Excessive prices in the Pharmaceutical Sector: re-inventing United Brands as a fairness-mechanism

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> "We may try to show that the decisions that seem to maximize wealth are required, not as instrumental decisions seeking to produce a certain state of affairs, of social wealth, utility, or any other goal of policy, but rather as decision of principle enforcing a plausible conception of fairness. We might aim, that is, at an explanation of principle, instead of an explanation of policy.",[1] Ronald Dworkin

1. Introduction

In a 2015 interview, competition commissioner Vestager pointed out that *fairness*, next to equal treatment and transparency, is one of the fundamental values underlying competition. Although these objectives are achieved through "making markets work better", in her reasoning, the aims of competition have a more ethical foundation than objectives like consumer welfare, market structures or even economic integration.[2] However renewing this may sound, the Treaties are no stranger to a notion like fairness themselves. Article 102(a) TFEU specifically mentions an unfair price as an example of an abuse of a dominant position.

The German Competition Act is even more specific, mentioning that an abuse exists if a dominant undertaking demands "payment or other business terms which differ from those which would very likely arise if effective competition existed".[3] The latter touches the core of the urge for competition authorities to enforce against excessive prices, namely to directly combat the negative effects of uncompetitive markets. Especially in regulated industries, or markets with non-artificial high-entry barriers, high prices, caused by a lack of competition, occur. Any deviation from an established —*competitive*—benchmark implies a loss in consumer welfare, when compared to a perfectly competitive market.[4]

Although in the past the Commission (European Commission), in the context of art.102 TFEU, focused on the so-called exclusionary abuses, at the moment, authorities seem not to be of the impression that enforcement against those alone suffices. After several investigations and follow-up decisions in national jurisdictions[5] the Commission announced on 15 May 2017 that it had opened a formal investigation into the pricing practices of Aspen Pharma. Vestager noted that "when the price of a drug suddenly goes up by several hundred percent, this is something the Commission may look at".[6] According to Vestager, this kind of situations are actually the reason "why the competition rules have been part of the Treaty since the very first day".[7] Ensuring fair competition is then not just about safeguarding the competitive process; there must be a fair outcome.

Subsequently, the question arises how this policy of fairness can be objectified in legal doctrine. Economists have argued that a price increase is considered "unfair" by the buyer when this bluntly benefits the seller.[8] It is, then, "unfair" to increase a price based on any other reasons than increased costs or innovative activities. Efficiency improvements, in that regard, may—obviously—lead to higher profits, but not to higher end-prices. Although profit margins are an essential component within the legal test, the efficiency consideration puts it in perspective. In a system of competition, a market or industry will never have a single appropriate profit margin. Therefore profits must be considered together with actual end-prices.

It is not difficult to translate these thoughts into the *United Brands* legal method for establishing an abusive price because a price-cost analysis already lies at the heart of this method. Comparisons with other prices are vivid as well. Some form of fairness is, therefore, evidently present in the legal analysis, loose from the question whether it is the fundamental aim of the law in place. In a more general sense, "merit-based competition", therefore also *merit-based pricing*, implies a sense of

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[1] R. Dworkin, "Is Wealth a Value?" (1980) 9(2) *Journal of Legal Studies* 223.

[2] J. Rivas, "Interview with Margrethe Vestager, European Commissioner for Competition" (2015) 38(2) *World Competition* 183.

[3] German Federal Ministry of Justice and Consumer Protection, "Act against Restraints of Competition" (2016), Translation by the language service of the Bundeskartellamt, para.19(2) under 2.

[4] Opinion of AG Wahl in *Autortiesību un komunicēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v Konkurences padome (Biedrība)* (C-177/16) EU:C:2017:286, para.101.

[5] Next to the discussed *Pfizer/Flynn* case, in 2016 the Italian Competition Authority (AGCM) already fined Aspen, see: AGCM, Case A480, *Aspen Pharma*, Press Release of 14 October 2016.

[6] Commission, Case COMP/A.40.394 *Aspen*, Press Release of 15 May 2017: *Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines* (IP/17/1323).

[7] M. Vestager, *Fighting for European values in a time of change*, Speech at the Europa Lecture of Leiden University 2017.

[8] This is based on the idea of dual entitlement, originating from: D. Kahnemann, J. Knetsch and R. Thaler, "Fairness as a Constraint on Profit Seeking: Entitlements in the Market" (1986) 76(4) *The American Economic Review* 732–733. As mentioned in: P. Akman and L. Garrod, "When Are Excessive Prices Unfair?" (2011) 7(2) *Journal of Competition Law & Economics*, s.3.1.

fairness.[9] Although this claim, in a general sense, is beyond the scope of the article, it will be showed that for the *United Brands* legal test it is correct.

The focus of this article is, in these regards, on the legal doctrine governing excessive pricing actions by competition authorities as laid down by the Court (the Court of Justice of the EU) in *United Brands*. The inconsistencies, which appear in practice, reveal the legal challenges the Commission faces in its *Aspen* investigation. An approach should be developed which balances the importance of affordable medication, as a matter of fairness and (social) welfare, with the need for legal certainty for commercial actors. Keeping this balance in mind, by reflecting on the jurisprudence and recent decision of the CMA (United Kingdom Consumer and Markets Authority) in the case of *Pfizer/Flynn*, I will come to appropriate norms which combine legal doctrine with the economic context of the pharmaceutical sector.

