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Excessive pricing cases in the pharmaceutical industry: Economic considerations and practical pitfalls

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1. Both national competition authorities and the European Commission have recently shown a new interest in pursuing excessive pricing cases in the pharmaceutical sector. The European Commission's launch of an investigation into the pricing of five cancer drugs by Aspen pharmaceuticals is the most recent case in this area. The UK authority already has two such cases, one against Pfizer and Flynn on the pricing of anti-epilepsy drug phenytoin and one against Actavis on the pricing of hydrocortisone tablets, while the Italian Competition Authority has already fined Aspen on the same conduct.

2. Economists have long questioned whether high prices, in the absence of other abuses, call for competition policy intervention. In section I, we briefly summarise the arguments that have been developed in this context. Section II argues that the pharmaceutical sector is an industry that is particularly ill-suited for intervention on excessive pricing grounds. Section III then discusses some of the practical pitfalls to avoid in determining whether prices can in fact be considered excessive.

I. Excessive pricing cases should be exceptional

3. In our view, the goal of antitrust should be to protect the competitive process and not to prevent high prices as such, since high prices are necessary to reward investment, and act as a signal to attract further investment and entry. As Carlton and Heyer (2008)[1] note, "*an essential element of antitrust policy is to allow firms to capture as much of the surplus that by its own investment, innovation, industry or foresight, the firm has itself brought into existence*," and antitrust enforcement should therefore focus on conduct that extents market power, rather than on conduct that merely extracts surplus. This view is consistent with US antitrust enforcement, which does not consider excessive prices as an abuse.

4. Even in jurisdictions where excessive prices are considered an antitrust violation, as in Europe, competition authorities have traditionally shied away from launching excessive pricing investigations, particularly when there is no other element of abuse,

* While the authors have been advising Flynn in the UK excessive pricing investigation, all views expressed in this article are strictly personal and are not meant in any way to represent the views of Flynn or of any other client.

1 D. W. Carlton and K. Heyer, Extraction vs. Extension: the basis for formulating antitrust policy towards single firm conduct, *Competition Policy International* 4 (Autumn): 285–305.

such as exclusion.[2,3] The general reluctance by investigating authorities to launch excessive pricing cases stems from the fact that such cases raise a number of practical and conceptual challenges. Conceptually, as dominance is not in itself an abuse, charging a monopoly price should not be considered abusive. As highlighted by Advocate General Nils Wahl, "*it would seem natural to expect a monopolist to charge the monopoly price. Interfering with such a pricing policy would be tantamount to interfere with dominance as such.*"[4] High prices, and potentially very high prices, are therefore no ground in themselves to justify antitrust intervention: additional—and very specific—conditions are necessary to establish an excessive price case.

5. As part of the modernization of European antitrust, the Commission rightly decided to focus its enforcement priorities on exclusionary rather than excessive prices,[5] and an interesting debate took place among economists and policymakers to determine under what specific circumstances excessive price cases could be justified.

6. In particular, Röller[6] proposed a logically consistent and very limited role for excessive pricing cases in Europe, i.e., to cover "gap cases" that would otherwise not be caught under Article 102 TFEU. Gap cases arise because Article 102 only applies to dominant firms, so exclusionary conduct that "*leads to a dominant position*" is not caught under Article 102; there is thus a possibility that a non-dominant firm would gain a dominant position through exclusionary means without infringing Article 102, and would subsequently exploit its gained dominance by imposing excessive prices. This approach can be extended to cases where dominance was not obtained on the merits, such as previously state-owned monopolies, recognizing also that sectoral regulators are better placed to fix prices than competition authorities.

7. Röller therefore proposed a cumulative five-condition test for the use of Article 102 in respect of exploitative conduct:

- There are significant entry barriers;
- The market is unlikely to self-correct;
- No (structural) remedy is available;
- There is no regulator or there is a regulatory failure; and
- The exploitative abuse stems from acquiring a dominant position as a result of an exclusionary abuse.

