THE POLITICAL ECONOMY OF EXCESSIVE PRICING IN THE PHARMACEUTICAL SECTOR IN THE EU: A QUESTION OF DEMOCRACY?

BY ROBERT O'DONOGHUE QC[1]

1 Robert O'Donoghue QC is a barrister with Brick Court Chambers, London and Brussels. robert.odonoghue@brickcourt.co.uk.

I. INTRODUCTION

At least in theory, one of the major schisms between EU and U.S. antitrust laws is that Section 2 of the Sherman Act 1890 does not sanction excessive prices as such whereas EU law does. Indeed, U.S. antitrust law might even be said rather to rub the EU's nose in it – in *Trinko* Justice Scalia considered the charging of monopoly prices not only not to be unlawful, but to involve "an important element of the free-market system," on the basis that the opportunity to charge monopoly prices is what attracts "business acumen" in the first place.[2]

In practice, this schism has, at least historically, been vastly overstated. As an absolute matter, there have literally only been a handful of excessive pricing cases in the EU. One oft-forgotten point is that the excessive pricing findings in the seminal EU case of *United Brands* were actually overturned on appeal.[3] The rare cases that have been brought have fallen into rather specific categories:

1) The first category concerns a series of cases involving the obscure topic of copyright management societies in the EU,[4] with *de jure* or *de facto* monopoly positions in each national territory, which, surprisingly, typically involve no regulation of their fees.

2) The second category concerns so-called parallel trade or market integration cases – a sacred cow in the EU – where the excessive price was a tool to discourage or prevent parallel trade.[5]

3) The final category concerns cases where the main issue was exclusionary conduct and the further concerns about pricing were really the corollary of other, successful abuses. *United Brands* was such as case since the primary antitrust complaints were price discrimination, sales conditions, and refusal to deal (albeit, as noted, the findings of excessive pricing were overturned on appeal).

In fact, under EU law there has never been a truly standalone finding of excessive pricing. The EU Commission's rejection of the excessive pricing complaint in *Port of Helsingborg*[6] were also thought effectively to have killed off excessive pricing, both as a matter of EU Commission administrative priority and in terms of the substantive hurdles that would need to be overcome by a complainant, competition authority, or plaintiff. In particular, the strong emphasis on "economic value" including demand-side considerations, and the value derived from the product or service by its users, made excessive pricing cases even more difficult than they are otherwise. The absence of excessive pricing from the EU Commission's 2009 abuse of dominance Guidance Paper was also striking.[7]

II. THE CHANGING TIDE?

To some surprise, the last couple of years have witnessed a dramatic resurgence of excessive pricing cases in the EU, nearly all of which have arisen in the pharmaceutical sector. The first sign was the €5 million fine imposed on Aspen by the Italian Antitrust Authority in respect of price increases of 1500 percent for four blood cancer drugs, subsequently upheld on appeal. In May 2017 the EU Commission then extended the investigation into the pricing of Aspen's cancer drugs EU wide (with the exception of Italy).

In December 2016 the United Kingdom's Competition and Markets Authority ("CMA") imposed a record £84.2 million fine on Pfizer, and a £5.2 million fine on its distributor, Flynn Pharma, for excessive prices for phenytoin sodium capsules, an anti-epilepsy drug. The drug was deb-

2 *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*, LLP, 540 U.S. 398, 407 (2004).

3 Case C-27/76 *United Brands v. Commission* EU:C:1978:22.

4 See Joined cases C-395/87 *Ministère public v. Jean-Louis Tournier* and C-110/88, 241/88 and 242/88 *Lucazeau v. SACEM and Others* EU:C:1989:215.

5 See Case C-26/75 *General Motors Continental v. Commission* EU:C:1975:150 and Case C-226/84 *British Leyland v. Commission* EU:C:1986:42.

