Economist's Note

Dominance and Market Definition in the Pharmaceutical Industry Following the ECJ Paroxetine Judgment

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I. Introduction

This paper discusses unilateral conduct aimed at foreclosing the entry of competitors, from an enforcement perspective. Such a conduct was recently considered in the Servier[1] and Paroxetine[2] cases in which originators (resp. Servier and GSK) were found by competition agencies (resp. the Commission and the Competition and Markets Authority, CMA) to have foreclosed the entry of generics.[3]

In the Servier decision, the European Commission found that Servier had infringed Article 102 TFEU, having foreclosed the market for perindopril by purchasing from Azad (another pharmaceutical firm) the IP rights pertaining to a production processes that might have allowed entry by generic firms without infringing Servier's existing patents. In the Paroxetine GSK decision, the CMA found that GSK had infringed chapter II of the Competition Act (the provision equivalent to Article 102 in UK law) by making cash payments and other value transfers to induce potential competitors to delay their potential independent entry in the UK paroxetine market (§1.17). At the time, GSK held a process patent, which had been challenged but had not been invalidated.

The agencies framed this conduct as an abuse of the dominant position that the originators held at the time of the abuse, focusing on competitive constraints exercised by actual competitors (typically other molecules also under exclusivity). The General Court failed to be convinced that Servier could be characterised as dominant given the competitive constraints exercised by other molecules mainly through non-price instruments and annulled the finding of dominance. The Competition Appeal Tribunal (CAT) also failed to be convinced that GSK was not subject to significant competitive constraints, notably through promotional efforts. The CAT raised questions of principles regarding the scope of competitive constraints that should be taken into account to assess the dominance of GSK and sought clarification from the European Court of Justice (ECJ) in a request for a preliminary ruling. The CAT asked whether the competitive constraint exercised by potential generic entrants should be taken into account before the loss of exclusivity enjoyed by an originator. The ECJ answered[4] that, as long as generic competitors have made preparation such that they are in a position to enter with sufficient strength, they exercise a competitive constraint that should be taken into account in market definition (even if the (in-)validity of the patent that prevents them from entering is unclear).

This note argues that neither the approach followed by the agencies nor the approach suggested by the ECJ provide a satisfactory framework for dealing with the

Key Points

- This paper discusses alternative ways in which unilateral conduct to foreclose the entry of generics can be framed.
- We argue that defining dominance in relation to the actual competitive constraints faced by the originators at the time of the abuse (as the Paroxetine and Servier decisions) is likely to lead to under-enforcement.
- The suggestion by the CAT, supported by the ECJ, to consider the competitive constraint exercised by the generics when entry is imminent does not help in addressing this under-enforcement.
- By contrast, an assessment of competitive constraints that is contingent on the abuse does not suffer from this shortcoming.

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1 Case AT 39612, 9 July 2014.

2 Case CE-9531/11, 12 February 2016.

3 The cases also involve pay-for-delay agreements that are not the focus of this note.

4 Case C-307/18, 30 January 2020.

foreclosure of potential entrants. We show that both approaches are misconceived and potentially involve significant false negatives (type II errors). We argue that it would be preferable to acknowledge explicitly that the relevant market is contingent on the abuse.

The note is structured as follows. Section II considers the consequences of the foreclosure of generics in terms of welfare and identifies (independently of any legal structure) the factors that should be taken into account to assess these consequences. Section III discusses the agencies' approach and the one put forward by the CAT/ECJ in light of this analysis. Section IV discusses an alternative framework involving an analysis of competitive constraints that is contingent on the alleged abuse. Section V concludes.

II. Economic perspective on the foreclosure of generics

To fix ideas, consider a situation in which different molecules protected by patents are to some extent substitutes from a therapeutic perspective. One of them is facing the entry of generics and the originator concerned attempts to foreclose the entry of generics. The consequences of this conduct can be assessed by comparing consumer welfare in the status quo (which would be prolonged as a consequence of foreclosure) and in the outcome that prevails with entry.

Prior to generic entry, promotional expenditures aimed at influencing practitioners' prescribing behaviour drives competitive interaction between drugs. For instance, according to Donohue et al (p. 497),[5] in 2005, originator firms spent, on average, 18 per cent of the revenues on promotion in its various forms: detailing, distribution of free samples, and adverts in specialised journals.

