Market Definition and Competition Policy Enforcement in the Pharmaceutical Industry

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Abstract

We focus on market definition in the pharmaceutical industry, where the introduction of generics in different markets provide a sequence of quasi natural experiments involving a significant competitive shock for the molecule experiencing Loss of Exclusivity. We show that generic entry alters competitive constraints and generates market-wide effects. Paradoxically, entry may soften competitive pressure for some originators. We obtain these results by econometrically estimating time-varying price elasticities and apply the logic of the Hypothetical Monopolist Test to delineate antitrust markets. They provide strong empirical support to the approach consisting in defining relevant markets contingent on the theory of harm. We discuss the relevance of these findings in the context of ongoing cases.

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> *Market definition and market power should be evaluated in the context of the alleged anticompetitive conduct and effect, not as a flawed filter carried out in a vacuum divorced from these factors.* (Salop 2000, p .191)

1. Introduction

Keeping medicine accessible at a reasonable cost is a challenge. An important component of public authorities' strategy has been to stimulate price competition from generics. Their volume market share progressed substantially, to reach 85% of drug prescriptions in 2016 (Bosworth et al., 2018). Yet, in terms of value, their 2018 market share only reached 26% in the U.K., 21% in Germany, and remains below 20% in countries such as France, Belgium, and Switzerland (Statista, 2020).

Alongside regulation, competition policy enforcement is a prima facie instrument to ensure that ethical drugs are available at the lowest possible cost to society. Merger control enforcement should ensure that competitive rivalry is not stymied by corporate acquisitions. Large fines (and prison sentences in some jurisdictions) are commonplace in the fight against price fixing. In May 2019, for instance, 44 US states announced a lawsuit against the most important generic suppliers for a price-gauging conspiracy. By August 2020, most of these drugmakers had agreed to pay penalties totaling almost $425m to settle their case. [4,5]

Unilateral conduct, in the form of foreclosure or abusive prices, can also result in competitive harm. In the EU, under Art. 102 of the TFEU, firms are liable to heavy sanctions if they are deemed to have abused their dominant position. National legislation of a similar kind also exists in all Member States (e.g. chapter 2 of the UK's Competition Act). In the US, section 2 of the Sherman Act prohibits monopolization or attempted monopolization.

In the jurisdictions listed above, a prerequisite to sanction unilateral conduct is that the firm under scrutiny enjoys a position of dominance.[6] As a first approximation, the assessment of dominance (or monopoly position) is made on the basis of the firm's market share. This paper focuses on the definition of the relevant antitrust market, which is the (unavoidable) first step in proceedings involving unilateral behaviour deemed to be anticompetitive.

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[4] Kuchler, Hannah, "US generic drug companies hit by price-fixing claims." *Financial Times*, May 13, 2019, and Kuchler, Hannah, "Teva Charged in US price-fixing investigation." *Financial Times*, August 20, 2020.

[5] Casual observation suggests that infringements are commonplace. A web search on the Financial Times website for articles published between January 1, 2016 and January 1, 2020 with the keywords "pharmaceutical anticompetitive antitrust" returns 125 articles (in November 2020). A Google search with the same keywords returned more than 5 million hits.

[6] In US parlance, that the firm is a monopoly, or will become one as a consequence of its actions.

Our analysis is in part motivated by a number of recent competition enforcement decisions involving unilateral behaviour by pharmaceutical firms, where market definition was pivotal. Market definition, which is usually a fairly routine exercise, turned out to be particularly complex (and controversial) in the Servier[7] and GSK/Paroxetine[8] cases that we briefly review in Section 4. In addition, the evidence and arguments put forward by the various parties raised interesting issues of substance.

In the Servier case,[9] the EU's General Court concluded that the EU Commission had "made a series of errors in defining the relevant market".[10] At the time of writing, the appeal to the European Court of Justice brought by the Commission is pending resolution. We conjecture that the thorny nature of market definition explains the relative scarcity of (pharma) unilateral conduct cases on both sides of the Atlantic.

This paper focuses the identification of relevant antitrust markets in the pharmaceutical industry. By "relevant" markets, we refer to the set of products (and geographic areas) that would be identified on the basis a Hypothetical Monopoly Test (HMT), leading to Small but Significant Non-transitory Increase in Price (SSNIP) of 5%-10%.

The HMT approach to market delineation was first endorsed in the US's Federal Trade Commission 1982 Merger Guidelines. The HMT also inspired the EU Commission Notice on Market Definition (1997), and is common reference point in academic textbooks (Motta 2004). Market definition has been critically analysed by legal scholars and practitioners as well as enforcers; by contrast, academic economists' contribution has been limited.[11]

While this approach rests on solid conceptual foundations, operationalizing the HMT is challenging.[12] In practice, competition authorities have had to approximate the HMT by exploiting historical data (customers' reactions to a significant price change), estimates of diversion ratios (e.g., inferred from customer surveys) or simulations—to name a few. In some rare instances, econometric estimation of demand elasticities was relied upon.

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[7] European Commission Decision, CASE AT.39612 - Perindopril (Servier), July 9 2014. Siotis worked at the European Commission at the time of the investigation into the Servier case as a member of the Chief Economist team. The views expressed in this paper are strictly his own views and rely solely on the published decision and judgment.

[8] Competition and Markets Authority, Case CE-9531/11, February 12 2016.

[9] General Court of the European Union, Ruling Case T-691/14, Servier/Commission, December 12 2018,

[10] General Court of the European Union, Press Release # 194/18, Luxembourg, 12 December 2018

[11] G. Stigler (1982) indicated that: "My lament is that this battle on market definitions, which is fought thousands of times what with all the private antitrust suits, has received virtually no attention from us economists. Except for a casual flirtation with cross elasticities of demand and supply, the determination of markets has remained an undeveloped area of economic research at either the theoretical or empirical level." In our view, this statement is still largely valid. Rare execeptions include Ivaldi and Lorincz (2011).

[12] https://www.justice.gov/atr/operationalizing-hypothetical-monopolist-test

Markets for prescription drugs are well suited to operationalize the HMT, rather than approximate it. First, extremely rich product level data are available. Second, markets are exposed to frequent competitive shocks in the form of generic entry that can be precisely identified and timed.

We find that generic entry generates market-wide shockwaves that reshape the nature and strength of competitive constraints. Concretely, we exploit multiple episodes of generic entry to measure the competitive pressure faced by originators still benefitting from exclusivity. We also analyse post-LoE competitive dynamics from the perspective of generic suppliers. Taken together, our empirical findings allow for a direct implementation of the HMT. This in turn points to multiple candidate markets that are relevant for enforcement purposes. It serves to highlight that there is no "ideal" or "unique" definition of the antitrust market: the delineation of the relevant market cannot be dissociated from the nature of the competitive concern.

Generic entry comes close to a quasi-natural experiment. It occurs frequently and its timing is largely exogenous to initial market conditions: most often, the event triggering entry is the expiration of patents that were filed several years before. The dataset at our disposal comprises individual prices, quantities and promotional efforts for 125 molecules sold in the US during forty quarters. Of these, 64 molecules in 31 different candidate markets lost exclusivity during the period of analysis. With consumption choices determined by prescribing doctors, the fall in promotional spend post LoE weighs heavily in the reallocation of demand (Lakdawalla and Philipson, 2012, Castanheira *et al*., 2019).

We find that on average, the entry of generic competitors for one drug shrinks the initial antitrust market: the genericized drug "drops out" in the sense of no longer constraining the pricing power of the drugs still enjoying exclusivity. That is, the intensification of *intramolecular* rivalry resulting from generic entry, reduces *intermolecular* competition.[13]

Next, we identify competitive constraints from the standpoint of generic producers. Unsurprisingly, we find that own- and cross-price elasticities among generics are high, meaning they have essentially no market power and face very strong competition from other generic producers of the same molecule. Applying a HMT post LoE points to narrow markets, limited to a single molecule and only encompassing generic suppliers.

Importantly, our results confirm that, from an enforcement perspective, market definition should be contingent on the nature of the competitive concern. This can be illustrated with a simple example. Imagine a market composed of three originator drugs, *A*, *B* and *C*, that benefit

[13] *Intramolecular* rivalry encompasses both competition between the originator drugs and its generic versions as well competition between generic versions of the same molecule. *Intermolecular* rivalry refers to competition between drugs used to treat a given therapeutic condition.

from exclusivity and that significantly constrain each other, i.e. a Hypothetical Monopolist controlling all three would be in a position to profitably and durably increase prices by 5-10% (or more). Thus, if the concern is coordinated behaviour, the candidate market is made up of *A, B* and *C*. However, if the infringement consists in foreclosing generic entry for drug *C*, the relevant antitrust may well be molecular, even though that market has not yet emerged. The reason is that, once generic entry occurs, a HMT limited to molecule *C* may indicate that a price increase would be profitable. With respect to mergers (which involves a forward looking assessment), our analysis points to the risk of Type II errors (*i.e.*, that an anticompetitive merger may be waived through). This is because vigorous intermolecular competition may vanish quickly if the drugs competing with those of the merged entity experience LoE. Suppose that drug *C* is the market leader with 60% market share, while *A* and *B* each command 20%. A merger between *A* and *B* may be cleared under the assumption that the merged entity would face significant constraints from *C*. Our analysis indicates that if *C* is close to expiry, and if there are no new product launches in the foreseeable future, the merger between *A* and *B* would create an entity that may rapidly enjoy very significant power as identified by a HMT (and possibly all the way to a monopoly position). The reason underpinning *C's* competitive constraint fading into irrelevance is the dramatic drop in promotional spending that follows LoE (Castanheira *et al*., 2019).

