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Evolving market boundaries and competition policy enforcement in the pharmaceutical industry

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Abstract

Competition investigations start with market definition, which establishes the perimeter of the competitive analysis. In this paper, we focus on the definition of economic markets in the pharmaceutical industry, where the entry of generics in different therapeutic areas provides a sequence of quasi-natural experiments involving a significant competitive shock for the originator producer. We show how generic entry modifies price and non-price competitive constraints over time, generating market-wide effects. Paradoxically, generic entry may soften the competitive pressure for brands other than the originator. We obtain these results by econometrically estimating time-varying price elasticities. We then apply the logic of the Hypothetical Monopolist Test to gauge the strength of competitive constraints under different market structures. Our results provide strong empirical support for an approach that defines relevant markets contingent on the theory of harm. We discuss the relevance of these findings in the context of ongoing cases.

Keywords Market definition · Pharmaceutical industry · Competition policy · Antitrust

JEL Classification D22 · I11 · L13

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).

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1 Introduction

Maintaining competition in the pharmaceutical industry has long been a challenge for regulators and competition authorities. The entry of an increasing number of generics should have "naturally" led to more competition and shrunk profit margins. Generic penetration is indeed high: the generics' share of market *volume* has increased substantially, reaching 85% of drug prescriptions in 2016 (Bosworth et al., 2018). However, in terms of value, they commanded a market share of 19% in the US, 26% in the UK, 21% in Germany, and below 20% in France, Belgium, and Switzerland, with similar figures in other countries (Statista, 2020).[1]

Before any potentially anti-competitive behaviour can be assessed, "a" relevant market must first be defined. Doing so can identify economically significant competitive constraints on a specific firm (or set of firms). Firms' exercise of market power is constrained by demand- and supply-side substitution, as well as by potential entry. Assuming an initially competitive context, market definition involves identifying which of these constraints ought to be countered (e.g., through exclusion or a merger) for the firm (or the set of merging firms) to exercise significant market power.

In this paper, we gauge whether competitive constraints evolve as a consequence of the "genericization" of a particular molecule in a therapeutic market. We show that traditional (often implicit) assumptions about the shape of the relevant market must be re-assessed in the case of the pharmaceutical industry. In particular, we find that the entry of a generic alters market boundaries, decreasing the relevance of analyses based on pre-entry data for anticipating ex-post market power, and vice versa. For instance, a Hypothetical Monopolist with control of all generic versions of a single molecule (but not of the originator) would be able, on average, to bring about a Small but Significant Non-transitory Increase in Price (SSNIP) of at least 5%-10%, despite the presence of substitutes. That is, the market for generics of a given originator drug represents a *relevant economic market* (or *relevant market* for short) on its own. Concomitantly, we observe a (post entry) *drop* in the elasticity of substitution between the drugs that had been competing with each other prior to the entry of a generic. In other words, generic entry produces a *softening of intermolecular competition.*

Our analysis is, in part, inspired by a number of recent competition enforcement decisions where market definition was pivotal. While market definition is often a fairly routine exercise, in a number of cases it turned out to be central: Servier/Perindopril[2] (EU), GSK/Paroxetine (UK),[3] and Vyera/Daraprim and Boehringer Ingelheim/Aggrenox (US), all reviewed in Sect. 4.

[1] https://www.statista.com/statistics/205036/proportion-of-brand-to-generic-prescription-sales/.

[2] European Commission Decision, CASE AT.39612—Perindopril (Servier), 9 July 2014. Siotis was working 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 and rely solely on the published decision and judgment.

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

In the Servier case,[4] the EU's General Court concluded that the EU Commission had "made a series of errors in defining the relevant market."[5] At the time of writing, the appeal to the European Court of Justice (ECJ) brought by the Commission is pending resolution. In GSK/Paroxetine, the UK's Competition Appeals Tribunal (CAT)[6] upheld the Competition and Markets Authority's finding of abuse, but adopted a different line of reasoning to delineate the relevant market. In Daraprim, the Federal Trade Commission (FTC) observed that a sustained price hike was direct evidence pointing to a narrow market. Meanwhile, in the Aggrenox case, the Connecticut District Court[7] reasoned that the post-generic entry price drop was direct evidence that the *relevant* market only included Aggrenox and its generic versions.[8] The econometric evidence reported below is consistent with the cogent economic reasoning of the CAT, FTC, and Connecticut District Court, while the ECJ has not yet pronounced itself.

To identify relevant markets in the pharmaceutical industry, we estimate residual demand functions under different market structures (Baker & Bresnahan, 1985; Scheffman & Spiller, 1987). Our empirical exercise is (conceptually) inspired by the logic of the Hypothetical Monopolist Test (HMT). While this approach rests on solid conceptual foundations, operationalizing the HMT is challenging.[9] 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, authorities have relied upon econometric estimations of demand elasticities.[10] Although the residual demand approach and the HMT have their differences,[11] both focus on the ability to raise prices above some competitive benchmark.

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

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

[6] Competition Appeals Tribunal, Supplementary Judgement, Case Nos: 1251–1255/1/12/16, 10 May 2021.

[7] United States District Court of Connecticut, Memorandum of Decision and Order, No. 3:14-md-2516 (SRU). 8 August 2016.

[8] The Court reached this conclusion in the context of rejecting a request for extensive disclosure. The latter was filed in an attempt to show that the *relevant* market was broader.

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

[10] In practice, demand-side substitution has been the main focus of competition authorities in the determination of antitrust market boundaries. For (rare) examples of the use of econometric techniques to delineate antitrust markets, see Ekelund et al., (1999), Argentesi and Ivaldi (2007), Ivaldi and Lorincz (2011) and Elizalde (2013).

[11] The HMT takes the narrowest product and geographical market as a starting point and evaluates whether a hypothetical monopolist would find it profitable to increase price by 5%-10%, assuming that all other prices remain fixed. In addition, all our results are averages across markets, while the HMT is built on a specific product (or initial set of products). We are grateful to an anonymous referee for highlighting the differences between the HMT and our approach.

In line with most panel econometrics approaches, we rely on the concept of an economic market (in the sense of Marshall 1920).[12,13] More precisely, we approach market delineation by estimating residual demands that factor in competitors' reactions. The estimation of own and cross-price elasticities allows for the identification of the source and strength of the competitive constraints faced by firms (Davis and Garcés 2010). This is in line with the European Commission's emphasis on (demand) substitution to delineate markets.[14] Baker and Bresnahan (1985) and Scheffman and Spiller (1987) pioneered the implementation of the residual demand function approach in order to delineate antitrust markets for enforcement purposes.

Markets for prescription drugs are well suited to the residual demand approach. First, extremely rich product-level data are available. The dataset at our disposal comprises individual prices, quantities and promotional efforts for 125 molecules sold in the US over forty quarters.

Second, markets are exposed to frequent competitive shocks in the form of generic entry, which can be precisely identified and timed. Generic entry (GE) occurs frequently, and its timing is essentially exogenous to initial market conditions: most often, the trigger is the expiration of patents that were filed several decades earlier. In our sample, 64 molecules in 31 different candidate markets lost exclusivity during the period of analysis.

We exploit GE episodes as a competition shock that can be used to measure the initial level and the change in competitive pressure faced by originators that still benefit from exclusivity. A defining feature of our procedure is the identification of the set of drugs that exercise competitive pressure on one another. More precisely, we begin our analysis by estimating cross-price elasticities, distinguishing between generic and branded competitors. Our results suggest that, on average, intermolecular competition is vibrant prior to GE, pointing to broad relevant markets comprised of various drugs. We also find that GE generates market-wide shockwaves that reshape the nature and strength of competitive constraints. On average, the entry of generic competitors for one drug *shrinks* the initial relevant market: the genericized drug "drops out" in that it no longer constrains the pricing power of the drugs that still enjoy exclusivity. In other words, the intensification of *intra*molecular rivalry resulting from GE softens *inter*molecular competition.[15] This occurs because a previously significant competitive constraint fades into economic insignificance. We use this preliminary analysis as a guide for identifying potentially relevant markets.