2. United Brands: the legal test

While the Court slightly touched upon the issue in the case of *General Motors* (1975), by stating that an "abuse might lie in the imposition of a price which is excessive in the relation to the economic value",[10] in *United Brands* (1978) the Court actually elaborated on the relation between economic value and the idea of an excessive price as a form of abuse of dominance. The Court held that the question must be raised whether a firm made use of its dominant position by reaping trading benefits "it would not have reaped if there had been normal and sufficiently effective competition". Consequently, the price of the product is excessive when "it has no reasonable relation to the economic value of the product supplied". If a price is found to be excessive, it must be determined whether it is also either "unfair in itself or when compared to competing products".[11] Although heavily disputed, until today, this two-step legal test of *United Brands* is still standard.

The Court annulled the part of the Commission decision that found unfair prices. According to the Court, the Commission was wrong in solely basing its assessment on the differences in customer prices across the community of the bananas of United Brands itself, and when compared to competitors.[12] These comparisons did not suffice in the given case to prove that there was "no reasonable relation to the economic value of the product". Economic value, which is crucial to establish excessiveness, is something which should also be determined independently from other products. The Commission had failed to consider the production costs of United Brands at all.[13] Therefore, the accusation of imposing unfair prices was not adequately substantiated with legal proof.[14] It was only proved that the end-prices were, to a certain extent, discriminatory.

The first step the Court developed requires excessiveness of a price to be based on an excessively high profit margin. The second step introduces the act of benchmarking. By analysing, as many as possible, comparable product-prices some sort of benchmark should be found.[15] This "benchmark" price, then, is equal to the "competitive" price in the relevant industry. Nonetheless, for the first step, it seems logical to compare the profit margin with the margins of other products to conclude that it is excessive. The second step corrects differences in profit margins which are due to the superior efficiency of the investigated firm. The latter, obviously, is part of "competition on the merits".[16] In the extreme cases, there is the possibility of a price to be "unfair in itself", without the necessity to make comparisons at the second stage of the test, though it is not yet clear what this requires.

Even if the Commission would have based its decision also on the production costs, the criterion of "reaping trading benefits" seems ambiguous. As Furse rightly points out, in extremis, it would mean that any exploitation of market power is abusive where the Court does not specify what a reasonable profit margin is. In any case, it is most certainly true that the "margin of excess" will "vary from industry to industry and from place to place".[17] Thereby, in some markets, identifying the production costs will be quite complicated. As Hou argues, audited financial data is often not suitable for competition law enforcement.[18] Usually, such data does not include R&D (Research and Development) costs. In a sector like the pharmaceutical one, R&D forms a significant part of the overall costs. Subsequently, failed R&D costs for products that have not been profitable at all are even more difficult to allocate. And again, the costs of failing research are part of the core business of originator pharmaceutical companies.

In any scenario, like the Court pointed out in *Tournier* (1989) and *Lucazeau* (1989), an abusive price only occurs there where a price is set on a level "appreciably higher" than those competitive prices which they are compared to.[19] In addition, it is inherent to a competitive price that it is also profitable, meaning it exceeds the product costs. Competition authorities and pharmaceutical companies

[9] See, for example: A. De Pablo, "Editorial: Competition Law as Fairness" (2017) 8(3) *Journal of European Competition Law & Practice* 147–148.
[10] *General Motors Continental NV v Commission of the European Communities* (26/75) EU:C:1975:150; [1976] 1 C.M.L.R. 95 at [9].
[11] *United Brands Co v Commission of the European Communities* (27/76) EU:C:1978:22; [1978] 1 C.M.L.R. 429 at [249]–[252].
[12] *United Brands* [1978] 1 C.M.L.R. 429 at [239]–[241].
[13] *United Brands* [1978] 1 C.M.L.R. 429 at [256].
[14] *United Brands* [1978] 1 C.M.L.R. 429 at [267].
[15] See L. Hou, "Excessive Prices within EU Competition Law" (2011) 7(1) *European Competition Journal* 58.
[16] 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/C 45/02), para.6.
[17] M. Furse, "Excessive Prices, Unfair Prices and Economic Value: The Law of Excessive Pricing under Article 82 EC and the Chapter II Prohibition" (2008) 4(1) *European Competition Journal* 64.
[18] Hou, "Excessive Prices within EU Competition Law" (2011) 7(1) *European Competition Journal* 48.
[19] See: *Ministere Public v Tournier* (395/87) EU:C:1989:319 at [38] and *Lucazeau v Société des Auteurs, Compositeurs et Editeurs de Musique (SACEM)* (C-110/88, C-241/88 & C-242/88) EU:C:1989:326 at [25].

will, however, often disagree on the allocation of these costs. Although authorities usually have a wide range of discretion in evaluating economic evidence, this issue will be central in judicial disputes.

