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ARTICLE

Excessive Pricing in Pharmaceuticals under Article 102 TFEU

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Abstract

High pharmaceutical pricing practices in Europe have been increasingly on the radar of the European Union, academia and civil society as a risk to Member State health budgets. It is therefore hardly surprising that, in recent years, competition authorities have resuscitated the excessive pricing prohibition contained in Article 102(a) TFEU. Focusing on this phenomenon, this piece highlights the diverse ways in which the United Brands test has been applied in pharmaceuticals by conducting a comparative study of the decisional practice of national competition authorities. Several observations and arguments are then derived therefrom, demonstrating that, while difficult (most notably in respect to patent-protected products), competition authorities and courts have established sophisticated ways of determining whether a pharmaceutical price is excessive in the sense of Article 102(a) TFEU. These findings should encourage hesitant competition authorities and private plaintiffs to at least carry out preliminary investigations when they suspect excessive pricing in pharmaceuticals is taking place.

Keywords: Access to medicines; Article 102 TFEU; excessive pricing; pharmaceutical sector

I. Introduction

The pricing of medicines has been an issue of intense academic and public debate for decades. This issue particularly came to the fore with the HIV/AIDS epidemic, "the first major international public health emergency in an era of newly-minted international patent rules".[1] Two decades later, it is not just low- and middle-income countries struggling to pay for medicines. Countries in the European Union (EU) increasingly find their considerably larger public health budgets under pressure. As noted by the Organisation for Economic Co-operation and Development (OECD), "In 2018, retail pharmaceuticals (excluding those used during a hospital treatment) alone accounted for around one-sixth of all health care expenditure, and represented the third largest spending component in EU countries after inpatient and outpatient care."[2] Public health academics are also paying increased attention to issues of pharmaceutical pricing. In 2020, the *British Medical Journal* dedicated an entire special issue to "Achieving Fair Pricing of Medicines".[3] Strikingly, one contribution highlighted that global expenditure on

[1] E 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (Amsterdam, Health Action International 2016) p 6.

[2] Organisation for Economic Co-operation and Development and European Union, *Health at a Glance: Europe 2020: State of Health in the EU Cycle* (Paris, OECD 2020) p 170.

[3] "Achieving Fair Pricing of Medicines" (2020) 368 BMJ Special Collection.

pharmaceuticals increased 56% between 2007 and 2017.[4] Hence, EU Member States face the risk of not being able to provide important and life-saving medicines for their populations.

It is therefore hardly surprising that, in recent years, competition authorities have resuscitated the excessive pricing prohibition contained in Article 102(a) TFEU, understanding that excessive prices are not necessarily self-correcting.[5] Of the forty identified Article 102 TFEU public enforcement investigations since 1974 in the pharmaceutical sector, eight concerned allegations of excessive pricing.[6] Infringements were identified in five of these cases[7] and settlements in two.[8] These figures exclude the excessive pricing cases that have taken place in the UK since Brexit.[9]

The increased enforcement of Article 102(a) TFEU also presents risks for dominant pharmaceutical undertakings. After a long period when their pricing practices in higher-income countries went largely unchallenged, they are now suddenly faced with the possibility of ex-post enforcement of the excessive pricing prohibition.

Several academic case studies exist that can be complemented by a comparative assessment of the rich body of Article 102(a) excessive pricing investigations in pharmaceuticals. However, excessive pricing as a general "theory of harm"[10] under Article 102(a) TFEU is itself already a controversial matter,[11] especially because the pharmaceutical industry is particularly innovation-driven. Indeed, it has been argued that the possibility of false positives may risk chilling effects on innovation.[12] Thus, before it was possible to assess how the excessive pricing prohibition has been applied in pharmaceutical cases, it was necessary to understand how an excessive price has been defined and established by the European Court of Justice (ECJ).

This article therefore presents the excessive pricing Article 102 TFEU theory of harm both in general and in pharmaceuticals in particular. Section II explores the ECJ's

[4] SG Morgan, HS Bathula and S Moon, "Pricing of Pharmaceuticals Is Becoming a Major Challenge for Health Systems" (2020) 368 BMJ 1.

[5] A Ezrachi and D Gilo, "Are Excessive Prices Really Self-Correcting?" (2009) 5 Journal of Competition Law & Economics 249.

[6] Office of Fair Trading, *Napp* [2001] CA98/2/2001; Autorité de la concurrence, *Ethicon et Tyco* [2009] Décision n° 09-D-38; Autorita' Garante della Concorrenza e del Mercato *Aspen* A480 [2016] n 26185; Konkurrencerådets afgørelse, *CD Pharma* [2018] DIPS-14/08469; Competition and Markets Authority, *Essential Pharma—Decision to Accept Commitments* [2020] no. 50951; Commission, *Aspen (EU)* C(2021)724 final; Autoriteit Consument & Markt, *Leadiant* [2021] ACM/20/041239; Competition and Markets Authority, *Pfizer/Flynn* [2016] [2016] CE/9742-13; Autorita' Garante della Concorrenza e del Mercato, *Leadiant* A524 [2022] n. 30156. Note that the *Pfizer/Flynn* case was sent back to the NCA in *Flynn and Pfizer v CMA* [2018] CAT 11; *CMA v Flynn* [2020] EWCA Civ 339, which re-confirmed its finding of an infringement: CMA, "£70 Million in Fines for Pharma Firms That Overcharged NHS" (*GOV.UK*, 21 July 2022) <https://www.gov.uk/government/news/70-million-in-fines-for-pharma-firms-that-overcharged-nhs> (last accessed 29 July 2022). As the infringement decision has not yet been published, the 2016 decision and appeals cases are discussed in this piece.

[7] *Napp (UK)*, supra, note 6; *Aspen (Italy)*, supra, note 6; *CD Pharma (Denmark)*, supra, note 6; Autoriteit Consument & Markt, *Leadiant* (1 July 2021) ACM/20/041239; CMA, *Pfizer/Flynn (UK)*, supra, note 6.

[8] *Essential Pharma (UK)*, supra, note 6; *Aspen (EU)*, supra, note 6.

[9] Notably, Competition and Markets Authority, *Liothyronine (UK)* [2021] no. 50395; Competition and Markets Authority, *Hydrocortisone* [2021] no. 50277.

[10] In competition law, a theory of harm explains "in exactly what way the agreement, practice, or merger is, or will be, anti-competitive": A Jones, B Sufrin and N Dunne, *Jones & Sufrin's EU Competition Law* (Oxford, Oxford University Press 2019) p 55.

[11] L Hou, "Excessive Prices Within EU Competition Law" (2011) 7 European Competition Journal 47, 48.

[12] Eg M Gal, "The Case for Limiting Private Litigation of Excessive Pricing" 5–6 and 9 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3463386> (last accessed 27 May 2021); DS Evans and AJ Padilla, "Excessive Prices: Using Economics to Define Administrable Legal Rules" (2005) 1 Journal of Competition Law & Economics 97, 100, 102, 109, 114–15 and note 83; C Calcagno, A Chapsal and J White, "Economics of Excessive Pricing: An Application to the Pharmaceutical Industry" (2019) 10 Journal of European Competition Law & Practice 166, 171; B Ignjatovic and P Hutchinson, "Excessive Intervention? A Review of Recent Excessive Pricing Investigations" (2019) 18 Competition Law Journal 29, 30.

definition of an excessive price and unpacks the *United Brands* two-limb test that has consistently been applied in pharmaceutical cases. Section III explains how competition authorities have established excessive pricing specifically in the pharmaceutical sector. Section IV discusses the possibility of finding a patent-protected medicine to be excessively priced, with a special focus on complaints filed by civil society groups regarding the drug Spinraza and on important considerations for competition authorities interested in taking up such a case. Section V concludes.

II. Defining and establishing an excessive price: *United Brands*

The oft-repeated definition of an excessive (or "unfair")[13] price in the sense of Article 102(a) TFEU was first given in *General Motors* and reiterated in *United Brands*. These cases defined an excessive price as a price that "has no reasonable relation to the economic value of the product supplied".[14] In such a situation, an undertaking is able "to reap trading benefits which it would not have reaped if there had been *normal and* sufficiently effective competition".[15]

To establish whether a price is excessive, in pharmaceutical cases competition authorities have resorted to the test laid down in *United Brands*, a profit test comparing revenues with "cost[s] of production"[16]. It is structured in two core analytical stages (Limbs 1 and 2). Limb 1 tests for "excessiveness" and asks "whether the difference between the costs actually incurred and the price actually charged is excessive". "[I]f the answer to this question is in the affirmative", Limb 2 tests for "unfairness" and asks "whether a price has been imposed which is either unfair in itself" (Limb 2.1) "or when compared to competing products" (Limb 2.2).[17] Thus, Limb 1 assesses "excessiveness" and (as will be seen below) generally involves comparing revenues to costs plus a reasonable measure of profitability. Limb 2 assesses whether this excess is "unfair". This two-stage analysis raises several questions, the answers to which inform its application.

