

Abuse of Dominance in the Pharmaceuticals Sector:

Excessive Pricing, Rebates and Discounts

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VAN BAEL & BELLIS

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Overview

I. Overview

II. Excessive Pricing

III. Conditional Rebates & Discounts

Pricing Cases in the Pharmaceutical Sector

Year	Companies	Investigated Practice	Country	Fines
Ongoing	Aspen	Excessive price increases	EU	
ongoing	Actavis	Excessive price increases	UK	
2016	Flynn / Pfizer	Excessive price increases	UK	£84.2 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
2009	Wyeth / Phadisco	Bundling	Cyprus	€400,000
2007	GlaxoSmithKline	Predatory pricing (annulled)	France	€10 million
2003	Sandoz	Bundling	France	€7.8 million
2003	Genzyme	Bundling	UK	£6.8 million
2001	Napp	Hospital discounts and excessive community prices	UK	£3.2 million
2001	Abbott	Exclusivity discounts	France	£2 million

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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.

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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.

Aspen

- On 29 September 2016, the Italian competition authority imposed a €5.2 million fine on Aspen Pharma for abusing its dominant market position by charging excessive prices for certain cancer drugs – Aspen increased the prices from 250% to 1500%.
- Authority emphasized the following points in finding an abuse:
 - Aspen business model to buy drugs and exploit market niches by raising prices
 - Aspen is a generics company and not engaged in R&D – no investment by Aspen to improve quality of the drugs
 - Aspen had made efforts to increase the prices in Italy up to the levels in other EU countries, in order to limit the levels of parallel trade of the product out of Italy.
 - Aspen threatened to withdraw the marketing authorization of the product if the health authority did not agree to the price increases.

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

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Conditional Rebates & Discounts

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

Conditional Rebates & Discounts

No clear rules:

- The Commission promotes an economic approach this is more coherent, but hard to apply in practice
- 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
- 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

Intel

- In 2014, the General Court upheld the €1.06 billion fine on Intel for exclusivity rebates
- Court defined three categories of rebates:
 - 1) *Presumptively lawful* – incremental volume rebates that pass on cost savings to customers
 - 2) *Presumptively unlawful* – rebates conditional upon the customer purchasing all or most of its requirements from the supplier (“exclusivity” or “fidelity” rebates)
 - 3) *Case-by-case assessment* – all other rebates or discount schemes
- Intel’s rebates were held to fall into the second category, and thus were held to be presumptively unlawful

Post Danmark II

- Case concerned a retroactive rebate falling into the third *Intel* category, requiring a case-by-case assessment of all of the circumstances
- Court of Justice focused on the retroactive nature of the rebate
 - Without any assessment of the actual percentages or volumes at issue, the Court
 - highlighted the “suction effect” caused by retroactive rebates
 - concluded that the rebate at issue produces an anti-competitive exclusionary effect (para 42).
- Court’s approach condemns a retroactive rebate structure without any assessment of the actual percentages and volumes

Summary

Type of Discount or Rebate	European Commission	EU Courts
Exclusivity	Case-by-case (AEC test)	Presumptively Illegal
Retroactive	Case-by-case (AEC test)	Case-by-case (No need for AEC test)
Incremental	Case-by-case (AEC test)	Case-by-case (no specific guidance)
Quantity	Presumptively lawful	Presumptively lawful

