged test:
  1. Whether the difference between the costs and the price is excessive; and
  2. Whether the price is either unfair
    - a) in itself or
    - b) when compared to the price of competing products.

# Problems with the Legal Test

- Is difference between price / costs excessive?
  - Difficult to determine costs
  - What is “excessive”?
- Is the price unfair “in itself”?
  - What is “in itself”?
- Is the price unfair when compared to competing products?
  - Comparisons difficult

# Difficulties with Applying Test in Pharma Sector

- Which costs? Most significant costs for drugs are the R&D costs. How do you allocate them over time and across countries?
  - Costs do not capture all the costs of the high failure rate in bringing a drug to market.
  - Higher prices may reflect superior efficacy and fewer side effects, which reduces long-term costs to national health budgets – need to look at health technology assessments.
  - National pricing and reimbursement regimes limit freedom of pharma companies in setting prices.

# Addressing Excessive Pricing in Pharma Sector: Policy Issues

- Competition authorities are generally reluctant to launch cases:
  - Application of legal test raises very difficult questions (e.g. what is the correct price)
  - Interference with pricing could chill innovation in a sector where innovation is key – high prices are the carrot that encourages companies to invest in R&D
  - Unnecessary in light of the strong buyer power exercised by national health authorities and other payors. Some Member States now considering joint buying arrangements.
  - Pricing of medicines a national issue for Member States

## Napp (UK)(2001)

- Napp sold sustained release morphine to hospitals at steep discounts and charged much higher prices to pharmacies, which the OFT found to be excessive.
- OFT found that the prices charged to pharmacies were above the level that would be charged in a competitive market.
- Exclusionary conduct in hospital sector linked to excessive pricing in pharmacy sector
- OFT looked at a range of comparators:
  - Prices were between 30 and 50% higher than competitors
  - List prices to pharmacies were, in some instances, more than 2000% higher than those in hospitals
  - Prices to pharmacies were 500% higher than those for export
  - Napp's gross market was over 80%, while it was less than 70% for Napp's most profitable competitor
  - CAT upheld the OFT's decision.



# Gilead

- On 22 December 2014, the European Commission declined to open an investigation into allegations of excessive prices for Gilead's hepatitis C drugs, despite pressure from members of the European Parliament.
- Commissioner Vestager responded to the Parliamentary Question (P-008636/2014) as follows:

*Pursuant to Article 168(7) TFEU, Member States are responsible for health and medical care, including the allocation of resources assigned to these areas. Each Member State may therefore take measures to regulate or influence the prices in these areas.*

*For this reason, price-setting by pharmaceutical manufacturers and healthcare systems in general takes place on a national level, allowing Member States to exercise their bargaining power. ...*

*Moreover ... the market for hepatitis C drugs is a rapidly moving therapeutic area, with several new classes of direct-acting antivirals now in advanced stages of development. This would seem to suggest that this is a dynamic market.*

# Gilead

- On 15 March 2015, Commissioner Vestager responded to a follow-up Parliamentary Question (000261/2015) as follows:

*Since the Commission's earlier response, as it can be ascertained from public sources, the factual situation surrounding this particular medicine has evolved further. For example, another novel medicine such as AbbVie's Viekira Pak has entered the market to compete with Sovaldi in addition to, for example, Janssen's Olysio. Furthermore, several Member States have concluded or are negotiating pricing and reimbursing agreements with respect to this group of novel Hepatitis C medicines.*

## Flynn Pharma / Pfizer

- In December 2016, the UK CMA fined Pfizer and Flynn Pharma a total of £89.4 million for charging excessive prices for an anti-epilepsy drug.
- According to the CMA, prior to 2012, Pfizer manufactured and marketed the drug under the brand name Epanutin.
- Pfizer then transferred the UK marketing rights to Flynn Pharma, which “genericised” the drug and started selling it in September 2012 at prices alleged to be 2,300% to 2,600% higher than Pfizer’s historical prices.
- The decision covered both Pfizer’s supply prices to Flynn Pharma and Flynn Pharma’s prices to the market.
- The CMA used a very narrow market definition to find dominance.