Given the implication of the above, namely that market boundaries may be very narrow, we focus on generic producers of a given molecule—the narrowest possible market we can possibly identify with our data. Unsurprisingly, we find that own- and

[12] A classically defined market is "that area and set of products within which prices are linked to one another by supply- or demand-side arbitrage and in which those prices can be treated independently of prices of goods not in the market" (Scheffman and Spiller, 1987, pp. 124–125).

[13] We are grateful to an anonymous referee for pointing this out.

[14] European Commission (1997), "Commission Notice on the definition of relevant market for the purposes of Community competition law," Official Journal (97/C 372/03).

[15] *Intramolecular* rivalry encompasses both competition between the originator drugs and their 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.

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. With such estimates, we can proceed to more formal hypothetical monopoly tests (HMT), which we describe in Sect. 3.

Taken together, our empirical findings point to the existence of multiple candidate markets that are relevant for enforcement purposes.[16] Our empirical results, which identify the "average effects" on an "average product" in a large market, indicate that intermolecular competition is vibrant prior to GE, largely driven by non-price instruments. Post-GE, the molecule becomes a relevant market where price competition is rife. Indeed, the relevant market post-GE may be even narrower: generic versions (i.e., excluding the originator) may constitute an antitrust market. This serves to highlight that there is no "natural" or "unique" definition of the antitrust market: the delineation of the relevant market cannot be dissociated from the nature of the competitive concern, i.e., the theory of harm.

The consubstantial nature of market definition with the theory of harm can be illustrated with simple examples inspired by the results of Sect. 3. Imagine a market composed of three originator drugs, *A, B*, and *C*. *C* is the market leader with a 70% market share, while *A* and *B* each command a 15% share. These drugs initially benefit from exclusivity and hence significantly constrain each other, such that a firm controlling all three would be in a position to profitably and sustainably increase prices by 5–10% (or more). Thus, if the concern is coordinated behaviour, the candidate market should consist of *A*, *B,* and *C*.

In the context of generic foreclosure, the exercise involves evaluating the competitive constraints the infringing firm faces in both factual and counterfactual (i.e., absent the behaviour that is a source of concern) terms. For instance, in the case of generic foreclosure by *B*, the relevant competitive constraint is exercised by the generic version of *B*, and the relevant antitrust may well be molecular, even though the molecular market has yet to emerge, and despite the molecule's comparatively low initial market share. The reason is that, following generic entry, a hypothetical monopolist limited to molecule *B* may be able to achieve a significant and profitable price increase over and above the competitive benchmark price.

With respect to mergers, our analysis indicates that, for a given theory of harm, market delineation may change in the event of generic entry. This is because vigorous intermolecular competition may vanish quickly if the drugs competing with those of the merged entities experience GE. 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 product launches in the near future, the merger between *A* and *B* would create an entity that could rapidly gain significant market power. The reason underpinning *C*'s competitive constraint fading into irrelevance is the dramatic drop in promotional spending that follows GE (Castanheira et al., 2019; Lakdawalla & Philipson,

[16] "Candidate markets" encompass the narrowest combination (group of) products and geographic areas that fulfil a SSNIP.

2012).[17] Such a situation would represent an instance of Type II error (an anticompetitive merger being waved through).

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. 2005, and Glasner & Sullivan, 2020 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 Sect. 3, we describe the data, implement our empirical analysis, and gauge how competitive constraints evolve over time. We also assess pricing power under different market structures. Section 4 discusses the potential implications of our results in light of past and ongoing cases. Section 5 concludes.

2 Competitive dynamics in the pharmaceutical industry

The Anatomical Therapeutic Chemical (ATC) classification groups drugs at different levels of aggregation, numbered 1–5. The ATC3 level encompasses the set of potential treatments for a given medical condition. As such, ATC3 groupings represent the potential substitute products that a given "customer"—here a patient-doctor pair—have at their disposal to address a medical condition. The EU Commission routinely uses ATC3 groupings as an initial step in defining a relevant market (Greenaway et al., 2009).

The definition of a "relevant market" 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, high promotion intensity,[18] regulation, and information asymmetries generates particularly complex competition dynamics. In such a

[17] The drop in promotion is an equilibrium effect, whereas the HMT logic involves assessing unilateral behaviour by one (or more, in the case of a merger) firm(s), assuming that other firms' behaviour remains constant. The argument can be reformulated in terms of a change in the factual: in the event of generic entry, firm *A* 's and *B* 's ability to increase price will be evaluated in an environment in which the price of molecule *C* is lower, but also where *C*'s promotion expenditures are insignificant. As a result, demand substitution towards *C* faced by *A* and *B* will be significantly lower.

[18] According to the 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.

context, market shares and competitors' price reactions, two standard indicators of market power, are less informative.[19]

2.1 Market shares

Market shares are often used as a screening device to gauge market power (Motta, 2004). However, the mapping of market 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 informed by the workings of the pharmaceutical industry, Lipatov et al. (2021) document the possibility that consumer welfare may be higher in concentrated markets. They also show that, somewhat surprisingly, the benefits of entry may be greater in less concentrated markets. These findings suggest that market shares (even derived from properly defined markets) may not be particularly informative for inferring potential harm (or its absence) 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 in the factual and counter-factual scenarios.[20] Under such circumstances, large rents are direct evidence of dominance (Browdie et al., 2018), making the calculation of market shares less relevant.

2.2 Competitors' and consumers' reactions to price fluctuations

Patents offer 20 years of intellectual property rights (IPRs) to the firm that develops a new potential treatment.[21] Patent expiration triggers a unique competitive shock as generics, which are near perfect substitutes, legally compete with the originator. These generics are often sold at less than half the price of the original branded product and quickly erode the originator's market share (Grabowski et al., 2014; Scott Morton &

[19] In the presence of non-price competition, price (and movement thereof), is not a sufficient statistic to either assess competitive intensity or consumer welfare. In pharma, non-price competition takes the form of promotional effort. A vast literature, spanning economics, management, psychology (and more) attempts to disentangle the informative (welfare enhancing) vs persuasive (market power enhancing) content of promotional effort. As observed by Sutton (1991), the underlying reason as to why advertising/promotion affects consumer choices is a question at the interface between economics and psychology. While formulating advertising as affecting utility, Sutton (1991) remains reluctant to draw welfare implications from his models. The underlying concern is that advertising involves some spurious differentiation that has no "real value" to consumers. In the context of our exercise, these considerations are of limited relevance. The reason being that the analysis is built around generic entry, i.e., when a long span of time has elapsed since product launch. By then, decision makers (physicians) are likely to be fully informed about the drug, and the informative content of promotional effort is likely to be nil (or negligible) as compared to the persuasive component.

[20] For instance, even if foreclosure is successful for an initial period of time, generic entry eventually occurs in all blockbuster markets. Hence, once that happens, it is possible to infer the level of rents enjoyed by the originator pre-GE.

[21] In the US, this exclusivity period can be extended for a further five years through a "patent term extension." A similar regime exists in the EU.

Kyle, 2012, Reiffen and Ward 2005). This is not surprising, as generics are bioequivalent products that have been explicitly recognized as such by health authorities.[22]

A perplexing feature of generic entry is that the prices of the other on-patent molecules in the same ATC3 category are barely affected (Jena et al., 2009; Lakdawalla, 2018), and their volume market share can even increase (Castanheira et al., 2019; Grabowski et al., 2014; Lakdawalla & Philipson, 2012; Regan, 2008). The lack of price reaction has sometimes led competition authorities (and scholars) to conclude that 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 rife with intermolecular competition.

Hence, for a given set of drugs, evidence from different points in time may either indicate narrow (molecular) markets or a broad (multi-molecule) market, potentially leading to controversy (see Sect. 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: delineating relevant markets in the pharmaceutical industry

This section proposes a three-pronged exercise. First, we perform an empirical estimation of a firm's own- and cross-price and advertising elasticities. We exploit the existence of natural experiments—the entry of generics after a patent expires—to test whether the elasticity coefficients of a molecule i vary around the date of generic entry. This allows us to gauge whether competitive constraints evolve as a consequence of the "genericization" of a particular molecule in a particular ATC3 market. This first set of results indicates that on-patent drugs are only constrained by drugs that also benefit from exclusivity. Note that this exercise is preliminary: it identifies a change in the competitive landscape triggered by generic entry, but does not allow us to establish market boundaries.