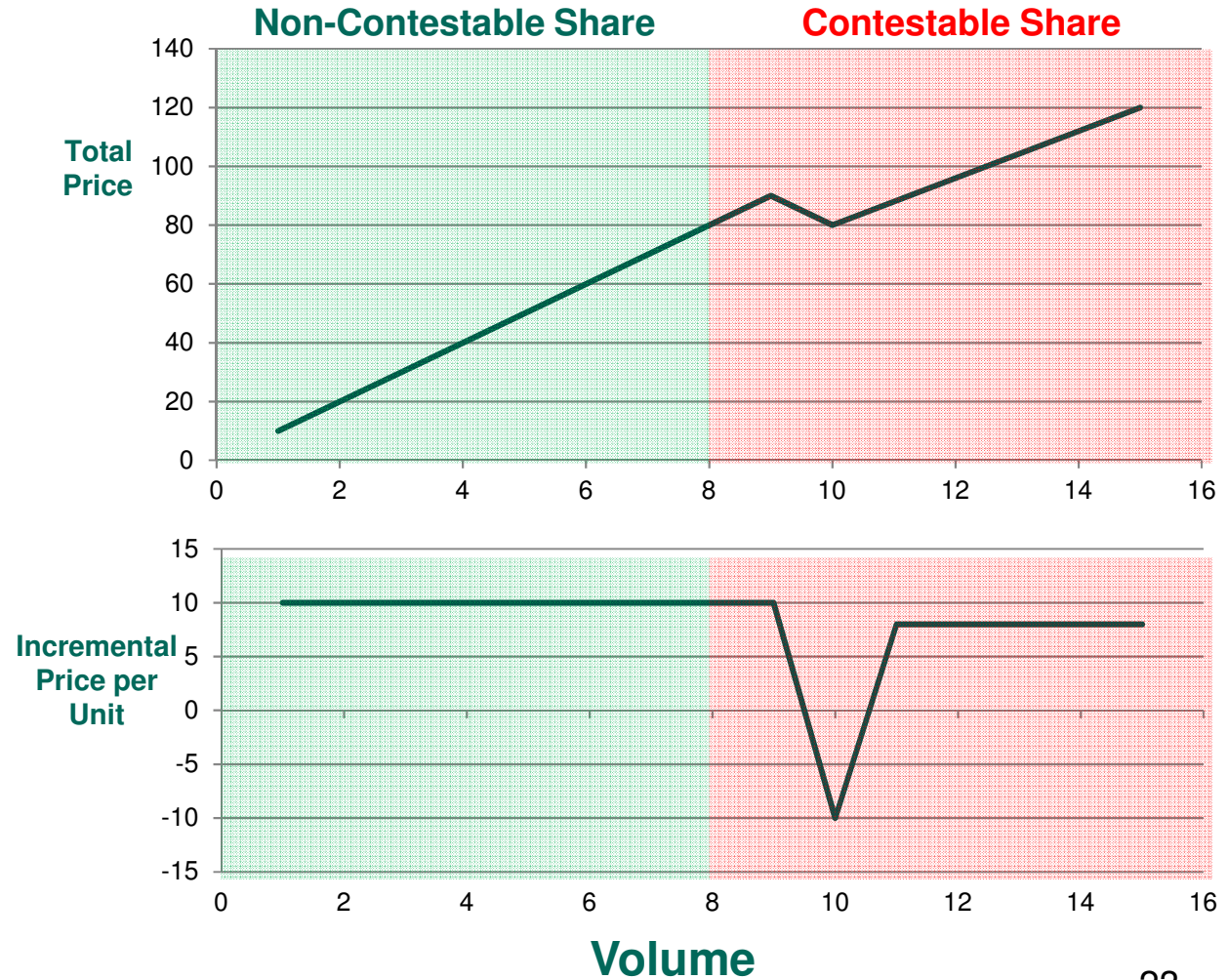
CMA Case Closure

- June 2015, the CMA issued guidance that rebates / discounts are more likely to give rise to competition concerns where the rebates or discounts:
 - are conditional on the customer obtaining all or most of its requirements from a dominant company,
 - are retroactive (i.e. only apply if the customer reaches a volume threshold, and trigger lower prices on units above and below the threshold), especially if the customer may wish to source some (but not all) of its demand from a competitor,
 - result in below-cost prices for contestable sales (i.e. the sales for which another supplier could compete), or
 - result in negative incremental pricing (i.e. if the customer purchases more from the dominant company, the total price paid by the customer goes down).

What is this “Suction Effect” from Retroactive Rebates?

