

**Addressing high prescription drug price increases in EU and U.S.  
pharmaceutical markets: which role for antitrust policy?**

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1. Introduction

The pharmaceutical sector always constitutes a fertile topic of study of several areas of law. Being an innovative and high-technology industry representing a significant part of the global economy and essential to public health, different concurring and conflicting interests within this sector coexist. On the one hand, the essential function carried out by the pharmaceutical activity for human health has led to the creation of a largely sectoral and particularly pervasive regulatory system, although there are differences between States, which covers all the steps of the production and distribution systems of the pharmaceutical product. Regulation by governments in this sector may be aimed at maintaining a high quality of pharmaceutical products, including their safety, efficiency and efficacy, and making them affordable by negotiating prices and setting up health insurance schemes, while promoting innovation and medical research. On the other hand, the development of new products implies very high costs - generally sustained by so-called originator companies and including the uncertainty regarding trials and the successful results in terms of safety and efficacy - and this has rendered necessary the creation of a legal framework of safeguards and incentives, typically in the form of barriers to entry through the tools provided by intellectual property (IP) law, but also through other regulatory exclusivities.

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The problem of high pharmaceutical drug prices is a permanent object of global political debate. Nowadays this debate encompasses many different types of drugs, from innovative products and biologics to generic ones. The existence of a stifling regulation is a traditional complaint by pharmaceutical companies, which justify the high prices of their products as a result of their compliance with regulatory requirements and of the high costs sustained in research and development (R&D), although this argument is controversial and challenged in literature and political debate. Moreover, the cost of developing a drug is generally considered very difficult to determine.

Antitrust enforcement has traditionally targeted anticompetitive behaviour in this sector, as evinced by the large amount of case law concerning the struggle of market entry between originator companies and manufacturers of generic drugs. However, recent antitrust investigations in the European Union (EU) have called attention to a different type of conduct, i.e., the imposition of excessive prices. Such investigations have surprisingly raised attention also in the United States (U.S.), where particularly controversial cases and discussions on appropriate measures addressing high drug pricing are a hot topic in the current policy debate.

This paper is structured as follows. First, the paper will analyse the rules governing market access, pricing and reimbursement in order to illustrate how regulation affects the way drug prices are set. This constitutes an area where clear divergences may be found, considering that in the U.S. no price regulation exists, whereas in the EU, generally at national level, Member States operate price controls on prescription drugs through different reimbursement schemes.

The paper will focus on price hikes due to exploitative conduct and will examine the approach adopted by competition agencies in the EU in their investigations addressing extraordinary price increases in the pharmaceutical sector, where the most known cases have regarded old off-patent drugs and post-acquisition strategies. Then, the U.S. context will be analysed, taking into consideration the renewed discussion on the appropriate way to deal with high prescription drug prices also from an antitrust perspective. Up to now, several initiatives outside of the antitrust scope aimed at addressing the problem of high prices, including bills proposing rate setting and price gouging practices, have been considered at State level in the absence of a unified federal approach. However, there is debate whether the appropriate remedy to such types of conduct should be found in the

sector-specific regulation, or instead, would require the intervention of antitrust agencies. On the one side, the Federal Trade Commission (FTC) and Department of Justice (DoJ) have reaffirmed that antitrust law does not recognize excessive pricing as an antitrust violation, and that the FTC and Food and Drug Administration (FDA) are working together to improve access to affordable drugs, including finding ways to keep drug companies from gaming the regulatory system to deter generic and biosimilar competition.<sup>1</sup> On the other side, 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 agency intervention in the wake of the European experience, claiming that the excessive pricing doctrine should be incorporated in the U.S. antitrust arsenal. Moreover, recent changes under the Biden administration suggest a reconsideration of traditional stances. Finally, this paper aims to analyse such experiences to evaluate which approach would be the most consistent to deal with extraordinary price increases in the pharmaceutical markets, and to discuss which role antitrust enforcement agencies may assume.

## 2. Market access and pricing and reimbursement policies in the European pharmaceutical market

An understanding of the regulatory framework governing pharmaceutical markets is fundamental in order to comprehend the peculiar features of this sector and behaviour of firms operating within such market.

Regarding market access, both the U.S. and EU rules require as an essential prerequisite for a medicinal product an approval by the competent authority. However, there are some important differences between these two systems.

In the EU, a drug may be placed on the market of a Member State only after the issuance of a marketing authorization (MA) by competent authorities upon request of the pharmaceutical company. Pharmaceutical companies may apply for a national

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<sup>1</sup> See United States note for OECD Roundtable, *Excessive Pricing in Pharmaceutical Markets*, 2018, DAF/COMP/WD (2018)111, at 12-13.

authorization within the concerned Member State, or for Union authorization, for which three methods are set: the centralized procedure (CP), which is used to obtain a marketing authorization valid in all EU countries, the mutual recognition procedure (MRP), and the decentralized procedure (DCP) - both concerning applications for authorization in more than one Member State. In addition, a national procedure, i.e., a country-specific approval scheme, exists at the State-level.<sup>2</sup> The submission strategy for a given product depends on the nature of the product, the target indications, the history of the product, and the marketing plan. In particular, the CP procedure is mandatory for biotechnology medicinal products, orphan medical products and products containing new active substances for the treatment of specific diseases, while it is optional for other products containing new active substances, products which constitute a significant therapeutic, scientific, or technical innovation or products for which the granting of an authorization would be in the interest of patients or animal health at Union level.<sup>3</sup> The applications are submitted to the European Medicines Agency (EMA) and evaluated by the Committee for Medicinal Products for Human Use (CHMP). Once granted, the MA is valid for five years and may be renewed based on the Agency's risk-benefit analysis upon application by the holder at least six months before the MA expires.<sup>4</sup> The refusal of a Community MA constitutes a prohibition on placing the medicinal product on the market throughout the Community.<sup>5</sup>

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<sup>2</sup> See Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, 67, and subsequent amending legislation; and Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, 1, and subsequent amending legislation. It is worth mentioning that specific rules are set out for Paediatric Use Marketing Authorisation by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 378, 27.12.2006, 1. In addition, Article 6(1) second subparagraph of Directive 2001/83/EC provides that when a medicinal product has been granted an initial marketing authorisation, any additional strengths, pharmaceutical forms, administration routes, presentations as well as any variations and extensions must also be granted an authorisation or be included in the initial marketing authorization: all these marketing authorisations are considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10 of the Directive, which lays down rules on data exclusivity and market protection.

<sup>3</sup> See Article 3(1) and (2) of Regulation (EC) No 726/2004.

<sup>4</sup> See Article 14 of Regulation (EC) No 726/2004.

<sup>5</sup> See Articles 12 (2) and 37(2) of Regulation (EC) No 726/2004. With regard to the other two procedures, they both concern the applications for MA in more than one Member State. National procedures have been harmonized by Directive 2001/83. The applicant must submit an application containing the same information required for the CP to the competent authorities of each of the Member States where MA is sought. Through the MRP, manufacturers which have previously obtained MA in a Member State, so called Reference Member State (RMS), can apply for its recognition in the other given Concerned Member States

Legislation also provides the possibility of requesting conditional MAs for drugs aiming at the treatment, prevention, or medical diagnosis of seriously debilitating or life-threatening diseases, or to be used in emergency situations in response to public health threats, and for orphan drugs.<sup>6</sup>

When a MA is requested for a generic product of a previously authorized drug, the applicant may file a so-called “abridged” application, exempting them from the requirement of proving safety and efficacy. A generic product is defined by EU legislation as “a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies”. In this case the EMA relies on the tests and trials for the reference product only after the expiration of the data exclusivity period of the reference product itself. An abridged application is also provided in the case of biosimilar applications (“similar biological application”).<sup>7</sup>

Apart from what happens with regard to marketing approval, the pricing and reimbursement of pharmaceutical products is not harmonized on a European level. The lack of a single pricing competence at the Community level has been viewed and criticized as a factor leading to a less competitive and robust pharmaceutical market.<sup>8</sup> 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 pharmaceutical trade within the Internal Market.<sup>9</sup> As a result, there are different health system schemes

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(CMSs). The DCP addresses the cases where a product has not been granted MA at the time of application. The different national applications must be based on an identical dossier, in the case of MRP as well as in the case of DCP, which rely on the principle of mutual recognition and thus provide that assessment on the medicinal product for the grant of an MA is only conducted by one Member State (the RMS).

<sup>6</sup> Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council, [2006] OJ L 92/6, Articles 4-7.

<sup>7</sup> Abridged applications (generic, hybrid, biosimilar) are regulated by Article 10(1), (2), (3) and (4) of Directive 2001/83.

<sup>8</sup> See A. R. Young, *Generic Pharmaceutical Regulation in the United States with Comparison to Europe: Innovation and Competition*, 8 WASH. U. GLOBAL STUD. L. REV. 165, 167 (2009).

<sup>9</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40, 11.2.1989, 8-11.

and rules between Member States. Moreover, each country may evaluate in a different manner the importance of a specific drug or have different priorities in treating diseases. Other factors that lead to price differences are the approaches adopted to regulate wholesale and retail distribution and the taxation of pharmaceuticals, in particular value added tax (VAT).

In most EU Member States, reimbursable medicines and prescription-only medicines are typically subject to a form of price control, apart from in a small number of European countries applying price control to all medicines,<sup>10</sup> so that there is a close linkage between pricing and reimbursement. In general, national health systems are funded by taxpayers and act as the main or sole payor (monopsonist) for prescription drugs (e.g., the dispensing pharmacies are reimbursed by the National Health Service (NHS) when fulfilling prescriptions covered by national reimbursement scheme). In some countries, patients or their insurers may be required to pay fixed charges or co-payments, e.g., for a prescription. Moreover, as pricing policies can be focused on specific groups of medicines (e.g., on-patent or off-patent medicines), or can target a specific sector or setting (e.g., hospital or outpatient) and may be applied as a sole, dominant, or supplementary policy for defined medicines, several pricing policies can be used in parallel within a country.

In general, the two main criteria used to regulate prices are internal referencing or benchmarking, and external price referencing or international reference pricing. Other criteria can include the regulation of prices based on cost, and regulation of profit or return on capital.<sup>11</sup> Internal benchmarking is based on the comparison of the price of the new drug to the price of one or more established medicines in the same class, including consideration of further relevant factors such as potential mark-ups for improved outcomes or superior value of the new product.<sup>12</sup> External referencing caps the price of a

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<sup>10</sup> Pharmaceutical pricing and reimbursement information (PPRI) is the name of one flagship project of GÖG Pharmacoeconomics Department. All information and documents are available at <https://ppri.goeg.at/index.php/>. Data used in this section are contained in PPRI Report 2018, available at: [https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI%20Report2018\\_2nd\\_edition\\_final.pdf](https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI%20Report2018_2nd_edition_final.pdf) (see p. 25).

<sup>11</sup> For an overview, see P. M. Danzon, *Regulation of Price and Reimbursement for Pharmaceuticals*, in P. M. DANZON & S. NICHOLSON (EDS.), *THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY*, OUP 2012, 266, 276.

<sup>12</sup> A particular case of internal benchmarking is reference price reimbursement (also called reference pricing, RP), according to which products are clustered for reimbursement based on either the same compound (generic RP) or different compounds with a similar mode of action or the same indication (therapeutic RP): all products in a group are reimbursed at the same price per daily dose and the reference

new drug in a specific country to an average, median, or minimum price of the same drug in selected other countries, thereby limiting the ability of manufacturers to discriminate in prices offered across countries.<sup>13</sup>

In the case of originator pharmaceuticals, most Member States adopt external price referencing (EPR).<sup>14</sup> The reference price is the lowest price - or an average of the lowest prices - in a basket comprising the selected countries, and EPR is used as a means to set a maximum price for a pharmaceutical product. EPR may be either applied at the launch of new medicines, where an average price rule is followed, or on an ongoing basis, where the use of a lowest price rule can result in price reductions over time.<sup>15</sup> In several European countries, regulation provides for statutory pricing, i.e. setting the price on a regulatory basis, accompanied by negotiations between healthcare bodies of Member States and manufacturers, which are particularly relevant with regard to reimbursement policies and possible discounts.<sup>16</sup>

Differences among Member States also exist regarding the pricing of generic products. The main pricing policy approach is based on linking generic prices to the originator price, a form of internal price referencing, but it is not applied in a consistent way across the EU (e.g., as seen in the range of price reductions required for first generic and subsequent products). Such a price linking policy is also applied to biosimilars, but less frequently.<sup>17</sup>

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price is set at the price of the lowest or a relatively low-priced product in the group. This model limits reimbursement but not the ability of the manufacturers to charge prices above the reference price, in which case patients must pay any excess.

<sup>13</sup> Danzon, *supra* note 11, at 283 et seq.

<sup>14</sup> See PPRI report, *supra* note 10, at 28.

<sup>15</sup> Even if EPR is a common cost-containment tool, it has received several critiques claiming that it is an arbitrary measure targeting prices that does not take into consideration other aspects of the market and the health priorities of each country concerned, creating also uncertainty for the industry, especially due to the impact of exchange rate fluctuations on reference prices. European Parliament, *Differences in costs of and access to pharmaceutical products in the EU*, 2011, p. 36, available at <http://www.europarl.europa.eu/document/activities/cont/201201/20120130ATT36575/20120130ATT36575EN.pdf>. EPR is also debated in economic literature. Among the most recent papers, see L. Maini & F. Pammolli, *Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market* (April 9, 2020), available at <https://ssrn.com/abstract=3694471>.

<sup>16</sup> S. Vogler & J. E. Martikainen, *Pharmaceutical Pricing in Europe*, in Z.-U.-D. BABAR (ED.), *PHARMACEUTICAL PRICES IN THE 21ST CENTURY* (Springer 2015), 343, 352.

<sup>17</sup> Other policies are available, including e.g. cost-plus pricing, which is not frequently used anymore, value-based pricing in outpatient sector and tendering in hospital sector. For details, see PPRI, *supra* note 10, at 33 et seq.

Different criteria may guide decision-making on pharmaceutical reimbursement, including the therapeutic benefit of a medicine, medical need, and financial considerations such as budget impact and cost-effectiveness.<sup>18</sup> Among the various tools complementary to the pricing mechanisms discussed earlier, the following must be considered: i) positive/negative formulary, i.e. a list of all pharmaceuticals that health insurance may reimburse, and if so, by how much; ii) internal reference pricing, frequently used to regulate off-patent drug prices, by which health insurance uses generic prices within a market – usually the lower-priced generics – to set a maximum reimbursement level for a particular product that has generic alternatives, the maximum reimbursement level called the reference price;<sup>19</sup> iii) health technology assessment (HTA),<sup>20</sup> introduced by an increasing number of Member States in pricing and reimbursement settings whereby the costs and benefits of a new drug are weighed against those of an existing therapeutic alternative; iv) performance-based and risk-sharing agreements, including different mechanisms to set the reimbursement price for new and expensive medicines with the aim of protecting insurers while enabling patients to have access to innovative medicines under certain circumstances. It is worth mentioning that HTA is used by many States to guide both their reimbursement and pricing decisions, and that at Community level, where there has been joint work within the European network for health technology assessment (EUnetHTA), a legislative proposal has been advanced with the aim of introducing a Regulation on Union-level HTA cooperation.<sup>21</sup>

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<sup>18</sup> In many countries the MA holder is required to submit an application dossier if it intends its medicine to be considered for reimbursement and scientific evidence on the medicine's benefit is commonly appraised by an independent expert committee tasked to advise decision-makers on reimbursement.