Second, we perform a SSNIP test by assessing how demand elasticities vary across market structures. We start from the narrowest possible candidate market in our data: the generic versions of a given molecule. We then consider a more concentrated hypothetical market: one involving a single supplier controlling both the originator product and the generic versions. As detailed by Davis and Garcés (2010, pp. 204–17), this exercise evaluates whether a SSNIP would be profitable in the absence of a price reaction by other producers.

Third, as a robustness check, we propose an additional exercise that we apply to the same candidate markets. This complementary exercise is in line with the 2010 US Horizontal Merger Guidelines, which seek to identify whether the hypothetical

[22] However, instead of observing a price drop by the originating firm, it is not uncommon to see the opposite (for empirical evidence, see Regan (2008) for the US, and Vandaros and Kanavos (2013) for the EU). Scherer (1993) calls this phenomenon the *generic entry paradox*.

monopolist would impose a SSNIP on at least one of the products under the control of the newly merged entity. Our implementation of these guidelines builds on Azar et al. (2018), and Azar and Vives (2020). Concretely, we use own- and cross-price elasticities to compute how a firm would separately modify the price of each of the varieties under its control, instead of holding all other prices constant. This exercise is also related to a Full Equilibrium Relevant Market (FERM) test, originally associated with the 1984 US Horizontal Merger Guidelines (see Davis and Garcés 2010, p162, and Ivaldi & Lorincz, 2011).

To summarize, we implement a SSNIP test using two approaches on two candidate markets. Implementing two methods in this way is similar to a sensitivity analysis and provides a robustness check of the market boundaries that we identify.

3.1 Data

Our starting dataset covers quarterly dollar revenues and physical quantities for all branded and generic prescription drugs sold in the US over the 40-quarter period 1994q1 to 2003q4. These have been obtained from the proprietary IMS-MIDAS database, which includes sales in both pharmacies and hospitals. The database is published by IMS-Health, one of the most important medical information providers (now known as IQVIA).

In the US, pricing is free in the sense that publicly funded Social Security does not negotiate a price cap price for drugs that benefit from exclusivity.[23] Only the monopsony power of Third Party Payers (principally private insurers) mitigates the pharmaceutical firms' pricing power.

All the drugs in IMS-Health are classified according to the Anatomical Therapeutic Chemical (ATC) classification system. In the IMS data, generics are listed under the name of the active ingredient.[24] We thus identified an initial list of ATC3 markets that feature at least one GE by selecting the markets where there are two or more different products for the same molecule name, and some of the drug names are the same as the molecule (*e.g.*, *Fluoxetine* is the active ingredient of *Prozac*).[25,26]

For each of the drugs belonging to the selected markets, we computed deflated revenues (R) by dividing the nominal value of sales by the producer price index for the pharmaceutical industry as 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

[23] On both sides of the Atlantic, the pricing of generic drugs is subject to less stringent conditions and may even be unregulated.

[24] Branded generics represent an exception to this classification, i.e., generic drugs that have been given a proprietary market name. We treat these drugs as "plain vanilla" generics.

[25] Throughout, we implicitly assume that the geographical dimension is national. This assumption is supported by the fact that, in the case of the US (our data), products are sold and regulated on a country-wide basis. In all the cases reviewed in this paper, the geographical dimension of the relevant market was national.

[26] We double-checked the list of markets with GE with information about patent expiration from the Orange Book of the Food and Drug Administration. Appendix 1 lists the name of the originator drug and the associated active ingredients as well as the date of generic entry.

or five millilitres of a liquid (i.e., one teaspoon). Standard units allow a comparison across drug forms and dosages, since all presentations are subsumed into the same unit of observation. We then computed the average price of a molecule (P) by dividing R – i.e., the revenues for all the different packages – by total quantity Q. We applied the same method to construct an average price index of competing molecules in the same market.[27]

We then purchased drug-level information on promotion expenditures in the most important ATC3 markets in terms of sales and promotional effort.[28] The promotion regressor used in the demand estimations is computed by applying the perpetual inventory method:

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

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.[29]

The final sample is determined by data availability: we include all the molecules for which we can compute all variables described above. The sample includes 31 different ATC3 markets encompassing 125 molecules, of which 64 experienced generic entry during our time window. The final sample includes the largest therapeutic markets by sales, such as proton pump inhibitors (used to suppress gastric acid), selective serotonin reuptake inhibitor (used to treat depression), statins (used to lower cholesterol), and all classes of anti-hypertensive drugs.

Table 1 provides descriptive statistics for these variables. We computed the "Promotion of Competing Molecules" as the total promotional spending on all other drugs in the same ATC3 market applying the perpetual inventory method described above. Since generic suppliers do not engage in promotion, this variable accounts for the promotional effort of originators.

With respect to price, we construct two indices: one pertaining to branded competitors and the other limited to generic suppliers. The "Price of competing branded (resp. generic) molecules in ATC3" is the ratio between total revenues and total quantities in the ATC3 market of branded drugs (resp. generics), after subtracting the revenues and quantities of drug i. The result represents the average price of all other branded molecules on the market as well as the average price of generics.

[27] 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.

[28] Promotional data include three main components: visits to office-based practitioners and hospital specialists; free samples dispensed to physicians; 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 1,200 office staff members in medical practices, while expenditures on 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.

[29] 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.

3.2 Intermolecular competition: specification and IV strategy

As summarized in the introduction to this section, the first set of regressions aims to assess whether price elasticities vary around GE. To this end, we estimate a log–log specification to obtain 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 drugs.[30] More precisely, prior to GE, the LHS variable pertains to the quantity market share of the originator drug. Post-GE, we use the quantity market share of the originator plus its generic versions. The case of the well-known antidepressant drug Prozac can serve as an illustration. The active ingredient in Prozac, which experienced GE in the third quarter of 2000, is *fluoxetine*. In this example, the dependent variable is the quantity market share of fluoxetine. The latter is equal to the quantity market share of Prozac prior to 2000q3, and to 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 markets where generic entry occurred, we estimate (average) elasticities for a typical molecule depending on its exclusivity status. Concretely, we let the quantity market share of a molecule i at quarter t, ms_{it}, depend on own and competitors' price p and advertising a (with all these variables expressed as logarithms):

$$\begin{aligned} ms_{it} = {} & \beta_1 p_{it} + \beta_2 a_{it} + \beta_3^B \left(1 - E_{it}\right) p_{-it}^B + \beta_3^G \left(1 - E_{it}\right) p_{-it}^G + \beta_4^B E_{it} p_{-it}^B \\ & + \beta_4^G E_{it} p_{-it}^G + \beta_5 \left(1 - E_{it}\right) a_{-it} + \beta_6 E_{it} a_{-it} + \mu_i + \mu_t + \varepsilon_{it} \end{aligned} \tag{1}$$

where p_{it} and a_{it} refer to the own price and advertising spend of drug i at time t, whereas the indices B and $-i$ in p_{-it}^B identifies the price of brand competitors and p_{-it}^G is the price of generic competitors, both in the same ATC3 market. E_{it} is an indicator taking a value of 1 when the LHS molecule i experiences generic entry at time t, and zero otherwise.[31] Equation (1) includes a complete set of molecule/drug (μ_i) and time (μ_t) fixed effects. The fixed effect μ_i captures persistent molecule-specific 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 the 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.

Since the variables are expressed in logarithms, the β coefficients measure the elasticity with respect to each of the associated variables, namely price (p) and advertising (a). This specification is similar to the one reported in Baker and Bresnahan (1985), who point out that, from an antitrust perspective, it is not necessary to

[30] We also estimated a conventional demand equation (i.e., quantity as the dependent variable), with total market size on the right-hand side. All the other coefficients reported in Table 3 barely moved; only some standard errors increased. The coefficient of total market size was slightly below 1, but not statistically different from 1.

[31] 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 a balanced panel in which patent expiration happens, on average, in the middle of the sample period.

determine whether it is competition from firm A or B that puts the most effective brake on C's market power: it is the combined effect of all other firms that is of interest.[32]

Thanks to the large set of GE events in our database, we can test whether competitive constraints are different before (β_3^B and β_3^G) and after (β_4^B and β_4^G) generic entry (E_{it}). If the point estimate of one of the β_3 elasticities turns out to be statistically different from the associated β_4, then we will infer that the constraints exercised by branded or generic competitors do change over the molecule's lifecycle. Similarly, the coefficients β_5 and β_6 reveal the impact of competitors' promotional effort before and after GE. Since generics generally do not advertise at all, it is not necessary to distinguish between promotional efforts by branded and generic competitors.

