Excessive pricing doctrine in the pharmaceutical sector: the space for reform

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Abstract

This chapter reflects on the evolution of competition law jurisprudence regarding the excessive pricing of pharmaceutical products, and suggests areas where improvements might be considered. This includes, first, establishing *per se* rules regarding pricing increases that might be considered excessive based on cost-plus baselines. This would facilitate the work of competition authorities and shorten prosecution timelines. The second set of improvements would involve identifying an appropriate methodology by which to determine reasonable baseline or normal prices to compare with the prices actually charged, particularly when a rule of reason analysis is required. Reasonable cost-plus baselines both for generic and originator products, taking account of risk, can be established. Finally, the so-called 'two-step' methodology for determining excessive pricing derived from the CJEU's 1978 decision in *United Brands* is revisited. Outside the *per se* circumstance, this chapter recommends unitary determination of excessive pricing based on cost and context.

Key words: pharmaceutical, excessive price, competition, per se rule, rule of reason, two-step, risk

1. Introduction

Excessive pricing doctrine is emerging as an important part of the competition law enforcement arsenal that is relevant to the pharmaceutical sector. The current status of the implementation and enforcement of excessive pricing doctrine suggests the need for improvements. This is not surprising given the comparatively short history of its doctrinal evolution.

This paper incorporates three phases of the development and implementation of the doctrine of excessive pricing in European competition law as it relates to pharmaceuticals.[1] The initial phase following the 1978 decision of the Court of Justice of the European Union (CJEU) in *United Brands v. Commission*[2] that initiated the trajectory of excessive pricing doctrine; the phase of the past decade in

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[1] The author refers to a previous work for general background on excessive pricing in competition law relevant to the pharmaceutical sector, Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, UC IRVINE LAW REVIEW, Volume 6, Issue 3, pp. 281-320, Dec. 2016, available at SSRN: https://ssrn.com/abstract=2719095. On the use of competition law to promote access to affordable medicines, see generally UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries, United Nations Development Program (ed. F. M. Abbott)(2014), available at SSRN: https://ssrn.com/abstract=2439416, and; forthcoming 2022 Supplement to the UNDP Guidebook. See also, OECD, Excessive Prices in Pharmaceutical Markets, Background Note by the Secretariat, DAF/COMP(2018).

[2] Case 27/76, United Brands Co. & United Brands Cont'l B.V. v. Comm'n of the European

which competition authorities have applied excessive pricing doctrine in the pharmaceutical sector, and; the phase to come.

a. Limited application

Notwithstanding an effectively express reference to excessive pricing in what is now the Treaty on the Functioning of the European Union (TFEU), for many years competition authorities in the EU (and elsewhere) were reluctant to apply the doctrine, and the *United Brands* decision was viewed more as a jurisprudential roadblock than an invitation for further development. Up until the past decade – the starting point for which might be viewed as the OECD's compilation of perspectives of competition authorities in 2011[3] – no cases had been brought against pharmaceutical companies for excessive pricing as such in Europe, and activity elsewhere had been very limited.

b. Threshold crossed

Once the initial hesitation had been overcome – and this can be substantially credited to the UK Competition and Markets Authority (UK CMA) – actions have proceeded against exclusively generic products (and suppliers). In the process, the challenges posed by *United Brands* have manifested themselves. This is largely, although not exclusively, a by-product of the so-called 'two-step' test, [4] which has in practice been viewed by judges as a three-or-more step test in some cases. A consequence of the jurisprudential complexity and ambiguity is the extended duration of the relevant legal actions. Another aspect is that competition authorities have yet to tackle a 'new' pharmaceutical product protected by patent and/or originator regulatory market exclusivity,[5] a type of case that is inherently more complex than those involving generic supplies, yet arguably more important.

c. Three elements for reform

This book focuses on competition law and the pharmaceutical sector in Europe. In that respect, the jurisprudence of the CJEU is of central importance. There is room to revisit and perhaps revise that jurisprudence. However, before turning to that, we begin by suggesting reforms that might be important to the application of excessive pricing doctrine without regard to specific national or regional jurisdiction.

2. Facilitating prosecution

Extended duration is a problem that affects competition prosecutions more generally. The difficulties appear acute with respect to action on excessive pricing. Much of this delay is not the result of the

Cmtys., 1978 E.C.R. I-207 (hereinafter 'United Brands'). The European Court of Justice or ECJ which decided the United Brands case is today referred to as the CJEU. This chapter will refer to that Court as the CJEU.