<sup>19</sup> Thus products whose price exceeds the reference price are either not reimbursed, or the patient has to pay the difference between the reference price and the actual price of the product out of pocket.

<sup>20</sup> Health technology assessment (HTA) is an evidence-based process that independently and objectively assesses a new or existing technology and compares it with other health technologies and/or the current standard of care. It may include medicinal products, medical devices or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare. HTA is primarily used to inform decision-making in Member States by providing a scientific evidence base for decisions on the pricing and reimbursement of health technologies.

<sup>21</sup> European Commission, Proposal for a regulation of the European parliament and of the council on health technology assessment and amending directive 2011/24/EU, COM (2018) 51 final 2018/0018 (COD). This proposal is currently under discussion. At EU level, cooperation on HTA has been ongoing since the 1980s and has led to three Joint Actions (EUnetHTA JA). The third one, launched in June 2016, has focused on developing common assessment methodologies, piloting and producing joint clinical assessments and full HTA reports, and on developing and maintaining common ICT tools. In addition, following the adoption of the Cross-Border Healthcare Directive (Directive 2011/24/EU), the HTA Network was established in 2013 to provide strategic and political guidance to the scientific and technical cooperation at Union-level.



In addition to the supply-side practices described above, pricing policies generally include demand-side practices with the aim of enhancing the uptake of generics, off-patent, and lower-priced medicines. Such practices are typically directed toward: doctors, requiring their prescribing by INN (International Non-proprietary Name, identifying pharmaceutical substances or active pharmaceutical ingredients) rather than by brand;<sup>22</sup> to dispensing pharmacists, such as through substitution laws, which entitle them to substitute a medicine with an equivalent cheaper version; and to patients, as many States provide for co-payments of outpatient medicines or other forms of cost sharing.<sup>23</sup>

National decisions on pricing and reimbursement have strong consequences, as they influence not only the accessibility and affordability of drugs, but also decisions by pharmaceutical companies on whether to market their products in a given country. As Member States often set pricing and reimbursement levels on the basis of those present in other Member States, it may be profitable for companies to commercialize their product first in a Member State that would afford the highest price or reimbursement level. This allows companies to influence prices in several States by putting forward the higher price already approved in those first countries, but also can lead to differences in market access across the EU, as apparently high-income Member States (such as Germany) gain access to pharmaceutical products before smaller States.

Two national systems are worth mentioning, the German and French ones, as they are currently of attention within the U.S..<sup>24</sup> In Germany, most people get health coverage from statutory health insurance (SHI), provided by numerous competing, not-for-profit, self-governing sickness funds, covering a basket of goods and services defined at the national level by law, general principles, and the Joint Federal Committee (*Gemeinsamer*

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<sup>22</sup> Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.

<sup>23</sup> According to PPRI report, among the three types of co-payments, the most commonly used is percentage co-payment, followed by prescription fees charged on reimbursable medicines and finally deductibles. Also combinations of different types of co-payments for outpatient medicines are possible being the mix of percentage co-payments and a prescription fee the most commonly applied one. States also have mechanisms in place to exempt and charge lower co-payments for some medicines and defined population groups. See PPRI report, *supra* note 10, at 48-53.

<sup>24</sup> See V.C. Raimond, W.B. Feldman, B.N. Rome & A.S. Kesselheim, *Why France Spends Less Than the United States on Drugs: A Comparative Study of Drug Pricing and Pricing Regulation*, 99 (1) THE MILBANK QUARTERLY 240 (2021); A.D. Stern, F. Pietrulla, A. Herr, A. S. Kesselheim & A. Sarpatwari, *The Impact of Price Regulation on the Availability of New Drugs in Germany*, 38(7) HEALTH AFFAIRS 1182 (July 2019); M.A. Rodwin, *Common Pharmaceutical Price and Cost Controls in the United Kingdom, France, and Germany: Lessons for the United States*, INT. J. HEALTH SERV. 1 (2021).

*Bundesausschuss* - G-BA).<sup>25</sup> Only a small part of population is covered by private insurance or special schemes. Whereas medicines used in inpatient care are fully covered by health insurance, compulsory health insurance covers more than the 80% of the expenditure for outpatient medicines and patients pay the remainder through co-insurance payments.<sup>26</sup> German law, in particular the *Arzneimittelmarkt-Neuordnungsgesetz* (AMNOG), provides for free pricing at product launch but requires a HTA is conducted by the G-BA - a college of representatives of the umbrella associations of physicians, dentists, hospitals and health insurance funds - aimed at verifying the “added therapeutic benefit” of the new medicine.<sup>27</sup> Positive assessments are followed by reimbursement price negotiations between the Association of Statutory Health Insurance Funds (GKV-SV) and the pharmaceutical company, taking into account the annual cost of therapy of other comparable pharmaceuticals and prices paid in other European countries as reported by the company, as well as the negotiated reimbursement price applied as of the thirteenth month after the initial product launch. If parties cannot reach an agreement, the reimbursement price is set by arbitration. In case of negative assessment, the new drug is included in a reference price cluster (*Festbetrag*) where possible; otherwise, a price is negotiated that should not be higher than the price of the appropriate comparator. If the manufacturer is not satisfied with the outcome of the assessment or of the arbitration procedure mentioned above, it can decide to opt out and withdraw its drug from Germany.

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<sup>25</sup> Statutory health insurance (SHI) is provided by funds on the basis of premiums paid by employers and employees and governmental subsidies for unemployed and retired. For details, see M. Wenzl & V. Paris, *Pharmaceutical Reimbursement Pricing in Germany*, OECD, 2018; R. Busse, M. Blümel, F. Knieps & T. Bärnighausen, *Statutory health insurance in Germany: a health system shaped by 135 years of solidarity, self-governance, and competition*, 390 LANCET 882 (2017).

<sup>26</sup> Wenzl & Paris, *supra* note 25, at 5. Patients are generally required to contribute to the costs of pharmaceuticals through a 10% co-insurance rate. When products are included in reference price clusters, subject to a unique maximum reimbursement amount, patients have to pay any difference between the market price and the maximum reimbursement amount.

<sup>27</sup> Such law has entered into force in 2011. The G-BA can conduct such assessment directly or can request it to the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, an independent body in charge of evaluating the quality and efficiency of health services and health products), as it is often the case, or to a third party. This process applies to all new patented medicines introduced in the German market, except those with annual SHI expenditure below EUR 1 million. For orphan drugs, additional therapeutic benefit is assumed by virtue of marketing authorisation without reference to an appropriate comparator in Germany for as long as annual SHI expenditure for the entire population treated with the drug remains below EUR 50 million. See Wenzl & Paris, *supra* note 25, at 6.

Then, it is worth mentioning that there are various price regulation mechanisms provided by the German system, ranging from price-freezing to compulsory rebates.<sup>28</sup>

In France, compulsory insurance schemes are employed, referring to both national and supplementary health insurance programmes (offered, for example, by private insurance companies). Prescription drugs are covered entirely or partially by the health insurance system and coverage for medications authorized by the Ministry of Health typically follows the recommendations of the Transparency Commission (TC), which assesses each drug's therapeutic value. In particular, the TC assigns each drug a score, corresponding to its value, referred to as the "medical service rendered" (*service medical rendu* or SMR), considering the gravity of the problem, the medication's effects, and its public health impact, and the classification determines the share of the drug's cost that national insurance will cover. Prices of reimbursed drugs are regulated through conventions negotiated between the manufacturer and the Economic Committee for Health Products (*Comité économique des produits de santé*), which includes representatives from the health and economic ministries, the national health insurer, and private complementary insurers. Such negotiation is framed by a national agreement and the price of a specific drug takes into account the product's added medical benefit [*amélioration du service médical rendu* (ASMR)], indicating the benefit of the drug in comparison with available alternatives. The TC ranks each drug on the basis of its ASMR on a 5-point scale,<sup>29</sup> with those belonging to the first three classes entitled to have list prices at a level similar to those in the United Kingdom, Germany, Spain, and Italy.

### 3. Market access and pricing and reimbursement policies in the U.S.

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<sup>28</sup> Mandatory rebates that pharmaceutical companies must grant include, e.g.: a general 7% discount of ex-factory price to sickness funds and other health insurers on patented pharmaceuticals that are not clustered in reference price groups; a 6% discount plus an additional discount not exceeding 10% for generics that are not clustered in reference price groups; price-freezing until end of 2022 for all pharmaceuticals launched before 1 August 2009. As a matter of fact, legislation prohibits price increases, as it requires manufacturers to grant a rebate equalling any price increase versus prices on 1 August 2009. Such "price moratorium" was extended through 2022, subject to an adjustment for inflation as of 2018, in the 2017 law strengthening the pharmaceutical supply (*Gesetz zur Stärkung der Arzneimittelversorgung – AMVSG*). See Wenzl & Paris, *supra* note 25, at 6.

<sup>29</sup> ASMR I), important (II), moderate (III), mild (IV), or absent (V).

The U.S. pharmaceutical market is the largest one in the world, driving innovation in the whole sector at global level. With regard to market access, a pharmaceutical company must obtain approval from the FDA in order to market a new drug product and different procedures apply according to the type of drug concerned. For a new drug, the approval process requires the submission of a New Drug Application (NDA), which comprises exhaustive information about the drug, including safety and efficacy studies, the method of producing the drug, and any patents issued on drug substance (active ingredient), drug product (composition or formulation), or methods of use.<sup>30</sup> Patent information submitted in NDAs is published in the “Approved Drug Products with Therapeutic Equivalence Evaluations”, otherwise known as the Orange Book.

Differently, an abbreviated procedure may be enacted for generic drugs, called Abbreviated New Drug Application (ANDA), through which the applicant must demonstrate bioequivalence with the branded drug. In such case, the FDA assigns the generic drug an “AB” rating and allows the applicant to not include safety and efficacy data and to instead rely on the NDA application of the patented drug, i.e. “piggybacking” on its predecessor’s clinical research.<sup>31</sup> To demonstrate bioequivalence, the applicant must acquire samples of the referenced branded drug and conduct testing comparing the generic version against it. The Biologics Price Competition and Innovation Act (BPCI Act), has created in 2010 an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product.<sup>32</sup>

A peculiar feature of the Hatch-Waxman Act, which cannot be found in other systems such as in the EU one, are the rules in place to incentivize generic entry into the market. According to such rules, when a generic manufacturer files an ANDA, it is also required to file a certification that, in the opinion of the applicant and to the best of his knowledge,

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<sup>30</sup> The basic food and drug law is the Federal Food, Drug, and Cosmetic (FD&C) Act [Pub. L. No. 75-717, 52 Stat. 1040 (1938)] which is codified into Title 21 Chapter 9 of the United States Code and, among the amendments to it, a fundamental point of reference is the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 [codified at 21 U.S.C. §§ 355, 360 (2012); 35 U.S.C. §§ 156, 271 (2012)], amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. With regard to NDA, see 21 U.S.C. § 355(b)(2). In addition, it is worth mentioning a further type of application, i.e. Investigational New Drug Application (IND). It is a request for authorization from the FDA to administer an investigational drug or biological product to humans across state lines before marketing application. See 21 U.S.C. § 312.

<sup>31</sup> 21 U.S.C. §355(j).

<sup>32</sup> Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (2010).

the proposed generic drug does not infringe any patent listed with the FDA relating to the patented drug. The generic manufacturer can satisfy this requirement by certifying one of the following options with respect to the patent for the listed drug: (I) that such patent information has not been filed, (II) that such patent has expired, (III) the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (commonly called Paragraph I, II, III, and IV certifications, respectively).<sup>33</sup>

When a would-be generic manufacturer attempts to enter prior to the expiration of the brand-name patent owner's filing of a paragraph IV certification, it must consult the Orange Book and provide written notice to each listed patent owner impacted by the ANDA. Technically, a paragraph IV certification constitutes an artificial act of patent infringement.<sup>34</sup> As a consequence, if the patent holder initiates an infringement suit within forty-five days after the generic applicant files its ANDA and paragraph IV certification, FDA approval of the generic drug automatically is stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed - in such case, and also if suit is not filed within that time, the ANDA can be approved immediately.<sup>35</sup> Moreover, in order to encourage generic entry and challenges to weak patents, the Hatch-Waxman Act rewards the first generic manufacturer who submits an ANDA and a paragraph IV certification by providing it with a 180-day period of marketing exclusivity during which the FDA cannot approve subsequent ANDA applications. During this period, the first filer's product will be the only generic equivalent on the market,<sup>36</sup> as a later filer may force the first filer to use its bounty (i.e.,

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<sup>33</sup> 21 U.S.C. §355(j)(2)(A)(vii).

<sup>34</sup> See R. Feldman & E. Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 507 (2016).

<sup>35</sup> It is worth mentioning that under the Act an NDA holder could obtain multiple thirty-month stays by strategically listing its patents related to a drug product in the Orange Book: in response to the 2002 FTC study on "Generic Drug Entry Prior to Patent Expiration", showing that brand-name drug companies had been abusing the thirty-month stay provision to delay generic entry, the FDA amended its rules to allow only one thirty-month stay and Congress codified these rules in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

<sup>36</sup> However, a first-filer can forfeit its exclusivity under certain conditions (e.g. due to a failure to market by a specified date, a failure to obtain tentative FDA approval, withdrawal of the ANDA, amendment of the ANDA to non-Paragraph IV status, commission of an antitrust violation, or expiration of the patent). See 21 U.S.C. § 355(j)(5)(D).

enter with exclusivity) or else lose it, only if the later filer wins a patent suit of its own.<sup>37</sup> Therefore, this exclusivity period is very valuable to generic manufacturers, as they can sell their product at a price significantly higher than they could if multiple generics were on the market, and creates a de facto duopoly between the brand and generic companies for the first six months of competition.<sup>38</sup>

With regard to drug pricing, the main distinctive feature of the U.S. system is that no price regulation for pharmaceutical products is in place. One of the reasons can be found in the traditional predominance in the U.S. of competing private health plans, which have influenced the sector more than have public insurance programs, such as Medicare and Medicaid.<sup>39</sup> The formulary system, establishing which drugs are reimbursed, is based on the definition of tiers that determine the level of payment drugs require. In theory, tiering should reflect the cost of a drug, but in practice, private and public payers impact prices set by pharmaceutical companies through the use of such formularies, offering preferred formulary positions to drugs that are advantageously priced in comparison to other drugs with similar therapeutic features.