The recent judgment of the Court in *Biedrība* (2017) puts, to a certain extent, the *United Brands*-criteria in perspective. In this case, about the fees charged by the Latvian copyright collecting association, the Latvian competition authority based its finding of an abuse merely on a comparison of the end prices with those in neighbouring countries. Whereas this causes friction with *United Brands* the Court held that "there are other methods by which it can be determined that a price is excessive".[20] Moreover it stated that:

> "when an undertaking holding a dominant position imposes scales of fees for its services which are appreciably higher than those charged in other Member States, and where a comparison of the fee levels has been made on a consistent basis, that difference must be regarded as indicative of an abuse of a dominant position".[21]

Thus, where cost allocation does not make sense, mere end-price comparisons among different jurisdictions can be used to indicate an abuse. It is then for the accused party to rebut this indication by providing economic evidence, for example related to administrative- or production costs.

The case of *Biedrība* must, however, be distinguished from *United Brands*. As Advocate-General (AG) Wahl pointed out, because of the nature of the service, a cost-price analysis in that case seemed impossible.[22] The essence of Wahl's arguments is however not, as the Court frames it, that there are several alternative tests. Wahl rather argues that as many methods as possible, "which are accepted by standard economic thinking and which appear suitable and available" should be applied together with regards to the first step of *United Brands*.[23] In any way, first, a benchmark/competitive price should be established and, secondly, it should be assessed whether the price in question is both *significantly* and *persistently* above this benchmark. Where a solid cost/price analysis can be made, the profit margin of a product logically lays in the centre of attention. The price of a loss-making product can never be used as—or contribute to—a benchmark since it is, like an excessively high price, not competitive.

Although the wordings of the Court confuse the presumed legal uniformity, there is no reason to believe that, especially where cost/price analyses can be made, the test of *United Brands* lost relevance. By stating that "there are other methods" to determine an excessive price the Court implies that *United Brands* can be circumvented, while Wahl, on the other hand, specifically mentioned that the question whether the price comparisons were appropriate and sufficient only concerns the first step of the *United Brands* analysis.[24] Then, it is indeed true that there are several methods to determine an excessive price, only where possible this must be based on price/cost analyses.

For the second step, which the Court apparently skipped, it could be argued that where price comparisons were sufficient in the first step to determine excessiveness, this indicates that the price is, following *United Brands*, also "unfair when compared to competing products", even though these competing products were in different markets. Such an indication seems similar to the—sort of—"object" restrictions there are in the category of exclusionary abuses. In the *Intel* case, for example, the Commission only needed to prove that the rebate scheme was "capable" of restricting competition.[25] For exploitative abuses this logic is problematic because the "effects" are the abuse, hence the core of the investigation. Moreover, the *United Brands*-test covers the whole competition law assessment, whereas all possible justifications (superior efficiency for example) can be placed within its second step. Once one classifies a price as "unfair" there is no turning back. Considering the ongoing investigations into excessive pharma prices, more clarity by the Court—even despite the factual differences between the cases—in the *Biedrība* judgment would have been useful.

3. Napp Pharmaceuticals (2001): keep comparing

A solid example of how the *United Brands*-test can be applied in the pharmaceutical sector is the British case concerning Napp Pharmaceuticals (Napp). In this case, the precursor of the CMA, namely the OFT (Office of Fair Trading), imposed on Napp a fine of £3.2 million for the abuse of a dominant position. In his opinion, AG Wahl specifically points to this case as an example of combining several methods to determine whether a price is excessive or not.[26]

However, it was not merely the excessive price that was condemned in this case. The OFT accused Napp of charging excessively low prices to the hospital sector and excessively high prices to the community sector, for the sales of the painkiller morphine.[27] By excluding competition in the hospital sector through "predatory prices", it remained dominant in the community sector, even though there it charged "excessive prices". The OFT established that in some cases the prices charged to the community sector were over 1,000 per cent higher than

[20] *Autortiesību un komunicēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v Konkurences padome (Biedrība)* (C-177/16) EU:C:2017:689 at [37].
[21] *Biedrība* EU:C:2017:286, para.38.
[22] *Biedrība* EU:C:2017:286, para.72.
[23] *Biedrība* EU:C:2017:286, para.43.
[24] *Biedrība* EU:C:2017:286, para.33.
[25] *Intel Corp Inc v European Commission* (C-413/14 P) EU:C:2017:632 at [142]–[143].
[26] *Biedrība* EU:C:2017:286, para.44.
[27] UK Office of Fair Trading (OFT), Decision in Case CA98/2/2001 *Napp Pharmaceuticals Holdings Ltd and Subsidiaries*, para.142.

those charged to the hospital sector.[28] The OFT recognised that Napp's high profits, compared to its three competitors, in part resulted from its efficient production. Moreover, as the former patent-holder, Napp was the only firm to manufacture the drug by itself.[29]

The OFT considered that to show that the prices charged in the community segment of the market were excessive, two elements must be proven. First, "it must be demonstrated that prices are higher than would be expected in a competitive market". Secondly, that "there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be".[30] The OFT followed the Court's approach in *United Brands*, meaning it used the profit margin of Napp as a starting point. It compared this profit margin with that of Napp's sales of other products and the profit margins of Napp's competitors. Based on these comparisons a "competitive price" was identified, representing the product's "economic value". The same comparisons were made for the actual sales prices. The approach of the authority was to combine comparisons of profit margins (first step of *United Brands*), fully considering different sorts of costs, and comparisons of sales prices (second step), taking full regard of a firm's efficiency. Like the *United Brands* criteria prescribe, the profit margins were compared with different own products of Napp and the sales prices were compared to competing products.