[3] OECD Directorate for Fin. & Enter. Affairs Competition Comm., Excessive Prices (2012) ('This document comprises proceedings in the original languages of a Roundtable on Excessive Prices held by the Competition Committee (Working Party No.2 on Competition and Regulation) in October 2011').

[4] See discussion of *United Brands*, *infra* [].

[5] But see orphan drug designation in ACM *Leadiant* case, infra []. This did not involve a 'new' product.

underlying complexity of the facts, but a combination of ambiguous judicial rulings and the obstacles that defence lawyers routinely place in the way of prosecution through legal motions and challenges of judgments, including appeals. Although it is tempting, fault in this regard should probably not be ascribed solely to the defence lawyers. They are paid to delay prosecution on behalf of their clients. The fault lies in the way the system for enforcing the rules has been designed. Mechanisms are needed by which competition enforcement actions can be streamlined; that is, made to progress more rapidly.

a. *Per se* rules and/or weight of presumptions

How might the jurisprudential system for enforcement be reformed to accelerate prosecutions from initiation to conclusion? The traditional tool for accelerating competition enforcement is the promulgation or adoption of '*per se*' rules that identify certain types of conduct as anticompetitive as a matter of law, without the possibility for any defence involving the demonstration of counterbalancing pro-competitive elements. *Per se* rules have generally been applied to certain types of agreement among enterprises, such as agreements to fix prices or allocate geographic territories between horizontal competitors. Such agreements are identified through routine evidentiary processes. The more complex balancing alternative is generally referred to as 'rule of reason' analysis.

To date, *per se* rules have not formed part of excessive pricing jurisprudence. Excessive pricing is not typically characterized by an agreement between enterprises or undertakings (although it can involve such an agreement). Excessive pricing is a subtype of 'abuse of market power', whereby a dominant enterprise extracts a price(s) that is unreasonable (or abusive) by virtue of its control over the relevant market (e.g., the market for a specific pharmaceutical product). The excessive price refers to the 'spread' between the 'normal' non-abusive price and the unreasonable/abusive price. Calculating that spread, or differential, entails establishing a cost (or other) baseline and comparing that with the price actually charged. Establishing a *per se* rule appears to require some agreement on what constitutes an acceptable level of spread, which in turn requires some agreement on the appropriate methodology (or methodologies) for determining the baseline.

For pharmaceutical products that are not protected by a grant of exclusivity (arising either from a patent or regulatory market exclusivity), otherwise known as 'generic' products, establishing the baseline for calculating the spread should not be difficult. The product has been on the market, and while there may have been R&D investment in improving the production process, for example, the costs can be calculated with some certainty. The price charged for the product by the producer can be determined (e.g. by examining invoices). Establishing the spread between the baseline 'normal' price and the price charged by the producer is straightforward. The differential may be stated as a percentage. During the past several years competition authorities in various jurisdictions in Europe have shown their ability to make sound determinations regarding the cost-plus baseline and the spread.

Is there some standard level at which the selling price of a generic pharmaceutical product exceeds the cost-plus baseline by so much that it should be considered abusive *per se*?

In the cases decided so far, and which are referred to by various contributors to this book, the differential between cost-plus price and the actual selling price is high. In several cases well over

1000%.[6] We might start by positing that for a generic producer to charge more than 10 times the cost of production plus a reasonable profit is excessive on its face – that is, *per se* excessive. That would seem relatively uncontroversial. Is there a level between the cost-plus (the baseline) and selling price that is less blatantly unreasonable but could still qualify as excessive on its face? Might that level be 150%, 300%, 500% or 750%? Does it matter that the price in question may have been in effect for a period of time, or whether it has recently been subject to a substantial increase?

There is no obvious social or economic norm to rely on for establishing what should be considered a lower bound on *per se* excessive pricing. Doubtless the pushback from the industry on a level like 25% would still be substantial, even though that percentage (and lower) is applied in some price gouging statutes.[7] We will leave the question open: what minimum threshold percentage level of price over cost might be considered *per se* excessive for a generic pharmaceutical product?

Should a producer be allowed to rebut an initial finding of *per se* excessive pricing by demonstrating that some special circumstance justified the extreme price differential (recognizing that this might not then be considered a *per se* rule as such)? It is difficult to know what such a special circumstance might be. For example, a producer might assert that the shortage of a particular chemical input on the market required it to pay far more for that input than it previously had, contending that the very high price was justified. However, the input price already would be included as part of the cost determination and should already have been taken into account.