In the absence of price regulation, the supply chain plays a crucial role in determining drug prices. The U.S. pricing and distribution system is based on manufacturers' list price, combined with discounts mechanisms. Pharmaceutical manufacturers typically sell drugs at a list price (wholesale acquisition cost, WAC) to wholesalers, which in turn distribute medicines to retail and hospital pharmacies, adding a mark-up to cover their distribution costs. Although there are list prices such as average wholesale price (AWP) which can be

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<sup>37</sup> According to the Hatch-Waxman Act [21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)], only an appellate win by the later filer triggers the first filer's obligation to enter with exclusivity, which it must do within seventy-five days or else forfeit the bounty. As clarified by C.S. Hemphill & M.A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L. J. 947, 964 (2011), "[t]he resulting delay from this process – file the ANDA, conduct the district court suit, win the appeal, wait until just before the end of seventy-five days, then wait another 180 days – can easily stretch to several years. Moreover, in some cases, the settlement between the brand-name firm and the first filer permits the first filer to launch upon FDA approval or launch of the later filer's product, further reducing the incentive to pursue this strategy." However, during the 180-days exclusivity authorized generics can be marketed, i.e. brand-name drugs sold under generic labels, manufactured by the pioneer drug firm and marketed and distributed by the firm itself, through a subsidiary or an external licensee.

<sup>38</sup> Feldman & Frondorf, *supra* note 34, at 508.

<sup>39</sup> In 2019 private health insurance coverage was more prevalent than public coverage, covering 68.0 and 34.1. See K. Keisler-Starkey & L.N. Bunch, *Health Insurance Coverage in the United States: 2019*, U.S. Census Bureau (2020), p. 3, available at: <https://www.census.gov/library/publications/2020/demo/p60-271.html>. A number of public safety net or private assistance programs may be available for Americans that either do not have insurance or have inadequate coverage.

used by payers as a basis for their reimbursement to pharmacies, significant discounts may occur between the payer and the pharmacy. Private payers may also negotiate discounts from manufacturers of patented drugs directly, thereby bypassing the intermediate retailing system and preventing price arbitrage: in such case, the average manufacturer price (AMP) received by producers include such discounts, whose availability and amount depends on the payer's ability of influencing drug use through its formulary design, whereas mandatory rebates are by statute provided to some public payers.<sup>40</sup> In the case of generic drugs, the negotiated discounts are given by the manufacturers directly to dispensing pharmacies, which are substantially the final decision-makers regarding off-patent products.<sup>41</sup>

In practice, drug manufacturers rarely receive the WAC or list price due to the discounts negotiated throughout the distribution system. Thus, the net price paid to the drug company, which is typically secret, is usually less than the list price. But the amounts paid by patients to insurance plans may be based on schemes referring to the list price rather than the net price, so that at the end, consumers may be deprived of the benefit of the rebates already bargained for. Practice shows the trend of list prices for branded drugs has sharply risen.<sup>42</sup>

A peculiar role in the drug supply chain is played by pharmacy benefit managers (PBMs), middle players between drug companies and health insurers whose task is to establish the drug formularies and negotiate discounts from manufacturers on behalf of private insurance plans. The power these intermediaries have on prices is related to their ability to design formularies with a number of tiers for different types of drugs with corresponding copayments, step edits (sometimes referred to as "fail-first policies", requiring patients to try drugs in a particular order in order to get reimbursement),<sup>43</sup> and prior authorization (according to which the physician may be required to obtain a prior approval from the insurer before reimbursement). Such mechanisms allow PBMs to

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<sup>40</sup> AMP is defined as the average price paid to drug manufacturers by wholesalers and retail pharmacies.

<sup>41</sup> P.M. Danzon, *Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA*, in A.J. CULYER (ED.), *ENCYCLOPEDIA OF HEALTH ECONOMICS*, 2014, vol. 3, 127.

<sup>42</sup> R. FELDMAN, *DRUGS, MONEY AND SECRET HANDSHAKE: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES* (Cambridge, 2019), at 9-10.

<sup>43</sup> Step edits are a mechanism designed by health insurers to control cost and provide for the rejection of reimbursement of a drug unless the patient meets certain conditions, such as prior failure on a generic alternative.

negotiate discounts in exchange for preferred formulary placement (or even the exclusion of a competing drug in the same class from being reimbursed).<sup>44</sup>

With regard to federal health care plans, Medicare is the largest payer in the U.S..<sup>45</sup> Medicare Part D is a voluntary outpatient prescription drug benefit provided through private plans, approved by the federal government, covering medicines that beneficiaries obtain from brick-and-mortar and mail-order pharmacies.<sup>46</sup> Beneficiaries can choose to enroll in either a stand-alone prescription drug plan (PDP) to supplement traditional Medicare, or a Medicare Advantage prescription drug plan which covers all Medicare benefits, including drugs. Private PBMs and PDPs act in a similar way to manage drug costs, negotiating price concessions and rebates with manufacturers in exchange for market share through the design of the formulary.<sup>47</sup>

A different system is applied in the case of the other public health plan, the Medicaid program, which is based on mandatory rebates, where a manufacturer is required to enter into an agreement with the Department of Health and Human Services (HHS) stating that it will rebate a specified portion of the Medicaid payment for the drug to the states, which in turn will share the rebates with the federal government.<sup>48</sup> In exchange, Medicaid programs cover nearly all of the manufacturer's FDA-approved drugs, and the drugs are eligible for federal matching funds. The Medicaid rebate amount is set by statute and

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<sup>44</sup> Feldman, *supra* note 42, at 20.

<sup>45</sup> It accounts for 34 percent of U.S. net drug spending when Part B and Part D are combined. See Table 16 in NHEA Tables (ZIP) link at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

<sup>46</sup> The Medicare program covers primarily 65 years old individuals and over. It is divided into four parts: Part A provides hospital insurance covering inpatient hospital services and a series of post-hospital and home health services; Part B covers a range of outpatient services, including physician-administered drugs; Part C, also called Medicare Advantage Plans, include plans offered by private companies approved by Medicare, which may provide the benefits of Part A and Part B combined and offer extra coverage on the basis of specific rules; Part D concerns prescription drugs coverage. The Centers for Medicare & Medicaid Services (CMS) reviews formularies to endure their consistency with federal requirements.

<sup>47</sup> Danzon, *supra* note 41, at 129.

<sup>48</sup> While Medicare provides coinsurance for which beneficiaries generally are responsible for twenty to twenty-five percent of brand-name drug costs, Medicaid provides full prescription drug coverage with a small co-pay sometimes required. On this point and for a comparison between the two systems, see M.A. Lemley, L.L. Ouellette & R.E. Sachs, *The Medicare Innovation Subsidy*, 95 NYU LAW REV. 75, 82 et seq., 88 (2020). The Medicaid Prescription Drug Rebate Program (MDRP) was created in 1990 by the Omnibus Reconciliation Act. Subsequently the Affordable Care Act of 2010 (ACA) made significant changes to the prescription drug rebate program, increasing, *inter alia*, the rebate amount for both brand drugs and generic drugs. The ACA was intended to increase the income threshold for coverage in order to include more low-income Americans. For updated data on States adopting the Medicaid expansion, see Kaiser Family Foundation, Status of State Medicaid Expansion Decisions: Interactive Map, available at <https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>.



ensures that the program gets the “best price” (meaning the lowest available price to any wholesaler, retailer, or provider, excluding certain government programs, such as the health program for veterans).<sup>49</sup> In addition to federal statutory rebates, several states negotiate with manufacturers for supplemental rebates, using placement on a preferred drug list as leverage. A significant role is played by managed care organizations (MCOs), which provide services and support to Medicaid beneficiaries and receive a monthly fee by states on the basis of risk-based contracts. Many states also use PBMs in their Medicaid prescription drug programs.<sup>50</sup>

As noted above, the debate over drug pricing is particularly heated in the U.S. and possible reforms are at the center of political debate. Recent proposals in literature, considering that drug benefit assessments are not routinely used in Medicare and Medicaid drug coverage decisions, suggest that lawmakers evaluate the approaches taken

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<sup>49</sup> An additional inflation-adjusted rebate, which effectively anchors the Medicaid price of any drug to its inflation-adjusted launch price, is provided. Medicaid statute defines Best Price as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or government entity within the United States.” Exclusions concern the Department of Veterans Affairs, the 340B program, the Department of Defense, the Public Health Service, the Indian Health Service. The Best Price includes rebates in general, but not Medicaid supplemental rebates or rebates provided through the Medicaid Drug Rebate Program [42 U.S.C. 1396r-8 (c)(1)(C)]. Under the Affordable Care Act of 2010 (ACA), the rebate formula provides for a discount of 23.1% of AMP, or the difference between AMP and “best price,” whichever is greater, for branded drugs. For generic drugs, the rebate amount is 13% of AMP, and there is no best price provision. Certain paediatric and clotting drugs have a lower rebate amount of 17.1%. It is worth mentioning that, as a condition of participation in the Medicaid Drug Rebate program, manufacturers are also required to participate in the federal 340B program [42 U.S.C. § 1396r-8 (a) (5)], which offers discounted drugs to certain safety net providers that serve vulnerable or underserved populations, including Medicaid beneficiaries. Medicaid system has been object of criticism, in particular with regard to its best price clause. According to empirical studies, Medicaid best price has led private sector rebates to decline as a matter of fact, such policy reduced manufacturer willingness to grant discounts to private payers in excess of the mandatory minimum Medicaid rebate, in particular with regard to drugs relatively highly used by Medicaid patients. This in turn led drugs with high Medicaid share to experience larger increases in prices to private payers. See M. Duggan & F.M. Scott Morton, *The Distortionary Effects of Government Procurement: Evidence From Medicaid Prescription Drug Purchasing*, 121(1) THE QUARTERLY JOURNAL OF ECONOMICS 1 (2006) (finding also empirical evidence that firms producing newer drugs with larger sales to Medicaid are more likely to introduce new versions and concluding that government procurement rules can alter equilibrium price and product proliferation in the private sector). See also Lemley, Ouellette & Sachs, *supra* note 48, 89-90.

<sup>50</sup> For updated data, see Kaiser Family Foundation, *Medicaid Managed Care Market Tracker*, available at <https://www.kff.org/data-collection/medicaid-managed-care-market-tracker/>; R. Dolan & M. Tian, *Management and Delivery of the Medicaid Pharmacy Benefit* (2019), available at <https://www.kff.org/wp-content/uploads/2019/12/Management-and-Delivery-of-Pharmacy-Benefits-in-Medicaid.pdf>.

in other countries, including those employed in Germany and France, using a form of comparative effectiveness analysis.<sup>51</sup>

Looking at the current policy, it is worth mentioning that the Biden Administration has supported numerous initiatives to improve affordability and access to prescription drugs through increased government regulations. In particular, echoing some previous proposals, a central component of Biden's plan to lower prescription drug prices includes allowing Medicare to negotiate drug prices, and the creation of an independent review board that would seek to limit the launch price of prescription drugs lacking competition. In addition, proposals including a year-to-year limit for prescription drug price increases to inflation to be introduced as a condition for coverage by Medicare and other public payers, and to cap out-of-pocket spending under Medicare Part D are considered.<sup>52</sup>

#### 4. Price hikes of prescription drugs: the case of off-patent drugs

The existence of a complex interplay between sectoral regulation and other areas of law is one of the main features of pharmaceutical markets. Pharmaceutical products -in particular essential medicines- are often price-demand inelastic. Markets for pharmaceuticals are characterized by persistent information asymmetry, as the final consumer (the patient), who lacks specific knowledge on the matter, has a low involvement in therapeutic choice and differs both from the decision-making subject (the doctor – and, in some cases, the pharmacist) and from the subject who pays all or part of

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<sup>51</sup>With regard to the German system, the benefit assessment model is assumed to provide a formal and transparent comparative effectiveness analysis with beneficial effects in terms of satisfactory price negotiations and no evidence of decreased access to the types of novel therapies that provide important clinical value. See Stern, Pietrulla, Herr, Kesselheim & Sarpatwari, *supra* note 24. See also F. Berkemeier, C. Whaley & J.C. Robinson, *Increasing Divergence in Drug Prices Between the United States and Germany After Implementation of Comparative Effectiveness Analysis and Collective Price Negotiations*, J MANAG CARE SPEC PHARM. 2019 Dec; 25(12):1310-1317 (arguing that in the 5 years before 2011, when comparative effectiveness analysis and collective price negotiations were mandated in Germany, U.S. prices for physician-administered drugs averaged 29.2% higher than those in Germany and the divergence between U.S. and German prices increased another 28.9% between 2012 and 2018); Lemley, Ouellette & Sachs, *supra* note 48, 95-96. The French system has been also considered by scholars a point of reference which could inform discussions of U.S. prescription drug policy and potential Medicare price negotiations. See Raimond, Feldman, Rome & Kesselheim, *supra* note 24.

<sup>52</sup> For a more detailed treatment, see K. A. Gavulic & S. B. Dusetzina, *Prescription Drug Priorities under the Biden Administration*, 46(4) J. HEALTH POLIT. POLICY LAW 599 (2021).

the price of the drug (typically, national health systems or private insurance companies).<sup>53</sup> Regulatory agencies' approval for marketing of pharmaceuticals constitutes one means to address such information asymmetry. Moreover, in the consumption of prescription drugs, the choice between different medicines is usually guided by their therapeutic appropriateness and effectiveness rather than by price. Where national or social health insurance systems are put in place, price regulation is a way to discipline moral hazard by suppliers, which tend to respond to the inelasticity of the demand by charging higher prices than would occur in the absence of reimbursement/insurance.<sup>54</sup>

The market for reimbursed medicines is object of particular attention of both sectoral regulation and competition law. Moreover, entry by generic drug manufacturers into pharmaceutical markets is a fundamental factor which regulatory policies and antitrust enforcement have traditionally focused on. Generally sustained by public authorities in light of the associated reduction of prices and benefit for consumers and governmental health systems, generic entry is the major concern for brand-name drug manufacturers. Originator companies strongly rely upon the period of exclusivity provided by patents and regulatory exclusivities in order to earn a return on the investment made in R&D for innovative products, and typically lose significant profits when facing generic competition.