# Summary Guidance

- High risks arise from drastic price increases after drug is on market:
  - UK and Italian cases concern drastic price increases (250% or more)
  - Cases involved drugs that were already on the market – easier to bring case as a “fair” price (i.e. the price prior to the increase) has already been established – no need to compare with competing products
- Such risks would not appear to arise in the context of:
  - Initial price setting or pricing and reimbursement negotiations with the health authority
  - Moderate price increases

## **B. Discounts/Rebates**

## Warning – A Complicated Topic

- Low prices are good except when they are bad
- If a company is dominant, granting conditional rebates or discounts could potentially constitute an abuse triggering large fines
- Competition enforcers struggle to strike a balance between allowing companies to compete vigorously on price and preventing companies with market power from using conditional discounts or rebates to foreclose competitors from the market

## What's the Problem?

- **The Basic Principle**: A dominant company may not impose an obligation on a customer to purchase all or most of its requirements of a product from it because competitors are then foreclosed from the market.
- **“Conditional” Rebates**: Rebates can achieve the same effect as a straightforward exclusive purchase obligation by making the grant of the rebate conditional on the customer obtaining all or a portion of its requirements from the dominant company.
- **Dominance**: Only a problem if company is dominant – no problem for products where company is not dominant.

## No Clear Rules

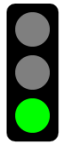
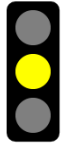
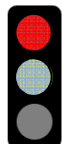
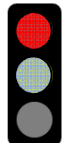
- The EU case law sets out formalistic rules that do not sit well with economic theory
  - The 2014 *Intel* judgment upheld the Commission's €1.06 billion fine for exclusivity rebates, relying on a form-based legal standard
  - The 2015 *Post Danmark II* judgment rejected the argument that an as-efficient competitor test is necessary to find that retroactive rebates violate EU competition law
- The Commission promotes an economic approach this is more coherent, but hard to apply in practice
- Can't ignore the case law because national courts and competition authorities may follow it and the Commission can fall back on it when it needs to



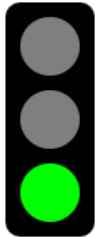
# European Commission

- In its Article 102 Guidance Paper, the European Commission sets out an analytical framework for the analysis of rebate/discount systems that is based on economic theory that can lead to results that are different from the rigid, formalistic rules developed in the case law
- The core concept is the “as-efficient-competitor” (AEC) test: if an equally-efficient competitor can compete effectively with the pricing conduct of the dominant company, the Commission says that it generally will infer that the dominant firm’s pricing is unlikely to have an adverse impact on effective competition and will be unlikely to intervene

# Types of Discounts and Level of Risk

	Type	Description	Level of Risk
	Unconditional Discount	Discounts applicable to all purchases, with no minimum volume thresholds	Low
	Volume Target (Incremental)	If the customer reaches a specified volume threshold, they receive a discount only on purchases above the threshold	Low-Medium
	Volume Target (Retroactive)	If the customer reaches a specified volume threshold, they receive a discount on all purchases (both below and above the threshold)	Very High
	Exclusivity	Discounts conditional upon the customer agreeing to purchase all or most of their requirements from the dominant supplier	Very High

# Unconditional Discounts



Discounts applicable to all purchases, with no minimum volume thresholds or conditions limiting purchase of competing products

- Unconditional discounts are generally unlikely to raise significant risks under EU competition law
- Low pricing is generally pro-competitive and necessary due to pressure from competitors or strong payors
- In theory, a pharmaceutical supplier could offer low prices in order to drive a competitor out of the market, and thereafter raise prices (referred to as predatory pricing), but
  - such a strategy seems unlikely in the pharmaceutical industry as payors will generally not allow any subsequent price increases; and
  - no cases by EU or national competition authorities successfully prosecuting predatory pricing in the pharmaceutical industry, absent an strategy by the pharmaceutical supplier to increase sales in another market