Nonetheless, one can imagine that a new rule might not be a *per se* rule, as such, but a strong presumption against the producer, still allowing some scope for demonstrating a legitimate justification.

Establishing an excessive pricing baseline in the case of originator products that involve research and development (R&D) and a degree of risk (variable depending on the circumstance) is more complex than the relatively straightforward cost-plus determination with respect to generic products. The originator pharmaceutical industry argues that the cost of developing new pharmaceutical products is highly indeterminate thereby justifying what may often appear to be excessive prices.

While some new originator products do indeed represent breakthrough therapies based on previously unknown science, there are also many originator products that are merely product line extensions based on minor modifications of existing formulations. For that latter category of product, looking at the differential between the price for the 'new and improved' product and its predecessor on the market, and comparing that to the cost of the improvement may not be so difficult.

For 'breakthrough therapies' that involve high-risk R&D, determining a baseline or normal price may be more difficult. The level of acceptable differential between development costs and selling price may be

[6] See, e.g., *Pfizer/Flynn* and *Leadiant* cases, *infra*.

[7] In fact, a number of US state price gouging statutes establish 10% above the pre-event price as excessive, subject, for example, to proof provided by the accused party of the additional costs it incurred. See, e.g., California Penal Code – PEN Sec. 396, and other statutes listed in https://www.findlaw.com/consumer/consumer-transactions/price-gouging-laws-by-state.html.

greater in order to account for the degree of risk and the extent of the benefit of the new therapy. This does not mean that the price of a new breakthrough originator drug may not be excessive, but probably less susceptible to *per se* analysis. With that said, there are means by which establishing the R&D costs of a new drug could be facilitated for competition law purposes and others, which are considered also in the following section.

b. Agreement on analytic tools

Whether or not there is agreement on *per se* rules, there will be circumstances in which in-depth analysis of factual elements is required. For example, in cases involving generic products when the level established as the *per se* anticompetitive level of the differential is not met, or in specific cases involving products protected by exclusivity rights where a balancing analysis may be more appropriate. We therefore move on to the second major area for reform, which is the possibility of agreement on the analytical tools by which excessive pricing can be identified.

i. Cost adjusted for risk

My own preference for a benchmark pricing methodology remains an analysis of cost elements, adjusted for risk. My prior work on this subject focused on overcoming the industry argument that determining a normal or reasonable benchmark price for a new pharmaceutical product is not possible because the data resides within a black box.[8]

Although matters are more complex than this,[9] the 'bottom line' is that the originator industry and its financial advisors and investors routinely place values on new product portfolios, whether in the R&D phase or the market approval phase. This entails a substantial degree of objective assessment of underlying economic data, including an assessment of the probabilities of success. This type of analysis is also used when making decisions about potential mergers and acquisitions. And, of course, pharmaceutical originator companies do not simply guess at their budgeting requirements. Within companies, there is an understanding of R&D costs. This is not to say that there is not an element of uncertainty associated with a cost/risk adjusted analysis.

One reason for the difficulty of pursuing cost-based assessment is gaps in access to company data. This gap has received substantial attention over the past several years but despite this, it is not clear that the business sector has lost the broad scope of protection against access to data, including by government authorities. The trend toward heightening the protection of trade secrets generally seems to be putting additional obstacles in the way.[10]

One way to address this gap would be to require the originators to provide their R&D and other cost data as part of the regulatory process, such as a condition of receiving regulatory marketing approval. In the context of regulatory approval, there would be a form of *quid pro quo* that might serve as an

[8] E.g., see, F. Abbott, *Excessive Pharmaceutical Prices, supra* note []..
[9] *Id.*
[10] In the competition law enforcement context data may be kept confidential within proceedings and in the body of public decisions.

inducement for the industry to overcome its reluctance to share. Another route would be to require pharmaceutical suppliers to provide evidence of R&D and other costs in connection with procurement by national or international procurement programmes.[11] A third option would be for governments to develop common formulas for determining originator costs based on the recommendations of expert groups. [12] Each these routes has been the subject of legislative proposals or rules in some jurisdictions.[13] Yes, establishing 'normal' or reasonable baseline prices for originator products will be more complicated than for generics that have a settled cost history; however, in an era in which processing of enormous amounts of complex data is commonplace, this approach is not out of reach.[14]

ii. Health Technology Assessment

There are alternatives for establishing reasonable or normal baseline originator prices, some of which have been suggested by economists associated with the Dutch Competition Authority. These include using some form of health technology assessment (HTA) to establish a benchmark for a normal or reasonable price.[15] Drug regulatory authorities (DRAs) in various jurisdictions use an HTA approach to decide whether to list new drugs for reimbursement by national health plans, and so on. It is thus not 'novel' to suggest using an HTA to establish reasonableness from a pricing standpoint. Perhaps blending risk-adjusted cost and HTA could be workable.