It is well-known that patents play a crucial role in the pharmaceutical sector as compared to other sectors having high rates of patenting. In industries such the pharmaceutical sector, in which new products include relatively few patentable elements, patents are generally used by firms to collect monopoly rents, whether by commercializing the inventions themselves, licensing them to other firms, or blocking rivals from developing competing technologies, ultimately leading to higher prices of

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<sup>53</sup> Medicines and healthcare products in general are typically considered as “experience” or “credence” goods. The former have features that are not observable for the consumer *ex ante*, but their quality is revealed after the purchase or the consumption; therefore consumer may evaluate *ex post* the quality of such products. The latter refer to those products whose quality cannot be assessed by consumers *ex ante* and it is hard to verify it even after purchase or use. Both situations may occur in the case of medicines, as patients are unable to assess the efficacy and the safety of a drug at the moment of the purchase and sometimes even after consumption. See M. Kyle & F. Scott Morton, *Markets for Pharmaceutical Products*, in M. V. PAULY, T. G. MCGUIRE & P. P. BARROS (EDS.), *HANDBOOK OF HEALTH ECONOMICS*, 2012, Vol. 2, 764, 765.

<sup>54</sup> See Danzon, *supra* note 11, at 266-267.

drugs.<sup>55</sup> This is a classic topic, and literature shows both scholars extolling the virtues of patent protection in promoting pharmaceutical innovation, and others criticizing patents for providing too much protection for pharmaceutical products. Prices of generic drugs are substantially lower than those of the originator product, and the entry of a competing generic product inevitably leads to a significant decline in the price and market share of the corresponding originator product. Governments and regulators are particularly concerned with market entry, being the natural tension between originator and generic companies fostered by regulation, as evinced by the peculiar systems for abbreviated marketing approval, the enactment of substitution laws present both in the EU and U.S. (typically allowing pharmacists to substitute a generic drug when presented with a prescription for its branded equivalent, unless a physician directs or the patient requests otherwise), in addition to the specific provisions such as those enacted by the Hatch-Waxman Act to challenge patents by generic producers mentioned above. Conversely, pharmaceutical companies are traditionally subject to antitrust scrutiny regarding the practices developed by incumbent originator companies in order to respond to generic entry and aimed at preventing and/or delaying such entry, often artificially extending their patent protection against new entrants to unduly preserve their market power (e.g. pay for delay, product hopping, etc.).<sup>56</sup>

However, this is only one facet of the problem of high drug prices, as extraordinary prices may also concern medicines that are not covered by patents when therapeutically equivalent drugs do not exist, and no competition has been put in place despite the absence of barriers in terms of IP protection. The positioning of patents as the undisputed cause of skyrocketing prices is to be reconsidered, taking into account the recent trend of price-hikes of non-patented products. This trend is of concern in both the European and the U.S. markets. The following paragraphs will analyse the main insights deriving from such experiences and will review responses that have been employed to address this issue.

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<sup>55</sup> R.S. Eisenberg, *The Shifting Functional Balance Of Patents And Drug Regulation*, HEALTH AFFAIRS 119, 120 (2001).

<sup>56</sup> Similar concerns regard the relationship between biologics and biosimilar products, despite the specific features of large molecules compared to small-molecule setting. In the case of biosimilars, disparagement constitutes a relevant concern. See M.A. Carrier, *Don't Die! How Biosimilar Disparagement Violates Antitrust Law*, 115 NW. U. L. REV. ONLINE 119 (2020).

#### 4.1. Excessive drug prices under antitrust law: the European experience

In recent years, controversial cases of price hikes have been documented in several European Member States, one of which has been subject to investigation by the EU Commission. The most known cases are those prosecuted in Italy and United Kingdom against Aspen, Pfizer and Flynn Pharma.

In Italy, in 2016 the Italian Competition Authority (ICA) fined the multinational pharmaceutical company Aspen more than Euro 5 million for having set unfair price increases of up to 1,500% on off-patent, life-prolonging and non-substitutable branded drugs acquired by GlaxoSmithKline (GSK) and used in the treatment of cancer, particularly in children and the elderly, in breach of Article 102 (a) TFEU.<sup>57</sup> Such drugs had been developed long before and were sold in niche markets at their original prices. Aspen engaged in an aggressive strategy of negotiating with the national regulatory agencies, using the threat of instrumental delisting (i.e. the removal of a medicine from the reimbursement list, thus shifting the cost of the drug to patients) and withdrawal of the products. The findings of the ICA's investigation were also confirmed before national Courts.<sup>58</sup> The case has been subsequently prosecuted by the European Commission and will be analysed in detail in the following paragraph.<sup>59</sup>

A different outcome resulted from the decision adopted in the same year in the UK by the Competition and Markets Authority (CMA), fining Pfizer and Flynn Pharma for the imposition of excessive and unfair prices for Epanutin (prices increasing by up to 2,600% overnight after the drug was de-branded in September 2012).<sup>60</sup> Here, the anticompetitive strategy consisted of the de-branding of phenytoin sodium capsules, an anti-epilepsy drug with a narrow therapeutic window and without the option of therapeutic substitution for already-existing patients. Also, this case included the acquisition of distribution rights for the medicines by Flynn Pharma from Pfizer. Under applicable rules at the time of the infringement, the de-branding of a product (making it a generic drug) allowed the

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<sup>57</sup> Autorità garante della concorrenza e del mercato (ICA), A480 – *Incremento prezzi farmaci/Aspen*, in Bollettino n. 36/2016, 29 September 2016.

<sup>58</sup> TAR Lazio, Judgement No. 8948/2017 of 26 July 2017; Council of State, Judgement No. 01832/2020 of 13 March 2020.

<sup>59</sup> European Commission, case AT.40394 – *Aspen*, 10.2.2021 (published on 15.4.2021).

<sup>60</sup> CMA, case CE/9742-13, decision published on 7 December 2016.

companies to put the medicines outside of statutory price control. Two years later, on appeal, the Competition Appeals Tribunal (CAT) did not uphold the decision of the Authority.<sup>61</sup> Afterwards, following the Court of Appeal's judgement released in 2020, the CMA decided to re-investigate the matters remitted by the CAT. In August 2021, the CMA issued a statement of objections, provisionally finding that the parties infringed competition law by charging unfairly high prices for phenytoin sodium capsules.<sup>62</sup> Moreover, in July 2021, the CMA concluded its investigation in another case concerning hydrocortisone, fining Auden Mckenzie and Accord-UK (previously, Actavis UK) and parent companies £155 million for charging the NHS excessive and unfair prices for hydrocortisone tablets for almost 10 years, from 2008 to 2018, increasing the price of 10mg and 20mg hydrocortisone tablets by over 10,000% compared to the original branded version of the drug.<sup>63</sup> Another investigation regarding liothyronine tablets (Advanz Pharma) is still pending at this time.<sup>64</sup>

In Denmark, in 2018 the Danish Competition Council (DCC) adopted an infringement decision concerning CD Pharma's abuse of dominance by charging an excessive and unfair price for the off-patent drug Syntocinon, containing oxytocin, an active substance given to pregnant women in connection with childbirth.<sup>65</sup> The decision of DCC, finding CD Pharma - which was dominant in the Danish market for the sale of oxytocin due to an exclusive distribution agreement with the manufacturer of the product - to have increased the price of the drug by 2000% in 2014, was upheld by the Danish Competition

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<sup>61</sup> *Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority* [2018] CAT 11. The CAT has also affirmed that: «[c]ases of pure unfair pricing are rare in competition law. Authorities find them difficult to bring and are, rightly, wary of casting themselves in the role of price regulators. [...] [E]x post price regulation through the medium of competition law presents many problems. However, the law prohibits unfair pricing in certain circumstances and in such cases there is no reason in principle why competition law cannot be applied, provided this is done on the correct legal basis and the analysis of evidence is sound.»

<sup>62</sup> See *Competition and Markets Authority v. Flynn Pharma Limited, Pfizer Inc & Ors* [2020] EWCA Civ 339; CMA, press release of 5 August 2021, <<https://www.gov.uk/government/news/cma-accuses-pharma-firms-of-illegal-pricing>>. The CMA gave Pfizer and Flynn the opportunity to respond to the provisional findings set out in the Statement of Objections.

<sup>63</sup> CMA, case reference: 50277 - Press Release, <<https://www.gov.uk/government/news/cma-finds-drug-companies-overcharged-nhs>>. The CMA has also fined Accord-UK and Allergan – as former parent – a further £66 million for paying two would-be competitors to stay out of the market.

<sup>64</sup> In November 2017 the CMA sent a Statement of Objections alleging that Concordia (now Advanz Pharma) charged unfair prices through an increase of almost 6,000% for liothyronine tablets, primarily used to treat hypothyroidism. See CMA, <<https://www.gov.uk/government/news/drug-company-accused-of-abusing-its-position-to-overcharge-the-nhs>>.

<sup>65</sup> DCC, case No. 15/08469, 31 January 2018.

Appeals Tribunal in 2018 and subsequently in 2020 by the Danish Maritime and Commercial Court.<sup>66</sup>

Particular attention is currently devoted to another case concerning an orphan drug. The Dutch competition authority (ACM) and the ICA, respectively in 2018 and 2019, opened an investigation against companies belonging to the Leadiant group for a suspected abuse of dominant position for the production and sale of chenodeoxycholic acid (CDCA)-based medicines for the treatment of a rare disease (cerebrotendinous xanthomatosis). While the Italian case is still pending,<sup>67</sup> ACM closed its investigation in July 2021, finding Leadiant liable for their abuse of their dominant position between mid-2017 and the end of 2019 by the imposition of excessive prices for CDCA-Leadiant, for which no alternatives existed in that period, and imposed a fine of 19,569,500 EUR.<sup>68</sup>

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<sup>66</sup> Case no. KL-2-2018, CD Pharma vs. The DCC; Danish Maritime and Commercial Court, Case BS-3038/2019-SHR, judgment of 2 March 2020.

<sup>67</sup> ICA, A524 - *Leadiant Bioscences/Farmaco per la cura della Xantomatosi Cerebrotendinea*, 8 October 2019 (conclusion lastly prorogated to December 2021). According to the preliminary statement of the ICA, Leadiant has implemented a single and comprehensive strategy aimed at foreclosing competitors' access to the market for the production of CDCA-based medicines and imposing unjustified excessive prices for the sale of its own medicine containing this active ingredient, called *Leadiant Chenodeoxycholic Acid*, which has been designated as orphan drug. It appears that the contract to exclusively supply CDCA, entered into by Leadiant with the chemical company Prodotti Chimici ed Alimentari S.p.A., one of the main producers of this active ingredient, prevents hospitals – wishing to ask their own pharmacies to set up galenic production of CDCA-based medicines – from obtaining the raw material necessary to produce medicine for the treatment of this rare disease. Furthermore, once it had received the MA for *Leadiant Chenodeoxycholic Acid*, Leadiant allegedly behaved in an obstructive way in order to obtain a very high sales price for this product as part of its negotiations with the AIFA, well aware of the fact that there cannot be other interchangeable medicine on the market.

<sup>68</sup> ACM, case No. ACM/20/041239, press release <<https://www.acm.nl/sites/default/files/documents/summary-of-decision-on-abuse-of-dominant-position-by-leadiant.pdf>>. According to ACM's investigation, after the acquisition of a CDCA-based drug from another manufacturer, Leadiant firstly changed the trade name of the drug to Xenbilox, and raised its price, and later applied for an orphan drug designation and MA for its CDCA-based drug for the treatment of CTX. Leadiant raised the price of Xenbilox, so that the selling price went up from 885 EUR to 3,103 EUR. The orphan drug designation was granted in late 2014. When Leadiant in April 2017 was also granted the MA, the company was granted the exclusive right for ten years to supply a CDCA-based drug for the treatment of CTX to the European market. Shortly thereafter, in June 2017, Leadiant introduced CDCA-Leadiant on the Dutch market, and the company stopped selling Xenbilox. Although differences in efficacy, safety, and form between the two drugs are absent, and Leadiant had already recouped the application costs at that point, Leadiant increased the selling price to 14,000 EUR. As a result, the drug costs approximately 153,000 EUR per patient per year. Leadiant charged this price of 14,000 EUR in the Netherlands until Amsterdam UMC succeeded in manufacturing the drug in its own pharmacy in January 2020. Further, in 2019 the Belgian Ministry of Economy has intervened announcing the imposition of a maximum price for Leadiant's orphan drug, while urging the national competition authority to prioritise a claim filed against it by the consumer organization. See Belgian Ministry for Economic Affairs, Press Release, 6 September 2019, available at <[https://www.vbb.com/media/Insights\\_Newsletters/CDCA\\_Woekerwinsten\\_maken\\_op\\_kap\\_van\\_pati%C3%ABnten\\_is\\_onaanvaardbaar\\_04092019.pdf](https://www.vbb.com/media/Insights_Newsletters/CDCA_Woekerwinsten_maken_op_kap_van_pati%C3%ABnten_is_onaanvaardbaar_04092019.pdf)>.

These investigations have renewed antitrust agencies' attention to the abusive behaviours of dominant companies, including excessive pricing, that are targeted under EU competition rules, whose application has been sporadic and particularly controversial. The normative basis in EU competition law (and reflected in national rules of Member states) is Article 102(a) TFEU, which prohibits conduct "directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions". Such prohibition represents one of the most striking differences between European and U.S. antitrust laws, as the latter does not consider charging profit-maximizing monopoly prices as an independent antitrust violation.<sup>69</sup>

This also constitutes a typical area of contention among scholars.<sup>70</sup> The main arguments supporting the abstention of antitrust intervention in this area are based on the assumption that excessive prices may be profitable for the dominant undertaking only in the short term, that sanctioning excessive pricing may negatively affect dynamic efficiency, and that a high risk of errors exists, considering that competition authorities (apart from sectoral regulators) are typically not equipped to regulate prices and that such control requires a complex, time-consuming and costly intervention by the public authorities.<sup>71</sup> On the other side, excessive prices have are not always self-correcting,<sup>72</sup> especially in markets where high and non-transitory barriers to entry exist.<sup>73</sup>

While the risk of both type I, or over-enforcement, and type II, or under-enforcement,

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<sup>69</sup> For an analysis of the rationales for the prohibition, see M. Gal, *Abuse of Dominance—Exploitative Abuses*, in D. GERADIN & I. LIANOS (EDS.), *RESEARCH HANDBOOK IN EU ANTITRUST LAW* (Cheltenham, Edward Elgar Publisher, 2013), 385; Id., *Monopoly pricing as an antitrust offense in the U.S. and the EC: Two systems of belief about monopoly?*, 49 *ANTITRUST BULLETIN* 343 (2004).

<sup>70</sup> For an overview, see Frederic Jenny, *Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment*, in Y. KATSOUACOS & F. JENNY (EDS), *EXCESSIVE PRICING AND COMPETITION LAW ENFORCEMENT* (Springer 2018), 5-70.

<sup>71</sup> See D.S. Evans & J. Padilla, *Excessive Prices: Using Economics to Define Administrable Legal Rules*, 1 *JOURNAL OF COMPETITION LAW AND ECONOMICS* 97 (2005).