The suggestion that the relevant market should be made contingent on the infringement (actual or potential) has been discussed for some time (Salop 2000, Rey *et al.* 2004, and Glasner and Sullivan 2019 for an in-depth exposition and analysis), but enforcers and courts have so far been reluctant to endorse the approach, at least in the European Union.

The remainder of the paper is organized as follows. Section 2 describes the dynamics of competition in the pharmaceutical industry before and after patent expiration. In Section 3 we describe the data, implement our empirical analysis and propose a direct implementation of the Hypothetical Monopoly Test. Section 4 discusses potential implications of our results for some ongoing cases. Section 5 concludes.

2. Competitive Dynamics in the Pharmaceutical Industry

The Anatomical Therapeutic Chemical (ATC) classification regroups drugs at different levels of aggregation, numbered 1-5. The ATC3 level encompasses the set of potential treatments for a given medical condition. Thus, it contains potential substitute products for a given "customer," here a patient-doctor-pair, to address a medical condition. The EU Commission routinely takes the ATC3 level as the starting point to define the relevant antitrust market (Greenaway *et al*. 2009).

The definition of a "relevant market" involves identifying the competitive constraints faced by a firm or by merging parties. The exercise can be complex when firms compete through price and non-price instruments (Sovinsky Goeree, 2008), and/or when other forms of public intervention dampen the role of price as a competitive tool. The combination of high R&D, promotion intensity,[14] regulation, and information asymmetries generate particularly complex competition dynamics. In that context, two standard indicators of market power, market shares and competitors' price reactions, carry less informative content.

Market shares

Based on the textbook industrial organization literature, market shares are often used as a proxy for market power (Motta 2004). However, the mapping of concentration onto consumer welfare is far from clear in the presence of product differentiation (e.g. quality differences) and non-price competition (e.g. promotion). For instance, in a model inspired by the workings of the pharmaceutical industry, Lipatov, Neven and Siotis (2020) show that consumer welfare may be higher in concentrated markets. They also show that, somewhat surprisingly, the benefits of entry can be higher in less concentrated markets. These findings suggest that the informative content of market shares (even derived from properly defined markets) to infer potential harm (or absence thereof) is limited in the context of the pharmaceutical industry.

In the scenarios described below, we propose to quantify market power directly. We compare competitive prices, quantities and profits to those that obtain as a consequence of the infringement.[15] Under such circumstances, large rents are direct evidence of dominance (Browdie *et al.*, 2018). When market power can be directly quantified, market shares calculation may be less relevant.

Competitors' and consumers' reactions to price fluctuations

Patents typically offer 20 years of intellectual property rights (IPR) to the firm that developed a new drug. The loss of exclusivity (LoE) that marks the end of that period triggers a unique

[14] According to figures in Donohue *et al.* (2007, p. 497), originator firms spent, on average, 18% of their revenues on promotion in various forms: detailing, distribution of free samples, and adverts in specialized journals. "Detailing" consists of individual visits by sales agents to provide information to practitioners. In the US, this is complemented by Direct-to-Consumer Advertising since 1997. The amounts spent on promotion are slightly above R&D expenditure, indicating the strategic role it plays in market competition. Gagnon and Lexchin (2008) report even higher estimates for the US, suggesting that promotional effort may be significantly above R&D expenditure. Lowe (2013) provides additional evidence to the same effect. The accounting category where advertising, promotion, and marketing end up is called "SG&A" (Sales, General and Administrative). This is a broader group as it also includes executive salaries. Lowe (2013) reports "that Merck's [SG&A] are at 27% of revenues [R&D: 17.3%], Pfizer is at 33% [R&D: 14.2%], AstraZeneca is just over 31% [R&D: 15.1%], Bristol-Myers Squibb is at 28% [R&D: 22%], and Novartis is at 34% [R&D: 22% according to their 2013 financial report]". For comparison, SG&A represents 21.5% of IBM's sales, 20% of 3M's and 6.5% of Apple's.

[15] For instance, even if foreclosure is successful, generic entry eventually occurs in all blockbuster markets. Hence, once that happens, it is possibly to infer the level of rents enjoyed by the originator pre-LoE.

competitive shock: generics, which are near perfect substitutes, can legally compete with the originator. These generics, which are often sold at less than half the price of the original branded product, quickly erode the originator's market share (Grabowski *et al.* 2014, Scott Morton and Kyle 2012, Reiffen and Ward 2015). This is not surprising, as generics are bioequivalent products that have been explicitly recognized as such by health authorities.[16] Clearly, the originator drug and generic versions thereof belong to the same antitrust market.[17]

A perplexing feature surrounding generic entry is that the price of the other on-patent molecules in the same ATC3 category is barely affected (Jena et al. 2009, Lakdawalla 2018), and their volume market share can even increase (Castanheira et al. 2019, Grabowski et al. 2014, Regan 2008, Lakdawalla and Philipson 2012). This lack of reaction has sometimes led competition authorities (and scholars) to conclude markets are molecular. However, drawing such conclusions is highly contentious: prior to generic entry, the drug may have been actively competing against other originators, pointing to a broader antitrust market, where inter-molecular competition was rife.

Hence, for a given set of drugs, evidence pertaining to slightly different points in time may point to narrow (molecular) markets or to a broad (multi-molecule) market, potentially leading to controversy (see Section 4 for concrete cases). In the next section, we show that these alternative market definitions need not be mutually exclusive. We also show that the "correct" market definition cannot be dissociated from the theory of harm.

3. Empirical Analysis: implementing the Hypothetical Monopoly Test

The empirical exercise proceeds in two stages. First, we define and estimate a specification to simultaneously investigate inter-molecular competition before and after patent expiration. Second, we identify competitive conditions for generic producers by separately identifying competitive constraints exercised by drugs depending on their status: originators still benefitting from exclusivity, generic versions of the same drug, and other molecules that experienced generic entry in the past. The observed variation in market structure allows us to directly implement the HMT.

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[16] Among generics, differences are residual (different excipient, packaging, or color); hence, we conjecture that intra-molecule competition should converge to the Bertrand outcome in the absence of capacity constraints (we test this hypothesis in Section 4.2).

[17] However, instead of observing the originating firm decreasing its price, it is not uncommon to observe the opposite (for empirical evidence, see Regan (2008) for the U.S., and Vandaros and Kanavos (2013) for the EU). Scherer (1993) coined this phenomenon the *generic entry paradox*.

3.1. Intermolecular competition: Data

Our dataset covers quarterly dollar revenues and physical quantities for hundreds of branded and generic prescription drugs sold in the U.S. in many therapeutic areas over the 40-quarter period 1994q1 to 2003q4. These have been obtained from the proprietary database IMS-MIDAS published by IMS-Health, one of the most important medical information providers.

All the drugs in IMS-Health are classified according to the Anatomical Therapeutic Chemical (ATC) classification system. In IMS data, generics have the name of the active ingredient. [18] We thus compiled an initial list of ATC3 markets with at least one generic by selecting the markets where there are two or more different products for the same molecule, and some of the drug names are the same as the molecule (*e.g*. *Fluoxetine* is the active ingredient of *Prozac*), as well as the name of its generic competitors.

We double-checked and completed this list with information about Loss of Exclusivity (LoE) from the FDA.[19] We then purchased drug-level information on promotion expenditure for the most important ATC3 markets in terms of sales and promotional effort.

For each of the drugs belonging to the selected markets, we computed deflated revenues (R) by dividing nominal value of sales by the producer price index for the pharmaceutical industry published by the Bureau of Labor Statistics. Quantities (Q) are reported in standard units that represent the number of dose units sold for each product; this corresponds to one capsule or tablet of the smallest dosage or five milliliters of a liquid (*i.e*. one teaspoon). Standard units allow comparison across different drug forms and dosages, as all different packages are subsumed into the same unit of observation. We then compute the average price of a molecule (P) by dividing R –*i.e*. the revenues for all the different packages– by total quantity Q as well as the average price of competing molecules in the same market.[20]

Promotional data include three main components: visits to office-based practitioners and hospital specialists; free samples dispensed to physicians (with their cost being estimated at the sales price of the drug); and advertising in professional journals. IMS Health data on detailing are constructed using a representative panel of physicians who track their contacts with sales representatives. The amount spent on free samples is based on a panel of approximately 1200 office staff members in medical practices, while expenditures on

[18] An exception to this classification is represented by branded generics, i.e. generic drugs that have been given a proprietary market name. We treat these drugs as "plain vanilla" generics.
[19] Appendix 1 lists the name of the originator drug and the associated active ingredients as well as the date of generic entry.
[20] This produces a price per standard unit. Note that our empirical specifications control for unobserved differences, such as quality and Defined Daily Dose (DDD), across molecules.

advertising in professional journals are computed by tracking ads placed in approximately 400 medical journals and then adding the publisher's charge for those ads.