1. What costs are included in the Limb 1 analysis?

Cost calculation has been described as "notoriously difficult".[18] The calculation of "costs actually incurred" takes into account both variable and fixed (and hence both short- and

[13] The ECJ has used these terms interchangeably to refer to the abuse itself. Indeed, the Art 102(a) TFEU prohibition itself uses the term "*unfair* purchase or selling prices", and the ECJ's aforementioned case law definition refers to a price that is "*excessive*": Case 26-75 *General Motors* [1975] EU:C:1975:150 [12]; Case 27/76 *United Brands* [1978] EU:C:1978:22 [250]; Case C-242/95 *GT-Link* [1997] EU:C:1997:376 [39]; Case C-52/07 *Kanal 5* [2008] EU:C:2008:703 [28]; Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v Konkurences padome (AKKA/LAA)* [2017] EU:C:2017:689 [35]; Case C-372/19 *Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM)* [2020] EU:C:2020:959 [28] and [31]. Also compare the ECJ's interchangeable use of unfair and "excessive" in their clarifications that other methods besides the *United Brands* two-stage test can be used to determine whether an infringement of Art 102(a) TFEU has occurred: *United Brands* [253]; *AKKA/LAA* [37]; *SABAM* [31].

[14] *United Brands*, supra, note 13, [250] slightly reformulating *General Motors*, supra, note 13, [12] to add a threshold of "reasonableness". In *General Motors*, the ECJ added to the definition "and which has the effect of curbing parallel imports by neutralizing the possibly more favourable level of prices applying in other sales areas in the Community, or by leading to unfair trade in the sense of Article 86 (2) (a)" [12]. However, it is clear from *United Brands*, supra, note 13, [250] and the later case law discussed herein that excessive pricing may constitute a standalone abuse and need not be a corollary of other exclusionary abuses as one might read from *General Motors*.

[15] *United Brands*, supra, note 13, [249], emphasis added. In French: "*concurrence practicable et suffisamment efficace*".

[16] ibid [251].

[17] ibid [252].

[18] Hou, supra, note 11, 59.

long-term) production costs.[19] This reflects the fact that there are certain industries whose costs are primarily fixed in nature and have lesser variable costs. Two particularly important observations for assessing pharmaceutical prices related to this point have been overlooked in the literature.

Firstly, it might be argued that, *prima facie*, the ECJ suggested in *United Brands* that Limb 1 only concerns *production* costs.[20] This would potentially exclude other important aspects of a given sector's cost structure, most notably research and development (R&D) costs integral to innovation-driven industries (such as pharmaceuticals) and also any regulatory fees or taxes involved in marketing that product. However, competition authorities have interpreted Limb 1 as not limited to production costs, since their analyses have simply assessed non-production costs under Limb 1 without further remark (see Section IV below). Even if this were not so, such costs could also arguably be assessed under the "unfairness" analysis (see below) or an objective justification efficiency gains analysis. Secondly, taken literally, if Limb 1 is to take into account only costs "actually incurred", this analysis should also include any public funding received by the undertaking for R&D or production. Such public funding is extremely common in the pharmaceutical sector.[21] To the extent that such public funds offset the costs incurred by the undertaking, they should be deducted from these costs in the analysis.

2. How should a reasonable measure of profitability be determined under Limb 1?

It is generally accepted that the determination of whether or not profit is "excessive" under Limb 1 should allow for a reasonable measure of profitability. This is typically referred to as a "costs-plus" measure, as it compares revenues to costs *plus* a reasonable measure of profitability.[22] While "rate of return" is the more common term, this article deliberately invokes "measure of profitability" to avoid conflating this measure of reasonableness with return on capital. In the majority of the pharmaceutical excessive pricing cases, competition authorities do *not* use return on capital as the measure of profitability.

There is no prescribed method for determining a reasonable measure of profitability. Thus, the case law uses various proxy measures depending on the context of the case, such

[19] In the sense of *United Brands*, supra, note 13, [252]: "Regarding the first limb of the test, it is settled case law that the 'costs actually incurred' do not only include variable costs but all the production costs, including fixed costs [*UB* 251 and 254]. The comparison between prices and costs actually incurred should therefore not be limited to short run marginal cost, but should also include fixed production costs": Commission, "Staff Working Document" SWD/2016/0385 final.

[20] *United Brands*, supra, note 13, [251] and [254]. This argument is supported by AG Pitruzella's statement in AG Opinion Case C-372/19 *SABAM* [2020] EU:C:2020:598 [57] that "the *United Brands* test suggests, at least implicitly, determining the value of the product or service provided by the dominant undertaking on the basis of its *costs of production*" (emphasis added) – though I would argue it was rather *explicitly* suggested.

[21] Eg taking into account the United States National Institutes of Health funding, "private industry pays for only about one-third of biomedical R&D": M Boldrin and DK Levine, *Against Intellectual Monopoly* (Cambridge, Cambridge University Press 2008) p 227. In 2016, the "Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies" (September 2016) 14 <http://www.unsgaccessmeds.org/final-repor> (last accessed 1 March 2022) noted that "[a]n analysis of spending on health technology R&D in wealthy countries found that 60% derived from the private sector and 40% from public and non-profit sources. The percentages were reversed for R&D in diseases that heavily affect low- and middle-income countries, including HIV, TB and malaria. For those conditions, the public sector provided approximately 60% of total R&D funding." In 2018, EG Cleary et al, "Contribution of NIH Funding to New Drug Approvals 2010–2016" (2018) 115 Proceedings of the National Academy of Sciences of the United States of America 2329 found that "NIH funding was associated directly or indirectly with every drug approved from 2010–2016 and suggests that the scale of this contribution is larger than generally appreciated" (p 2333).

[22] Eg Commission, *Port of Helsingborg* [2004] Case COMP/A.36.568/D3 [221].

as average returns for the undertaking[23] or for the industry.[24] The use of these proxy measures will itself involve contextual decisions about what data to include and exclude. This will be addressed more fully below. For now, it suffices to note that the relevant product price allowing for more than a reasonable profit is considered indicative of an excessive price, permitting the analysis to move on to Limb 2.

3. What is the meaning of each type of Limb 2 "unfairness"?

In terms of establishing whether a price is "unfair in itself" under Limb 2.1, this analysis could involve an intertemporal comparison of the product prices charged by the same undertaking. This can establish unfairness where substantial price increases by the focal undertaking are not explained by cost-related factors.[25] Care should be taken first to determine whether the previous price itself bore a reasonable relationship to the economic value of the product or service. In that regard, it should be confirmed that the price is neither too high nor too low to serve as a meaningful benchmark of comparison for determining whether the contemporary price is unfair,[26] at least without being adjusted. Finally, and in connection to the first question, non-production costs (and arguably any associated public funding) could be analysed under Limb 2.1 if excluded from the Limb 1 analysis. After accounting for these costs, a finding that the price reasonably reflects total costs could act as an indicator in favour of the focal undertaking that the price is not necessarily unfair in itself.

With respect to the meaning of unfairness in the sense of Limb 2.2 "compared to competing products", this refers to a benchmarking exercise. Appropriate comparators seem *not* to be limited to "competing" products in the sense of a market definition analysis. Product market definitions are generally limited to products considered interchangeable from the perspective of the consumer.[27] It is wise not to restrict the Limb 2.2 comparison to products that compete in a market definition sense. Otherwise, there would be no product of comparison in many markets scrutinised through the lens of Article 102(a) TFEU, because these markets are by definition subject to the dominance of the focal undertaking, meaning that there may not be any competitors in this sense. This interpretation is supported by the ECJ's and Court of First Instance (CFI)'s decisions in *Scippacercola*. In those cases, the EU Courts endorsed the Commission's comparison of the focal service price to prices charged for "competing services". These "competing services" were other undertakings providing the same service in other geographical areas[28] and

[23] ibid [225].

[24] ibid. See also the measures used to calculate industry average as the reasonable rate of return used in *Aspen (EU)*, supra, note 6, described in Section III.