<sup>72</sup> See 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).

<sup>73</sup> See D. Geradin, *The Necessary Limits to the Control of 'Excessive' Prices by Competition Authorities—A View from Europe*, Tilburg University Legal Studies Working Paper, 2007, available at <http://ssrn.com/abstract=1022678>.



errors exists,<sup>74</sup> the main concerns regard the former and a number of economists have proposed screens aimed at limiting the intervention of antitrust agencies. For instance, Evans and Padilla have proposed 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 exists a risk that those prices may prevent the emergence of new goods and services in adjacent markets.<sup>75</sup> Motta and de Streel have elaborated another test requiring three cumulative conditions: 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 super-dominant position has been achieved through special and exclusive rights or to un-condemned past exclusionary anticompetitive practices rather than market competition; and iii) no sectoral regulator has the jurisdiction to solve the matter.<sup>76</sup> Röller has proposed a test with five cumulative conditions: i) significant entry barriers exist; ii) the market is unlikely to self-correct; iii) no (structural) remedy is available; iv) no regulator exists, or regulatory failure occurs; and v) there are “gap cases” or “mistake cases”.<sup>77</sup> Fletcher and Jardine have suggested a policy 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 actions; 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; and vi) seek alternative structural remedies to price

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<sup>74</sup> Risks deriving from type I errors (or false positives) are deemed to be high, because the market may self-correct in the absence of intervention, and an error will impact on dynamic inefficiency related to low investments and innovation. Type II errors (or false negatives) are generally considered to have a relatively low cost, mainly related to allocative inefficiency. See C. Calcagno & M. Walker, *Excessive Pricing: Towards Clarity and Economic Coherence*, (2010) 6 JOURNAL OF COMPETITION LAW AND ECONOMICS 891.

<sup>75</sup> Evans & Padilla, *supra* note 71.

<sup>76</sup> 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).

<sup>77</sup> L.H. Röller, *Exploitative Abuses*, in C.-D. EHLERMANN & M. MARQUIS (EDS.), EUROPEAN COMPETITION LAW ANNUAL 2007 – A REFORMED APPROACH TO ARTICLE 82 EC (Hart Publishing 2008), 525 (defining: “gap” cases as referring to the enforcement gap in EU competition law which prosecutes only firms that are already dominant, so that exploitative abuse cases should be based on acquiring a dominant position through anticompetitive exclusionary conduct; and, “mistake” cases those situations in which for some reason an antitrust authority may not have effectively prosecuted an exclusionary abuse).

regulation.<sup>78</sup> In any case, the application of excessive pricing has been defined as a messy and difficult business.<sup>79</sup>

The main reasons supporting the antitrust intervention against exploitative conduct in the EU are adduced as, in addition to the wording and legislative intent of Article 102(a), the direct and indirect protection of consumer welfare as the goal of competition policy.<sup>80</sup> Moreover, such prohibition may address the so-called “gap” cases, as Article 102 does not prohibit the acquisition of dominance (as the Sherman Act does), but only the abusive conduct of firms already holding a dominant position. This, 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 patent ambush, i.e. not disclosing its patent in the context of a standard-setting process).<sup>81</sup>

Despite this, in practice, the European Commission has been reluctant to resort to excessive pricing decisions and the existing jurisprudence on the matter is not well developed. The main jurisprudential point of reference for these cases is the landmark ruling given by the Court of Justice in *United Brands*.<sup>82</sup> According to the Court, the crucial point of the abuse is charging a price which is excessive because it has no reasonable relation to the economic value of the product.<sup>83</sup> Such excess could be objectively determined by assessing the excessiveness of the “profit margin” by comparing the selling price of the product in question and its cost of production (“cost-plus” method),<sup>84</sup> and the unfairness of the price. Thus, on the basis of a two-limb test, it

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<sup>78</sup> A. Fletcher & A. Jardine, *Towards an Appropriate Policy for Excessive Pricing*, in EHLERMANN & MARQUIS, *supra* note 77, 533. See also E. Paulis, *Article 82 EC and Exploitative Conduct*, *ibid.*, 515 (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). For an overview, see OECD, *Background Paper, Excessive Pricing in Pharmaceutical Markets*, *supra* note 1, at 8 et seq.

<sup>79</sup> Calcagno & Walker, *supra* note 74.

<sup>80</sup> European Union, *Article 102 and Excessive Prices*, Contribution to the 2011 OECD Roundtable, at 309 et seq. 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); P. Akman & L. Garrod, *When Are Excessive Prices Unfair?*, 7(2) J. COMPETITION L. & ECON. 403 (2011).

<sup>81</sup> See Commission Decision of 9 December 2009, Case COMP/C-3/38626 (*Rambus*).

<sup>82</sup> ECJ, Judgment of 14 February 1978, Case 27/76, *United Brands Company and United Brands Continentaal BV v Commission*, [1978] ECR 207.

<sup>83</sup> See para. 250.

<sup>84</sup> See para. 251.

is first necessary to determine “whether the difference between the costs actually incurred and the price actually charged is excessive; and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.”<sup>85</sup>

However, the application of this test is a complex task. Uncertainties remain surrounding, e.g., determining the “economic value”, identifying at which level a price becomes excessive, and defining “unfair in itself”.<sup>86</sup> Analysing the methodological issues and related case law on the matter is outside the scope of this paper. Suffice it to say that methods other than the price-cost test are available, including comparator tests (e.g. comparison across competitors, across time, or on a geographic basis).<sup>87</sup> In such event, the competition authority has the choice of the most appropriate method to apply, having to ensure that the comparison used is based on comparators selected in accordance with objective, appropriate, and verifiable criteria, and is made on a consistent basis.<sup>88</sup> The Court of Justice has further clarified that the price difference between the product in question and similar comparator products is appreciable, and thus may be indicative of an abuse of a dominant position when it is “both significant and persistent on the facts, with respect [...] to the market in question”, without there being any specific or fixed minimum threshold.<sup>89</sup> Once it has been ascertained that an excess exists between the price actually charged by the dominant undertaking and the benchmark price, one must determine the extent to which that actual price is unfair, either in itself or when compared to competing products, in order to investigate whether the difference in price is the result of an abuse of market power by the dominant undertaking, or is the consequence of other

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<sup>85</sup> See para. 252 of the Judgment. It is worth mentioning the position expressed by Motta & de Stree, *supra* note 76, 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”).

<sup>86</sup> It is worth mentioning that the European Commission, in the *Scandlines Port of Helsingborg* decision (Case COMP/A.36.568/D3—*Scandlines Sverige AB v Port of Helsingborg*, paras. 226-227), explained that the economic value must be determined with regard to the circumstances and by taking into account non-cost-related factors, particularly the demand-side aspects. For an updated overview on the case law and the methods that can be employed under Article 102(a), see M. Botta, *Sanctioning unfair pricing under Art. 102(a) TFEU: yes, we can!*, 17(1) EUROPEAN COMPETITION JOURNAL 156 (2021).

<sup>87</sup> See Opinion of Advocate General Wahl of 6 April 2017, *Autortiesību un komunikēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome*, Case C-177/16, EU:C:2017:286, point 19 and cited case-law.

<sup>88</sup> Judgment of 14 September 2017 in *Autortiesību un komunikēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome*, C-177/16, ECLI:EU:C:2017:689, paras. 41 e 44.

<sup>89</sup> *Id.*, para. 55.

legitimate reasons.

In the following paragraph, the issue will be treated through the analysis of the *Aspen* case, the first decision issued by the European Commission concerning excessive pricing in the pharmaceutical sector.

#### 4.1.2. *Aspen*

The European Commission started its investigation concerning the pharmaceutical company Aspen in 2017, covering the entire European Economic Area except Italy, where, as mentioned above, a separate infringement decision was issued by the ICA in 2016. The contested conduct started in some Member States in mid-2012 with high price increases, often by several hundred percent, and resulted in very high price and profitability levels of the prescription drugs sold under the brand names Alkeran IV and Alkeran Oral (melphalan), Purinethol (mercaptopurine), Leukeran (chlorambucil), Lanvis (tioguanine) and Myleran (busulfan), used as essential and non-substitutable medicines for the treatment of certain types of cancer and for specific group of patients, including elderly persons and children. Aspen acquired the products from GSK in 2009 as part of a bundle of transactions paid for with Aspen shares. Aspen has been outsourcing the manufacturing and packaging of the drugs as well as most of the commercialisation and distribution to third parties. When it took over the management of the products in 2011, it developed a plan to increase their prices.

In its Preliminary assessment, the Commission found that, in the vast majority of the relevant markets, Aspen maintained very high market shares between July 01, 2012, through June 30, 2019 (often 90-100%, or between 70-80% to 90-100%). In such markets there was no entry, or, where entry happened, it was limited and did not lead to a decrease in prices. In light of the application of excessive pricing prohibitions and the *United Brands* test, under the first limb the Commission compared the costs of production to the revenues earned by Aspen, and then assessed the excessiveness of the resulting profits by comparing Aspen's profitability with that of a sample of other undertakings which sell similar products and have a profile similar to Aspen. From such analysis, it was determined that Aspen has reached profitability levels much higher than those of the comparators and earned revenues exceeding the cost-plus level with each product in

almost all of the relevant markets.<sup>90</sup> Under the second limb, the Commission found Aspen's prices as unfair in themselves. The high profits gained by the company appeared to derive from the exercise of market power arising from a lack of effective competition, whereas no legitimate reasons in terms of commercial risk-taking activity, innovation, investment or any improvement of the products could be found.<sup>91</sup> The Commission looked at the following factors: whether Aspen had carried out any particular activity in relation to the products; the characteristics of the medicines (that had been off-patent for decades, but are still essential for a number of cancer patients); the blunt disproportion between the limited increases in the costs of the products and the very high price increases, and the magnitude of the excessiveness of Aspen's profits. In addition, it is worth noting that the Commission considered also the dominant undertaking's conduct and its economic motives at this stage.<sup>92</sup> Then it took into account as an additional factor the means by which Aspen imposed the higher prices and the likely harm those prices may have caused to patients and the national health budgets.<sup>93</sup> It is also worth mentioning that the ICA in its national investigation on Aspen pointed out that no consideration can be given to the consumer's willingness to pay, which, in the case of non-substitutable life-saving drugs, would be infinite, thereby potentially justifying any price.<sup>94</sup>

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<sup>90</sup> Commission decision, para. 103 et seq. and para. 144 et seq. Acknowledging that several measures can, in principle, be suitable to assess suspected price abuses, the Commission, on the basis of the specific circumstances of the case, has decided to focus on two measures of profitability, namely gross margins and EBITDA margins. While gross margin refers to net sales minus direct costs (and thus not considering indirect costs), EBITDA margin is a net profitability measure that takes into account all direct costs and all indirect costs, with the exception of depreciation and amortisation costs (that cover impairment costs, which are thus also excluded). The preliminary assessment used the latter as the main profitability measure to assess the profitability of the products, since it accounts for a broader set of costs and therefore provides a more complete picture of the costs required to carry out a given economic activity. See paras. 117-121.

<sup>91</sup> *Id.*, paras. 165 et seq.

<sup>92</sup> The Commission, recalling the Opinion of AG Wahl in *AKKA/LAA* case (*supra* note 87, point 118), affirmed that the objective reasons behind the pricing policy of the pharmaceutical company are highly relevant. There is no reference to previous case law in this point.

<sup>93</sup> *Id.*, para 191 et seq. From a methodological point of view, the Commission stressed that the two ways provided by the *United Brand* test to assess unfairness (i.e., whether the price is unfair in itself or when compared to competing products) are alternative, so that only one must be fulfilled. Nonetheless, the preliminary assessment also considered the potential suitability of some other products for assessing unfairness to reply to Aspen's arguments in this respect and reached the preliminary conclusion that potential generic and innovative price comparator products put forward by Aspen do not challenge the preliminary finding that Aspen's prices are in themselves unfair. See para.196 et seq. The application of this part of the test is one of the most controversial arguments opposing the ruling adopted in *Pfizer/Flynn* by the CAT, according to which, in assessing unfairness, an authority can apply either alternative of the *United Brands* test but must give due consideration to any *prima facie* convincing argument that the pricing is actually fair under either alternative. See note 98.

<sup>94</sup> ICA decision, para. 137.

With regard to the pan-European strategy adopted by Aspen to implement price increases, it comprises attempts made by the pharmaceutical company to overcome the resistance of national regulatory authorities to accept the price increase by means of threats and occasional implementation of delisting and withdrawals.<sup>95</sup> Moreover, Aspen employed a strategic sequencing of price increases with the aim of defeating the external reference pricing system, and to avoid parallel trade. Aspen started the price increase in Germany, as, under German law, it had the freedom to unilaterally set new list prices for the products. Although a statutory claw-back applied with the aim of preventing increases of real net prices in Germany itself, Aspen could influence the price formation process elsewhere by using the increased German list prices in its applications in other Member States, considering many States used the German official list price as reference in their external reference pricing system. Moreover, through delistings or withdrawals, Aspen could prevent Member States from including low prices, which the company itself did not manage to increase, in their reference pricing basket.<sup>96</sup> Finally, a stock allocation system, consisting of allocating quotas and, if necessary, withholding deliveries for the products in some Member States, was in place.

The proceedings closed four years later after the Commission accepted the commitments proposed by Aspen, including a both a price and a supply commitment, i.e. a consistent price reduction and the guaranteed supply of the drugs for a certain period.<sup>97</sup> The adoption of a commitment decision under Article 9 of Regulation 1/2003, as an alternative remedy to prohibition decisions, has the advantage of typically granting a quicker impact on the market, more tailored remedies, and a swifter implementation by the undertakings concerned, which may further avoid fines and a formal finding of

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<sup>95</sup> Commission decision, paras. 87 et seq.

<sup>96</sup> *Id.*, paras. 97-99. In the Italian context, the ICA's investigation contains details of the very aggressive negotiation strategy adopted by Aspen towards the Italian Medicines Agency (AIFA). It is worth mentioning that 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 – i.e. class for non-reimbursed drugs, thereby leaving the cost of the drug to the patients.

