Market Definition and Competition Policy Enforcement in the Pharmaceutical Industry

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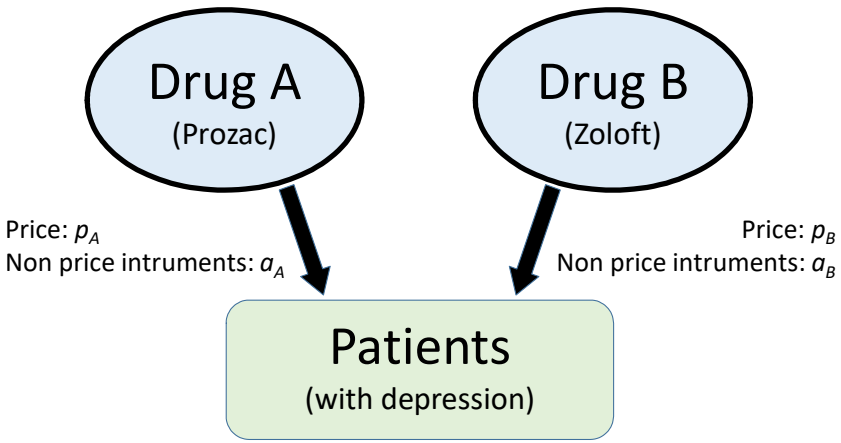
Question and Motivation

- Pharmaceutical industry: many attractive characteristics from an IO perspective
  - Oligopolistic competition



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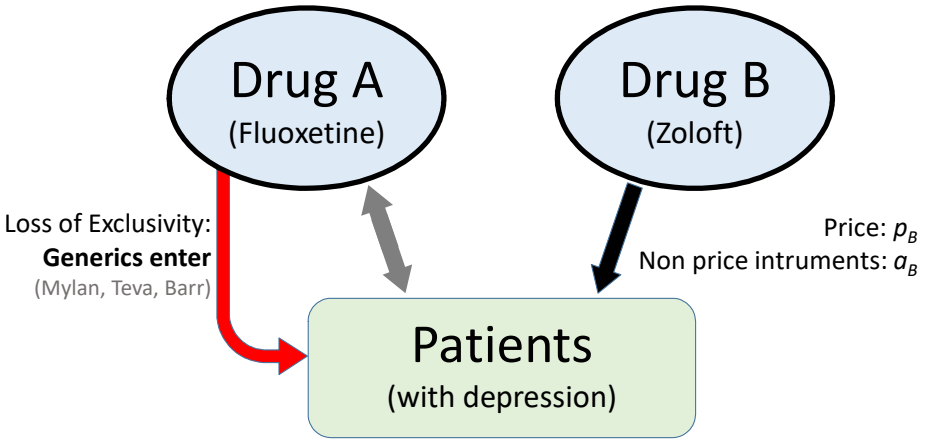
- Pharmaceutical industry: many attractive characteristics
  - Loss of patent protection: generic drugs compete with one molecule



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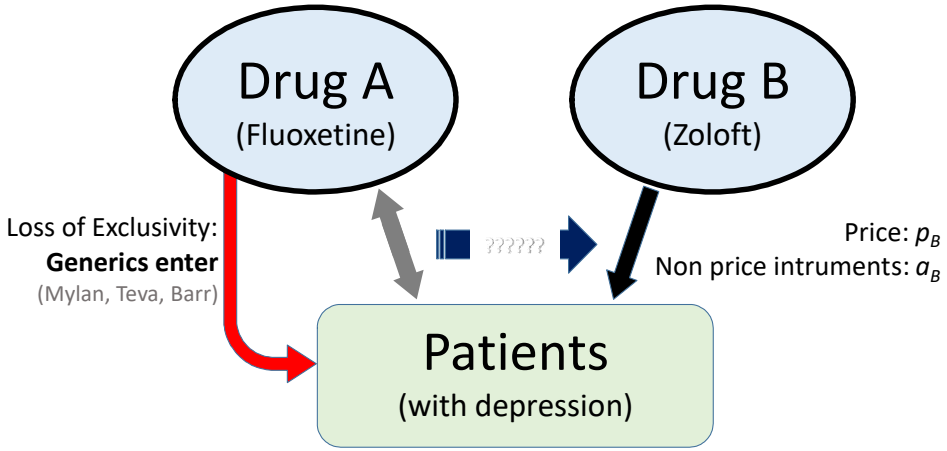
  - **OUR QUESTION**: are market boundaries affected by generic entry?



