Antitrust Scrutiny of Excessive Prices in the Pharmaceutical Sector: a Comparative Study of the Italian and UK Experiences

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Abstract: Excessive pricing has generally been seen as a problem to be addressed through sector-specific regulation rather than through antitrust intervention. Literature on the issue is divided between scholars calling for an interventionist approach and those supporting a non-interventionist approach on the basis of conflicting rationales. However, recent cases have called attention to the imposition of excessive prices in the pharmaceutical sector. The Aspen and the Flynn cases, in particular, constitute emblematic examples of such practice in the field of off-patent drugs. The analysis of the investigations conducted by national competition authorities in these cases provides some important insights into the controversial issues of ascertaining when antitrust intervention can be considered justified and of determining which methodology may be properly adopted in order to assess whether a drug price is unfairly high.

1. Introduction

The notion of “abuse” under Article 102 TFEU comprises two categories, i.e. exclusionary abuses (meaning those practices through which the dominant undertaking seeks to harm the competitive position of its competitors or to exclude them from the market) and exploitative abuses (i.e. those conducts whereby the dominant undertaking takes advantage of its market power to exploit its customers). In particular, Article 102 TFEU (a), by prohibiting conduct which consists in “directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions”, has been interpreted as prohibiting not only prices which are unfairly low – such as predatory pricing – but also those which are unfairly high.1

As a matter of fact, the traditional distinction between exclusionary and exploitative abuses has typically confined the latter as a residual category, its application by competition agencies being particularly controversial. The reluctance of competition agencies, including the European Commission, to resort to it is based on two main points. Firstly, with regard to the long-standing debate on the application of competition law versus sector specific regulation, there is dispute over whether it is appropriate for competition agencies to act as price regulators. Secondly, determining when a price is considered as unfair is an extremely difficult task.

Recent case law in the pharmaceutical sector has called attention to this area, typically overlooked by competition policy. Competition agencies in many countries (such as in Italy, in the UK and also in the US) are currently looking at excessive pricing in this industry. This paper aims to conduct a comparative analysis of the recent case law, examining in particular the Italian and UK experience, with the purpose of analysing some key issues that arise in the application of competition law to exploitative practices in the pharmaceutical sector.

The paper is therefore structured as follows. After a brief review of the existing literature on excessive prices and practice in EU competition policy (para. 2), the paper will focus on the features of such conducts in the pharmaceutical sector, having regard to recent case law in several

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states (para. 3). It will then examine two emblematic investigations conducted by the Italian Competition Authority (ICA) and by the English Competition and Markets Authority (CMA), these being respectively, the Aspen and Flynn cases, concerning excessive pricing of off-patent drugs, i.e., outside the monopoly granted by the patent. Aspects of the tests used by these two national competition authorities (NCAs) will be analysed in detail, taking into consideration the difficulties hidden in the choice and application of the appropriate methodology (para. 4).

2. Excessive pricing under EU competition policy

The existence of both potential anti-competitive effects (high prices are the typical evil of monopolistic power) and pro-competitive effects (without barriers to entry, the “opportunity to charge monopoly prices - at least for a short period - is what attracts ‘business acumen’ in the first place”, according to Justice Scalia in Trinko) has led to the formulation of two opposing approaches on the intervention of competition agencies in this field.5

In short, on the one side, scholars supporting the abstention of antitrust intervention argue that excessive prices may be profitable for the dominant undertaking only in the short term and that sanctioning excessive pricing may negatively affect dynamic efficiency.4 Moreover, the high risk of errors derives both from the difficulty of calculating the costs sustained by the undertaking for an antitrust evaluation and from the fact that competition authorities are typically not equipped to regulate prices, as price regulation is a long-term effort which requires quasi-permanent supervision.5 This argument also goes hand-in-hand with the idea that a clear distinction should be preserved between the mandate of competition authorities, which is broad and generalist, and that of regulators, which is carved out on the specific sector concerned.6 On the other side, scholars supporting a different approach afirm that prohibiting excessive prices is one of the original objectives of EU competition law7 and claim that excessive prices are not always self-correcting.8 This would happen in markets where high and non-transitory barriers to entry exist, where a large number of scholars consider that antitrust intervention, even if exceptional, should be justified.9 However, all these arguments suggest that a high risk of both type I (or over-enforcement) and type

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4 D.S. Evans & J. Padilla, Excessive Prices: Using Economics to Define Administrable Legal Rules, 1 Journal of Competition Law and Economics 97 (2005) (supporting the idea that a per se legality approach to pricing should be adopted); contra, P. Akman & L. Garrod, When are Excessive Prices Unfair?. 7(2) Journal of Competition Law and Economics 403, 407 (2011) (claiming that such a per se legality stance would require an amendment to the Treaty and would also rule out the possibility of interventions in exceptional circumstances where adverse effects are minimal and direct harm to consumers may persist in the long run in the absence of intervention).
6 See, e.g., M. Motta & A. de Streel, Excessive Pricing in Competition Law: Never say Never?, in Konkurrensverket (Swedish Competition Authority), The Pros and Cons of High Prices, 2007 (arguing that in case of exploitative abuses antitrust authority should abstain when a sectoral regulator has jurisdiction to act, or, at the minimum, if the antitrust authority intervenes, it should prove, in addition to the excessive price, that the decision of the sectoral regulator was manifestly wrong). See also E. Paulis, Article 82 EC and Exploitative Conduct, in C.-D. Ehlermann & M. Marquis (eds.), European Competition Law Annual 2007: A Reformed Approach to Article 82 EC (Oxford, Hart Publishing, 2008), 515; B. Blumenthal, Discussant Comments on Exploitative Abuses under Article 82 EC, ibid., 575.
8 A. Ezrachi & D. Gilo, Are Excessive Prices Really Self-Correcting?. 5 Journal of Competition Law and Economics 249 (2009) (claiming that in a majority of cases and irrespective of whether entry barriers are high or low, excessive prices alone are insufficient to attract new entry, and that intervention on the basis of excessive prices may encourage rather than discourage entry as it may allow undertakings a better understanding of post-entry prices, which are the elements that potential entrants consider when deciding whether to enter).
9 Geradin, supra n. 5.
II (or under-enforcement) errors exists.\(^\text{10}\)

In general, up to now a cautious approach by antitrust agencies has prevailed. This appears obvious with regard to the US, where merely charging profit-maximizing monopoly prices is not considered an independent antitrust violation: high prices may be indicative of an underlying anticompetitive practice, such as abuse of monopoly power or price-fixing under Section 2 and Section 1 of the Sherman Act respectively, but setting high prices is not seen as a potential antitrust violation as such.\(^\text{11}\). However, it is true also in the EU, where, in practice, antitrust cases of excessive pricing are few and are prosecuted mostly at national level, for instance by the relatively young national competition authorities (NCAs) in new EU Member States.\(^\text{12}\)

In the EU, three main reasons have been identified in favour of the antitrust intervention against exploitative conduct,\(^\text{13}\) i.e.: i) the wording of Article 102(a), suggesting that the legislative intent behind it was to cover both exclusionary and exploitative abuses;\(^\text{14}\) ii) the goal of competition policy, whose aim is to protect (directly and indirectly) consumer welfare; iii) the so-called “gap” cases, deriving from the fact that Article 102 does not prohibit the acquisition of dominance (as the Sherman Act does),\(^\text{15}\) but only the abusive conduct of firms already having a dominant position,

\(^{10}\) Organisation for Economic Cooperation and Development (OECD), Excessive Prices, Roundtable, Background Paper, 2011, at 27. A number of economists have proposed screens aimed at limiting the intervention of competition authorities and the risk of type I errors. See Evans &Padilla, supra n. 4 (proposing a test with three conditions for antitrust intervention, i.e., that: i) the firm enjoys a (near) monopoly position in the market, which is not the result of past investments or innovations and is protected by very high legal barriers to entry; ii) the prices charged by the firm widely exceed its average total costs; and iii) there is a risk that those prices may prevent the emergence of new goods and services in adjacent markets); Motta & de Streel, supra n. 6 (proposing another test with three cumulative conditions, i.e., that: i) high and non-transitory barriers exist, so that it is only “super-dominant” or “quasi-monopolistic” firms which should be the object of excessive price actions; ii) the quasi-monopolistic position has been achieved through special and exclusive rights or to un-condemned past exclusionary anticompetitive practices rather than market competition; iii) no sectoral regulator has the jurisdiction to solve the matters); L.H. Röller, Exploitative Abuses, in European Competition Law Annual 2007, supra n. 6, 525 [arguing that excessive pricing cases should be limited to certain special circumstances (mainly to “gap cases”, where anticompetitive exploitation exists if and only if exclusionary abuse – or government actions – have led to a dominant position), and proposing a test with five cumulative conditions; i) significant entry barriers; ii) market is unlikely to self-correct; iii) no (structural) remedy is available; iv) no regulator or regulatory failure; v) “gap cases” or “mistake cases”]; A. Fletcher & A. Jardine, Towards an Appropriate Policy for Excessive Pricing, ibid. (suggesting a policy approach which would i) limit intervention when there is no possibility of successful new entry within a reasonable period; ii) consider carefully the pricing of other elements of the undertaking’s portfolio, the competition it faces in those other markets, and the impact on consumers’ choices; iii) exclude fines and private damages action; iv) not intervene during the patent period of an innovative product; v) consider carefully the effect of any ex post intervention on ex ante investment incentives; (vi) seek alternative structural remedies to price regulation]; Paulis, supra n. 6 (arguing that the only reasonable criterion to identify markets that could be candidates for interventions against excessive prices is the presence of very high and long lasting barriers to entry and expansion).