6 EU Commission decision *Scandlines v. Port of Helsingborg* COMP/36.568. At a national level, cases like *Attheraces Limited v. British Horseracing Board Limited* [2007] EWCA Civ 38 (which refers to *Port of Helsingborg*) had a similar practical effect.

7 Communication from the EU Commission: Guidance on its enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings. OJ C 45, 24.2.2009, p. 7–20. Whilst true that the issue of fair, reasonable and non-discriminatory ("FRAND") royalties has featured prominently in antitrust law in the EU and elsewhere this concerns a rather different, and specific, aspect of antitrust law where a firm has committed to offering FRAND licenses and the courts' function is to work out a rate if there is a dispute.

randed and the prices increased by up to 2,600 percent compared to the previous (regulated) branded price.[8] The CMA's findings on abuse were overturned in a striking judgment rendered by the Competition Appeal Tribunal ("CAT") on June 7, 2018,[9] due to various legal errors in the CMA's assessment. The CMA is seeking permission to appeal this judgment. The CMA is also pursuing a surprisingly large number of other investigations into excessive prices in the pharmaceutical sector that were, prior to the CAT's judgment in *Phenytoin*, also at a relatively advanced stage.

These developments in the pharmaceutical area are not simply confined to the EU.[10] But what is unique to the EU relative to the U.S. and most other countries is that the antitrust laws on unilateral conduct are being used successfully to target excessive prices for these pharmaceutical products.

Finally, in September 2017 the EU Court of Justice ("CJEU") rendered a very important ruling in the so-called *Latvian Copyright* case.[11] The CJEU's judgment, and the opinion of Advocate General Wahl in the same case, are highly significant, since they constitute the first real opportunity that the most senior EU court has had to deal with excessive pricing since its seminal judgment in *United Brands* in the 1970s.

III. THE POLITICAL ECONOMY OF PHARMACEUTICALS

Pharmaceutical products are subject to unique levels of regulation – perhaps more so than any other product or service. In the pre-marketing stage, there are, rightly, extraordinary levels of safety and efficacy checks. The cost of bringing new drugs to market is often of the order of hundreds if not millions of pounds/Euro/dollars due to clinical trials and other testing.

But in the EU there are also very high levels of regulation of pharmaceutical products at the post-marketing stages as well. In particular, direct and indirect forms of State-sanctioned price and/or profit controls and caps are the norm and the State in its various avatars is normally the sole ultimate end-purchaser. The detailed explanation of the extraordinarily complex systems that exist with the 28 EU Member States is well outside the scope of this short opinion piece but the following points bear mention:[12]

1) National health systems in the EU are funded by taxpayers, either through general taxation or through specific social security charges. Typically, a budget is allocated to health services/products and a portion of that budget is then sub-allocated to the funding of drug purchases, both patented and off-patent (generic), branded or unbranded. Thus, the taxpayer underwrites the system, with the national health service as the ultimate sole or main payor. The practical operation of this underwriting mechanism varies but, in most countries, the dispensing pharmacies will be reimbursed by the national health service when fulfilling prescriptions covered by State reimbursement schemes. In some countries patients or their insurers have to make contributions or co-payments or pay fixed charges for, e.g. a prescription.

2) Direct price regulation remains a feature in many EU Member States, usually consisting of a fixed or a maximum price, typically on an *ex-ante* basis but *ad hoc ex-post* price freezes are also possible. Direct price control schemes may have an express statutory basis or may involve collective agreements between the State purchasing entity/ies and the participants in the regulated scheme

8 Pfizer considers this characterization unfair. It said this historic price was loss-making and that the new price was intended to achieve some level of parity with the price paid by the national health service for an identical phenytoin sodium tablet product.

9 *Pfizer Inc and others v. Competition and Markets Authority* [2018] CAT 11. I acted for Pfizer in this appeal but the views expressed here are personal ones only and do not directly touch on the issues in the *Pfizer* case.