[25] Eg in Case 226/84 *British Leyland* [1986] EU:C:1986:421; *General Motors*, supra, note 13; CMA, *Pfizer/Flynn (UK)*, supra, note 6 (sent back for re-assessment); *CD Pharma (Denmark)*, supra, note 6; *Aspen (Italy)*, supra, note 6. Indeed, using past prices of the focal undertaking "seems to be a natural interpretation of whether a price is 'unfair in itself'": P Akman and L Garrod, "When Are Excessive Prices Unfair?" (2011) 7 Journal of Competition Law & Economics 403, 419.

[26] On the one hand, the previous price might have already been too high to be considered a suitable benchmark for the focal price (eg if the previous market also involved a dominant undertaking charging excessive prices or if the product had previously been on patent, thereby implying the previous price was higher for the purposes of recouping R&D costs). On the other hand, the previous price might be too low to be considered a suitable benchmark (eg if there is evidence that certain costs (such as production costs) or regulatory fees have increased).

[27] Commission, "Notice on the Definition of Relevant Market for the Purposes of Community Competition Law" [1997] OJ C372/5 [15]. See also [13], which emphasises that "demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a given product".

[28] Both the CFI and ECJ referred to this as a comparison of the focal service to "competing services", despite the fact that they are clearly not "competing" in the sense of belonging to the same relevant market: Case T-306/05 *Scippacercola* [2008] EU:T:2008:9 [103]; Case C-159/08P *Scippacercola (Order)* [2009] EU:C:2009:188 [44]–[48]. See similarly Commission, *Port of Helsingborg*, supra, note 22 [147].

therefore not competing in the sense of a market definition analysis. Moreover, focal undertakings may also offer the same product in other geographical areas. These offerings could have the capacity to constitute a relevant comparator under Limb 2.2. The Commission undertook such a comparison in *United Brands*.[29] Although the ECJ overturned the infringement decision, it did not do so on the grounds that the comparison was primarily made against prices of United Brands' own products in different areas.

Importantly, it might legitimately be asked whether the price of a comparable product in another geographical area is truly comparable when the geographical area in question is not characterised by entirely "free" competition but is instead subject to price regulation. So long as the price is derived from the conduct of undertakings that is not itself abusive, it can arguably still serve as a reasonable point of comparison, and differences in costs can be accounted for accordingly. Yet it must still be asked how one is to determine whether or not a given product or service is a valid comparator.

For this, one can turn to the *AKKA/LAA* case.[30] This case involved a comparative test independent from the *United Brands* test, whereby the prices charged in other Member States were used as comparators. According to the Court, a comparator is "relevant"[31] if it is a valid benchmark for determining whether or not the focal price bears a reasonable relationship to the product's economic value. The ECJ asserted that such benchmarks must be "selected in accordance with objective, appropriate and verifiable criteria".[32] Moreover, the comparison must be made "on a consistent basis".[33]

The ECJ gave further advice on the relevant "criteria" in situations when a comparison is to be made with a product price in a different geographical area. The Court stated that they "may include, inter alia, consumption habits and other economic and sociocultural factors, such as [GDP] per capita and cultural and historical heritage".[34] These considerations are especially important to bear in mind in the pharmaceutical sector, where "regulation differs significantly across countries" and prices vary considerably.[35] Although the ECJ has been criticised for not accounting for "differences in taxes or supply costs"[36] in their list of criteria for selecting reference geographical areas, this criticism seems to overlook: (1) the Court's use of "inter alia", which implies that the criteria are not exhaustive; (2) the fact that the ECJ did name "economic ... factors" in their list of possible criteria; and (3) that the ECJ appears to suggest in *AKKA/LAA* that it is more appropriate to account for such differences (or "objective dissimilarities"[37]) in the justification stage of the Article 102(a) TFEU analysis.

In terms of how to carry out a comparison "on a consistent basis", the ECJ advised the referring court that, for a geographical comparison, it had to (1) verify that the method for calculating prices was "analogous to the method of calculation" used with respect to the focal service and (2) take into account the purchasing power parities index where prices were compared to geographical areas with differing economic conditions.[38] Additionally, the ECJ stated that the prices charged by the focal undertaking when compared to those charged in other geographical areas were contrary to Article 102(a) TFEU where the focal

[29] See the discussion on this below in the concluding observations of this Section III in respect to the price comparison made with Ireland.

[30] *AKKA/LAA*, supra, note 13.

[31] ibid [41].

[32] ibid.

[33] ibid [44].

[34] ibid [42].

[35] Calcagno et al, supra, note 12, 169.

[36] M Botta, "Sanctioning Unfair Pricing under Art. 102(a) TFEU: Yes, We Can!" (2021) 17 European Competition Journal 156, 174.

[37] *AKKA/LAA*, supra, note 13, [57].

[38] ibid [45].

undertaking's prices were "appreciably higher".[39] The difference between focal prices and benchmark prices is appreciable if it is both "significant" and "persistent".[40] That is, the "difference must persist for a certain length of time and must not be temporary or episodic".[41]

4. Are Limbs 1 and 2 cumulative or alternatives?

The ECJ's wording shows that the two main limbs of the *United Brands* test are cumulative, seemingly because a determination of the product/service's price–cost difference cannot in itself reliably demonstrate that the price is unfairly high to the extent that it infringes Article 102(a) TFEU. Further inquiry into the context of the profitability measure identified in Limb 1 must be made in order to attribute meaning to it and ultimately determine whether or not the focal price is abusive.[42]

5. Are Limbs 2.1 and 2.2 cumulative or alternatives?

There is a contemporary debate about whether Limbs 2.1 and 2.2 are cumulative or alternative requirements of assessment.[43] The disjunctive conjunction "either/or" invoked by the ECJ between Limbs 2.1 and 2.2 implies that they are in fact *alternative* bases for establishing an infringement of Article 102(a). The ECJ's *Scippacercola* Order endorsed this interpretation.[44] This will be discussed further with respect to the *Pfizer/Flynn (UK)* saga in Section III below.

III. Excessive pricing cases in the EU pharmaceutical sector

This section explores how competition authorities assessed Limbs 1 and 2 in Article 102 TFEU pharmaceutical cases. The cases discussed here include *Aspen (Italy)* 2016,[45] the original *Pfizer/Flynn (UK)* decision from 2016,[46] *CD Pharma (Denmark)* 2018,[47] *Leadiant (Netherlands)* 2021[48] and *Aspen (EU)* 2021.[49] The discussion is somewhat complicated by the fact that each decision provides a different level of detail. For instance, many of the relevant data are redacted in *CD Pharma (Denmark)*, and only a summary of *Leadiant (Netherlands)* is available. This has not significantly obstructed this section's investigation

[39] ibid [38].

[40] ibid [55].

[41] ibid [56].

[42] See for a similar argument R O'Donoghue and J Padilla, *Law and Economics of Article 102 TFEU* (3rd edn, London, Bloomsbury 2020) p 750.

[43] Eg Botta, supra, note 36, arguing that after *CMA v Flynn*, supra, note 6, it is "unclear" whether Limbs 2.1 and 2.2 are cumulative or alternatives.

[44] Case C-159/08P *Scippacercola (Order)*, supra, note 28, [47]: "As the wording of [*United Brands* (252)] is clear, the appellants' argument that the examination of the unfair price must be based on a cumulative application of those criteria ... cannot therefore succeed."

[45] *Aspen (Italy)*, supra, note 6.

[46] CMA, *Pfizer/Flynn (UK)*, supra, note 6, and the appeals in CAT, *Flynn and Pfizer v CMA*, supra, note 6; *CMA v Flynn*, supra, note 6.

[47] *CD Pharma (Denmark)*, supra, note 6.

[48] Autoriteit Consument & Markt, *Leadiant*, supra, note 7.

[49] *Aspen (EU)*, supra, note 6. Four excessive pricing cases are excluded. These include the UK cases *Liothyronine (UK)*, supra, note 9; *Hydrocortisone (UK)*, supra, note 9, because Art 102 TFEU no longer applied in these cases. *Essential Pharma (UK)*, supra, note 6, is also excluded because the settlement does not indicate what analytical method might have been deemed appropriate to assess whether the price was excessive in that case. Finally, as this article was written before the Autorita' Garante della Concorrenza e del Mercato, *Leadiant*, supra, note 6, decision was published, this case is also excluded.

of how competition authorities measured key concepts from the Limb 1 analysis, most notably costs actually incurred and a reasonable measure of profitability, and whether and how they performed a Limb 2.1 or 2.2 analysis.

