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## **COMPETITION ON DRUGS ABUSIVE CONDUCTS IN THE PHARMACEUTICAL INDUSTRY**

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# 1. Introduction

## 1.1. Introduction

To be sustainable in the long run, balance is required. Law is no exception. It needs to continuously evolve and adapt to society, to regulate not only every situation already occurring, but also future unforeseen and unforeseeable circumstances and human behavior. The constant evolution of society impacts the law in two ways (often seen complementary rather than alternative): the need to introduce new regulations and the development of innovative case law. The legislative bulimia that affects an ever increasing number of countries seems to point in the direction of the first method rather than the second way, at least in civil law jurisdictions. The production of new legislation is however often slow and sluggish and fails to keep up with a dynamic and ever-changing society.

Antitrust law seems to be the exception. The flexibility built in its brief provisions delineates its chameleonic traits and makes it a universal, all-encompassing, regulation, oblivious to the passing of time. IP law is instead perceived as more rigid, having sacrificed flexibility on the altar of legal certainty. This is supposed to be what society wants, certainty. At the same time, however, people tend not to like strings and snares (*lacci e lacciuoli*) and want rules aligned with their everyday reality. Rules should keep the game fair and entertaining, not end up being purposeless and ineffective burdens.

A question thus follows, what is the purpose of the law? The answer to this question would require a thesis on its own but for the purposes of this work it will need to be answered in a few lines. Every rule has one (or more) immediate purpose(s) and every purpose is different. However, in a democracy it is (or should be) the people that are regulating,<sup>1</sup> and it is the interest of the people that the law (every law) is pursuing. This is often forgotten, sometimes considered too distant of an objective from the case to be decided. It is true, not every decision can deal with what is best for the people, but the thought needs nonetheless to be always there. The reason is simple, society evolves, needs change, new laws are passed, and conducts in the interest of the few and to the detriment of the many change shape and form to slip into the cracks of the legal system. The law is used as a shield not to protect society but to protect against society. Society itself creates and pays for the weapon used to its detriment.

This is what this work is ultimately about. Is IP law a weapon for or against the people?<sup>2</sup> What is the role of competition law in IP-related conducts? This work aims to demonstrate that IP is (*rectius*, can be) as flexible as antitrust and courts should apply it according to its principles, objectives and *ratio*. IP and antitrust share a common (direct or indirect) objective, enhance long-term consumer welfare.<sup>3</sup> They do it in different ways, using

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<sup>1</sup> The term democracy comes from the Greek δῆμος (dêmos) ‘people’ and κράτος (kratos) ‘power’ or ‘rule’, democracy is thus ‘rule of the people’.

<sup>2</sup> For the purposes of this work, the terms “people”, “society”, and “consumers” will be often used interchangeably.

<sup>3</sup> This work is premised on the so-called theory of complementarity (expression used, *inter alia*, by O. Kolstad, Competition Law and Intellectual Property Rights – Outline of an Economics-based Approach, in J. Drexler (ed.), Research Handbook on Intellectual Property and Competition Law, Edward Elgar, 2008), on the basis of which antitrust and IP rules complement each other converging towards the common objective of enhancing consumer welfare. Antitrust intervention is thus aimed at correcting defects of the IP system that prevent it from reaching its

different tools, but their purpose, the *ratio* of their existence, coincides. As traditionally applied (although this “tradition” is not common to every court, practitioner or scholar, quite the opposite), IP has forgotten its (indirect) “pro-consumer” objective,<sup>4</sup> while antitrust is sometimes oblivious to the relevance of “long-term” effects.<sup>5</sup> By looking at how courts and scholars have qualified conducts at the intersection between IP, traditionally concerned about long-term innovation rather than short-term consumer welfare, and antitrust, traditionally viewed as per-se opposing monopolies, this work comes at the conclusion that the ultimate objective of IP and antitrust does not fundamentally differ and the two sets of regulations complement and strengthen each other.<sup>6</sup>

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objectives. These principles can be found, *e.g.*, at par. 7 of the European Commission Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, 2014/C 89/03, 28 March 2014: “[B]oth bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof.” See also the U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, 6 April 1995, par. 1, “*The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare. The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. [...] The antitrust laws promote innovation and consumer welfare by prohibiting certain actions that may harm competition with respect to either existing or new ways of serving consumers.*”