10 Aspen for example is also under investigation by the South African Competition Commission, where Aspen is headquartered. In the U.S. there was enormous public outcry when Gilead charged $84,000 for a 12-week course of treatment for a hepatitis C drug, leading to $14 billion in sales in the first year, for a drug said to cost $350 to produce. Even before his criminal conviction, Martin Shkreli became a controversial figure when his company increased the price for Daraprim, used to treat certain AIDS-related diseases, to $750 a pill, from $13.50. The issue became a major political football during the 2016 Presidential Election. Indeed, prescription medicine prices remain a major political issue in the United States, leading to the publication in May 2018 of "*American Patients First The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*:" see: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

11 Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība* EU:C:2017:286.

12 See documents collected at: http://ec.europa.eu/DocsRoom/documents?locale=en&tags=Pharmaceutical%20pricing%20and%20reimbursement%20systems and the documents referenced therein. See also: http://whocc.goeg.at/.

(or both).[13] Regulation does not simply apply the manufacturer level: most Member States also have regulated margins for wholesalers and pharmacies for reimbursable medicines and many seek to clawback discounts offered by wholesalers/manufacturers, in an effort to reimburse as close as possible to the true price paid. As with all forms of direct *ex-ante* pricing regulation, price and/or profit controls are complex to implement for both the regulator and the regulated. They also place significant informational and other resource demands on the parties.

3) A particularly prevalent form of price control in the EU is external reference pricing ("ERP"). The WHO Collaborating Centre for Pricing and Reimbursement Policies defines ERP as: "The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country." So price movements in one reference country can affect the prices in the country applying ERP. It is a form of international price benchmarking. A major recent study shows that most EU Member States applying ERP to a greater or lesser extent.[14] The study considered 31 European countries (28 EU Member States plus Iceland, Norway, and Switzerland). All but two used ERP to some extent. The majority of the countries use ERP as the main systematic criterion when setting the price of a new drug, while others, like Belgium, Finland, Italy, Poland, Spain and Germany, use it as a supportive criterion. The content of individual ERP schemes varied enormously. The number of reference countries included in the basket for comparison purposes varied from 1-31. The particular methodology also varied; 15 countries used average prices, 7 countries used the lowest price, and 7 countries used other calculation methods.

4) In general, EU Member States impose the most onerous forms of regulation on patented drugs and often leave generic drug pricing to the market. But the practical reality is more complex than this. Some Member States have price controls for generic medicines as well. Other Member States have statutory or non-statutory powers to regulate the price of generic medicines, if it is felt that competition is not working well. Complexities also arise because in many countries the pricing of generic medicines has a direct effect, under the relevant statutory scheme or other price control measure, on the pricing of patented products, e.g. once a generic comes on the market the reimbursement price for the originator equivalent automatically drops by "X" percent. More generally, the pricing impacts of generic entry on originator products may be either muted or non-existent. Kanavos summarizes the position as follows:[15]

> …the literature on the influence of generic competition on originator brand name prices and market share is somewhat divided. While some studies have found that the price response to generic entry is as expected, in that originator prices decline following generic entry, others have found that prices of originator brands may rise upon generic entry. In addition, while increased competition between generic producers has been found to decrease prices of generic drugs, the price of branded drugs is not necessarily reduced by increased generic competition. It has also been shown that originator brand manufacturers do not respond to generic market entry by decreasing prices, but rather generic entry may correspond to a decrease in the speed of originator price increase. Evidence also suggests that manufacturers will often not compete on price once generic competitors enter the market.