Napp put forward the defence that its profit margins needed to be higher than its competitors because R&D costs had to be compensated for. High profit margins in the sales of their successful drugs were also meant to cover the costs for the many unsuccessful ones, which it found inherent to the business model of an innovative company. Moreover, it sought to protect its brand value.[31] The first argument was easily rejected by the OFT, and later on by the Competition Appeal Tribunal (CAT or the Tribunal),[32] because the period of patent protection was considered to be sufficient for compensating the R&D costs. The OFT, furthermore, accepted that Napp could charge higher prices in the community sector than its competitors because of its brand value; this did not, however, justify a premium of 40 per cent.[33]

In the view of the OFT, the importance of economic context of the pharmaceutical market, in which lots of R&D costs will render unsuccessful, is relative when a patent has expired. So, the case, in its essence, was not about a clash between IP-protection and competition law. In principle the R&D costs must be recouped in the patent period. Perhaps under exceptional circumstances this could be different, but Napp failed to provide any figures on its initial investments.[34] As Abbot argues, pharmaceutical originator companies tend to act mysteriously about their expenses. In this regard, competition law can be used as a tool for more transparency, which is according to Vestager even a fundamental value of it.[35] If a certain company delivers the relevant data, the costs of failures should be considered. The decision was upheld by the CAT. The Tribunal held that the comparisons made were appropriate to establish a competitive price. The fact that Napp's price in the community market had remained unchanged for ten years after the patent expired, while Napp still held a market share of 96 per cent, supported the proposition that it had not been subject to competitive pressure.[36]

4. Pfizer/Flynn (2016): the reasonable rate of return

On 7 December 2016, the British competition authority fined Pfizer and Flynn Pharma for charging excessive prices to the NHS (National Health Service) for Epanutin, an anti-epilepsy drug.[37] When Pfizer sold the marketing authorisations for the drug to Flynn Pharma it was de-branded. No longer subject to price regulation, the price of the drug increased. Although the drug was de-branded, which meant that there was the legal possibility of competition, the NHS remained fully dependent on Flynn Pharma, and in the end on Pfizer, to deliver the drug. There was a cheaper alternative, from 2013 on, but pharmacies observed the principle of "Continuity of Supply", which resulted in Pfizer and Flynn having a so-called "captive customer base". Therefore, there was no effective competitive pressure and partly on this basis the CMA found Pfizer and Flynn to have dominant positions, Pfizer effectively having a monopoly.[38]

Interestingly, the CMA supported its assessment of dominance with the finding that Pfizer and Flynn were able to charge such high prices.[39] Because the medication was remunerated by the NHS the end-consumers did not directly suffer from the high prices, eventually it was on the account of the taxpayer. After Pfizer de-branded Epunatin in the UK it started to exclusively sell it to Flynn Pharma at prices between 780 per cent and 1,600 per cent of the price it was sold for before. Subsequently, Flynn Pharma, as the new distributor, sold the drug on to wholesalers at price levels between 2,300 per cent and 2,600 per cent of the original price. Although the

[28] *Napp* (OFT), para.218.
[29] *Napp* (OFT), para.225.
[30] *Napp* (OFT), para.203.
[31] *Napp* (OFT), para.208. See also in Appeal: UK Competition Appeal Tribunal (CAT), Case 1001/1/1/01, *Napp Pharmaceutical v OFT*, 2002, para.356.
[32] CAT, *Napp Pharmaceutical v OFT*, 2002, paras 416–417.
[33] *Napp* (OFT), paras 209–211.
[34] CAT, *Napp Pharmaceutical v OFT*, 2002, para.407.
[35] F. Abbott, "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health" (2016) 6(281) *UC Irvine Law Review* 125.
[36] CAT, *Napp Pharmaceutical v OFT*, 2002, para.397.
[37] CMA, Case CE/9742-13, *Pfizer/Flynn*, Press Release of 7 December 2016: "CMA fines Pfizer and Flynn £90 million for drug price hike to NHS".
[38] CMA, Case CE/9742-13, *Pfizer/Flynn*, 2016, para.4.211.
[39] CMA, Case CE/9742-13, *Pfizer/Flynn*, 2016, paras 4.222–4.225.

regulatory market circumstances are complicated, it seems factually beyond any doubt that Pfizer and Flynn were dominating.

Unlike the Court in its recent judgment, the CMA does clearly attempt to walk through the two steps of *United Brands*, though in a very technical manner. The CMA starts by pointing out that different methods and approaches might be used to determine whether a price charged is unfair. The *United Brands* test involves the question "whether a price had no reasonable relation to the economic value of the product supplied".[40] Subsequently the CMA stressed that it had to measure the "costs actually incurred in supplying the product in question".[41] Further, it emphasised the flexibility necessary in costs assessments, which must, however, include reasonably attributable indirect costs as well. The next step, according to the CMA, consists of determining a reasonable rate of return, which accordingly is a matter of "judgment" and "appreciation".[42] Nonetheless, the CMA refers to earlier cases in which prices that exceeded the costs incurred (plus a reasonable rate of return) by 46.8 per cent (*Albion Water II*[43]) and 25 per cent (*Deutsche Post*[44]) were accepted to be excessive by a judgment of the CAT and in a decision of the Commission, even though these cases took place in different industries. The relevance of these past excessive return rates is unclear, whereas it is, within the *United Brands*-test and the fairness-concept of this article, only useful to make comparisons with prices set in competitive markets.