1. Limb 1 in pharmaceutical cases

a. Aspen (Italy)

The national competition authority (NCA) resorted to two types of profitability analyses in their Limb 1 analysis in the first pure excessive pricing case, *Aspen (Italy)*. The first involved a measure of the gross profit margin (the difference between net sales and the cost of goods sold (COGS)).[50] The NCA found profit margins (pre-price increase) of between 20–30% (for Leurakan) and 70–80% (for Purinethol)[51] and costs of 30%.[52] Thus, after the price increase of 300%–1,500%, they found that Aspen's revenues significantly exceeded total costs.[53] The second profitability measure assessed the difference between revenues and costs-plus.[54] The latter included direct costs (COGS), indirect costs (supply chain management and marketing authorisation (MA) fees)[55] and a rate of return on sales (ROS) regarded as reasonable.[56] To establish reasonability, the NCA used the worldwide average ROS of the two largest generic companies (Teva and Mylan), which was 13%.[57] They opted to assess ROS instead of return on capital because of the undertaking's limited investments in R&D and lack of production and marketing activities.[58] Again, they observed that Aspen's revenues over costs were much higher than this costs-plus figure, with values ranging from 100–150% to 350–400%.[59]

b. Pfizer/Flynn (UK)

In the next excessive pricing decision, *Pfizer/Flynn (UK)*,[60] the NCA conducted separate analyses for the producer, Pfizer, and the distributor, Flynn. For Pfizer, to calculate costs, the NCA used a long-run average cost measure that considered both direct costs and indirect costs.[61] For direct costs, the NCA included COGS and distribution costs.[62] For calculating indirect costs, where allocation of common costs was possible, the NCA used the output-based method of allocation,[63] since sufficient data for an input-based analysis were not provided.[64] The most appropriate volume-based measure for which data were available was sales volume by pack,[65] but two other methods were also used as part of the sensitivity analysis.[66] Secondly, the NCA determined the appropriate measure of profitability and considered three methods in this respect: return on capital employed

[50] *Aspen (Italy)*, supra, note 6, [138] and [142].
[51] ibid [146]–[147].
[52] ibid [152].
[53] ibid [155].
[54] ibid [156].
[55] ibid [165].
[56] ibid [156] and [171].
[57] See ibid [174], [182], and note 136.
[58] ibid [171]–[173].
[59] ibid [184].
[60] CMA, *Pfizer/Flynn (UK)*, supra, note 6.
[61] ibid [5.28]–[5.29]. Indirect costs included common costs [5.30] (neither undertakings had joint costs [5.31]).
[62] Pfizer: [5.67]. Flynn: [5.14].
[63] CMA, *Pfizer/Flynn (UK)*, supra, note 6, [5.39]. This is "where indirect costs are allocated using output indicators": [5.38(b)].
[64] ibid [5.40].
[65] ibid [5.44].
[66] ibid [5.46].

(ROCE), gross margins and ROS, the latter being its primary measure in this case (like *Aspen (Italy)*).[67] To determine a "reasonable" profitability threshold for calculating costs-plus,[68] the NCA assessed the relevance of Pfizer's internal ROS on its whole business, the allowed ROS under the Pharmaceutical Price Regulation Scheme (PPRS) and other companies' ROS rates.[69] They ultimately identified 6% as the appropriate benchmark. This was the ROS allowed by the applicable profit control scheme from which the product was removed after debranding (which enabled the price increase in the first place).[70] This figure was slightly higher than Pfizer's internal ROS.[71] They also applied a 9% figure, based on other measures, to cross-check their subsequent findings.[72] The NCA found that Pfizer's revenues exceeded costs-plus by at least 29%, 100%, 705% and 690% for the different capsule strengths,[73] totalling £49–57 million over the four-year period.[74] The sensitivity analysis excesses were similarly large and deemed excessive.[75]

As for Flynn, for direct costs, the NCA took account of purchase, distribution and sales costs.[76] The NCA considered the same measures used for the assessment of Pfizer's costs for the purposes of determining Flynn's relevant indirect costs,[77] profitability[78] and the reasonable profitability measure.[79] For the latter, however, it found that the PPRS rate was only somewhat appropriate for a benchmark of Flynn's reasonable measure of profitability,[80] since they were a distributor. In any event, they used the 6% figure in light of the nature of the capsules ("far from new and innovative") and the nature of the activities undertaken and risk incurred by Flynn (a "nominal role" in distribution).[81] The NCA found that Flynn's revenues exceeded the costs-plus benchmark by at least 133%, 70%, 31% and 36% for the different capsule strengths,[82] totalling £27.5–32.5 million.[83] Both this primary analysis and the sensitivity analysis produced the same conclusion of excessiveness.[84]

For both parties, the NCA found that there were no additional non-cost-related factors that put the economic value above the costs-plus benchmark.[85] For this analysis, they took account of the characteristics of the medicines at issue (that they were "very old", no longer "first or second line", had long been sold at a much lower price and had no material change in costs).[86] They also took account of the health payer's willingness to pay the premium, highlighting that the health authorities were "actually paying the prices under

[67] ibid [5.84]. While ROCE is usually the CMA's preferred measure, there were limitations to its use in this case for Pfizer: ibid [5.82]. Gross margin was deemed inappropriate because it does not take into account all "support activities": [5.83].

[68] CMA, *Pfizer/Flynn (UK)* (n 6) [5.86].

[69] ibid [5.87].

[70] ibid [5.93].

[71] ibid [5.98].

[72] These included Pfizer and other companies' weighted average cost of capital (WACC) and the PPRS return on capital (ROC) [5.108]. The WACC for comparable companies identified by the CMA was 9–12%, which was similar to Pfizer's: ibid [5.110].

[73] ibid table 5.8.

[74] ibid [5.130].

[75] ibid [5.135].

[76] ibid [5.145].

[77] ibid [5.150]–[5.151].

[78] ibid [5.156]–[5.159]. Their reasoning for not considering ROCE appropriate was redacted.

[79] ibid [5.163].

[80] ibid [5.201].

[81] ibid [5.166]–[5.167].

[82] ibid [5.218].

[83] ibid [5.225].

[84] ibid [5.239].

[85] ibid [5.261].

[86] ibid [5.268]–[5.272].

protest".[87] On appeal, the Competition Appeal Tribunal (CAT) found several flaws with the NCA's costs-plus methodology, arguing that it was not a sufficient basis for a finding of excessiveness and that the NCA should have assessed multiple bases of analysis, in particular a hypothetical benchmark price.[88] However, Green LJ and Vos LJ of the Court of Appeal agreed this to be wrong in law.[89] The CAT had also found that the decision "was defective in its treatment of the economic value that may be derived from patient benefit" (ie non-cost-related factors).[90] They concluded that this factor should have been incorporated to some degree.[91] The Court of Appeal agreed with this point.[92] It remains to be determined how the NCA's new finding of infringement took this into account.

c. CD Pharma (Denmark)

For what can be considered Limb 1, the NCA in *CD Pharma (Denmark)* undertook several price–cost comparisons. The relevant information is largely redacted, but it shows that all of these comparisons found profit margins of over 70%.[93] The only exception was the estimate involving the costs considered relevant by CD Pharma.[94] The calculation of costs actually incurred was slightly different in this case because CD Pharma was a parallel importer, buying the drug from Sigma-Tau. Thus, the NCA could use the purchase price as the main cost measure.[95] Despite CD Pharma having no documentation of several other relevant costs, the NCA allowed the inclusion of the following: transport costs, distribution costs, cold storage costs, interest and overhead costs.[96]

The central estimate of CD Pharma's profit margin that the agency deemed the most accurate (but still apparently conservative) was 80–90%.[97] The NCA does not appear to have settled on a reasonable measure of profitability but simply to have concluded that the profit margin was significant.[98] The NCA moreover appears to place special emphasis on the fact that the UK NCA in *Pfizer/Flynn* used a 6% ROS figure for a pharmaceutical distributor (like CD Pharma).[99] This comparison is peculiar, since it is not directly comparable to profit margin.

d. Leadiant (Netherlands)

Only a summary is available for the *Leadiant (Netherlands)* decision, but it nevertheless offers a considerable degree of insight into how the NCA assessed each limb. In the Limb 1 analysis, the "costs" accounted for included the distribution fee for wholesalers,[100] as well as those costs associated with acquiring the orphan designation and MA, investments made in the drug, manufacturing and distribution costs and risks of failure.[101] The NCA found that Leadiant's chenodeoxycholic acid (CDCA) project of obtaining formal orphan status for the drug was low cost and low risk.[102]

[87] ibid [5.274]–[5.275].
[88] CAT, *Flynn and Pfizer v CMA*, supra, note 6, [310] and [443].
[89] *CMA v Flynn*, supra, note 6, Green LJ [125] Vos LJ [248] and [254].
[90] CAT, *Flynn and Pfizer v CMA*, supra, note 6, [419]. See also [412].
[91] See the overview by Green LJ in *CMA v Flynn*, supra, note 6, at [166].
[92] ibid Green LJ [165] and Vos LJ [281].
[93] *CD Pharma (Denmark)*, supra, note 6, table 4.15.
[94] ibid [939]–[941].
[95] ibid [978] and [989].
[96] ibid [981]–[989].
[97] ibid [[990]–[991].
[98] ibid [1025].
[99] ibid [1024]
[100] Autoriteit Consument & Markt, *Leadiant*, supra, note 7, [10].
[101] ibid [10]–[11].
[102] ibid [12].