5) An unusual feature of prescription medicines is that the person who decides what drug is used – the clinician – does not pay for or dispense the drug in question and may, all else equal, be agnostic as to the economic consequences of exercising a particular choice. The same may be true of the patient unless there is some form of contribution or co-payment that: (i) varies depending on the underlying drug price; and (ii) is relatively significant. These dynamics and incentives may lead to either patient/prescriber inertia or in some cases even over-consumption. It may also mean that, where a choice exists between drugs, prescribing decisions may be motivated by various subjective factors or by the zealousness of marketing representatives of drug companies.[16] An indirect form

13 For example, the British Pharmaceutical Price Regulation Scheme is a voluntary agreement between the Department of Health and the Association of the British Pharmaceutical Industry to control the prices of branded medicines sold to the national health service ("NHS"), by regulating the maximum prices of branded medicines; and the profits that manufacturers are allowed to make on their sales to the NHS.

14 See External Reference Pricing Of Medicinal Products: Simulation Based Considerations For Cross-country Coordination, Final Report by Toumi, Rémuzat, Vataire & Urbinati (2014), available at: https://ec.europa.eu/health//sites/health/files/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf.

15 Kanavos, Measuring Performance In Off-Patent Drug Markets: A Methodological Framework And Empirical Evidence From Twelve EU Member States, *Health Policy* 118 (2014) 229–241, at 230.

16 For example, a patient may have some irrational fear that a different color pill may affect his or her condition and the clinician may prescribe that more expensive product for sake of a quiet life.

of regulation in the EU therefore concerns measures designed to impose some structure on decision-making on the demand side. These include clinical practices' guidelines and prescription guidelines, education and information methods (e.g. computerized software), and obligations to prescribe generic or other cheaper alternatives where they exist (e.g. parallel trade). Discounting and rebate practices on the demand side can also have a significant impact on pharmaceutical pricing, particularly where the State "claws back" the effective price paid by the dispenser.

6) The fact that the State in the EU is the ultimate payor, and in most cases also the regulator, may vest various forms of buyer power in the State. As a matter of economics, a sole buyer ought to have monopsony power. The fact that the ultimate customer is also the regulator and, effectively, part of the Government, normally adds to that power. In practice therefore if the State is concerned about drug prices it will have various formal and informal levers at its disposal that may allow it to "make an offer than cannot be refused." The ultimate threat of extending direct regulation also plays a part here – it is perhaps unique that the regulator can also seek legislation to move the goalposts. The State purchasing entity may therefore engage in discussions with the firm requesting information about the product and inviting them to reduce their prices by consent, "invite" them to join existing regulatory schemes, make threats to impose direct regulation where none currently exists, threaten to expel the firm from an existing (favorable) regulatory scheme, or threaten to seek new legal powers if corrective action is not taken.

IV. THE QUESTIONS OF POLITICAL ECONOMY AND DEMOCRACY

The purpose of this short piece is not to attack or defend the recent decided cases on excessive pricing of pharmaceuticals in the EU or to critique the general principles of abuse of dominance under EU competition law (and national law analogues).[17] Nor does this piece decry or assuage concerns expressed over: (i) the general increases in public spending on prescription drugs (which has increased at rates faster than total health spending and gross domestic product in the EU and other Western countries); or (ii) the specific price increases in the cases described earlier in this piece (which, to the extent they remain *sub judice*, must run their own course).

Instead, a narrow, and more fundamental, point is made. The argument proceeds on the following cumulative points.

The first point is an important legal point that public health remains an area of exclusive national competence under EU law, i.e. it is not a competence held by the EU institutions or even shared with them.[18] Article 168(7) TFEU states that the "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."

The second point is that acting on their exclusive competence in public health matters EU Member States have, for better or for worse,[19] decided to regulate pharmaceutical pricing in extraordinarily detailed ways. As noted above, EU Member States have in particular adopted pricing rules for drugs and decided which treatments they wish to reimburse under their national health/social security systems. The details of the different regulatory schemes vary enormously since how much an EU Member State is able, and wishes, to spend, first, on healthcare and, second, on funding prescription medicines is ultimately a political question, which will depend in part on how rich that country is, what its healthcare needs

17 The state of EU competition law on this issue following the CJEU opinion and judgment in Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība* EU:C:2017:286 is a fascinating topic for further detailed exploration. For a discussion see *Pfizer Inc and others v. Competition and Markets Authority* [2018] CAT 11.