\(^{11}\) Against this view, see F.M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health, 6(3) UC Irvine Law Review (2017, forthcoming), at 13 and 22 (arguing that there is no reason in principle why the Sherman Act should not address excessive pricing in itself).

\(^{12}\) A. Svetlicicini & M. Botta, Article 102 TFEU as a Tool for Market Regulation: “Excessive Enforcement” against “Excessive Prices” in the New EU Member States and Candidates Countries, 8(3) European Competition Journal 473 (2012).

\(^{13}\) European Union, Article 102 and Excessive Prices, Contribution to the 2011 OECD Roundtable, supra n. 10, at 309 et seq.

\(^{14}\) In the literature also the idea that the provision was intended to apply to only exploitative abuses and not exclusionary ones has been supported. See Akman, supra n. 7 (examining the travaux préparatoires of Article 82 EC - now Article 102 TFEU). See also T. Ackermann, Excessive Pricing and the Goals of Competition Law, in D. Zimmer (ed.), The Goals of Competition Law (Edward Elgar, 2012), 349 et seq. (affirming that in the EU there are institutional reasons to believe that the prevention of undeserved monopoly profits can be a legitimate object of competition law through the application of Article 102 (a) if regulatory measures fail).

which in turn means that there may be cases where intervention against unilateral exclusionary conduct is legally not possible without the intervention against exploitative conduct (e.g., in the cases of excessive royalties charged by a company which has obtained its dominant position as a result of not disclosing its patent when it was involved in discussions on setting a standard for the industry).  

However, in practice, the European Commission seems to have adhered to a prudent approach, as it has acknowledged that intervening directly against unfairly high prices may be costly or difficult, and it has generally focused on exclusionary abuses, the only ones to which the 2009 Guidance Paper applies. No surprise, then, that the existing jurisprudence on the matter is not very well developed. The European Court of Justice (CJEU) acknowledged that excessive prices and charging a price which has no relation to the product’s economic value can constitute an abuse of dominant position firstly, in a very general way, in General Motors, then, in United Brands. In United Brands the Court elaborated a two-prong test, which - even if not exclusive - remains the main point of reference for these cases. According to this test, first the excess must be determined by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin. Nonetheless, the Court also referred to other ways devised by economists for identifying unfair prices. Then, it must be determined whether the excessive price is unfair. However the Court did not provide further guidance on how to determine whether a price-cost difference is excessive nor when unfairness occurs. The Commission has clarified that in the first part of the test an assessment of the true underlying costs incurred by the dominant undertaking is required, giving consideration not only to the cost of capital but also to the investment risks involved in the industry concerned. As for the second part of the test, it is therefore necessary to ascertain whether a high profit margin originates from the exercise of market power due to a lack of effective competition or from superior efficiency in terms of costs or innovation: if the high profit margin results from the dominant company being very efficient, it cannot be said that the prices are unfair in themselves.

Subsequent case law on the matter is limited, leading only to occasional statements on the methods applicable for establishing an excessive price within the scope of Article 102 TFEU. Case law typically concerns markets with a strongly rooted dominant position where entry and expansion of competitors could not be expected to introduce effective competition in the

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17 EU Contribution to the 2011 OECD Roundtable, supra n. 13.  
21 See paras. 249-250 and 253 of the Judgment. In United Brands the Court of Justice developed its test because the Commission had not analysed United Brand’s production costs, although it could have done so.  
22 See para. 252 of the Judgment. It is worth mentioning the position expressed by Motta & de Streel, supra n. 6, at 39 (disagreeing with the majoritarian view of many commentators -including Commission officials- and arguing that “the test imposed by the Court is not necessarily cumulative and both parts of the test aimed to prove the same thing: that a price is above its competitive level”).  
23 Geradin, supra n. 5.  
24 On this point, see EU Contribution to 2011 OECD, supra n. 10, at 319.  
25 Ibid.  
The European Commission has recently started paying more attention to exploitative abuses and the Commissioner Vestager, *inter alia* referring to the pharmaceutical sector, claimed that it is the Commission’s responsibility to intervene and protect consumers from exploitation. It is worth mentioning that a debate over enforcement against excessive pricing has also developed in Israel, where some years ago an Opinion released by Professor Gilo, at the time Antitrust Commissioner, called for intervention in this area by the Israeli Antitrust Authority (IAA). The Opinion raised much criticism and in 2017 a new Opinion streamlined it, indicating the EU policy as an example, due to the fact that the relevant provisions of the Israeli Restrictive Trade Practices Law are (in a limited way) similar to those of TFEU. However, the door is open to excessive pricing to be prosecuted in courts through private enforcement, mainly by class actions.

### 3. Excessive pricing in the pharmaceutical sector

As mentioned above, recent case law has called attention to the imposition of excessive prices in the pharmaceutical sector. Being a very intensively regulated sector, where innovation plays a fundamental role to be preserved, intervention by competition authorities has been limited and in any case a distinction must be drawn between innovative drugs, where there has, to date, been no indication for antitrust action on high prices, and old off-patent ones. As a necessary premise, it is worth stressing that, contrary to the US system (where the open market determines prices), in the EU pricing and reimbursement of pharmaceutical products is not harmonized on a European level. The lack of a pricing competence at the Community level has been criticized, as it would lead to a less competitive and robust pharmaceutical market. A certain degree of harmonization exists only with regard to the transparency of measures regulating the pricing and reimbursement of pharmaceuticals through the Transparency Directive, which defines a series of procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the pharmaceutical trade within the Internal Market. So pricing and reimbursement of pharmaceutical products belong to the exclusive competence of the member states, which closely regulate the prices of pharmaceuticals through single-payer state health systems. As a result, there are different statutory health schemes and rules within each European country.

In Italy, on 29 September 2016 the ICA fined the multinational pharmaceutical company Aspen more than Euro 5 million for allegedly having set unfair price increases of up to 1,500% on lifesaving and non-substitutable drugs (specifically, medicines with the active ingredients

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30 IAA, Opinion 1/17 Considerations of the Antitrust Commissioner in the enforcement of the prohibition on unfair excessive pricing.

31 For more details, *see* Solomon & Achmon, *supra* n. 29.


chlorambucil, melphalan, mercaptopurine and thioguanine) used in the treatment of patients affected by cancer, including children and elderly patients in particular, in breach of Article 102 (a) TFEU.\textsuperscript{35} Subsequent to the investigation into Aspen in Italy, the Spanish authority and the European Commission have both started investigating Aspen’s pricing practices.\textsuperscript{36}

In the UK, in 2016 the CMA fined Pfizer and Flynn Pharma for the imposition of excessive and unfair prices for phenytoin sodium capsules, an anti-epilepsy drug (prices increasing by up to 2,600% overnight after the drug was deliberately de-branded in September 2012).\textsuperscript{37} The CMA’s fine was its highest ever issued since its establishment in 2013, with the declared aim of sending a clear message to companies operating in the pharmaceutical market. Moreover the CMA released a Statement of Objections against Actavis, which has increased the price of hydrocortisone tablets (a lifesaving drug on which thousands of patients rely, leaving the NHS no choice but to continue purchasing it) by over 12,000% compared to the branded version of the drug.\textsuperscript{38} Then, in November 2017 the CMA sent a Statement of Objections alleging that Concordia breached UK and EU competition law by charging excessive and unfair prices with regard to an increase by almost 6,000% in relation to the supply of liothyronine tablets, primarily used to treat hypothyroidism.\textsuperscript{39}

Outside Europe, in the US the topic of excessive prices in the pharmaceutical sector has been raised as a result of Turing Pharmaceuticals’ 5,000% increase in the price of pyrimethamine (Daraprim), a decades-old drug used primarily to treat toxoplasmosis.\textsuperscript{40} In another case, the Mylan company raised the price of a life-saving device (EpiPen) which delivers epinephrine to treat anaphylactic shock, resulting in an increase of more than 400%.\textsuperscript{41} In these cases a debate has arisen on whether the appropriate remedy to such conduct should be found within the powers of the Food and Drug Administration (FDA) or instead requires the intervention of the Federal Trade Commission (FTC). Some scholars, noting that a number of undertakings have adopted the strategy of acquiring old drugs already in the market and then raising prices, have called for antitrust intervention.\textsuperscript{42} Congress is considering possible ways to reform current laws in order to address the problem of high drug prices.\textsuperscript{43}