Own price and promotion are likely affected by endogeneity and measurement problems. Endogeneity can be due to feedback from market share shocks to subsequent price and promotional effort (reverse causality). Potential measurement errors of both price and promotion stem from the difficulty in observing and monetarily quantifying the effort of sales representatives when they visit physicians. Both of these issues can result in correlation between our regressors and the error term. To address them, 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 Eq. (1).

Following the methodology proposed by Chaudhuri et al. (2006), our first set of instruments consists of the number of presentations, linear and squared.[33] The rationale for using this instrument is that the introduction of a new presentation is generally accompanied by increased promotional activities. Recall that our measure of promotional effort includes the distribution of free samples, which should increase when a new dosage or formulation is launched on the market. While the number of presentations is likely to be highly correlated with promotion expenditures, it is likely not correlated with the measurement error, since the number of presentations can be accurately measured in our data. At the same time, as explained in Chaudhuri et al. (2006), the number of presentations is related to a molecule's average price p, since variations in p stem in part from variations in presentations available in each period.

As a second set of instruments, we also use the number of quarters before/after generic entry, linear and squared. These instruments capture the dramatic changes in pricing and promotion strategies by a brand manufacturer in the periods leading up to and following GE. As patent expiration is exogenous (unrelated to patients and doctors' decisions) 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)

[32] As noted by Baker and Bresnahan (1985, p. 427), in the context of the beer industry: "It is not particularly important to determine whether it is competition from Miller or competition from Stroh (or from Heileman, or …) which puts the most effective brake on Anheuser-Busch's pricing. Only the total effect of these other firms and the particular effect of competition from Pabst are of interest."

[33] Pharmaceutical products are available in multiple presentations, which vary in terms of dosage forms (e.g., capsule, tablet), strength (e.g., 50 mg vs 100 mg), and packet sizes (e.g., 50 tablets vs 100 tablets). Presentations are sometimes referred to as to as stock-keeping units or SKUs.

for under-identification, the Hansen J-test for over-identifying restrictions, and the C-statistic to test for the endogeneity of one or more instruments (regressors), as shown in the tables below.

Two last clarifications are in order. First, our reduced-form regression is similar to the standard logit demand model, although it has additional flexibility in estimating cross-price elasticities. The main difference with respect to a logit model is that cross-price elasticities are not assumed to be proportional to market shares and/or to the prices of competing products (see Werden & Froeb, 1994 and Nevo, 2000).[34] Second, in the context of this paper, a nested logit with a pre-determined set of nests would impose excessive restrictions: our purpose is precisely to assess whether the nest structure is affected by GE.

3.3 Intermolecular competition: results of the first exercise

Table 2 reports the estimates of price and promotion elasticities in our sample. Column (1) presents the results with molecule and time fixed effects, but before instrumenting for either price or promotion. All the coefficients are of the right sign and significant, save for competitors' price post-GE. In column (2), we instrument for promotion but not for prices. The point estimates increase in absolute value, while the level of precision 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, and the magnitude of the estimated coefficients increases further.

To be sure, a panel analysis can only reveal average effects, and is not a substitute for a detailed investigation by enforcement authorities, which must evaluate competitive constraints in the context of each particular case. However, we contend that the results reported below offer valuable background information. In particular, they reveal that, paradoxically, a drug may exercise less competitive pressure on substitutes when its price goes down as a consequence of generic entry.

Table 2 reveals a number of findings: first, both own price and own advertising are important drivers of a drug's market share. In column (1), we do not instrument for prices or advertising. As a result, we would expect a price elasticity biased towards zero, since higher prices may be associated with more intense advertising. In column (2), where we instrument for promotion, this conjecture does appear to be confirmed, as both own price and promotion elasticities increase. In column (3), where we also instrument for prices, both coefficients increase further. Note that they are precisely estimated across all specifications.

[34] A logit model would imply the following regression: $\log\left(\frac{q_{it}}{msize_t}\right) - \log\left(\frac{q_{0t}}{msize_t}\right) = \beta_1 p_{it} + \beta_2 a_{it} + \beta_5 (1 - E_{it}) a_{-it} + \beta_6 E_{it} a_{-it} + \mu_i + \mu_t + \epsilon_{it}$, where q_{0t} is the quantity of the outside good. Since $\log\left(\frac{q_{it}}{msize_t}\right) - \log\left(\frac{q_{0t}}{msize_t}\right) = \log(q_{it}) - \log\left(msize_t - \sum_j q_{jt}\right)$ and, in our specification, $ms_{it} = \log\left(\frac{q_{it}}{\sum_j q_{jt}}\right) = \log(q_{it}) - \log\left(\sum_j q_{jt}\right)$, time fixed effect μ_t would absorb the difference between $\log\left(msize_t - \sum_j q_{jt}\right)$ from the logit model and $\log\left(\sum_j q_{jt}\right)$ in our model. The price of competitors p_{-it}. would not be needed in the logit model to recover cross price elasticities.

Turning to the competitors' promotion, we see a similar stability in statistical significance and the increasing magnitude of the point estimates. Interestingly, drug *i*'s market share is as sensitive to its competitors' advertising after generic entry as it was before.

The large point estimates of β_2, β_5, and β_6 in column (3) confirm that promotion is a central driver of competitive interactions in the pharmaceutical industry. While own promotion may be a match for robust marketing by branded competitors, the dramatic drop in promotion activities after GE means that generic producers will only compete for a significantly smaller market share.

Cross-price elasticities offer insights on how each category of competitors can constrain a firm's market share through price competition. We focus our comments on column (3), where we instrument for both price and promotion. Prior to GE, we find that only brand competitors exercise a competitive pressure on molecule i ($\beta_3^B = 0.647$, significant at the 5% level).[35] 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.[36] When one of its competitors loses exclusivity, the latter's price ceases to influence the drug's market share (χ^2 test for $\beta_3^B = \beta_3^G$: 3.12; *p*-value: 0.077). Insofar as cross-price elasticities reveal the boundaries of an economic market, this implies that a genericized drug "exits" its *former* ATC3 market.

The picture is different for genericized drugs (coefficients β_4^B and β_4^G). After drug i experiences generic entry, its market share becomes dependent on the prices of branded as well as generic competitors: the respective cross-price elasticities are 0.387 and 0.488, both significant at 5%. For competing genericized molecules, the cross-price elasticity grows 14-fold in comparison to the pre-GE period. This points to intermolecular rivalry among (low-priced) generics. Thus, the number of relevant competitors *increases* for genericized molecules, in contrast with the drugs that still benefit from exclusivity.

An important corollary of this contrast is that competitive constraints appear to be asymmetric: on-patent drugs do restrain genericized molecules, but the reverse is not true. The asymmetry is even more notable when we include non-price competition in the picture: post-GE, molecules continue to be 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

[35] Since this coefficient pertains to the period when the molecule is patent protected, the dependent variable is the quantity market share of the brand.

[36] A caveat applies to this statement, since the price of the brand experiencing GE forms part of the "brand price index." However, since the quantity sold of the brand dwindles fast after generic entry, its weight in the price index quickly becomes negligible (i.e., whatever competitive pressure the brand facing generic entry may exercise would be a short term, transitory phenomenon). We also experimented with slightly different specifications, whereby the brand experiencing generic entry was removed from the index and entered as a separate regressor. The coefficient on this regressor was never significant at the 10% level, while the other coefficients were qualitatively similar. Moreover, since the own-price elasticity is essentially unaltered, our findings would continue to hold. The reason we continue to have the brand experiencing GE in the index is that, in the short term, removing it leads to an artificial jump in the index.

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 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	97,899	208,890	1	2,021,052
Promotion of competing molecules	3870	548,659	953,257	1	5,739,914

drugs to expand their quantity market shares. Hence, Table 2 identifies a marked change in the competitive landscape over a relatively short period of time, caused by the exogenous event of a GE, which results in the intensification of competition for a single pre-existing drug.