18 The only EU legislation of interest for these purposes is Council Directive 89/105/EEC of December 21, 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40, 11.2.1989, p. 8–11. It provides for a limited degree of transparency of measures established by Member States to control the pricing and reimbursement of medicinal products. It mainly operates to define certain procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the pharmaceutical trade within the EU's internal market. Of significance is that in 2015 a proposal to replace the Directive was withdrawn due to objections from the EU Member States.

19 Price regulation will not really affect existing drugs whose development costs are already sunk. But it may affect the development of new innovative drugs if the cumulative effects of regulation make it more attractive for firms and their investors to put their capital into other areas. This is a very complex issue but the basic intuition is that the exercise of monopsony power will depress output by sellers. Price regulation by the sole buyer can be seen as the ultimate expression of monopsony since few buyers are both regulators and customers. This argument is obviously truer of patented drug price regulation than generics.

are, and the other competing political priorities.[20] Regulation raises delicate political questions since there will often by political pressure to fund expensive new drugs that offer marginal quality of life or life-extension benefits over existing ones.[21] In other words, whether, to what extent, and how an EU Member State seeks to regulate pharmaceutical pricing is a political decision *par excellence*, made, as noted, in furtherance of exclusive powers deliberately retained from the EU.[22]

Third, the basic legal predicate of abusive conduct is competition that is not "normal." In *Hoffmann-La Roche* the CJEU defined an abuse as conduct "which, through recourse to methods different from those governing normal competition in products or services on the basis of transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition."[23] More specifically, an excessive price under EU competition law is defined as one that is significantly and persistently above a normally competitive price or, put another way, as a price not obtainable in a normal and effectively competitive market. In *United Brands*, the CJEU defined unlawful pricing by reference to "whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition." (para 249) (emphasis added)

Drawing together the above points leads to the following basic thesis:

1) EU Member States have, quite deliberately, reserved unto themselves exclusive competence over public health matters, including notably pharmaceutical price regulation. The case for the EU Commission effectively re-evaluating those decisions – including decisions not to regulate particular prices or to do so in one way but not another – raises important constitutional issues to do with the division of power between the EU and its Member States. Being candid, it is not within the EU's competence to re-regulate prices or force the EU's view of pharmaceutical price regulation on a country that has made other arrangements.

2) Quite apart from the above constitutional point, the endemic nature of price and related forms of regulation for pharmaceutical products at a national level in the EU makes it impossible to apply the central concepts of "normal competition" (for abuse generally) and a price that is significantly and persistently above a normally competitive price (for excessive pricing specifically) to regulated pharmaceutical products. Put simply, in regulated markets there is no "normal" counterfactual against which a proper assessment can be made. One cannot have a "normally" competitive price in a market that is inherently distorted by regulation intended to achieve a whole host of other aims.

3) Indeed, one can go further than 2). As noted above, the regulation of pharmaceutical price is inherently a political decision by each EU Member State that depends on a myriad of complex social, political, economic and other factors particular to that country. The essential question: how much a Member State wishes to pay for healthcare services/products, and how much of that it wishes to allocate to prescription medicines, is a domestic political question. The notion that that decision gets subcontracted to generalist antitrust authorities – whether at the EU or national levels – is a dubious one. There is no particular framework or cardinal under the antitrust laws on abusive unilateral conduct to suggest that the analysis of excessive pricing there has anything to commend it for pharmaceutical products. Under EU law on abuse of dominance (and its domestic law analogues) the overarching question is the

20 In principle an EU Member State could decide to impose no or light-touch regulation of pharmaceutical prices for any number of reasons. For example, innovative drug production may be a major feature of its economy.