In Canada, the Government is taking action to lower the cost of prescription drugs significantly and in May 2017 launched a consultation aimed at modifying the Patented Medicines Regulations with the declared objective of providing the Patented Medicine Prices Review Board (PMRPB) with new regulatory tools to better protect consumers from excessive prices while reducing the regulatory burden on patentees\textsuperscript{44}, and published the proposed amendments in December 2017.\textsuperscript{35} In South Africa, in June 2017, the Competition Commission launched an investigation into three major

\textsuperscript{35} Autorità garante della concorrenza e del mercato (ICA), decision No. 26185, 29 September 2016.
\textsuperscript{37} CMA, case CE/9742-13, decision published on 7 December 2016.
\textsuperscript{38} CMA, Statement of Objections issued on 16 December 2016.
\textsuperscript{39} CMA, Statement of Objections issued on 21 November 2017.
\textsuperscript{42} See H. First, Unfair Drug Prices and Section 5, CPI Antitrust Chronicle 2015, 2 (claiming for the application of Section 5 to such conducts). See also Abbott, supra n. 11, at 10 et seq. (extending the issue also to on-patent drugs).
\textsuperscript{43} For an analysis of the US system, see J. L. Graber, Excessive Pricing of Off-Patent Pharmaceuticals: Hatch It or Ratchet?, 92 NYU Law Review 1146 (2017).
pharmaceutical manufacturing companies for alleged excessive pricing of cancer drugs (Roche and Genentech, Pfizer, and Aspen). In China, in November 2017, the National Development and Reform Commission (NDRC) released its Guidelines on Pricing Conduct by Business Operators for Drugs in Shortage and Active Pharmaceutical Ingredients; some months prior it had issued two decisions sanctioning local pharmaceutical companies for excessive pricing in relation to off-patent products.

Given this brief overview on the several countries dealing with excessive pricing practices, the following paragraphs will examine the Italian Aspen case and the UK Flynn case, as emblematic examples of the antitrust enforcement against unfair pricing in the pharmaceutical sector.

3.1. Italy

The South African group Aspen, operating mainly in the production and distribution of generic drugs, entered the European market in 2009 through the acquisition from GlaxoSmithKline (GSK) of trademark and marketing rights over a group of anticancer drugs called “Cosmos”, becoming the only company to have marketing authorization for them. It is worth noting that Aspen bore only distribution costs; it did not invest in R&D (as these drugs were developed by another company and are no longer protected by patent law) nor in promotional activities (due to the long-established use of them), since other contracting companies were also producing them. According to the ICA, Aspen adopted a very aggressive negotiation strategy towards the Italian Medicines Agency (AIFA), in order to obtain a re-categorization of Cosmos drugs from the A and H classes to the C class (so-called “delisting”), so that they would no longer be subject to the NHS reimbursement scheme but directly sustained by patients at the prices freely set by the pharmaceutical company. The declared aim of Aspen was to bring the prices in Italy into line with those charged for the same drugs in other member states. AIFA is entrusted with negotiating prices of medicines subject to the public reimbursement system with pharmaceutical companies and, under the Italian rules, if the negotiations on prices between the regulator and the undertaking concerned are unsuccessful, drugs are then classified in the C class mentioned above.

The proposal made by Aspen was not acceptable to the AIFA, as Cosmos drugs are, according to AIFA’s scientific committee and expert oncologists, essential and non-substitutable medicines used for the treatment of cancer for specific categories of patients. When AIFA refused Aspen’s proposal and asked for a new one that would permit the drugs concerned to be kept under the national reimbursement scheme, Aspen persevered in requesting a substantial upward revision of prices or the delisting of the drugs, asking the regulator to take a quick decision. The pharmaceutical company put strong pressure on the regulator through the credible threat of reducing or withdrawing the drugs concerned from direct sale in the Italian market and of making them available only through other countries (foreign packs).

The ICA investigation gives account of the details of the various steps in the negotiation process and of the AIFA’s resistance to the aggressive behaviour adopted by Aspen, reiterating its requests through the instrumental use of the right of renegotiating prices with the aim of obtaining unfair

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The ICA reconstructed Aspen’s whole strategy aimed at increasing prices in several member states. It also clarified the logic of Aspen’s “oncology allocation mechanism”, used to plan the quantities of Cosmos drugs for distribution in the countries concerned, with the aim of containing parallel trade due to the price differentials of the products: crucially, this allocation system was used for the creation of an artificial scarcity of Cosmos drugs in the market concerned, employed as a means to exercise the company’s bargaining power in the national markets concerned.

With regard to the structure of the markets concerned, Aspen holds a dominant position, as it is the sole holder of marketing authorization for drugs based on the active ingredients of Cosmos drugs. It is worth mentioning that the absence of barriers to entry in these markets is not controversial, as the active ingredients mentioned above are not covered by any patent or supplementary certificate protection. According to Aspen, the extremely low initial prices made it unprofitable for other generic companies to enter the market; according to the ICA, the absence of competitors was due to the small economic dimension of the relevant markets (and thus of the economic prospects), the drugs concerned being limited to specific and infrequent diseases.

According to Aspen, the new pricing policy derived from the fact that, unlike the previous holder (for whom the Cosmos drugs were not of particular value), Aspen does not invest in innovative products and these drugs are crucial in its activity in the European market. Moreover, repudiating the allegation of the strategic use of the oncology allocation program, whose declared purpose is to guarantee a regular supply of the products, Aspen defended its right to ask for re-classification of its drugs and disputed that it held such bargaining power that an abuse of its dominant position through the imposition of unfair prices could exist: according to the pharmaceutical company, AIFA would own a countervailing buyer power, as regulator-monopsonist which conducts negotiations on behalf of the national health system. According to the ICA, all the elements of the investigation led to a very different outcome as they would demonstrate that the bargaining power of AIFA did not succeed in contrasting or even tempering the market power held by Aspen, which abused its dominant position by imposing unfair prices through an instrumental and distorted use of the negotiation with the regulator and finally obtained a price increase of 300% to 1,500% as compared with the initial prices previously charged by GSK.

In line with the principles affirmed by the Court of Justice in United Brands, the ICA used a two-step test. Firstly, the ICA evaluated whether there was an excessive imbalance between the cost borne for the production and the price effectively requested by the company. The existence of a strong disproportion (higher than 25%, considered abusive in other cases) was confirmed by the application of two distinct methodologies, i.e.: i) the Gross Margin, providing an estimate of excessiveness measured by the percentage Gross Margin (Gross Margin/Revenues %) granted by the drugs under scrutiny, and ii) the so-called “Cost Plus” method, with the rate of profitability measured by a Return on Sales (ROS) which equalled 13%, revealing an extremely significant excess of prices over the Cost Plus (from 150% to 400%). The ICA complemented this analysis by carrying out an inter-temporal price analysis and a comparison of the firm’s internal rate of

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50 ICA, supra n. 35, paras. 352 et seq.
51 The ICA defined the relevant markets at ATC5 level, i.e. molecule level, corresponding to the single active ingredients of Cosmos drugs, considering the lack of both direct substitutes (i.e. other generic drugs) and indirect ones (i.e. other drugs belonging to the same therapeutic sub-category and authorized for the treatment of the same diseases treated by Cosmos drugs).
52 European Commission, Deutsche Post, supra n. 24; UK Competition Appeal Tribunal, Albion Water Ltd, 7.11.2008.
53 See Lanza & Sfasciotti, supra n. 48. The percentage gross margin at starting prices (i.e. prices applied before the “negotiated” increase) for each of the 5 drugs was well above the percentage total common and fix costs and absolutely in line with the average group gross margin. In other words, each Cosmos positively contributed to Aspen’s profits before the huge increase in their prices: this implies, in turn, that the new prices applied by Aspen turned into a proportional increase in profit.
54 Within the Cost Plus method the benchmark price is construed by adding a reasonable rate of return to the sum of the direct costs and of an appropriate apportionment of indirect costs.
55 Ibid.
return for the Cosmos products with the weighted average cost of capital (WACC). The ICA ascertained that there was no reasonable justification for the price increase established by Aspen, having considered all the relevant elements, such as: the comparison itself between ex ante and ex post prices (increase between +300% and +1,500%); the absence of any economic justifications for such a relevant increase; the nature of the drugs (old off-patent life-saving drugs) and of substitutes leading to inelastic demand; the absence of any non-cost related factor leading to an improvement in quality of the products; the business model adopted by Aspen, which appeared to be merely speculative; the characteristics of the company, which does not invest in R&D, and; the misuse of NHS limited resources.

The ICA’s decision was then confirmed by the Administrative Court, which has rebutted the numerous arguments put up by Aspen in its appeal: among the various issues, the pharmaceutical company has alleged the erroneous evaluation of Aspen’s market power and of its negotiation strategy, the inadequate analysis of the excessiveness of prices, and the exorbitance of the sanction imposed. The Court shared the view expressed by the ICA, finding in Aspen’s behaviour, considered in its entirety, an anticompetitive “quid pluris”.