8. Similarly, Motta and de Steel[7] proposed a cumulative three-condition test:

- High and non-transitory barriers to entry leading to a super dominant position. According to the authors the threshold should be higher than the existence of mere dominance or super dominance. These are cases where the dominant or super dominant position is unlikely to be challenged by potential entrants.
- The super-dominant position is due to current/past exclusive/special rights or to un-condemned past exclusionary anticompetitive practices. To ensure that excessive pricing cases do not reduce incentives to invest and innovate, the position of dominance should not have been earned by business acumen, past risky investments or effort.
- No sector-specific regulator has jurisdiction to solve the matters. If an industry-specific regulator exists, which is likely in industries in which the previous two conditions hold, then the regulator is more suitable to intervene in questions of excessive pricing.

9. The cumulative aspect of the proposed tests is essential: high barriers to entry and the unlikeliness of the market to self-correct are a necessary but not sufficient condition to justify intervention. The restriction to cases where dominance was not obtained on the merits (legal monopoly or past exclusionary behaviour) is necessary, as is the absence of (a more efficient) regulatory solution. Except if these specific conditions are met, it is not socially optimal to intervene.

10. Even in cases where dominance was not obtained on the merits, but through historical state intervention, excessive pricing intervention is not automatically justified. As Evans and Padilla[8] point out, many incumbents in the telecoms and energy sector in Europe invest significant amounts on infrastructure in competition with entrants. They find that consumers are generally better off without intervention in industries where innovation and investment play a key role and that intervention should

2 For example, in the *Napp* case, where Napp was accused of charging excessively low (exclusionary) prices in the hospital segment and excessively high prices in the community segment for its sustained release morphine tablets, Vickers explained that "*the OFT explicitly viewed Napp's pricing policy as a whole and in the appeal case went on to say that it would not wish to maintain excessive pricing abuse if the pricing to the hospital segment was not judged to be exclusionary.*" J. Vickers, How Does the Prohibition of Abuse of Dominance Fit With the Rest of Competition Policy?, Paper for the eighth annual EU competition law and policy workshop at the European University Institute, Florence, 6 June 2003.

3 According to the opinion of Advocate General Nils Wahl, intervention on the basis of excessive pricing alone has been generally limited to regulated industries. Opinion of Advocate General Wahl, delivered on 6 April 2017, following a request for a preliminary ruling by the Latvian Supreme Court on the conditions under which the rates set by the Latvian collecting society AKKA/LAA are excessive under Article 102.

4 N. Wahl (2007), Exploitative high prices and European competition law – a personal reflection, in Konkurrensverket – Swedish Competition Authority (ed.), *The Pros and Cons of High Prices*, p. 51.

5 Communication from the Commission – Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, 2009.

6 L. H. Röller (2007), Exploitative Abuses, in Ehlermann and Marquis (eds.), *European Competition Annual 2007: A reformed Approach to Article 82*.

7 M. Motta and A. de Streel (2007), Excessive Pricing in Competition Law: Never say Never?, in Konkurrensverket – Swedish Competition Authority (ed.), *The Pros and Cons of High Prices*, p. 14.

8 D. S. Evans and A. J. Padilla (2004), Excessive Prices: Using Economics to Define Administrable Legal Rules, *CEMFI Working Paper* No. 0416.

be limited to situations where the dominant firm enjoys a legal monopoly and where the excessive prices charged by the legal monopoly may prevent the launching of new products in adjacent markets.[9]

11. In any case, enhancing static efficiency through antitrust intervention aimed at curbing excessive prices, at the possible cost of dynamic efficiency, would be short-sighted. Even if, taking an *ex-post* perspective, it may be tempting for a competition authority to impose lower prices, this may be misguided from an *ex-ante* perspective given the chilling effect of such intervention on investment. This consideration calls for extreme caution in pursuing excessive price cases, which is further reinforced by a competition authority's inferior ability to regulate prices, compared to a sector-specific regulator.

II. The pharmaceutical sector is ill-suited to excessive pricing cases

12. The conditions set out above are generally not met in the pharmaceutical industry.

13. Firstly, the pharmaceutical sector is a dynamic industry, where innovation is key in the successful introduction of new products. The role of patent protection is exactly to provide incentives to firms to engage in risky R&D activities by rewarding them with a period of protection during which they can earn higher profits. Antitrust intervention for excessive prices in the pharmaceutical industry would therefore limit the rewards for innovation, with a likely outcome of limiting the introduction of new, and potentially life-saving drugs. Dominant positions enjoyed by pharmaceutical companies have been achieved on the merits, and are normally not the result of previous state monopolies or exclusionary conduct. There is thus no reason to prevent firms which have ahieved dominance through competitive means to reap the rewards for their investments and innovation.

