

# Orphan Drugs under EU Competition Law: The Price is not Right

Andrea Parziale\*

### ABSTRACT

In principle, pharmaceutical producers lack the incentives to develop orphan drugs, i.e. medicines intended to treat rare diseases. Regulation (EC) n. 141/2000 addresses the issue, providing orphan drug producers with accelerated approval, tax benefits, and a ten-year market exclusivity period. Today, orphan drug prices are extremely high and are set independently of ordinary pharmaceutical pricing criteria. Consequently, some scholars suggest that a competition law action for unfair prices under Art. 102, let. a, TFEU may be warranted. This paper claims that the prohibition of abuse of dominant position could play a role in reducing orphan drugs' prices. First, it is shown that market exclusivity provides orphan drug manufacturers with a dominant position in their reference markets. Then, the paper applies and adapts the excessive price test developed by the ECJ to orphan drugs. Civil liability could also play a role, by compensating the damages suffered by NHSs. Finally, recent enforcement developments in the EU concerning excessive prices of medicines confirm the potential role of competition law in curbing orphan drug prices.

### KEYWORDS

Competition Law – Orphan Drugs Pharmaceutical Regulation – Pharmaceutical Pricing – Reimbursement Regimes – Abuse of Dominant Position – Unfair Prices – Civil Liability

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\* Ph.D. Candidate, Sant'Anna School of Advanced Studies (Italy).

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## 1. Introduction

*Quod ideo dico quia iustum pretium rerum quandoque non est punctaliter determinatum, sed magis in quadam aestimatione consistit, ita quod modica additio vel minutio non videtur tollere*  
Thomas Aquinas

Orphan drugs, i.e. medicinal products aiming at treating rare diseases, run the risk of being neglected by pharmaceutical companies, as the low demand for these products would not allow pharmaceutical producers to obtain a sufficient return on capital. This may lead to a market failure, where a lack of economic incentives leaves determinate categories of patients without valid therapeutic treatments<sup>1</sup>.

As a result, several legal systems have adopted *ad hoc* incentive regulations<sup>2</sup> to make pharmaceutical companies occupy market sectors that a mere profit-led logic would leave untouched. Such a goal, as we will see *infra*, par. 2, has been pursued via many different incen-

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<sup>1</sup> BERMAN, *Rare Diseases and Orphan Drugs*, London, 2014; HERNBERG-STÄHL and RELJANOVIĆ, *Orphan Drugs: Understanding the Rare Disease Market and its Dynamics*, Cambridge, 2013; *Orphan Drugs and Rare Diseases*, ed. by PRYDE and PALMER, Cambridge, 2014; JACKSON, *Medical Law: Text, Cases, and Materials*, Oxford, p. 510; COTÉ, XU and PARISER, *Accelerating Orphan Drug Development*, in *Nat. Rev. Drug. Discov.*, 2010, 9, p. 901.

<sup>2</sup> CAFAGGI and MUIR WATT, *The Regulatory Function of European Private Law*, Cheltenham-Northampton 2009; FOLLESDALL *et alii*, *Multilevel Regulation and the EU*, Leida, 2008; SCHEPEL, *The constitution of private governance: product standards in the regulation of integrating markets*, EUI, Florence 2003.

tivizing methods, in particular through forms of market exclusivity in favor of the producer. However, empirical evidence (see *infra*, par. 3) shows that pharmaceutical companies, within the fragmented landscape of EU medicine pricing and reimbursement regimes, manage to sell orphan drugs at very high prices, compared to those set for common drugs. As these prices are set independently of ordinary pricing criteria, some legal scholars maintain that this phenomenon might fall under the scope of an abuse of dominant position, consisting in the setting of excessive prices, under Art. 102, let. *a*), TFEU (see *infra*, par. 4).

This paper aims at developing this starting idea, hypothesizing that EU competition law may contribute to reducing orphan drug prices, in an attempt at striking the balance between the general interest in incentivizing pharmaceutical companies to produce drugs for rare diseases and the as general interest in affordable prices for National Health Systems (hereinafter, NHSs).

From this point of view, while par. 5 shows that orphan drug producers hold a dominant position in the relevant reference market, par. 6 reconstructs the test, developed by the EU Court of Justice (hereinafter, EU CJ) case law, according to which a product's price can be deemed abusive "in itself" or compared to competing products' prices. Then, by applying such a test to the case of orphan drugs, the paper identifies several possible lines of intervention for competition law (see *infra*, par. 7 and 8). It will be shown that a "comprehensive" approach to studying orphan drug regulation, in the frame of pharmaceutical regulation at large, may help the interpreter apply the unfair price test to the market sector at issue.

Our hypothesis is that such an approach could pave the way to an action under Art. 102 TFEU in this field. In fact, competition law could impose a reduction in the prices of orphan drugs as well as monetary sanctions having deterrent effects towards both the undertaking and the pharmaceutical industry at large (see *infra*, par. 9). In addition, civil liability could also play a role, by compensating the monetary damages suffered by NHSs due to publicly funded reimbursement of excessive prices (see *infra*, par. 10).

The considerations developed by the article seem to be supported by recent enforcement developments in excessive pricing (and pharmaceuticals) in Italy and at the EU level (par. 11). Eventually, the conclusive par. 12, on one hand, summarizes the results of this analysis, which is conducted with a black letter method and with reference to relevant economic background information<sup>3</sup>. On the other hand, it identifies some research questions that should be furtherly developed.

These reflections are aimed at striking the balance between the need for ensuring the sustainability of public pharmaceutical expenditure and the need for offering sufficient incentives to pharmaceutical production. An excessive reduction in orphan drugs' prices

<sup>3</sup> EFPIA (EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS), *The Pharmaceutical Industry in Figures, Key Data*, 2014; EUROPEAN COMMISSION, *Pharmaceutical Industry: A Strategic Sector for the European Economy*, Bruxelles, August 2014; DING, ELIASHBERG and STREMERSCHE, *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research and Policies*, New York 2014.

could take away any economic interest in producing this kind of products. Rather, the aim of this research line should be to coordinate regulation, competition law, and civil liability to contribute to a more effective protection of patients' health.

## 2. Economic problems of orphan drugs and incentive regulations in the USA and the EU

The lack of sufficient profit motives to develop medicinal products for rare diseases has led several legislators to introduce incentivizing measures.

*In subjecta materia*, the reference model is the US *Orphan Drug Act* (hereinafter, *ODA*)<sup>4</sup>, whose par. 316.3 (b), (10)<sup>5</sup> defines orphan drugs as medicinal products intended to treat diseases concerning less than 200,000 people in the US or a disease that does not offer producers a reasonable expectation that R&D costs will be recovered through the sales of the product in the US market.

The *ODA* provides orphan drug producers with three main incentives. In the first place, federal funds support clinical trials<sup>6</sup>. In the second place, R&D costs benefit from wide tax exemptions<sup>7</sup>. In the third place, producers are granted with a 7-year market exclusivity period starting from the day on which the marketing authorization is issued by the competent public authority (in the US, the Food and Drug Administration, FDA)<sup>8</sup>.

Following the example of the US *ODA*<sup>9</sup>, the EU has established a largely similar legal framework with reg. (CE) n. 141/2000, which defines as "orphan" those drugs intended to treat a condition concerning no more than 1 in 10,000 people in the EU or a condition unlikely to offer sufficient economic incentives with reference to the initial investment [Art. 3, par. 1, let. a), reg. (CE) n. 141/2000]. Moreover, there must not be an already author-

<sup>4</sup> *National Organization for Rare Disorders (v. Rare Diseases and Orphan Products: Accelerating Research and Development*, ed. by BOAT and FIELD, Washington 2011, p. 24).

<sup>5</sup> «Orphan-drug designation means FDAs act of granting a request for designation under section 526 of the act». According to par. 526, (2) *ODA*, «[f]or purposes of paragraph (1), the term "rare disease or condition" means any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made».

<sup>6</sup> Par. 5 (*Grants and Contracts for Development of Drugs for Rare Diseases and Conditions*).

<sup>7</sup> Par. 4 (*Tax Credit for Testing Expenses for Drugs for Rare Diseases or Conditions*). See ROHDE, *The Orphan Drug Act: an engine of innovation? At what cost?*, in *Food Drug Law Journal*, 2000, 55, 1, p. 125-143.

<sup>8</sup> Par. 527 (*Protection for Unpatented Drugs for Rare Diseases or Conditions*). See YIN, *Market incentives and pharmaceutical innovation*, in *Journal of Health Economy*, 2008, 27, p. 1060-1077.

<sup>9</sup> Art. 77-2, *Pharmaceutical Affair Law*, 1993.

ized method of diagnosis, prevention, or treatment for that condition or, if such a method exists, the medicinal product concerned must have a significant impact on those suffering from the abovementioned condition [Art. 3, par. 1, let. *b*), reg. (CE) n. 141/2000]. For a drug to qualify as orphan, the producer ought to submit a request to the European Medicines Agency (EMA). Then the latter, after the positive evaluation of the Committee for orphan medicinal products, submits the dossier to the Commission for the final decision to be adopted. [Art. 5, reg. (CE) n. 141/2000].