The Aspen case constitutes an important decision in the enforcement policy of the ICA, which has been demonstrated over the years to be particularly attentive to the pharmaceutical sector. This case arouses interest not only for the application of excessive pricing abuse and the methodology adopted, but also with regard to the relationship between the ICA and AIFA, which was put into question in another controversial case concerning off-label use of medicines, where the two agencies were in conflict. In Aspen, AIFA proved that it was held hostage to the negotiation strategy enacted by the pharmaceutical company and turned out to have no adequate bargaining power to counter it, due to the national rules providing for the delisting in class C of the drugs on which the negotiation fails. In other words, Aspen’s conduct recalls typical regulatory gaming behaviour, i.e., the conduct of a private operator harnessing sector-specific rules and using them for anticompetitive purposes, frequent in the pharmaceutical sector (as in the landmark case AstraZeneca).

3.2. UK

In September 2012 Pfizer Limited sold its UK distribution rights for an anti-epilepsy medicine, named Epanutin (based on phenytoin sodium), to Flynn Pharma Limited. Flynn de-branded the medicine (which became Phenytoin Sodium Flynn Hard Capsules) and overnight increased its price by as much as 2,000-2,200%. In May 2013 the CMA opened a formal investigation to check whether the two companies had illegitimately applied unfair prices.

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56 In particular, the ICA compared the WACC for the “pharmaceutical sector as a whole” (8%) with Aspen’s internal rate of return (IRR) which ranged between 20-30% and 30-40% and between 10-20% and 30-40%, when the rate of return of 13% is excluded from calculation. See ICA, supra n. 35, paras. 190-192.


58 It is also worth mentioning that Aspen has alleged the wrongful definition of the relevant market (see supra n. 51), on which it postulates the possibility of a reference for a preliminary ruling before the Court of Justice.

59 ICA, decision of 5 March 2014, No. 1760 (known as Avastin/Lucentis case). The case has been object of a reference for a preliminary ruling before the CJEU [Judgment of 23 January 2018, case C-179/16, F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato (not published yet)]. It is worth mentioning that ICA and AIFA have signed a cooperation protocol on 19 January 2017.

60 S.L. Dogan & M.A. Lemley, Antitrust Law and Regulatory Gaming, 87 Tex. L. Rev. 685, 689 (2009) (arguing that the pharmaceutical industry represents a perfect storm for regulatory gaming).

61 See the landmark AstraZeneca case (ECJ, Judgment of 6 December 2012, Case C-457/10 P, AstraZeneca AB and AstraZeneca plc v European Commission).

62 Under UK pharmaceutical law, only branded medicines can be subject to a direct price controls (see sections 262 and 263 of the NHS Act). Generics are, instead, freely priced.
Firstly, based on a very narrow market definition, due to the limited substitutability of phenytoin sodium capsules with other antiepileptics,\(^{63}\) the CMA considered both Pfizer and Flynn as dominant in the markets for, respectively, production and distribution of phenytoin sodium capsules in the UK.\(^{64}\) Secondly, the CMA considered that the increase in the price of phenytoin sodium capsules was unfair and therefore constituted an abuse of the companies’ dominant position. In particular, the CMA found that under the terms of the deal, Pfizer continued to manufacture the medicine and sold it to Flynn at prices between 8 and 17 times higher than its historic resale price. In turn, Flynn resold the product to wholesalers at prices between 25 and 27 times higher than Pfizer’s historic price.

The CMA calculated the excessiveness of these prices using the Cost Plus method where the reasonable rate of return was calculated by using the ROS allowed under the PPRS scheme (equal to 6%)\(^{65}\) and by cross-checking the result with the calculation by the ROCE. The comparison between the Cost Plus and the price charged by Pfizer and Flynn allowed the CMA to conclude that Pfizer’s and Flynn’s excess in percentage over the Cost Plus ranged, respectively, from around 30% to almost 700% and from around 30% to over 130%.

This excess was also considered to be unfair, because of: i) the substantial disproportion between the applied price and the benchmark price; ii) the absence of any R&D effort or improvement in production and/or distribution or high commercial risk; iii) Flynn’s and Pfizer’s awareness of the adverse effect of the price increase on the end consumer (the NHS), witnessed also by Pfizer’s reputational concerns behind the divestiture of the Epanutin business; and iv) the fact that similar price increases were not introduced in five other EU member states, where the product was, except in one case, sold profitably. These elements were considered sufficient to support the finding of unfairness in itself of the price increase and rendered, according to the CMA, unnecessary to prove its unfairness through a comparison between the price of the PSFHC with those of other competitors’ products.\(^{66}\)

The two companies objected that, since Epanutin was loss-making, the price rise was necessary to avoid the discontinuation of the product. Nevertheless, according to the CMA, the price increase went beyond what was necessary to re-establish profitability, since the losses were offset within two months.

The CMA finally ascertained that the price increase resulted in a significant increase in the NHS’s annual expenditure on phenytoin sodium capsules from approximately £2 million in 2012 to approximately £50 million in 2013, approximately £42 million in 2014 and approximately £37 million in 2015. In light of these considerations, in late 2016 the CMA fined Pfizer £84.2 million and Flynn £5.2 million, after concluding that for four years they had charged excessive prices for Phenytoin Sodium Flynn Hard Capsules (PSFHC) sold to wholesalers and pharmacies without any apparent justification, and ordered the two companies to lower their prices. The decision was

\(^{63}\)The CMA found that patients could hardly switch away from PSFHC, since phenytoin sodium has a very narrow therapeutic index, that is, even very small changes in the dose can result in disproportionate changes in the level of the active substance in the body, leading to possible therapeutic failure or toxicity. This induced prescribers and dispensers in the UK to maintain patients who were currently taking a particular manufacturer’s phenytoin sodium product on that specific product (see CMA, supra n. 37, paras. 4.40, 4.48 et seq., 4.84 - 4.106). This, according to the CMA, impeded any meaningful competition between PSFHC and other antiepileptic drugs present in the market (even if based on the same active substance). \textit{Ibid.}, paras. 4.57 et seq. and 4.157-4.179.

\(^{64}\)\textit{Ibid.}, paras. 4.210-4.218.

\(^{65}\)Pursuant to section 261 of the NHS Act, the NHS’s Pharmaceutical Price Regulation Scheme (PPRS), agreed every five years between the Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI), regulates both the increase of prices of branded medicines (on-patent and off-patent) and the profits that manufacturers are allowed to make on their sales to the NHS. Pharmaceutical companies can freely set the price of new medicines, but any future increase must be either approved by the DH or offset by reductions in the price of other medicines so that the overall total expenditure for the NHS comply with the PPRS commitments.

\(^{66}\)CMA, supra n. 37, par. 5.505. For a critical view on this, see N. Meershoek, \textit{Excessive prices in the pharmaceutical sector: re-inventing United Brands as a fairness-mechanism}, in 39(4) ECLR 167 (2018), at 172 and 174 (arguing that this choice renders that CMA’s test far from fairness-based and rather arbitrary).
appealed by both Flynn and Pfizer at the beginning of 2017 and the judicial proceeding before the CAT is still pending.

4. Similarities and differences across the English Channel

Both the Aspen and the Flynn cases deal with the increase of several hundred percent in the price of old off-patent pharmaceutical products that the defendant companies bought from third parties which had developed them long before.

Whilst the Cosmos drugs seem, prima facie, very different from PSFHC - the former being brand-name drugs and the latter being a generic -, on deeper inspection they prove to be similar, insofar the investment made for their development had in both instances already been recouped. The age of the products, thus, hardly justified the price increase. However, thanks to two different business strategies, the proprietor companies managed to achieve such an objective.

On the one hand, by “genericizing” Pfizer’s Epanutin, Flynn exited the PPRS Scheme and gained freedom of pricing. This allowed the increase in price for PSFHC. The commercial practice of charging high prices for generics is becoming more and more frequent in the pharmaceutical sector and partially disproves the myth that generics are always priced at a very low level and that, thanks to this feature, after patent expiry the prices of drugs always fall significantly. On the other hand, following a business strategy that pharmaceutical companies have also been applying in recent times in relation to old drugs that are used to treat diseases that have a low incidence in the population, Aspen “converted” the Cosmos drugs into “speciality” drugs for which it demanded very high prices.

The main feature that determined the success of these manoeuvres is attributable to the fact that both PSFHC and the Cosmos drugs were basically shielded from competition, since they could not, each for different reasons, be replaced by other medicines: the former because PSFHC has a very narrow therapeutic index, which renders the switch to other products based on the same active substance dangerous for patients; the latter because of the small size of the market, which since then had not attracted the development of new products. The price rise was, thus, of great concern from a consumer welfare point of view, since, due to their necessity, in the absence of valid therapeutic alternatives, patients (or the NHS) could do nothing but pay the new high prices.