List Price
1 unit = €10

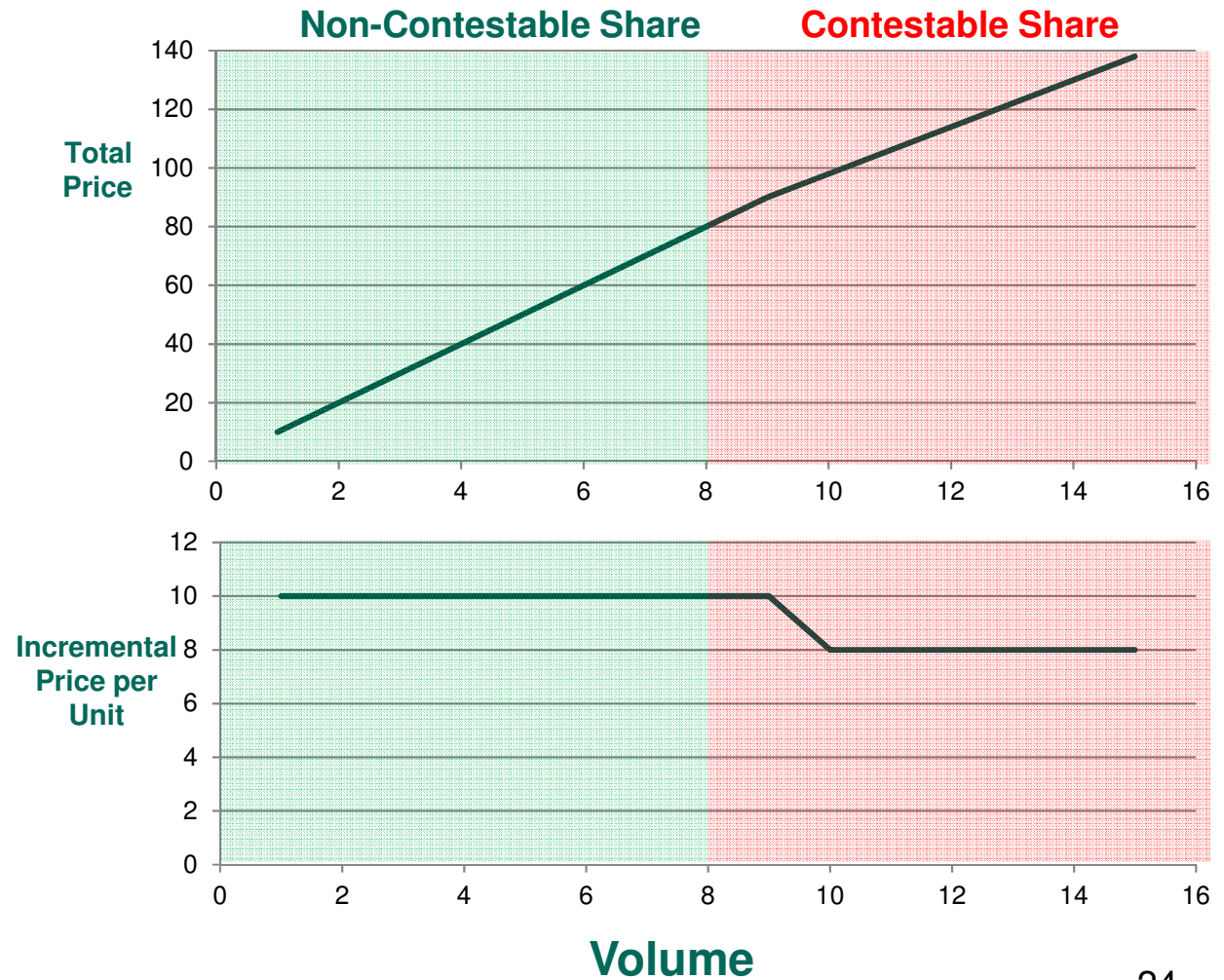
Volumes	Retroactive Rebate
0-9	0%
10-15	20%



Incremental Rebates Create Less Risk

List Price
1 unit = €10

Volumes	Incremental Rebate
0-9	0%
10-15	20%



Incremental Rebates

- While incremental rebates bear less risk than exclusivity or retroactive rebates, they are not without risk
 - Could foreclose competitors, particularly if the incremental discounts are very substantial
 - Commission's Article 102 Guidance:
 - Necessary to conduct an as-efficient competitor test
 - Incremental discounts should not result in anti-competitive foreclosure if the net price is above average cost (long run average incremental cost)
 - There are few cases on incremental rebates, so no clear legal standard established by the EU Courts
- Incremental rebates may also qualify as presumptively lawful quantity rebates, if the rebates simply pass cost savings onto the customer