14. Secondly, following the end of the patent protection period, there are generally few barriers to entry as generic manufacturers can generally enter the market swiftly, with strong price effects. Although smaller product markets may attract fewer generic entrants, and generic entry may be less swift in some cases, one can generally expect that high prices would then make such entry more profitable.[10]

15. Thirdly, pharmaceuticals is an already heavily regulated sector. If there is regulatory failure, is competition policy the right tool to address this? In cases where there are other elements of abuse, such as exclusionary behaviour, competition policy may be the right instrument, but if the concern is purely one of pricing, then it is less clear that competition policy is the correct tool to use. Regulating prices is not an easy task as it requires deep industry knowledge, which may not be available to more generalist enforcers such as competition authorities. This is the reason why most industries that require price regulation have specialised regulators responsible for enforcing it. Additionally, price regulation is burdensome; it cannot be implemented with a one-off decision, but requires significant resources to monitor adherence, which could be onerous for busy competition authorities.

16. The Commission generally recognizes the importance of rewarding innovation, and therefore has not shown any indication that it would intervene to curb high prices for new and innovative drugs. For example, the European Commission has so far declined to open an investigation into allegations of excessive pricing for Hepatitis C drugs on the basis that it was a rapidly moving therapeutic area with several new medicines in advanced stages of development.[11]

17. The Commission and national authorities thus appear to draw a distinction between expensive but innovative medicines, on the one hand, and old off-patent medicines that experience significant price increases, on the other hand. Indeed, recent cases focus on older molecules, where price increases have been observed, and for which there are allegedly high barriers to entry.

18. However, in our view, the mere observation of high price increases and barriers to entry are not sufficient to justify intervention. Indeed, such cases do not fall under the realms of legal monopolies or past exclusionary conduct. If, in exceptional circumstances, the specific market conditions are such that they should be treated as natural monopolies, sector-specific regulation appears better placed to solve the issue than antitrust policy.

9 For an extensive overview and discussion of the economic screens proposed to minimise the costs of excessive pricing investigations, *see* in particular F. Jenny, Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment (September 11, 2016). Available at SSRN: https://ssrn.com/abstract=2880382.

10 For example, Kanavos finds that the size of the market is an important determinant of the likelihood of generic entry. P. Kanavos (2014), Measuring performance in off-patent drug markets: a methodological framework and empirical evidence from twelve EU Member States, *Health Policy*, Volume 118, Issue 2, pages 229-241. Similar findings have also been made in other empirical papers. *See*, for example: P. Danzon and M. Furukawa M. (2011), Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs Physician-Driven Markets, *NBER Working Paper* No. 17226; E. Glowicka, S. Lorincz, E. Pesaresi, L. Sauri Romero and V. Verouden (2009), Generic Entry in prescription medicines in the EU: Main Characteristics, Determinants and Effects. Available at http://ec.europa.eu/dgs/competition/economist/prescription_medicines.pdf; L. Magazzini, F. Pammolli and M. Riccaboni. (2004), Dynamic Competition in Pharmaceuticals: Patent Expiry, Generic Penetration, and Industry Structure, *European Journal of Health Economics* 5: 175–182.

11 Commissioner Vestager's responses to parliamentary questions (P-008636/2014 and 000261/2015).

19. Abstracting from the more normative question of whether authorities should investigate excessive pricing cases in the pharmaceutical sector, we now turn to the practical pitfalls of excessive pricing cases in the context of pharmaceuticals.

III. Determining whether prices are excessive: Practical pitfalls

20. Once an authority has decided to open an investigation into excessive pricing, the first consideration is what framework to use to assess whether prices are excessive. In excessive pricing cases enforcers will typically examine the level of prices relative to costs and assess whether prices or profits are excessive usually by comparing these to appropriate benchmarks.[12] From a practical perspective, establishing what an appropriate benchmark is in each case is far from an easy task. For example, in industries characterised by significant investments and innovation, as in the pharmaceutical sector, or economies of scale, competitive prices can be expected to be well above the marginal costs of production. Additionally, even if an appropriate benchmark is found, establishing whether prices or profits are above, at or below the benchmark is not straightforward as it may depend on the way costs are measured and on the method used to allocate common costs. Thirdly, from a conceptual and practical point of view, establishing when prices are excessive, i.e., by how much do prices or profits need to be above the benchmark to be considered excessive, is inevitably a matter of judgement. There is therefore no set rule or guidance to determine when prices or profits can be considered excessive.