This feature correctly frames the boundaries of the intervention of the two antitrust authorities against unfair prices, which is in general justified when the market is not capable of self-correcting. Contrary to common belief, however, this is not so uncommon in the pharmaceutical sector. Indeed, the side effects arising in certain patients and, more generally, the inelasticity of demand to price, limit substitution between medicines; also, the non-profitability of certain product markets discourages entry, thereby stifling an effective competitive pressure.

Not only was the price rise facilitated by the market structure, but also regulation played a role in this sense: the request for reclassification of a pharmaceutical product into the C class and the “genericization” of a drug are both allowed by, respectively, Italian and UK pharmaceutical law. In

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67 Graber, supra n. 43, at 1154-1155, reporting that the price of certain generics has increased by a range by 650% (Simvastatin) and by 10.000% (Doxycyclin). A.M. Hill, M.J. Barber & D. Gotham, Estimated costs of production and potential prices for the WHO Essential Medicines List, BMJ Glob Health, 2018, at 6, affirm that many generic medicines are sold at prices far higher than would be expected based on their production costs.

68 ICA, supra n. 35, paras. 129 and 349; Graber, supra n. 43; Lanza & Sfasciotti, supra n. 48, at 3.

69 Röller, supra n. 10, at 3.

70 E.g., De Coninck & Koustoupamardi, supra n. 32, at 11, minimize the number of occasions in which market forces do not operate in the pharmaceutical sector and in which generics do not exert enough competition pressure on brand-name drugs. However, see US FDS, Generic Competition and Drug Prices, available at https://perma.cc/MJ6E-RJUS (accessed 10 March 2018), where the FDA has found that introducing generic competition cause prices to fall to as little as 6 % of the patent-protected price.

both cases, however, the regulators lose their control over prices.\textsuperscript{72} This means that these rights can be used by pharmaceutical companies as a tool to avoid price regulation.\textsuperscript{73}

The conducts implemented by Pfizer, Flynn and Aspen therefore represent two different ways of strategically exploiting the loopholes existing in pharmaceutical price regulation. The enforcement action of the two authorities is thus also in line with the suggestions proposed by some commentators who accept antitrust intervention on excessive prices when no regulation is present or when there is a regulatory failure.\textsuperscript{74}

Finally, the methodologies used by the two NCAs to ascertain the anticompetitiveness of the defendants’ pricing policies, represent an application of the \textit{United Brands} two-partite test and are largely overlapping. The analysis of some specific elements of the applied methodologies may provide theoretical hints on some key issues that arise in the application of competition law to unfair pricing policies in the pharmaceutical sector.

\textbf{4.1 How to ascertain the unfairness of pharmaceutical prices? The price-cost test}

There is no legally prescribed methodology for establishing a benchmark against which one can measure the excessiveness of a price from an antitrust point of view. Indeed, the legal standard established by the Court of Justice in \textit{United Brands} cannot be considered as the method: after having established the two-prong test, the Court has in fact clarified that “\textit{[o]ther ways may be devised [...] of selecting the rules for determining whether the price of a product is unfair (emphasis added)}”, thereby suggesting that there exist alternative methodologies.

The mentioned “\textit{other ways}”\textsuperscript{75} represent an alternative not only to the second prong of the test (the unfairness) but also to the test as a whole. The fact that the Commission and/or the Court of Justice have sometimes resorted to different methodologies – mainly comparative methods, such as the cross country comparison,\textsuperscript{76} the competitors’ benchmarking,\textsuperscript{77} the inter-temporal price analysis\textsuperscript{78} or the comparative profit analysis\textsuperscript{79} - and indeed disregarded the price-cost test\textsuperscript{80} altogether, leads to the conclusion that the latter is not a compulsory step in the analysis.\textsuperscript{81}

\textsuperscript{72} CMA, supra n. 37, paras. 5.289, 5.290, 5.293-5.312. See F. Bokhari & B. Lyons, \textit{Can drug price hikes via debranding be prevented?}, The Prescriber, April 2017, 44-46 (arguing that competition law may work only as a short-term patch and advocating changing the regulation itself in order to address the loophole).

\textsuperscript{73} More in general see Arnaudo & Pardolesi, supra n. 48, at 492, underlining that negotiating the reimbursement price after a company has obtained a marketing authorization allows the latter to meanwhile market its product within the above-mentioned C class and to “built” a demand for its own product, which can be used as a tool that could be exploited by pharmaceutical companies during the price negotiation.

\textsuperscript{74} See Motta & de Streel, supra n. 6, at 26-29; C. Desogus, \textit{Nuove frontiere tra regolazione, proprietà intellettuale e tutela della concorrenza nel settore farmaceutico: le pratiche di brevetto strategica}, 2 Rivista della Regolazione dei Mercati, at 95 (2014), arguing that the intersection between competition law and regulation (as well as intellectual property rights law, as a form of regulation of innovation) is not \textit{ex ante} defined, but it is characterized by moving boundaries that change on a case-by-case basis, and that competition law expands its area of application to correct regulatory failures.

\textsuperscript{75} This method either compares the prices charged by the dominant firm in the involved market with those charged in other markets (see ECI, \textit{Pompe funèbres}, supra n. 26, in \textit{SACEM II}, supra n. 26, paras. 25-30, in case C-395/87 Ministère Public v. Tournier (\textit{SACEM III}), para. 38; CJEU, Judgment of the 14 September 2017, Case C-177/16, Autoritesību un komunicēšanās konsultāciju āģentūra - Latvijas Autoru apvienība v. Konkurences padome, paras. 37-38) or to different customers (see ECI, Judgement of the 11 November 1986, Case C-226/84 British Leyland Limited Company v Commission of the European Communities, para. 29).


\textsuperscript{77} See ECI, \textit{British Leyland}, supra n. 75, para. 29; ICA, supra n. 35, paras. 330-336.

\textsuperscript{78} A product’s price is considered excessive either when the firm’s return on capital for that product is greater than its WACC or when the profit rates are greater than the profits obtained by similar companies in other markets. Cf. European Commission, \textit{Scandlines Sverige}, supra n. 26, para. 156, where the method was envisaged but eventually not applied because of the difficulties in establishing valid benchmarks.

\textsuperscript{79} This method compares the costs of production of a given good and its price, aiming at identifying a threshold price above which the price charged by a dominant firm can be considered excessive. The Cost Plus analysis, the Gross
From the case law it appears that none of the mentioned tests is considered to be superior in respect to the others\(^ 81\) and the choice rather depends on the specific circumstances of the case and/or of the features of the involved market.\(^ 82\) Furthermore, as already described, no indication comes from the Court of Justice’s case law in relation to the most appropriate way of ascertaining the unfairness of prices of pharmaceutical products specifically, as none of the cases dealt with this specific sector. Thus, the analysis of the approach adopted by the ICA and by the CMA appears to be of great importance, at least for certain specific cases of price hikes.

In particular, in many instances in the *Flynn* decision the CMA stressed the fact that a price is “unfair” when it is not “cost-justified”.\(^ 83\) And in so doing, the authority appears to suggest that the price-cost analysis is the preferable methodology.\(^ 84\) Such a conclusion might be supported by the fact that the ICA, with respect to the choice of the test, also took the same stance. Indeed, this preference has some grounds. Notwithstanding the difficulties involved in calculating the cost of manufacture of a pharmaceutical product – such as the consideration of fixed costs and the right apportionment of common costs when the dominant firm is a multi-product company,\(^ 85\) the comparative methods might be even more difficult or methodologically flawed.\(^ 86\)

Both the CMA and the ICA had to face the above-mentioned limit: the analysis of unfairness of the price charged by the defendant companies could not be based on a comparison with competitor products, because there were no substitutes – as was the case for the Cosmos drugs – or because the alternative drugs could not be considered real competitor products or could also be charged with excessive prices –\(^ 87\) as was the case for the *phenytoin sodium tablets*. These pitfalls show that the benchmarking method might not be always applicable, either because it is impossible or because it is inappropriate.

Interestingly, the two authorities instead took a different stance towards the cross-country comparison. The ICA chose not to make use of it, since the prices of the Cosmos drugs had already been negotiated at a higher, probably excessive, level in the other European countries; taking them as a reference could thus have distorted the analysis of excessiveness.\(^ 88\) Vice versa, the CMA performed a cross-country comparison: it looked at the price that Pfizer applied to the 100mg dose of *phenytoin sodium capsules* in five other European countries, where the price increase did not take place, thereby concluding that the pricing policy applied in the UK for PSFHC was not only excessive but also unfair.\(^ 89\)

This difference seems to be fact-specific and arising from the fact that Pfizer and Flynn were focusing on a single country strategy, while Aspen was applying a pan-European strategy. In the absence of this specificity, the ICA could probably have looked at the prices charged by Aspen in other European countries. However, careful attention should have been paid, since the comparison of the prices charged for the same medicine across Europe might not necessarily be informative: the differences in the pharmaceutical regulation, in the institutional aspects governing the pharmaceutical policies, in the level of incidence of a given disease in the population, and in the ability of a given country to pay, are such that a cross-country comparison might not be made on the

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\(^{81}\) Cf. Jenny, *supra* n. 3, at 8.