3.4 Generics: intra- and intermolecular competition

While the above analysis reveals information about the evolving boundaries of the relevant market around GE, it falls short of evaluating whether and when a SSNIP may be profitable. We must accordingly start from the narrowest market, and from there explore how extending a firm's control over products (say, through the acquisition of competitors) would modify its pricing power.

In our data, the narrowest candidate market is that of a given producer of a generic drug. In our sample, there are on average 12.45 generic producers of a single drug after GE (median 11). In line with the previous exercise, we proceed by estimating the following equation:

$$ms_{it}^{G} = \gamma_1 p_{it}^{G} + \gamma_2 p_{it}^{-G} + \gamma_3 p_{it}^{B} + \gamma_4 p_{-it}^{G} + \gamma_5 p_{-it}^{B} + \gamma_6 a_{it}^{B} + \gamma_7 a_{-it}^{B} + \mu_i + \mu_t + \varepsilon_{it}^{G} \quad (2)$$

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).

As in Eq. (1), the variables denoted by a subscript "$-i$" refer to the other molecules/drugs in the same ATC3 market: p_{-it}^{G} is the price index of other drugs that had already lost patent protection before molecule *i,* and p_{-it}^{B} is the price index of other branded products still covered by patent protection (*e.g.* Merck's Zoloft). Finally, the specification includes the advertising effort made by the originator of molecule *i* (to account for the few instances where advertising on molecule *i* is sustained after

Table 2 Price and advertising elasticities before and after loss of exclusivity

Dependent variable: market share of molecule *i*				
Endogenous Vbl:		(1) FE	(2) FE-IV Prom	(3) FE-IV Prom & Price
Regressors:	Coeff.:			
Price of molecule *i*	β_1	−0.788**	−1.102***	−1.721**
		(0.35)	(0.28)	(0.71)
Promotion of molecule *i*	β_2	0.539***	1.075***	1.257***
		(0.08)	(0.16)	(0.25)
Promotion of competitors (before GE of molecule *i*)	β_5	−0.192***	−0.410***	−0.501***
		(0.04)	(0.09)	(0.13)
Promotion of competitors (after GE of molecule *i*)	β_6	−0.199***	−0.404***	−0.489***
		(0.04)	(0.09)	(0.12)
Price of brand competitors (before GE of molecule *i*)	β_3^B	0.353**	0.461***	0.647**
		(0.17)	(0.18)	(0.26)
Price of generic competitors (before GE of molecule *i*)	β_3^G	0.063	0.046	0.034
		(0.06)	(0.08)	(0.08)
Price of brand competitors (after GE of molecule *i*)	β_4^B	0.196	0.355**	0.387**
		(0.15)	(0.17)	(0.17)
Price of generic competitors (after GE of molecule *i*)	β_4^G	0.280**	0.297**	0.488**
		(0.13)	(0.13)	(0.24)
Obs		3870	3870	3870
Underidentification[a]			< .0001	0.0052
Endog_Test[b]			.0012	.0016
Hansen_pval[dcxs]			.2124	.1658
Hansen_df			3	2

Robust standard errors clustered at the molecule level in parentheses. *signif. at 10% level; **signif. at 5%; ***signif. at 1%. Endogenous variables: Own promotion in column (2) and own price and promotion in column (3). Instruments: #Presentations (linear and squared) and Time to/from GE (linear and squared)*a. p* value for the Kleibergen-Paap rk-statistics testing the null 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

patent expiration)[37] and the 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 (2). 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, our dataset contains 21 different generic producers of fluoxetine.

[37] This pattern is observed for drugs that become "household names," leading to patient brand loyalty.

Table 3 Summary statistics of generic producers

	Obs	Mean	S.D	Min	Max
MS of molecule *i* by generic firm *G*	60,136	0.012	0.033	< 0.001	0.814
Price of molecule *i* by generic firm *G*	60,136	1.086	8.605	0.001	452.174
Price of generic competitors (same *i* molecule)	60,136	0.795	7.919	0.001	450.079
Price of brand competitors (same *i* molecule)	60,136	2.086	17.864	0.001	371.177
Price of generic competitors (other molecules)	60,136	1.103	9.541	0.010	213.786
Price of brand competitors (other molecules)	60,136	3.961	27.178	0.034	361.810
Promotion of molecule *i*	60,136	6846.7	37,817	0	677,264
Promotion of competitors (other molecules)	60,136	303,743	796,338	0	5,839,280

Columns (1) and (2) in Table 4 contain the regression results of specification (2) above. We comment on columns (3) and (4) in the next sub-section. As in Table 2, column (1) is the specification without instrumental variables. In column (2), we instrument for both prices and promotion. *Ceteris paribus*, more generic entries reveal higher profit margins prior to GE, leading to steeper price drops (Reiffen & Ward, 2005; Scott Morton & Kyle, 2012). Accordingly, in column (2), we instrument for price and promotion using the number of generic producers of the same molecule and the headcount of producers of other drugs, on top of the number of presentations (linear and squared) that we used in specification (1). Comparing the coefficients in columns (1) and (2), we observe an almost tenfold increase in the size of the own-price elasticity and a 20-fold increase in the cross-price elasticity of other generic competitors. The Kleibergen-Paap rk-statistic (K–P) confirms the presence of endogeneity and the Hansen J-test validates the hypothesis that these instruments are both relevant and exogenous.

Focusing on column (2), the own- and cross-price elasticities for given generic producers of a single 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.

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 the genericized molecule is constrained by the price and promotion of other on-patent molecules.

Lastly, 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,

Table 4 Competition among generic producers

Dependent Variable:		*MS* of molecule *i* by firm *G*		*MS* of molecule *i*	
Endogenous variables:		(1)	(2)	(3)	(4)
		FE	FE-IV	FE-IV	FE-IV
			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 molecule *i*)	γ_2	0.342***	6.643***		
		(0.05)	(1.07)		
Price of brand competitors (same molecule *i*)	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 molecule *i*)	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		60,136	60,136	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

Robust standard errors clustered at the molecule level in parentheses. *signif. at 10% level; **signif. at 5%; ***signif. at 1%. Endogenous variables: Own price and promotion of competitors. Instruments: #Presentations (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

promotional effort also benefits direct competitors—promotion for Prozac, for example, benefits the generic producers of fluoxetine.

Since our dependent variable is the quantity market share, the cross-price results indicate that, following an increase in the price of one generic, the quantities would be principally diverted to other generics of the same molecule, while the leakage to the originator, other generics, or other drugs under exclusivity would be (very) limited. From Table 4, a 1% price increase by one generic producer would increase the combined market share of the other producers of the same molecule by 6.6%.

3.5 Simple (and direct) market delineation

With these results in hand, we are now in a position to perform our second and third exercises, each of which involves a different methodology. However, both address the same question: could a firm profitably increase its price if it controlled a wider proportion of the market?

To this end, we build on the results of Table 4. When there are multiple generic producers, a firm that only controls one version of the generic G would choose the price p_i^G that maximizes (static) profits:

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

where A_i is a demand shifter and $\varepsilon(<0)$ is the own-price elasticity. In the logic of residual demand analysis, A_i depends on the competitors' prices and promotion, as well as intrinsic characteristics that we captured through time- and product-specific fixed effects. The resulting pricing power obtained from the Lerner index is $\frac{p-c}{p} = -\frac{1}{\varepsilon}$ 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, which we use as our competitive market benchmark.

We build two counterfactual (hypothetical) scenarios, starting from different initial market structures. The aim of each is to delineate the relevant market, conditional on a prior degree of competitive rivalry.

3.5.1 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 that of a single molecule and limited to non-originator producers. Hence, the test involves assessing whether a single firm gaining control of all the generic versions of molecule i could achieve a 5% price increase.

In the spirit of the HMT, our second exercise supposes that all other prices, and hence A_i, would remain unchanged. The sole objective is to assess how the own-price elasticity of demand would vary if a single firm were to control the entire generic market of a given molecule (imposing that the price of all varieties would vary proportionally—we return to this issue in our third exercise below). This second exercise is thus a straightforward but direct test: if the elasticity drop justifies an increase in the price-to-cost ratio of more than 5%, then the boundaries of the relevant market will have been identified.