The orphan drug marketing authorization is subject to a centralized procedure, which is valid across the EU [Art. 7, reg. (CE) n. 141/2000; whereas n. 7-8, reg. (CE) n. 726/2004]. Orphan drugs are part of the mandatory scope of the centralised procedure (Article 3). In addition, Art. 2, n. 3, reg. (CE) n. 507/2006 allows producers to get the conditional marketing authorization of an orphan drug, if, even in lack of complete clinical data about its safety and efficacy, the conditions provided by Art. 4, reg. (CE) n. 507/2006 are met<sup>10</sup>. Likewise, Art. 14, n. 9, reg. (CE) n. 726/2004 provides that «when an application is submitted for a marketing authorisation in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure». Therefore, if the request is accepted, the deadline for the opinion of the Committee for medicinal products for human use to be issued is reduced from 210 [Art. 6, n. 3, par. 1, reg. (CE) n. 726/2004] to 150 days. It is worth noting that conditional marketing authorization and accelerated assessment are not mutually exclusive.

After the release of the marketing authorization, the main incentive orphan drug producers are provided with is a 10-year market exclusivity. Over this period, under Art. 8, n. 1, reg. (CE) n. 141/2000, the EU and the Member States cannot accept any marketing request for similar drugs treating the same condition<sup>11</sup>. Yet, the EMA can reduce the length of the market exclusivity period to 6 years, on condition that the product concerned is sufficiently lucrative. In addition, producers can ask for scientific advice and protocol assistance to perform clinical trials and develop the drug at issue (Art. 6, reg. (CE) n. 141/2000). Eventually, «medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Community and by the Member States» (Art. 9, reg. (CE) n. 141/2000)<sup>12</sup>.

<sup>10</sup> «a) [T]he risk-benefit balance of the medicinal product, as defined in Article 1(28a) of Directive 2001/83/EC, is positive; (b) it is likely that the applicant will be in a position to provide the comprehensive clinical data; (c) unmet medical needs will be fulfilled; (d) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required ».

<sup>11</sup> EU COMMISSION, Communication n. 4077/2008 (*Guideline on aspects of the application of Article 8(1) and (3) of Regulation (EC) No 141/2000: Assessing similarity of medicinal products versus authorised orphan medicinal products benefiting from market exclusivity and applying derogations from that market exclusivity*).

<sup>12</sup> . T. GAMMIE – C.Y. LU – Z.U. BABAR, *Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries*, in *PLoS One*. 2015 Oct 9; 10(10):e0140002. doi: 10.1371/journal.pone.0140002.

Since these incentive regulations were enacted, orphan drug marketing authorizations have been increasing significantly both in the USA and in the EU<sup>13</sup>.

### 3. Pricing and reimbursement of orphan drugs in the EU: the risk of excessive prices

When an orphan drug enters the market, it is necessary to refer to the applicable pricing and reimbursement mechanisms.

Orphan drug pricing in the EU follows the same rules as common drug pricing. Price and reimbursement are exclusive competence of the Member States. At the European level, dir. n. 105/1989/CEE and dir. n. 2011/24/UE only provide for a general principle of transparency in the negotiations between public authorities and pharmaceutical companies, whereas enforcement of specific rules is reserved to national legislations. From this viewpoint, Member States adopt many different pricing mechanisms, belonging to either a free-price model (such as in Germany) or a fixed-price one (such as in Italy).

Fixed price systems are based on State intervention in drug pricing. For instance, in Italy it is the Italian Agency for Medicinal Products (*Agenzia Italiana del Farmaco*, AIFA) that holds the competence to determine reimbursed drugs' prices through a bargaining process involving producers<sup>14</sup>. Likewise, in the French system prices are fixed or free if the relative drug is reimbursed or not, respectively<sup>15</sup>.

Reimbursement mechanisms are subject to national competence, too. In Germany, for instance, drugs are reimbursed automatically after being granted marketing authorization, besides some exceptions, that do not usually include orphan drugs<sup>16</sup>. The German reimbursement system is based on a reference price mechanism, according to which the amount to be reimbursed is determined based on the prices set for comparable drugs<sup>17</sup>.

<sup>13</sup> *Global Markets for Orphan Drugs*, BBC Research 2010 (<http://www.bccresearch.com/market-research/pharmaceuticals/orphan-drugs-market-phm038c.html>); *Evaluatepharma Orphan Drug Report 2014* (<http://info.evaluategroup.com/od2014-lp-ep.html>); *Global Orphan Drug Market to Reach US\$ 120 Billion by 2018*, in PRNewswire, 7<sup>th</sup> February 2014 (<http://www.prnewswire.com/news-releases/global-orphan-drug-market-to-reach-us-120-billion-by-2018-244195511.html>).

<sup>14</sup> See Italian law 24th November 2003, n. 326; AIFA, *Negoziazione e rimborsabilità*, <http://www.agenziafarmaco.gov.it/it/content/negoziazione-e-rimborsabilit%C3%A0>). GIORGETTI, *Legislazione e organizzazione del servizio sanitario*, Rimini 2010, p. 182; SILANO, *Medicinali di uso umano: aspetti economici, normativi, procedurali e tecnici*, Milan 2001, p. 492; AUTERI, *Il mercato del farmaco. Tra andamenti e prospettive*, Padova, 2013, p. 77; *Eppur si muove: come cambia la sanità in Europa, tra pubblico e privato*, ed. by PELLISERO and MINGARDI, Turin 2010, p. 85; *Disciplina degli acquisti di servizi e beni nelle aziende sanitarie*, ed. by BOTTARI, Rimini 2013, p. 145.

<sup>15</sup> SAUVAGE, *Pharmaceutical pricing in France: a critique*, in *Eurohealth*, 2008, vol. 14, n. 2, p. 6-8.

<sup>16</sup> *Sozial Gesetzbuch*, V, par. 34.1. V. PARIS – E. DOCTEUR, *Pharmaceutical Pricing and Reimbursement Policies in Germany*, 2008, n. 39, OECD Publishing, p. 10 ss. doi: <http://dx.doi.org/10.1787/228483137521>.

<sup>17</sup> HERR and SUPPLIET, *Co-Payment Exemptions and Reference Prices: an Empirical Study of Pharmaceutical Prices in Germany*, HEDGE, York University, 2012, July, p. 4-6. Disponibile su <http://www.york.ac.uk/media/economics/documents/>

However, since an orphan drug, by definition, does not have comparable products, its price is usually fully reimbursed<sup>18</sup>. On the contrary, in France, drugs are reimbursed according to their “medicinal value”, which means that almost all orphan drugs are reimbursed<sup>19</sup>. Finally, in Italy, orphan drugs are usually reimbursed by AIFA, since drugs of this kind are authorized to treat conditions lacking valid therapeutic alternatives<sup>20</sup>.

In sum, while in a minority of Member States pharmaceutical producers can freely set the orphan drug’s price, in the remainder they must bargain with public monopsonies. In addition, NHSs usually reimburse almost all orphan drugs<sup>21</sup>. Consequently, the fact that producers can set very high prices for orphan drugs greatly contributes to the unsustainability of public pharmaceutical expenditure across Europe<sup>22</sup>.

In fact, the relevant regulatory framework provides for an interesting reaction tool. Under Art. 8, n. 2, reg. (CE) n. 141/2000, EMA could reduce the market exclusivity period to 6 years, as long as the product is deemed sufficiently lucrative. However, EU institutions have adopted a self-restraint policy, fearing that the exercise of such a power could curtail the economic incentives to develop orphan drugs. In addition, empirical studies show that, even after the end of the market exclusivity period, there is no potential competition able to drive prices down, given the low level of demand for the product concerned<sup>23</sup>. Therefore, the reduction of the market exclusivity period would prove to be largely ineffective.

#### 4. The role of Art. 102 TFEU: abuse of dominant position

In sum, market regulation alone does not offer sufficiently effective reaction tools vis-à-vis orphan drugs’ extremely high prices. From this standpoint, *Eurordis*, the European organization for rare diseases, in its study *How much is a life worth? How Swedish patients*

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herc/wp/11\_18.pdf.

<sup>18</sup> GARAU and MESTRE-FERRANDIZ, *Access Mechanisms for Orphan Drugs: A Comparative Study of Selected European Countries*, in OHE Briefing, November 2009, p. 6 (<https://www.ohe.org/publications/access-mechanisms-orphan-drugs-comparative-study-selected-european-countries>).

<sup>19</sup> GAMMIE, LU and BABAR, *Access to Orphan Drugs*, see note n. 12.

<sup>20</sup> FOLINO-GALLO, MONTILLA, BRUZZONE and MARTINI, *Pricing and reimbursement of pharmaceuticals in Italy*, in *European Journal of Health Economics*, 2008, 9, p. 305-310.

<sup>21</sup> J.C.P. ROOS *et alii*, *Orphan drug pricing may warrant a competition law investigation*, in *BMJ* 2010;341:c6471, doi: <http://dx.doi.org/10.1136/bmj.c6471> (17th November 2010).