\(^{82}\) See Geradin, *supra* n. 5, at 4, 20 and 42, affirming that this explains the reluctance of the European Commission and of the Court of Justice to apply competition law to excessive prices.

\(^{83}\) See ECJ, *United Brands*, *supra* n. 20, para. 251. See also Jenny, *supra* n. 3, at 8, note 20.

\(^{84}\) CMA, *supra* n. 37, para. 5.487.


\(^{86}\) Cf. Motta & de Street, *supra* n. 6, at 34; Williams, *supra* n. 79, at 147.

\(^{87}\) More in general the application of a cross-country comparison implicitly questions the possibility for companies to price discriminate. See Geradin, *supra* n. 5, at 11; contra Abbott, *supra* n. 11, at 11.

\(^{88}\) CMA, *supra* n. 37, paras. 5.487 and 5.504.

required consistent basis.\textsuperscript{90} For this reason, this method might rather be used, as the CMA did, to eventually complement the price-cost test, once a first benchmark price has been already established.

4.1.1 The definition of an appropriate benchmark price for drugs

Determining an appropriate benchmark price requires rigor in order to avoid any potential flaw undermining the correctness of the test. Two specific topics arising from the Flynn and the Aspen cases seem to be of importance in this respect: the identification of the relevant costs to be included in the benchmark price when the drug has been bought from third parties and the determination of the appropriate rate of return, which is the issue at the core of the potential pitfalls that may affect the antitrust analysis of unfair pricing policies. Both issues revolve around the notion of “reasonableness”.

In relation to the first issue, it emerges that Aspen’s total costs were affected by the financial investment made by the company to buy the marketing rights of the Cosmos drugs from GSK (i.e. the trademarks). Indeed, even if these expenses did not have a direct impact on the activity of production and distribution of the Cosmos drugs, they represented a related economic burden. Despite this, the ICA decided not to include these expenses within the costs that it used to define the benchmark price.\textsuperscript{91} That is, it excluded from the notion of “costs” all the economic burdens that were not indispensable for the production and/or distribution of the goods and that were, rather, caused by erroneous business decisions taken by the company, thereby representing potential sources of inefficiencies. If one had to justify the ICA’s decision in the words of the CMA, these costs were excluded because they were not “reasonably incurred”\textsuperscript{92}

The enforcement action undertaken by the ICA, therefore, signals that prices charged to consumers should not repay “bad deals”.\textsuperscript{93} This outcome is totally consistent with the Court of Justice’s case law, where the Court stated that internal inefficiencies cannot justify unfair prices.\textsuperscript{94}

The notion of reasonableness is also at the centre of the determination of the rate of return within the Cost Plus analysis. The identification of an appropriate margin, in fact, is not a matter of mathematics, but a question of judgment and appreciation. In this respect, the CMA stated a very important principle of law where it affirmed that in exercising such judgment and appreciation “regard, in particular, [must be paid] to the interests of [...] patients and to the interests of the customer, the NHS. Those are the interests which the legislation is primarily designed to protect although, of course, the interests of suppliers are also important” (emphasis added).\textsuperscript{95}

By this wording the CMA affirmed that a rate of return is considered reasonable when it maximizes the consumers’ welfare and at the same time allows the companies’ R&D incentives to be preserved. However, the CMA also clearly prioritized between these two interests, as the former came first. It seems, thus, that from the CMA’s perspective, not all interests have the same value. This is consistent with the general principles of competition law: in the context of Article 101 (3)

\textsuperscript{90} Cf. CJEU, Autortiesību un komunicēšanās konsultāciju aģentūra, supra n. 75, paras. 41, 44 and 51.

\textsuperscript{91} ICA, supra n. 35, para. 179. However, as a cross check, the ICA calculated the excess over the Cost Plus also after having included the costs for purchasing the Cosmos drugs’ trademarks from GSK, without that this changed the conclusions already reached in relation to the disproportion between prices and costs (para. 185). Also CMA, supra n. 37, para. 3.342 and 3.434, where Flynn is described as having very high cost of production, since its activity was affected by the high supply prices that the company paid to Pfizer, which were themselves excessive. By taking Flynn’s production costs, the benchmark price and, as a consequence, also the Flynn’s price excess over the benchmark price, would have been distorted. Without resorting to an abstract benchmark cost, however, the CMA calculated Flynn’s costs (as well as the benchmark price and the price excess) by adjusting the supply prices that Flynn paid to Pfizer and removing Pfizer’s excesses from those prices. Even after such an adjustment the prices charged by Flynn resulted excessive with respect to the Cost Plus.

\textsuperscript{92} CMA, supra n. 37, para. 5.17; see also ECJ, SACEM III, supra n. 75, para. 42.

\textsuperscript{93} Cf. Abbott, supra n. 11, at 33-34.

\textsuperscript{94} ECJ, SACEM II, supra n. 26, para. 29.

\textsuperscript{95} CMA, supra n. 37, para. 5.19 and 5.92 citing CAT, Genzyme Remedy, paras. 255-256.
TFEU, e.g., innovation, of which profit (read: rate of return) might under certain circumstances be considered as a proxy, has an antitrust relevance and is considered to be capable of offsetting a restriction to competition only when it benefits consumers.\(^{96}\)

In the pharmaceutical sector, such a hierarchy reflects the fact that the activity of producing and distributing medicines touches upon fundamental rights. For instance, the impact of a pricing policy on the human right to have the widest possible access to medicines might have a role in the analysis of unfairness. This seems to be indirectly recognized by both the CMA and the ICA when they considered the defendant companies’ misuse of the NHS’ limited resources, in a context of budget restraint, for the only purpose of increasing the companies’ profit, as an important element of the overall unfairness of the companies’ conduct.\(^{97}\) From this point of view, it seems that both the CMA and the ICA weighed up the values of the two interests concerned from a social point of view.\(^{98}\)

This reading of the *Flynn* decision, in particular, poses an issue of great importance, since the inclusion of social values within the scope of protection of competition law entails the risk of sanctioning companies’ pricing policies that are incompatible with the collective interests of the right to access to medicines at reasonable price even when the regulator has approved them, thereby creating an undue overlap between antitrust enforcement and regulation.

In this regard, it should be remembered, firstly, that antitrust enforcement should come into play only where a regulatory failure takes place, i.e., when the health regulator cannot pursue its objectives, due, for instance, to a loophole that impedes the control of prices (* Flynn*) or that weakens the bargaining power within the negotiation of pharmaceutical prices (*Aspen*). Secondly, it should also be recalled that in the cases hereby considered the balancing exercise was not influenced by any consideration of the preservation of the incentives to invest in innovation. In *Flynn*, as well as in *Aspen*, the conducts under scrutiny had been put in place in relation to old pharmaceutical products whose investment in R&D had been already recouped. More cautious considerations should therefore be made when it comes to innovative products for which R&D expenses have not already been repaid.\(^{99}\)

The criteria used by the CMA to define the reasonable rate of return reflect the mentioned peculiarity of this case. The authority judged the age of the product, the absence of R&D activity or of any other investment in the improvement of the production and/or the distribution, as well as the low commercial risk due to the stability of the demand, as good reasons for considering a 6% rate of return appropriate.\(^{100}\)

Another interesting feature of the *Flynn* decision in this respect is that the CMA determined the reasonable rate of return by making reference to the profit cap used within the field of

\(^{96}\) See L. Toffoletti, *Progresso tecnico e bilanciamento di interessi nell’applicazione dei divieti antitrust* (Milano, Giuffrè, 2009).


\(^{98}\) Cf. J. Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Ashgate Publishing Company, 2015), at 65 and 225, who advocates a human right framework for intellectual property and innovation that aims at enhancing access to existing essential medicines. This reading of the *Flynn* decision should not be considered as necessarily supporting the distributional view of competition law suggested, *inter alia*, by J. Baker & S. Salop, *Antitrust, Competition Policy, and Inequality*, The Georgetown Law Journal online, 104 (2015), since it represents an application of the traditional consumer welfare standard, where the distinction is between consumers and producers as groups, but not among the various types of consumers on the basis of income.

\(^{99}\) Excessive pricing cases involving on-patent innovative products are controversial in the literature. For instance, Fletcher & Jardine, *supra* n. 10, at 9, affirm that “there should be no intervention against excessive prices for an innovative product within that product’s patent life. It is noteworthy that in the Napp case, the OFT argued that the patent period provides an opportunity for recoupment of ex ante investment. While not made explicit, the tenor of this discussion suggests that the OFT would not have brought the case had the drug still been within patent.” Contra Abbott, *supra* n. 11, at 10 et seq. In general, on the application of Article 102(a) to patented products, see S. D. Anderman & H. Schmidt, *EC Competition Policy and IPRs*, in S. D. Anderman (eds.), *The Interface Between Intellectual Property Rights and Competition Policy* (Cambridge University Press, 2007), 37, at 52 et seq.

