Excessive Pricing Theories in Pharmaceuticals: Making Headlines Around the Globe, and Sparking Cases in Europe

Mateo Domecq, Associate

Hogan Lovells
Brussels

I. Introduction

Drug pricing has been back in the headlines in a major way over the past year. In many ways, the drugs that have been the focus of these headlines have little in common. In some cases, the focus has been on the cost of new, breakthrough patent-protected medicines such as drugs for the treatment of Hepatitis C that are more effective and easier for patients to take; at other times the focus has been on increases in the price of mature drugs post-patent expiry, such as was the case with Martin Shkreli and Turing's Daraprim. Among the many policy discussions sparked by these headlines, is what, if any, role the antitrust laws might have to play in addressing situations like these.

In the U.S., Congress has held hearings, launched investigations and called for the Federal Trade Commission (FTC) to do the same, presidential candidates have proposed new regulatory tools,[1] and the FTC and state attorneys general have launched antitrust investigations.[2] Despite this considerable level of activity, there is broad consensus that high prices alone do not violate the antitrust laws. Indeed, the FTC has expressly stated that it "has no authority to regulate the price of any product."[3] Instead, the focus to date has been on whether these high prices and/or price increases have been achieved through "unfair methods of competition, such as illegal anticompetitive agreements among competitors to increase prices or restrict supply, and illegal exclusionary or predatory practices."[4]

This consensus is not surprising given the long line of case law establishing it as a central

[1] Factsheet, Hillary's Plan to Respond to Unjustified Price Hikes for Long-Available Drugs, https://www.hillaryclinton.com/briefing/factsheets/2016/09/02/hillarys-plan-to-respond-to-unjustified-price-hikes-for-long-available-drugs/.

[2] The FTC Is Probing Martin Shkreli's Former Company Over Its Drug Prices, Reuters (Jan. 22, 2016), http://fortune.com/2016/01/22/martin-shkreli-ftc-drug-prices/; Christie Smythe and Caroline Chen, Turing Drug Distribution Probed by N.Y. After Price Hike, Bloomberg (Oct. 13, 2015), https://www.bloomberg.com/news/articles/2015-10-13/turing-questioned-by-new-york-ag-over-drug-distribution-network.

[3] Alan Friedman, From the antitrust mailbag: What can the FTC do about prescription drug price spikes?, Federal Trade Commission (May 18, 2016), https://www.ftc.gov/news-events/blogs/competition-matters/2015/05/antitrust-mailbag-what-can-ftc-do-about-prescription.

[4] *Id.*

tenet of U.S. antitrust law. "A natural monopolist that acquired and maintained its monopoly without excluding competitors by improper means is not guilty of 'monopolizing' in violation of the Sherman Act…and can therefore charge any price that it wants,…for the antitrust laws are not a price-control statute…"[5] As Judge Learned Hand famously explained, "[t]he successful competitor, having been urged to compete, must not be turned upon when he wins."[6] Moreover, the U.S. antitrust agencies have generally been skeptical of their ability to determine what may constitute an excessive price, even if the law permitted them to intervene in such cases.

In contrast, the landscape in Europe has proven to be quite different. Excessive pricing cases have been brought and the courts have accepted the general notion of excessive pricing as an antitrust theory of harm. That said, European antitrust enforcers have historically demonstrated little appetite for opening investigations and bringing decisions solely on the basis of excessive pricing concerns. However, these theories have re-emerged as the subject of renewed attention and consideration as certain regulators have recently demonstrated an interest and willingness to pursue investigations and pursue decisions on the basis of these theories. Indeed, the European Commissioner for Competition, Margrethe Vestager, recently acknowledged that although care should be taken when dealing with excessive pricing cases, *"there can still be times when we need to intervene."*[7] In this regard, the Italian Competition Authority's (ICA) recent decision to impose a fine on Aspen Pharmacare (Aspen) in excess of EUR 5 million (approx. USD 5.7 million), and more significantly the U.K. Competition Market's Authority (CMA) decision to fine two drug companies a total of GBP 89.4 million (approx. USD 107 million) are examples of cases where, at least, national competition authorities seem prepared to intervene.

Section I of this article provides an overview of excessive pricing theories in Europe and a summary of key cases. Section II provides a deep dive into a recent decision by the Italian Competition Agency finding that Aspen Pharmaceuticals engaged in excessive pricing. Section III analyses the ICA's ruling in *Aspen* and its implications going forward. Section IV closes with some thoughts on the prospects for the application of excessive pricing theories by competition agencies around the world going forward.