The principal reason for questioning the use of HTA in establishing baselines for excessive pricing determinations is that the HTA essentially attempts to calculate the benefit to society from the introduction of a drug product. But pharmaceutical products are, by their nature, expected to provide a benefit to society. What is the purpose of conferring an additional reward to a pharmaceutical company for doing what it is expected to do, and which is already addressed by granting a patent and regulatory exclusivity that allow companies to charge 'higher-than-competitive-market' prices? Recall that the excessive pricing doctrine is directed only towards the abuse of market power, not toward precluding a fair reward to the innovator.

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[11] See, e.g., Italian decree requiring the submission of data regarding subsidization of R&D in connection with pricing and reimbursement negotiations, Svět Lustig Vijay, *Italy Publishes National Regulation Requiring Pharma Disclosure of Public Support for R&D on New Drugs,* Health Policy Watch, July 28, 2020, https://healthpolicy-watch.news/76047-2/.

[12] See, e.g., Li Zhou, *The new bipartisan Senate bill aimed at making Big Pharma lower drug prices*, explained ('it would commission a study conducted by the National Academies of Science, Engineering, and Medicine. The National Academies would review key information about the drug, including its prices in other countries, distribution costs and the amount of investment that went into research and development. They would use this data to determine how best to figure out a reasonable price', Vox.com, July 31, 2019, https://www.vox.com/policy-and-politics/2019/7/31/20746601/senate-prescription-drug-prices-chris-van-hollen-rick-scott-we-paid-act.

[13] See notes 13-14, supra. [Need to confirm information provided to author regarding legislative proposals in US Congress to require submission of R&D data in connection with new drug approval.]

[14] A different field of regulation in which determining costs is important concerns antidumping and countervailing duty cases in the field of international trade. Economists within trade ministries, such as the US Department of Commerce International Trade Administration (ITA), use highly detailed methodologies to assess the cost of goods in order to establish benchmarks against which allegedly dumped or subsidized products may be evaluated.

[15] See Marcel Canoy and Jan Tichem, *Lower drug prices can improve innovation*, EUROPEAN COMPETITION JOURNAL, Vol 14, No 2-3 (2018) (tandfonline.com).

Recognizing that there is often a value in heterogeneous approaches to regulatory matters, which may over time reveal the 'best' alternative(s), the development of a preferred common approach to addressing excessive pricing of originator pharmaceutical products, and generic products that are subject to rule of reason analysis, may help competition authorities face the inevitable judicial challenges.

d. Industry response

The response of the pharmaceutical industry to any proposal to make it easier to prosecute competition enforcement actions will be that it is unfair to deprive them of their right to self-defence. The importance of process will be invoked, and this is indeed the approach being taken in the negotiation of trade and investment agreement chapters addressing competition.[16] The industry knows what it is doing. It wants to slow things down, and it wants to bring in the government finance and trade people to help to achieve this.

e. Deterrence

A counter-argument to the proposition that excessive pricing prosecutions should be made more efficient is that a limited number of prosecutions adequately serves the purposes of public policy because the imposition of substantial penalties, even in a limited number of cases, has a deterrent effect that will police the market effectively. Given the fairly limited number of successful prosecutions to date, it is doubtful that a large enough dataset exists to draw any meaningful conclusions about deterrent effects, particularly as cause and effect in terms of industry pricing may be very difficult to link.

A significant objection to excessive pricing actions raised in the 2018 OECD study was that the risk of errors (Type 1) that would deter future investment in R&D may exceed the benefits of strict enforcement.[17] As with the general argument about deterrence, it seems doubtful that sufficient data exists to robustly predict the potential adverse impact of enforcement on future R&D.