\(^{100}\) CMA, *supra* n. 37, para. 5.102 where it affirms that in cases where a substantial investment was made, or substantial capital employed or where there are significant commercial risks, a rate of return greater than 6% would be fully justified also for generics.
pharmaceutical regulation to indirectly regulate prices within the UK. This choice has a very important impact, on both a practical and a theoretical level. The reference to pharmaceutical pricing regulation – rectius: to the analysis that could have been performed by the health regulator within the context of the pricing negotiation, in the absence of any regulatory loophole that impeded the exercise of such competence - can provide a useful benchmark to evaluate the potential excessiveness and unfairness of the prices of pharmaceutical products.101

In other words, regulation can provide an anchor that helps overcome the hardships that competition authorities might encounter in the task of proving the unfairness of a pricing policy. The reference to pharmaceutical pricing regulation seems to be well placed, insofar as the latter pursues objectives that can be considered, in this specific field, in relation to exploitative abuses, largely overlapping with those of competition law, i.e., the enhancement of allocative efficiency by granting wider and more affordable access to medicines. The anchoring to regulation, in addition, allows a space for competition authorities to be carved out that coherently ex post complements the role of regulators by pursuing the same regulatory objectives in those described specific instances where this was not ex ante possible for the latter102. This should help to minimize the risks of “field invasion” feared by some commentators.103

4.1.2 The consideration of non-cost related factors for drugs’ prices

The European Commission has established that the economic value of a product may exceed the benchmark price - and still be reasonable -, as a result of non-cost related factors, including, where applicable, additional benefits not reflected in the cost of supply and any particular enhanced value from the customer perspective.104

That does not mean that a reasonable price is whatever price the market can bear. It is, rather, what the market can (again) reasonably bear.105 The meaning of “reasonable” in this context has been interpreted in the UK case law as identifying a situation where the consumer is readily willing to pay a premium price for a certain product, as opposed to a situation where it was unwillingly paying such a price, which makes that price unreasonable.106

With reference to the NHS, this interpretation might have grounds: for instance, evidence of the fact that the NHS is concerned about the price level can contribute to the conclusion that there are no non-cost related factors that justify the price increase, which is thus unreasonable.107 On the contrary, it does not seem to be appropriate when referred to patients: the inelasticity of their demand to price, either because of the lack of a substitute product, due to clinical reasons, or because they do not pay for the required medicine, or because the involved drugs are life-saving products, puts patients in the situation of having to be willing to pay a price even if it unreasonable.

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101 In some instances, regulators (e.g. the UK National Institute for Clinical Excellence) negotiate the price of drugs based on the desired outcome of the years of life or disability, i.e. by referring to measures such as disability-adjusted life years (DALYs) or quality-adjusted life years (QALYs), available at http://www.pharmatimes.com/news/nice_turns_down_rare_skin_disease_implant_1214791. Contra see H. Brennan, A. Kapczynski, C. H. Monahan & Z. Rizvi, A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18(1) Yale Journal of Law and Technology 275 (2016), at 324.

102 Contra the CMA’s approach see Meershock, supra n. 66, at 173, arguing that to find a truly reasonable rate of return the profit margin should be preferably compared to the profit margins of similar products throughout industry, as this would lead to an application of the United Brands test based on fairness.

103 See supra n. 6.

104 Cf. European Commission, Scandlines Sverige, supra n. 26, para. 266.

105 CMA, supra n. 37, para. 5.251.


107 CMA, supra n. 37, para. 5.274 et seq.
In line with the Court of Justice’s case law,\(^{108}\) this has been clearly pointed out by the ICA,\(^ {109}\) where it affirmed that in the analysis of unfairness patients’ willingness to pay should not be considered, since, following the outcome of a “hostage bargaining model”,\(^ {110}\) they would be willing to pay any price, even skyrocketing ones, without them having any reasonable relationship with the value of the products. For the same reason, a pharmaceutical’s price cannot be considered fair when it is equal to the benefits it brings about in terms of savings for the general health budgets (e.g. savings in hospitalization, surgery costs),\(^ {111}\) since the latter might justify very high prices, without these having any relationship with the costs which the company incurred and the effort provided in innovation.\(^ {112}\) The consideration of non-cost related factors, thus, rather identifies a “\textit{a wider and thorough assessment}” of the case-specific elements, of the market context, of the regulatory framework and of the nature of the products and of the companies involved.\(^ {113}\)

As already described, the analysis of the unfairness performed by the two authorities is in this respect very similar, as it is based on the mentioned overall assessment of the non-cost related factors that would justify the price increase. It is interesting to note that such an evaluation, which was explicitly categorized by the CMA as a way to prove a price’s unfairness in itself,\(^ {114}\) can be considered as a first application of the second alternative of the second prong of the \textit{United Brands} test, which has never been concretely substantiated by the Court.\(^ {115}\)

One might object that the analysis of the unfairness performed, in particular, by the ICA missed the fact that the price increase could have been justified by the fact that Cosmos drugs were irreplaceable and still proved to be essential to treat certain types of cancer, even after a long time. Despite being old, they would thus be as essential as newly discovered drugs targeting diseases for which there was no cure or a less effective treatment.\(^ {116}\) However, such essentiality might be (and was in the \textit{Aspen} case) due to the peculiar features of the market, which deterred entry by other companies and shielded the product from effective competition, and not to special characteristics of the drug. Furthermore, legitimizing, on the above-mentioned grounds, significant price increases for old off-patent products whose R&D expenses had been already recouped long before, would have adverse effects on the system: it would imply that consumers never stop paying for innovation, even after such innovation has been already rewarded, and by so doing it would undermine the innovation incentive-scheme underlining patents, a policy tool designed to spur innovation that does not provide for a permanent reward of the investments made.\(^ {117}\)

\subsection*{4.2. The antitrust analysis of unfair prices of off-patent drugs: insights from \textit{Flynn} and \textit{Aspen}}

The analysis above showed that in the two cases at hand the prices-cost test served the purpose of ascertaining the excessiveness of the investigated prices and that both authorities, for different reasons, did not resort to the comparison with competing products to show unfairness but the latter was mainly based on a thorough analysis of the (absence) non-cost related factors (“\textit{unfairness in itself}”). The combination of comparative methodologies was then used as a cross-check of the excessiveness (\textit{Aspen}) or of the unfairness (\textit{Flynn}).

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\(^{108}\) See ECJ, Judgment of the 13 February 1979, Case 85/76 \textit{Hoffmann-La Roche & Co. AG v. European Communities Commission}, para. 41. See also the Opinion of the AG Jacobs in \textit{Tournier}, para. 65.

\(^{109}\) ICA, \textit{supra} n. 35, para. 137; OECD, \textit{supra} n. 10, par. 58.

\(^{110}\) Cf. \textit{Abbott}, \textit{supra} n. 11, at 24.

\(^{111}\) Cf. \textit{Actis Perinetto}, \textit{supra} n. 48, at 106.

\(^{112}\) CMA, \textit{supra} n. 37, paras. 5.313-5.314.

\(^{113}\) Cf. \textit{Lanza & Sfasciotti}, \textit{supra} n. 48, at 2.

\(^{114}\) CMA, \textit{supra} n. 37, paras. 5.339-5.475.

\(^{115}\) Cf. \textit{Meershoek}, \textit{supra} n. 66, at 168.

\(^{116}\) Cf. \textit{Actis Perinetto}, \textit{supra} n. 48, at 108.

\(^{117}\) CMA, \textit{supra} n. 37, para. L7 and L8, citing \textit{Napp}. 
It is apparent from the above that, although the exam of non-cost-related factors and the application of a cross-check methodology played an important role, the backbone of the analysis performed by the two authorities was given by the comparison between prices and costs. More precisely, it was the absence of non-cost related factors potentially justifying the price increase that made the significant disproportion between prices and costs illegal by itself, without the need of a full analysis of the competitive conditions prevailing in the markets where potential competitor products were sold.

The question that arises is then whether this reading can be justified in light of the Court of Justice’s case law and whether the price-cost analysis alone is sufficient to establish the unfairness of a pricing policy applied by a dominant company.

The case law of the Court of Justice clarifies that the excessiveness test alone cannot be considered sufficient to this purpose, and has to be complemented with the consideration of non-cost factors. On the contrary, it seems that the comparative methods need not be complemented by other tests, since, for instance, when the cross-country comparison was applied, the Court contented itself with just this method. This difference might be explained by the fact that the comparative methods already embody the consideration of non-cost related factors, whereas the price-cost test allegedly does not.

This reading of the case law, however, appears to be rather formalistic, as it overlooks the fact that a price-cost test also encompasses the consideration of non-cost related factors. For instance, both the CMA and the ICA determined the reasonableness of the rate of return based on the consideration of the characteristics of the product, of the company and of the demand, etc. In addition, the consideration of these elements, rectius: the absence of non-cost related factors that could justify a much higher price than the benchmark price, in the Flynn decision especially, gave the significant disproportion between prices and costs major relevance in the analysis of the unfairness of the prices, to the point where the latter was considered not only one of the key indicia, but also sufficient by itself to prove the unfairness of the prices.