<sup>22</sup> DE VARAX, LETELLIER and BÖRTLEIN, *Study on orphan drugs: phase I – overview of the conditions for marketing orphan drugs in Europe*, Alcimed report n. 26: [http://ec.europa.eu/health/files/orphanmp/doc/pricestudy/final\\_final\\_report\\_part\\_1\\_web\\_en.pdf](http://ec.europa.eu/health/files/orphanmp/doc/pricestudy/final_final_report_part_1_web_en.pdf)).

<sup>23</sup> BRABERS *et alii*, *Does market exclusivity hinder the development of Follow-on Orphan Medicinal Products in Europe?*, in *Orphanet Journal of Rare Diseases* 2011, 6:59, doi:10.1186/1750-1172-6-59.

*fought to have access to a very expensive orphan drug* (May 2008)<sup>24</sup> has shown that common drugs' prices are usually set according to several factors, such as disease prevalence, production costs, molecular complexity, the need for recouping initial investments, and the perceived medical benefit. This study, however, indicates that orphan drugs' prices are set independently of these parameters.

Consequently, some scholars have argued that such a situation could meet the conditions of an abuse of dominant position, consisting in setting excessively high prices, under Art. 102, let. *a*), TFEU<sup>25</sup>.

This paper aims at developing such an idea, hypothesizing that the abovementioned competition law institution, in conjunction with civil liability, could play a role in reducing the excessive prices set for orphan drugs, thus contributing to making public pharmaceutical expenditure more sustainable and patients' health protection more effective.

To this end, the following paragraphs investigate the essential elements required by Art. 102 TFEU, that is a dominant position in the reference market (par. 5) and its abusive exploitation by the undertaking (par. 6).

## 5. Dominant position: market exclusivity and monopoly

To begin with, any dominant position refers to a determinate reference market. The latter notion was first introduced by the EUCJ case law<sup>26</sup>, and then was considered by a Communication issued by the European Commission<sup>27</sup>. This Communication, followed by the subsequent EUCJ case law<sup>28</sup>, states that the relevant market is made up of two different dimensions: the product market and the geographic market. The former includes all goods and services that are interchangeable by consumers. The latter is given by the area in which the good or service is marketed, provided that competitive conditions are comparable. In the orphan drug market, the market exclusivity prevents consumers from carrying out substitutive behaviors, so every orphan drug defines its own product market.

<sup>24</sup> See [http://archive.eurordis.org/article.php?id\\_article=1733](http://archive.eurordis.org/article.php?id_article=1733).

<sup>25</sup> GHEZZI e OLIVIERI, *Diritto Antitrust*, Turin, 2013, p. 199 ss.; MARABINI, *L'abuso di posizione dominante nella giurisprudenza comunitaria*, Turin, 2004, p. 164.

<sup>26</sup> EUCJ, 9 November 1983, C-322/81, *Michelin v. Commission*, in *Racc.*, 1983, p. 3461.

<sup>27</sup> *Commission notice on the definition of relevant market for the purposes of Community competition law*, in *Off. Bull. EC*, C 372, 9th December 1997, p. 5.

<sup>28</sup> EUCJ, 16th May 2000, C-344/98, *Masterfood HB v. Commission*; in *Racc.*, 2000, p. 11369; EUCJ, 24th October 2002, C-82/01, *Aéroport de Paris v. Commission*, in *Racc.*, 2002, p. 9297; EUCJ, 15th February 2005, C-12/03, *Commission v. Tetra Laval*, in *Racc.*, 2005, p. 987; EUCJ, 14th October 2010, C-280/08, *Deutsche Telekom v. Commission*, in *Racc.*, 2010, p. 9555.

The geographic market, instead, spreads to the whole EU territory, since orphan drugs are subject to a centralized marketing authorization (see *supra*, par. 2).

Under Art. 102 TFEU, the dominant position of an undertaking (a) ought to refer to the entire single market or a substantial part thereof (b) and to restrict (either actually or potentially) interstate trade (c).

*Sub* (a), according to the prevailing understanding<sup>29</sup>, the undertaking holds a dominant position in the reference market when it is significantly and durably able to prevent an effective competition or if it can behave independently of competitors and consumers. This ability is usually assessed by measuring the market power held by the undertaking, that is the market share held by the latter<sup>30</sup>. In fact, in the case of orphan drugs measuring market power is not necessary, since market exclusivity incentive prevents an effective competition<sup>31</sup>. In other words, the dominant position of the orphan drug producer in the reference market constitutes a direct consequence of the incentives set out in the relevant EU legislation concerning orphan drugs.

Yet, a dominant position could not be able to effectively restrict competition, if it is not durable or if there is a sufficient level of potential competition<sup>32</sup>.

From the former point of view, one could argue that, in the orphan market, the monopoly period is so limited in time that it cannot warrant a proper dominant position. However, patients are not able to wait for the market exclusivity period to expire, to purchase an orphan drug at a lower price in the future<sup>33</sup>. Therefore, market exclusivity amounts to a relatively durable barrier to free competition<sup>34</sup>.

From the latter point of view, potential competition may have restraining effects on the behavior of a dominant undertaking. However, US empirical studies<sup>35</sup> show that, once the market exclusivity period has ended, competing pharmaceutical companies do not threaten the position of dominant undertakings, given the low demand barrier featuring the market

<sup>29</sup> EUCJ, 14th February 1978, C-27/76, *United Brands Company and United Brands Continental BV v. Commission*, in *Racc.* 1978, p. 207, n. 65.

<sup>30</sup> EU COMMISSION, *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, Communication 2009/C 45/02.

<sup>31</sup> EUCJ, 13th February 1979, C-85/76, *Hoffmann – La Roche & Co. AG v. Commission*, in *Racc.*, 1979, p. 461, n. 39.

<sup>32</sup> G. BRUZZONE, *L'abuso di posizione dominante*, in L. PACE (ed.), *Dizionario sistematico del diritto della concorrenza*, Jovene editore, Napoli 2013, p. 99). 3 EUCJ, 14th February 1978, C-27/76, *United Brands Company and United Brands Continental BV v. Commission*, in *Racc.* 1978, p. 207 ss., par. 122; EC Trib., 23th October 2003, case T-65/98, *Van den Bergh Foods Ltd v. Commission*, in *Racc.*, 2003, II, p. 4662.

<sup>33</sup> J.C.P. ROOS *et alii*, *Orphan drug pricing may warrant a competition law investigation*, in *BMJ* 2010 341:c6471, doi: <http://dx.doi.org/10.1136/bmj.c6471> (17th November 2010), p. 6.

<sup>34</sup> *Ibid.*

<sup>35</sup> SEOANE-VAZQUEZ *et alii*, *Incentives for orphan drug research and development in the United States*, in *Orphanet Journal of Rare Diseases*, 2008, 3:33 (doi:10.1186/1750-1172-3-33); HARACOGLU, *Competition Law and Patents: A Follow-on Innovation Perspective in the Biopharmaceutical Industry*, Northampton 2008, p. 31.

sector at hand.

*Sub* (b), the undertaking's dominant position concerns the entire single market, as the market exclusivity incentive is valid across the EU (Art. 7, reg. (CE) n. 141/2000).

*Sub* (c), for the same reasons, restriction of interstate trade is always possible.

It follows that the market exclusivity incentive provides the undertaking with a dominant position under Art. 102 TFEU. Accordingly, the European Commission could hold the competence to investigate and intervene under Art. 105, n. 1, TFEU.

## 6. Abusive pricing

Turning to the other requirement under Art. 102 TFEU, it is worth noting that, under competition law, the dominant position of an undertaking is not relevant in itself. Art. 102 TFEU provides that competent authorities ought to intervene only when the undertaking abusively exploits such a dominant position. Consequently, otherwise lawful conducts can be sanctioned if they are carried out by a dominant company<sup>36</sup>.

Art. 102 TFEU lists a few examples of abuse of dominant position, including «directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions»<sup>37</sup> [Art. 102, let. *a*), TFEU].

In the event of unfair prices the EU Commission tends to intervene only under exceptional circumstances. In fact, such an action is deemed as an *extrema ratio*, to resort to when market mechanisms alone are not able to drive prices down. For that reason, unfair price investigations are conducted only when the relevant market is featured by high and durable entrance barriers and the undertaking holds a “super-dominant” position there<sup>38</sup>. For the reasons explained *supra*, par. 5, orphan drugs' prices may well fall under the scope of Art. 102, let. *a* TFEU.

Since *United Brands*<sup>39</sup> the EUCJ case law has developed a test to assess prices' “unfairness”<sup>40</sup>.

<sup>36</sup> See the notion of “special responsibility” of the dominant undertaking (EUCJ, 9th November 1983, C-322/81, *NV Nederlandsche Banden Industrie Michelin v. Commission*, in *Racc.* 1983, p. 3461, n. 57).

<sup>37</sup> “Other unfair conditions” may refer to so-called bundling practices (*Genzyme Ltd v. Office of Fair Trading* [2005] CAT 32; GHEZZI and OLIVIERI, *Diritto Antitrust*, p. 247 ss.; EU COMMISSION, decision 24 March 2004, *Microsoft*, (COMP/C-3/37.792); EU COMMISSION, *Competition DG. Pharmaceutical sector inquiry – preliminary report*, 28th November 2008: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary\\_report.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf)). Since the paper focuses on the problem of excessive prices, this aspect will not be furtherly investigated.