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- **Market boundaries: identify competitive constraints**
  In pharma, constraints are determined by the set of products considered by doctor for a given condition
  - Decision tree: health and cost considerations
    (with prescriptions: *a priori*, prices matters less)
- **Our analysis**: **Hypothetical Monopoly Test**
  - Identify constraints (elasticities) in each market situation
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  - *Inter*molecular competition more vibrant *before* generic entry
  - **Generic entry**: relevant market often becomes molecular

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- Identifying market boundaries central to the case assessment when it comes to mergers and monopolisation/abuse of dominance cases
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- These market shares:
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  - There are sound analytical foundations underpinning the importance assigned to market definition (1-to-1 in Cournot)
  - Legal certainty

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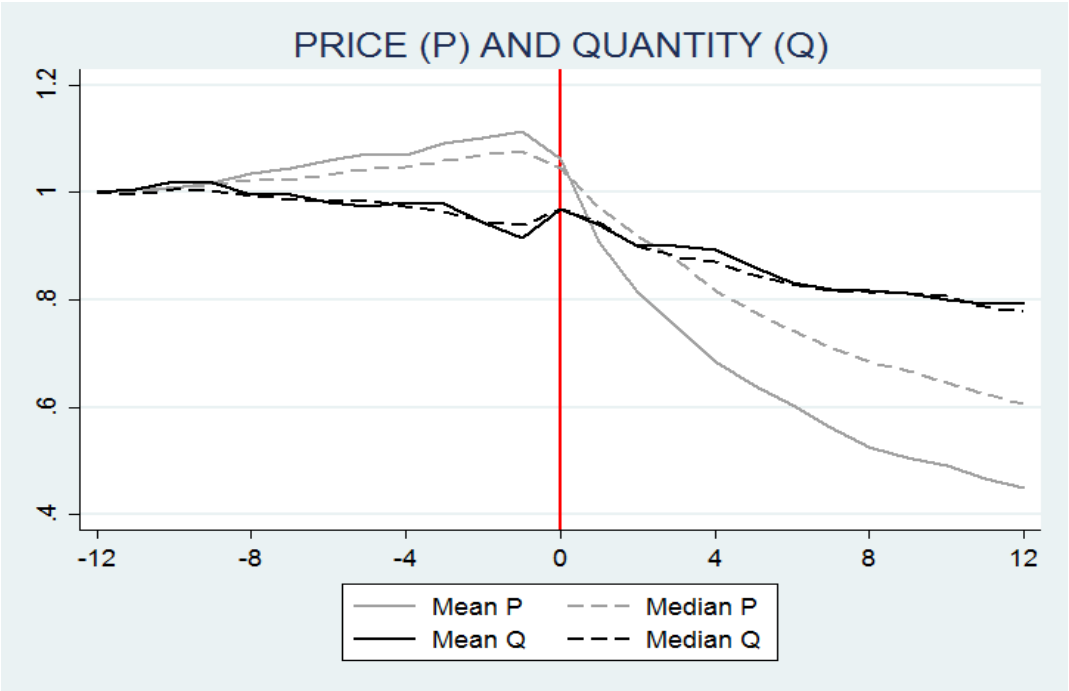
- **GSK/Paroxteine:**
  - Paroxetine is an anti-depressant
  - CMA deemed that GSK was dominant (molecular market).

Motivation: Role of Market Definition in Competition Policy

- If they exist, competition authorities tend to stick to precedents w.r.t. to market definition.
- We investigate whether antitrust market boundaries may change over (a short period of) time in the absence of:
  - Regulatory change
  - Technological improvements
  - Changes in trade policy
  - Launch of new product varieties
- Assess the importance of non-price instruments in determining market boundaries
- Should firms with a (*conventionally defined)* low market share fall under Art. 102?

A puzzle: "wrong elasticities"?