<sup>4</sup> See *Motion Picture Patents Co. v. Universal Film Co.*, 243 U.S. 502, 1917, pp. 518-519 (“*Such a restriction is invalid because [...] to enforce it would be to create a monopoly in the manufacture and use of moving picture films wholly outside of the patent in suit and of the patent law as we have interpreted it. [...] A restriction which would give to the plaintiff such a potential power for evil over an industry which must be recognized as an important element in the amusement life of the nation [...] is plainly void because wholly without the scope and purpose of our patent laws, and because, if sustained, it would be gravely injurious to that public interest, which we have seen is more a favorite of the law than is the promotion of private fortunes.*”) While patents may increase costs to society in the short term by restricting competition, they often generate greater and more dynamic benefits as a result of innovators striving to be the first to bring a new or improved product to the market. In turn, consumers benefit from having more innovation in the long term and a wide range of products at arguably lower (or differentiated) prices. While static efficiency may increase consumer welfare in the short run, dynamic efficiency, including societal gains from innovation, is an even greater driver of consumer welfare in the long run. See N. Economides, W.N. Hebert, *Patents and Antitrust: Application to Adjacent Markets*, 6 *Journal on Telecommunication & High Technology Law*, 2008, p. 457 (“*At least in theory, the grant of a patent trades a reduction in allocative and possibly productive static efficiency for an increase in innovative activity. Under the assumption that innovative activity is underprovided without patents, some increase in innovative activity will increase dynamic efficiency*”).

<sup>5</sup> See T. Curzon Price, M. Walker, *Incentives to Innovate v Short-term Price Effects in Antitrust Analysis*, *Journal of European Competition Law & Practice*, 2016, pp. 1-3, who repeatedly stress the importance of dynamic efficiency in competition policy (“*competition policy should be concerned with facilitating dynamic efficiency, and not just static efficiency. [...] Our view is that competition policy has traditionally under-valued dynamic competition considerations and instead has focused too much on static efficiency. [...] [A] competition authority needs to facilitate the competitive environment within which innovation can take place*”).

<sup>6</sup> See footnote 3 above. This position has been recently confirmed by S. Tokic, *The Role of Consumers in Deterring Settlement Agreements Based on Invalid Patents: The Case of Non-Practicing Entities*, *Stanford Tech. Law Review*, 2012, p. 2, noting that antitrust law and patent law are complementary, as both share the same goal of “*promoting innovation and enhancing consumer welfare*”. As said by the U.S. Supreme Court, “*patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’ – and consequently antitrust law immunity – that is conferred by a patent.*” (*FTC v. Actavis*, 133

To study the intersection between IP and antitrust, with a focus on consumer welfare, there is no better industry than the pharmaceutical one. It stands at the crossroads of numerous and diverse policy objectives, as well as technical and administrative intricacies and social issues: public health and consumer welfare, health and safety regulations and patent law, competition and innovation.<sup>7</sup>

Aim of this work is to show that IP and antitrust can (and should) be interpreted and applied with consumer welfare as their ultimate goal, thus to ensure both continuing innovation (by protecting inventors from free-riding) and access to drugs (in terms of limiting excessive pricing and eliminating barriers to generic entry).

## 1.2. Pharmaceutical Market Dimension (and Significance)

The importance of the pharmaceutical industry is not merely theoretical. Pharmaceuticals represent a major economic sector whose significance keeps on rising. In 2008, global pharmaceutical sales amounted to nearly \$800 billion. In 2013, they were already close to \$1 trillion, which was reached and passed in the course of 2014. On average, the growth rate between 2005 and 2014 has been of 6% per year.<sup>8</sup>

Globally, the biggest markets are still the U.S. and Europe, with a joint share of total sales above 60% and sales in 2014 amounting to \$406 billion and \$243 billion respectively.<sup>9</sup>

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S.Ct., 2013, p. 2231) As clearly stated by T. Curzon Price, M. Walker, *Incentives to Innovate v Short-term Price Effects in Antitrust Analysis*, *Journal of European Competition Law & Practice*, 2016, p. 3, “*Caring about dynamic efficiency and thinking that this is often under-valued by competition authorities do NOT imply that competition authorities should automatically take a non-interventionist stance. Certainly, in the presence of dynamic efficiency concerns, it is important to avoid focusing too much on static harm and on trying to micro-manage or micro-intervene. But this is not the same as taking a 'hands-off' approach. Indeed, [...] there are increasingly frequent situations in which caring about dynamic efficiency implies greater intervention than would be justified purely on the basis of static efficiency concerns.*”