To assess the would-be elasticity associated with this hypothetical market structure, we estimate a variant of Eq. (3) where we aggregate the quantities of all the generic producers of a given molecule as a function of the average price of all other producer groups (e.g., generic suppliers of other molecules in the same ATC). The dependent variable then corresponds to the quantity market share of, say, all generic versions of fluoxetine (e.g. fluoxetine produced by Teva, Barr, Mylan, etc.). The results are presented in column (3) of Table 4. We find that the hypothetical

entity with a monopoly on all generics of a given drug would face a price elasticity of −4.5. Applying the same profit maximization logic, the hypothetical entity would set a price resulting in a price-to-cost ratio of 1.29.[38] In comparison with the benchmark price–cost ratio of 1.13 (and assuming constant marginal cost), this yields a price increase of 14%, meeting the SSNIP threshold. This is despite the fact the firm would still be constrained by the originator (cross-price elasticity: 2.9), other branded drugs (1.6), and generics of other molecules (0.61).

Our third exercise is less straightforward and allows the hypothetical entity to separately determine the price of each generic version of the drug. This is closely in line with the 2010 US Horizontal Merger Guidelines, article 4.1.1, which reads "Specifically, the test requires that a hypothetical profit-maximizing firm, not subject to price regulation […] likely would impose at least a [SSNIP] *on at least one product* […]. For the purpose of analysing this issue, the terms of sale of products outside the candidate market are held constant." This third exercise is also close to a FERM test (Full Equilibrium Relevant Market, originally associated with the 1984 US Horizontal Merger Guidelines, Davis and Garcés 2010, p. 162)

To perform this exercise, we build on Azar et al. (2018), and Azar and Vives (2020). Their setting can be transposed to analyse the more complex problem of a firm separately choosing the prices of each version of the same genericized molecule. Taking the example of two generic 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:

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

where χ is the cross-price elasticity. We find that an interior solution to this optimization problem only exists for sufficiently small χ and λ. 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) of Table 4 is 6.6, implying a corner solution. In other words, the hypothetical entity would actually prefer to "choke" all but one version of the generics, to maintain one variant (e.g. Teva fluoxetine, and drive the production of Barr fluoxetine to zero).

Given that this firm would maintain all but one variant, intramolecular substitution would be limited to the originator. Hence, the own-price elasticity faced by this hypothetical firm can be proxied by $\varepsilon + \chi = -8.693 + 6.643 = -2.05$. 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). The higher predicted price increase (as compared to the elementary SSNIP test) aligns with theory. The Azar et al. inspired test

[38] The quantities we aggregate and the average price we derive have been generated in a competitive environment. Hence, the "monopolist" is genuinely "hypothetical": a true monopolist would re-optimize. Hence, our results and their interpretation should represent a lower bound of the price increase that would result from the merger of all generic producers of a particular molecule (except, of course, if demand dramatically flattens at higher prices). As noted by Baker and Bresnahan (1958, p. 433): "Calculation of the exact, quantitative increase in market power as a result of the merger rests on the assumption that the elasticity of demand does not change along the demand curve. Estimates based on pre-merger historical data cannot reveal the elasticity of demand at the hypothetical post-merger point."

provides a direct quantification of the diversion effects that a hypothetical monopolist would internalize. In the same spirit, a FERM test should point to narrower markets than the elementary SSNIP test.

While the two approaches produce different predicted price increases (14% and 73%), both clearly identify a narrow relevant market made up of a single molecule and limited to generic producers. Both estimates are below those obtained from comparisons of drugs that have attracted a differing number of generic entrants. For instance, Scott Morton and Kyle (2012, Fig. 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-GE brand price.[39]

3.5.2 Scenario 2: from duopoly to monopoly on a molecular market

Our results indicate that, for an average market (panel analyses only yield average effects), the relevant market of a generic producer is the market of generics itself. This finding is obtained under a competitive benchmark of vigorous competition between generic suppliers of the same molecule. Market delineation may thus vary if the competitive benchmark is different.

We thus apply our second and third thought exercises to a different initial benchmark: a molecule duopoly consisting of the originator and a single generic supplier. Under this market structure, we assess whether a hypothetical monopolist encompassing the originator and the generic versions of a particular molecule would lead to a SSNIP. In contrast to the initial situation in column (2) of Table 4, the answer is immediate: by transitivity, moving from the crowded market (12.45 generic producers) to a monopoly at the molecular level must necessarily result in a SSNIP, since a hypothetical monopolist limited to generic versions of the drug would already 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-estimate Eq. (2) with the total quantity market share (i.e. generic versions plus the originator) as the dependent variable. The results are displayed in column (4) of Table 4. The point estimate of the 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% threshold.

Applying the third test, 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, which may appear high. Still, this magnitude is not dissimilar to the point estimates implied by Table 2, column (3), and are compatible with the price differences depicted in Scott Morton and Kyle (2012, Fig. 12.6).

The findings of our "elementary SSNIP" and "Azar et al." tests are thus twofold. First, the two proposed methods yield price increases that range from conservative to high price hikes, but both approximations point to the same relevant market, given

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

the competitive benchmark. In that sense, the resulting relevant market delineation should be considered to be robust.

Second, this evidence indicates 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 molecule itself, i.e. excluding other originators or genericized molecules in the same ATC3. Finally, 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 the 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 Relevance for enforcement

This section discusses the relevance of our findings for competition enforcement in the EU and the US. We review instances of foreclosure (Sect. 4.1 and 4.2), pay for delay (Sect.4.3) and excessive (or unfair) pricing (Sect. 4.3).[40]

In the EU, current practice in abuse of dominance proceedings requires that the market share of the firm under investigation be above a certain threshold (typically, 40%-50%) as a pre-requisite to establish "dominance."[41] 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 behaviour (i.e., prior to generic entry in our example). This is often referred to as the "concomitance requirement."

4.1 Foreclosure: EU cases

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 market share of 20–30%. That firm successfully manages to temporarily block generic entry. According to our estimates in Sect. 3, large-scale generic entry would lead to an expected drop in prices of about 30–55%–note that most observed price dynamics after generic entry tend to 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.

[40] As indicated by the hypothetical examples in Sect. 2, our results are also relevant for mergers. In these cases, contingent on a theory of harm, the market definition may evolve following generic entry. We omit merger enforcement in this section, as we are unaware of concrete, ongoing mergers for which our results would provide useful insights.

[41] US authorities also require large market shares in the relevant market to initiate proceedings under Sect. 2 of the Sherman Act.

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 that the foreclosure led to (i) significant consumer harm in the form of higher prices and (ii) additional rents for the incumbent.

Three avenues provide a means of addressing this conundrum. We first reflect on two of them, highlighting their limitations. We then argue that a third avenue, that of the theory of harm, should guide market delineation as it meets the concomitance and dominance requirements; the novelty lies in identifying antitrust markets that have not yet emerged at the time of the infringement.

4.1.1 First avenue: under-enforcement

The first avenue consists of refraining 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. However, margins (measured as the price to cost ratio) and sales tend to remain high pre-GE, even in crowded markets.[42]

4.1.2 Second avenue: narrow market definition pre-Generic Entry

The second avenue involves defining narrow markets prior to generic entry. Under this 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), have taken this route, defining molecular markets pre-GE. Presumably, this was driven by the case law pertaining to the application of Art. 102 or Sect. 2 of the UK's Competition Act. We briefly describe two cases of generic foreclosure and how they unfolded.

In the Servier/Perindopril case, the EU Commission imposed a fine for violations of Art. 101 and Art. 102. Our discussion focuses on the concomitance requirement in market definition and hence only applies to the "abuse of dominance" (Art. 102) leg of the Decision.[43] The EU Commission deemed that Perindopril (an ACE inhibitor to treat hypertension) and its generic versions formed an antitrust market on their own.[44] This conclusion was largely motivated by the observation that the drop in

[42] Glasner and Sullivan (2020) 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, though they would fall if the transaction were blocked. In such a case, the merger entrenches market power. According to the authors (p. 32), "If entrenchment theories are not used to challenge mergers, that choice should be made explicitly as a matter of policy—not because the mechanics of market definition inadvertently preclude bringing such cases."

[43] European Commission Decision, Case AT.39612 – Perindopril (Servier), 9 July 2014.