My own view is that the levels of revenue and profit that might be achieved through the successful launch of a new originator product are enough to overcome any insecurity caused by the risk of enforcement against excessive pricing.

f. Price controls

A typical response to the problem of enforcement is to point to the main alternative for controlling expressive pricing, namely some form of legislative or regulatory price control mechanism that nips the

[16] See Frederick M Abbott, *Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity,* IIC - International Review of Intellectual Property and Competition Law, March 2018, Volume 49, Issue 3, pp 259–266, https://doi.org/10.1007/s40319-018-0683-5.
[17] See OECD 2018, at 11.

practice in the bud.[18] It is probably true that competition law enforcement is second-best to price controls under the current circumstances. That said, however, price controls in the pharmaceutical sector have their own built-in problems, including a tendency to cause underinvestment in implementation of new technologies because maximum prices are frozen; the main way to improve margins then becomes cutting costs. That has been illustrated in India, and perhaps in China as well.

g. Sector inquiries or studies

Another common response to the temporal challenge of enforcement is the encouragement of 'sector inquiries' or 'studies' and the potential outcome of proposals for legislative or regulatory reform.[19] Sector inquiries or studies are a valuable tool and should be encouraged, and they may well point the way toward subsequent enforcement actions. They are not, however, a substitute for enforcement action as the latter entails injunction/prohibition, monetary penalty and other remedies (e.g., licensing and monitoring).

3. European jurisprudence on excessive pricing

a. The legitimate exclusivity conundrum

The extraction of an excessive price typically requires market dominance, and the competition cause of action is a subset of abuse of market dominance.[20] In order for market dominance to be actionable from a competition law standpoint, the dominant actor must engage in an abusive act to secure or maintain market power. Pursuant to article 102(a) of the Treaty on the Functioning of the European Union, 'directly or indirectly imposing unfair purchase or selling prices' may constitute such an abuse.

Prosecuting excessive pricing by the owner of a patent or market exclusivity presents a potential conundrum in that the patent/exclusivity may have been obtained lawfully, and exclusive rights are part of the legislative patent/exclusivity package. If a patent-owning pharmaceutical company enjoys a dominant position in the market (e.g. in its therapeutic class), that market power may have been conferred intentionally by the national/regional legislature. The legislature must therefore have recognized that the holder of an exclusive right would be able to charge more than a hypothetical purely competitive market price.

[18] See, e.g., OECD 2018.
[19] Id.
[20] It is the power to dictate prices in the absence of effectively countervailing forces that competition law seeks to protect against. See *Standard Oil Co. v. United States*, 221 U.S. 1, 50 (1911). There should not be a preference whether remediation is achieved by fixing market structure or fixing results/effects.

Nevertheless, the recent decision by the CJEU in *Generics (UK) v. CMA*,[21] confirming and extending earlier CJEU jurisprudence in this area[22] (and along the same lines as the 2013 decision by the U.S Supreme Court in *FTC v. Actavis*),[23] makes it clear that owning a patent does not insulate the patent owner from prosecution for abuse.

b. Addressing the two-step test

This book includes contributions from academic authors and those working for competition authorities regarding recent excessive pricing cases. This chapter foregoes a detailed description, jurisprudential or otherwise, of those cases in the interests of addressing a specific jurisprudential element. Namely, the 'two-step' test, and whether this is due for an overhaul. The test is widely understood to have been articulated by the CJEU in 1978 – more than 40 years ago – in *United Brands* in a context far-removed from the pharmaceutical sector with its important public interest aspect.

i. Illustrating the problem – *CMA v. Pfizer/Flynn*

The problem of the two-step test is illustrated by the UK CMA's prosecution of Pfizer and Flynn.[24] The initial decision of the CMA was rendered in December 2016, with fines against Pfizer and Flynn of approximately £84 million and £5 million respectively. This author has previously analysed and addressed the problematic decision of the UK Competition Appeal Tribunal (CAT), which rejected and remanded important parts of the CMA decision.[25] The UK Court of Appeal subsequently overruled the key mistake of the CAT. [26] The Court of Appeal, consistent with CJEU jurisprudence, held that in applying the second step of the two-step test, an adverse decision under only one prong (unfair in itself *or* in comparison to prices in other markets) needed to be satisfied. However, in saying this, the Court of Appeal added a new twist. If the accused party offered evidence that its conduct had been justifiable on the prong of the second step that had not been relied on, the competition authority should nonetheless consider that evidence. Oddly enough, in the present case the accused parties had not provided

[21] CJEU Judgment (Fourth Chamber), Case C-307/18, 30 January 2020. The decision of the CJEU, which largely followed the recommendation/opinion of Advocate General Kokott, held that the presumption of validity conferred on the owner of a patent as a matter of law does not establish that the patent subject matter is insulated from competition law scrutiny.