<sup>7</sup> “*The pharmaceutical industry presents some of the most challenging issues in antitrust law. Several characteristics demonstrate its complexity. Markets are nuanced. Multiple regulatory regimes apply. Generic entry is an event with dramatic consequences. These characteristics have encouraged brand-name drug firms to engage in an array of conduct that exploits this complexity to delay generic entry.*” (M.A. Carrier, United States. *Pharmaceutical Antitrust Law in the United States*, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 477) As the European Commission notes: “*Fair payment mechanisms and sustainable and predictable expenditures are required to guarantee access while effective competition among pharmaceutical companies and sufficient rewards for innovation are crucial to foster innovation. Hence issues related to pharmaceutical expenditure require a comprehensive approach design*” (Commission Staff Working Document, *Pharmaceutical Industry: A Strategic Sector For The European Economy*, SWD(2014) 216 final/2, 1 July 2014, p. 9).

<sup>8</sup> See <http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/2014/World%20figures%202014.pdf>, accessed on 6 August 2016. See also <http://thomsonreuters.com/en/press-releases/2014/thomson-reuters-annual-pharmaceutical-factbook-projects-industrys-sales-will-reach-1-trillion-in-2014.html>, accessed on 6 August 2016.

<sup>9</sup> See <http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/Global%20Prescription%20Sales%20Information5%20World%20figures%20by%20Region%202015-2019.pdf>, accessed on 6 August 2016; see also EFPIA, *The Pharmaceutical Industry in Figures, Key Data, 2014*, available at: [http://www.efpia.eu/uploads/Figures\\_2014\\_Final.pdf](http://www.efpia.eu/uploads/Figures_2014_Final.pdf), p. 4, accessed on 6 August 2016. In the EU, public spending on health accounts for over 7% of GDP. By 2060, public expenditure on acute health care and long-term care is expected to rise potentially reaching 9% of GDP (Commission Staff Working Document, *Pharmaceutical Industry: A Strategic Sector For The European Economy*, SWD(2014) 216 final/2, 1 July 2014, p. 3).

This is probably linked to both the cost of developing new drugs, that U.S. and European companies have the resources to bear, and the (consequential) cost of new drugs for consumers, too expensive for most of the population of second and third world countries.

The geographical allocation of (R&D, production and) sales, as well as the importance in shaping the legal landscape, confirms it is appropriate to focus on U.S. and EU IP and antitrust laws. Not only these two bodies of laws served and serve as reference for governments and authorities all over the world; they also regulate the conducts of some of the biggest companies operating worldwide.

Structurally, the pharmaceutical industry is characterized by a large number of drugs and companies. Markets are however usually very narrow, comprising a limited number of interchangeable drugs (often as low as one or two), and profitability varies significantly. The top-10 drugs accounted for almost \$90 billion in 2014<sup>10</sup> and the top-10 companies' sales reached \$360 billion.<sup>11</sup> These numbers help painting the picture of an industry in which a single "blockbuster drug" is capable of ensuring its patent holder revenues from 5 to 10 billion every year, and ten companies are in charge of more than 1/3 of total industry sales worldwide. Not only. The pharmaceutical industry has been identified as one of the top performing industry in the U.S., counting on return on revenues and return on assets around 18%, compared to an average of 4-5% for Fortune 500 companies.<sup>12</sup> As recently stated,

*"[t]he U.S. pharmaceutical industry has been topping the list of the most profitable sectors in the U.S. economy for almost two decades, never dropping below third place; an accomplishment unmatched by any other manufacturing sector."*<sup>13</sup>

### 1.3. Pharmaceutical Industry Structure – The Players

The biggest players in the industry, those developing and marketing innovative drugs, are called "originators". They are often large multinational companies investing substantial sums into R&D with the objective to discover, develop, manufacture and commercialize new drugs.<sup>14</sup> Originators' products are usually patent protected, allowing them to recoup the significant upfront investment in research and development and providing them with a strong incentive to take the risk and invest the amounts necessary to continue innovating.<sup>15</sup>

On the supply side, the industry is also characterized by the presence of another

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<sup>10</sup> See [http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/2014/Top\\_20\\_Global\\_Products\\_2014.pdf](http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/2014/Top_20_Global_Products_2014.pdf), accessed on 6 August 2016.

<sup>11</sup> See [http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/2014/Top\\_20\\_Global\\_Corporations\\_2014.pdf](http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/2014/Top_20_Global_Corporations_2014.pdf), accessed on 6 August 2016.