21 In most Western democracies, older voters are on average more likely to vote than younger voters. The "gray" vote may therefore be able to bring powerful political pressure to bear and healthcare will naturally be high on their concerns.

22 It also bears emphasis that the issue is a holistic one that extends far beyond the realms of regulation of pharmaceutical prices. For example, some EU Member States regulate alcohol pricing and/or sales channels as a public health measure. Developed States are also taking increased measures to increase public health and avoidable illness, to reduce healthcare expenditure.

23 Case 85/76, *Hoffmann-La Roche & Co AG v. Commission* EU:C:1979:36, para. 6 (emphasis added).

"economic value" of a product or service.[24] But given the diversity of price and related regulation of pharmaceutical products within the EU Member States, it seems highly unlikely that the antitrust-based notion of a "fair" price – even assuming (heroically) that there is such a thing – has any necessary connection with the multifarious political and other non-economic objectives sought to be achieved as respects healthcare in that country. For example, value-based pricing is a particular feature of pharmaceutical regulation in the EU. In the United Kingdom measures such as quality-adjusted life year ("QALYS") are used to make value-based funding and other decisions on medicines: "QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance."[25] There are also institutional questions as to whether generalist antitrust authorities have any real competence to conduct such "holistic" assessments and indeed whether they should be conducting them at all given the legal and political delegation of these tasks to specialist regulators and bodies.[26]

In short, there is a compelling policy and legal argument that the political economy of pharmaceutical pricing in the EU is such that it is simply inappropriate to use the antitrust laws on unilateral excessive pricing as a response to pharmaceutical pricing concerns.

V. DEALING WITH SOME STRAW MEN

Two categories of straw men points are worth responding to. The first is that the above approach is not some paean for a "do nothing" approach as respects pharmaceutical pricing. The point made here is that the decision on how much to pay for pharmaceutical products is one of the most fundamental, and complex, expressions of democratic decision-making, will, and sovereignty. If a Member State wishes to regulate pharmaceutical prices – and I take an entirely neutral position on that issue – it should use its existing pharmaceutical regulations or, if there is a lacuna and sufficient democratic and political support, adopt new regulatory laws. The latter point is important since virtually all of the cases which have arisen in the EU concern allegations of "circumvention" of or "gaps" in regulation, e.g. where "de-branding" leads to lesser regulation.[27] The short answer is that if that is indeed the case the gap should be plugged by sector-specific regulation. The notion of using the antitrust laws on unilateral conduct as some form of panacea or to make up for regulatory failures is an unsound one. Equally, if regulators suitably empowered cannot be bothered to use their powers and act, antitrust laws on unilateral conduct should not be seen as some fail-safe or catch-all. The application of antitrust laws should not depend on the diligence of one set of public servants over another.

The second point to deal with concerns the different strands of case law from the EU Courts which, superficially, appears dismissive of "regulatory distortion"-type arguments.

The first strand concerns EU law on abuse of dominance cases where the CJEU has noted the distortive features of pharmaceutical regulation but has refused to treat those as an "exempting" feature that rendered the abuse of dominance laws inapplicable. Notably, in *Glaxo*

---

24 See Case C-27/76 *United Brands v. Commission* EU:C:1978:22, paras 250-253: ("250.…charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse. 251 This excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin; however the Commission has not done this since it has not analysed [United Brands'] costs structure. 252 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. 253 Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair.").

25 See: https://www.nice.org.uk/glossary?letter=q.

26 There is also an issue of fairness and consistency. Antitrust authorities and courts can only ever deal with a finite range of the disputes that happen to come before them. If antitrust law is applied to pharmaceutical pricing as opposed to specific regulation, this will inevitably lead to asymmetric or *ad hoc* controls over certain companies' prices but not others. If prices are to be controlled, better that it be done on a symmetric basis to avoid unintended consequences or happenstance. Asymmetric regulation is only appropriate where one firm stands in total contrast to all other market actors, e.g., a communications firm owning an essential facility.