Without elaborating upon their underlying reasoning, the NCA stated that they used a 15% return on investment (ROI) figure as a reasonable measure of profitability.[103] Likewise, in the absence of an indication of Leadiant's own ROI, the NCA came to the conclusion, under the Limb 1 analysis, that Leadiant's prices were "exorbitantly high"[104] and hence excessive in the sense of this Limb.

e. *Aspen (EU)*

Finally, we turn to *Aspen (EU)*. As this case was settled with commitments, the Commission provided only preliminary conclusions. Nevertheless, the authority gave substantial insight into how they would establish whether the Limb 1 threshold was met. For this Limb, they relied on the costs-plus analytical method. In that regard, they indicated how they calculated costs (direct and indirect),[105] revenues (ie net sales, which included gross sales minus certain expenditures such as wholesale discounts, rebates, promotions and returns)[106] and a reasonable measure of profitability.[107] With respect to the latter and most decisive factor, the Commission primarily relied on a median earnings before interest, taxes, depreciation and amortisation (EBITDA) profit margin measure of a sample of other undertakings similar to Aspen,[108] selected according to objective criteria.[109] In essence, the criteria were that the comparator undertakings "sell mainly generic or off-patent branded medicines with at least a material part of their revenues stemming from medicines that are similar to the Products in terms of active substance".[110] Similar medicines were defined as those in the same Anatomical Therapeutic Classification (ATC)-2 category.[111] The Commission also ensured that there were no indications that the comparator undertakings did not operate under conditions of sufficiently effective competition.[112] The average EBITDA margin and hence reasonable measure of profitability for the sample was 23%.[113] Thus, to assess whether or not the *United Brands* Limb 1 threshold was surpassed, the Commission assessed whether or not the undertaking's revenues for each product during the relevant period exceeded costs plus 23%.[114] They then calculated the average excess over costs-plus (280–300%).[115] The Commission also presented their findings on excessiveness per product in the different geographical markets, which were often several hundred per cent higher than the 23% average.[116] There were a few exceptions to this for some drugs below the profitability comparator in some Member States.[117] The Commission thus preliminarily concluded that, overall, the profits were excessive under Limb 1.[118]

[103] ibid [12].
[104] ibid [12].
[105] *Aspen (EU)*, supra, note 6, s. 4.6.3.2.1. The Commission primarily used a COGS method of calculating indirect costs [114].
[106] ibid s. 4.6.3.2.2, ie [116].
[107] ibid s. 4.6.3.3.1.
[108] ibid [139].
[109] ibid [129].
[110] ibid [129].
[111] ibid [129].
[112] ibid [128].
[113] See ibid table 3 and [139].
[114] ibid [140] and [144].
[115] See ibid table 4.
[116] ibid [146]–[151], with the highest profit excess being 900–920% for Purinethol sales in Malta: [148].
[117] Eg Alkeran IV in one of twenty-two Member States (ibid [146]); Alkeran Oral in four of twenty-four Member States [147]; Purinethol in two of twenty-three Member States [148], Leukran in five of twenty-five Member States [149]; Lanvis in five of twenty-two Member States [150]; and Myleran in two of twenty Member States [151].
[118] ibid [152].

The Commission then responded to Aspen's counterarguments related to the Limb 1 analysis. Firstly, the Commission accepted that direct computation "of the capital employed in the Products and the associated cost of capital" could be an acceptable method to assess Limb 1 excessiveness. This would have been an alternative to the industry average EBITDA margin. However, the Commission noted that the relevant data were not readily available in this case.[119] Moreover, the Commission also rejected the price of acquiring the cancer drug portfolio as a potential proxy for capital cost. The argument was that this was conceptually incoherent. Because the acquisition price is "likely to reflect mainly the capitalised value of future expected profits ... as opposed to the value of the assets",[120] the acquisition price paid was "likely to significantly overstate the value of the underlying assets" and in turn to "significantly under-estimate the underlying profitability of the Products".[121] While the Commission could have further attempted to identify the underlying capital and costs thereof, they were confident that this would be unnecessary in light of the aforementioned "clear concerns identified in the Limb 1 analysis".[122] In any event, even using Aspen's proposed cost of capital (acquisition cost), Aspen's ROIs were still "several-fold greater", thus "confirming" their profitability assessment.[123]

2. Limb 2 in pharmaceutical cases

a. Aspen (Italy)

In terms of how unfairness has been assessed, in *Aspen (Italy)*, the NCA mostly relied on factors that can be considered to fall under Limb 2.1. The core aspect of the Limb 2 assessment was a comparison of Aspen's prices over time.[124] This analysis showed that the prices were 300–1,500% higher than the previous prices, which already guaranteed a profit.[125] In terms of other factors considered in the unfairness analysis, the NCA noted that the prices were not justified by economic reasons. This was because the Italian pricing legal framework did not provide grounds for price increases not attributable to drug production cost increases.[126] Moreover, even taking into account the US$300–400 million acquisition of the multi-country generic cancer drug portfolio, revenues remained 100–150% and 300–350% above cost.[127] Returns were between 20–30% and 30–40% higher than the 8% generic industry average return on capital.[128] The third ground for considering the prices as unfair was the lack of any non-economic benefits of the price increases for patients.[129] Separate to an unfairness analysis but interpretable as a Limb 2.1 consideration, the NCA highlighted Aspen's coercive negotiation strategy for obtaining the unfair price.[130] Thus, the conclusion of unfairness was based predominantly on Limb 2.1 grounds, besides the comparison of returns to the generic industry 8% average.

[119] ibid [155]: "Aspen ha[d] not accounted for any specific tangible or intangible assets acquired by Aspen in connection with the Products."

[120] ibid [156].

[121] ibid [157]. Therefore, this creates a circularity problem in calculating return on capital and hence profitability [156]. See likewise "since the acquisition price should be interpreted as largely a transfer of expected future profits from GSK to Aspen, and not as the valuation of specific tangible or intangible assets acquired by Aspen, it would be also conceptually incorrect to treat the acquisition price as a relevant cost of production or cost of supplying the product, within the meaning of Limb 1 of the United Brands judgment": [157].

[122] ibid [155].

[123] ibid [158].

[124] ibid [330]–[336].

[125] ibid [335].

[126] *Aspen (EU)*, supra, note 6, [337].

[127] ibid [341].

[128] ibid [342].

[129] ibid [344].