Regarding the calculation of costs the CMA found that there were no indirect costs which could be allocated to the drug. Pfizer and Flynn did not provide sufficient data for the CMA to allocate common costs.[45] Moreover, it held that value-based cost drivers, based on demand-side factors, were not appropriate for competition law enforcement. Consumer willingness to pay was especially problematic in this case, since the prices were charged to the NHS. For Pfizer, the CMA found 6 per cent to entail a reasonable rate of return based on the average yearly returns of Pfizer, arguing that for a non-innovative product such as Epanutin this should not be higher, and the allowable return rate under the PPRS price regulation.[46] Contrary to the discussed case of *Napp*, the CMA did not use profit margins of other specific actors in industry for comparisons, even though Pfizer submitted return rates of three other pharmaceutical companies.[47] In the end, without diving into the technicalities of the costs/price assessments, the CMA found the prices to be excessive simply by observing that the prices exceeded the (direct) costs plus a reasonable rate of return.

Instead of the artificially inserted "reasonable rate of return" upon the overall costs, for the second step of *United Brands* the CMA dived into the notion of economic value.[48] Certain non-cost related factors could exceed the economic value far beyond the accepted costs plus a reasonable rate of return. The CMA rightfully points out that the economic value is not determined merely by how much the customer is willing to pay, since this would render the unfair pricing prohibition meaningless.[49] The non-cost related factors should be unique to the seller in the sense that it would maintain under potential competitive pressure, like in the Commission cases of *Sundbusserne* and *Scandlines*.[50] In this regard the captive customer base, partly because of the "Continuity of Supply", could not work in favour of Pfizer and Flynn.

The CMA neglected the argument of Pfizer that its assessment should include a reasonable allocation of its overall R&D costs. Pfizer argued that it had to make sure that all of "its current products make a reasonable contribution to its R&D overhead".[51] Like the CAT argued in *Napp*, the CMA found that the period of patent-protection is for recovering R&D costs. But where the patent expires this means that the price and/or market share must drop. As well as in *Napp*, the "portfolio pricing" argument failed. Pfizer did, however, not specify on this argument. While it seems logical that overall R&D costs of an enormous company like Pfizer cannot form an excuse for such a big price increase, if Pfizer would have provided data on investments for innovations on Epanutin or for improving other medication for the specific group of consumers (epilepsy patients) the conclusion could have been different. In this case, it is perhaps impossible to outbalance the extra costs charged to the NHS.

Eventually the CMA found that there were no such non-cost related factors which could increase the economic value of the drug.[52] Most importantly, the drug, which was first marketed in the 1930s, had long been off patent and there were no recent innovations that could increase its economic value. The prices charged by Pfizer and Flynn, then, were found to be "unfair in themselves" because the disparities between sales prices and economic value were "substantial", but more importantly, these

[40] CMA, Case CE/9742-13, *Pfizer/Flynn*, 2016, para.5.9.
[41] CMA, Case CE/9742-13, *Pfizer/Flynn*, 2016, para.5.14 and *United Brands* [1978] 1 C.M.L.R. 429 at [252].
[42] CMA, Case CE/9742-13, *Pfizer/Flynn*, 2016, paras 5.18–5.21. See also: *Genzyme Ltd v Office of Fair Trading* [2005] CAT 32 at [279].
[43] *Albion Water Ltd v Water Services Regulation Authority (formerly Director General of Water Services)* [2006] CAT 36 at [199].
[44] Commission, Decision in Case COMP/36.915, *Deutsche Post AG*, 2001, paras 166–167.
[45] *Pfizer/Flynn*, para.5.34.
[46] *Pfizer/Flynn*, paras 5.85–5.102.
[47] *Pfizer/Flynn*, paras 5.103–5.106.
[48] *Pfizer/Flynn*, from para.5.247 onwards.
[49] *Pfizer/Flynn*, para.5.253. See also: Furse, "Excessive Prices, Unfair Prices and Economic Value" (2008) 4(1) *European Competition Journal* 64, 71.
[50] Commission, Decision in Case COMP/A.36.570/D3, *Sundbusserne v Port of Helsingborg*, 2004, paras 200–222. In this case the non-cost related factor which increased the economic value of the Port of Helsingborg was its geographically unique location.
[51] CMA, Case CE/9742-13, *Pfizer/Flynn*, paras 5.331–5.334 and Annex L.
[52] CMA, Case CE/9742-13, *Pfizer/Flynn*, para.5.268.

prices were significantly increased by Pfizer without material changes to the product.[53] Again contrary to the case of *Napp*, the CMA did not compare the end price of the product with the prices of similar products. Like Vestager mentioned, it is the "sudden" price increase which triggers competition law enforcement. For now, Pfizer failed the almost impossible task to explain the legitimacy of its behaviour.