21. These challenges imply that enforcers are likely to make incorrect judgements when investigating excessive pricing cases, i.e., there will be cases where prices are considered excessive when in fact they are not (Type I errors) and cases where prices are not considered excessive when they are (Type II errors). Type I errors entail costs to consumers in the medium to longer term as *ex-post* intervention reduces companies' incentives to invest and innovate. In the pharmaceutical sector, where research and development is essential in ensuring new life saving treatments are discovered and brought to the market, the social costs of Type I errors could be particularly significant.

12 The legal framework for analysing whether prices are excessive was originally set out in the *United Brands* case, where the European Court of Justice proposed the following test, sometimes referred to as the "United Brands test.""*The questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.*" Judgment of the Court of 14 February 1978, *United Brands Company and United Brands Continentaal BV v. Commission of the European Communities – Chiquita Bananas*, case 27/76.

22. Leaving aside the conceptual shortcomings of excessive pricing cases, there are thus also a number of practical pitfalls to avoid in determining whether a price is in fact excessive. We highlight below some of the traps that competition authorities should avoid in this respect.[13]

1. Defining markets too narrowly

23. In order to build an excessive prices case, authorities first have to establish dominance. They may be tempted to do so by defining very narrow markets, so that the shares of the company under investigation appear very high. In extreme cases, an authority may consider that a market could be defined just on the basis of a molecule, the form, and even exclude generic competitors from the market. While such approaches do indeed lead to high computed shares, these are, however, not indicative of dominance.

24. Authorities may point out that some customers are somehow captive, which would justify such an approach of excluding generic competitors if customers do not switch between drugs of different manufacturers, due, e.g., to a drug's narrow therapeutic index. However, in the absence of price discrimination at the customer level, such market definitions based on customer subgroups are flawed as producers' prices also reflect competition that they face for non-captive customers (e.g., for new customers not yet treated).

2. "You know it when you see it"

25. Competition authorities officials have on some occasions referred to US Supreme Court Justice Steward's "*you know it when you see it*" statement regarding the difference between hard-core pornography and obscenity. However, adopting such an approach in order to identify excessive pricing cases would be very problematic.

26. Beyond the pure arbitrariness of such a test, the issue with such an approach is that it provides no guidance to firms as to when they may be infringing competition law. It is important to think of the impact of competition policy beyond a specific case under review, but also in terms of the behaviour modification that it imposes on firms more generally. If firms are afraid that they may be infringing competition law, they may choose to price below the socially optimal level, with potential negative effects for investment and innovation. In the pharmaceutical industry, this would be particularly worrying given the importance of rewarding investment in life-saving drugs.

13 Some of the practical limitations of excessive price cases have been known for long, such as the difficulty of cross-country price comparisons highlighted in *United Brands*, which we are not repeating here. For further reference, *see*, e.g., D. Geradin, The Necessary Limits to the Control of 'Excessive' Prices by Competition Authorities – A View from Europe, *Tilburg University Legal Studies Working Paper*. Available at SSRN: https://ssrn.com/abstract=1022678.

27. Moreover, the lack of specific guidance on when prices or profits can be considered excessive creates additional uncertainty for companies, as they cannot be sure whether their pricing infringes or not. This uncertainty can create a chilling effect on investment particularly in dynamic sectors such as pharmaceuticals, where the success of R&D is already inherently uncertain.

3. Arbitrary cost plus method

28. There may be a temptation for competition authorities to determine whether a price is excessive based on whether the price exceeds cost plus a certain arbitrary percentage (so-called "cost-plus" approach). The CMA in its recent decision on the pricing of Phenytoin relied on such a "cost-plus" approach and used a 6% ROS as a reasonable return on the basis that it is the allowable return-on-sales (ROS) under the Pharmaceutical Price Regulation Scheme (PPRS).[14] Such a crude approach is particularly misguided in our view, as it is bound to lead to a high number of Type I errors. Indeed, there is no common return on sales that could be deemed reasonable across the board. Returns are highly product-specific, and therefore whether a return is truly out of the ordinary can only be determined by comparisons with similar benchmark products.