[130] ibid [352]–[377].

b. Pfizer/Flynn (UK)

In the initial *Pfizer/Flynn (UK)* decision, under the Limb 2 analysis, the NCA first assessed whether there were any non-cost-related factors that were capable of increasing the economic value of the relevant product.[131] They found that there were not.[132] They did, however, find that the pricing was unfair on the basis of Limb 2.1.[133] Their grounds were that the drug was very old and off-patent, that it was no longer a first- or second-line treatment, that it had been sold much cheaper for a long time and that the price increase was not based on any change in costs, R&D or risk level.[134] "[F]or completeness",[135] the NCA also assessed whether any relevant ("meaningful")[136] comparators existed to conduct a comparative analysis under Limb 2.2. Three potential products were assessed in this regard. These included parallel imports, a generic version and a tablet version. None was deemed suitable.[137] Nevertheless, on appeal, the CAT ruled that the NCA "did not properly assess the possible impact of meaningful comparators (in particular, phenytoin tablets)".[138] They held that the NCA did not consider the suitability of tablets as a comparator in "sufficient depth",[139] especially in relation to the "competitive conditions surrounding this drug".[140] The CAT concluded that there was enough material for the NCA to have considered, "at the very least, whether there was a *prima facie* case of fairness" or not under Limb 2.2.[141]

This finding especially mattered because the CAT decided that the NCA was wrong to conclude that Limbs 2.1 and 2.2 were alternatives in that case.[142] At the Court of Appeal, Green LJ agreed. He made a compelling argument that the NCA's margin of manoeuvre, in terms of whether they assess Limbs 2.1 and/or 2.2, was limited. He forwarded that, while competition authorities are not always obliged to analyse both limbs, they cannot "ignore exculpatory evidence of another type if it is prima facie relevant"[143] when presented by the undertaking(s). He reasoned that the *United Brands* "ruling is a far cry from saying that if [a competition authority] selects one method, but a defendant undertaking serves relevant exculpatory evidence upon some other basis then [a competition authority] can avoid fairly evaluating that evidence".[144]

Green LJ's argument that evidence forwarded by undertakings must be assessed by the competition authority is not objectionable. However, his framing of the assessment of such arguments in this way, in the Limb 2 analysis, is inconsistent with the ECJ's case law.[145] The assessment of "exculpatory evidence" belongs under the objective justification stage of the analysis. Thus, competition authorities are only obliged to establish that the price is indicative of an abuse under Limb 2.1 *or* 2.2, and it is then open to an undertaking to submit such "exculpatory evidence" to demonstrate that the pricing practice was somehow justified and therefore not abusive. This includes evidence related to the Limb on which the authority did not rely for establishing that the price was indicative of an abuse. Overall,

[131] ibid Section "Economic value" starting at [5.247]. They framed this as separate from unfairness, but as observed above it appears to be part of an unfairness in itself (Limb 2.1) assessment.
[132] CMA, *Pfizer/Flynn (UK)*, supra, note 6, [5.260]–[5.338].
[133] ibid [5.339] and [5.475].
[134] Summarised in ibid [5.356].
[135] ibid [5.478].
[136] ibid [5.479]
[137] ibid [5.479].
[138] CAT, *Flynn and Pfizer v CMA*, supra, note 6, [362].
[139] ibid [379].
[140] ibid [391].
[141] ibid 11 [392].
[142] ibid [367].
[143] *CMA v Flynn*, supra, note 6, [75].
[144] ibid [75].
[145] See Section II above.

therefore, the CAT and the Court of Appeal are incorrect to take the position that Limbs 2.1 and 2.2 are "not (truly) standalone alternatives".[146]

c. CD Pharma (Denmark)

In *CD Pharma (Denmark)*, the NCA compared the dominant undertaking's prices to several benchmarks that fall under either Limb 2.1 or Limb 2.2. The first comparison was of CD Pharma's prices during the relevant period to historical prices of Syntocinon on the Danish market over time (Limb 2.1).[147] The increase compared to the highest historical price was approximately 2,000%.[148] The NCA noted that no changes in product quality or in the prices of raw materials could explain the relevant increase.[149] The second comparison was between CD Pharma's prices during the relevant period to the prices of competitor Orifarm and former distributor Sobi (Limb 2.2).[150] CD Pharma's prices were 2,100% higher than Orifarm's (a subsequent supplier)[151] and 2,050% higher than Sobi's (a previous supplier).[152] The NCA also compared CD Pharma's prices to the undertaking's own prices in other (redacted) countries (Limb 2.2).[153] While the differences between CD Pharma's prices were usually in the range of several hundred per cent, in one country prices were 8,400% lower than those charged by CD Pharma in Denmark.[154] Additionally, the NCA also assessed whether or not any other non-cost-related factors could imply a higher "economic value" for Syntocinon (Limb 2.1).[155] They concluded that there were none.[156] Thus, the NCA found that the prices were unfair in the sense of Limbs 2.1 and 2.2, on the basis of all three measures of unfairness.[157]

d. Leadiant (Netherlands)

In the NCA's summary of why, in the *Leadiant (Netherlands)* case, they considered the price unfair, they took account of factors pertinent to both Limbs 2.1 and 2.2. For Limb 2.1, these factors included the circumstances in which the orphan designation and orphan MA were obtained. In particular, they highlighted that the designation and MA were acquired without introducing a new innovation, additional therapeutic value or increased safety or efficacy.[158] For Limb 2.2, they took into account the previous price of CDCA charged by other undertakings and by Leadiant.[159] They also considered the price of the hospital-made CDCA from the Amsterdam University Medical Centre (Limb 2.2).[160] Thus, their ultimate finding of unfairness was based on both Limb 2.1 and Limb 2.2 analyses.[161]

[146] O'Donoghue and Padilla, supra, note 44, 751–52.
[147] *CD Pharma (Denmark)*, supra, note 6, [1027]–[1035].
[148] ibid [1028].
[149] ibid [1030].
[150] ibid [1036]–[1047].
[151] ibid [1037].
[152] ibid [1043].
[153] ibid [1048]–[1074].
[154] ibid [1062] and table 4.18.
[155] ibid [1072]–[1093].
[156] ibid [1092]–[1093].
[157] ibid [1111].
[158] Autoriteit Consument & Markt, *Leadiant*, supra, note 7, [13].
[159] ibid.
[160] ibid.
[161] ibid [14]–[15].

e. *Aspen (EU)*

Finally, in *Aspen (EU)*, the Commission assessed unfairness in the sense of Limb 2.1 and whether there were any relevant comparators for a Limb 2.2 analysis. The Commission considered the pricing unfair "in itself" for three core reasons. Firstly, the prices were unfair in themselves because there were no "legitimate reasons" underlying the prices and profits. This was in view of (1) the "nature" of Aspen's products (old and off-patent, recovered R&D costs and highly inelastic demand) and (2) the fact that there had not been "any commercial risk-taking activity, nor innovation, nor investment, nor any material improvement regarding the Products".[162] Indeed, It was already a well-established portfolio and brand that, pre-acquisition, reaped profits nearly double the industry average.[163] Aspen also did not carry out any R&D or add any improvements,[164] did not make enhancements to commercialisation or distribution[165] and moreover could not contribute to technical efficiency, since manufacturing was outsourced.[166]

The second reason for considering the prices unfair in themselves was because the Commission found that the price increases were disproportionate to any existing increases in costs.[167] So too were the magnitudes of the prices and profits vis-à-vis the comparative benchmarks derived from the aforementioned industry sample average.[168] This was confirmed by Aspen's evidenced strategy to exploit its market power and to increase profits.[169] The preliminary conclusion that prices were unfair in themselves, derived from those three factors, was supplemented by "additional elements" of evidence. These included the coercive means and methods employed by Aspen to overcome the resistance of public authorities to the price increases.[170]

The Commission acknowledged that it was unnecessary to assess whether or not the prices were also unfair in the sense of Limb 2.2 of *United Brands*,[171] but it nevertheless assessed the availability of suitable comparators to address Aspen's arguments.[172] It concluded that recent generic entrants with prices broadly aligned to Aspen's were not suitable comparators. The latter's prices were unlikely to be reflective of sufficiently effective competition, since there were no more than two competitors on any of the relevant markets and because it takes longer for prices to drop to competitive levels in smaller markets.[173] The Commission also deemed innovative medicines to be unsuitable comparators because they follow different pricing and reimbursement rules, in light of R&D-related efforts associated with patent-protected innovative products. Hence, they could not provide insight into price levels that would have reflected sufficiently effective competition for off-patent drugs.[174] Having fulfilled both Limbs of the test, the Commission preliminarily concluded that in most of the relevant markets "Aspen's prices may not have had, and continue not to have, any reasonable relation to the economic value of the Products supplied".[175]

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[162] *Aspen (EU)*, supra, note 6, [171].
[163] ibid [172].
[164] ibid [173].
[165] ibid [175].
[166] ibid [174].
[167] ibid [177]–[180].
[168] Noting at ibid [184], for example, that "90% of the profitability observations for the Profitability Comparators are at a profitability level below 37% EBITDA. By comparison, at portfolio level, Aspen earned an EBITDA margin of [80–90]%. Not a single Comparator company in the entire sample of observations achieved such a high margin."
[169] ibid [186]–[189].
[170] ibid [191].
[171] ibid [196].
[172] ibid [197].
[173] ibid [199].
[174] ibid [200].
[175] ibid [208].