Apart from this failure, the CMA's approach towards the legal test is far from *fairness-based*. By choosing to consider the prices as "unfair in themselves" it refrains from substantiating the unfairness with economic evidence beyond the pricing practices of the companies themselves. As Akman and Garrod point out, the second step of *United Brands* makes sure that it is not *unfair* to reap the benefits of improved efficiency where this does not harm the consumer.[54] By doing so, it also objectifies the principle of fairness into the test, by making it relative to prices of comparable products (*benchmark-* or *reference* prices). The CMA, on the other hand, chose for the seemingly objectivity of the mathematical application of the reasonable rate of return. Despite this intention, it has the effect of making its assessment rather arbitrary. The CMA, actually, called the reasonable rate of return a matter of judgement and appreciation. Basing the return rate on the *average yearly returns* of Pfizer shows great indifference to how competition in the pharmaceutical sector takes place. For the Commission, which is explicitly pursuing fairness, the task arises to effectively use all the fairness-related components—which are therefore related to the economic context—of the second step of *United Brands*. Considering the extensive experience of the Commission in the pharmaceutical sector, it is the least we can expect.

5. Developing a fair approach

5.1. Appreciating the economic context

The essence of the arguments against excessive pricing actions is that markets should rely on "the invisible hand", wherefore authorities should refrain from intervening if a problem in the market can also be solved by the market itself.[55] Market correction is, then, preferred over government intervention, because the latter would be inefficient, complicated and costly. As AG Wahl cites Easterbrook: "the economic system corrects monopolies more readily than it corrects judicial errors".[56] This argument is quite relative when applied to the pharmaceutical sector, in which markets are highly regulated anyway—often even price-regulated—for public health reasons. As Abbott appropriately mentions: "no market is less free than the pharmaceutical market".[57] Self-correction, thereby, might take much longer than desirable, again, for reasons of human health and the sustainability of public budgets.

The first—and most apparent—requirement scholars have found to be feasible for excessive pricing enforcement is the existence of "high and non-transitory entry barriers leading to a super dominant position".[58] It is, however, unsure what these barriers can consist of. It is true that in the Commission Guidance Paper on enforcement against exclusionary conduct it is stated that barriers to entry may consist of significant investments made by the incumbent.[59] Efficiency could be incorporated in this concept. In literature, it is argued that super-efficient dominant firms can charge high prices without attracting new market entries.[60] In the end, it is therefore not the pre-entry price that attracts new market entries, but rather the post-entry price. Thus, even though efficiency is a lawful entry barrier, this does not mean that it cannot be used to impose unlawful prices.

Whether this is always true or not, it seems that high entry barriers as a requirement is quite ambiguous in the pharmaceutical sector. As the CAT accurately pointed out in its judgment in *Napp*, when medicine prices do not drop after the (long) period of patent protection, and this is due to the maintenance—or passing along—of a patent-monopoly, it indicates a flaw in market-functioning.[61] When this causes sufficient harm to consumers and/or public health budgets, it is irrelevant whether this is due to high entry barriers or not. The recent cases of *Pfizer/Flynn* and *Aspen* reveal that if a price suddenly increases with several hundred per cent, the issue of fairness is difficult to rationalise by hypothetical self-correction.[62] Because of public health, the market, then, needs fixing immediately. If excessively high prices are maintained for a persistent period the "super dominant position" is mostly self-evident.

Furthermore, it is often held that excessive prices are hard to define and that competition authorities are not suitable bodies to regulate prices.[63] The first one is true for the pharmaceutical sector and will be addressed. The latter one is, however, meaningless. First, sectoral authorities might be misled or used by dominant firms to

[53] CMA, Case CE/9742-13, *Pfizer/Flynn*, paras 5.365–5.366.
[54] Akman and Garrod, "When Are Excessive Prices Unfair?" (2011) 7(2) *Journal of Competition Law & Economics*, in particular p.3 and p.10.
[55] See: Hou, "Excessive Prices within EU Competition Law" (2011) 7(1) *European Competition Journal* 48.
[56] *Biedrība* EU:C:2017:286, para.103 referring to Easterbrook, "The Limits of Antitrust" (1984) 63(1) *Texas Law Review* 15.
[57] Abbott, "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health" (2016) 6(281) *UC Irvine Law Review*, p.122.
[58] Motta and de Streel, "Excessive Pricing in Competition Law: Never say never?", *The Pros and Cons of High Prices* (Konkurrensverket (Swedish Competition Authority), 2007), p.22. See also: Hou, "Excessive Prices within EU Competition Law" (2011) 7(1) *European Competition Journal* 48 and *Biedrība* EU:C:2017:286, para.4.
[59] Commission (2009/C 45/02), para.17.
[60] A. Ezrachi and D. Gilo, "Are Excessive Prices Really Self-Correcting?" (2009) 5 *Journal of Competition Law & Economics* 262–263.
[61] *Napp* (OFT), para.397.
[62] See Commission, Case 40394, *Aspen*, Press Release of 15 May 2017 (IP/17/1323).
[63] Motta and de Streel, "Excessive Pricing in Competition Law: Never say never?", *The Pros and Cons of High Prices*, 2007, pp.26–28 and Hou, "Excessive Prices within EU Competition Law" (2011) 7(1) *European Competition Journal* 48–49.