Following generic entry, the competitive environment changes drastically. There is overwhelming evidence that generics are typically sold at a fraction of the price of their branded equivalent and exert strong competitive pressure on the original branded product. For instance, Grabowski et al[6] show that, for originator drugs that faced generic entry in 2011–2012, brands retained, on average, only 16 per cent of the molecule market after one year. This is not surprising as a generic is a bioequivalent product that has been explicitly recognised as such by health authorities.

Among generics, differences are residual (different excipient, packaging, or colours); in that context, it is unlikely that drugs will be promoted as promotional spend in the presence of (near)-perfect substitutes is likely to spillover to competitors.

The entry of generic with respect to one molecule also affects the interactions between the other molecules that retain exclusivity, typically softening competition between them. This effect stems from the disappearance of promotional effort for the genericised molecule.[7]

The effect of the generic entry on consumers is thus a priori unclear. It (i) leads to intense price competition for one molecule (ii) but reduces non-price competition between the genericised molecule and other drugs still benefitting from exclusivity and (iii) softens competition among these other drugs. In a companion paper (Lipatov et al[8]), we develop a model in which competition takes place through price and non-price instruments. We find that foreclosure of generics reduces consumer welfare more strongly, if consumers find promotion less valuable, and if promotion involves more business stealing. The consequences of the foreclosure of generic entry thus depend on some features of non-price competition that in principle would have to be evaluated on a case-by-case basis.[9] This analysis shows that negative effects of generic foreclosure on consumers also arise when the originator is subject to significant competitive constraints in the status quo. To the extent that consumers attach more value to price competition from generics than promotion among originators, they will be harmed even when there is intense non-price competition in the status quo. In addition, intense non-price competition among originators might in some circumstances dissipate rents while bringing little benefit to consumers. Here again, intense non-price competition will not be attractive for consumers relative to price competition associated with generic entry.

Interestingly, we also find that for parameter values, which yield a promotion intensity consistent with observed intensities (such that promotion account for up to 15–25 per cent of sales), the foreclosure of generics reduces consumer welfare. This supports a prior that the foreclosure of generics is anticompetitive and suggests that type II error (i.e. the erroneous rejection of consumer

5 JM Donohue, M Cevasco, & MB Rosenthal, 'A Decade of Direct-to-Consumer Advertising of Prescription Drugs' (2007) 357 The New England Journal of Medicine 673–681.

6 H Grabowski, G Long, & R Mortimer, 'Recent Trends in Brand-Name and Generic Drug Competition' (2014) 17:3 Journal of Medical Economics 207–14.

7 M Castanheira, C Ornaghi, & G Siotis, 'The Unexpected Consequences of Generic Entry' Journal of Health Economics (2019) 68.

8 V Lipatov, D Neven, & G Siotis, 'Dominance and the pre-emption of competition following the Servier and Paroxetine GSK judgments, mimeo' (2020).

9 The companion paper (Lipatov et al, 2020) also discusses how the consumer welfare arising from non-price competition can be assessed.

harm) could be a significant concern in any enforcement framework.

The ability and incentive of the originator to foreclose generic competitors can also be considered. Given that price competition from generics drives profits to very low levels, the originator will prefer the status quo. It might have the ability to prevent entry to the extent that, as intense price competition soon materialises following entry, generic suppliers will have a limited willingness-to-pay for any asset that may be required to enter (as in the Servier case), or can be easily paid off to stay out (as in the Paroxetine case). By contrast, the willingness-to-pay of the originator (for inducing the generic to stay out) is likely to be large as it will reflect the amount that she has to lose (which is determined by the status quo). The asymmetry arises from the fact that the originator is already established and this, in turn, is a consequence of the intellectual property rights of the originator.

III. Dominance in the Servier and Paroxetine case

As mentioned above, the agencies (the Commission and the CMA) framed the conduct as an abuse of the dominant position that the originator held at the time of the abuse, focusing on the competitive constraints exercised by other originators.

In light of the discussion above, it is immediately clear that this approach is unsatisfactory; the foreclosure of generics will be attractive and lead to consumer harm even in those circumstances in which the originator is subject to significant competitive constraints from other molecules in the status quo. Hence, by requiring the absence of significant actual competitive constraints on the originator in the status quo, the Commission and the CMA will fail to capture circumstances in which the conduct leads to consumer harm. There is a concern about type II errors.

The CAT was however confronted with a different view regarding market definition and dominance expressed by Prof. Shapiro. He expressed the opinion that the competitive constraints that are taken into account for market definition should not be independent of the conduct under scrutiny. In this instance, because the conduct concerns the exclusion of generics, the relevant market should naturally include them. Specifically, in the CAT's words 'if, as here, the issue concerns conduct directed specifically at excluding independent generic paroxetine from the market, then it would be inappropriate and misleading to leave generic companies out of consideration when seeking to define the market just because they were not on the market' (§395).