II. An Overview of Excessive Pricing Theories in Europe

Article 102 of the Treaty on the Functioning of the European Union (the Treaty), which is the European analog to Section 2 of the Sherman Act, generally prohibits dominant firms from abusing that position in a way that damages competition. Article 102 enumerates a list of examples of commercial practices that are considered abusive, one of which is *"directly or indirectly imposing unfair purchase or selling*

[5] *See e.g., Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995).

[6] *U.S. v. Aluminum Co. of America*, 148 F.2d 416, 430 (2d Cir. 1945).

[7] Speech by European Union Commissioner for Competition, Margrethe Vestager, on 21 November 2016, *"Protecting consumers from exploitation"*, Chillin' Competition Conference (Brussels). See: https://ec.europa.eu/commission/2014-2019/vestager/announcements/protecting-consumers-exploitation_en

prices or other unfair trading conditions."[8] This is the provision of the European competition laws that European competition regulators and the courts have focused on in considering the issue of excessive pricing.

Despite the inclusion of this provision in the Treaty, the abuse of excessive pricing has been considered in only a handful of cases. This section provides an overview of the case law developed by the Court of Justice of the European Union (CJEU), the European Commission's (the Commission) last excessive pricing decision, and the only other excessive pricing case previously brought by a national competition authority in the pharmaceutical industry.

A. CJEU and the concept of "Economic Value"

There have been only three cases where the CJEU has reviewed a Commission decision on excessive pricing—*General Motors*, *United Brands*, and *British Leyland*.

The Court first addressed the issue of excessive pricing in the mid 1970's when it annulled a Commission decision finding that *General Motors*[9] had abused its dominant position by charging an "excessive" fee for inspections of vehicles imported into Belgium. Although the Court overturned the Commission's conclusion that this constituted excessive pricing, it did accept the notion that the imposition of a price that is "excessive in relation to the economic value of the service, and which has the effect of curbing parallel imports" could amount to an abuse.[10]

A few years later, in *United Brands* the Court again overturned a Commission decision finding excessive pricing, and again offered further guidance on what may constitute an excessive price.[11] Specifically, the Court linked the concept of "economic value" with production costs and articulated a two-step analysis for determining when prices are excessive, and therefore abusive. First, the excess can be "determined objectively" by comparing the price of the product and its cost of production. If the differential is excessive, the second prong of the test requires a determination as to whether the prices charged are either unfair in themselves or when compared with competing products. The Court also left open the door to "other ways" of determining whether a price is unfair, but did not explain what that might include.

The first judgment upholding an excessive pricing finding came in 1986 when the CJEU confirmed that British Leyland had abused its dominant position by charging prices six times higher for inspections of left-hand drive cars than for right hand cars, despite the fact that the costs associated with each were approximately the same.[12] The Court concluded that the fees charged were disproportionate to the economic value of the service and that the fees were set this way solely to discourage the re-importation of left-hand drive vehicles.[13] It should be noted that in this case excessive pricing was not the only abuse British Leyland was found to have committed; indeed, British Leyland was also

[8] Article 102 (a) TFEU.

[9] Judgment of 13 November 1975, *General Motors v. Commission*, C-26/75, EU:C:1975:150.

[10] *Id*. at ¶ 12.

[11] Judgment of 14 February 1978, *United Brands v. Commission*, C-27/76, EU:C:1978:22.

[12] Judgment of 11 November 1986, *British Leyland v Commission*, C-226/84, EU:C:1986:421.

[13] *Id*. at ¶ 29.

found to have engaged in a range of exclusionary conduct.[14]

To put the significance of *British Leyland* in perspective, two points are worth bearing in mind. First, this was a case concerning an undertaking that enjoyed an administrative monopoly (i.e. the monopoly for the issuance of certificated of monopoly). In other words, this was not a case concerning a firm that had beat the competition and secured its market position through commercial prowess. Second, as pointed out above, British Leyland was also found to have committed other abuses which, combined with the excessive pricing abuse, were all aimed at limiting the re-importation of vehicles and were thus contrary the "single market" imperative[15] of the EU, which aims to integrate national markets.[16]

B. Excessive Profits, Value to the Purchaser, and Beyond: Other cases from around the EU

There have also been a number of other excessive pricing cases from around the EU, reflecting a range of analytical approaches. For the purposes of this article, the focus will be limited to two key decisions: the European Commission's decisions in *Helsingborg Port* and the UK's *Napp* decision.

- *Helsingborg Port* (European Commission, 2004).