[44] 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."

price associated with generic entry into other anti-hypertensive drugs did not seem to dent the sales of Perindopril (in Sect. 2, we highlighted that this is a common outcome in the industry, even when two drugs are substitutes; in Sect. 3, we report that market boundaries are indeed narrow after generic entry). In a similar case, the UK's CMA established that the relevant market was molecular in the context of Paroxetine, a Selective Serotonin Reuptake Inhibitor (SSRI, an antidepressant) initially produced by GSK.[45] The CMA also relied on the lack of price response following GE events among competitors to Paroxetine.

Our reading of these cases is that there is prima facie evidence of consumer harm resulting from foreclosure (monopoly prices beyond the –legitimate– period of exclusivity). The extent of consumer harm can be gauged by the observed –delayed– price drops once the GE materialized. 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 December 2018.[46] The GC found that the Commission had committed a series of errors in its analysis of the relevant market (§ 1589) and thus annulled the Art. 102 leg of the Decision. 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 8 March 2018.[47] Regarding the alleged violation of Sect. 2 of the UK's Competition Act, the CAT was not convinced by the CMA's analysis.[48]

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

Based on our results in Sect. 3, we would label the Servier and GSK/Paroxetine cases as Type III errors: the correct decision (i.e., there was an abuse) based on an incorrect premise (with the null hypothesis defined as no competition infringement).[49] Both involved significant consumer harm, even though the infringers were not "dominant" at the time of the abuse in the sense that they did

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

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

[47] Competition Appeals Tribunal, Case Nos 1251–1255/1/12/16.

[48] 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."

[49] Glasner and Sullivan (2020, p. 321) make a similar point in the case of Cellophane: "To make the point another way, what the Court did in Cellophane was not to define the wrong market as define the right market for the wrong question."

not command a sufficiently large market share on the observable market at the time.

4.1.3 Third avenue: market definition contingent on the competitive concern

The third avenue for resolving this apparent tension is to explicitly recognize that a "natural" and "unique" antitrust market may 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, this approach has been discussed for some time, but enforcers and courts have so far been reluctant to endorse it, at least in the European Union.

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

Given these considerations, the market definition exercise for enforcement purposes should be contingent on the nature of the infringement. This 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.[50] The empirical evidence reported in the previous section indicates that this is compatible with a multi-molecular market definition pre-GE. The advantage of this contingent market definition approach is that it avoids the need to artificially define 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.

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 observed that a SSNIP test that compares pre- and post-entry prices would have indicated a narrow, molecular, market.

The CMA's stance is compatible with a market definition that is contingent on the nature of the alleged infringement. In addition, the CAT clearly recognized that other on-patent drugs exercised less competitive pressure than did generics.[51] Although the CAT was not convinced by the CMA's market definition, it was attracted by the idea of a molecular market.[52] The CAT wondered whether the constraint by generics that are not yet on the market, but soon will be, ought to be taken into account when defining the relevant market. As the CAT noted (§ 403): "The definition sought is of the *relevant* market: this is not an absolute but should reflect relevance to the issue

[50] Our results indicate that a market solely made up of generic suppliers would meet the HMT price increase threshold. A fortiori, a molecular market also including the originator (as in Servier/Perindopril and GSK/Paroxetine) would also fulfil the SSNIP test.

[51] § 402 of the aforementioned judgement.

[52] § 409, 2018: "Accordingly, we would uphold the Decision on market definition [i.e., a molecular market], albeit on a rather different basis from the CMA's reasoning."

under consideration, and can vary accordingly" (emphasis in the original). The UK Court recognized "that this approach is novel" (Ibid). In order to clarify the matter, the CAT requested a preliminary ruling from the European Court of Justice (ECJ) on March 27, 2018.[53] In January 2020, the ECJ ruled that, as long as generic competitors have made preparations 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 factored into the market definition exercise.[54]

Moreover, the opinion of the ECJ's Advocate General (AG) also took the momentous step of recognizing that market boundaries may evolve over a short period of time.[55] In its judgment,[56] the ECJ was more circumspect, but essentially endorsed the approach.[57]

The ECJ's recognition that market boundaries may change over time opened the door for the CAT to define a molecular market, albeit using a reasoning that departed

[53] 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?"

[54] 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). Judgement of the Court, Fourth Chamber, Case C-307/18, Generics (UK) Ltd and Others v Competition and Markets Authority, 30 January 2020. As Neven and Siotis (2020) point out, the ECJ's approach is not entirely satisfactory as it "allows originators seeking to foreclose generics to escape the discipline by acting before entry is imminent."

[55] "222. Such an examination of the competitive constraints faced by a certain undertaking, based on the conditions of competition and the structure of supply and demand on a certain market, is naturally dynamic in character. It is therefore quite conceivable that the emergence of a new supply of products alters the structure of the relevant market in such a way as to exclude other products which previously formed part of it. It follows that, in the present case, it cannot be ruled out that the relevant market on which paroxetine evolved was, as the CAT appears to consider, *composed of all SSRIs at the beginning of the life-cycle of that active substance, whereas that market altered in such a way as to comprise only paroxetine when the threat of market entry by the generic versions of that molecule emerged.*" [Emphasis added]. Conclusions de l'Avocate Générale Kokott, Affaire C-307/18 Generics (UK) Ltd e.a. contre Competition and Markets Authority, 20 Jan. 2020. The AG's conclusions are thus fully consonant with our empirical results.

[56] In the EU's legal order, the ECJ's judgement is preceded by the AG's opinion. The ECJ usually follows the AG's conclusions, but it is not bound by them.

[57] "131 As regards, in particular, the definition of the product market to which, for the possible application of Article 102 TFEU, an originator medicine belongs such as, in the main proceedings, the paroxetine marketed as 'Seroxat,' which can be therapeutically substituted with other SSRIs, it is clear from the point made in the preceding paragraph of the present judgment that a supply of generic medicines containing the same active ingredient, in this case paroxetine, could lead to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market, limited exclusively to medicines which contain that active ingredient." Judgement of the Court, Fourth Chamber, Case C-307/18 Generics (UK) Ltd and Others v Competition and Markets Authority, 30 January 2020. The reference to the "professional circles concerned" would appear to reflect a recognition that demand formation for prescription drugs is idiosyncratic. The ECJ's judgement is also consonant with our empirical findings.

from that initially applied by the CMA to reach the same conclusion. Consequently, the CAT confirmed the finding of abuse in a supplementary judgement.[58]

GSK argued that, since the CAT had established that the CMA's reasoning contained errors, it would be "entirely inappropriate" to "uphold the Decision on other grounds" (§90 CAT 2021). The CAT reminded GSK that it was "entitled to make any decision which the CMA could itself have made." This would suggest that the CMA had reached the right conclusion but based on a flawed reasoning, an error that we christen as "Type III."

4.2 Foreclosure: US

In the US Daraprim case, the FTC addressed the issue of market definition by directly applying a SSNIP test. The infringement essentially amounted to preventing the emergence of supply-side constraints on the pricing of Daraprim.

In the US, Daraprim (generic name pyrimethamine) is a drug treatment for toxoplasmosis, a parasitic infection that is normally fought off by the immune system but which can lead to fatal brain or lung infections for vulnerable patients. Daraprim was first approved by the FDA in 1953. Although it no longer benefits from any patent protection, it is the only FDA-approved pyrimethamine product (branded or generic) on the market in the United States. Daraprim faced little competition from imperfect substitutes to treat toxoplasmosis, such as (non-FDA approved) compounded pyrimethamine, or non-pyrimethamine drugs.

In 2015, Vyera acquired the right to market Daraprim in the US and increased its price by 4000%, from $17.5 to $750 per tablet. In order to sustain this price level, Vyera engaged in a three-pronged generic foreclosure strategy. First, it signed exclusivity agreements with the two Active Pharmaceutical Ingredient (API, i.e., pyrimethamine) suppliers that could potentially have supplied the input to other generic producers. Second, it prevented the sale of Daraprim samples to potential entrants (the FDA requires generic applicants to conduct bioequivalence testing comparing its product to samples of the original drug). Third, Vyera signed "data-blocking" agreements with distributors to prevent them from selling their Daraprim sales data to third-party data market intelligence providers, such as IQVIA. The purpose was to hide the profitability of the price hike to potential entrants.