<sup>12</sup> M.O. Adams, Drugs Company Profits In The United States: Are They Excessive? Evidence from Public Administration Perspectives, 4(2) Journal of Business & Economics Research, 2006, p. 85.

<sup>13</sup> M. Boldrin, D.K. Levine, Against Intellectual Monopoly, Cambridge University Press, 2010, pp. 255-257.

<sup>14</sup> "In addition to large originator companies there are numerous SMEs, which typically lack the resources required to conduct all necessary steps from basic research to the marketing and distribution of the finished product. SMEs in the pharmaceutical sector, therefore, tend to specialise in innovation in a well-defined and narrow field (niche), for example focusing on specific indications or pharmaceutical formulations" (European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf), accessed on 6 August 2016 par. 55).

<sup>15</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, p. 2132.

player, the generic company. Generic companies (or generic manufacturers) manufacture and sell drugs that are “bioequivalent” to drugs already in the market, once their patent has expired (or is found invalid). Generic drugs are defined by Directive 2001/83/EC<sup>16</sup>, Art. 10(2)(b), as drugs having “*the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference [drug], and whose bioequivalence with the reference [drug] has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.*”<sup>17</sup>

In sum, generic drugs contain the same quantity and quality of active substance and are in the same pharmaceutical form as the originator (“reference” or “brand-name”) drug, but might contain different salts or esters, provided that they do not affect the drug’s safety or efficacy.

The process to obtain the authorization to market the generic version of a drug is usually less burdensome than that provided for the brand-name drug. Generic companies need to file a so-called “abridged” application, which does not require new pre-clinical tests and clinical trials, being sufficient to rely on those submitted for the reference product, provided that bioequivalence is demonstrated.<sup>18</sup>

Generic companies compete between each other and with originators mainly on price and efficiency. Generic products are sold at significantly lower prices (up to 90% lower) than brand-name drugs, and generic entry generally leads to a shift of volumes from the originator to the generic companies (unless the market moved to a second generation product before generic entry).

#### **1.4. Generic Drug Prices and Generic Substitution**

The importance of generics entry cannot be underestimated. The entire patent system (and the difficult balance it strikes between short-term price competition and long-term innovation) is premised on the idea that patent rights are limited in time. As soon as the patent expires, society expects to benefit from competitive prices on the once patented product (in this case a drug), close to its marginal cost (notoriously very low in the case of drugs). This is particularly relevant in the pharmaceutical industry, where a decrease in prices means increased access to drugs and lower health expenditure for consumers, hospitals, insurances and States.

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<sup>16</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

<sup>17</sup> In the U.S., the FDA defines generic drugs as “*copies of brand-name drugs [which] are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.*” (see FDA, Understanding Generic Drugs, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/>, accessed on 6 August 2016)

<sup>18</sup> Art. 10 of Directive 2001/83/EC provides: “*the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community*”. Regulation in the US does not differ significantly (see Orange Book Preface, available at <http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm>, accessed on 6 August 2016). A generic drug is considered bioequivalent if it contains the same active pharmaceutical ingredient as the originator drug, is the same dosage, strength and form, and exhibits a similar rate and extent of absorption.

Studies show that the first generic enters the market at approximately 80% of the price of the brand-name drug.<sup>19</sup> In analyzing drugs that for the first time faced generic competition between 2000 and 2007, also the European Commission found that generics became available at a price about 25% lower than the originator's before patent expiry.<sup>20</sup> As the number of generics increases, prices to consumers decrease even further. Two years after generic entry, prices have been estimated to be as low as 40% below the price charged by the originator before loss of exclusivity.<sup>21</sup> Recently, the European Commission found that "*price drops of up to 90% were observed upon generic entry to the UK market*".<sup>22</sup> In the U.S., the FTC has shown a price decrease of 85% on average from pre-entry brand-name drug price.<sup>23</sup>

As a result of price competition, as well as policies and regulations favoring drug substitution, substantial volume shifts from the originator company to the generic companies take place just after generic entry. It has been estimated that brand-name drugs retain only 14% of their prescription volume 12 months after generic entry.<sup>24</sup> A different study concluded that "*sales of originator drugs drop as much as 75 percent within weeks following the entry of a generic copy into the market.*"<sup>25</sup> Recently, generic penetration in the U.S. has been calculated in 80% six month after expiration of the patent and first generic entry.<sup>26</sup>

In its sector inquiry, the European Commission has estimated that generic entry in the EU happens on average seven months after patent expiry (only four months for the highest

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<sup>19</sup> See FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impacts, 2011, p. 48, available at <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>, accessed on 6 August 2016.