In *Helsingborg Port*, the Commission adopted a pair of decisions[17] rejecting excessive pricing complaints brought against Helsingborgs Hamm AB (HHAB), a company responsible for management of the port of Helsingborg in Sweden. Among other things, HHAB was accused of charging excessive port fees for services provided to ferry operators.

In its analysis, the Commission followed the two-part approach articulated by the CJEU in *United Brands*. With respect to the first part of the test, after examining price-cost margins and profitability, including taking into account the sunk costs associated with the port itself, the Commission concluded that the fees charged significantly exceeded costs. As for the second part of the test, the Commission ultimately concluded that the fees charged were not unfair when compared to the prices charged by other ports for the same services.[18] The Commission also took into account non-cost factors in weighing the economic value of the port services provided, including the significant demand for the port due to the location of the port of Helsingborg which was ideally suited to the needs of ferry operators.[19]

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[15] Pinar Akman & Luke Garrod , *"When are excessive prices unfair?"*, Journal of Competition Law & Economics, 28 January 2011, 7 (2), p.424.

[16] *United Brands* and *Deutsche Post* were also cases where excessive pricing abuses were alleged alongside exclusionary abuses. Case COMP/C-1/36.915, *British Post Office v Deutsche Post AG*, Commission Decision of 25 July 2001, L 331/40. In this case, the Commission found Deutsche Post AG, who had statutory monopoly in relation to cross-border mail, to have abused its dominant position by engaging in the following abuses: discrimination, refusal to supply, excessive pricing and limitation of the provision of a certain service.

[17] Case COMP/A.35.568/D3, *Scandlines Sverige AB v Port of Helsingborg*, Commission Decision of 23 July 2004; Case COMP/A.36.568/D3, *Sundbusserne v Port of Helsingborg*, Commission Decision of 23 July 2004.

[18] *Scandlines*, *supra* note 17 at ¶¶ 180, 185, 201, 206; *Sundbusserne*, *supra* note 17 at ¶¶ 157, 162,182.

[19] *Scandlines*, *supra* note 17 at ¶ 232; *Sundbusserne*, supra note 17 at ¶ 207.

- *NAPP Pharmaceuticals (UK Competition Commission Appeal Tribunal, 2002)*

In *Napp*, the UK Competition Commission Appeal Tribunal (CAT) upheld a decision[20] by the Director General of Fair Trading ("DGFT") fining Napp Pharmaceutical for excessive pricing and predatory pricing in relation to its sustained release morphine product, which was post-patent expiry at the time.[21] At the time, Napp had market shares in excess of 90% in both of the primary customer segments for sustained release morphine products—patients (also referred to as the "community" segment) and hospitals.[22]

The DGFT found that prices were 1400% higher in the community segment than the hospital segment and approximately 500% higher than exports sales and 30-50% higher than competitors' prices.[23] According to the DGFT, a price is excessive where: (i) it is above that which would exist in a competitive market; and (ii) where it is clear that high profits will not stimulate new entry within a reasonable period.[24]

In the context of analyzing whether Napp's prices were above those which would exist in a competitive market, the DGFT took two approaches. The first followed the price-cost approach called for under the first prong of the *United Brands* test. Specifically, the DFGT analyzed the profit margins earned in the community segment and compared them with Napp's margins for other products as well as the margins achieved in other markets. Next, the DGFT endeavoured to determine what the competitive price would be. The DGFT identified a proxy for the competitive price by looking at the prices of competitors as well the prices Napp charged elsewhere and determining whether Napp would be able to earn a reasonable profit by applying those prices.[25]

Regarding the second prong of the test, the DGFT observed that Napp's high market share was reinforced by the existence of high barriers to entry resulting from regulatory barriers, Napp's first mover advantage,[26] the high sunk promotional costs required to enter the market, and strategic barriers arising from Napp's predatory conduct in the hospital segment.[27]

C. Remarks on the case law and decisional practice

As is apparent from the above cases, there are very few Commission precedents on excessive pricing and of those ultimately reviewed by the CJEU, only one was ultimately upheld. This track record would seem to suggest that, at least until recently, there has been little appetite at the Commission to focus on excessive pricing cases. This lack of appetite may simply reflect the fact that these cases have

[20] Decision of the Director General of Fair Trading (DGFT) No CA98/2/2001, *Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp)*, 30 March 2001.

[21] *Napp Pharmaceuticals Holdings Limited and Subsidiaries v Director General of Fair Trading [2002]* Comp AR 13.

[22] *DGFT, Napp Decision, supra* note 20 *at* ¶ 100.