27 For example, in the United Kingdom, there was a legal question as to whether existing regulation allowed price regulation of a generic product if the manufacturer happened to be a member of another statutory or voluntary scheme. In a belt and braces approach, the UK legislature adopted Section 4 of the Health Service Medical Supplies (Costs) Act 2017 to put the scope to regulate beyond any question.

Greece,[28] the pharmaceutical manufacturers made the perfectly fair point that parallel trade only arose in the first place because divergent price regulation created scope for arbitrage between low- and high-priced countries. The CJEU was actually sympathetic to that argument. It held that:

> 67. Although the degree of price regulation in the pharmaceuticals sector cannot therefore preclude the Community rules on competition from applying, the fact none the less remains that, when assessing, in the case of Member States with a system of price regulation, whether the refusal of a pharmaceuticals company to supply medicines to wholesalers involved in parallel exports constitutes abuse, it cannot be ignored that such State intervention is one of the factors liable to create opportunities for parallel trade.
>
> 68 Furthermore, in the light of the Treaty objectives to protect consumers by means of undistorted competition and the integration of national markets, the Community rules on competition are also incapable of being interpreted in such a way that, in order to defend its own commercial interests, the only choice left for a pharmaceuticals company in a dominant position is not to place its medicines on the market at all in a Member State where the prices of those products are set at a relatively low level.
>
> 69 It follows that, even if the degree of regulation regarding the price of medicines cannot prevent any refusal by a pharmaceuticals company in a dominant position to meet orders sent to it by wholesalers involved in parallel exports from constituting an abuse, such a company must nevertheless be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests.

Two related points can therefore be made. First, the CJEU accepts that the distortive pricing features of regulation can affect the application of the antitrust laws on unilateral conduct. Second, the thesis advanced here is not for a total "exemption" of pharmaceutical pricing from the antitrust laws on unilateral conduct. Rather, it is a narrower point that if the benchmark of excessive pricing is the normally competitive market, then there is no such benchmark where prices are regulated and therefore distorted, i.e. the market is abnormal through regulation. So, on its own terms, the laws on abuse of dominance cannot be applied in a coherent manner in these circumstances.

The second strand concerns EU free movement of goods cases under Article 34 TFEU where the CJEU has held that national market regulation does not prevent the application of these rules: it is "a matter of no significance that there exist as between the exporting and importing Member States, price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product."[29] Two points can be made. First, this is a free movement of goods, and not an antitrust case, and the more recent CJEU findings in *Glaxo Greece* – which was an antitrust case – seem therefore more apposite here. Second, the *ratio* of the case concerned a rather specific point of EU and national trademark law. The CJEU's primary finding was that the exercise, by the owner of a trade mark, of the right which enjoyed under national law to prohibit the sale, in that State, of a product which has been marketed under the trade mark in another Member State by the trade mark owner was contrary to the EU free movement rules. The point about regulation was simply that that did not justify the sales prohibition. This is all rather remote from the thesis being considered here.

The third strand concerns telecommunications cases where the decisions of national regulatory authorities ("NRAs") created under EU secondary legislation cannot prevent the Commission from taking action in respect of the same pricing under primary EU law on abuse of dominance, even if the NRAs have applied EU law on abuse of dominance in their decisions.[30] This line of case law is controversial,[31] but it does not in any event undermine the point made above. For one thing, the regulation of telecommunications is an EU competence, which was partly shared with the EU Member States via the creation of NRAs under the so-called Common Regulatory Framework for communications. Public health, by contrast, is an exclusive competence of the EU Member States. Furthermore, the gravamen of these cases is that the NRAs were lazy, captured, or misapplied EU law on abuse of dominance. This is not the underlying issue in the thesis outlined above.