<sup>38</sup> EU COMMISSION, *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, Communication 2009/C 45/02.

<sup>39</sup> EUCJ, 14th February 1978, C-27/76, *United Brands Company and United Brands Continental BV v. Commission*, in *Racc.* 1978, p. 207.

<sup>40</sup> ROOS *et al.*, *Orphan drug pricing may warrant a competition law investigation*, in *BMJ* 2010 341:c6471, doi: <http://dx.doi.org/10.1136/bmj.c6471> (17th November 2010); EUCJ, 6th October 1982, C-262/81, *Coditel v. Ciné*, in *Racc.*, 1982, p. 3381; ANAND, *Lucrative niches – how drugs for rare diseases became lifeline for companies*, in *Wall Street Journal*, 15th

According to this test, it is first necessary to determine if the difference between costs and prices is excessive; in case it is so, it is then necessary to assess if the price is unfair “in itself” or compared to competing products (n. 252). In fact, some scholars<sup>41</sup> maintain that the Commission first assesses if the difference between prices and costs is a positive sum, and, if this is the case, then they assess price unfairness<sup>42</sup>. In fact, in its recent opinion, that will be discussed *infra*, par. 11, Advocate General Wahl states that, first, competent authorities have the burden of showing a significant difference between the economic value of the product and its price. Then, it is up to the undertaking to demonstrate that such a difference is not unfair<sup>43</sup>. This is in line with the *SACEM II* precedent<sup>44</sup> and is perfectly reasonable, since public authorities may lack the information needed to assess whether the price exceeding the benchmark value is actually unfair. It is likely that such information is held or at least easily obtainable by undertakings.

A product price can be deemed unfair either in itself or compared with competing products<sup>45</sup>.

In fact, according to the EUCJ case law, the latter method may refer either (a) to the price set by the same undertaking in a different market, for the same product or a comparable one<sup>46</sup> or (b) to the price set by other companies in the same market<sup>47</sup> or in different markets<sup>48</sup>. *Sub* (a), the price set for the same drug in a different national market could be taken as a reference data (see *supra*, par. 3), thus turning the price unfairness issue into a problem of discriminatory pricing<sup>49</sup>. *Sub* (b), as market exclusivity prevents the same product or comparable products from being marketed, a comparison between reference

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November 2005; WHISH, *Competition law*, Oxford, 2009, p. 192 ss.; GHEZZI and OLIVIERI, *Diritto Antitrust* p. 227 ss.; EUCJ, 14th February 1978, C-27/76, *United Brands Company* see note n. 39; *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, [2002] CompAR 13, par. 412-413; *Pricing and the Dominant Firm: Implications of the Competition Tribunal's Judgment in the Napp Case*, in *European Competition Law Review*, 2003, 70, p. 82-86.

<sup>41</sup> *Scandlines Sverige AB v Port of Helsingborg*, par. 122. Commission, decision 11th November 1986, case 226/84, *British Leyland Public Limited Company v Commission*; EUCJ, 10th February 2000, C-147/97, *Commission v. Deutsche Post*, 2010 I-07831.

<sup>42</sup> L. HOU, *Excessive Prices Within Eu Competition Law*, in *European Competition Journal*, 2011, vol. 7, n. 1, p. 61.

<sup>43</sup> A.G. WAHL, *Opinion*, 6th April 2017, C-177/16, *AKKALAA v. Konkurences padome*, ECLI:EU:C:2017:2861, paras 132-136.

<sup>44</sup> EUCJ, 13th July 1989, joint cases 110/88, 241/88 and 242/88, *Francois Lucazeau et alii v. Société des Auteurs Compositeurs et Editeurs de Musique* (SACEM II), in *Racc.*, 1989, p. 2811 ff.

<sup>45</sup> EUCJ, 14th February 1978, C-27/76, *United Brands*, par. 252.

<sup>46</sup> EUCJ, 13th November 1975, case 26/75, *General Motors*, in *Racc.* 1975, p. 1367.; EUCJ, 11th November 1986, case 226/84, *British Leyland v. Commission*, in *Racc.*, 1986, p. 3263.

<sup>47</sup> EUCJ, 29th February 1968, case 24/67, *Parke Davis*, in *Racc.*, 1968, p. 82; EUCJ, 5th October 1988, case C-53/87, *Cicra and A. v. Renault*, in *Racc.*, 1988, p. 6039.

<sup>48</sup> EUCJ, 8th June 1971, case C-78/70, *Deutsche Grammophon*, in *Racc.*, 1971, p. 487; EUCJ, 4th May 1988, *Bodson v. Pompes Funebres*, in *Racc.*, 1988, p. 2479.

<sup>49</sup> MOTTA and DE STREEL, *Excessive pricing in competition law: never say never?*, in MULTIPLE AUTHORS, *The Pros and Cons of High Prices*, Konkurrensverket, Lenanders Grafiska, Kalmar 2007, p. 35.

prices is statutorily made impossible.

As for the former assessment method, the price of a product can be deemed unfair if it has no “reasonable relation” with its “economic value”.

As detailed in *Helsingborg*<sup>50</sup>, the economic value of a product should include both production costs and “non-cost related factors”, *i.e.* factors related to the characteristics of the demand<sup>51</sup>. In *Helsingborg*, the EUCJ held that the economic value of a ferry service had to be assessed considering its production costs as well as the circumstance that it offered a unique, quick transport service to consumers.

In fact, the EUCJ case law sometimes holds that a mere cost-plus approach is sufficient, depending on the features of the reference market<sup>52</sup>.

Each method of assessing price unfairness can be applied using many different tests. Both the Commission and the EUCJ tend to utilize as many different assessment methods as possible, deeming a price unfair only if all tests applied show convergent results<sup>53</sup>.

## 7. Orphan drug pricing

In sum, the price of an orphan drug can be deemed unfair either in itself or compared to the price set for the same product in a different national market.

From the letter point of view, some member States follow a fixed price approach through negotiations between private monopoly and public monopsony.

In a system where a national public regulator operates, is it legitimate to let the Commission carry out an investigation and an action for excessive prices? The issue is not new at all. In fact, the Commission has already opened several procedures for excessive prices in the telecommunication sector, where a national regulator is in charge. However, none of these procedures has resulted in a formal decision either because an agreement was reached or because national regulators had “jurisdiction to act”<sup>54</sup>. In the pharmaceutical sector, no precedents are recorded at EU level. However, two national antitrust causes could be useful to clarify this notion. Firstly, in the British competition law case *Napp Pharmaceutical* an action brought by the national competition authority was considered

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<sup>50</sup> EUROPEAN COMMISSION, decision 23rd July 2004, *Scandlines Sverige AB v Port of Helsingborg*, in *Common Market Law Review*, 2006, 4, p. 1224.

<sup>51</sup> *Ibid.*

<sup>52</sup> MOTTA and DE STREEL, *Excessive pricing in competition law: never say never?*, in SWEDISH COMPETITION AUTHORITY, *The Pros and Cons of High Prices*, Kalmar 2007, p. 39-40.

<sup>53</sup> *Ibid.*

<sup>54</sup> MOTTA and DE STREEL, *Excessive pricing in competition law: never say never?*, p. 31.

legitimate<sup>55</sup>, within a national pricing framework where pharmaceutical prices are indirectly regulated, through the regulation of the profit margin that the producer can acquire<sup>56</sup>. Secondly, in the recent case *Aspen* the Italian Competition Authority (AGCM) has intervened in a national regulatory environment where reimbursed drugs' prices are negotiated between AIFA and producers<sup>57</sup>. These cases show that national agencies, despite having some regulatory powers, do not have "jurisdiction to act" when producers hold a relevant market power. In fact, the (frequent) lack of alternatives and the innovative character of many drugs provide pharmaceutical companies with the power to impose almost any price *vis-à-vis* a relatively weak public counterpart.

Empirical studies show that an orphan drug may have a significantly lower price in fixed price systems than in free price ones. For instance, in some legal systems the price thus bargained is defined as a reasonable price<sup>58</sup>. Therefore, the price set in a fixed price country could constitute a reference value in assessing the (un)fairness of the price of an orphan drug in another national market. However, different prices between different national markets do not automatically prove that the higher prices are unfair, since such a difference can have either positive or negative effects on consumers' wealth<sup>59</sup>. Thus, one should assess on a case by case basis whether the overall effects of price discrimination are beneficial or detrimental to consumers. Yet, in *SACEM II* the EU CJ held that an undertaking selling a given product at a significantly higher price in a determinate market is likely to abuse its dominant position. As a result, it is the undertaking that has the burden to prove that such a difference in price is justifiable considering objective differences be-

<sup>55</sup> «First, as already stated, the PPRS [i.e. the main English drug pricing mechanism] is primarily directed to ensuring that a pharmaceutical company does not exceed the permitted ROC [return on capital] on the totality of its NHS business. The PPRS is not directed to the question whether or not the price of an individual product sold in a market where there is dominance is above the competitive level, which is the essential question in the present case. In our view, the fact that a pharmaceutical company is subject to the PPRS does not, of itself, give that company any kind of exemption from the Chapter II prohibition in general, or from section 18(2)(a) in particular, as regards the prices of individual products. In so far as Napp argues that its prices for MST cannot be excessive under the Chapter II prohibition simply because it is subject to the PPRS, any such argument has, in our view, no foundation in law or logic. In our judgment that argument, and indeed Napp's whole argument based on "portfolio pricing", impermissibly directs attention away from the specific product market 108 which we are required to consider when deciding whether there is an abuse of a dominant position under section 18 of the Act. In our view, it is not appropriate, when deciding whether an undertaking has abused a dominant position by charging excessive prices in a particular market, to take into account the reasonableness or otherwise of its profits on other, unspecified, markets comprised in some wider but undefined "portfolio" unrelated to the market in which dominance exists» (*Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, [2002] CompAR 13, par. 412-413).