The promotion level used in the reported demand specifications is computed with the perpetual inventory method, commonly used for physical capital, as follows:

$$A_{it} = (1-\rho)\, A_{it-1} + I_{it},$$

where I_{it} is the quarterly expenditure on promotion for drug i retrieved from IMS, and ρ is the quarterly depreciation rate, assumed to be 0.1 – *i.e.* about 35% per year.[21]

The final sample for which we can compute all the variables above includes 31 different ATC3 markets, covering 125 molecules, of which 64 experience generic entry during our time window. Table 1 reports descriptive statistics for these variables. Note that "Promotion of Competing Molecules" refers to the sum of promotion spending by all other the drugs in the same ATC3 market, each computed according to the equation above. At the same time, the "Price of Competing Molecules in ATC3" refers to the average price of all the other molecules in the market, generics included. It is computed as the ratio between total revenues and total quantities in the ATC3 market, after subtracting the revenues and quantities of drug *i*.

Table 1: Descriptive Statistics

	Obs	Mean	S.D.	Min	Max
Market shares of molecule *i*	3870	0.139	0.183	0.001	0.982
Price of molecule *i*	3870	19.410	73.571	0.023	618.870
Price of competing molecules	3870	9.074	28.300	0.027	182.599
Price of competing generic molecules	3870	3.500	10.456	0.015	102.456
Price of competing branded molecules	3870	15.959	53.596	0.087	361.810
Promotion of molecule *i*	3870	97899	208890	1	2021052
Promotion of competing molecules	3870	548659	953257	1	5739914

3.2 Intermolecular Competition: Specification and IV Strategy

We estimate the elasticity of a given molecule's volume market share with respect to its own price and promotion effort, as well as the corresponding cross-elasticities for competing

[21] This depreciation rate is one of the most commonly used in the literature (see Rizzo (1999) among others). Our results are robust to reasonable variation around this value.

drugs. Our dependent variable is the log of a molecule's quantity market share within an ATC3 market. More precisely, prior to LoE, the LHS variable pertains to the quantity market share of the originator drug. Post LoE, we use the quantity market share of the originator plus its generic version. The case of the well-known antidepressant drug Prozac can serve as an illustration. The active ingredient in Prozac is *fluoxetine*, and this branded drug experienced LoE in the third quarter of 2000. In this example, the dependent variable is the quantity market share of fluoxetine. The latter coincides with the quantity market share of Prozac prior to 2000q3, while it is the combined market share of Prozac and its generic competitors (e.g., Teva fluoxetine, Barr fluoxetine etc.) from 2000q3 onwards.

Taking advantage of the fact that our dataset contains many molecules that have experienced LoE, we are in a position to estimate elasticities for a molecule depending on its exclusivity status. By comparing price and promotion elasticities before and after LoE, we can thus evaluate whether patent expiration leads to substantial change in the set of drugs exercising meaningful competitive pressure on a molecule.

Concretely, we let the market share of a molecule i at quarter t depends on own and competitors' price p and advertising a (with all these variables expressed as logarithms):

$$MS_{it} = \beta_1 p_{it} + \beta_2 a_{it} + \beta_3(1 - E_{it})p_{-it} + \beta_4 E_{it} p_{-it} + \beta_5(1 - E_{it})a_{-it} + \beta_6 E_{it} a_{-it} + \mu_i + \mu_t + \varepsilon_{it}, \quad (1)$$

where sub-index *–i* refers to competitors in the market. E_{it} is an indicator taking value 1 if (the LHS) molecule i has experienced generic entry at time t, and zero otherwise.[22] Equation (1) includes a complete set of molecule/drug fixed effects μ_i and time dummies μ_t. The fixed effect μ_i captures molecule-specific persistent differences in market shares driven by unobserved factors such as the vintage of the drug, the quality of the sales force or the reputation of the pharmaceutical companies marketing those drugs. The fixed effect μ_t controls for time-specific shocks that are common to all molecules. Finally, the error term, ε_{it}, captures molecule-specific demand shocks as well as measurement errors.

As the variables are expressed in logarithms, the coefficient β_3 (respectively β_5) measures the elasticity with respect to competitors' price (advertising) *before* drug i loses exclusivity, whereas the coefficient β_4 (respectively β_6) captures the cross-price (advertising) elasticity *after* it loses exclusivity, and hence when generic versions of molecule i entered the market. If the point estimate of β_3 is statistically different from β_4 then we can conclude that the constraints exercised by *i's* competitors do change over the molecule's lifecycle. Similarly, the

[22] The average value of E for the whole sample is 0.21. Its value for the set of drugs experiencing patent expiration is 0.49 (standard deviation 0.50), which indicates that patent expiration happens, on average, in the middle of our sample period.

coefficients β_5 and β_6 allow us to gauge the impact of competitors' promotional effort on a molecule's market shares before and after LoE.

To delve deeper in the details of inter-molecular competition, in specification (2), we distinguish the price of Branded competitors (superscript *B*), p^B_{-it} from the price of Generic competitors (superscript *G*), p^G_{-it}. The former includes both branded drugs that are patent protected as well as originator drugs that have lost exclusivity:

$$MS_{it} = \beta_1 p_{it} + \beta_2 a_{it} + \beta_3^B (1 - E_{it}) p^B_{-it} + \beta_4^B E_{it} p^B_{-it} + \beta_3^G (1 - E_{it}) p^G_{-it} + \beta_4^G E_{it} p^G_{-it}$$
$$+ \beta_5 (1 - E_{it}) a_{-it} + \beta_6 E_{it} a_{-it} + \mu_i + \mu_t + \varepsilon_{it}. \qquad (2)$$

To re-iterate, as long as a drug is patent protected, the dependent variable –the molecule's market share in the ATC3– is that of the branded (and patent protected) drug. After the molecule experienced LoE, the dependent variable is the molecule's quantity market share within the ATC3, which is now made up of the original brand as well as any generic version. Hence, we are able to identify a molecule's competitors throughout its lifecycle, as it moves from being a patent protected drug to a molecule experiencing generic entry.

In (2), we can test whether the competitive constraints exerted by branded and generic competitors are statistically different by comparing the point estimates of β_3^B and β_3^G. By the same token, by comparing β_3^B (respectively β_3^G) to β_4^B (respectively β_4^G), we can assess whether competitive constraints exercised on molecule *i* change before and after *i*'s LoE.

Own price and promotion are likely affected by two types of problems. The first is endogeneity, *e.g.* due to feedback from market share shocks to subsequent price and promotional effort (reverse causality). The second is measurement error of both price and promotion, stemming from the difficulty to observe and quantify monetarily the work of sales representatives when they visit physicians. Both would result in correlation between our regressors and the error term. To address these issues, we implement an IV strategy based on two sets of instruments that should be highly correlated with supply-side changes in promotion and prices, but not with the error term in equations (1) and (2).

Following the methodology proposed by Chaudhuri *et al.* (2006), our first set of instruments consists in the number of packages, linear and squared. The rationale for using this instrument is that the introduction of a new package is generally accompanied by increased promotional activities. Recall that our measure of promotional effort includes the distribution of free samples, which ought to increase when a new dosage or formulation is launched on the market. While number of packages is likely to be highly correlated with promotion expenditures, it is plausibly uncorrelated with the measurement error, since the number of packages can be accurately measured in our data. At the same time, as explained in Chaudhuri

et al. (2006), the number of packages is related to a molecule' average price p, as variations in p stem in part from variations in the set of packages available in each period.

We also use the number of quarters to/from generic entry, linear and squared as a second set of instruments. These instruments capture the dramatic changes in pricing and promotion strategies by a brand manufacturer and its generic competitors in the periods leading to and following LoE, as documented in Section 2. As patent expiration is exogenous (unrelated to patients and doctors' decision) and can be accurately timed, these instruments can be reasonably considered unrelated to the error term, ε_{it}. Before discussing our results, we note that this choice of instruments is validated by the Kleibergen-Paap rk-statistic (K-P) for under-identification, the Hansen J-test for over-identifying restrictions, and the C-statistic to test of endogeneity of one or more instruments (regressors), as shown in the tables below.