extend their domination, as happened in the case of *AstraZeneca*.[64] Secondly, competition law in the EU has constitutional value. While sectoral regulators employ non-competition based objectives in their enforcement. Moreover, it cannot be prolonged from sectoral regulators to know when they are dealing with a "dominant undertaking" in the sense of art.102 TFEU. This is simply not their job. From the Court's judgment in *Deutsche Telekom*, it is clear that EU competition law may be used to discipline national regulators.[65]

5.2. Guidance for interventionism

Like Ezrachi and Gilo mention, if the attention is taken away from entry barriers, enforcers should look at whether the excessive prices stimulate new investment, and the practical difficulties of proving a price to be unfair.[66] Most importantly, competition law should promote a system of "dynamic competition". In such a system, the protection of Intellectual Property (IP) rights is fundamental for businesses to recoup R&D costs and therefore to innovate, enhancing future competition.[67] Thereby, IP-protection, as envisioned in art.17 of the Charter of Fundamental Rights of the EU, has foundational value in the EU legal system as well. Law enforcement must, thus, strive to be consistent with the system of patent protection.

In these regards, enforcement must not undermine the lawful exercise of IP-rights. This means that, in principle, there should be no enforcement against patent holders.[68] The bargaining power such rights holders have against national procurers is normally legitimate. As mentioned in the cases of *Napp* and *Pfizer/Flynn* the period of patent protection enables companies to recoup their R&D costs and legitimises them to set high prices. In that line, it also legitimises competition authorities to enforce against excessive prices if the patent has expired and prices do not drop, even more so where they suddenly increase. It is certainly true that the prices of patent-protected drugs are—perhaps even more than non-protected drugs—often considered high, sometimes even the subject of political debate. To some extent, this is inherent to IP systematics, and competition law enforcement is then not the right tool to combat this.

When the absence of competitive pressure on the incumbent is not due to a lawful IP-right, the price-setting has to endure the legal test the Court developed in *United Brands*. A price is, then, unfair when it "*has no reasonable relation to the economic value of the product*".[69] The OFT, in its decision against *Napp*, added the requirement that there should be no prospect of effective competitive pressure to bring the price down to a competitive level.[70] For the first step it is unavoidable, illustrated by the facts of the *United Brands* case itself, to consider costs. To subsequently find a *truly-reasonable* rate of return the profit margin should be compared to the profit margins of similar products throughout industry. Similarity, in this regard, relates to regulatory context, the necessity of innovative activities and period of patent-expiration. In a case like *Pfizer/Flynn*, where there is no innovation at all, it might be sufficient to use the average profit margin of the company at stake, but also comparing it to those of competitors, like in *Napp*, should be preferred. The latter, moreover, brings already some *fairness* in the first step. Linguistically, the term *excessive* implies a certain level of normality to be exceeded. Normality, then, occurs in competitive markets, where competition is *free* and the prices are *fair*.

Following the Court's reasoning in *United Brands*, there are subsequently two ways to go. An excessive price can be found "*unfair in itself or compared to competing products*".[71] Because high profits might be due to superior efficiency it is useful to compare the actual sales price with those of competing products. Not only the price itself and the profit margin should, then, be compared to those of similar drugs, special focus must be on the margin of the price drop after the patents of the other drugs expired. The benchmark or competitive price then reflects all these comparisons. With regards to the comparisons of post-patent price drops, the economic context, which AG Wahl refers to, will mostly be broadly similar.[72] If it is, then, found that the price is "significantly" and "persistently" above the benchmark price it can be considered unfair.[73] Because low drug prices are essential for public health, the significance and persistency are best assessed dynamically, meaning that the higher the price, the less persistent it needs to be.

Theoretically, the second option for finding a price to be unfair is possible in the pharmaceutical sector as well. In cases like *Pfizer/Flynn* and *Aspen*, where prices increase extremely it is tempting to apply the criterion of "unfair in itself" where this is certainly easier. The recent handling of this criterion by the CMA, however, reveals evidence-based shortcomings. These shortcomings particularly relate to fairness where there are no comparisons made to fair end-prices. In that regard, the

[64] Commission, Decision in Case COMP/37.507, *Generics/AstraZeneca*, 2005, *AstraZeneca AB v European Commission* (T-321/05) EU:T:2010:266 and *AstraZeneca AB v European Commission* (C-457/10 P) EU:C:2012:770.
[65] *Deutsche Telekom AG v European Commission* (C-280/08 P) EU:C:2010:603 at [80]–[90]. The same reasoning is apparent in *AstraZeneca AB v European Commission* (C-457/10 P) EU:C:2012:770 at [131].
[66] Ezrachi and Gilo, "Are Excessive Prices Really Self-Correcting?" (2009) 5 *Journal of Competition Law & Economics* 262, 268.
[67] J. Turner, *Intellectual Property and EU Competition Law*, 2nd edn (Oxford University Press, 2015), pp.3–5. In its sector inquiry, the Commission also uses the term *dynamic competition* referring to a system in which competition is stimulated by IP-rights, see: Commission, *Pharmaceutical Sector Inquiry*, Final Report, 8 July 2009, para.1568.
[68] This criterion is also visible in A. Fletcher and A. Jardine, "Towards an Appropriate Policy for Excessive Pricing", in: C. Ehlermann and M. Marquis (eds), *Competition Law Annual 2007: A Reformed Approach to Article 82 EC* (Hart Publishing, 2008), pp.533–547.
[69] *United Brands* [1978] 1 C.M.L.R. 429 at [249]–[252].
[70] *Napp* (OFT), para.203.
[71] *United Brands* [1978] 1 C.M.L.R. 429 at [239]–[241].
[72] *Biedrība* EU:C:2017:286, para.84.
[73] *Biedrība* EU:C:2017:286, para.106.