- Price and quantities around LoE (Loss of Exclusivity)



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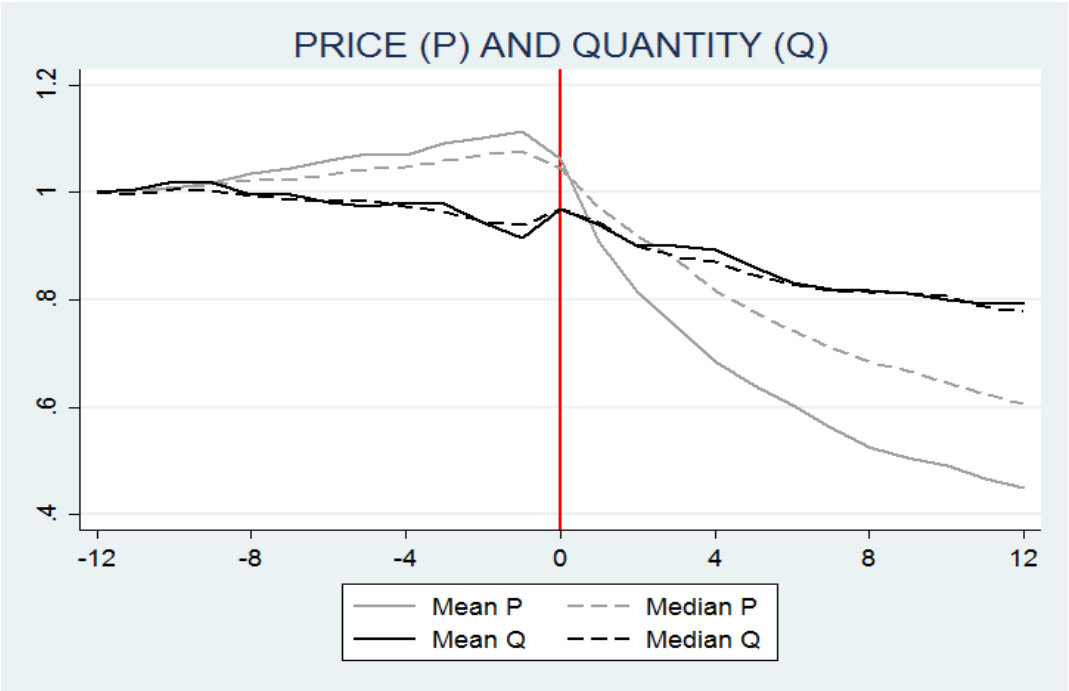
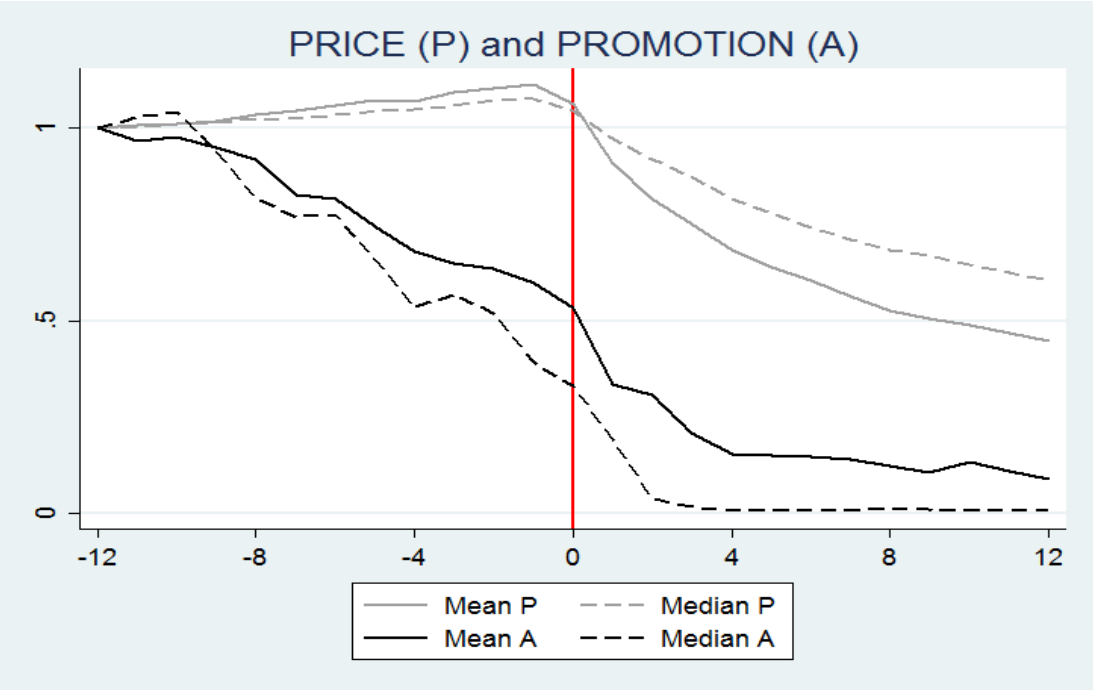


- Price elasticity with "wrong" sign?
- Q competitors ↑: negative cross-price elasticity?