3.3. Intermolecular competition: Results

Table 2 reports the estimates of price and promotion elasticities in our sample. Column (1) presents the results before instrumenting for either price or promotion. All the coefficients are of the right sign and significant, save for competitors' price post-LoE. In column (2), we control for the endogeneity of promotion but not for that of prices. The instruments used are the number of packages (linear and squared) and the time to/from generic entry (linear and squared). With these instruments, the point estimates increase in absolute value, whereas the precision of the estimates is maintained. In column (3), we augment the analysis by also instrumenting for price. The sign and precision of all the point estimates are maintained, but the magnitude of the estimated coefficients increases further.

Table 2: Price and Advertising Elasticities before and after Lost of Exclusivity

Dependent Variable: Market Share of Molecule *i*							
		(1)	(2)	(3)	(4)	(5)	(6)
		FE	FE-IV	FE-IV	FE	FE-IV	FE-IV
Endogenous variables →			Prom	Prom & Price		Prom	Prom & Price
Regressors:	Coeff.:						
Price of molecule *i*	β_1	-0.746**	-1.065***	-1.709**	-0.788**	-1.102***	-1.721**
		(0.34)	(0.28)	(0.66)	(0.35)	(0.28)	(0.71)
Promotion of molecule *i*	β_2	0.535***	1.034***	1.227***	0.539***	1.075***	1.257***
		(0.08)	(0.15)	(0.24)	(0.08)	(0.16)	(0.25)
Price of competitors	β_3	0.242*	0.300*	0.462**			
(before molecule *i's LoE)*		(0.14)	(0.16)	(0.22)			
Price of competitors	β_4	0.238	0.368**	0.554**			
(after molecule *i's LoE)*		(0.15)	(0.17)	(0.25)			
Promotion of competitors	β_5	-0.189***	-0.396***	-0.491***	-0.192***	-0.410***	-0.501***
(before molecule *i's LoE)*		(0.05)	(0.09)	(0.12)	(0.04)	(0.09)	(0.13)
Promotion of competitors	β_6	-0.228***	-0.424***	-0.547***	-0.199***	-0.404***	-0.489***
(after molecule *i's LoE)*		(0.06)	(0.09)	(0.15)	(0.04)	(0.09)	(0.12)
Price of brand competitors	β_3^B				0.353**	0.461***	0.647**
(before molecule *i's LoE)*					(0.17)	(0.18)	(0.26)
Price of generic competitors	β_3^G				0.063	0.046	0.034
(before molecule *i's LoE)*					(0.06)	(0.08)	(0.08)
Price of brand competitors	β_4^B				0.196	0.355**	0.387**
(after molecule *i's LoE)*					(0.15)	(0.17)	(0.17)
Price of generic competitors	β_4^G				0.280**	0.297**	0.488**
(after molecule *i's LoE)*					(0.13)	(0.13)	(0.24)
Obs		3870	3870	3870	3870	3870	3870
Underidentification[a]			<.0001	0.0014		<.0001	0.0052
Endog_Test[b]			.0017	.0023		.0012	.0016
Hansen_ pval[d]			.2215	.2042		.2124	.1658
Hansen_df			3	2		3	2

Notes: Robust standard errors clustered at molecule level in parentheses. * signif. at 10% level; ** signif. at 5%; *** signif. at 1%. Endogenous variables: Own promotion in column (2) and (5) and own price and promotion in columns (3) and (6) and. Instruments: #Packages (linear and squared) and Time to/from Generic Entry (linear and squared). [a] P-value for the Kleibergen-Paap rk-statistics testing the null hypothesis that the model is under-identified. [b] P-value of C (GMM distance) test of endogeneity for own price and/or own promotion. [c] P-value of C (GMM distance) test of exogeneity of price. [d] Hansen J test of overidentifying restrictions with degrees of freedom reported below.

Two findings emerge: first, the large point estimates of β_5 and β_6 confirm that promotion is a central driver of competitive interaction in the pharmaceutical industry. While own promotion may be a match for robust marketing by branded competitors, the dramatic drop in promotion activities after LoE means that a genericized molecule will only exercise a competitive constraint via prices. Second, the fact that the cross-price elasticities β_3 and β_4 have similar magnitude before and after LoE suggest that there are no major changes in the competitive environment over a molecule's life cycle. However, as we show below, this interpretation would be misleading.

The refinement embodied in specification (2) provides a more accurate picture of the evolving competitive landscape over a molecule's lifecycle. We focus our comments on column (6), where we instrumented for both price and promotion. Prior to LoE, we find that only brand competitors exercise a competitive pressure on molecule i ($\beta_3^B = 0.647$, significant at 5% level).[23] By contrast, genericized molecules do not exercise a constraint ($\beta_3^G = 0.034$ and statistically non-significant). In other words, while a drug is on patent, it is only price constrained by other on-patent drugs. Hence, once genericized, molecules in the same ATC3 class cease to exercise a constraint on drugs that still benefit from exclusivity, despite commanding a much lower price. Since genericized molecules benefitted from exclusivity in the past, this implies that a genericized drug "exits" its *former* market. *Ceteris paribus*, the antitrust market for drugs still benefitting from exclusivity shrinks when competing drugs experience generic entry.

Post-LoE, both brand and generic competitors exercise competitive pressure on molecule *i*: the respective coefficients are 0.387 and 0.488, both significant at 5%.[24] The coefficient for competing genericized molecules has been multiplied by 14 pointing to inter-molecular rivalry among (low-priced) generics. The estimates also provide direct evidence of asymmetric competitive constraints: genericized molecules do not constrain on-patent drugs, while the reverse applies. The asymmetry is even more notable when we include non-price competition in the picture: post-LoE keep being constrained by the promotion of other molecules ($\beta_6 = -0.489$, statistically significant at the 1% level).

These empirical findings are consistent with Grabowski et al. (2009) and Castanheira *et al.* (2019) who noted that generic entry generally allows other on-patent drugs to expand their quantity market shares. Beyond that observation, Table 2 identifies a marked change in the

[23] Since this coefficient pertains to the period when the molecule is patent protected, the dependent variable is the quantity market share of the brand.
[24] Since this coefficient pertains to the period after the molecule lost its patent protection, the dependent variable is the quantity market share of the brand plus that of its generics.

competitive landscape over a relatively short period of time, caused by the intensification of competition for a single, pre-existing, product.

3.4. Generics: Intra- and Intermolecular Competition

The results in the previous section identified competitive constraints from the perspective of a given drug/product over its lifecycle, and highlighted market-wide implications of generic entry. One finding is that patent protected drugs are largely shielded from the competitive pressure stemming from genericized molecules in the same (ATC3) market.

In this section, we focus on the post generic competitive environment. Our contribution is to simultaneously analyze intra-molecular and inter-molecular competition post LoE to guide market delineation.

Starting from a narrow candidate market, we propose two avenues to carry out the HMT for the purpose of delineating antitrust market boundaries. This exercise highlights that, if the HMT is taken seriously, a single (and "ideal") antitrust market does not exist. Concretely, our findings illustrate why market definition cannot be dissociated from the competitive concern. The workings of the pharmaceutical industry provide a rich environment to show that market definition should be made contingent on the competitive distortion (actual or potential) that is a source of concern.

To this end, we proceed by estimating the following equation:

$$MS_{it}^{G} = \gamma_1 p_{it}^{G} + \gamma_2 p_{it}^{-G} + \gamma_3 p_{it}^{B} + \gamma_4 p_{-it}^{G} + \gamma_5 p_{-it}^{B} + \gamma_6 a_{it}^{B} + \gamma_7 a_{-it}^{B} + \mu_i + \mu_t + \varepsilon_{it}^{G} \quad (3)$$

where MS_{it}^{G} and p_{it}^{G} are respectively the ATC3 quantity market share and the price of a molecule i produced by generic firm G at time t (*e.g.* Teva fluoxetine, one of the generic versions of Prozac). We denote with $-G$ the other generic producers of the same molecule (*e.g.* Mylan fluoxetine). Accordingly, the variable p_{it}^{-G} refers to the price set by these other generic companies for that same molecule i, whereas p_{it}^{B} is the price of the originator company (Eli Lilly's Prozac).

The variables denoted by a subscript $-i$ refer to the other molecules in the same ATC3 market: p_{-it}^{G} is the price index of other molecules that already lost patent protection before molecule i, and p_{-it}^{B} to other branded molecules, still covered by patent protection (*e.g.* Merk's Zoloft). Finally, the specification includes the advertising effort made by the originator of molecule i (for the few instances when they decide to go on advertising molecule i after patent expiration) and total advertising effort of other brand producers of molecules still covered by patent protection in the same ATC3.

Table 3 reports summary statistics for the variables used in specification (3). Note that the number of observations is substantially larger. This is because the unit of observation is no longer a molecule, but a molecule and generic producer pair. For instance, in our dataset, we observe more than 10 producers of fluoxetine. Moreover, while the dataset used in Section 3.1 requires that a molecule is covered by a patent at the beginning of the sample period, we can now include all generic molecules, even those that were genericized before 1994.