<sup>20</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 1560.

<sup>21</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 1560. An analysis by the FDA estimated that the first generic is priced only about 6% lower than the brand drug. Entry of a second generic lowers the price to approximately half the brand-name drug price. Generic drug prices fall to 33% of the brand-name drug price when five generic competitors are in the market, and where six or more generics are present, prices fall to a quarter of the brand-name drug price. The price drops to 13% of the original price when the generics in the market reach 15 (FDA, Generic Competition and Drug Prices, available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>, accessed on 6 August 2016.

<sup>22</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 3. See also par. 1149 ("*In the present case, when generic entry did eventually take place in the UK, following the rejection by the Court of Appeal to continue the injunction which had been granted against Apotex at first instance, Servier's volumes eroded significantly as the average market price dropped by as much as 90%*").

<sup>23</sup> FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, 2010, p. 8.

<sup>24</sup> M. Aitken, E.R. Berndt, D.M. Cutler, Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point, Health Affairs, 2009, w155.

<sup>25</sup> G. Glover, Prepared Witness Testimony before the House Committee on Energy and Commerce, "Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals," 13 June 2001.

<sup>26</sup> IMS, The Use of Medicines in the United States: Review of 2011, 2012, available at: [https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202011/IHII\\_Medicines\\_in\\_U.S\\_Report\\_2011.pdf](https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202011/IHII_Medicines_in_U.S_Report_2011.pdf), accessed on 6 August 2016.

selling drugs)<sup>27</sup> and generic penetration rate reaches 30% one year after entry and 45% after two years.<sup>28</sup> As seen above, if these figures were to be confirmed, this would mark a sharp difference between generic penetration in the U.S. and in the EU.

The use of generics has generated large savings for consumers. In 2013 alone, the Generic Pharmaceutical Association estimated that the U.S. health care system saved \$239 billion thanks to generics.<sup>29</sup> In the EU, the Commission estimated that between 2000 and 2007 generic drugs contributed to save approximately €15 Billion within the European Union.<sup>30</sup>

In addition to the price decrease, the presence of generic firms in the marketplace is a factor stimulating originators to innovate. With generic entry originators lose most of their market share and profits – to maintain their revenue flows, originators are thus incentivized to research and develop new, patentable drugs.<sup>31</sup> As noted by the European Commission,

*“Originator and generic companies [...] agree that generic competition creates and maintains incentives for innovation. Since generic competition limits the period during which originator companies can recoup their investments, originator companies are incentivised to constantly search for new medicines”.*<sup>32</sup>

## 1.5. Tendency and the Future

Promote innovation and ensure access to necessary drugs to the highest number of individuals, while keeping public health spending under control, has characterized the latest years’ development of both regulation and enforcement. As clearly stated by the European Commission:

*“[T]he challenge during the years to come consists in finding a balance between the emergences of new and often more costly pharmaceutical therapies and the legitimate expectation of patients to get access to innovative and effective medicines, on the one hand, and the need to ensure sustainable public healthcare budgets on the other hand. [...] Public authorities face the challenge to accommodate different objectives with constrained resources, i.e. striking a balance between guaranteeing patients’ access to state-of-the-art medical treatment and ensuring that incentives are provided for the industry to*

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<sup>27</sup> The delay in generic entry reported by the European Commission is probably due to the fact that an explicit exception to patent infringement from conducting the necessary studies and trials to enter the market has been introduced in the EU only in 2004 (Art. 10.6 Directive 2001/83/EC, as amended in 2004, provides: “conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”).

<sup>28</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 232.

<sup>29</sup> FTC, Concordia Healthcare/Par Pharmaceutical, Docket NOs. C-4553 and C-4554, Complaint, 30 October 2015, p. 17.

<sup>30</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 219.

<sup>31</sup> C. Priddis, The Pharmaceutical Sector, Intellectual Property Rights, and Competition Law in Europe, in S. Anderman, A. Ezrachi (eds.), Intellectual Property and Competition Law: New Frontiers, Oxford University Press, 2011, p. 248.

<sup>32</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 92.