The final strand concerns instances where there is a State action defense to the application of EU antitrust law. Under these rules undertakings cannot be found to abuse their dominant position if: (1) the persons engaging in the restrictive conduct are acting in the public interest; or (2) the undertakings concerned were compelled to participate by a State measure; or (3) State regulation eliminated the possibility

28 See Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE,* EU:C:2008:504.

29 Case 15-74 *Centrafarm BV and Adriaan de Peijper v. Sterling Drug Inc.* and Case 16-74 *Centrafarm BV and Adriaan de Peijper v. Winthrop BV* EU:C:1974:90.

30 The leading case is Case C-280/08P *Deutsche Telekom*, ECLI:EU:C:2010:603.

31 See O'Donoghue, Regulating the Regulated: Deutsche Telekom v. European Commission, *Competition Policy International*, May 15, 2008.

of competitive activity. Undertakings participating in a State-implemented scheme that restricts competition can raise these points as a defense for their participation.[32]

The third category seems potentially the most relevant here. But, again, the thesis advanced here concerns a different point. The argument is not that regulation compelled the pharmaceutical manufacturers to act anti-competitively, such that the laws on abuse of dominance should not sanction the resulting price. Rather, the point is that, assuming EU law on abuse of dominance can in principle apply, are the (legal) conditions under which it applies to excessive pricing in pharmaceuticals – notably "normal competition" and a price that is excessively benchmarked against a normal effectively competitive pharmaceutical market – logically impossible to apply where competition is not normal due to pervasive and deep regulation.

VI. CONCLUSION

The surprising renewed interest in excessive pricing cases under EU and national antitrust laws in respect of pharmaceutical pricing has blithely proceeded on the assumption that one can simply apply the usual general legal principles, albeit taking some account of the features of pharmaceutical markets.

The thesis advanced in this short piece is that this is wrong-headed on multiple levels. In the first place, the legal definition of abuse of dominance is conduct which is not "normal competition." Pharmaceutical pricing is highly regulated in the EU so competition is distorted, not normal. In particular, if the benchmark for an excessive price is one significantly and persistently above pharmaceutical prices in a normally and effectively competitive market, then they cannot be logically applied since, by virtue of regulation, there is no such market. To repeat, this thesis is not an argument for doing nothing. Rather, it strongly counsels against using the antitrust laws on abuse of dominance as a panacea for the plea that "something must be done." If something must be done, a problem caused by regulation should, if necessary, be solved by regulation.

There are also important democratic and constitutional reasons for this. At the EU level, there is simply no competence over national public health decisions and their resourcing. At a national level, if there is to be price regulation, it is more constitutionally appropriate that the would-be subjects of regulation have the benefit of a proper legislative process by which new or adapted laws are promulgated. Doing this by stealth under antitrust law raises important questions about the rule of law.

Finally, there is an institutional component. Each of the EU Member States has set up a vast machinery to regulate pharmaceutical pricing, including Government bodies and regulators who are empowered, and trained, to consider a wide range of non-antitrust objectives and considerations when deciding whether and how much to pay for prescription medicines, and how such funding fits within the wider healthcare service.[33] The rather narrow consumer welfare based approach of antitrust, and the institutions that apply this approach, are not well equipped, or even designed, as proper delegates for these purposes. In short, how much you, or more specifically the State, are willing to pay for a drug is simply not an antitrust question. It is a political one that demands a political answer arrived at through a proper democratic process.

32 See O'Donoghue & Padilla, *The Law And Economics Of Article 102 TFEU*, 2nd ed, Hart Publishing, chapter 1. p22. These defenses are available irrespective of whether or not the prior State measure appears to be legal, i.e. the defendant is not required, as a condition of this defense, to challenge the validity of the measure in question. However, once the measure has been declared contrary to EU competition and/or national law, any immunity ceases with immediate effect.

33 For example, it may be a good idea to pay what seems like a lot for a drug if the savings in avoided hospital time through the use of that drug are greater. An antitrust authority or court cannot easily factor such "total welfare" issues into its assessments.