Table 3: Summary statistics of Generic Producers

	Obs	Mean	S.D.	Min	Max
Price of molecule *i* by generic-firm *G*	60136	1.086	8.605	0.001	452.174
Price of generic competitors (same *i* molecule)	60136	0.795	7.919	0.001	450.079
Price of brand competitors (same *i* molecule)	60136	2.086	17.864	0.001	371.177
Price of generic competitors (other molecules)	60136	1.103	9.541	0.010	213.786
Price of brand competitors (other molecules)	60136	3.961	27.178	0.034	361.810
Promotion of molecule *i*	60136	6846.7	37817	0	677264
Promotion of competitors (other molecules)	60136	303743	796338	0	5839280

Clearly, generic entry is endogenous. For instance, one observes steeper price drops in markets that attracted a larger the number of generic sellers (Reiffen and Ward, 2005; Scott Morton and Kyle, 2012). But higher levels of entry should be expected when initial price-cost margins are higher. Accordingly, in column (2), we instrument for price and promotion using the number of packages (linear and squared), the number of generic producers of the same molecule, and the headcount of producers of other drugs. Comparing the coefficients in columns (1) and (2), we observe an almost tenfold increase in the size of the own price elasticity and a twentyfold increase for the cross-price elasticity of other generic competitors. The Kleibergen-Paap rk-statistic (K-P) confirm the presence of endogeneity and the Hansen J-test validate the hypothesis that these instruments are both relevant and exogenous.

Table 4: Competition among Generic Producers

Dependent Variable:		*MS* of molecule *i* by firm *G*		*MS* of molecule *i*	
		(1)	(2)	(3)	(4)
		FE	FE-IV	FE-IV	FE-IV
Endogenous Variables:			Price & Prom	Price & Prom	Price & Prom
Regressors:	Coeff.				
Price of molecule *i*	γ_1	-0.925***	-8.693***	-4.467***	-2.701***
		(0.03)	(1.32)	(0.63)	(0.44)
Price of generic competitors (same *i* molecule)	γ_2	0.342***	6.643***		
		(0.05)	(1.07)		
Price of brand competitors (same *i* molecule)	γ_3	0.129**	0.730**	2.866***	
		(0.06)	(0.29)	(0.53)	
Price of generic competitors (other molecules)	γ_4	0.324***	0.264	0.611**	0.348
		(0.06)	(0.26)	(0.30)	(0.24)
Price of brand competitors (other molecules)	γ_5	0.304***	1.200***	1.605***	2.261***
		(0.08)	(0.37)	(0.40)	(0.38)
Promotion of brand competitors (same *i* molecule)	γ_6	0.065***	0.211**	0.386***	0.509***
		(0.02)	(0.09)	(0.13)	(0.10)
Promotion of brand competitors (other molecules)	γ_7	-0.061***	-0.323***	-0.585***	-0.501***
		(0.01)	(0.12)	(0.19)	(0.14)
Obs		60136	60136	9625	9625
Underidentification[a]			<0.0001	0.00029	0.00014
Endog_Test[b]			<0.0001	<0.0001	<0.0001
Hansen_pval[c]			.4493	0.7392	0.1903
Hansen_df			2	2	2

Notes: Robust standard errors clustered at molecule level in parentheses. * signif. at 10% level; ** signif. at 5%; *** signif. at 1%. Endogenous variables: Own price and promotion of competitors. Instruments: #Packages (linear and squared), Number of generic producers of the same molecule, and Number of producers of other molecules. [a] P-value for the Kleibergen-Paap rk statistics testing the null hypothesis that the model is under-identified. [b] P-value of C (GMM distance) test of endogeneity of own price and promotion of competitors. [c] Hansen J test of overidentifying restrictions with degrees of freedom reported in parentheses.

Focusing on column (2), the own- and cross-price elasticities for given generic producers of a same molecule (*e.g.* Barr and Teva fluoxetine) are large (resp. -8.693 and 6.643) and precisely estimated. This indicates that intramolecular competition is best described as undifferentiated Bertrand with no capacity constraints. By contrast, despite being bioequivalent, the originator drug behaves as a differentiated product, with a cross-price elasticity of 0.730. Still in column (2), the coefficient for the price of other genericized molecules within the same ATC3 has the right sign but is not significant.

As in the previous set of results, we observe a pattern of asymmetric competition: the price and promotion of other patent-protected molecules do exercise a significant constraint on genericized molecules. Hence, generic producers are between "a rock and a hard place": they face fierce competition from other generic producers of the same molecule, and the overall market share of this genericized molecule is constrained by the price and promotion of other on-patent molecules.

Last, in column (2), γ_6 the coefficient for the promotion of the originator's brand, has a positive sign and is significant. In our example, this would be the promotion for Prozac when the dependent variable is Teva fluoxetine or Barr fluoxetine. What this reflects is the well-known result that, absent significant differentiation, promotional effort also benefits direct competitors. In the context of our example, promotion for Prozac benefits generic producers of fluoxetine.

3.5. Simple (and direct) implementation of the Hypothetical Monopoly Test (HMT)

In the remainder of this section, we build on the results of Table 4 to gain insights on how changes in market structure (understood as variations in the number and identity of competitors) affects firms' pricing power. The exercise is driven by the conceptual underpinnings of the HMT: whether a *hypothetical* monopolist could profitably achieve a SSNIP (Small but Significant Non-Transitory Increase in Price).

To this end, we assume that firm *i* that only controls product *i* maximizes static profits:

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

where A_i is a demand shifter that depends of the competitors' prices and promotion, and ε is the own-price elasticity. The resulting pricing power obtains from the Lerner index, $\frac{p-c}{p} = -\frac{1}{\varepsilon}$ or equivalently a price-to-cost ratio $p/c = \frac{\varepsilon}{\varepsilon+1}$. From column (2) of Table 4, the own-price elasticity of a given generic producer is estimated to be $\gamma_1 = -8.693$. This implies a price-to-cost ratio equal to 1.13.

Next, we build counterfactual (hypothetical) scenarios, starting from different initial market structures. The aim of each of these exercises is to delineate the relevant antitrust market, conditional on a given degree of competitive rivalry. For instance, this allows us to assess whether a narrow market definition is warranted post LoE in markets that experienced large scale generic entry.

Scenario 1: merger between generic suppliers

The first scenario we contemplate is that of a merger between generic suppliers of a particular molecule *i*. Under these circumstances, the narrowest candidate market is molecular and

limited to non-originator producers. Hence, the HMT involves assessing whether a single firm gaining control over all the generic versions of molecule *i* could achieve a SSNIP. The challenge consists in estimating the price-to-cost ratio that would be chosen by such a firm and evaluate the price increase with respect to the initial situation. This exercise is a direct application of the HMT: if the price to cost ratio increases by more than 5%-10%, then the boundaries of the relevant market will have been identified.

We propose two simple avenues to address this question. First, we estimate a variant of equation (3) where we aggregate the quantities of all the generic producers of a given molecule, as a function of the average price of all these producers. The dependent variable then corresponds to the quantity market share of, say, all generic versions of fluoxetine (e.g. fluoxetine by Teva, Barr, Mylan, etc). The results are presented in column (3) and are meant to proxy a situation where there is a single generic producer alongside the originator. Applying the same profit maximization logic, the hypothetical entity would face a price elasticity of –4.5, yielding a price-to-cost ratio of 1.29. In comparison with an initial price-cost ratio of 1.13, this yields a price increase of 14%, meeting the HMT threshold. This is despite the fact the Hypothetical Monopolist would still be constrained by the originator (cross-price elasticity: 2.9), other branded drugs (1.6) and generics of other molecules (0.61).

A second, perhaps less straightforward, approach to implementing the HMT is to focus on the cross-elasticities estimates of column (2). 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:

$$(p_i - c)q_i + \lambda(p_j - c)q_j = (p_i - c)\, A_i\, p_i^{\varepsilon}\, p_j^{\chi} + \lambda(p_j - c)A_j\, p_i^{\chi}\, p_j^{\varepsilon}\,,$$

where χ is the cross-price elasticity. We find that an interior solution to this optimization problem only exists for χ and λ sufficiently small. For $\lambda = 1$ (full control of firm *j*), χ would need to be smaller than 0.3 to warrant an interior solution. Instead, the estimate in column 2 is 6.6, implying a corner solution. In other words, 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 (1.13).

While the two approaches produce different expected price increases (14% and 73%), both clearly identify a narrow antitrust market made up of a single molecule (and limited to generic

producers). Both estimates are below those that obtain from comparing drugs that have attracted a differing number of generic entrants. For instance, Scott Morton and Kyle (2012, Figure 12.6) provide "mirror image" evidence: price drops as a function of the number of entrants. They report that for molecules with 6 to 13 generic suppliers, prices are around 23% of the pre-LoE brand price.[25]

In our sample, the average number of generic producers per molecule is 11.45, which corresponds to a highly competitive environment. Thus, our approach consisting of adding up the market shares of the different generic producers is akin to having a single supplier, but that behaves competitively. Under this approach, the predicted price increase stemming from having a single generic supplier is bound to be conservative.