<sup>97</sup> The commitments include the reduction of Aspen's prices across Europe for the six cancer medicines by approximately 73%, which is on average below the prices of 2012, before Aspen's price increases started (with reduced net prices applying for a period of 10 years); and the guaranteed supply of the medicines for the next five years, and, for an additional five-year period, the continuation of supply or the availability of its MA to other suppliers. The reduction of net prices is fixed to be effective retroactively as from 1 October 2019, the date when Aspen first approached the Commission with a concrete commitment proposal, until such time as Aspen has effectively implemented the price reductions to public and private entities that ultimately pay or reimburse medicine prices in the Member States.

infringement. However, in this case the Commission may apply Article 102 TFEU without an extensive economic and legal assessment, and commitment decisions provide limited chance for judicial review. For this reason, the recourse to such tool raises strong criticism in novel and complex competition cases. This is exactly the case of *Aspen*, where the Commission has made this choice, failing to meet the expectation of having a full assessment which would eventually be scrutinised before a Court in order to give further guidance to the industry and enforcers. As a matter of fact, the existence of a certain degree of uncertainty in the application of the *United Brands* test in excessive pricing cases had been further demonstrated by the critics of the CMA decision in *Pfizer/Flynn Pharma* case and its outcome before UK courts.<sup>98</sup>

#### 4.2. Off-patent drugs' price hikes in the United States

In the U.S., the problem of high prices for pharmaceuticals is continually at the heart of social and political debate, as prescription drug prices are particularly high in comparison to other countries and drug spending has increased at a faster rate than any other component of the healthcare industry.<sup>99</sup> The main reasons for high prescription drug

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<sup>98</sup> Contrary to what asserted by the CAT, the Commission clarified that the two ways provided by the *United Brand* test to assess unfairness (i.e. whether the price is unfair in itself or when compared to competing products) are alternative, so that only one must be fulfilled (Commission decision, para. 196). In its ruling, the CAT (see *supra* note 61) concluded that the CMA did not correctly apply the legal test for excessive pricing, stating, *inter alia*, that it did not appropriately consider what was the right economic value for the product at issue and it did not take sufficient account of the situation of other comparable products. As regards unfairness, the Tribunal emphasized that the CMA erred by considering unnecessary to prove the unfairness of the price through a comparison between the price of the investigated product with those of comparable products, such as a 100 mg unbranded tablet using the same phenytoin sodium molecule, while Epanutin was a capsule. In the appeal to the Court of Appeal, the European Commission intervened to support the CMA, taking the position that the Tribunal erred in law in its articulation of the test for abuse of dominance and arguing that if the law is as laid down by the Tribunal it would be impracticable and unworkable. Furthermore, according to the Commission, the Tribunal misinterpreted the general scheme of *United Brands* and of the *AKKA/LAA* case (*supra* note 88). See Court of Appeal, *supra* note 62, paras. 41-42. However, the Court of Appeal found that the “in itself” and “competing products” tests should not be interpreted in an unduly rigid and literal way, as the CMA did, as they are not “strict alternatives” and that the CMA was wrong considering that once it has relied upon one alternative to find abuse, then it had no obligation in law to evaluate other *prima facie* evidence that prices were fair adduced by a defendant undertaking. See Court of Appeal, *supra* note 62, paras. 57 and 117.

<sup>99</sup> National spending on retail prescription drugs in the United States reached nearly \$370 billion in 2019, with spending expected to increase by an average of more than 5% per year between 2021 and 2028. See data reported by Gavulic & Dusetzina, *supra* note 52. For updated data on health and pharmaceutical spending, see: OECD (2021), Health spending (indicator), available at: <https://data.oecd.org/healthres/health-spending.htm#indicator-chart>; Id., Pharmaceutical spending (indicator), available at <https://data.oecd.org/healthres/pharmaceutical-spending.htm#indicator-chart>.

prices relate to both high prices at launch and significant periodic price increases, and greater use of prescription drugs by the population.

The combined effect of the Hatch-Waxman Act and the rules incentivizing pharmacy substitution have contributed to high-generic volume share and competition in this market, where prices have been traditionally lower than in major European countries. Additionally, high prices affect strongly branded medicines and “specialty drugs”,<sup>100</sup> which jeopardize savings deriving from generic competition to some extent.<sup>101</sup> However, as will be seen in this paragraph, recent experience shows that price increases also affect generic and off-patent products.

As anticipated, excessive prices are not an issue in U.S. antitrust law, which does not restrict the prices charged by a firm that lawfully acquired market power. The well-known quote from the *Trinko* judgment clearly explains the traditional stance: “[t]he mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts “business acumen” in the first place; it induces risk taking that produces innovation and economic growth. To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*.”<sup>102</sup>

This approach has come under discussion after recent cases of extraordinary price increases in the pharmaceutical sector. In 2016, an investigation started by the bipartisan Senate Special Committee on Aging into dramatic price increases of off-patent prescription drugs revealed key elements of the strategies used by companies to exploit market failures, i.e.: acquiring a sole-sourced gold standard drug, with only one manufacturer and no immediate competition, serving a small market which would be

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<sup>100</sup> Although no consistent definition can be found, they are typically considered including those drugs which are novel therapies with ongoing clinical assessment, are used to treat rare conditions, or require special handling, monitoring or administration; Medicare uses a threshold to define specialty tier drugs, including those that currently cost more than \$670 per month. See [https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020\\_8.pdf](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020_8.pdf).

<sup>101</sup> Feldman, *supra* note 42, at 8.

<sup>102</sup> *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). See also *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 454 (2009).



unattractive to competitors; creating a closed distribution system or other means to block competitors; and engaging in price gouging by charging as much as possible.<sup>103</sup>

Perhaps the most known case concerns Daraprim, a decades-old drug used primarily to treat toxoplasmosis. In 2015, Turing Pharmaceuticals (now Vyera Pharmaceuticals) purchased from Impax the rights to Daraprim (pyrimethamine), which was sixty-two years old and no longer protected by a patent, and soon thereafter raised the price from \$13.50 per tablet to \$750. Despite the fact that there were no patents or other forms of market exclusivity protecting the drug, Turing could implement the price hike due to the relatively small market in the U.S. for pyrimethamine, facing no entry by other generic manufacturers.<sup>104</sup> The features of this case are not so different from those previously discussed in the European context, as it concerns a post-acquisition strategy involving a substantial and unjustified increase in price of an off-patent drug, without any innovative effort pursued by Turing, in a market with no competitors.<sup>105</sup> Turing (which also employed tactics leading to an antitrust lawsuit in 2020) and other cases signaled this worrying trend, which has led to increased scrutiny and concern.<sup>106</sup>

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<sup>103</sup> Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Healthcare System* (2016), available at <https://www.congress.gov/114/crpt/srpt429/CRPT-114srpt429.pdf>. For details see P. FitzGerald, *State Regulation of Generic Drug Price Gouging*, BELMONT HEALTH L. J: Vol. 2, Article 7 (2019).

<sup>104</sup> At the same time, apparently as a condition of the sale to Turing, pyrimethamine was switched to a controlled distribution system (called Daraprim Direct), in which prescriptions or supplies of the product could be obtained only from a single source, Walgreen's Specialty Pharmacy. As a consequence, Daraprim was available only through this new system and only registered clients could obtain it: patients could receive the drug only by mail order and not through a local pharmacy and hospitals were prevented to obtain the drug from a general wholesaler. Such system affected also other manufacturers wishing to obtain samples of the drug for use in bioequivalence studies supporting an ANDA, thereby undermining efforts by generic firms to enter the market. On these points, see M. A. Carrier, N. Levidow & A. S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH L. J. 1379 (2017). In 2020 the FTC filed a complaint in federal court against Vyera Pharmaceuticals, LLC (formerly Turing Pharmaceuticals) alleging an elaborate anticompetitive scheme to preserve a monopoly on Daraprim.

<sup>105</sup> H. First, *Excessive Drug Pricing as an Antitrust Violation*, 82 (2) ANTITRUST L. J. 701, 728 (2019).

<sup>106</sup> Another case that has gained attention of scholars and media has regarded EpiPen, an injector delivering epinephrine typically used for emergency treatments for anaphylaxis. In 2007 Mylan acquired Merck's generic pharmaceutical business and the exclusive right to market and distribute the EpiPen, whereas Meridian, a Pfizer subsidiary, retained the manufacturing of the device. Whereas epinephrine is not patented, the injector is. The events are rather complex and here only the main elements relevant for our purposes will be mentioned. In 2012 Mylan and the holders of the patent on the injector settled a patent infringement suit they brought against Teva, a generic manufacturer agreeing not to enter the market until 2015, which was ten years before the patent's expiration. However, Teva had production problems and did not enter the market at the agreed upon time. In 2013 the School Access to Emergency Epinephrine Act (called the "EpiPen" bill even though no direct mention of the EpiPen was included in the bill) gave funding preferences for schools maintaining emergency supplies of epinephrine, having a strong impact on both

Some scholars have called for an antitrust intervention in this area. Harry First, making explicit reference to the European experience with *Aspen* and *Pfizer/Flynn Pharma* cases conducted by national competition authorities, has claimed that the existing approach makes the U.S. an “international outlier”.<sup>107</sup> First has challenged the conventional wisdom regarding the ability of Section 2 of the Sherman Act to address excessive pricing. According to First, the failure to address excessive pharmaceutical prices under U.S. antitrust law is rooted in policy rather than on legal problems, and excessive pricing could satisfy the monopolistic conduct requirement. In support of this argument, reference is made to cases in which exploitation of consumers through the charging of high prices has been asserted as a type of competitive harm, leading to the FTC’s increased scrutiny of standard-essential patents (SEPs) and FRAND licensing.<sup>108</sup> Academic and political debate focuses on determining which means could be used for antitrust intervention, including the possibility of relying on the Section 5 of FTC Act, which gives the Commission the authority to address both “unfair or deceptive acts or practices” and “unfair methods of competition”. Scholars supporting this solution claim that this tool would allow the FTC to bring administrative proceedings specifically against those companies that engage in such kinds of exploitative conducts, and not against those that raise prices in response to normal market forces.<sup>109</sup>

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sales and reputation of the EpiPen. Between 2009 and 2016, Mylan raised the price of this life-saving device of more than 400% than previous price. EpiPen faced little competition (from Auvi-Q and Adrenaclick). In 2018 the FDA finally approved Teva’s application to produce a generic version of the EpiPen. On this case, see M. A. Carrier & C. J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53 (2017). On EpiPen and on the connection between patents and the FDA’s role in governing drug-device combination products, see J.S. Sherkow & P.J. Zettler, *Patents, and Life and Death*, 96 NYU LAW REV. ONLINE 164 (2021), available at <https://www.nyulawreview.org/wp-content/uploads/2021/08/SherkowZettler-fin-1.pdf>.

<sup>107</sup> First, *supra* note 105, 737. See also F. M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6(3) UC IRVINE L. REV. 281, 293 (2016).

<sup>108</sup> First, *supra* note 105, at 719-720 (affirming that: “The SEP holders in these cases were able to extract monopoly rents because they controlled something “essential” to their licensees and then acted either deceptively or opportunistically to exploit that power. Put in an antitrust framework, there was monopoly power, plus anticompetitive conduct, and harm to consumer welfare. See also J.L. Graber, *Excessive Pricing of off-Patent Pharmaceuticals: Hatch it or Ratchet?*, 92 NYU L. REV. 1146, 1184 (2017). See, e.g., Complaint, In the Matter of Negotiated Data Solutions LLC, Doc. No. C-4234 at 28 (2008), available at <https://www.ftc.gov/sites/default/files/documents/cases/2008/09/080923ndscomplaint.pdf>.

<sup>109</sup> Graber, *supra* note 108, at 1183. See also H. First, *Unfair Drug Prices and Section 5*, CPI ANTITRUST CHRON. (Nov. 2015). It is worth mentioning that an interesting case (although different from those of price hikes mainly object of this paper) of application of Section 5 by the FTC in the pharmaceutical sector is *FTC v. Mylan Laboratories, Inc., Cambrex Corporation, Profarmaco S.R.I., and Gyma Laboratories of America, Inc.* (Nov. 9, 2000). In this case the FTC brought action under Sections 5 and 13(b) of the FTC Act, seeking permanent injunctive and other equitable relief, including disgorgement. The FTC’s complaint

Until now, such positions have not been upheld by antitrust agencies, which, in their note sent to the OECD in 2018 as part of the roundtable devoted to excessive pricing in the pharmaceutical sector, have confirmed that “limiting the freedom to set prices may well conflict with the underlying premise of antitrust policy, *i.e.* promoting a robust competitive process that produces high-quality, innovative goods at low prices.”<sup>110</sup> Moreover, in 2019, in response to a directive from Congress, the FTC issued a report to the House and Senate Appropriations Committees on the use of its standalone authority under Section 5 of the FTC Act to address high pharmaceutical prices. Specifically, the Committees requested the FTC, in consultation with the FDA, to examine Congress’s intent regarding unfair methods of competition in 15 U.S.C. 45(n) and in the FTC’s standalone Section 5 authority with regard to unreasonable price increases, including those that occur over multiple years, on off-patent pharmaceutical drugs and biologics when there are no alternatives available to the consumer, and when price increases are unreasonable, unavoidable, and not due to increased manufacturing costs of the product.<sup>111</sup> The majority of FTC commissioners supported that the use of Section 5 alone is not an effective tool for prohibiting unreasonable price increases of pharmaceutical drugs, unless the increase is accompanied by some other exclusionary or collusive conduct, or in an extreme circumstance, where the FTC can show that the price increase constitutes an unfair or deceptive act or practice. In particular, this solution would hardly be successful before Courts, which typically decline to impose antitrust liability for unilateral pricing decisions and consider determining the reasonableness of prices

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charged Mylan with restraint of trade, monopolization and conspiracy to monopolize the market for two generic drugs used to treat anxiety, lorazepam and clorazepate, through exclusive dealing arrangements. Moreover, the FTC alleged that Mylan, Gyma Laboratories of America, Inc., Cambrex Corporation and Profarmaco S.R.L. conspired to deny Mylan’s competitors ingredients necessary to manufacture lorazepam and 40 clorazepate. Therefore, according to the complaint, Mylan could and did raise prices approximately 2000-3000% depending on the bottle size and strength (e.g., in January 1998, Mylan raised the wholesale price of clorazepate from \$11.36 to \$377.00 for a 500-count bottle of 7.5 mg tablets, and, in March 1998, of lorazepam from \$7.30 to \$190 for a 500-count bottle of 1 mg tablets). The Commission’s December 1998 complaint, filed in the District Court for the District of Columbia, alleged that through its agreements with the other defendants, Mylan had earned an additional \$120 million. The case was concluded through a \$100 million settlement. Details are available at <https://www.ftc.gov/news-events/press-releases/2000/11/ftc-reaches-record-financial-settlement-settle-charges-price>.

<sup>110</sup> United States submission to the OECD, *supra* note 1, at 3.