<sup>56</sup> DEPARTMENT OF HEALTH, *The Pharmaceutical Price Regulation Scheme 2014*, p. 23 ff.

<sup>57</sup> AGCM, decision n. 26185, 29<sup>th</sup> September 2016.

<sup>58</sup> «[T]he Australian Pharmaceutical Benefit Scheme considers that a reasonable price may be identified by observing the results of bargaining between a monopoly supplier and a monopsony purchaser» (ABBOT, *Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health*, in *UC Irvine Law Review*, vol. 6, issue 3, forthcoming (see: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095&download=yes](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095&download=yes)).

<sup>59</sup> PAPANDROPOULOS, *How should price discrimination be dealt with by competition authorities?*, in *Concurrences*, 2007, n. 3, p. 34-38.

tween the markets at issue and is beneficial to consumers<sup>60</sup>.

As an alternative, a drug's price can be deemed unfair in itself. The main national competition law precedents concerning drugs' prices (*Napp Pharmaceuticals* and *Aspen*) apply many different methodologies both to determine relevant costs and to estimate a "reasonable" profit margin, deeming a price unfair only if all applied tests show convergent results. From this viewpoint, however, pharmaceutical producers can argue that a reasonable relation can be established between the product's price and its economic value. First, from a cost perspective, an orphan drug can have considerable R&D (and production) costs. Second, from a non-cost perspective, purchasers have a high will and ability to buy the product, as they want to avoid more costly alternatives and have huge financial resources at their disposal, respectively. Third, a small and risky market makes it necessary for producers to apply a wide mark-up.

In fact, a comprehensive approach to studying this phenomenon, considering the interactions between orphan drug legislation and pharmaceutical regulation in general, can shed more light on the relation between products' prices and their economic values, thus paving the way to an action under Art. 102, let. a), TFEU.

In the first place, relevant costs are reduced by incentive regulations providing for financial aids and tax exemptions<sup>61</sup> as well as non-monetary advantages, such as the right to early market access and to protocol assistance (see *supra*, par. 3). Moreover, the pharmaceutical industry massively benefits from publicly funded research on rare diseases.

Particularly, early access paths make for a reduction in authorization time and shift human experimentation costs and risks to clinical practice. When a drug is authorized based on incomplete data, patients are practically employed as guinea pigs without being protected by the safeguards and guarantees legally provided for clinical trials. Likewise, participation in compassionate use programs under Art. 83, reg. (CE) 726/2004<sup>62</sup> can help the pharmaceutical producer save money, even though drugs are offered for free<sup>63</sup>, as physicians are burdened with almost all relevant civil liability risks<sup>64</sup>. Also, the undertaking could have just purchased the selling license of an orphan drug from the actual developer and pro-

<sup>60</sup> EUCJ, 13th July 1989, joint cases 110/88, 241/88 and 242/88, *Francois Lucazeau et alii v Société des Auteurs Compositeurs et Editeurs de Musique (SACEM II)*, in *Racc.*, 1989, p. 2811 ff.

<sup>61</sup> FRANCO, *Orphan drugs: the regulatory environment*, in *Drug Discovery Today*, 2013, vol. 18, issue 3-4, p. 163-172; BARAK and NANDI, *Orphan drugs: pricing, reimbursement and patient access*, in *International Journal of Pharmaceutical and Healthcare Marketing*, 2011, 5, 4, p. 299-317; VILLA, COMPAGNI and REICH, *Orphan drug legislation: lessons for neglected tropical diseases*, in *International Journal of Health Planning and Management*, 2009, 24, 1, p. 27-42.

<sup>62</sup> PLATE, *The Impact of Off-Label, Compassionate and Unlicensed Use on Health Care*, *Ibidem*, Stuttgart 2014; SAENZ, *The 'Compassionate Exemption' in Spain: Not Asking for Compassion*, in *Opinio Juris in Compratione*, 2010, vol. 1, Paper n. 1; CUZZOLIN, ZACCARON and FANOS, *Unlicensed and off label uses of drugs in pediatrics: a review of the literature*, in *Fundamental & Clinical Pharmacology*, 2003, 17, p. 125-131.

<sup>63</sup> Under Italian law, see Art. 4, n. 3, ministerial decree 8th May 2003.

<sup>64</sup> Art. 4, n. 2, let. a), *id.*

ducer. In this case, the “high R&D costs” argument, of course, cannot be invoked<sup>65</sup>. In the second place, the characteristics of the demand, such as the high will and ability of the buyer to pay for the product, cannot justify an exorbitant orphan drug price. In fact, orphan drugs are offered by a legal monopolist, who can impose a very high price under the threat that the product will not be offered in the marketplace. Under these circumstances, such an approach is unacceptable, as it allows the producer to set very high prices for essential products by threatening their withdrawal<sup>66</sup>. For this reason, in the orphan drug market and, more generally, in the pharmaceutical market, *non-cost related factors*, such as the characteristics of the demand of the product, should not be invoked to establish a reasonable relation between price and economic value. The recent Italian competition law case *Aspen* confirms this conclusion<sup>67</sup> by observing that generally willingness to pay for medicines without valid alternatives is infinite, which could justify any increase in their price.

Thirdly, few sales makes the producers apply a wide mark-up to recoup initial investments. Yet, physicians can prescribe a drug even for indications different from those specifically authorized by regulators (so called off-label use), provided that determinate conditions are met<sup>68</sup>. From this viewpoint, pharmaceutical companies can utilize pharmacogenetic techniques to select small patient groups fitting the requirements for orphan drug designation. Then, the product is widely sold and prescribed to a far larger audience through off-label uses. This practice, known as *disease stratification* (or *high-tech salami slicing*), is particularly common in oncology<sup>69</sup>. In addition, a determinate drug can receive multiple orphan designations<sup>70</sup>. Under these circumstances, an exorbitant mark-up is not justifiable, given

<sup>65</sup> See the Italian *Aspen* case (AGCM, decision n. 26185, 29<sup>th</sup> September 2016, par. 23).

<sup>66</sup> «The pharmaceutical industry prefers that discussion about price be based on the “value” to healthcare systems in terms of alternatives (...) This type of assessment is essentially a “hostage” bargaining model. The drug is under the control of the monopoly patent owner, and the price of ransoming the drug is whatever the party seeking to obtain it can pay [...] It is only a bargain because of the threat (...) That does not make the value reasonable» (ABBOT, *Excessive Pharmaceutical Prices and Competition Law*, p. 19: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095&download=yes](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095&download=yes)).

<sup>67</sup> AGCM, decision n. 26185, 29<sup>th</sup> September 2016, § 129-137.

<sup>68</sup> CAVALLA, *Off-label Prescribing: Justifying Unapproved Medicine*, Oxford, 2015; GUIDI, NOCCO and DI PAOLO, *La prescrizione off-label: dentro o fuori la norma?*, in *Resp. civ. prev.*, 2010, p. 2165 ss.; LENK and DUTTGE, *Ethical and legal framework and regulation for off-label use: European perspective*, in *Therapeutics and Clinical Risk Management*, 2014, vol. 10, p. 537-546; MASSIMINO, *Recenti interventi normativi e giurisprudenziali in materia di prescrizione dei farmaci off label*, in *Danno e resp.*, 2010, p. 1104).

<sup>69</sup> PULSINELLI, *The Orphan Drug Act: What's Right with It*, in 15 *Santa Clara Computer & High Tech. L.J.*, 1999, p. 332-36; KESSELHEIM *et al.*, *The Prevalence and Cost of Unapproved Uses of Top-Selling Orphan Drugs*, in *PLoS One [Internet]*, 21 February 2012. doi: 10.1371/journal.pone.0031894; FAEH, *A Just Distribution of Health Care in the Case of Orphan Medicinal Products*, in *European J. of Social Security*, 2012, p. 21.

<sup>70</sup> «A single drug can receive multiple orphan designations if it targets multiple distinct niche markets [...] In particular, “[d]rug developers could genetically subdivide diseases that affect a large portion of the population into groups small enough to qualify for orphan drug status”» (GIBSON and LEMMENS, *Niche markets and evidence assessment in transition: a critical review of proposed drug reforms*, in *Medical Law Review*, 22, 2, p. 206). See the interesting example of *Glivec*: <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>; [ec.europa.eu/health/documents/community\\_register/html/](http://ec.europa.eu/health/documents/community_register/html/)

the real size of the relevant market<sup>71</sup>. Moreover, supposed marketing risks are markedly smoothed by the fact that these products are largely purchased and reimbursed by public authorities.