Scenario 2: from duopoly to monopoly on a molecular market

The logic of the above exercise carries over to answer the following question: would a hypothetical monopolist encompassing the originator and the generic versions of a particular molecule lead to a SSNIP? As compared to an initial situation corresponding to column (2), the answer is immediate: by transitivity, moving from the crowded market (11.45 generic producers) to a monopoly at the molecular level must result in a SSNIP, since a hypothetical monopolist limited to generic versions of the drug would impose a SSNIP.

However, the answer is less obvious if the starting point is a duopoly made up of the originator and a single generic producer. To answer that question, we re-estimated eq. (3) with the total quantity market share (i.e. generic versions plus the originator) as the dependent variable. The results of that exercise are displayed in column (4). 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 (a 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 now: $-8.693 + 6.643 + 0.730 = -1.32$, yielding a price-cost ratio of 4.125, which appears as unreasonably high. Still, this magnitude is not dissimilar to the point estimates reported in Table 2, column (6), and compatible with the price differences depicted in Scott Morton and Kyle (2012, Figure 12.6).

The section's findings are thus twofold. First, the two proposed methods to implement the HMT yield ranges for price increases that go from conservative to hikes that may be perceived

[25] As discussed above, the more pronounced price movements reported in Scott Morton and Kyle (2012) may, at least in part, reflect a selection bias.

as excessive. In that sense, the fact that both approximations yield the same market delineation, the resulting antitrust market should be considered as resting on solid foundations.

Second, the appropriate market definition is intrinsically linked to the competitive concern. To illustrate, it is possible to think of different merger scenarios. If the merger involves a subset of generic versions of a particular molecule, our results indicate that the relevant market should only encompass generic suppliers of that particular molecule, leaving out the originator. If the proposed merger encompasses the generic suppliers and the originator, then the adequate market should be limited to the particular molecule, i.e. excluding other originators or genericized molecules in the same ATC3. Last, if the proposed transaction involves originators that still benefit from exclusivity, the relevant market should not include genericized molecules in the same ATC3 class. A similar reasoning applies to case of foreclosure or abusive prices (cf. next section). These examples only serve to illustrate that the definition of the relevant market cannot be dissociated from the theory of harm.

4. Implications for ongoing cases

This section discusses the implications of our findings in terms of enforcement in cases of foreclosure ("exclusionary abuse") and excessive (or unfair) pricing ("exploitative abuse").[26] Imagine an originator company selling a blockbuster drug in a crowded market (a situation akin to our sample). In terms of revenue, the firm is the largest seller, but only commands a 20-to-30% market share. That firm successfully manages to temporarily block generic entry by combining "pay for delay settlements" with input foreclosure.[27] According to our estimates in Section 3, once large-scale generic entry eventually occurs, the (average) price of the drug should drop by about 30-55% (most observed price dynamics after generic entry in our sample fall in that range). This magnitude provides a clear indication of the rents that accrued to the incumbent because of (temporary) foreclosure and the resulting consumer harm.

Market shares

To deal with unilateral behavior (the input foreclosure described above), the EU Commission relies on Art. 102 of the TFEU (abuse of dominance). Current practice requires that the market share of the firm under investigation be above a certain threshold (typically, 40%-50%) to

[26] As indicated by the hypothetical examples in section 2, our results are also relevant for mergers. We omit merger enforcement in this section, as we are unaware of ongoing mergers for which our results would provide useful insights.
[27] "Pay for delay" refers to situations whereby originators launch court proceedings alleging IPR violations against generic producers who are about to launch a generic version. Typically, the parties settle prior to the ruling, with the originator compensating the generic producer. These agreements are also labelled as "reverse payment settlements" as the compensation from the (allegedly) aggrieved party (the originator that claims its IPR are not respected) and not the other way around. In the US, the *Actavis* case made it to the Supreme Court. (Aaron *et al*. 2013).

establish "dominance". In addition, according to our reading of case law, a finding of abuse requires that the firm be dominant at the time of the allegedly illicit behavior (i.e. prior to generic entry in our example). This is often referred to as the "concomitance requirement".

4.1 Foreclosure

In the hypothetical case described above, a narrow application of the market share threshold criteria combined with concomitance would not allow for the opening of proceedings (market share below 40%-50% at the time of the abuse). This, despite direct evidence of that foreclosure led to (i) significant consumer harm in the form of higher prices and (ii) additional rents for the incumbent. There are three avenues to address this conundrum. We first dwell on two of them, highlighting their limitations. We then argue that the theory of harm should guide market delineation. This third avenue meets the concomitance and dominance requirements; the novelty lies in identifying antitrust markets that had not yet emerge at the time of the infringement.

First avenue: under-enforcement

The first is to refrain from pursuing the infringement on the basis that the concomitance condition (high market share at the time of the abuse) is not met. This entails the risk of significant Type II errors: an abuse of dominance left unprosecuted. Type-II errors are a likely concern in the pharmaceutical industry since large markets (with one or more blockbuster drugs) attract entry in the form of me-too drugs, resulting in low market shares. While entry may dampen price hikes, margins (measured as the price to cost ratio) and sales remain high pre-LoE, even in crowded markets. These are situations where (i) market shares are unlikely to meet the dominance threshold[28] and (ii) the incentive to foreclose is strong. Turning a blind eye on foreclosure would lead to consumer harm.[29]

Second avenue: narrow market definition pre-LoE

The second avenue consists of defining narrow markets prior to generic entry. With that approach, market share thresholds and concomitance requirements are –formally– met. Two sophisticated competition authorities, the EU Commission and the UK's Competition and Markets Authority (CMA), went down that route, defining molecular markets pre-LoE.

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[28] Market shares may be sufficiently high at the launch of a new treatment of superior efficacy. However, if the market is large enough, the launch of me too drugs (which may or may not be superior in terms therapeutic efficacy) will follow. Examples abound: treatment of high blood pressure, depression, or cholesterol. Since generics' foreclosure is a late stage development, the market is likely to be crowded and individual market shares below the critical threshold.

[29] Glasner and Sullivan (2019) identify a similar "market definition issue" in the context of merger control. There may be instances whereby allowing a merger would leave prices unchanged in the relevant market, but that they would fall if the transaction were blocked. In such a case, the merger entrenches market power. According to these authors, "If entrenchment theories are not used to challenge mergers, that choice should be should be made explicitly as a matter of policy—not because the mechanics of market definition inadvertently preclude bringing such cases".

Presumably, this was driven by the case law pertaining to the application of Art. 102 or Section 2 of the UK's Competition Act. We briefly describe two cases of generic foreclosure and how they unfolded.

In the Servier case, the EU Commission imposed a fine for violations of Art. 101 and Art. 102; our comments only to apply to the "abuse of dominance" (Art. 102) leg of the Decision. [30] The EU Commission deemed that Perindopril (an ACE inhibitor to treat hypertension) and its generic versions formed an antitrust market on their own.[31] This conclusion was largely motivated by the observation that the drop in price associated with generic entry into other anti-hypertensive drugs did not seem to dent the sales of Perindopril (in Section 2, we highlighted that this is a common outcome in the industry, even when two drugs are substitutes). In a similar case, the UK's CMA established that the relevant market was molecular in the context of the Paroxetine, a Selective Serotonin Reuptake Inhibitor (SSRI, an antidepressant) initially produced by GSK.[32] The CMA also relied on the lack of price response following competitors experiencing LoE.

Our reading of these cases is that there is prima facie evidence of consumer harm resulting from foreclosure (inflated prices beyond the –legitimate– period of exclusivity). The extent of consumer harm can be gauged by the observed –delayed– price drops once it materialised. At the same time, the "market share at the time of the abuse" requirement has apparently led competition authorities to define excessively narrow markets prior to generic entry, despite evidence pointing to the contrary.

Both Servier and GSK appealed pointing to vigorous intermolecular competition among patent protected molecules. In Servier, the EU's General Court (GC) issued its ruling on 12/12/2018.[33] The GC found that the Commission had committed a series of errors in its analysis of the relevant market (§ 1589) and thus annulled the part of the Decision that was based on the finding that Servier held a dominant position. In particular, it found that the European Commission had not properly evaluated the role played by non-price competition when establishing market boundaries. In the Paroxetine case, the UK's Competition Appeals Tribunal (CAT) rendered its judgement on March 8, 2018.[34] Regarding the alleged violation

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[30] European Commission Decision, Case AT.39612 – PERINDOPRIL (SERVIER), July 9 2014.