[22] Chris Fonteijn, Ilan Akker and Wolf Sauter, *Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse*,' in THE INTERPLAY BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY: AN INTERNATIONAL PERSPECTIVE, Gabriella Muscolo and Marina Tavassi (eds) (Kluwer Law International, Alphen a/d Rijn 2019) 411-425 (Chapter 25).

[23] 570 US 136 (2013).

[24] Frederick M. Abbott, *The UK Competition Appeal Tribunal's Misguided Reprieve for Pfizer's Excessive Pricing Abuse*, IIC - International Review of Intellectual Property and Competition Law (2018), https://doi.org/10.1007/s40319-018-0734-y.

[25] The UK Competition Appeal Tribunal (CAT), relying on an opinion of CJEU Advocate General Wahl, but not the case law of the CJEU itself, said that the analysis of the CMA was flawed because it should have applied multiple methodologies under the second step as a 'sanity check'.

[26] In the Court of Appeal (Civil Division), Case No: C3/2018/1847 & 1874, Neutral Citation Number: [2020] EWCA Civ 339, Date: 10/03/2020.

evidence that would have supported a finding under the second (comparison) prong. The case was remitted to the CMA to pursue this 'new and improved' jurisprudence.[27]

The CMA has rendered new findings in a 'provisional view' (Statement of Objections) against Pfizer and Flynn, who now have an opportunity to respond (again).[28] And, from a European law standpoint we now have the 'changed circumstance' that the UK is no longer a part of the EU so that whatever is ultimately decided within the British judicial system will not be EU law. Thus, in principle, it should not alter the methodology of the *United Brands* precedent.

It does not seem a radical conclusion to suggest that the jurisprudence that is arising out of the *CMA v Pfizer/Flynn* case is a 'mess'. On the positive side, the case supports the proposition that it appears to be possible to prosecute pharmaceutical companies for excessive pricing violations.[29] On the negative side, the case also shows that it can take eight years or so between investigating a case and completing the process, and at this stage even that timeline appears optimistic.[30]

ii. Revisiting the two-step test

Recognizing that much 'water has passed under the bridge' since its decision in 1978, the CJEU perhaps was misunderstood to have established a two-step test in *United Brands*, notwithstanding that in subsequent jurisprudence the Court itself seems to have accepted this premise.

What happened in United Brands? The Commission accused a large multinational producer and distributor of bananas (based in the United States) of multiple forms of abuse of dominant position in

[27] In fairness, one of the judges on the British Court of Appeals reminded his colleagues that they were dealing with a clear case of abuse of the National Health Service to the detriment of the consumer, which might have been evident to just about anyone following the facts of the case.

[28] The CMA has provisionally found that Pfizer and Flynn abused their dominant positions to overcharge the NHS for vital anti-epilepsy drugs, after reassessing the case.
Source: https://www.gov.uk/government/news/cma-accuses-pharma-firms-of-illegal-pricingPress release, CMA accuses pharma firms of illegal pricing, August 5, 2021**,** https://www.gov.uk/government/news/cma-accuses-pharma-firms-of-illegal-pricing.' 'CMA accuses pharma firms of illegal pricing**.** The recently announced provisional view of the CMA in the remanded case is not public, so we cannot yet see the jurisprudential approach followed by the CMA.

[29] See recently, Press release: CMA finds drug companies overcharged NHS, The CMA has imposed fines totalling over £260 million for competition law breaches in relation to the supply of hydrocortisone tablets. 15 July 2021, From: https://www.gov.uk/government/news/cma-finds-drug-companies-overcharged-nhs; Press Release, 'Following an investigation, the Competition and Markets Authority (CMA) has found that from 2009 until 2017 the pharmaceutical company Advanz charged excessive and unfair prices for supplying liothyronine tablets which are used to treat thyroid hormone deficiency.' ; 29 July 2021, Source: https://www.gov.uk/government/news/cma-fines-pharma-firm-over-pricing-of-crucial-thyroid-drug

[30] Recently, too, the European Commission Competition Directorate successfully secured a settlement from Aspen regarding the alleged excessive pricing of certain anticancer drugs. See note [] infra. The prosecution and settlement are discussed in another author's contribution to this book. It is worth noting, at least, that the Commission decided to accept a settlement rather than risk a decision in the courts, and this may have been due to the uncertain state of jurisprudence in this area, including taking into account the views of Advocate General Wahl.

certain parts of the EU market. The Commission proved that United Brands had abused its dominant position (i) by refusing to supply a distributor, and (ii) charging different prices in different EU member states without justification, thus effectively partitioning the market. The Commission also sought to make out a claim of excessive pricing, but here it failed.