4. Not considering a variety of benchmarks

29. Whether a price is out of the ordinary can only be determined by comparison to a wide range of benchmarks. Indeed, even for similar products, it is not abnormal to observe quite different returns. In other words, even for products that are relatively similar on many dimensions and which are not considered excessively priced, one can observe a range of prices and returns. A finding that returns are higher compared to a single benchmark is no indication that they are excessive, as this would lead to too many Type I errors. It is only when the returns of a product are way out of line compared to all comparison products that this could be an indication that prices are excessive.

30. According to Advocate General Wahl in his recent opinion, in order to minimise the risk of Type I errors investigating authorities should "*strive to examine a case by combining several methods*" of determining whether prices are excessive and that it is of utmost importance for the authority to consider other indicators that may corroborate or conversely cast doubt on the results of that method.[15]

5. Using an average calculated over a portfolio of products as a benchmark

31. While it is essential to compare the observed price (or margin) to a range of comparable products, care should be taken when comparing a single price to the average calculated over a portfolio of products. This is because an average hides a wide variation in prices and profits: comparing a single product to an average may thus not be informative as to whether the single product's price or profitability is excessive.

32. For example, it is well known that in the pharma industry some drugs are "hits" and other are not. The very essence of conducting risky investments and having a portfolio of pipeline products is that some will be successes and others will be failures. Some projects may even lead to losses, bringing the average profit measure down.

33. Rather than focusing on averages over a portfolio, it is thus more meaningful, if the data are available, to look at the distribution of returns over comparable products and to then observe whether the product in question is at odds with the observed distribution. That is, the price of an observed product may well be above the average of a portfolio of drugs, but as long as there are comparable benchmark products with similar price/profitability, there is no ground for finding an excessive price.

6. Using a competitive benchmark for a dominant firm

34. Another common mistake is to compare prices of a dominant firm to a competitive benchmark. By definition, a competitive product is not an appropriate benchmark for determining whether a price by a dominant firm is excessive. Indeed, pricing close to marginal cost would not be expected for a product that has significant market power, even if prices were not excessive. Being dominant is certainly not an abuse in itself, and hence it cannot be considered infringing for a dominant firm to price above a competitive level (otherwise, the pricing by all dominant firms would be considered abusive). An appropriate benchmark should thus operate under similar competitive conditions as the product investigated for excessive prices.

7. Relying on insufficiently comparable benchmarks

35. It is important that the benchmark used is sufficiently comparable to the product under investigation. In particular, care should be taken to compare products that have relatively similar cost structures. Indeed, the profitability of a product that e.g. has significant sales and promotional efforts could be different to the profitability of a second product that has limited such activities, and hence not provide an appropriate benchmark for this second product.

14 CMA Decision *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, case CE/9742-13.

15 Opinion of Advocate General Wahl, delivered on 6 April 2017, following a request for a preliminary ruling by the Latvian Supreme Court on the conditions under which the rates set by the Latvian collecting society AKKA/LAA are excessive under Article 102.

36. Yet, competition authorities are sometimes tempted to use vastly different products as comparators, which may lead to serious errors in their assessment. For example, comparing returns of generic and branded drugs is inappropriate to establish excessive prices, as generic and branded drugs have different business models, are at very different points of their life cycles, which in turn typically implies different competitive conditions, marketing expenditures and so on.

8. Rejecting meaningful benchmarks because they might themselves be excessive

37. Authorities may also be tempted to reject comparisons showing that a product is not priced excessively in comparison to another similar product on the basis that this other product should itself be considered as being priced excessively. Such an approach would be particularly ill-suited if the authority has not opened an investigation into excessive prices for that other product. Indeed, in such a case, there is no way for the company under investigation to know that the benchmark it used was not appropriate. The situation would be different, of course, if the competition authority had already adopted a decision that the comparable product's price was excessive (or at least publicly opened an investigation), in which case the investigated company could reasonably know it should not use it as a benchmark.