These findings are summarised in Table 1. In particular, for each pharmaceutical case Table 1 documents whether or not the medicine was exclusivity protected, as well as the factors considered in the Limb 1 excessiveness assessment and the Limb 2 unfairness assessment. It includes information about the costs, measure of actual profitability and reasonable measure of profitability (Limb 1) and about the basis on which the price was considered unfair (Limb 2).

Several observations to inform future cases in the pharmaceutical and other sectors emerge from the preceding outline of how competition authorities have applied Limbs 2.1 and 2.2 of *United Brands* in pharmaceutical cases.

Firstly, these analyses are very context-specific. The sheer breadth of the range of measures used to assess different factors suggests as much. For instance, and strikingly, a variety of measures have been used to assess reasonable profitability. *Aspen (Italy)* and *Pfizer/Flynn (UK)* used ROS, *Leadiant (Netherlands)* used ROI and *Aspen (EU)* used EBITDA profit margin. This variety highlights the imprecision of the expression "reasonable rate of return"; the term "reasonable measure of profitability" is preferable.

It can also be observed that, in line with the recommendation of Advocate General Wahl in *AKKA/LAA*,[176] in many instances of both the Limb 1 and Limb 2 analyses, the competition authorities, of their own accord, relied on multiple measures instead of a single tool to verify whether or not a relevant criterion was fulfilled. Similarly, they often assessed both Limb 2.1 and Limb 2.2, despite only being obliged to establish unfairness under one of these Limbs (contrary to the understanding of the CAT and Court of Appeal). Indeed, even in the cases where the competition authority did *not* deem the prices unfair compared to competing products, this was only due to the lack of any relevant comparators.

The NCAs also tended to show due consideration for the alternatives proposed by the dominant undertakings. In particular, they would typically highlight why the proposed measure was unsuitable or would otherwise explain why the employment of the alternative measure would still demonstrate unreasonableness or unfairness. This comprehensive approach, assessing every suitable measure for which data are available, should instil confidence that these cases were not false positives. Of course, where one of multiple measures deployed to assess Limbs 1, 2.1 or 2.2 falls on appeal, it must be remembered that, as the case law makes apparent, it is perfectly valid to prove excessiveness (Limb 1) or unfairness (Limb 2) according to a single measure. Nevertheless, the *Pfizer/Flynn* saga highlights the importance of continued study, by both academics and competition authorities, of the excessive pricing theory of harm in pharmaceuticals.

Finally, given the range of different contexts in which the discussed pharmaceutical cases occurred, this body of case law can be relied upon to inspire future inquiries into how pharmaceutical costs should be calculated, what a reasonable measure of profitability is and/or what factors might indicate unfairness. This is most pertinent to future Article 102 TFEU excessive pricing cases, but it can also inform academic and public policy debates on this issue.

IV. Excessive pricing of a patent-protected medicine?

There is nothing in the above overview that rules out the possibility of considering a medicine protected by a patent (or regulatory exclusivity) to be excessively priced.[177] The

[176] Case C-177/16 *AKKA/LAA* Advocate General Opinion [2017] EU:C:2017:286 [43].

[177] The series of excessive pricing investigations in pharmaceuticals inevitably gave rise to such considerations. See eg C Fonteijn, I Akker and W Sauter, "Reconciling Competition and IP Law" (ACM Working Paper 2018) 14; Altroconsumo, "Spinraza Unfairly Priced" (2019) <https://www.altroconsumo.it/organizzazione/international/press-releases/2019/spinraza-unfairly-priced-italian-and-belgian-antitrust-authorities-urged-to-investigate> (last accessed 3 June 2020).

Table 1. Application of the *United Brands* test in pharmaceutical cases.

	Excessiveness			Unfairness	
Case details	Costs	Baseline measure reasonable profitability	Excess	Unfair in itself	Unfair compared to competing products
Aspen (Italy) 2016 Generic	• Direct costs (COGS) • Indirect costs (supply chain management costs, MA fees)	Average ROS of two largest generic companies (13%)	100–150% to 350–400%	✓ Intertemporal comparison; no economic justification; no non-cost-related factors; coercive negotiation strategy	✓ Comparison to generic industry average
Pfizer/Flynn (UK) 2016 Generic	• Pfizer: direct costs (COGS, distribution costs) and indirect costs • Flynn: direct costs (purchase, distribution and sales costs) and indirect costs	PPRS ROS (6%)	Pfizer: 29%, 100%, 705% and 690% Flynn: 133%, 70%, 31% and 36%	✓ Old and off-patent; intertemporal comparison; no cost increases	No relevant comparators available
CD Pharma (Denmark) 2018 Generic	• Purchase price, transportation costs, distribution costs, cold storage costs, interest and overhead costs	ROS (*Pfizer/Flynn*) (6%)	Undetermined (profit margin significant in itself)	✓ Intertemporal comparison; no non-cost-related justifications	✓ Comparison to prices charged by competitors; geographical comparison
Leadiant (Netherlands) 2021 Orphan exclusivity	• Distribution fee, orphan designation fee, MA fee, investments made in drug, manufacturing and distribution costs, risks of failure	ROI (15%)	Undisclosed	✓ Circumstances of orphan designation and MA	✓ Comparison to prices charged by competitor
Aspen (EU) 2021 Generic	• Direct and indirect costs (excluded acquisition costs)	EBITDA margin of sample of other undertakings similar to Aspen (23%)	280–300%	✓ No legitimate reasons (old and off-patent; no risk, innovation, investment, nor improvement); disproportionate to cost increase; strategy to exploit market power	No relevant comparators available

COGS = cost of goods sold; EBITDA = earnings before interest, taxes, depreciation and amortisation; MA = market authorisation; PPRS = Pharmaceutical Price Regulation Scheme; ROI = return on investment; ROS = return on sales.

NCA in *Leadiant (Netherlands)* took the first step in this direction.[178] In that case, the dominant undertaking was condemned for the prices it charged after it acquired an orphan exclusivity. Yet the medicinal product concerned was not new; rather, it had long been on the market.[179] This meant that the NCA's costs analysis in the Limb 1 excessiveness assessment did not have to wade into the difficult waters associated with assessing costs for products based on novel active pharmaceutical ingredients (APIs). However, this is exactly the type of question that will face the Italian and Belgian NCAs if they take up the excessive pricing complaints filed by civil society groups Altroconsumo and Tests-Achats about Spinraza (nursinersen).[180]

Spinraza is an orphan drug that was the first to be used to treat the underlying cause of the rare genetic condition spinal muscular atrophy (SMA). SMA is estimated to affect 21,000–25,000 people in Europe.[181] Biogen claims that around 11,000 patients have received Spinraza worldwide.[182] Yet Spinraza's pricing is largely a "black box" because of confidentiality clauses in pricing agreements with health authorities or insurers.[183] Following their own investigations, the civil society groups estimate that the drug has a price of €210,000–280,000 per year per patient in Italy and of €529,800 per patient in the first year and €264,900 per year per patient thereafter in Belgium. The worldwide annual revenue for the product was around US$2 billion through 2018–2021.[184] If 11,000 patients receive the medicine in one year, this puts the average worldwide price per patient per year at US$181,818. MA holder Biogen says it bases its pricing on "clinical benefit" and the "prices of other orphan drugs".[185] However, the civil society groups object that Biogen invested US$648 million in the development of the medicine.[186] If this is correct, then (based on the aforementioned average worldwide price per patient per year) Biogen would have recouped its direct R&D costs after treating 3,564 patients in one year.

The competition authorities have yet to make any public statements on whether they will investigate. They may be waiting to observe how Spinraza's pricing is affected by the entry of two other originator SMA medicines, Zolgensma (a one-time treatment priced at over US$1 million) and Evrysdi (requiring daily administration but expected to be cheaper than Spinraza).[187] If the NCAs decide to investigate, they will have to answer difficult questions, entering new territory in both the Limb 1 and Limb 2 analyses.

[178] *Leadiant (Netherlands)*, supra, note 6.

[179] ibid [2].

[180] M Metta, "Spinraza, Il Farmaco per La Cura Della SMA Dal Prezzo Esorbitante. La Nostra Denuncia" (24 July 2019) <https://www.altroconsumo.it/salute/farmaci/news/spinraza> (last accessed 17 December 2021); Test-Achats, "Plainte contre Biogen pour le prix excessif du Spinraza" (2019) <https://www.test-achats.be/sante/soins-de-sante/couts-de-la-sante-et-assurances/news/prix-excessif-spinraza> (last accessed 23 February 2022).