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

Pop Quiz 1

Urgent request for legal approval:

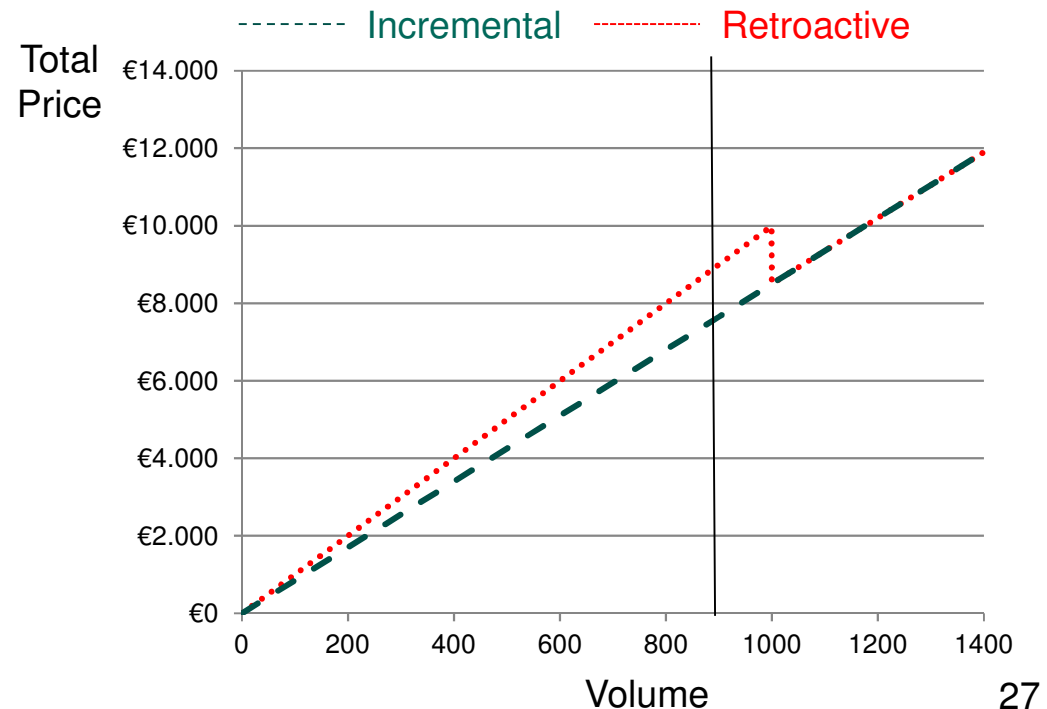
Proposal: We will supply Wonderdrug for 1000 patients at a discount of 15%

Critical Question:

- **Is the discount retroactive?**

Risk Assessment:

- **If retroactive – higher risk**
- **If not retroactive – flat pricing – low risk**



Pop Quiz 2

Urgent request for legal approval:

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 – this is the rebate applied in Post Danmark II***
- ***If incremental – need to apply as-efficient competitor test***

Pop Quiz 3

Urgent request for legal approval:

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 as-efficient competitor test*

Pop Quiz 4

Urgent request for legal approval:

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***

Pop Quiz 5

Urgent request for legal approval:

Proposal: We will give them an extra discount if they purchase more than 70% of their requirements from us

Critical Question:

- ***Is the extra discount retroactive or incremental?***

Risk Assessment:

- ***If retroactive***
 - ***higher risk***
 - ***May also qualify as an exclusivity rebate***
- ***If incremental – need to apply as-efficient competitor test***

Summary Guidance

- Exclusivity rebates or discounts will create very high risks – presumptively unlawful
- Retroactive rebates create high risks
 - *Post Danmark II* illustrates that courts or national competition authorities may take a very form based-approach, with no or little numerical assessment
 - The Article 102 Guidance is only binding on the European Commission, not national authorities
- Incremental rebates
 - Lower risk than exclusivity or retroactive rebates
 - Necessary to apply as-efficient competitor test to evaluate risk of anti-competitive foreclosure
- Flat pricing without any volume requirements is generally low risk