An explanation: promotional effort (15%-20% of revenues)

- Promotion and Prices



Likely Mechanism (Castanheira et al. 2019, JHE)

- Probable mechanism behind the result:
  - Non-price competition dominant pre-LoE
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  - Makes little sense to spend on promotion in the presence of perfect substitutes
- Promotion drop means that doctors' decision-tree is modified
  - They treat generics of the **same molecule** as substitutes...
  - ...but not in the same basket as other on patent (Branded) molecules
  - Collateral damage: drug A's capacity to exercise competitive pressure on B also drops

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Empirical strategy

- Test idea that definition of relevant market is contingent on competitive concerns
  - $\longrightarrow$ **We take the SNIPP seriously**
- SNIPP: what products (and geogr. areas) should hypothetical monopolist control to $\uparrow$ prices by 5% or more
- **Empirical challenge**: need to test **evolution** of own and cross price elasticities

Data

- IMS data for the US: 10 years / quarterly frequency
- **Prices** and **quantities** for all drug-package pairs sold in the US during 1994 Q1 through to 2003 Q4
- Market = **ATC3 level** (common starting point in EU merger)
- Drug level **promotion**: detailing (personal visits to physicians), distribution of free samples, and adverts in specialised journals
  - Data for the most important ATC3 markets (sample: of 49 ATC3 markets, 231 molecules of which 89 experience generic entry)
- **Precise timing of generic entry** (double checked with FDA)
- Clear identification of **originators** *vs.* **generic producers**

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$$\ldots + \overbrace{\beta_5 (1-E) a_{-it} + \beta_6 E a_{-it}}^{\text{x-advert, before vs after}} + \mu_i + \mu_t + \varepsilon_{it}$$

Empirical Model (I): intermolecular competition pre and post LoE

- We also measure the differences between BRAND and GENERIC

$$MS_{it} = \beta_1 p_{it} + \beta_2 a_{it} + \overbrace{\beta_{3B}(1-E)\,p_{-it} + \beta_{4B} E p_{-it}}^{\text{x-price } \textbf{BRAND}\text{, before vs after}} + \ldots$$

$$\ldots + \overbrace{\beta_{3G}(1-E)\,p_{-it} + \beta_{4G} E p_{-it}}^{\text{x-price } \textbf{GEN,}\text{ before vs after}} + \ldots$$

$$\ldots + \overbrace{\beta_5(1-E)\,a_{-it} + \beta_6 E a_{-it}}^{\text{x-advert, before vs after}} + \mu_i + \mu_t + \varepsilon_{it}$$

Results

	(1) FE-IV	(2) FE	(3) FE-IV	(4) FE-IV	(5) FE	(6) FE-IV	(7) FE-IV
	(P)		(Ad)	(Ad & P)		(Ad)	(Ad & P)
own *P*	-0.152	-0.746**	-1.102***	-1.574***	-0.788**	-1.145***	-1.608***
own adv		0.535***	1.078***	1.271***	0.539***	1.127***	1.370***
comp' *P* (pre LoE)	0.143	0.242*	0.301*	0.413*			
comp' *P* (post)	0.095	0.238	0.383**	0.541**			
comp' adv (pre)		-0.189***	-0.413***	-0.504**	-0.192***	-0.431***	-0.543***
comp.' adv (post)		-0.228***	-0.439***	-0.543***	-0.199***	-0.422***	-0.525***
brand comp' *P* (pre)					0.353**	0.480**	0.626***
brand comp' *P* (post)					0.196	0.388**	0.469**
gen' comp' *P* (pre)					0.063	0.058	0.055
gen' comp' *P* (post)					0.280**	0.315**	0.442***
Obs	3870	3870	3870	3870		3870	3870
Underidentification	<.0001		<.0001	0.0172		<.0001	0.0287
Endog_Test	.2723		.0091	0.0083		.0110	0.0001
Exog_Test			.5095			.7535	
Hansen_p val	.0006		.1443	0.2077		.1303	0.2493
Hansen_df	2		2	3		2	3