The CJEU emphasized strongly that the best mechanism for proving excessive pricing was to establish the cost of production of the accused party and comparing that cost with the price actually charged. The Court fully acknowledged that establishing the cost of production can be a complicated task when taking account of factors such as administrative and indirect costs, of allocating costs of facilities and other elements. But the Commission did not directly determine the cost to United Brands of producing and distributing bananas (e.g. using cost accounting methodology). Instead, the Commission looked at the price in one country market, Ireland, for which United Brands had stated in a letter that it had made little profit. The Commission inferred from that statement (which United Brands had retracted) that the price in the Irish market must represent United Brands' cost price.[31] The Commission attempted to justify its lack of direct proof of cost by referencing the fact that United Brands was headquartered in the United States (even though its European subsidiary was a party in the case) and that for some reason United Brands did not provide the Commission with sufficient data.

The Commission's explanation did not satisfy the CJEU, which pointed to databases maintained by the FAO and UNCTAD which it suggested would have been adequate to establish the cost of the bananas. Moreover, United Brands asserted that the prices in the various member state markets were justified based on business factors. Even though United Brands failed to support that assertion with concrete evidence, the CJEU said that it was for the Commission to prove the costs and to refute United Brands' argument. The Court said that it was open to the Commission's alternative methodology of comparing the costs for the same product in different member state markets (in this case, relying on Ireland for its baseline), but the Court was *very clear* that this was *not* its preferred alternative. The Court was sceptical of the Commission's approach and ultimately rejected it.

The Court's decision in *United Brands* is internally ambiguous. The decision states that a price is excessive if it is not reasonably related to the economic value of the product. At one point, the Court says that after the Commission demonstrates that a price is excessive, it should also demonstrate that it is unfairly so.[32] It does not explicitly say what it means by this. But subsequently, in the same part of the decision, the Court collapses the distinction it has apparently drawn between 'excessive' and 'unfair', stating: 'although it is also true that the price of Chiquita bananas and those of its principal competitors is different, that difference is about 7%, a percentage which has not been challenged and which cannot automatically be regarded as *excessive and consequently unfair*' [italics added](United Brands, paragraph 266).

Here, the Court equates 'excessive' and 'unfair'. Has the court really established a two-step test? It seems to say that if the price is excessive, it is also unfair. Moreover, it is also hard to ignore the very

[31] United Brands indicated it had in fact suffered losses in the Irish market,

[32] 'The question to be determined is therefore whether the difference between the costs actually incurred in 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' (United Brands, para 252).

strong language the Court uses in support of basing excessive pricing determinations on the difference between cost and price, acknowledging that accounting issues may be tricky.

There is not space in this chapter to go through the academic commentary and subsequent court decisions that turn the initial *United Brands* decision into a mandate for a two-step test,[33] including a second step with two prongs (i.e. unfair in itself or compared to products in other markets).[34] It may have made better sense all around to say that the test for excessive pricing involves determining the differential between cost and price and whether that differential is justified. In an exceptional case in which a cost baseline cannot reasonably be established, some other basis for looking at a normal baseline can be used.

Eliminating the two-step test as it presently stands would not make determining excessive pricing in the European Union easy. Determining the cost of bananas was not so easy. But such a change in perspective would help avoid the jurisprudential discord over meeting the criteria of different steps and prongs, which has been a significant obstacle to prosecution. It would be up to the competition authority, whether the European Competition Directorate or the relevant national authority, to make the case on cost versus price and contextual elements – a type of rule of reason assessment. It would be up to the courts to decide whether the abuse had been proven, but that decision could be based on factors relevant to the specific case. We would no longer be asking whether a price may be excessive and yet fair. There would be a single decision to be made: is the price excessive under the circumstances?

iii. ACM and *Leadiant*

A recent decision by the Netherlands Authority for Consumers and Markets (ACM)[35] provides a useful illustration of how a contextual approach to decision-making concerning excessive pricing could be applied, bearing in mind that the Dutch Authority acted in accordance with the two-step test and consistently with prevailing EU jurisprudence.