[23] *Id*. at ¶¶ 207-234.

[24] *Id*. at ¶ 203.

[25] *Id*. at ¶¶ 204-205.

[26] The DGFT observed that Napp's first mover advantage was accentuated by the following features of demand in the community segment: (i) community practitioners are strongly influenced by the reputation of a product; (ii) reluctance on the part of general practitioners to experiment with new products they have not directly experienced; and (iii) lack of price sensitivity among general practitioners.

[27] *DGFT Napp Decision*, *supra* note 20 at ¶ 138.

not resulted in the development of a clear analytical framework to determine what actually constitutes an excessive price.

Taking the first prong of the *United Brands* test involving the price-cost comparison, neither the CJEU nor the Commission has offered clear guidance as which costs can or should be attributed to a given product or service. In many ways, this is not surprising given the Court itself acknowledged that such an exercise would involve "considerable" and "very great" challenges. The difficulties inherent in making these sorts of determinations were made apparent in *Helsingborg Port*, where the sunk costs associated with the port were a significant factor. Indeed, the Commission acknowledged that there were "uncertainties" involved in determining the appropriate cost basis in that case because many components comprising the precise economic value of the services provided by HHAB were "intangible".[28] Where this is the case, such an exercise requires not only identifying appropriate non-cost factors, but also attributing what would in many cases be arbitrary values to those factors. Similarly, in *Napp*, the CAT acknowledged that measuring whether a price is above the level that would exist in a competitive market is "*rarely an easy task*."[29]

Even assuming that these difficulties could be addressed, the price-cost prong of the *United Brands* test also requires the determination of what constitutes a reasonable profit margin. While there may be a temptation to refer to the average profit margins of competing firms as benchmarks, such an approach raises its own issues. For example, such an approach could have an undesirable effect on incentives as it could penalize firms that enjoy a higher profit margin than peers as a result of superior products and/or business acumen.

The second prong of the *United Brands* test—the unfairness prong—also presents its own difficulties. The Court has to date accepted a range of metrics for assessing unfairness, including comparing the prices charged by the dominant firm to different customers[30]; comparing prices charged by the dominant firm with prices charged by its competitors[31]; comparing the prices charged by the dominant firm in different customer segments where some customer segments are more competitive than others[32]; comparing prices charged by the dominant firm in different countries[33]; and looking at the evolution of prices over time.[34] As is apparent from *United Brands*, comparisons with prices charged in other geographical areas can problematic—particularly with respect to certain types of products such as pharmaceuticals where prices can vary significantly between national markets for reasons unrelated to competitive conditions.

III. A new dawn for excessive pricing theories in Europe? The *Aspen* decision

On September 29, 2016, the Italian Competition Authority ("ICA") found that Aspen Pharma Trading Ltd, Aspen Italia s.r.l. and Aspen Pharmacare Holdings Ltd (collectively "Aspen") had breached Article 102 TFEU by imposing excessive prices in relation

[28] *Scandlines*, *supra* note 17 *at* ¶ 209; Sundbusserne, *supra* note 17 at ¶ 185.

[29] *CAT Napp Decision*, *supra* note 21 at ¶ 392.

[30] *See British Leyland.*

[31] *See United Brands and General Motors.*

[32] Judgment of 4 May 1988, *Corinne Bodson v. Pompes Funebres*, C-30/87, EU:C:1988:225.

[33] *See United Brands.*

[34] *See British Leyland.*

to five cancer drug products (the "Cosmos drugs") it had acquired from GlaxoSmithKline (GSK) in 2009: Leukeran (tablet), Alkeran (tablet and injectable), Plurinethol (tablet), and Thioguanine (tablet).[35]

A. Background

In its decision, the ICA concluded that Aspen was able to secure price increases of 300-1500% by employing an "*aggressive*" negotiation strategy with the Italian Drug Agency ("AIFA") in 2013.[36] Specifically, the ICA found that Aspen had achieved these prices by exerting leverage through three primary means, each of which is described below.