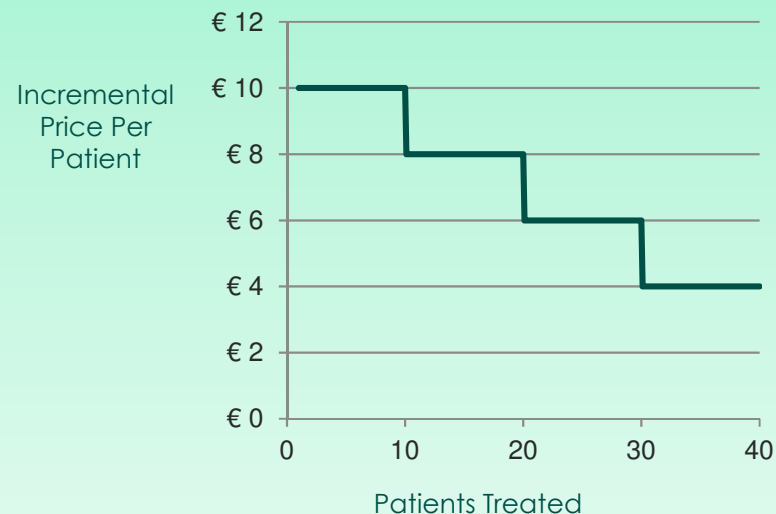
# Incremental Volume Discounts



The customer receives a discount if they reach a specified volume threshold, but the discount only applies to purchases above the threshold

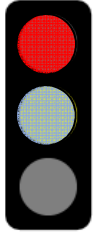
## Example:

Prices are €10 per patient, with the following incremental discounts: 20% above 10 patients, 40% above 20 patients, 60% above 30 patients



- Incremental discounts raise less risk than exclusivity or retroactive discounts, but are not without risk
- There are few cases on incremental discounts, so no clear legal standard established by the EU Courts
- The European Commission's guidance indicates that such discounts may be illegal if they unfairly exclude competitors
- In order to assess the level of risk, it is necessary to conduct a price-cost test

# Retroactive Volume Discounts



The customer receives a discount if it reaches a specified volume threshold, and the discount applies on all purchases (both below and above the threshold)

## Example:

Our prices are €10/per patient, but we will grant you a 10% discount on all patients if at least 10 patients are treated

Under this discount, if the customer treats

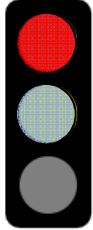
9 patients, the price is €90 ( $€10 * 9$  patients, with no discount)

10 patients, the price is still €90 ( $€10 * 10$  patients, with a 10% discount on all patients)

The effect of this discount is that the last treatment is free, which means that the customer would never purchase that treatment from a competitor

- Likely illegal under EU competition law if a supplier is dominant
- Discounts do not explicitly prevent a customer from buying from competitors, but the discounts may have the same effect
- Smaller competitors and new entrants may not be able to compete, even if their prices (on average) are lower than those of the dominant supplier
- While some retroactive discounts may not harm competition from other suppliers, they still raise high risks because the EU Courts consider them to be almost always illegal

# Exclusivity Discounts



Discounts granted on the condition that the customer purchases *all or most* of their requirements from the dominant supplier

## Examples:

We will grant you an extra discount if you purchase exclusively from us (and not from competitors) for a period of 1 year

You will receive an extra discount if you agree to purchase at least 75% of your needs from us

*Even if a customer is only required to purchase 75% from the Company, it could still constitute “all or most” of the customers requirements, and thus be treated as an exclusivity discount*

Almost always illegal under EU competition law if a supplier is dominant

Can make it difficult or impossible for smaller competitors or new entrants to compete in the market

It is not necessary for an authority to examine the effects of an exclusivity discount in order to find that it is illegal

Intel was fined €1.06 billion for imposing exclusivity discounts that limited the ability of AMD to compete

## Additional Issues

- Price-based foreclosure in the pharmaceutical sector is most likely in pricing and reimbursement negotiations with payors
  - In many countries, doctors are not price sensitive and/or do not know the net prices
  - Need to assess whether a proposed pricing strategy would unfairly cause a payor to limit access of a competitor to the market (e.g. refusing or limiting reimbursement)
- Commercial pricing strategies differ significantly in the pharmaceutical sector than in other industries
  - Payors have fixed annual budgets and yet limited scope to control the volumes of products used each year
  - Discounts are often necessary to address concerns regarding uncertain level of demand – raising a possible objective justification