In 2008, the pharmaceutical firm Leadiant acquired a drug (CDCA) used to treat a rare metabolic disorder (CTX) on the Dutch market, which at the time was selling for €46 per pack of 100 capsules. Patients need the treatment to survive. In 2009, Leadiant changed the drug's name and raised the price twenty-fold to €885. In 2014, it changed the name again, sought an orphan drug designation, and raised the price to €3,103. In 2017, having secured an orphan drug designation, Leadiant raised the price to €14,000, yielding a per-patient annual cost of treatment to €153,300. Orphan drug designation – granted in this case because of the small number of patients – established an exclusive position on the

[33] For a recent description of the test and its application by a competition authority, see European Commission Competition DG, CASE AT.40394 – Aspen, Antitrust Procedure, Council Regulation (EC) 1/2003 Article 9 Regulation (EC) 1/2003 Date: 10/02/2021.

[34] By the time this gets to AG Wahl and his 'sanity check' he would have the Court saying that you really need to prove something as an excessive price in a plethora of ways, and if you fail on any of them it is not an excessive price.

[35] See Autoriteit Consument & Markt, Summary of decision on abuse of dominant position by Leadiant, ref. ACM/UIT/557, case no ACM/20/041239, 1 July 2021. The Summary is Chapter 1 of the decision. The full text is not public at the time of this writing.

market in the Netherlands for a period of ten years. Leadiant asserted that it intended to negotiate a much lower price with Dutch health insurers and the government, but took little action to do so.

The ACM established that Leadiant occupied a dominant position on the market (i.e. 100%) for the relevant period (2017-19). It used a cost-plus-reasonable-profit (15%) methodology to establish a baseline, giving credit to Leadiant for investments it had made when it decided to pursue orphan drug designation, while noting that no therapeutic value had been added to the treatment. It looked at the price increases starting just before when Leadiant decided to seek orphan drug designation (from €885 to €14,000), observing that this amounted to an increase of more than 15 times, or greater than 1500%.

The ACM indicated that the increased price charged by Leadiant was 'exorbitantly high' and went on to also decide that Leadiant's pricing was 'unfair', referring to a number of factors, including: (1) orphan drug designation was secured without added innovation or change in therapeutic value of the relevant drug; (2) Leadiant had failed to pursue effective or serious negotiations on price reductions with health insurers or the relevant ministry; (3) the drug in question is indispensable to the patients needing it, and; (4) other producers (e.g. a compounder) of the same drug are able to produce and sell it at much lower prices.

It fined Leadiant €19,569,500, noting that Leadiant's conduct had affected Dutch society as a whole because of the added cost to the government, private health insurers and individuals.

As suggested earlier in this chapter, when the price of a drug that has long been available on the market is raised by 1500% with no corresponding justification, deciding that this is an excessive price increase seems uncontroversial and might be the subject of a *per se* rule. The decision by the ACM does not shed light on whether a lesser increase of 150% (by way of illustration) might be considered *per se* excessive. The orphan drug designation involving no value-added does not appear to change the assessment equation. Putting that to one side, the 'other factors' considered by ACM confirmed its view that Leadiant had acted unreasonably and unjustifiably. These factors might broadly be considered, under the rubric of rule of reason analysis, to support a decision that any purported benefits of Leadiant's behaviour (e.g. maintaining the availability of a treatment used by a limited number of patients) was more than offset by its abusive conduct. Such a contextual analysis does not require categorization between 'prongs'.

3. The future

Europe is methodically developing an excessive pricing doctrine that should restrain the practices of the pharmaceutical industry. However, there remains a challenge beyond the comparatively straightforward cases addressed so far of excessive pricing by generic producers, for whom R&D costs are typically a minor part of their baseline costs. The more difficult cases, which have yet to be pursued, will involve new originator patent or market exclusivity protected pharmaceutical products, making it more challenging to determine risk-related R&D costs.

Imposing controls on pharmaceutical originator companies with respect to pricing has proven particularly difficult from a legislative standpoint, particularly in the United States where prices are highest, but also in Europe. The explanation is probably mundane. The cash flows to the originator companies are so large that lobbying and political campaign contributions establish a wall that is difficult

to climb or smash through. This is one reason why competition authorities are needed, even if direct regulation might be a more efficient method of controlling prices. In the United States, the prices of pharmaceuticals have been an issue already since the 1950s, and not much has changed despite pronouncements during political campaigns and general statements by holders of high office.

The prosecution of excessive pricing actions has so far proven to be heavily resource-intensive for competition authorities, and prosecutions generally drag on. If the effective application of excessive pricing doctrine is to take place, the system by which it is applied should be made more efficient. It is worth bearing in mind that the ultimate beneficiaries are the individuals who make up our society.