- **Delisting requests.** On 13 April 2013, Aspen made a request to have the Cosmos drugs delisted as and re-listed as C-class drugs.[37] This would render the Cosmos drugs not subject to reimbursement and would mean that their price would be determined freely. Absent this change, for prescription drugs such as the Cosmos drugs, prices can only be increased every two years but the increase may not exceed the expected inflation. AIFA informed Aspen that the de-listing request was not admissible given the "*indispensable*" nature of the Cosmos drugs.[38]
- **Threats to discontinue marketing.** Following AIFA's refusal of Aspen's request for a price increase, Aspen sent another letter to AIFA informing it of the need to obtain a significant price increase to align the Italian prices with prices offered in other EU countries. The letter set a deadline in which AIFA had to decide between accepting the proposed price increase or accepting the de-listing request. Failure to accept one of these two options would result in Aspen suspending the direct sale of the products in question in Italy, though Italian patients would still be able to purchase the drugs in other EU countries.[39]
- **Stock shortages and the Aspen "Allocation Program".** Aspen operated an allocation programme for cancer drugs for the different geographical markets in which it is active in which Aspen would develop demand forecasts on the basis of local demand data. According to Aspen, the aim of this program was to ensure a stable and continuous supply of these products to meet the local demand of each country. According to the ICA, this allocation program enabled Aspen to contain parallel trade by limiting the amount of product that could be resold into other EU countries at higher prices for the relevant drugs than prevailed in Italy.[40] The ICA also found evidence that (1) the allocation program

[35] Case A480, *Incremento Prezzo Farmaci Aspen*, Decision of the Autorità Garante della Concorrenza e del Mercato (the Italian Competition Authority) dated 29 September 2016.

[36] *Id.* at ¶ 308.

[37] In Italy, a distinction is made between drugs depending on the type reimbursement regime they are subject to. A-class drugs are drugs that are deemed essential and that are used to treat chronic illnesses. They are entirely reimbursed by the national health system and are distributed via pharmacies and public health structures. H-class drugs are used in hospitals, they paid for by the national health system, and are distributed through hospitals and public health structures. C-class drugs are not subject to reimbursement. The price-setting for drugs in Italy will vary depending on the classification of the drug.

[38] However, Aspen was told that it was entitled to submit a proposal for a price increase. *Id.* at ¶¶ 91-95.

[39] *Id.* at ¶¶ 96-98.

[40] *Id.* at ¶¶ 112-114.

resulted in product shortages coinciding with the month preceding AIFA's acceptance of the price increases, and (2) post-price increase shipment quotas might be increased and Aspen considered removing Italy from the allocation program because the Italian prices had been aligned with the prices charged in other Member States.[41]

From the view of AIFA, the prices proposed were not sustainable for the national health system. AIFA requested that Aspen provide data regarding the entry into force of the new prices in each EU country so that it could calculate the new price increases in Italy based on an average of the effective new prices in the EU.[42]

On 16 January 2014, Aspen essentially re-submitted the same price offer without providing all the data that had been requested by AIFA. This omission was noted during a meeting held between the parties on 29 January 2014, but two days later the proposed prices were accepted.[43]

According to the ICA, Aspen was able to exert this leverage for a range of reasons. First, demand for the Cosmos products was rigid because they were life-saving and had specific characteristics (e.g., pill form) that made them better suited for the treatment of children and the elderly during home treatment periods.[44] Second, at the time of negotiations, Aspen was the only company in Italy with a marketing authorization for the drugs and there were no pending requests for marketing authorisations for generic versions of any of the drugs in question, despite the fact that the Cosmos drugs were no longer covered by patents.[45] Due to the time required to secure a marketing authorization entry was unlikely in the near term. Further undermining the likelihood of entry was the fact that, following the price increase, total annual sales for the Cosmos drugs were only EUR 5-10 million due to the limited size of the patient population and the fact that the drugs were predominantly used in one specific phase of cancer treatment.[46]

B. The ICA's application of United Brands

In assessing whether the prices agreed with AIFA were excessive, the ICA followed two-part *United Brands* test. In doing so, the ICA took into account both economic and "contextual" considerations.

1. *The economic analysis*

In determining whether the prices were excessive vis-à-vis the costs incurred, the ICA used two methodologies.

The *first methodology* involved analyzing the gross margins of each drug. Prior to the price increase, the ICA observed that the gross margins for the products varied between 20-80%; and the costs of goods sold varied between 30-80%. [47]The ICA compared these gross margins with Aspen's group financial statement ending in June 2014 and concluded that the profitability of Aspen's products in Italy was largely in line with profitability of the entire group[48]. Thus, according to the ICA, even prior

[41] *Id.* at ¶¶ 115-122.

[42] *Id.* at ¶¶ 99-106.

[43] *Id.* at ¶¶ 107-109.

[44] *Id.* at ¶¶ 300-302.

[45] *Id.* at ¶¶ 294-296.

[46] *Id.* at ¶ 297.

[47] *Id.* at ¶ 146.