The CAT recognised some of the observations of Prof. Shapiro but failed to adopt his approach. Specifically, the CAT confirmed that the degree of competition between alternative molecules before loss of exclusivity 'pales into insignificance compared with the effect of generic paroxetine'. The CAT further observed that 'it is the competitive effect of generic entry that was the incentive for GSK to conclude the agreements here at issue' (§402). However, rather than concluding that the competitive constraints of generics should be considered because exclusion is targeted at them, the CAT concluded that 'it is not illogical to find that as a pharmaceutical product approaches the stage when generic entry becomes a realistic possibility, the generic product is then taken into account in determination of competitive constraints' (§402). The CAT thus took the view that competitive constraints from generics should be considered only if their entry is sufficiently imminent.

As this approach would be rather novel, the CAT decided to seek guidance from the ECJ. As part of its request for a preliminary ruling, the CAT thus asked: '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 a 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'?

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).

The question asked by the CAT and the answer provided by the ECJ lead to a situation that is also unsatisfactory, as it allows originators seeking to foreclose generics to escape the discipline by acting before entry is imminent. As in the case of the approach adopted by the agencies, there is thus a concern about anticompetitive conduct escaping enforcement, or type II errors.

There is another respect in which the Court judgment is troublesome. The Court observed that the process patent held by GSK did not offer any certainty that generics competitors could not enter (§137). Yet, the Court concluded that in the absence of certainty with respect to its validity, the existence of a process patent was not decisive

to assess the imminence and strength of the competitive constraint: 'the fact that the manufacturer of originator medicines relies on an intellectual property right over the process of manufacturing the active ingredient concerned as capable of possibly impeding the market entry of generic versions of the originator medicine containing that active ingredient cannot be sufficient ground for any other finding' (§136).

The Court, following the Advocate General (AG) in this respect[10] (§226–227), thus takes a radical view with respect to the stochastic nature of the validity of the process patent as a barrier to entry.[11] According to the AG (§67), a stochastic patent is not barrier that is unsurmountable and facing stochastic patent is a normal feature of the competitive interactions in the pharmaceutical sector. This perspective fails to recognise that the competitive constraints exercised by a generic producer are stronger when it is more likely to prevail in a dispute about the validity of the process patent. In the framework of Aaron et al,[12] there is a correspondence between the strength of a patent and the expected time of entry (for instance, a patent that has a probability of 0.8 of being valid can be seen as one in which the entry will take place after 80 per cent of the time remaining to expiry). In this respect, entry against a weak patent can be seen as more imminent than entry against a strong one. The competitive constraint exercised by generics in the former is thus stronger.

IV. Dominance contingent on the abuse

The explicit recognition that market definition and, more generally, dominance is contingent on the abuse however provides a satisfactory framework. According to the approach (i) the relevant market for considering the pre-emption of entrants is the market in which the originator and the generics interact[13]; (ii) the originator has a dominant position in that market at the time of the pre-emption because of the exclusivity (and first mover advantage) granted by the patent that he holds (and has not been successfully challenged); and (iii) the abusive conduct (pre-emption) is directly related to the source of dominance (the temporary exclusivity). This approach would effectively lead to the conclusion that with respect to the foreclosure of generics, originators are always in a dominant position.[14] Accordingly, there is no scope for under-enforcement and type II errors that is built in (as in the other approaches).

The suggestion that the relevant market and dominance could be contingent on abuse has been discussed for some time[15] but enforcers and Courts have so far failed to endorse it. In this respect, it is worth emphasising however that framing the pre-emption of generics as an abuse of dominance in the market in which the exclusion takes place would appear to fit well with the definition of relevant market, dominance, and abuse (at least seen through the lens of an economist).

First, market definition is meant to identify the competitive constraints faced by a firm so as to delineate a set of transactions over which anticompetitive effects could arise.[16] The hypothetical monopolist test indeed defines the set of sales of which a hypothetical monopolist could exercise a certain degree of market power, or in other words, the set of transactions over which a certain degree of anticompetitive harm could arise. Focusing on existing producers in carrying out the test is appropriate when existing transactions can be impaired. However, in the case of pre-emption, the anticompetitive effect arises with respect to transactions that would take place if entry were possible. It is thus appropriate to focus on those transactions.