fairness of the *other* prices is assumed where they occurred in competitive markets. Especially where the accused parties submit comparisons to support the fairness of their prices, it is in line with the recent tendency of the Court that these arguments are examined.[74]

The latter is only possible within the framework of determining a price to be "unfair compared to competing products", while considering the prices "unfair in themselves" deprives the accused parties of effectively defending themselves. At its best (although not preferred), considering prices "unfair in themselves" will slightly shift the burden of proof to the accused. The upcoming British court decision, in appeal to the CMA decision against *Pfizer/Flynn*, will perhaps give guidance on how the criterion of "unfair in itself" fits within a system of rule of law. Anyhow, pursuing fairness, the Commission should take matters in its own hand and make use of the second step of United Brands to objectively establish "unfairness".

Originator pharmaceutical companies will often argue, like in *Napp* and *Pfizer/Flynn*, that high prices are needed to recover R&D costs. In principle, that is what the patent protection period is for, so outside its protection period it is an invalid argument.[75] This reasoning, coming from the case of *Napp*, implies that within the patent period competition authorities should refrain from excessive pricing actions, as I already considered. Not all R&D efforts, however, lead to profits. As Hou observes, including failed R&D costs is complicated, though not impossible per se.[76] For the big originator companies, it is true that their innovation comes along with big investments in R&D which do not lead to direct economic value.

Even though a patent has expired, in a truly dynamic market, companies must be able to calculate these losses into their prices somehow. Law enforcement should not undermine the business models of originator firms, as far as these strive for innovation. An excessive price is then justified if, within the period of charging it, the firm has made significant losses on R&D for other products which possess, by the characteristics of the illness they ought to cure, a relationship with the excessively priced drug. Contrary to the neglected argument of Pfizer these losses need to be specified. Referring to overall R&D costs should never suffice, especially not for companies with a range of products as wide as that of Pfizer. The relationship between the costs and the high-priced products will most logically consist of end-users falling within the same customer-group. If a pharmaceutical company succeeds in being transparent about these costs it can rebut the affirmation of the first step of the *United Brands*-test in which a price is held to be excessive based on its profit margin. The extra costs narrow down the margin of profit. The categorization of costs can only be dealt with on a case-by-case basis. The burden of proof will, naturally, lay on the accused, making this possibility a reward for transparency.

6. Conclusion

The most apparent truth about the issue of excessive prices seems to be that it is both very simple, nearly self-explanatory, as well as very complicated. Of course, only the extreme cases draw the attention from authorities, such as the sudden price increases in the cases of *Pfizer/Flynn* and *Aspen Pharma*. But in a rule of law-system these need to be proved by sufficient economic evidence as well. Moreover, certainty about the unfairness of a price is necessary to maintain a dynamically-competitive pharma sector, attracting investment. The methodology of *United Brands*, when used to its full extent, enables legal analysis which fairly balances these aspects against the need for affordable medication.

Most importantly, in its upcoming case, the Commission will need to show that the pricing practices of Aspen are not in any way part of "normal" —commercial—exploitation. Making comparisons with the prices and profit margins of other products in the same branch of industry is the best way to do so. A higher similarity between products makes a more credible comparison. Referring to excessive profit margins of products from different sectors which occurred in past cases, like the CMA repeatedly did in *Pfizer/Flynn*, seems to me quite meaningless. Moreover, it fails to conserve the credibility of the analysis where high profit margins, in themselves, could be the result of efficiency.

Eventually, there inherently is a relation between—excessively—pricing beyond what is normal among competitors and considering the issue of fairness. Neglecting the relativity of this fairness-concept does not make the assessment more "objective", rather the purpose of the law is forgotten. Although activists or politicians might argue that even regular pharmaceutical prices are exceeding costs in an unfair way, regardless of whether this is true, art.102 TFEU is only suitable to deal with excesses, in the sense that they exceed normality based on an objective benchmark. It should be clear that art.102 TFEU cannot be used as a general price-regulation tool, specific cases, as those against *Aspen*, are, however, suitable for the Commission to show the more ethical understanding it seems to attach to competition law enforcement these days. As long as the Commission conforms to a high standard of proof, a *more ethical* understanding does not have to imply a *less economic* approach.

[74] *Intel* EU:C:2017:632. In the *Intel* case, regarding exclusionary abuse of dominance, the Court set aside the judgment of the General Court because it had not examined all of Intel's arguments because the rebates at issue were considered "*by their very nature capable of restricting competition*" ([142]).
[75] CAT, Case 1001/1/1/01, *Napp Pharmaceutical v OFT*, 2002, para.87.
[76] Hou, "Excessive Prices within EU Competition Law" (2011) 7(1) *European Competition Journal* 49.