[31] In recital # (2549), the Commission concluded that: "The relevant market is defined as comprising of original and generic perindopril in each of the four national markets defined above".

[32] Competition and Markets Authority, Case CE-9531/11, 12/02/2016. The CMA concluded (# 4. 97 of the Decision) that: "On this basis, the CMA finds that the relevant market in this case is no wider than the supply of paroxetine in the UK."

[33] General Court of Justice, Ruling of 12. 12. 2018, Case T-691/14

[34] Competition Appeals Tribunal, Case Nos 1251-1255/1/12/16

of Section 2 of the UK's Competition Act, the CAT wondered whether GSK was dominant prior to generic entry and was not convinced by the CMA's analysis.[35]

Hence, the posterior judicial review by the EU's General Court and the UK's Competition Appeals Tribunal (CAT) highlight the pitfalls associated with a narrow, time invariant, market definition. Both the CAT and GC rulings pointed to intermolecular competition prior to LoE.

Based on our framework of analysis, we venture to label the Servier and GSK/Paroxetine cases as Type III errors: the correct decision based on an incorrect premise (with the null hypothesis defined as no competition infringement).[36] Both involved significant consumer harm, but the infringers were not "dominant" at the time of the abuse in the sense that they did not command a sufficiently large market share on the observable market at the time.

Third Avenue: market definition contingent on the competitive concern

Thus, these two avenues present significant limitations, opening the door to either type-II or type-III errors. If either (or both) errors are frequent, abusive behavior may be emboldened.

We thus propose a third avenue to resolve this apparent tension: explicitly recognize that an "idealized" and "unique" antitrust market does not exist. We argue that, as a consequence, the definition of the relevant antitrust market should be contingent on the (actual or potential) competitive concern. As indicated above, this approach has been discussed for some time but enforcers and courts have so far been reluctant to endorse the approach, at least in the European Union. In the post scriptum below, we return to the Paroxetine and Servier cases as they may lead to a reassessment of past practice.

In terms of the two cases described above, this approach would naturally lead to a molecular market. Neven and Siotis (2020) argue that this avenue fits the circumstances of generic foreclosure particularly well. First, market definition should serve to identify the transactions that could be affected by an infringement (Glasner and Sullivan 2020). In a case of pre-emption, the relevant transactions are the ones that would take place if entry were to materialise. Second, in the EU, dominance is defined as "a position of economic strength enjoyed by an undertaking that enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers, and ultimately consumers".[37] If the relevant

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[35] More precisely the CAT (§ 402) found that "There was a large degree of therapeutic equivalence between paroxetine and other SSRIs. They provided some competitive constraint in that they stimulated GSK's promotional efforts to persuade doctors to prescribe paroxetine. Thus we accept that before generic companies became potential entrants, paroxetine probably did not constitute a separate market"

[36] Glasner and Sullivan (p. 29) make a similar point in the case of *Cellophane* "To make the point another way, what the Court did in *Cellophane* was not so much define the wrong market as define the right market for the wrong question".

[37] European Court of Justice, 1978, United Brands, case 27/76, §65.

market includes potential entrants, the incumbent is in position of economic strength because of (temporary) exclusivity. Moreover, the incumbent is not constrained by other incumbents in its endeavour to exclude generics. Third, under EU case law, an abuse is often associated with an ability to alter market structure and hinder the growth of competition. On that count too, foreclosure of generics fits the bill.

Hence, the nature of the infringement naturally leads to a market definition exercise that takes as a starting point the originator and the generic suppliers of the drug.[38] As our empirical results indicate, a HMT is likely to confirm that this is the relevant antitrust market. While this market has not yet emerged at the time of the abuse (or rather, it has not materialized because of it), this is the *relevant* market.

In the Servier and GSK/Paroxetine cases, we conjecture that, having correctly identified the relevant markets to be molecular post-LoE, competition authorities felt compelled to define molecular markets pre-LoE, even though the evidence was pointing in the opposite direction, as evidenced by the judicial review. Authorities were looking for dominance (high market share) on a market that was not the relevant one.

Acknowledging that, for enforcement purposes, the market definition exercise should be made contingent on the nature of the infringement leads to the conclusion that (i) the boundaries of the relevant market may change at the time of the (potential) entry of generic producers and (ii) the relevant market can narrow down to the molecular level ex post. The empirical evidence reported in the previous section indicates that this is compatible with a multi molecular market definition pre LoE. The advantage of this contingent market definition approach is to avoid the need to define unrealistically narrow markets prior to generic entry. Properly identifying the relevant market, even if it has not yet emerged at the time of infringement, would reduce the risk of Type III errors.

Post scriptum on Servier and GSK/Paroxetine

As mentioned above, both authorities had relied on the lack of a price response following the launch of cheaper (generic) versions of competitors' molecules to define narrow markets. One notable difference between the two cases is that the CMA noted that a HMT applied at the molecular level with post entry prices would have pointed to a narrow market.

The CMA's stance would thus seem to be compatible with a market definition that is contingent on the nature of the alleged infringement. In addition, the CAT clearly recognized

[38] Our results indicate that a market solely comprising generic suppliers would meet the HMT price increase threshold. A fortiori, a molecular market also including the originator (as in Servier and GSK Paroxetine) would also pass the HMT.

that other on-patent drugs exercise less competitive pressure as compared to generics.[39] The CAT wondered whether the constraint by generics that are not yet on the market, but will soon be, ought to be taken into account when defining the relevant market. As the CAT noted (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" (emphasis in the original). The Court recognized "that this approach is novel" (recital 403). In order to clarify the matter, the CAT requested a preliminary ruling from the European Court of Justice (ECJ) on March 27, 2018.[40] In January 2020, the ECJ ruled that, as long as generic competitors have made preparation such that they are in a position to enter with sufficient strength (i.e. entry is "imminent"), generics exercise a competitive constraint that should be taken into account in the market definition (even if is not clear whether entry is at all feasible as the process patent might be valid).[41]

This ruling will have a bearing on the Servier case, where the Commission's appeal of the EU General Court's December 2018 ruling is pending before the European Court of Justice. At this stage, we can only note that the request from the CAT and the ensuing ECJ ruling do not resolve the underlying issue. As Neven and Siotis (2020) note, the ECJ's approach "allows originators seeking to foreclose generics to escape the discipline by acting before entry is imminent".

4.2 Exploitative abuse (abusive prices)

Our results also have a direct bearing on potential abuses post generic entry: this is a situation in which the initial market has "shrunk": rivalry is primarily intramolecular. In economically significant markets, large-scale entry ensures a competitive outcome: with no capacity constraints the own and cross-price elasticities reported in Table 4 point to a Bertrand outcome. The converse implication is that a single supplier would have the opportunity to exercise significant market power, absent regulatory constraints. Since free pricing is the default rule in genericized markets, our results suggest that a single generic supplier would be in a position to extract monopoly rents.

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[39] Recital 402 of the aforementioned judgement.

[40] A request for a preliminary ruling to the ECJ is aimed at ensuring that national courts adequately interpret EU law. In the case at hand, the CAT's question was :*"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?"

[41] In its preliminary ruling, the ECJ found that the competitive constraint from generics should be taken into account 'if the manufacturers concerned of generic medicines are in a position to present themselves within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine already on the market' (§133). Case C-307/18, Generics (UK) Ltd and Others v Competition and Markets Authority, January 22 2020.

A number of recent cases support our inference of narrow (molecular) antitrust markets post-LoE. Aspen, a South African generic producer, purchased the rights of a series of anti-cancer treatments from Glaxo Smithkline (GSK). The patents for these four active ingredients (chlorambucil, melphalan, mercaptopurine, tioguanine and busulfan) had lapsed long before. These active ingredients are used in drugs sold in the EU under different formulations (tablets or injections) and different brand names (*e.g*. Cosmos in Italy).[42] After purchasing the rights, Aspen imposed very significant price increases in a number of EU countries, among them Italy. When the Italian health authority manifested its reluctance to pay inflated prices, it was threatened with withdrawal of supply. Through these tactics Aspen obtained high price increases, ranging between 300% and 1500% of the initial prices. The Italian Competition Authority (ICA) opened proceedings and concluded that this practice was unfair. The ICA noted that the evolution of Aspen's costs could not reasonable such price increases. In May 2017, the EU Commission opened proceedings against Aspen related to its practices in various Member States (except Italy).[43]

Aspen would not have been able to impose such price increases had it been competing with other generic producers of the same molecules.[44] Aspen was a *de facto* monopolist on the molecular market, and acted accordingly; this behaviour also appears to be at the core of the EU's proceedings. The question then arises as to whether Aspen's high price would have attracted entry on that market. While it is not possible to reach a definite conclusion, two remarks are in order. First, the fact that patent protection had lapsed does not mean that entry is costless, let alone immediate. Second, it is not clear that a potential entrant would be attracted into a market where margins would be quickly driven back to the competitive level (the zero profit Bertrand duopoly). Hence, it is doubtful that potential entry of near perfect substitutes would have disciplined Aspen's behaviour.[45] Presumably, Aspen's price increase was restrained by the risk of triggering intermolecular competition. In other words, price was set at a level that prevented a *widening* of the relevant market.