It follows that, under certain circumstances, the price-cost test alone can provide a prima facie complete measure of the relationships existing between the price and the economic value of a product. The finding of illegitimacy is then completed by an exam of other potential economic justifications (i.e. other non-cost related factors) to the prices increase.

From this point of view, the analysis performed by the two authorities might resemble the kind of analysis required to show the existence of a “by object” restriction of competition under art. 101 TFEU, where the standard of proof required in order to allege a violation of this provision is met when, in consideration of the legal and economic context, a sufficient degree of harm to competition is proved. An agreement can be considered restrictive by object without that its effects are necessarily investigated (i.e. that a deviation from a competitive counterfactual is proved) when the analysis of its economic function, in light of the nature of the involved goods and of the conditions of functioning and structure of the market, shows that it will highly likely display negative effects on competition and, ultimately, on consumers. Similarly, within the context of exploitative abuses, a price hike can be considered contrary to Article 102 (a) TFEU without that a competitive benchmark, against which the unfairness of the pricing policy can be measured through.

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119 See CJEU, Autorītesibu un komunicēšanās konsultāciju aģentūra, supra n. 75, paras. 37-38.
120 CMA, supra n. 37, par. 5.165.
121 CMA, supra n. 37, para. 5.359. At para. 5.344 the CMA cites the Sirena case affirming that “[t]he Court of Justice has also recognised that absent some objective justification a ‘particularly high’ excessive price may be a ‘determining factor’ in assessing whether a price is also unfair”. Also, at para. 5.353, the CMA affirmed that in Albion Water II the Competition Appeal Tribunal (CAT) held that “the very excessiveness of a price could be sufficient to establish that the price bears no reasonable relation to the economic value of the product/service being provided”.
122 See CJEU, 11 September 2014, in case C-67/13 P, Groupement des cartes bancaires (CB) c. European Commission par. 53. See also the AG Wahl’s opinion on the case, paras. 58 e 60.
123 See the AG Wathelet’s opinion on the case C-373/14 P Toshiba Corporation c. European Commission, para. 67.
a comparative approach, is necessarily found. This would be possible when, already in light of the nature of the involved goods and of the conditions of functioning and structure of the market, the price increase appears clearly unjustified. The two cases at hand seem to satisfy this condition: the involved products bore some characteristics whose peculiarity in fact played an important role in the two authorities’ heavy reliance on the price-cost test. In essence, the fact that the Cosmos drugs and the PSFHC were both old products, whose R&D investments were already recouped, and that the companies did not make any investment in the improvement of production and/or distribution, made the price-cost test alone sufficient to prima facie ascertain the unfairness of prices.

One may object that the Aspen and the Flynn cases are exceptional, since the disproportion between the benchmark price and the applied price was quite striking, and that normally the difference is not such that the price-cost test alone can be considered complete. Certainly, as much as the notion of restriction by object is of strict interpretation, the proposed sort of “truncated rule of reason” to the analysis of unfair prices under Article 102 TFEU would be appropriate in cases having features similar to those hereby examined. Such a proposal does not exclude the application of other methodologies. Quite to the contrary, the robustness of the outcome of the price-cost test should be preferably always cross-checked.

The combination of methods does not seem to be an obligation for competition authorities stemming from the Court of Justice’s case law: the Court has, in fact, required a completion of the method used only when the price-cost test is applied, since, as already mentioned, the latter is commonly thought not to be a comprehensive method. However, based on the view hereby supported that the price-cost test by itself can also be comprehensive, it seems more appropriate to go beyond the wording of United Brands and to interpret the requirement of the two-prong test as an indication of the necessity of combining several methods.

This view has been echoed recently by the Advocate General (AG) Wahl in his Opinion in the Latvian copyright collective society case, where he proposed the combination of methods as the “most perfect of imperfect solutions” to the practical difficulties that an antitrust authority might encounter in establishing whether the applied prices are unfair (although the Court of Justice seemed to distance itself from this approach in the subsequent decision on the same case), and, as above described, also followed in both the Aspen and the Flynn decisions, as well as previously in other national cases where the two-prong United Brands test was substituted by a “preponderance-of-the-evidence” approach.

5. Conclusions

“Is there any such thing as unfair prices?” The AG Wahl answers this question in the recent Latvian copyright collecting society case already mentioned by saying that “a price significantly in excess of a competitive price is more unlikely to occur in markets where there is a sectoral regulator whose task is, inter alia, to fix or control prices charged by the undertakings active in

124 See CJEU, Cartes Bancaires, supra n. 122, para. 58.
125 See Motta & de Streel, supra n. 6. The proposed reading (see supra n. 22) of the United Brands decision can be agreed upon on policy considerations; however, the latter is not supported by the case law of the Court of Justice and by the decisions of the European Commission (cf. Scandlines Sverige, supra n. 26).
126 See AG Wahl, supra n. 27, para. 43, and Motta & de Streel, supra n. 6, at 38. Contra Evans & Padilla, supra n. 4, at 109, and Williams, supra n. 79, at 145.
127 See supra n. 75.
128 See OFT Decision of 30 March 2001, Napp Pharmaceutical Holdings Limited [2001] UK CLR 585; CAT, case 1001/1/1/01 Napp Pharmaceutical Holdings Limited and subsidiaries v Director General of Fair Trading, judgment of 15 January 2002. The OFT relied primarily on a price-cost test and added a price benchmarking (between the hospital and the community segment, in comparison with competitors and in terms of time). See also UK Competition Appeal Tribunal, case No. 1001/1/1/01, Napp Pharmaceutical Holdings Limited and Subsidiaries/Director General of Fair Trading, 15 January 2002, at 397: “in our view those [price and margin] comparisons, taken together, amply support the Director’s conclusions that Napp’s prices were ... well above what would have been expected in competitive conditions.” The quoted definition comes from Evans & Padilla, supra n. 4, at 17.
that sector. (...) [A]ntitrust infringements in those situations should be mainly confined to cases of error or, more generally, to regulatory failures: cases where the sectoral authority should have intervened and erroneously failed to do so."\textsuperscript{129}

In the field of the pharmaceutical legislation governing pricing and reimbursement, public health budgets strive to put the brakes on expenditure strongly affected by high prices for pharmaceutical products, and the likely possibility of undertakings exploiting a monopoly position when facing relatively inelastic demand for medicines has led many countries to regulate prices through a variety of tools.\textsuperscript{130} It is well-known that, being a complex regulatory system, the pharmaceutical sector presents several instances of regulatory gaming. The Aspen and Flynn cases represent emblematic examples of such conducts and show how regulators may find themselves dramatically exposed to the strategic behaviour of dominant undertakings without having the proper means to react in accordance with the sectoral regulation, eventually being incapable of safeguarding the interests they represent. We support the idea that the intervention of competition agencies on excessive prices should be exceptional, but that, consistently with a case-by-case approach, in cases such as those examined in this paper should be deemed as justified.

In any case, the antitrust intervention on prices requires caution and a sound economic analysis. The most controversial issue is the question of which method should be considered the most appropriate in the pharmaceutical sector. We support the idea that a price-cost analysis, although difficult, is the most appropriate methodology from which the assessment should start.

The criterion of reasonableness should generally guide the application of the price-cost test: the Aspen case establishes that, when the dominant company had to agree on a bad deal to acquire the product involved, the resultant economic burden cannot be considered among the costs that were reasonably incurred by that company to deliver the product to the market. The Flynn case, instead, establishes a very important principle in relation to the calculation of the reasonable rate of return, which can be considered as such when it is defined having regard to the interests of the patients and of the NHS first, and by making reference to the objectives pursued by the pharmaceutical regulation. This latter feature of the Flynn decision, in particular, should guide antitrust authorities in cases of enforcement actions targeting pricing policies applied to pharmaceutical products.

In relation to price hikes like those observed in the cases at issue, which specifically relate to old products whose R&D investments have been already recouped and that do not exhibit any particular justification for the high prices, the price-cost test, already comprising also the examination of non-cost related factors, may play a major role within the assessment of unfairness. In other words, when the likelihood of unfairness is in a certain way obvious and there are no plausible justifications for the price increase, the price-cost test may provide a prima facie indication of illegality of such increase, which can be then confirmed by the analysis of the existence of potential economic justifications to it.

The proposed approach should in any case be complemented by the application of other methods. A cross-check analysis is always not only preferable, but necessary to ensure the robustness of the finding of illegitimacy under Article 102 (a) TFEU.

\textsuperscript{129} See Wahl, supra n. 27, para. 39. See also Id., Exploitative high prices and European competition law – a personal reflection, in The Pros and Cons of High Prices, supra n. 6.

\textsuperscript{130} For more details, see OECD, Pharmaceutical Pricing Policies in a Global Market, Health Policy Studies, 2008.