Interpretation of the results

- For the purpose of identifying competitive interaction, promotion must be accounted for, particulalrly pre LoE
- Evidence of asymmetric constraints: originators pricing and promotion squeeze genericized molecules' market share
- Generics do not constraint on patent originators in the same therapeutical market.
- **Since genericised molecules where once on patent, this implies that genericisation results in molecules "dropping out" of the antitrust market, despite much lower average prices**
- Lumping on patent originators and genericised molecule in a single competitors' price index reduces precision
- Post LoE, inter-molecular competition is somewhat subdued

Simple and Direct Implementation of the HMT

- *Hypothetical* Monopolist that controls a single product:

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$$\pi_i = (p_i - c)q_i = (p_i - c)A_i p_i^{\varepsilon}$$

where:

  - A_i is a demand shifter that depends on competitors' price and promotion
  - Marginal cost is asumed to be constant
  - $\frac{(p-c)}{p} = -\frac{1}{\varepsilon}$ or equivalently $\frac{p}{c} = \frac{\varepsilon}{\varepsilon+1}$

- Changes in $\frac{p}{c}$ associated with changes in market structure indicate whenther a Hypothetical Monopolist would have the incentive to increase prices by 5% or more.

Empirical Model (II): inter and intramolecular competition post LoE

- What are the market boundaries for a given generic producer?

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$$\begin{aligned} MS_{it}^{G} = \beta_1 p_{it}^{G} &+ \beta_2 p_{it}^{-G} + \beta_3 p_{it}^{B} + \ldots \\ &+ \beta_4 p_{-it}^{G} + \beta_5 p_{-it}^{B} + \ldots \\ &+ \beta_6 a_{it}^{B} + \beta_7 a_{-it}^{B} + \mu_i + \mu_t + \varepsilon_{it} \end{aligned}$$

where:

  - i stands for **same molecule** / $-i$ for **other** molecule
  - G stands for **generic** / $-G$ for other generic versions of i
  - B is for **brand**

- Generic producer/drug pair market share post LoE (1&2):
- Single generic producer (3) and single originator/generics producer (4)

Results: MS of a single generic producer (1&2) and MS of a molecule (3&4)

	(1) **FE**	(2) **FE-IV**	(3) **FE-IV**	(4) **FE-IV**
		(P & Ad)	**(P & Ad)**	**(P & Ad)**
Price of molecule *i*	-0.925***	-8.693***	-4.467***	-2.701***
Price other generics (same molecule)	0.342***	6.643***	**XXXX**	**XXXX**
Price originator brand (same molecule)	0.129**	0.730**	2.866***	**XXXX**
Price generics (other molecules)	0.324***	0.264	0.611***	0.348
Price brands (other molecules)	0.304***	1.200***	1.605***	2.261
Advertising originator brand (same molecule)	0.065***	0.211**	0.386***	0.509***
Advertising other molecules	-0.061***	-0.323***	-0.585***	-0.501***
Obs	60136	60136	9625	9625
Underidentification		<0.0001	0.00029	0.00014
Endog_Test		< 0.0001	< 0.0001	< 0.0001
Hansen_pval		.4493	0.7932	0.1903
Hansen_df		2	2	2

Interpretation of the results (1)

- A single generic producer (column) (1) would face an elasticity of $\varepsilon = -8.7$, implying $\frac{p}{c} = 1.13$. De facto Bertrand.
- Merger between generic suppliers of a single molecule (and excluding the originator still producing that molecule: $\varepsilon = -4.5$, implying $\frac{p}{c} = 1.29$. Merger only involging generic versions (and not including the originator) would, on average, be profitable (14% increase in $\frac{p}{c}$), despite constraints (originator of the same molecule, other originators, other generics, and the associated promotion).