At the time of writing (November 2020), Aspen had entered in settlement discussions with the EU Commission.[46] In exchange for the EU Commission ending proceedings, Aspen has offered to reduce its prices by 73% on average, across the European Economic Area.[47]

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[42] Prior to the sale of the rights by GSK to Aspen, prices were *de facto* capped.

[43] Commission Press Release IP/17/1323, available at: https://ec.europa.eu/commission/presscorner/detail/en/IP_17_1323

[44] Note that the number of competing generic producers also matters to achieve the competitive outcome (see, *e.g.* Reiffen and Ward, 2005).

[45] This is an illustration of the limits of "contestability theory" in its simplest form.

[46] A settlement, if reached, involves commitments by the party under investigation (Aspen in this case) in exchange for the competition authority (EU Commission) to close proceedings and hence not adopt a formal decision (exonerating or imposing a fine). Settlements are made possible on the basis of Article 9 of the EU's 2003 antitrust Regulation.

[47] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1347

Interestingly, this settlement offer to re-establish competitive pricing is within the range implied by our estimates. The EU Commission has since launched a consultation on these commitments, requesting the opinion of interested third parties to manifest whether Aspen's proposed course of action would address the competitive concerns identified by the EU Commission.

The UK's Competition and Markets Authority (CMA) has also been actively pursuing cases of alleged abusive pricing. In one instance, an originator (Pfizer) "colluded" with a generic producer to raise prices. The core of the case is built on the fact that, in the UK, the pricing of generic drugs was unregulated. Pfizer had developed an anti-epilepsy drug phenytoin sodium sold under the brand name Epatunin. In 2012, Pfizer ceded the distribution of the drug to Flynn who then sold it as a generic, unbranded, product. Because branded drugs were subject to price controls and generics were not, the change of ownership allowed the companies to raise the price by as much as 2600%. Annual National Health Service spending on the drug shot up from £2m to £50m. In December 2016, the CMA imposed a fine of more than UK£84 million to Pfizer, and Flynn more than 5 million.[48]

Our estimates (cf. Section 3) indicate that post LoE, a HMT points to molecular markets. The results also indicate that the relevant market may be even narrower, and limited to generic suppliers (i.e. not encompassing the originator). The Aspen case provides support to that conclusion: a monopolist on the generic market did achieve a very significant SSNIP. As regards Pfizer/Phenytoin, the alleged "collusion" between the originator and a single generic producer, our findings indicate that a HMT would point to a slightly broader molecular market that encompasses both generics and the originator. This corresponds to the second scenario presented in Section 3.5. Again, the Pfizer/Phenytoin case confirms that a monopolist on the molecular market would result in a substantial SSNIP.

The upshot is again one of defining the *relevant* market conditional on the alleged abuse. When the risk of abuse is confined to the market for generics, the relevant market is limited to the different producers of a same generic. When the risk of abuse stretches involves both the originator and its generic equivalents, the relevant market is that of the molecule.

5. Conclusion

Market definition is built around the identification of competitive constraints. The Hypothetical Monopoly Test (HMT) is a thought exercise geared towards identifying which limitations to pricing power must be neutered to achieve a profitable SSNIP. While the HMT

[48] The parties appealed to the Competition Appeals Tribunal who quashed the initial ruling and sent the case back to the CMA in June 2017. The basis of the decision is that the CMA had not proven that the prices were abusive.

rests on solid analytical foundations, it is rarely directly applied. Instead, competition authorities rely on approximations (e.g., diversion ratios) to delineate antitrust markets.

This paper was initially motivated by the controversies surrounding market definition in the context of unilateral behaviour in the pharmaceutical industry. The market delineation established by two sophisticated enforcement agencies, the EU Commission (Servier) and the UK's CMA (GSK/Paroxetine) failed to convince the competent courts. Enforcers defined narrow markets that yielded the "required" market shares to allow for the cases to be prosecuted, despite abundant evidence of vibrant competition among drugs. While the two cases are pending a final ruling, there can be little doubt that the issues they raise are non-trivial.

The pharmaceutical industry represents an interesting laboratory: it is replete with competitive shocks across numerous markets in the form of generic entry. In addition, non-price competition plays a prominent role and detailed product level data are available. For a given set of products, the variation in market structure and competitive dynamics allows for a direct application of the HMT. The HMT requires the identification of a competitive baseline. Conditional on the theory of harm, the frequent quasi natural experiments associated with generic entry provides a clear indication of what the relevant competitive baseline price is.

In the event of a proposed merger involving on patent drugs, prevailing competitive conditions (and prices) are natural inputs to identify the candidate market. However, one caveat applies: despite belonging to the same therapeutic class, genericised molecule should generally not be included the relevant market – this is because they do not appear to exercise a meaningful competitive constraint. By extension, the same would apply to a soon-to-be genericised molecule, as merger evaluation is forward looking. By contrast, in a case of generic foreclosure, the reference competitive prices are the ones that would obtain absent the infringement. Hence, competitive conditions prevailing prior to generic entry are largely irrelevant.

Our empirical results clearly indicate that the market definition exercise must be contingent on the nature of the alleged competitive infringement, i.e. the theory of harm. As noted by Glasner and Sullivan (2019, p. 52): "Because there is no economically meaningful natural market, relevant markets must be analytic devices. Because analytic devices are tied to the subject of analysis, relevant markets can be defined only by reference to specified theories of harm". What our paper does is to provide a concrete and quantified illustration of the ontological relationship between the theory of harm and a cogent market definition. Accepting this premise may hopefully reduce the risk of what we christened Type III errors on the part of enforcement agencies.

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APPENDIX

Table A1: List of Branded Drugs Losing Patent Protection

Brand Name	Generic Name	Generic Entry Date	Brand Name	Generic Name	Generic Entry Date
Ansaid	Flurbiprofen	1994q2	Navelbine	Vinorelbine	2003q1
Axid	Nizatidine	2001q3	Nolvadex	Tamoxifen	2002q4
Blenoxane	Bleomycin	1996q3	Pepcidine	Famotidine	2001q2
Bumex	Bumetanide	1995q1	Plaquenil	Hydroxychloroquine	1995q3
Calcijex	Calciox	2003q1	Platinol	Cisplatin	1999q4
Capoten	Captopril	1995q4	Prozac	Fluoxetine	2000q3
Capozide	Captopril+Hydrochlorothiazide	1997q4	Questran	Colestyramine	1996q3
Carafate	Sucralfate	1996q4	Relifex	Nabumetone	2001q3
Cardura	Doxazosin	2000q4	Retin-A	Tretinoin	1998q2
Ceclor	Cefaclor	1994q4	Rocaltrol	Calcitriol	2001q4
Cerubidine	Daunorubicin	1998q2	Seroxat	Paroxetine	2003q3
Ciproxin	Ciprofloxacin	2003q2	Serzone	Nefazodone	2003q3
Cordarone	Amiodarone	1998q2	Staril	Fosinopril	2003q4
Cylert	Pemoline	1999q2	Tagamet	Cimetidine	1994q2
Cymevene	Ganciclovir	2003q3	Tambocor	Flecainide	2002q1
Cytotec	Misoprostol	2002q3	Taxol	Paclitaxel	2000q4
Daypro	Oxaprozin	2001q1	Tenex	Guanfacine	1995q4
Dormicum	Midazolam	2000q2	Ticlid	Ticlopidine	1999q2
Drogenil	Flutamide	2001q3	Toradol	Ketorolac	1997q2
Duricef	Cefadroxil	1996q1	Ultram	Tramadol	2002q2
Floxstat	Ofloxacin	2003q3	Unat	Torasemide	2002q2
Flumadine	Rimantadine	2001q4	Urispas	Flavoxate	2003q4
Heitrin	Terazosin	1999q3	Vaseretic	Enalapril+Hydrochlorothiazide	2001q3
Hydrea	Hydroxycarbamide	1995q4	Vasotec	Enalapril	2000q3
Lariam	Mefloquine	2002q2	Viroptic	Trifluridine	1996q2
Leponex	Clozapine	1997q4	Voltaren	Diclofenac	1995q3
Lodine	Etodolac	1997q1	Zantac	Ranitidine	1997q3
Losec	Omeprazole	2002q4	Zavedos	Idarubicin	2002q3
Mevacor	Lovastatin	2001q4	Zestoretic	Hydrochlorothiazide+Lisinopril	2002q2
Mexitil	Mexiletine	1995q2	Zestril	Lisinopril	2002q2
Mutamycin	Mitomycin	1995q2	Ziac	Bisoprol+Hctz	2000q3
Myambutol	Ethambutol	2000q2	Zovirax	Aciclovir	1997q2