In sum, the price of an orphan drug can be deemed unfair either compared to the price set in a different national market or in relation to an unreasonable difference between price and costs.

Each option has its own advantages and shortcomings.

While comparative assessments can rely on objective reference values, they cannot consider that the lower reference price could be unfair too. Also, compassionate use programs often prevent this kind of referencing. Eventually, an increasing number of Member States is embracing a fixed price system. In contrast, unfairness in itself does not have these limits. Yet, measuring relevant costs is no easy task, and the determination of a just profit margin could prove to be arbitrary (see *infra*, par. 9). In fact, the Commission's Communication of the 3rd June 2013, n. 167<sup>72</sup>, suggests that a reasonable profit margin could be determined by referring to the margins practiced in comparable product markets<sup>73</sup>. It has been shown *supra* that a high profit margin is no longer justifiable if the relevant market is sufficiently large, e.g. though off-label uses. Therefore, the mark-up practiced by the dominant undertaking or by its competitors in selling common drugs with similar costs and sale volumes could represent a useful benchmark.

In addition, authoritative Italian scholars suggest that competition authorities should enrich their analytical tools by drawing on the recent developments in behavioral and cognitive sciences<sup>74</sup>. These authors maintain that, building on the existing literature on consumers' perception of price fairness, additional experimental tools could be envisaged to contribute to the assessment of a price's fairness<sup>75</sup>. Human sentiments about price (un)fairness should be considered as a reflection of unwritten social rules of cooperation rooted in

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xalforphreg.htm.

<sup>71</sup> In a recent opinion, Advocate General H. Saugmandsaard has assessed the relevance of off-label uses to the definition of the reference market, stating that «in the pharmaceutical sector, the content of marketing authorisations for medicinal products is not necessarily decisive in the determination of the relevant product market. In particular, the fact that the marketing authorisation for a medicinal product does not cover certain therapeutic indications does not preclude that medicinal product from forming part of the market for medicinal products used for those indications, provided that it is actually used interchangeably with medicinal products whose marketing authorisation covers those indications. That is true even where there is uncertainty regarding the compliance with the applicable regulatory framework for the prescribing and marketing of medicinal products with a view to their use for therapeutic indications and by methods of administration not covered by their marketing authorisations» (H. SAUGMANDSAARD, *Opinion*, 21<sup>st</sup> September 2017, C-179/16, *F. Hoffmann-La Roche Ltd et alii v. AGCM*, ECLI:EU:C:2017:714, par. 187, n.1).

<sup>72</sup> Practical Guide - Communication on quantifying harm in antitrust damages actions (available at: [http://ec.europa.eu/competition/antitrust/actionsdamages/quantification\\_guide\\_en.pdf](http://ec.europa.eu/competition/antitrust/actionsdamages/quantification_guide_en.pdf)).

<sup>73</sup> *Id.*, par. 111.

<sup>74</sup> ARNAUDO-PARDOLESI, *Sul giusto prezzo, tra Aquino e Aspen*, in *Mercato, concorrenza e regole*, n. 3/2016, p. 479-498.

<sup>75</sup> *Id.*

the evolutionary history of our species<sup>76</sup>. These tests should be complementary to those already applied in the field, under the established “converging results” standard of proof. While showing high analytical potential prospectively, the literature on price perception is still faced with some shortcomings. In fact, despite the importance of price perception, research on the topic is surprisingly limited and yet highly heterogeneous.

The first problem with this literature is that a commonly acknowledged methodology is not yet established, which leads to contradictory results. *E.g.*, while participants to a study regarded as unfair the price remaining high when cost decreased<sup>77</sup>, another study had found exactly the opposite<sup>78</sup>.

Secondly, behavioural and cognitive processes are in themselves subject to distortionary schemes and limitations. For instance, different framings of the same research question can impact the behavior of the subjects, all other things remaining equal<sup>79</sup>. Also, subjects are likely to underestimate information that is difficult to process, even when they are given support (such as additional knowledge)<sup>80</sup>.

Thirdly, the existing literature does not consider two variables that are relevant in the pharmaceutical market as well as in the orphan drug sector. The first variable is the impact of reimbursing mechanisms on price perception: the perception of the fairness of a price is likely to vary depending on whether or not the subject is going to pay directly for the product. The second variable is, at a more general level, the relationship between price fairness perception and willingness to pay: if a subject (either a patient or a NHS) has an “infinite” will to pay for a product, s/he will tend not to deem its price unfair. This way, there is a risk that, through cognitive tools, willingness to pay could surreptitiously enter the price fairness assessment process in a market where demand-side factors should not be considered, as they could automatically justify any increase in price (see *supra*).

In sum, behavioural and cognitive research on price perception could provide for useful indications to determine whether a price is fair or not. However, these methods should be used only in conjunction with traditional economic models. Moreover, the above-

<sup>76</sup> ARNAUDO, *La ragione sociale. Saggio di economia e diritto cognitivi*, LUISS University Press, Rome 2012, p. 141 ff.

<sup>77</sup> HUANGFU-ZHU, *Do consumers' perceptions of price fairness differ according to type of firm ownership?*, in *Social Behavior and Personality: An international journal*, May 2012, 40, p. 693-698

<sup>78</sup> KHAHNEMAN *et alii*, *Fairness and the assumptions of economics*, in *The J of Business*, vol. 59, n. 4, 1986, p. 299.

<sup>79</sup> *E.g.*, the role of the framing bias is clear in a price perception research conducted by KHAHNEMAN *et alii*, *Fairness and the assumptions of economics*, in *The J of Business*, vol. 59, n. 4, 1986, p. 299.

<sup>80</sup> “A series of studies demonstrates that consumers are inclined to believe that the selling price of a good or service is substantially higher than its fair price. Consumers appear sensitive to several reference points—including past prices, competitor prices, and cost of goods sold—but underestimate the effects of inflation, overattribute price differences to profit, and fail to take into account the full range of vendor costs. Potential corrective interventions—such as providing historical price information, explaining price differences, and cueing costs—were only modestly effective” (BOLTON *et alii*, *Consumer Perception of Price (Un)fairness*, in *J of Consumer Research*, March 2003, vol. 29, p. 474). Indeed, it is widely known by cognitive scientists that too much information is in fact no information at all.

mentioned considerations suggest that the methodological validity of already conducted studies should be carefully assessed and the design of future research on the topic should be improved, also considering its compatibility with established rules and standards on excessive prices.

## 8. When market exclusivity expires: the persistent relevance of competition law

The considerations developed in the previous paragraphs could maintain their validity when the producer sets an excessive price after the expiration of the market exclusivity period. However, in this event, competent authorities should measure the market share held by the undertaking, as they cannot refer to market exclusivity anymore (see *supra*, par. 5).

We may assume the hypothesis that, once market exclusivity expires, one or more competitors of the undertaking succeed in developing comparable products, thus driving prices down. Yet, recent cases have shown that competitors are able to manipulate regulatory rights and duties for anticompetitive purposes. An interesting example is the Italian competition law case *Avastin-Lucentis*<sup>81</sup>, where the pharmaceutical companies *Roche* and *Novartis* carried out a particularly sophisticated anticompetitive agreement. Such a strategy was aimed at protecting a product authorized to treat an ophthalmic disease from the competitive pressure coming from the authorization of a competing product prescribed off-label for the very same indication. To this end, the competitor accepted a share in the extra-profits earned by the undertaking through the sales of the product used on-label. In return, the competitor promised not to submit any request for the authorization of the competing prescription and to publicly overestimate the risks associated with the off-label use of the competing product. On one hand, not to submit a request for marketing authorization is perfectly in line with the regulatory framework<sup>82</sup>, but it had no economic meaning, as the product was safely and effectively prescribed off-label by physicians. On the other hand, the spread of information about the risks concerning the ophthalmic use of the competing product was the result of the realization of pharmacovigilance obligations, but in a completely distortionary and selective manner<sup>83</sup>. The Italian Competition Authority held that such a complex strategy had met the requirements of an anticompetitive agreement and an abuse of dominant position. A similar strategy could be carried out to practically extend the market exclusivity period beyond its formal expiration.

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<sup>81</sup> AGCM, 27th February 2014, n. 24823.

<sup>82</sup> Arts. 6 ff., dir. 2001/83/EC and Arts.3 ff., reg. (EC) 726/2004.

<sup>83</sup> Arts. 101 ff., dir. 2001/83/EC; Arts. 21 ff., reg. (EC) 726/2004.

## 9. Effects of competition law remedies and sanctions on orphan drug pricing

It has been shown that very high orphan drug prices may warrant an action under Art. 102 TFEU. This could result in products' prices being reduced and in fines being inflicted to producers.

From the former point of view, determining a product's "fair" price is no easy task, and could have distortionary economic effects. As an alternative, some scholars suggest that regulators should make the market itself more competitive structurally by reducing entry barriers (such as market exclusivity), to make prices lower. This suggestion, however, is not feasible. First, market exclusivity is one of the main incentives for producers to market orphan drugs. Second, removing this incentive would be useless, as low demand prevents competition in the first place. Third, recent EUCJ case law strengthens the market exclusivity barrier<sup>84</sup>. Therefore, no alternatives to "direct" price reduction seem to be left.