Interpretation of the results (2)

- Alternative to own price elasticity: focus on the cross price elasticity. In the spirit of Azar et al. (2018), and Azar and Vives (2020). We consider the more complex problem of a firm that separately chooses the prices of each version of the same genericized molecule.
- Taking the example of two generics drugs of the same molecule for simplicity, a firm that commands 100% of the profits of version i and a fraction λ of the profits of version j would maximize:

$$\begin{aligned} \pi_i &= (p_i - c)q_i + \lambda(p_j - c)q_j = \\ & (p_i - c)A_i p_i^{\varepsilon} p_j^{\chi} + \lambda(p_j - c)Ajp_i^{\chi} p_j^{\varepsilon} \end{aligned}$$

- Where χ stands for the cross-price elasticity

Interpretation of the results (3)

- For $\lambda = 1$ (full control of firm j), χ would need to be smaller than 0.3 (interior solution). Column 2: 6.6, implying a corner solution (i.e., if all generic producers of fluoxetine were to merge, the new entity would only maintain one variant - e.g. Teva fluoxetine).
- Given that this firm would shut down all but one variant, intramolecular substitution would be limited to the originator. Hence, the remaining own-price elasticity of this hypothetical firm can be proxied as $\varepsilon + \chi = -8.693 + 6.643 = 2.05$. A firm facing that elasticity would select a price-cost ratio of 1.95, implying a price increase of 73% above the initial level (in line with *Aspen*).

Interpretation of the results (4)

- Would a monopolist encompassing all genric producers and the originator find it profitable to increase prices above the HMT threshold?
- The point estimate of own price elasticity that this hypothetical producer would face stands at -2.7, yielding a price-to-cost ratio of 1.59. Hence, moving from a molecular duopoly to a single seller would result in a 23% price increase (price-cost ratio of 1.59 vs. 1.29), again surpassing the 5%-10% HMT threshold.
- Applying the second approach, the sum of own and cross price elasticities is: $-8.69 + 6.64 + 0.73 = -1.32$, yielding a price-cost ratio of 4.125 (high). But similar to Scott Morton and Kyle (2012).

Conclusions (I)

- Ignoring promotion: failure to properly capture competitive interaction (reminiscent of CET, Glowicka et al., 2009)
  - Servier case, in recital #(2517) "*the Commission considers that competition in promotion should not be regarded as a source of significant competitive constraints from the specific perspective of the relationship between perindopril and its potential competitors*".
- When a drug is on patent, it is only price constrained by other on patent drugs
- Hence, when a branded molecule experiences LoE, it stops exercising a constraint on its patent protected former peers
  - Effectively: "drops out" of the relevant antitrust market
- Significant cross price elasticities and the HMT
- Post-LoE, competition is primarily, but not exclusively, intra-molecular

Conclusions (II)

- EU case law: requires dominance **at the time of illicit behaviour**
- Imagine a firm that blocks generic entry with "pay for delay/reverse payments", input foreclosure, sham patenting, evergreening with no therapeutical value...
  - This is **before LoE**: she competes with other brands. The firm is not dominant according to the market share metric
  - Earn rents proportional to price drop following generic entry, but the latter are not yet on the market
- After LoE: no longer competes with other brands, only with generics...
- ...**how does this fit EU case law? Servier**
- General Court quashed the 102 leg of the Servier case on 12/12/2018 on the basis that Servier was not dominant.

Conclusions (III)

- **Related UK case:**
  - UK Competition Appeals Tribunal (CAT):
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  - *"Where a patented pharmaceutical drug is therapeutically substitutable with a number of other drugs in a class, and the alleged abuse for the purpose of Article 102 is conduct by the patent holder that effectively excludes generic versions of that drug from the market, are those generic products to be taken into account for the purpose of defining the relevant product market, although they could not lawfully enter the market before expiry of the patent if (which is uncertain) the patent is valid and infringed by those generic products?"*

Conclusions (IV)

- **Question**: should one consider constraint by generics that are not yet on the market?
- CAT, recital 403: *"The definition sought is of the* **relevant** *market: this is not an absolute but should reflect relevance to the issue under consideration, and can vary accordingly"*
- (Highly welcome) Link between the nature of the infringement and market definition.
- ECJ answer to the request for a preliminary ruling: entry must be "imminent" (unsatisfactory)
- Our findings are also relevant for **expoitative abuses**
- Market definition should not (cannot be dissociated) from the competitive concern.

Conclusions (V)

- But: market power that GSK enjoys in the hypothetical market in which exclusion does not take place *is not instrumental* in making the exclusion feasible.
- Dominance on the molecular market because of IPRs. First mover advantage. Given that intense price competition materialises post entry, generics have a limited willingness to pay for assets (Servier) or can easily be "bought off" (GSK/Paroxetine).
- In market pre-emption cases, risk of serious Type II errors if the traditional approach is adhered to (large market share requirement and cocomittance).
- Enforcement gap? Type III errors