Second, turning to (single-firm) dominance, it is defined by the Courts as 'a position of economic strength enjoyed by an undertaking that enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers, and ultimately consumers'.[17] If the relevant market includes the set of transactions with potential entrants,[18] the

10 Case C-307/18, 22 January 2020.

11 The radical perspective of the Court is presumably motivated, to some extent, by the concern that any position that gives significance to the magnitude of the strength of the patent would require an assessment that competition authorities are not well positioned to undertake (see §79, AG and §50 of the ruling).

12 E Aaron, S Hemphill, H Hovenkamp, & C Shapiro, 'Activating Actavis' (2013) No. 1 Antitrust 16–23.

13 As observed by the CAT, quoting Prof. Shapiro (§395 of the CAT judgment), if the possible abuse involved a product tie between the originator drug and homecare service, the relevant market might include all SSRIs.

14 At least as long as no entry has taken place.

15 P Rey, J Gual, M Hellwig, A Perrot, M Polo, K Schmidt, R Stenbacka, 'An Economic Approach to Article 82' (2004) Report of the Economic Advisory Group on Competition Policy, Brussels.

16 D Glasner & S Sullivan, 'The Logic of Market Definition' (2020) Forthcoming Antitrust Law Journal.

17 United Brands, case 27/76, §65.

18 It is sometimes argued that there is a requirement under the European Union (EU) law for the abuse to be contemporaneous with the dominant position. If there is indeed such a requirement, it would be satisfied under the approach that we recommend to the extent that the exclusion is taking place when the originator has a dominant position in the molecule market as a consequence of its right to exclude.
This market is not the market in which originator is actually competing at the time of the abuse but it is nonetheless dominant in this hypothetical market at the time of the abuse. If the requirement under EU law is for the abuse to be contemporaneous with an actual dominant position, then the only feasible approach would be that followed by the Commission and the CMA. This state of affairs would be highly unsatisfactory: this approach

originator has a position of economic strength arising from the patent that grants it a temporary exclusivity and hence a first mover advantage such that it can prevent effective competition.[19]

Finally, an abuse is often defined by the Court as 'an objective concept relating to the behaviour of an undertaking in a dominant position, which is such as to influence the structure of a market where, as a result the very presence of the undertaking in question, the degree of competition is weakened and (. . . .) has the effect of hindering the maintenance of the degree of competition still existing on that market or the growth of that competition'.[20] The pre-emption of generics fits the description of an abuse as it influences the structure of the market and hinders the growth of competition. In addition, the abuse is related to the dominant position. Indeed, what is instrumental in making the exclusion feasible is the first mover advantage of the originator, which is itself a consequence of the patent it holds.

Overall, it seems that there is nothing in the principles underlying market definition, dominance, and abuse that would be in contradiction with the suggestion of marking market definition and dominance contingent on the abuse. The notice on market definition[21] is however a source of difficulty. While the notice recognises that market definition may lead to different results 'depending on the nature of the competition issue being examined' (§12), it also focuses on the 'actual competitors of the undertakings involved that are capable of constraining those undertaking's behaviour' (§2). This wording reflects the main pre-occupation of the notice, which was to define relevant markets for merger control, focusing on unilateral effects as the main theory of harm. As discussed for instance by Glasner and Sullivan,[22] the policy discussions and enforcement decisions have increasingly recognised how the analysis of competitive constraints should differ across different instruments and theories of harms. The notice would benefit from a revision that reflects these developments.

V. Conclusion

This paper has discussed alternative ways in which conduct to foreclose the entry of generics can be framed. We argue that defining dominance in relation to the actual competitive constraints faced by the originators at the time of the abuse is likely to lead to under-enforcement. The suggestion by the CAT, supported by the ECJ, to consider the competitive constraint exercised by the generics when entry is imminent does not help in addressing this under-enforcement. In addition, both approaches fail to make a meaningful link between dominance and its abuse. By contrast, an assessment of competitive constraints that is contingent on the abuse (leading to molecule market in this instance) does not suffer from these shortcomings.

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would require a dominant position with respect to a conduct that does not derive from the dominant position and, as discussed above, would result in under-enforcement.

19 This approach also recognises that the originator does not face any competitive constraints in carrying out the potentially abusive conduct. The incentive to carry out the conduct is affected by the competition that it faces from other originators in the status quo but its ability to carry out the conduct does not depend on the other originators.

20 Hoffman Laroche, case 85/76, §91.

21 Commission notice on the definition of relevant market for the purposes of Community competition law (97/C 372/03).

22 See note 18.