The Commission's *Practical guide* to the abovementioned Communication on damages quantification may play a role in determining an orphan drug's "fair" price, that is the price that the producer would have set in lack of anticompetitive behaviors. The *Practical guide* suggests that the investigating authority determine relevant costs and add a reasonable profit margin to them, based on that set for drugs having similar sale volumes. This idea, however, should be furtherly discussed and developed.

From the sanction point of view, the Commission ought to set the fines provided under Arts. 23-24, reg. (EC) n. 1/2003.

In this regard, EU institutions state that fines should have a deterrent effect towards the undertaking and other companies<sup>85</sup>. On the other hand, they concede that «*the use of ever higher fines as the sole antitrust instrument may be too blunt, not least in view of the job losses that may result from an inability to make payments, and calls for the development of a wider range of more sophisticated instruments*»<sup>86</sup>.

Operationally, the 2006 *Guidelines* provide that the Commission should determine the amount of the sanction by quantifying the value of the sales of all relevant goods and services occurred in the last year of the infringement (*Guidelines on setting fines*, § 13). Then, the fine is determined as a percentage (30% maximum) of this basic amount. The percentage varies according to the severity and the duration of the infringement at issue (*id.*, § 19

<sup>84</sup> «[T]he ten-year period of market exclusivity with which an orphan medicinal product is endowed by virtue of Article 8(1) of Regulation No 141/2000 "cannot be curtailed as a result of the fact that there exists an orphan medicinal product which has received marketing authorisation for the same therapeutic indications and which benefits from market exclusivity for those indications"» (EUCJ, 3 march 2016, C-138/15, *Teva Pharma v. EMA and Commission*, par. 39).

<sup>85</sup> EU COMMISSION, *Guidelines on setting fines*, Communication 2006/C 210/02.

<sup>86</sup> EUROPEAN PARLIAMENT, resolution 20 January 2011.

and 21). In assessing the severity of the infringement, the Commission should particularly consider the nature of the infringement, the market share held by the undertaking(s), the geographic area of the infringement, and the actual or potential nature thereof (id., § 22). As an orphan drug producer holds a monopoly throughout the EU and has set an excessive price, the balance tips towards higher rates. In the event of an anticompetitive agreement (see *supra*, par. 8) the proportion of the value of the sales considered for this sanction will be set at the higher end of the scale (id., § 23).

However, if the sale volume is not big enough to make for an effectively deterrent effect *vis-à-vis* the undertaking, then the Commission can increase the fine “to be imposed on undertakings which have a particularly large turnover beyond the sales of goods or services to which the infringement relates” (id., § 30), but not beyond the caps set by the *Guidelines* themselves (id., § 32-33). This provision certainly applies to pharmaceutical companies, whose profits are generally high beyond the sales of (excessively priced) orphan drugs.

Finally, in fixed price systems the bargaining between the producer and the NHS may amount to a mitigating circumstance, as “the anti-competitive conduct of the undertaking has been authorized or encouraged by public authorities or by legislation” (id., § n. 29). However, if the undertaking holds such a market power as to practically force its counterpart to accept any price, such a mitigation should not apply. In fact, if there is no alternative to the product, competent authorities have no ability to “walk away”. Therefore, the competent public institution’s acceptance of such an “offer” should not be considered as an authorization amounting to a mitigating circumstance under § n. 29 of the *Guidelines*.

## 10. The role of civil liability

Competition law remedies and fines are not intended to deal with the issue of compensating the pecuniary damages suffered by NHSs for reimbursing excessively priced orphan drugs<sup>87</sup>.

National competition laws provide that anticompetitive infringements amount to civil wrongs (or torts)<sup>88</sup>. This kind of provisions could not be effectively enforced due to the dif-

<sup>87</sup> CAFAGGI, *A Coordinated Approach to Regulation and Civil Liability in European Law: Rethinking Institutional Complementarities*, EUI Working Paper LAW n. 2005/13, p. 6; COMANDÉ, *Risarcimento del danno alla persona e alternative istituzionali. Studio di diritto comparato*, Turin 1999, p. 369.

<sup>88</sup> In Italy, see Cons. Stato, sez. VI, 12th February 2014, n. 693, in *Rass. dir. farmaceutico*, 2014, p. 336; ALPA, *Appunti sul divieto di abuso del diritto in ambito comunitario e sui suoi riflessi negli ordinamenti degli Stati membri*, in *questa rivista*, 2015, p. 245); in Germany, see par. 33, *Wettbewerbsbeschränkungen*, 2005; in the UK, see, Art. 47a, *Competition Act*, 1998.

faculties inherent in the burden of proof<sup>89</sup>. Yet, dir. n. 2014/104/EU promises to empower plaintiffs *vis-à-vis* those responsible for anticompetitive violations<sup>90</sup>.

As for damages, the directive addresses two main issues.

On the one hand, it describes damages in terms of *damnum emergens*, *lucrum cessans*, and interests, while stating that “full compensation shall place a person who has suffered harm in the position in which that person would have been, had the infringement of competition law not been committed” (Art. 3, n. 2). Therefore, punitive damages as well as any other forms of overcompensation are prohibited (Art. 3, n. 3).

On the other hand, Art. 4 of the directive provides that “Member States shall ensure that all national rules and procedures relating to the exercise of claims for damages are designed and applied in such a way that they do not render practically impossible or excessively difficult the exercise of the Union right to full compensation for harm caused by an infringement of competition law” (so called effectiveness principle). Accordingly, upon the request of plaintiffs, judges can order the defendant or third parties to disclose relevant evidence (Art. 5, n. 1). Moreover, Art. 17, n. 1 of the dir. provides that national courts shall have the power “to estimate the amount of harm if it is established that a claimant suffered harm but it is practically impossible or excessively difficult precisely to quantify the harm suffered on the basis of the evidence available”<sup>91</sup>. Eventually, national courts can ask for assistance from national competition authorities (Art. 17, n. 3)<sup>92</sup>.

In quantifying relevant damages, the competent authority ought to compare the real situation with a non-infringement scenario, with an estimation of a reference non-infringement price. The *Practical guide* attached to the Commission’s Communication of 13th June 2013, n. 167 describes several methods to do so. They include, on one hand, comparative techniques, based on data concerning normal periods of markets not affected by the infringement; and, on the other hand, economic models simulating the counterfactual scenario. In any event, “equitable” estimates will be inherent in such complex assessments. However, these difficulties are widely smoothed in case of a Commission’s decision to reduce an orphan drug’s excessive price. The decision could prove to be helpful in quantifying the pecuniary damages suffered by the NHS concerned. In fact, under Art. 16, reg. (EC) n. 1/2003, «when national courts rule on agreements, decisions or practices under Article 81 or Article 82 of the Treaty [now Arts. 101 and 102] which are already the subject of a Commission decision, they cannot take decisions running counter to the decision adopted

<sup>89</sup> PARDOLESI, *Danno antitrust e (svuotamento dell’) onere probatorio a carico del consumatore*, in *Foro it.*, 2014, I, c. 1729.

<sup>90</sup> MALAGOLI, *Il risarcimento del danno da pratiche anticoncorrenziali alla luce della direttiva 2014/104/UE*, in *Contratto e impr./Eur.*, 2015, p. 390; MARINO, *Alcune novità nel private enforcement del diritto della concorrenza*, *ivi*, 2014, p. 75; SIMONINI, *Causalità nella fattispecie dell’illecito anticoncorrenziale*, in *Contratto e impresa*, 2015, p. 777.

<sup>91</sup> Under Italian law, Art. 17, n. 1 of the directive refers to Art. 1226 Civil Code (equitable measure of damages).

<sup>92</sup> TODINO, *Il danno risarcibile*, in *Annali it. dir. d’autore*, 2015, 1, p. 15 ss.

by the Commission». This way, the difficulties inherent in determining non-infringement prices are shifted from damages compensation to the fine-setting stage.

In fixed price systems, however, systems public agencies contribute to the formation of (reimbursed) drugs. “Price fixing” agencies and “reimbursing” authorities could be seen as different entities or as two expressions of one unitary entity (i.e. the Public Administration), so the former could be considered either as a different tortfeasor or as an auxiliary of the damaged party, respectively. Therefore, a comparative civil liability (or a contributory negligence) of these entities could arise, thus reducing the amount of damages to be paid for by the undertaking. However, comparative liability (or contributory negligence) should be assessed based on the actual contribution of the defendant (or the victim) to the negative consequences of the civil wrong<sup>93</sup>. It has been already noted that in the orphan drug sector the lack of alternatives provides the producer with a strong market power even against a public monopsony, which has no ability to “walk away”. Consequently, in this case the contributions of public entities to price determination should have no relevance under civil liability law.

Secondly, the decision to reimburse an excessively priced orphan drug does not seem to meet the requirements of a consent justifying the harm (*volenti non fit iniuria*). To a large extent, producers’ market power in the orphan drug sector is so high that speaking of a *consensus* of the public counterpart is in fact a myth. Also, on a formal ground, the reimbursement decision expresses no real “consent” on the part of the Administration, which must reimburse a drug automatically if the relevant legal requirements are met.