<sup>111</sup> FEDERAL TRADE COMMISSION, REPORT ON STANDALONE SECTION 5 TO ADDRESS HIGH PHARMACEUTICAL DRUG AND BIOLOGIC PRICES, June 2019, available at <https://www.ftc.gov/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices>.

charged by lawful monopolists to go beyond their competence.<sup>112</sup> The report lists several factors that would limit the use of standalone Section 5 authority to challenge high drug prices, including: limiting unilateral freedom to set prices diminishes companies' incentives to compete and innovate; interfering with market pricing mechanisms may distort supply and demand and lead to reduced supply rather than lower pricing; both courts and the FTC would find it extremely difficult to set up and enforce an accurate and meaningful standard for what constitutes an excessive price increase; and market conditions and government-granted barriers to entry may inhibit the ability of the FTC to police drug pricing. Such position has not been shared by Commissioners Chopra and Slaughter, who, in their dissenting statement, claimed that the FTC needs to consider the full breadth of its statutory authority under Section 5, and suggesting the use of such tool through the prohibition on unfair or deceptive acts or practices "in situations where (1) a price increase involves off-patent drugs that lack therapeutic alternatives, and where research, production, and regulatory barriers would prevent near-term entry, (2) the price increase bears no reasonable relationship to manufacturing or production cost increases or changes in supply and demand conditions, and (3) the harm to patients is not outweighed by other benefits."<sup>113</sup>

It is worth noting that the scope of Section 5 of the FTC Act is often debated between those supporting a broad interpretation of the rule and others claiming a more restrictive approach.<sup>114</sup> The position expressed by the FTC in its 2019 report is compliant with the

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<sup>112</sup> *Id.*, at 5-7.

<sup>113</sup> Statement of Commissioners R. Chopra and R.K. Slaughter, June 24, 2019, p. 2, available at [https://www.ftc.gov/system/files/documents/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices/p180101\\_section\\_5\\_report\\_dissenting\\_statement\\_by\\_chopra\\_and\\_slaughter\\_6-27-19.pdf](https://www.ftc.gov/system/files/documents/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices/p180101_section_5_report_dissenting_statement_by_chopra_and_slaughter_6-27-19.pdf).

<sup>114</sup> See W.E. Kovacic & M. Winerman, *Competition Policy and the Application of Section 5 of the Federal Trade Commission Act*, 20 MINN. J. INT'L L. 274 (2010) (noting that "several factors explain why Section 5 has played so small a role in the development of U.S. competition policy principles. Probably the most important is that the Sherman Act proved to be a far more flexible tool for setting antitrust rules than Congress expected in the early 20th century"); M.K. Ohlhausen, *Section 5 of the FTC Act: principles of navigation*, 2(1) JOURNAL OF ANTITRUST ENFORCEMENT 1 (2014); *Id.*, *The Procrustean Problem with Prescriptive Regulation*, 23 COMM'LAW CONCEPTUS 1 (2014) (calling for regulatory humility and arguing that consumer welfare must be among the guiding lights for the FTC to apply its Section 5 authority to cases outside the reach of traditional antitrust laws and, before taking action, the FTC ought to establish substantial harm to competition or the competitive process, and thus to consumers, relying on robust economic evidence that the challenged conduct is anticompetitive and reduces consumer welfare). A different approach is sponsored by R. Chopra & L. Kahn, *The Case for "Unfair Methods of Competition" Rulemaking*, 87 U. CHI. LAW REV. 357 (2020). For an overview, see H.J. Hovenkamp, *The Federal Trade Commission and the Sherman Act*, 62 FLA. L. REV. 1 (2010). One of the arguments supporting the

2015 *Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act* (hereinafter 2015 UMC Statement), adopted on a bipartisan basis during the Obama Administration and aimed at addressing the requests for a clear guidance on the issue. The 2015 UMC Statement indicated three principles apt to guide the decision on whether to challenge an act or practice as an unfair method of competition, i.e.: the promotion of consumer welfare as guidance; evaluation of the act or practice at issue under a framework similar to the rule of reason; no likelihood of use of Section 5 if enforcement of the Sherman or Clayton Act is sufficient to address the competitive harm arising from the act or practice concerned.<sup>115</sup> The topic is currently under attention again, and the 2015 UMC statement, which has been generally considered as narrowing the FTC’s ability to bring more expansive antitrust claims, has been subject to withdrawal in July 2021 by the new FTC chaired by Lina M. Khan.<sup>116</sup> Thus, it remains to be seen if the recently announced changes will lead to a shift in the antitrust approach to high drug pricing. Additionally, President Biden has released a wide-ranging Executive Order on Promoting Competition in the American Economy,<sup>117</sup> which, among the numerous points, also includes specific reference to high prescription drug prices.

Before looking at the ongoing actions under the Biden-Harris administration, and aside from the antitrust approach, it is worth noting that several bills addressing excessively

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expansion of the FTC authority is based on the fact that the prohibition of monopolizing conduct under Section 2 of the Sherman Act is narrower than the prohibitions used, e.g., in the EU, which addresses abuses of a dominant position. Hovenkamp (at 5) clarifies that such difference “can become quite important when conduct is not reasonably calculated to maintain or create a monopoly but rather represents the dominant firm’s attempt to use its power in some complementary or collateral market in which monopoly cannot be proven to result.” In his view, “the FTC Act’s “unfair methods of competition” seem well suited for such applications, provided that they are limited to situations in which competitive harm is likely”.

<sup>115</sup> FTC, *Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act* (Aug. 13, 2015), [https://www.ftc.gov/system/files/documents/public\\_statements/735201/150813section5enforcement.pdf](https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf). See also Dissenting Statement of Commissioner Ohlhausen, available at: <https://www.ftc.gov/public-statements/2015/08/dissenting-statement-commissioner-ohlhausen-ftc-act-section-5-policy>.

<sup>116</sup> FTC, *Statement of Chair Lina M. Khan Joined by Commissioner Rohit Chopra and Commissioner Rebecca Kelly Slaughter on the Withdrawal of the Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act*, July 1, 2021, available at [https://www.ftc.gov/system/files/documents/public\\_statements/1591498/final\\_statement\\_of\\_chair\\_khan\\_joined\\_by\\_rc\\_and\\_rks\\_on\\_section\\_5\\_0.pdf](https://www.ftc.gov/system/files/documents/public_statements/1591498/final_statement_of_chair_khan_joined_by_rc_and_rks_on_section_5_0.pdf). See also Dissenting Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson, available at [https://www.ftc.gov/system/files/documents/public\\_statements/1591710/p210100phillipswilsondissentsec5enforcementprinciples.pdf](https://www.ftc.gov/system/files/documents/public_statements/1591710/p210100phillipswilsondissentsec5enforcementprinciples.pdf).

<sup>117</sup> Exec. Order No. 14036 on Promoting Competition in the American Economy, 86 Fed. Reg. 36,987 (July 9, 2021). For a first comment, see H. Hovenkamp, *President Biden’s Executive Order on Promoting Competition: an Antitrust Analysis*, July 18, 2021, available at: <https://ssrn.com/abstract=3887776>.

priced prescription drugs have been proposed in Federal Congress in recent years. But the most relevant efforts have been taken at State level, where concerns about the rising costs of drugs have led to the adoption of legislative measures specifically targeting “price gouging” or “unconscionable” price increases.<sup>118</sup> Such legislation includes several types of laws.<sup>119</sup> For the purposes of this paper, only legislations aimed at regulating directly drug prices will be considered, including price gouging, rate setting, and unsupported price increase laws. The main problem with state laws is that they are particularly exposed to challenges and have been challenged by industry organizations under the dormant Commerce Clause, patent law, trade secret, the Takings Clause, the First Amendment, and the Due Process Clause.<sup>120</sup>

Price gouging laws, generally adopted in light of price increases on necessary goods during emergency situations, have been applied to “unconscionable” or “excessive” prices for prescription drugs. Through this kind of legislation, also referred to as fair pricing bills, drug manufacturers may be required to justify certain price increases or face penalties, or to provide rebates when prices exceed a certain threshold.<sup>121</sup> After earlier efforts made in 2005 by the District of Columbia to regulate the prices of patented

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<sup>118</sup> For an overview, see P. FitzGerald, *State Regulation of Generic Drug Price Gouging*, 2 BELMONT HEALTH LAW JOURNAL (2019); W. V. Padula, *State and Federal Policy Solutions to Rising Prescription Drug Prices in the U.S.*, 22 J. HEALTH CARE L. & POL’Y 15 (2019); S. Reed, *Preventing Drug Price Gouging: Government Power and Initiatives*, 19 HOUS. J. HEALTH L. & POLICY 167 (2019); M. M. Mello & R. E. Woltz, *Legal Strategies for Reining In “Unconscionable” Prices for Prescription Drugs*, 114 NW. U. L. REV. 859 (2020).

<sup>119</sup> Mello & Woltz, *supra* note 118, at 873, reporting data according to which in 2019, more than 300 bills were filed at the state level to address prescription drug costs. An updated database of this kind of initiatives is the legislative tracker provided by the Nat’l Acad. For State Health Policy (NASHP), available at <https://www.nashp.org/rx-legislative-tracker/>. For an overview, see K. L. Gudiksen & J. S. King, *The Burden of Federalism: Challenges to State Attempts at Controlling Prescription Drug Costs*, 39 J. LEG. MED. 95 (2019) 1733 (identifying the following main ways state bills try to address pharmaceutical costs: 1) requiring biosimilar substitution; 2) eliminating gag-clauses for pharmacists, preventing them from informing customers when their insurance copay or cost-sharing exceeds the price of the drug without insurance; 3) restricting when insurers and PBMs can change formularies or require step therapy; 4) overseeing PBMs; 5) increasing transparency in drug pricing and its impact on insurance premiums - Such laws, which provide information to the public, must be distinguished from “reporting” legislation, which provides information to regulators alone; 6) importing drugs from other countries; 7) prohibiting price gouging for drugs; and 8) regulating drug prices).

<sup>120</sup> See Mello & Woltz, *supra* note 118, at 863; R. Feldman, B. Chang Rowe, R. Oral, A.J. Gu & K. Gudiksen, *The Patent Act and the Constitutionality of State Pharmaceutical Regulation*, 45 RUTGERS COMPUT. & TECH. L. J. 40 (2019) (analysing Takings and patent-preemption challenges); Gudiksen & King, *supra* note 119.

<sup>121</sup> Yale Glob. Health Just. Partnership, *Curbing Unfair Drug Prices: A Primer for States*, 2017, at 6, available at: [https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing\\_unfair\\_drug\\_prices-policy\\_paper-080717.pdf](https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf);

medications through the Prescription Drug Excessive Pricing Act have been invalidated on the grounds of the patent preemption clause,<sup>122</sup> subsequent state-level price gouging bills have typically focused on off-patent and generic drugs.<sup>123</sup> One of the most notable examples has been HB 631, the Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs, adopted by Maryland in 2017, addressing “unconscionable increases”, meaning an increase in the price of a prescription drug that is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health, and which results in patients who need the drug having no choice but to purchase the drug at the increased price because of the importance of the drug to their health, and insufficient competition in the market concerned.<sup>124</sup> Maryland’s legislation has been challenged, and the Fourth Circuit Court of Appeals held Maryland’s law unconstitutional under the Dormant Commerce Clause (reaching transactions outside the State territory), whereas the vagueness argument (in violation of the Due Process clause of the Fourteenth Amendment) was not fully litigated.<sup>125</sup> In February 2019, the Supreme Court denied certiorari for Maryland’s

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<sup>122</sup> Prescription Drug Excessive Pricing Act of 2005, D.C. CODE ANN. §§ 28-4551 to 28-4555 (LexisNexis 2001 & Supp. 2008) declared unconstitutional by *Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007). The Act prohibited drug manufacturers and licensees from selling patented medications in the District of Columbia for an excessive price, stating, “[i]t shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.” The law defined an “excessive price” by referencing prices paid in high-income foreign countries. It established a *prima facie* case of excessive pricing if the wholesale price of a patented medication was more than 30% higher than that medicine’s price in any high-income country in which the product is protected by patents or other exclusive rights. For a comment, see S. Lipski, *Excessive Pricing and Pharmaceuticals: Why the Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. TOL. L. REV. 913 (2008).

<sup>123</sup> D.C. CODE § 28-4551 (2005). *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007). For a thorough analysis, see Mello & Wolitz, *supra* note 118, 873 et seq.

<sup>124</sup> HB 631, Gen. Assembly Md. (Nov. 28, 2017).

<sup>125</sup> After the district court dismissed the dormant Commerce Clause claim but preserved the vagueness claim, the Fourth Circuit reversed the dismissal of the dormant Commerce Clause claim and invalidated the statute on that basis. *Ass’n for Accessible Medicines v. Frosh*, 887 F.3d 664, 673-74 (4th Cir. 2018). According to the dormant Commerce Clause doctrine, which is a corollary of the Commerce Clause, states cannot interfere with or burden interstate commerce (which is a federal competence).

appeal.<sup>126</sup> Maryland's legislation, and its unsuccessful enactment, has been particularly influential on other states' efforts to introduce similar bills and in inspiring imitators.<sup>127</sup>

Different tools, which are not intended to be confined to non-patented products, are: rate-setting laws, providing "drug affordability boards" to address unconscionable pricing by setting a cap, an upper limit on the amount that public and private payers may be required to pay within a state;<sup>128</sup> and legislation regulating excessive or unsupported price increases (UPIs), which, although new and not yet widely adopted, impose a tax or penalty when a drug's price increases by more than a specified percentage (such as the rate of general inflation) over a defined period.<sup>129</sup>

As anticipated, efforts by states to pass legislation to address rising drug costs have been aggressively challenged by industry, and the lack of a federal intervention crucially matters. There is an acknowledgement that, despite widespread recognition of the problems related to drug pricing, legislative and regulatory reform attempts have failed to address the problem. In any case, justifying fairness determinations is a difficult task. In literature, different approaches have been proposed, relying on various comparison factors including: systems based on the cost of developing a drug; affordability-based rate-setting models; reference pricing; value-based pricing; and price capping.<sup>130</sup> In

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<sup>126</sup> *Frosh v. Ass'n for Accessible Meds.*, 139 S. Ct. 1168 (2019). For details, see Mello & Wolitz, *supra* note 118, at 881 (noting that, "Maryland's price gouging law remains void until it is reworked to be consistent with the Fourth Circuit's ruling. Because the vagueness argument was not fully litigated, it remains a viable basis for legal challenges to future statutes like HB 631.")

<sup>127</sup> Gudiksen & King, *supra* note 119, at 111, report that sixteen states considered legislation in 2018 and none of these passed state legislatures, and in 2019, only five states considered similar bills.

<sup>128</sup> Gudiksen & King, *supra* note 119, at 112, report that in 2018, eight states – California, Florida, Maryland, Minnesota, New Jersey, New Mexico, Ohio, and Rhode Island – considered such legislation and three of those states (Maryland, Minnesota, and New Jersey) introduced bills based on the National Academy for State Health Policy's (NASHP) Rate-Setting Model Legislation. In 2019, the NASHP legislative tracker listed fifteen bills introduced in nine states. For details on NASHP model legislation, see Mello & Wolitz, at 883 et seq. (clarifying that in the NASHP model legislation the determination of whether a drug's cost is excessive is not made primarily by reference to the manufacturer, but the primary criterion pertains to "commercial payor, provider, and consumer costs.")