[181] EMA, "Briefing Document to the Clinical Trial Readiness in Spinal Muscular Atrophy (SMA) SMA Europe" 59, 3.

[182] Biogen, "Biogen Announces First Patient Treated in RESPOND Study Evaluating Benefit of SPINRAZA® (Nusinersen) in Patients Treated With Zolgensma® (Onasemnogene Abeparvovec)" (8 January 2021) <https://investors.biogen.com/news-releases/news-release-details/biogen-announces-first-patient-treated-respond-study-evaluating> (last accessed 26 October 2022).

[183] S Simoens and I Huys, "Market Access of Spinraza (Nusinersen) for Spinal Muscular Atrophy: Intellectual Property Rights, Pricing, Value and Coverage Considerations" (2017) 24 Gene Therapy 539, 541.

[184] US$1.7 billion in 2018 and US$2.1 billion in 2019 and 2020 (Biogen, "Annual Report 2020" (2020) 56 <https://investors.biogen.com/static-files/0b109c48-3d3c-4554-8249-74b06c09797e> (last accessed 1 March 2022)) and US $1.9 billion in 2021 (Biogen, "Q4 and Full Year 2021" (3 February 2022) 28 <https://investors.biogen.com/static-files/019bc8a4-527e-4565-a58b-91ef680630c1> (last accessed 1 March 2022)).

[185] Simoens and Huys, supra, note 183, 541.

[186] Altroconsumo, supra, note 177.

[187] A Liu, "Roche's Low-Price Evrysdi Will Take 'Meaningful' SMA Share from Biogen's Spinraza: Analyst" (*FiercePharma*, 11 August 2020) <https://www.fiercepharma.com/marketing/roche-s-low-price-evrysdi-will-take-meaningful-sma-share-from-biogen-s-spinraza-analyst> (last accessed 28 February 2022).

Firstly, they will have to judge how to calculate the costs actually incurred by Biogen in the production and development of Spinraza. This will entail the consideration of issues such as public funding and the royalties and fees paid by Biogen to Ionis for licensing the drug for clinical development and exploitation.

Secondly, they will have to determine a reasonable measure of profitability, which is a more difficult issue when it comes to patent-protected medicines. Indeed, for these medicines, prices may reflect controversial and difficult-to-quantify factors, such as R&D investment and risk. This does not appear to constitute an insurmountable challenge. In fact, the measure used by the Commission to calculate the 23% benchmark for the measure of profitability in *Aspen (EU)* can arguably be extrapolated to patent-protected medicines based on novel APIs. This would involve the NCAs using objective criteria for defining the sample of comparable undertakings. This sample may include, for example, originator patent-protected drugs in similar ATC-2 categories or with other similar features. It would also entail ensuring that the relevant comparators are subject to sufficiently effective competition. Moreover, as other authorities have done with respect to calculating costs, the NCAs in the *Spinraza* cases could use several measures to calculate the "plus" factor for innovative medicines, generating further confidence that a decision would not be a false positive.

Thirdly, the authorities in *Spinraza* will have to decide whether to assess just one of the types of "unfairness" or both, and how to do so. In that respect, medicines for which there is no intra-API competition lend themselves to an "unfairness in itself" analysis to a greater degree than to an "unfairness compared to competing products" analysis, as seen in the *Aspen* cases.

Should the NCAs investigate the excessive pricing allegations against Spinraza, they will enter new territory by virtue of the case's relation to a patent-protected medicine based on a novel API. This new territory is constituted by the need to determine whether and how to account for different factors in calculating the costs incurred and the reasonable measure of profitability, as well as assessing unfairness. But difficult does not mean impossible. It is arguably only a matter of time before an excessive pricing investigation into such a patent-protected drug is brought under EU competition law.[188]

V. Conclusion

The pharmaceutical excessive pricing case law demonstrates how an excessive price can be established in the sense of Article 102(a) TFEU, one of several options in the "'toolbox' of price-reducing measures".[189] While it is sometimes claimed that ex-post intervention may risk having chilling effects or lead to false positives,[190] no evidence so far suggests that the enforcement of this provision has restricted pharmaceutical innovation. Such risks may be more minimal than anticipated. Compared to the very real risk that Member States will be unable to afford important and life-saving medicines, the scales appear weighted in one direction. Firstly, intervention in long off-patent generic markets does not present a risk of harming innovation incentives, since such drugs do not involve innovation. Moreover, the lack of intervention to date in pricing practices related to novel medicinal products suggests that competition authorities take a cautious approach and tend to be quite sensitive to the ex-ante

[188] Eg as argued by Fonteijn et al, supra, note 177, 14, who state that "excessive pricing cases addressing patented products are bound to follow".

[189] A den Exter, "Fighting Excessive Pharmaceutical Prices: Evaluating the Options" (2020) 30 European Journal of Public Health 80.

[190] See sources in note 12, supra.

choice of the legislator to shield such products from imitation-based competition in order to stimulate innovation. While "[a]n innovation context requires additional analysis and adds further complexity",[191] it is also true that "applying excessive pricing in an innovation context is feasible and does not need to harm investment incentives".[192]

To summarise, the ECJ has established an identifiable definition and method of establishing an excessive price in the sense of Article 102 TFEU (Section II). Competition authorities in pharmaceutical cases have resorted to numerous concepts to calculate measures relevant to Limb 1, such as costs incurred and reasonable profitability, and to identify meaningful comparators under Limb 2 (Section III). The selection of measures depends on the availability of evidence and on the context of the case at hand. This does not, however, prevent this rich body of decisional practice and case law in the pharmaceutical sector from yielding insights for future cases and studies. The existing analytical framework could also be deployed to assess whether a patent-protected drug based on a novel API is excessively priced (Section IV). These findings are particularly relevant for the complaints related to Spinraza in Belgium and Italy.

Assessing these issues is far from easy. Fortunately, competition authorities are far better equipped than health authorities to do so. Indeed, competition authorities have wide-ranging legal competences to demand the production of financial and accounting data by the undertakings subject to their investigation,[193] minimising the aforementioned risks of false positives. Moreover, innovation considerations can be considered in the objective justification stage of the analysis.[194] Of course, competition authorities and courts "must, at a minimum, recognise and balance the potential for both Type I errors (false positives) and Type II errors (false negatives) when considering intervention".[195] But there is nothing to suggest that competition authorities have failed to recognise this, perhaps owing to the continual reminders to this effect in the literature.

It remains to be seen whether any *private* enforcement of Article 102(a) TFEU will occur, given the complexities associated with proving an excessive price, but it is imaginable that a large payer such as a national health authority or private insurer may pursue such a case. Private parties can minimise their risks of bringing unwinnable claims by studying the case law presented here. It is worth noting that, from a competition *policy* perspective, competition authorities tend to prioritise the most egregious forms of harm. Hence, cases to date involve price increases of several hundred or thousand per cent. This does not preclude the possibility of courts finding infringements of Article 102 TFEU for lower price increases, which may be especially relevant to private enforcement.

Ultimately, caution remains warranted with respect to theories of harm that can impact innovation incentives if incorrectly applied. Yet it is apparent from the findings presented here that proper legal-analytical tools can be identified to determine whether or not a high

[191] I Akker and W Sauter, "Excessive Pricing of Pharmaceuticals in EU Law: Balancing Competition, Innovation and Regulation" in P Parcu, G Monti and M Botta (eds), *The Interaction of Competition Law and Sector Regulation* (2022) 17 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3991903> (last accessed 2 February 2022).

[192] ibid.

[193] Eg under Regulation 1/2003 on the implementation of the rules on competition laid down in Arts 81 and 82 of the Treaty [2003] OJ L1/1, "the Commission may request the undertakings or associations of undertakings concerned to supply the information necessary for giving effect to Articles [101] and [102] of the Treaty and may carry out any inspections necessary for that purpose" (Art 17(1)). They may also "require undertakings and associations of undertakings to provide all necessary information" (Art 18(1)).

[194] Botta, supra, note 36, 183.

[195] Calcagno et al, supra, note 12, 171.

medicine price is harmful in the sense prohibited by Article 102 TFEU. Competition authorities should not be deterred from conducting at least preliminary investigations where they suspect harm to the objectives of EU competition law. Moreover, private plaintiffs should be encouraged by the possibility to study the rich body of case law discussed herein and ultimately bring their own claims.

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