## 11. Recent enforcement developments in excessive pricing (and pharmaceuticals)

The potential role of competition law in countervailing the current trend towards ever increasing orphan drug prices seems to be confirmed by recent developments in competition authorities’ enforcement practices and by the recent opinion delivered by Advocate General Wahl in an unfair prices case (see *infra*).

As mentioned *supra*, in October 2017 the Italian Competition Authority (AGCM) imposed a fine of about 5 million euros on the pharmaceutical company Aspen for violating art. 102, letter a), TFEU, as the undertaking had fixed unfair prices with increases up to 1500%

<sup>93</sup> “Liability is solidary where the whole or a distinct part of the damage suffered by the victim is attributable to two or more persons. Liability is solidary where: a) a person knowingly participates in or instigates or encourages wrongdoing by others which causes damage to the victim; or b) one person’s independent behaviour or activity causes damage to the victim and the same damage is also attributable to another person. c) a person is responsible for damage caused by an auxiliary in circumstances where the auxiliary is also liable” (Art. 9:101, n. 1, *Principles of European Tort Law*); “Liability can be excluded or reduced to such extent as is considered just having regard to the victim’s contributory fault and to any other matters which would be relevant to establish or reduce liability of the victim if he were the tortfeasor” (Art. 8:101, n. 1, *Principles of European Tort Law*).

for life-saving drugs with no alternatives treating oncological patients<sup>94</sup>. To this end, the company threatened Italian health authorities to withdraw the products from the market should they reject their application to increase prices<sup>95</sup>. Following this decision, the European Commission officially opened an EU-wide investigation into Aspen's pricing strategies for niche oncological medicines<sup>96</sup>. As the commissioner in charge of competition policy puts it in a press release, «when the price of a drug suddenly goes up by several hundred percent, this is something the Commission may look at»<sup>97</sup>. Just like in the Italian case, the Commission has information that the company is making withdrawal threats to national authorities to impose extremely high prices. The behavior of the undertaking might breach art. 102, let. A, TFEU<sup>98</sup>. In addition, the AGCM has conducted a thorough investigation into the human vaccines market, highlighting several anticompetitive risk factors, such as the presence of a powerful oligopoly of four multinationals and severe lack of information about costs and prices<sup>99</sup>. The report states that, while the current trend towards concentrating public demand for vaccines into few purchase centers is positive, information should be more transparent<sup>100</sup>. In fact, a recent editorial about this investigation claims that, while competition should be favored by adopting more transparent procurement mechanisms in the first place, also competition law can play a role in promoting sustainable access to vaccines (and essential medicines)<sup>101</sup>.

The abovementioned opinion of Advocate General Wahl is interesting for our purposes too. It is about a case concerning the Latvian collecting Society for the public performance of musical works. This authority, which enjoys a legal monopoly, was fined by the national competition council for abusing its dominant position, by applying excessive rates in comparison with those applicable in Estonia and in other Member States<sup>102</sup>. The administrative proceeding that followed has led the Latvian judges to ask several preliminary questions to the EUCJ about the application of Art. 102, let. a, TFEU<sup>103</sup>. The case is relevant to potential competition actions in the orphan drugs market too, as it concerns a legal monopoly imposing extremely high prices, where there are difficulties in determining the economic

<sup>94</sup> AGCM, decision n. 26185, 29<sup>th</sup> September 2016.

<sup>95</sup> *Ibid.*, par. 354 ff.

<sup>96</sup> EUROPEAN COMMISSION, *Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines*, Press release, Brussels 15<sup>th</sup> May 2017 ([http://europa.eu/rapid/press-release\\_IP-17-1323\\_en.htm](http://europa.eu/rapid/press-release_IP-17-1323_en.htm)).

<sup>97</sup> *Ibid.*

<sup>98</sup> *Ibid.*

<sup>99</sup> AGCM, *Indagine conoscitiva relativa ai vaccini per uso umano* (ICE 50) ([http://www.agcm.it/component/joomdoc/allegati-news/IC50\\_testo.pdf/download.html](http://www.agcm.it/component/joomdoc/allegati-news/IC50_testo.pdf/download.html)).

<sup>100</sup> *Ibid.*, p. 98 ff.

<sup>101</sup> PITRUZZELLA - ARNAUDO, *Vaccini, mercati farmaceutici e concorrenza, in una prospettiva (anche) di diritti umani*, in *Italian Journal of Legal Medicine*, 2017, vol. 1, pp. 1 ff.

<sup>102</sup> A.G. WAHL, *Opinion*, 6<sup>th</sup> April 2017, C-177/16, *AKKALAA v. Konkurences padome*, ECLI:EU:C:2017:286, paras 8-12.

<sup>103</sup> *Ibid.*, paras 13-14.

value of the product and its relationship with the price thereof. To this end, the Advocate General reconstructs the *United Brands* test as a two-step assessment.

As underlined *supra*, the first step is to determine if there is a significant and persistent difference between the actual price of the product and the benchmark competitive price<sup>104</sup>. Fixing the latter is no easy task. Therefore, the Advocate General acknowledges that as many different methods as possible should be applied<sup>105</sup>. If these methodologies are not flawed in themselves, a convergence of result may be an indicator of the possible benchmark price<sup>106</sup>. So far, the opinion Advocate General is consistent with the case law and administrative practices on unfair prices, as reconstructed *supra*. Then, he indicates some criteria that competent authorities should use in choosing the methods to assess the excessive character of a given price. In particular, the methods should be appropriate, correct, and sufficient<sup>107</sup>.

In par. 7 two methods were selected that might be used to assess orphan drugs prices, namely a comparison between different geographical markets and with reference to the profit margins applied to products with similar cost and sale volume characteristics. Both are likely to pass the test purported by AG Wahl. First, they are appropriate, as they are supported by the communication of the Commission on antitrust damages quantification<sup>108</sup>. Second, they are correct if they make use of data selected according to objective, appropriate and verifiable criteria. For instance, price comparison across the EU is correct only if reference is made to Member States sharing similar characteristics. Third, they seem to be sufficient to establish the benchmark price, since they use relatively objective data (e.g. prices fixed in other countries, production costs, profit margins of comparable products).

Finally, according to the AG, additional indicators should be considered. For instance, the presence of a sectoral regulator and of a powerful buyer makes unfair prices more unlikely to occur<sup>109</sup>. In the orphan drug sector, national and European regulators play a role and usually businesses bargain price and reimbursement issues with public monopsonies. However, it was shown *supra* (par. 7) that even these important players are not able to effectively countervail the market power held by producers.

<sup>104</sup> Theoretically, any price above competitive levels yields an inefficient allocation of resources and reduces consumers' welfare. However, this does not imply that an action under Art. 102, let. a, TFEU is always warranted. First, calculating the competitive price is a complex and uncertain task. Second, and consequently, it is difficult for undertakings to estimate in advance the borderline between competitive and excessive price. Third, a strict approach would result in competition authorities becoming price regulators. Therefore, an action under Art. 102, let. a, TFEU should be warranted only if the price exceeds significantly and persistently the benchmark price (*ibid.*, paras 101-106).

<sup>105</sup> *Ibid.*, paras 36-42.

<sup>106</sup> *Ibid.*, paras 43-45.

<sup>107</sup> *Ibid.*, paras 57-80.

<sup>108</sup> *Practical Guide - Communication on quantifying harm in antitrust damages actions*, par. 111.

<sup>109</sup> A.G. WAHL, *Opinion*, 6th April 2017, C-177/16, *AKKALAA v. Konkurences padome*, ECLI:EU:C:2017:286, paras 49-50.

## 12. Conclusions

Conclusions are devoted (a) to summarize the results of the analysis that has been conducted so far and (b) to indicate possible research lines to be furtherly investigated.

*Sub* (a), an orphan drug's price could be deemed unfair under Art. 102, let. a, TFEU if a discriminatory pricing takes place among different national markets or there is no reasonable relation between the product's price and its economic value. Regulatory benefits and incentives should be considered in determining relevant costs. Also, in assessing the reasonableness of the profit margin, competent authorities should not neglect the fact that producers can expand an orphan drug's market in many ways. Each method to assess price unfairness utilizes many different estimate methods. In line with EUCJ case law and Commission decisions, the burden of proof under Art. 102, let. a, TFEU shall be satisfied only if all the methods applied show convergent results. Finally, fines and civil damages should not be reduced considering the role of public authorities in fixing prices and reimbursing drugs, since the undertaking holds a "super-dominant" position in the market. *Sub* (b), further interdisciplinary disciplinary investigation on the matter should focus on the following issues.

Firstly, the conditions under which different prices across different national markets may amount to discriminatory pricing should be clarified.

Secondly, in assessing the (un)fairness of a price in itself, difficulties inherent in quantifying relevant costs and a reasonable profit margin could be furtherly smoothed by referring to the law and economics literature about Art. 102, let. a, TFEU, which translates the issue of determining the "fair price" of a product into that of determining its competitive price. From this point of view, the role of simulation techniques should be discussed and investigated.

Thirdly, cognitive research on price perception could be a useful complementary tool to assess prices' (un)fairness; yet, the limited and heterogeneous existing literature on the topic should be read critically to assess their validity and improve the design and methodology of future studies.