9. Reverse cellophane fallacy

38. One of the traps that authorities can easily fall into is to compare the price of the investigated product with the price of a regulated product. This could be for example the case where a drug increases its price (potentially very significantly) once it is no longer subject to a previously applicable regulation. In such a case, the price before the increase would not provide a proper benchmark, as it is not determined by the market but set exogenously at low levels (which may even be loss-making for the manufacturer).

39. This phenomenon has been described as a "reverse cellophane fallacy."[16] Under the reverse cellophane fallacy, the reference price is not appropriate as it does not correspond to competitive market conditions, but rather than being too high (as in the cellophane fallacy), the reference price is too low.

40. Most recent pharmaceutical excessive pricing investigations involve old, off-patent products that experienced significant price increases since they became generic. Comparing the prices of these products to their pre-generic regulated levels would not be appropriate if the regulated prices were loss making or very low due to regulation. In countries such as the UK where profits are regulated on a portfolio of products under the PPRS framework, the profits on a single product may be very low but compensated by higher profits on other products. In fact companies under this framework may choose to price their older products at lower levels in order to be able to set higher prices on their newer products and still remain within the regulated profit limit. Choosing the low profit product as a benchmark would therefore be inappropriate, as a loss making or artificially low price is clearly not the right benchmark.

10. Focusing on high percentage price increases

41. Percentage increases of several thousand percent are headline grabbing, but provide a poor guide of whether a price is excessive. Indeed, for the reason mentioned above, the previous price may not provide a meaningful benchmark. But even further, high price increases in percentages are often associated with low absolute numbers. Indeed, if a pill used to cost cents, even a high percentage price increase will represent a limited amount in euros, which may actually be needed to ensure a sufficient profitability to incentivise companies to keep providing the drug. Therefore, high percentage price increases in themselves provide no indication of whether a product is priced at an excessive level.

11. Using accounting instead of economic measures of return on capital

42. It may appear practical for authorities to use accounting measures of profitability, as such measures are readily available. However, as is well-known,[17] such measures may be misleading. In economic terms profitability of an investment is assessed in terms of net present value, taking into account revenues over the product's life cycle. Accounting measures in contrast regard profitability at a point in time, where the value of assets is based on accounting rules.

43. To compute the economic rate of return, information is required on the cash flows generated over the lifetime of the investment as well as the value of the investments. This approach is, however, often impractical in excessive pricing cases, which typically concern limited time periods. Alternative profitability measures are therefore used by competition authorities, such as the Return on

16 D. J. Aron and D. E. Burnstein, Regulatory Policy and the Reverse Cellophane Fallacy (December 4, 2010), *Journal of Competition Law and Economics*, Vol. 6, Issue 4, pp. 973–994, 2010. Available at SSRN: https://ssrn.com/abstract=1171292.

17 *See*, e.g., the classic article by F. M. Fischer and J. J. McGowan, On the Misuse of Accounting Rates of Return to Infer Monopoly Prices, *American Economic Review*, 1983, Vol. 73 No. 1, pp. 82–97.

Capital Employed (ROCE),[18] Return on Sales (ROS),[19] profit contributions[20] as well as gross margin measures.

44. For instance, the ROCE measures profits relative to the value of the assets used to generate them. Estimating the value of the assets used to generate profits can present the authorities with a number of challenges.

45. The first challenge relates to the difference between accounting and economic value of the assets. Most companies book their fixed assets at historical cost, which bears no resemblance to the cost of replacing the asset with a modern equivalent (this is called the "Modern Equivalent Asset (MEA) approach" to measuring assets), particularly if the asset is old. In cases where the assets are old and mostly depreciated but still have a useful life, an adjustment needs to be made to the accounting value of the assets. The MEA approach measures the cost of replacing the assets with a modern equivalent and is the preferred approach. However, many fixed assets do not have active trading markets that would enable an easy evaluation of the cost to replace the asset with a modern equivalent.