[48] *Id.* at ¶ 145.

to the price increase, the price of the Cosmos drugs already exceeded the economic value of the goods, which the ICA defined as the sum of the direct or indirect costs incurred. Therefore, following the price increase, these prices would significantly exceed the costs of the products.[49]

The *second methodology* involved comparing the prices of the products with the sum of direct and indirect costs of the Cosmos drugs and a rate of return.[50] The ICA fixed the indirect costs of the Cosmos products on the basis of the consolidated annual reports of the ultimate parent company, APHL, and took a proportion of those costs into account.[51]

With respect to the rate of return, the ICA analyzed a metric it referred to as the Return on Sales ("ROS"). The ICA concluded that this was the appropriate metric for several reasons, including the fact that Aspen made limited investments in R&D, especially as regards the Cosmos drugs, and manufacturing and distribution of the Cosmos drugs was handled by third parties. Aspen's marketing activities in Italy in relation to these drugs were limited to ordering and storage activities, which did not require significant investments.[52]

In terms of the level of the ROS, the ICA concluded that 13% would be an appropriate benchmark as it corresponds to the average rate of return for the years 2013-2014 of the two largest pharmaceutical companies worldwide active in the manufacturing of generic drugs.[53] The ICA did not provide any explanation as to why their average profitability constituted an appropriate benchmark or how Aspen was comparable to them. Furthermore, the ICA used an average of all the products sold by these companies as a benchmark against which to compare data from Aspen for five individual products.

To assess whether the excessive nature of the price increase under this methodology was unfair, the ICA compared the profitability of the Cosmos drugs before and after the price increase. The ICA's calculations revealed that prior to the price increase, the excess of Purinethol and Alkeran products was of 70-80% or 20-30% respectively (even when an ROS of 13% was included in the calculation). For Leukeran and Thioguanine, on the other hand, the calculations showed negative figures (a decrease of 10-20% for Leukeran and 0-5% for Thioguanine).[54] Following the price increase, the prices of the products exceeded the costs (including a rate of return) by 100-400%[55, 56].

On the basis of these calculations, the ICA concluded that there was a significant excess between the costs incurred and the new prices negotiated by Aspen. The ICA noted that this

[49] *Id.* at ¶¶ 154-155.

[50] *Id.* at ¶ 156.

[51] These indirect costs were attributed according to the ratio of the cost of goods sold of each product for the Italian market and the total costs of the good sold registered in the annual report of the parent company. This was done because Aspen operated a buy and sell model in Italy whereas it operated a consignment model in other European countries. Therefore, the figures in the annual reports of the European subsidiaries only concern figures derived from direct commercialisation of the Cosmos products in the consignment model countries.

[52] *Id.* at ¶¶ 171-173.

[53] *Id.* at ¶ 174.

[54] In other words, the price for these products was below the sum of direct and indirect costs plus the rate of return.

[55] *Id.* at ¶ 184.

[56] Interestingly, the ICA did not stop there, but rather carried out an alternative calculation, which consisted in including the costs corresponding to the acquisition of the Cosmos trademarks for the Italian market as a direct cost. The excess in percentage figures under this calculation varied between 100-150% and 300-350%.

disproportion far exceeded the 25% excess that was deemed abusive by the European Commission in the *Deutsche Post AG* case.[57] The ICA noted that even under a more "conservative" alternative approach proposed by Aspen, the excess would still be significant—ranging between 100-300%.[58]

2. Contextual Factors

The ICA also found that contextual and behavioural factors confirmed the excessive nature of the prices. Each of the factors considered by the ICA is discussed below.

- **Price evolution over time.** The ICA found that the prices for the Cosmos products had not been altered since they were first introduced into the market. The ICA concluded that this was meaningful because the prices set by the regulator when the products were first commercialised would have factored in the need to compensate the investments incurred by GSK in research & development. Moreover, the ICA was not able to compare the prices at issue in Italy with those in other member states as the CJEU had done in *United Brands* because such a comparison would be skewed given differences between the healthcare systems and pharmaceutical regulations of the different Member States.[59]
- **Absence of economic justifications.** The ICA noted that the only reasoning provided by Aspen for the price increase was the need to align Italian prices with the prices charged in other European countries and thus concluded that no economic justifications had been offered to support the need for the price increase. The ICA observed that the AIFA guidelines require companies, when renegotiating prices, to keep records of the increases to their productions costs. Although the ICA acknowledged that Aspen had made general references to costs in its correspondence with AIFA, no analysis or data supporting these statements was found in the documents seized by the ICA or provided by Aspen. Nonetheless, the ICA highlighted that it had taken a conservative approach when calculating the excessive nature of the prices by assuming that the costs borne by Aspen in Italy had increased by 25%.[60]
- **Lack of extra-economic benefit.** The ICA concluded that the price increases did not correspond to improvements made to the products or associated services. On this basis, the ICA found that there was no extra-economic benefit for the patient or the national health system which added economic value to the products such as would justify the significant price increase.[61]
- **Rigid demand and absence of alternatives.** The ICA noted that these products are used for the treatment of cancer patients who are particularly fragile and for whom there are no suitable alternative treatments for specific stages of their illness. This lack of substitutes, combined with the preference of doctors and patients for therapeutic continuity, resulted in demand for these products that was highly rigid.[62]
- **The price increases were not necessary to preserve incentives for innovation.** The ICA highlighted the fact that Aspen is