# Example

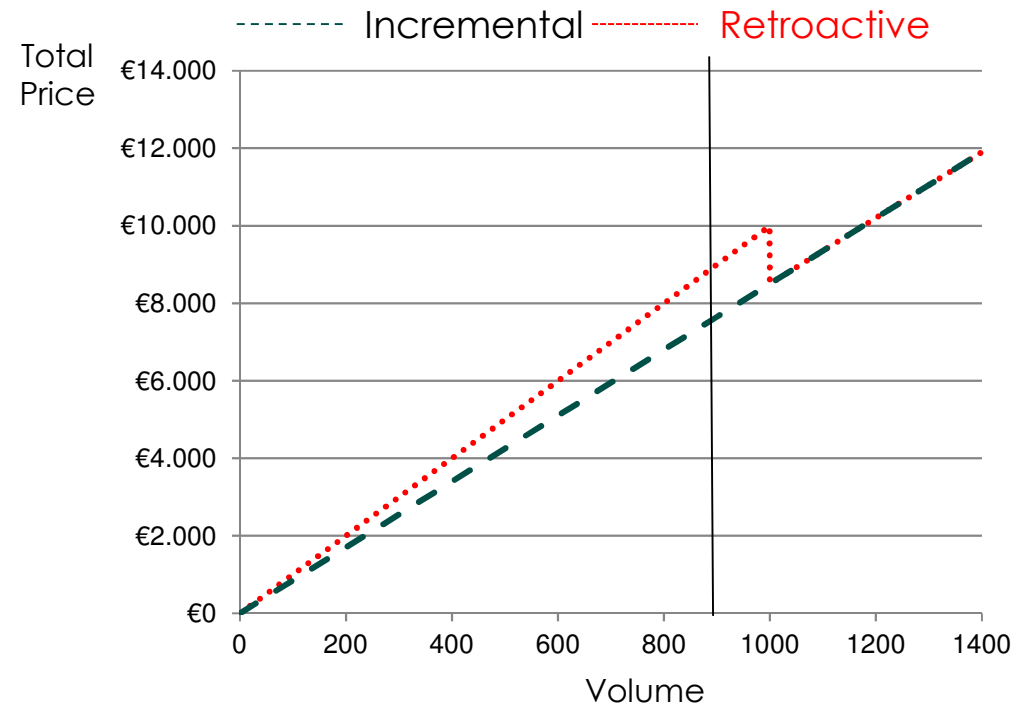
**Proposal:** We will supply Wonderdrug for 1000 patients at a discount of 15%

Critical Question:

Is the 15% discount retroactive?

Risk Assessment:

- If yes – higher risk
- If no – low risk





# Example

## Proposal:

Volume (units)	Discount
30,000	6%
75,000	7%
150,000	8%
300,000	9%
500,000	10%
750,000	11%
1,000,000	12%
1,500,000	14%
2,000,000	16%

## Critical Question:

Is the scheme retroactive or incremental?

## Risk Assessment:

- If retroactive – higher risk
- If incremental – need to apply price-cost test

## Example

**Proposal:** *We will give them a 15% discount if they increase their purchases from last year*

Critical Question:

Is the 15% discount retroactive or incremental?

Risk Assessment:

- If retroactive – higher risk
- If incremental – need to apply price/cost test

## Example

**Proposal:** The hospital has said that they will buy all of their requirements from us if we offer an extra 10% discount

Risk Assessment:

Very high risk – exclusivity discount

The fact that it is requested by the customer is not a valid defense

# Summary Guidance

- Exclusivity discounts will create very high risks – presumptively unlawful
- Retroactive discounts also create very high risks
  - Courts or national competition authorities may take a very formal approach, with no or little quantitative assessment
  - The Article 102 Guidance is only binding on the European Commission, not national authorities
- Incremental discounts
  - Lower risk than exclusivity or retroactive discounts
  - Necessary to apply cost-price test to evaluate risk of unfair harm to competitors
- Flat pricing without any volume requirements is generally low risk