46. The second challenge relates to the measurement of intangible assets, such as patents, licences and know-how, which are an important part of the assets of pharmaceutical companies. The accounting treatment of intangible assets rarely corresponds to the true economic value of the asset, which in itself is hard to measure. In accounting, internally generated IP is treated as an expense and does not appear in the balance sheet. Therefore in such cases an adjustment is required to recognise these R&D expenditures as assets. In the case of externally acquired IP, the accounting method is to value the asset at the historical purchase cost, amortized over a certain period. However, the amortization schedule used in accounting may not reflect the economic depreciation of the asset, where the net value of the asset is equal to the present value of the future cash flows it would bring. In both cases, adjustments need to be made to the accounting value of the intangible assets, which are not straightforward.

47. The third challenge involves the estimation of capital employed for specific products. Excessive pricing cases usually involve specific products. In multi-product firms, such as pharmaceutical companies, it can be challenging to allocate certain common fixed assets (manufacturing plants, machinery, office buildings, etc.) to particular products.

48. Last, the ROCE method is not appropriate to use in asset light businesses, e.g., in cases where the product is merely being distributed by a company. In such cases a measure such as the ROS (%), gross margins or product contributions may be more appropriate to use. Though computationally less problematic, these measures are not without difficulties. For example, when using a ROS (%) measure, common costs are required to be allocated, so the allocation issues are relevant here too.

12. Improper allocation of common costs

49. In many of the profitability measures, with the exception of profit contributions and gross margins, authorities need to estimate the net profits earned by the products under investigation. Whereas it is straightforward to measure sales revenues and direct costs at a product level, indirect or common costs need to be allocated, and the allocation method needs to be considered carefully.

50. Allocating common costs on the basis of sales revenues without further adjustment could be inappropriate in excessive pricing cases, as a disproportionate amount of the common costs would be allocated to the products under investigation. On the other hand, allocating common costs on the basis of volumes is not ideal either in cases of multi-product firms with heterogeneous volumes, which is characteristic of most pharmaceutical firms. In situations where the allocation of common costs is not straightforward, ideally authorities should test the robustness of their findings under a range of alternative cost allocation methods and also under a range of profitability measures.

13. Using WACC as a benchmark to determine excessive prices

51. Having arrived at a preferred profitability framework, the authorities would then need to choose an appropriate benchmark against which to compare the profitability of the investigated products. This is far from an easy task. A ROCE measure of profitability is sometimes compared against the WACC of the business. However, finding that a ROCE of a product is higher than the WACC does not automatically imply that returns are excessive. The WACC is the minimum return that investors would expect in order to undertake an investment. A ROCE can be higher than the WACC due to a number of procompetitive reasons, such as higher efficiency, successful innovation, cyclical factors or even just luck.

Given the inherent uncertainties of the product development and commercialisation process, *ex-post* realised profitability may very well turn out to be higher than expected *ex ante* (and conversely). Therefore, a comparison against the WACC is not in itself informative on whether profits are excessive.

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18 The formula of the ROCE is ROCE (%) = $\frac{Net\ profits}{Capital\ Employed}$

19 The formula of the ROS is ROS (%) = $\frac{Net\ profits}{Sales}$

20 Profit contribution is computed by subtracting from revenues those costs that can be directly attributed to the product in question (COGS, sales and promotion, distribution costs, amortisation of product specific investments, etc.).

14. Ignoring the role of regulation

52. Finally, antitrust intervention for excessive prices begs the question of why regulatory intervention would not be more adapted if there are true market failures that need to be addressed. Competition authorities have, time and again, repeated that they do not see themselves as price regulators. Indeed, competition authorities are not well placed to fix and monitor prices, given their lack of industry expertise and the need for continuous intervention. Second-guessing sector-specific regulation therefore does not, in our view, constitute desirable antitrust policy.

IV. Conclusion

53. This short article has highlighted the conceptual difficulties with excessive prices cases. In our view, in light of both these difficulties and the high probability and cost of errors in such cases, competition authorities should simply not run cases resting on excessive prices alone. At the very least, excessive pricing cases should be limited to truly exceptional circumstances. And we find that the pharmaceutical sector is particularly ill-suited for running excessive price cases.

54. But when competition authorities decide to nonetheless pursue such cases, they should in any case be extremely cautious about how they determine whether prices are excessive. In particular, we have highlighted some of the numerous practical difficulties in determining whether a price can be considered as excessive, and the main pitfalls that authorities should (hopefully) avoid. ■