The Federal Trade Commission (FTC) filed a complaint on 27 January 2020 for violation of Sect. 2 of the Sherman Act (analogous to abuse of dominance in the EU's legal order).[59] A settlement involving compensation for the aggrieved parties was reached on 7 December 2021. The FTC defined the relevant market as comprising the

[58] Competition Appeals Tribunal, Supplementary Judgement, Case Nos: 1251–1255/1/12/16, 10 May 2021. While the abuse was confirmed, the fines were reduced.

[59] Complaint, Fed. Trade Comm'n v. Vyera Pharms. et al., No. 20–00,706 (S.D.N.Y. Jan. 27, 2020) (public version available at https://www.ftc.gov/system/files/documents/cases/161001vyerapharm-redactedcomplaint.pdf).

territory of the US,[60] and limited to FDA-approved pyrimethamine products (§ 292). It pointed to the price increase, concluding that Vyera enjoyed durable monopoly power, the erosion of which was prevented by the successful foreclosure of generic entrants. The FTC furthermore applied a SSNIP test and decided that the relevant market was molecular and limited to FDA-approved drugs (§ 302).

4.3 Pay for delay: Boehringer/Aggrenox

"Pay for delay" refers to situations in which (potential) entrants challenge incumbent patents as being either invalid or not infringed, while the originator alleges an IPR infringement. "Pay for delay" involves the parties settling prior to the ruling, with the originator rewarding the generic producer to postpone entry. These agreements are also known as "reverse payment settlements" since the compensation flows from the (allegedly) aggrieved party (the originator, who claims infringements of its IPR), to the "infringer" (the generic challenger).[61]

Since an agreement between two (or more) parties is involved, the "high market share" pre-condition does not apply (for instance, in the EU, pay for delay agreements are covered under Art. 101). However, the issue of market definition has been implicitly addressed in a US reverse patent settlement case: the Aggrenox[62] case, heard before the US Connecticut District Court. On the basis of the evidence, the Court concluded that the market should be defined narrowly (Aggrenox and its bioequivalent), hence refusing the defendants' requests for discovery into other drugs that were therapeutic substitutes of Aggrenox. The Court concluded that such discovery and evidence would be "irrelevant."[63]

The Court's reasoning was both clear and cogent:

> Moreover, market power exists in degrees. […] The patented drug could face some competition from imperfectly interchangeable drugs (which may or may not themselves be supracompetitively priced) yet still have a meaningful degree of market power, enabling it to be sold profitably at supracompetitive prices
>
> […] (p. 5).
>
> Moreover, in this case we have a history of actual market data because generics have already entered, and the effect of new competitors entering a market provides an additional direct basis to evaluate the question of supracompetitive

[60] The FTC (§ 304) established the geographical dimension on the basis that "Pharmaceutical products are sold and regulated on a nationwide basis. Additionally, […] the US market is limited to FDA-approved products."

[61] Since monopoly profits are (by definition) greater than the sum of oligopoly profits, there exists a compensation such that both parties (originator and generic supplier) will enter into such an agreement. In the US, since the Supreme Court's seminal decision in FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013), these agreements can be deemed to violate US antitrust laws. The EU Commission has also fined a number of firms on the basis of Art. 101 of the TFEU.

[62] Aggrenox is a slow-release combination of aspirin and dipyridamole to reduce the risk of cardiovascular accidents.

[63] United States District Court of Connecticut, Memorandum of Decision and Order, No. 3:14-md-2516 (SRU). August 8, 2016.

> pricing. We have data from a less competitive market of the molecule in question, and we have data from a more competitive market of that molecule.
>
> […] (pp. 7–8).
>
> Sales and pricing data about other drugs would at best be redundant, because any substitution effect constraining the price of Aggrenox will already be "priced in" to this analysis.
>
> [p. 8].

Essentially, the Court established a competitive benchmark in the absence of the restrictive practice (the reverse payment settlement), i.e., the counterfactual. The latter was directly observed, since generic versions of Aggrenox did eventually launch. This allowed the Court to argue that a single supplier of Aggrenox and its generic version would have been able to sustain supracompetitive pricing, consequently defining a narrow molecular market. The District Court's reasoning is thus consonant with the conjecture that post-GE, a SSNIP would point to such a market. Our econometric results likewise indicate that this is, on average, the correct assessment.

4.4 Exploitative abuse (abusive prices)

Our results also have a direct bearing on potential abuses following generic entry: a situation in which the initial market has "shrunk" and rivalry becomes primarily intramolecular. In economically significant markets, large-scale GE ensures competitive conditions: with no capacity constraints, the own- and cross-price elasticities reported in Table 4 point to a near-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 indicate that a supplier with a monopoly on generics would be in a position to extract significant rents.

A number of recent cases support our inference of narrow (molecular) antitrust markets post-GE. Aspen, a South African generic producer, purchased the rights to a series of anti-cancer treatments from GlaxoSmithKline (GSK). The patents for these five active ingredients (chlorambucil, melphalan, mercaptopurine, tioguanine, and busulfan) had long since lapsed. They are used in drugs sold in the EU under different formulations (tablets or injections) and brand names (e.g., Cosmos in Italy).[64] After purchasing the rights, Aspen imposed very significant price increases in a number of EU countries, among them Italy. When the Italian health authority indicated 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%. 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 justify such price increases. In May 2017, the EU Commission

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

opened proceedings against Aspen related to its practices in various Member States (except Italy).[65]

Aspen would not have been able to impose such price increases had it been competing with other generic producers of the same molecules.[66] It was a de facto monopolist on the molecular market, and acted accordingly; this behaviour also appears to be at the core of the EU proceedings.

Aspen entered discussions with the EU Commission with a view to settle.[67] In exchange for the EU Commission ending the proceedings, Aspen offered to reduce its prices by an average of 73% across the European Economic Area.[68] Interestingly, this settlement offer is within the range implied by our estimates reported in Sect. 3. On 10 February 2021, the Commission deemed that Aspen's commitments were satisfactory, and the matter was settled.[69]

5 Conclusions

Market definition is built around the identification of competitive constraints. The Hypothetical Monopoly Test (HMT) is a thought exercise geared towards discerning the limitations to pricing power that must be neutered to achieve a profitable SSNIP. While the HMT rests on solid analytical foundations, it is rarely 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.

Our empirical results provide two important takeaways. The first is that the market definition exercise ought to be contingent on the nature of the alleged

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

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

[67] 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 finding an infringement and possibly imposing a fine). Settlements are made possible on the basis of Article 9 (1) of the EU's 2003 antitrust Regulation.

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

[69] A summary can be found at https://ec.europa.eu/commission/presscorner/detail/en/ip_21_524 .

competitive infringement, i.e., the theory of harm. As noted by Glasner and Sullivan (2020, p. 330): "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." Our paper provides a concrete and quantified illustration of the ontological relationship between the theory of harm and a cogent market definition. Accepting this premise may contribute to reducing the risk of what we term Type III errors (a correct decision based on the wrong premises) on the part of enforcement agencies.

The second takeaway is that estimating a logit (or nested logit) demand system may not be adequate in certain circumstances (this holds for pharma, but similar issues could arise in other industries). This is because entry (here, by generics) may alter market structure, i.e., the underlying nests. Our results imply that, following GE, the market may split, giving rise to a different nest structure, despite the fact that the physical properties of the products remain unaltered. In terms of enforcement, a molecular market may be warranted in a GE foreclosure case. By contrast, in a merger of two producers of different drugs, the relevant market is likely the broader intermolecular market (with the proviso that a competing drug may lose patent protection soon, and then "drop out" of the relevant market).

The cases discussed in this paper may have a bearing in Servier (the Commission's appeal of the EU General Court's December 2018 ruling is pending before the European Court of Justice). In its supplementary judgement, the CAT noted that "neither the Advocate General nor the CJEU gives any support to the concept of the relevant market being assessed according to the conduct under scrutiny" (§ 86 CAT 2021). Our analysis indicates that conditioning market definition on the nature of the competitive concern would appear to be the only (cogent) path out of the Servier conundrum.

Appendix

See Table 5.

Table 5 List of branded drugs experiencing generic entry

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 + Hydrochloro-thiazide	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

Table 5 (continued)

Brand name	Generic name	Generic entry date	Brand name	Generic name	Generic entry date
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

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Declarations

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