[57] *Id.* at ¶ 317.

[58] *Id.* at ¶ 326.

[59] *Id.* at ¶¶ 330-332.

[60] *Id.* at ¶¶ 337-341.

[61] *Id.* at ¶¶ 344-345.

[62] *Id.* at ¶ 347.

company primarily active in the field of generics and as such its investments into R&D were limited. Consequently, in the view of the ICA, this excludes the possibility that the prices charges were necessary to cover investments into R&D.[63]

- **Harm to the national health system.** As a result of the increase, the national health system had fewer resources available for other public health objectives.[64]

The ICA fined Aspen just over EUR 5 million on the basis of its findings of excessive pricing. In addition, the ICA required Aspen to make its best efforts to define fair prices for these drugs and to abstain from engaging in similar abusive conduct in the future. Aspen was requested to report to ICA within 60 days regarding the initiatives taken by Aspen to comply with the decision.

C. Where are we in the wake of *Aspen*?

At the outset, it is important to note that Aspen has already announced its intention to appeal the decision. In that sense, the issue is not necessarily fully settled. Pending further developments in the case, however, there are still some important take-aways that can be gleaned.

First and foremost, the particular significance of this case lies in the fact that unlike *British Leyland*, *United Brands*, *Deutsche Post*, *Helsingborg Port* and *Napp*, it is a pure excessive pricing case. As explained in Section II of this article, all of these other cases also involved – in addition to the excessive pricing element – allegations of exclusionary behavior. In that sense, *Aspen* could usher in a new era of excessive pricing scrutiny should other member states or the Commission take up the baton from the ICA.

That said, it may be too soon to conclude that this case represents anything more than a limited expansion of scrutiny into pharmaceutical pricing. In particular, it is notable that the drugs at issue were no longer protected by patents and that the charges targeted price increases negotiated by a company that had recently acquired the drugs. These circumstances are significantly different than, for example, a situation involving the launch price of a newly developed, patent-protected drug, which would greatly complicate the analysis and constitute a much greater and more troubling expansion of antitrust scrutiny.

Second, the ICA does not appear to have deviated in any significant way from the *United Brands* test as interpreted and applied by the Commission in *Helsingborg Port*. It is therefore perhaps not entirely surprising that some of the flaws and difficulties in determining what constitutes an excessive price likewise appear in this decision. For example, it is clear from the decision that, as the Court in *United Brands* warned, determining the costs to be taken into consideration for the economic analysis is not a straight forward task. Indeed, this is demonstrated by the fact that the ICA had to employ assumptions in order to conduct key aspects of the analysis and the discussion in decision on how to allocate indirect costs as well as the costs associated with the acquisition of trademarks. It should be noted that these difficulties were significant even though the ICA was examining a relatively simple business model by pharmaceutical standards – namely, Aspen was not engaged in significant R&D efforts which would need to be taken into account.

Another troubling aspect of the ICA's analysis is its reliance on the profit margin

[63] *Id.* at ¶ 348.

[64] *Id.* at ¶ 351.

figure in *Deutsche Post* (25%), even as a corroborating factor of the ICA's conclusion. Not only did *Deutsche Post* involve a statutory monopoly, but it was a statutory monopoly in a completely different industry with a different cost structure. For these reasons, without more, such cross-industry benchmarking is inappropriate.

In, addition, the ICA did not provide any explanation as to why the average profitability of the two largest pharmaceutical companies worldwide active in the manufacturing of generic drugs constituted an appropriate benchmark or how Aspen was comparable to them. Furthermore, the ICA used an average of all the products sold by these companies as a benchmark against which to compare data from Aspen for five individual products. This approach is notable because it appears to be inconsistent with the objective of determining whether prices bear no reasonable relation with the economic value of *an individual product*. Indeed, because 13% is an average of multiple products, there may well be products manufactured by these companies with a significantly higher ROS.