<sup>129</sup> M. M. Mello & T. Riley, *To Address Drug Affordability, Grab the Low-Hanging Fruit*, JAMA Health Forum, February 25, 2021, available at <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2777036?widget=personalizedcontent&previousarticle=2768092> (explaining that the underlying logic of UPI laws is that, given the freedom to set launch prices, base prices represent a fair return on companies' investment in research and development, so if companies are not able to justify large price increases—for example, by presenting new evidence about the drug's clinical value or by showing that an ingredient became more expensive—most of the revenue generated from the disallowable portion of the price increase is taxed).

<sup>130</sup> See Mello & Wolitz, *supra* note 118, at 888 et seq., 950, 962 et seq.; Yale Glob. Health Just. Partnership, *supra* note 121, at 13; G. Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 942 et seq. (2021). In addition to the initiatives mentioned in this paragraph, it is worth mentioning that many States are



addition to the problems mentioned above concerning the application of state legislation to patented products, challenges based on vagueness deserve particular attention, as they reproduce the recurring problem of what constitutes an excessive or unfairly high price, showing how defining and evaluating a “fair” price is *the* controversial task in areas of law beyond antitrust law too.<sup>131</sup>

As mentioned above, in general the current administration has expressed concerns and the need for an intervention regarding drug pricing. In his Executive Order, President Biden has mentioned several objectives in this area, including the effort to improve access to prescription drugs and biologics and urging, *inter alia*, the Secretary of Health and Human Services (hereinafter, HHS) to submit a plan “to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging”.<sup>132</sup> Such a plan was released on September 9, 2021 by the HHS, and identifies three “guiding principles” for drug pricing reform, i.e.: i) making drug prices “more affordable and equitable,” in particular through Medicare direct price negotiations with drug manufacturers and limits on price increases; ii) improving competition through market changes that promote biosimilars and generics and increase transparency; and iii) fostering innovation through research and aligning incentives to promote discovery of new treatments, and not “market gaming”.<sup>133</sup> More specifically, HHS has called for “bold legislative action” and identified potential legislative policies Congress could pursue, including, *inter alia*: drug price negotiations in Medicare Parts B and D (which are currently forbidden), with those negotiated prices also available to commercial plans and employers who want to participate; Medicare Part D reform, including a cap on catastrophic spending to protect beneficiaries from unaffordable out-of-pocket costs; and legislation to slow price increases over time on

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adopting aggressive laws setting caps on insulin costs, as life-saving treatment, through a variety of methods. See J. K. Paradise, *Insulin Federalism*, 27 B.U. J.SCI. & TECH. L. 102, 158 (2021) (arguing that it seems an appropriate and equitable public health action to cap insulin costs at the federal level).

<sup>131</sup> On void-for-vagueness challenges, see Mello & Wolitz, *supra* note 118, at 888 et seq.

<sup>132</sup> Other measures include the mandate to FDA to work with states and tribes to safely import prescription drugs from Canada and the encouragement of FTC to ban pay-for-delay and similar agreements by rule.

<sup>133</sup> Secretary X. Becerra, *U.S. Department of Health and Human Services, Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy* (September 9, 2021), available at: <https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices>.

existing drugs.<sup>134</sup> At the time of writing, options for future reforms and their implementation are under discussion.

##### 5. The role of antitrust enforcement on excessive drug prices

Regulation, where in place, rather than antitrust, has typically dealt with pharmaceutical pricing. Price regulation, whose effects in pharmaceutical markets have been the object of extensive economic literature,<sup>135</sup> is inherently distant from and often in contrast with antitrust policy, as it is at odds with the idea of the free formation of prices as a result of the interaction between supply and demand, which is deemed essential for the efficient functioning of the markets and the allocation of resources.<sup>136</sup> As seen in the previous pages, there is at the global level an increasing attention and concern for high prices and price hikes of prescription drugs, which drives the thinking on how competition policy may play a fundamental role in this area. To date, the main experience has dealt with off-patent products, and a resurgence of excessive pricing prohibition has been observed within the EU. In reality, it still remains to be seen whether and to what extent such a resurgence will effectively spread. However, some considerations derive from existing practice.

As stated before, looking at the European experience, the *Aspen* case represents the

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<sup>134</sup> Other measures include: legislation to speed the entry of biosimilar and generic drugs, including shortening the period of exclusivity, and policies in Medicare Part B to increase the prescribing of biosimilars by clinicians; prohibition on “pay-for-delay” agreements and other anti-competitive practices by drug manufacturers; investment in basic and translational research to foster innovation, including the President’s proposal to create the Advanced Research Projects Agency for Health. The Report also identifies administrative tools HHS can use, including: testing models using value-based payments in Medicare Part B, in which payment for drugs is directly linked to the clinical value they provide patients; testing models providing additional cost-sharing support to Medicare Part D Low-Income Subsidy Beneficiaries for using biosimilars and generics; testing total cost of care models in Medicare to determine whether they produce changes in drug utilization, reductions in total spending, and improvements in patient outcomes; data collection from insurers and PBMs to improve transparency about prices, rebates, and out-of-pocket spending on prescription medications; continuing to implement the Food and Drug Administration’s Biosimilars Action Plan and Drug Competition Action Plan, and clarify the approval framework for generic drugs to make the process more transparent and efficient; working with states and Indian Tribes to develop drug importation programs that reduce costs to consumers without increasing risks to safety.

<sup>135</sup> See, e.g., M.K. Kyle, *Pharmaceutical price controls and entry strategies*, 89(1) REV. ECON. STAT. 88 (2007); P.M. Danzon & L.W. Chao, *Does regulation drive out competition in pharmaceutical markets?*, 43(2) J. LAW. ECON. 311 (2000).

<sup>136</sup> M. MOTTA, *COMPETITION POLICY: THEORY AND PRACTICE* (Cambridge University Press 2004), at 69.

first decision issued by the European Commission concerning excessive pricing in the pharmaceutical sector, and follows other investigations conducted by competition agencies at national level. This case is meaningful for various reasons. The main features of the case - including the magnitude of the price hikes, the absence of R&D and investment, recoupment or innovation justifications for it, the absence of self-correction of the market and of therapeutic alternative products, and the inability of regulators to provide an appropriate response to the price increase – confirm the justification of antitrust intervention, which meets in such circumstances the stringent screens and tests elaborated in literature, as mentioned above.<sup>137</sup> For the purposes of this paper, in the view of the role of competition rules and their intersection with regulation, it is worth stressing that a peculiar aspect of this case concerns the strategy and the means adopted by the undertaking, to which the antitrust decision gives particular relevance, despite it is not essential for the finding of unfair pricing. On closer inspection, this distinctive element of the case resembles a type of regulatory gaming behaviour, i.e. conduct of a private operator harnessing sector-specific rules and using them for anticompetitive purposes. This comes not as a surprise in the pharmaceutical sector, which “presents a perfect storm for regulatory gaming”, as some scholars emblematically argued.<sup>138</sup> In other words, the pharmaceutical company was able to strategically exploit the failures of the existing sectoral regulatory framework and exercise its bargaining power towards regulators as the dispute concerned drugs that, although off-patent, are still essential and non-substitutable for patients, and thus are indispensable for national health systems. In this context, antitrust intervention served as a help for regulators rather than in conflict with them and there is no room for possible concerns for an overlapping or a trespassing by competition agencies in their area of competence.

On a more general level, a fundamental question is whether antitrust policy may constitute an appropriate tool to intervene on pharmaceutical prices, and which role antitrust enforcement should play in this area. This concerns not only the European context, but also the U.S. one, given the debate analysed in the previous paragraphs. It is generally agreed that, even when it is admitted by law, competition agencies should

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<sup>137</sup> M. Colangelo & C. Desogus, *Antitrust Scrutiny of Excessive Prices in the Pharmaceutical Sector: A Comparative Study of the Italian and UK Experiences*, 41(2) *WORLD COMPETITION* 225, 237 (2017).

<sup>138</sup> S.L. Dogan & M.A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 *TEX. L. REV.* 685, 689 (2009).

intervene only as a last resort and when there is a regulatory failure.<sup>139</sup> In the EU, the difficulties in applying an appropriate methodology for excessive prices have been stressed and appear particularly challenging in the pharmaceutical context. Given the EU pharmaceutical regulatory system, with extensive price regulation based on national public policy, regulatory failure that results in unfairly high prices could be properly addressed through regulatory intervention, including remedy to the existing failure or providing alternative bargaining strategies between the buyer and the seller.<sup>140</sup> In this perspective, antitrust intervention, where needed, might work as a pathway to help regulation addressing the failures, fostering effective coordination between competent agencies.<sup>141</sup>

Where a system of price regulation is not in place, as in the U.S., one may ask whether a sporadic antitrust intervention could help avoid more invasive measures. On the one side, it has been argued that the implementation of antitrust enforcement may allow regulators to not resort to more intrusive regulatory schemes, such as more general pharmaceutical price regulation, which may carry larger risks to innovation and entrepreneurial freedom.<sup>142</sup> However, in the U.S., the possible adoption of price control mechanisms and specific legislative measures addressing high drug prices are already present in the political agenda, as seen above. On the other side, the prosecution of exploitative conduct under U.S. antitrust enforcement would require a clear indication of a rethinking of the traditional stance excluding exploitation through high prices as an antitrust offense. In any case, considering also the current European experience, antitrust

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<sup>139</sup> See also Wahl, *supra* note 87, para. 39.

<sup>140</sup> See C. Calcagno, A. Chapsal & J. White, *Economics of Excessive Pricing: An Application to the Pharmaceutical Industry*, 10(3) JECLAP 161, 171 (2019).

<sup>141</sup> See G. Monti, *Excessive Pricing: Competition Law in Shared Regulatory Space*, TILEC working paper (2019) <https://www.tilburguniversity.edu/sites/tiu/files/download/Monti%20Excessive%20pricing.pdf>, at 16-17. It is worth considering that in the UK the loophole in the sectoral regulation has been addressed: the Health Service Medical Supplies (Costs) Act 2017 was introduced to give the government additional powers to control the price of drugs, particularly unbranded generic products, and so prevent manufacturers from de-branding in order to significantly increase prices such as in *Pfizer/Flynn*. It is also worth mentioning that in Italy in 2017 the ICA and the AIFA have signed a memorandum of understanding in order to strengthen cooperation in areas of mutual interest, also in order to make the ICA duly informed about possible business conducts of antitrust relevance. See also OECD, *supra* note 78, at 25, 31 (affirming that, among the various tools that competition authorities have at their disposal, an important one is market studies, which would help competition agencies to understand market developments and fine-tune the most appropriate response, and advocacy for the adoption of appropriate regulation, or the adoption of initiatives in tandem with sectoral regulators).

<sup>142</sup> First, *supra* note 105, 739-740.

intervention, which is always ex-post and includes risks of errors, can work only as a fact-specific tool in limited circumstances rather than be a viable solution to high price increases in the pharmaceutical markets.

## 6. Concluding remarks

This paper has analysed the issue of high drug pricing and the possible roles and interface between regulation and antitrust in this area through the recent experience in the EU and the U.S. concerning exponential price increases for off-patent drugs. Both types of intervention face various issues.

Further consideration should then be given to patented drugs, which constitute a worrying topic. Despite the fact that no cases of excessive pricing concerning medicines covered by patents have been prosecuted up to now, the potential widening of the scope of competition enforcement against unfair prices to patented drugs requires careful consideration. In recent years, some authors have suggested that the existence of patent protection should not be seen as a reason to absolutely exclude the enforcement of excessive pricing prohibition, which might take the incentives for innovation into account.<sup>143</sup> According to this approach, this can be done by looking at the ex-ante probability of success, which is especially important in the pharmaceutical context where only a limited percentage of products reach the market. It has been argued that the cost of developing and approving a new product must include a risk factor, i.e. the R&D that goes into the discovery and refinement of the product, including the costs inherent to clinical assessment and potential failures to develop a successful drug.<sup>144</sup> Against such views, intervention on patented products is generally excluded, also considering the

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<sup>143</sup> C. Fonteijn, I. Akker & W. Sauter, *Reconciling Competition and IP Law: The Case of Patented Pharmaceuticals and Dominance Abuse*, ACM Working Paper (8 Mar. 2018), <<https://www.acm.nl/sites/default/files/documents/2018-03/acm-working-paper-reconciling-competition-and-ip-law-2018-03-07.pdf>>, pp. 14-15.

<sup>144</sup> Abbott, *supra* note 107, at 303 (also criticizing, at 316-317, the *United Brands* test). Moreover, some of these authors also propose methodological adjustments arguing that applying the prohibition on excessive prices, e.g. above the quality-adjusted life year (QALY), would not necessarily harm investment incentives but rather improve and drive investment decisions on socially relevant products. See Fonteijn, Akker & Sauter, *supra* note 143, at 14-15.

screens and tests described previously.<sup>145</sup> In addition to the main argument relating to the likely detrimental effects on investments and development of innovative products, it is affirmed that estimating the cost of developing and bringing a new medicine to the market may be a very complex exercise, and no widely accepted methodological standard exists.<sup>146</sup> In general, as excessive pricing cases are by their nature hard to build and often difficult to prosecute, it is also difficult that a case concerning a patented product would succeed in court.

Despite this, competition agencies may be under strong public pressure to prosecute such conduct in the pharmaceutical sector, considering the impact of high prices on public health and the circumstance that public funds often contribute to R&D activity.<sup>147</sup> This pressure, together with severe criticism and reputational issues that have concerned the pharmaceutical companies for years, is highly perceived, and resorting to antitrust in situations where other approaches have failed may provide an appealing solution. Antitrust enforcement has usually played and still plays a fundamental role in the pharmaceutical sector, in particular against exclusionary practices. A very cautious approach in considering whether to further expand antitrust enforcement on exploitative conduct concerning drug prices is appropriate.

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<sup>145</sup> See, e.g., Fletcher & Jardine, *supra* note 78, 541-542; R. O'DONOGHUE & J. PADILLA, *THE LAW AND ECONOMICS OF ART. 102 TFEU* (Hart Publishing, 3rd edition, 2020), 742. 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, 52 et seq.

<sup>146</sup> Calcagno, Chapsal & White, *supra* note 140, at 170. The Authors, in particular, with regard to the assessment of excessive profitability, have noted that many costs in the pharmaceutical industry are shared across multiple products and allocating these costs to specific products can be complicated. Moreover they add that: i) the profitability of any given product within a company's portfolio depends on what countries it is sold in, the size of the treatment population and price regulation; ii) product development in the pharmaceutical industry requires high levels of profitability on successful products to attract appropriate investments.

<sup>147</sup> See A. Jones & C. Stothers, *Establishing Unfairly High prices: The Implications of the CAT's Judgment*, 17(1) *BIO-SCIENCE LAW REVIEW* 19, 26 (2018).