The decision also demonstrates that, despite the pains that antitrust regulators have gone through to disclaim any role as a price regulator, such a role is unavoidable when excessive pricing theories are pursued. The fact that ICA has merely made a finding of an abuse without stipulating the prices that need to be charged, does not alter that fact. Indeed, this is borne out in the remedy imposed as it requires Aspen to notify to ICA the measures it has taken to define "fair" prices for the Cosmos drugs. This necessarily means that the new prices would need to be set at a level below the prices that were deemed abusive (presumably, bearing in mind the ICA's economic analysis) and that the ICA would have to subsequently take on some form of price monitoring role.

Decisions such as these impose an incredible burden on potentially dominant firms, which are forced to engage in what is in many respects a guessing exercise to trying to determine what costs can be taken into consideration and what is reasonable profit margin to avoid incurring in excessive pricing. Even if we assume for the sake of argument that a firm is reasonably able to engage in such an exercise, it is unlikely to have access to the information necessary to engage in the benchmark comparisons conducted by the ICA as it would necessitate the sharing of potentially sensitive information about firms that may compete with one another.

Third, the ICA's emphasis on the life-saving nature of the Cosmos drugs creates potentially troubling incentives as it could discourage firms from developing drugs that are likely to be viewed as essential by patients for fear that marketing such drugs would leave them open to allegations of excessive pricing. That said, the fact that the Cosmos drugs were no longer protected by patents may have made it easier for the ICA to decide to bring the case. For example, had the Cosmos drugs still been protected by patents, the ICA would have had to engage in a complex assessment of determining appropriate level profitability in light those patents.

Fourth, the fact that the new prices were secured following a negotiation strategy that has been dubbed as being "*aggressive*" seems to have been given significant weight in the ICA's analysis. What is not entirely clear from the ICA's findings, however, is whether the threat to terminate the commercialisation of a product if an agreement on price is not reached, on its own is now considered abusive behavior for a dominant firm. While dominant companies have, a "special responsibility" under EU

competition not to distort competition, defining this responsibility in this way would significantly undermine the fundamental principle that firms generally have the right to choose to whom it sells its products.

Fifth, enjoying comparable weight in the ICA's analysis is the fact that this case concerned markets where the entry of new players seemed unlikely due to a lack of economic incentives. In this regard, the ICA's analysis resembles the second part of the test outlined by the DGFT and confirmed by CAT in *Napp*, which requires analysis regarding whether "effective competitive pressure" is expected "to bring [prices] down to competitive levels..."

In sum, in the wake of *Aspen* it would seem that the ICA's decision to intervene was primarily driven by a combination of public policy considerations, the imposition of significant price increases for a drug no longer covered by patents, the lack of any actual or potential competitive constraints, contextual factors, including evidence of an aggressive negotiation strategy on the part of Aspen.

II. What comes next?

Excessive pricing cases are unlikely to go away any time soon and pharma is likely to remain a key target. Recent remarks made by Commissioner Vestager appear to confirm that fact. After acknowledging that the Commission had to date proceeded with caution when dealing with excessive pricing cases, she stated that "there can still be times when we need to intervene" *and highlighted the Commission's* on-going investigation into Gazprom as well as the investigations into excessive pricing abuses by Member State competition authorities in the pharmaceutical industry as being examples where competition authorities need to intervene.[65]

More significantly, the UK's CMA has recently issued a decision fining two drug companies a total of GBP 89.4 million (approx. USD 107 million) for charging excessive prices. The details of the decision have not yet been made public. The CMA's focus on excessive pricing in the pharmaceutical sector is probably far from over. Indeed, the Chairman of the Case Decision Group for the CMA's investigation stated that this decision "sends out a clear message to the sector that we are determined to crack down on such behaviour and to protect customers" and the press release issued by the CMA announcing its decision states that the CMA has four other ongoing investigations into the pharmaceutical sector.

As we await the decisions in these cases, however, it is worth recalling that at least some competition authorities have acknowledged that they must proceed with caution in pursuing these cases, especially in order to avoid "taking away the rewards that encourage businesses to innovate."[66] So, although we may yet see more cases brought alleging excessive pricing theories, antitrust authorities would be better off focusing their resources on exclusionary practices as too much focus on excessive pricing could risk taking away the rewards that encourage businesses to innovate.

[65] *See* Speech by M. Vestager, *supra* note 8.

[66] *See* Speech by M. Vestager, *supra* note 8.