*continue to invest in pharmaceutical R&D.*<sup>33</sup>

In the U.S., producers of generic drugs got an easier access to the market in 1984, thanks to the introduction of the Hatch-Waxman Act. In 1996, 22 years later, generics reached 43% of the prescription segment in the U.S., more than double what it was before the Act.<sup>34</sup>

On the enforcement side, since the mid-1970's, the U.S. Federal Trade Commission (FTC) dedicated a division within the Bureau of Competition to investigate potential antitrust violations in the health care sector. The Health Care Division consists of approximately thirty-five officials who work exclusively on health care and pharmaceutical antitrust matters. In a recent speech, Bill Baer, Assistant Attorney General for the U.S. Department of Justice Antitrust Division, reiterated the importance of the pharmaceutical industry in everybody's everyday life.<sup>35</sup> A similar position was expressed by Edith Ramirez, chairwoman of the FTC:

*“Protecting American consumers from anticompetitive conduct by pharmaceutical companies continues to be one of the Commission’s most important responsibilities. The Commission is committed to enforcing the antitrust laws in pharmaceutical markets to promote competition and prevent conduct that is likely to harm consumer welfare.”*<sup>36</sup>

At the European level, the importance of the pharmaceutical industry is long recognized and has been expressed with emphasis by the at-the-time Commissioner for Competition, Neelie Kroes, in opening the inquiry into this sector.<sup>37</sup> In her speech, she noted:

*“I chose the pharmaceuticals sector to be the focus of the Commission’s next sector inquiry because in my term as Competition Commissioner I have focused on solving competition problems that make a difference to the lives of individuals. Few things make more of a difference than this. The pharmaceuticals sector is vital to the health of Europe’s citizens. As well as being a vital sector of the economy, medicines are a major expense. Medicines cost us all a lot of money— we spend around 200 billion euros each year on pharmaceuticals; that’s around 400 euros for every man, woman and child in the 27 Member States of the European Union.”*<sup>38</sup>

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<sup>33</sup> Commission Staff Working Document, Pharmaceutical Industry: A Strategic Sector For The European Economy, SWD(2014) 216 final/2, 1 July 2014, pp. 7-9.

<sup>34</sup> M. Boldrin, D.K. Levine, *Against Intellectual Monopoly*, Cambridge University Press, 2010, pp. 241-242.

<sup>35</sup> “The rising cost of health care affects Americans every time they pay their health insurance premium, visit a doctor, receive hospital care, and fill a prescription. Because health care is fundamental to our lives, we share an interest in maintaining and fostering competitive markets that will keep prices in check, improve quality and spur innovation.” (B. Baer, Workshop on Examining Health Care Competition Opening Remarks, 25 February 2015, p. 1, available at <https://www.justice.gov/atr/file/518886/download>, accessed on 6 August 2016)

<sup>36</sup> E. Ramirez, Oversight of the Enforcement of the Antitrust Laws, speech before the U.S. Senate, 9 March 2016, available at [https://www.ftc.gov/system/files/documents/public\\_statements/934563/160309enforcementantitrustlawstest.pdf](https://www.ftc.gov/system/files/documents/public_statements/934563/160309enforcementantitrustlawstest.pdf), accessed on 6 August 2016.

<sup>37</sup> The European Commission launched its pharmaceutical sector inquiry in January 2008, following signals of declining innovation regarding new chemical agents and delayed market entry of generic medicines. It covered the period 2000-2007 and investigated a sample of 219 drugs.

<sup>38</sup> N. Kroes, Commission launches sector inquiry into pharmaceuticals, 16 January 2008, available at [europa.eu/rapid/press-release\\_SPEECH-08-18\\_en.htm?locale=en](http://europa.eu/rapid/press-release_SPEECH-08-18_en.htm?locale=en), accessed on 6 August 2016.

In a recent document, the European Commission reiterated the importance of a well-functioning pharmaceutical market emphasizing that the demographic transition the EU is undergoing, with the number of EU residents aged 65 and over expected to increase from 92 million in 2013 to 148 million in 2060, is one of the major challenges for the financial sustainability of the health care systems.<sup>39</sup> In its recent conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States, the Council of the European Union invited the European Commission to “[c]ontinue and where possible intensify [...] the monitoring, methods development and investigation [...] of potential cases of market abuse, excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union.”<sup>40</sup>

Not only the U.S. and the EU are taking steps to address potential issues in the pharmaceutical market, the need to find the right balance between intellectual property and competition policy in this sector is at the center of attention also at the UN level. To tackle this issue, in May 2014 the UN Development Programme published a guidebook for low- and middle-income countries on how to use competition law to promote access to drugs.<sup>41</sup>

## 1.6. Cost and Time of Developing a Drug

One of the most important things to keep in mind to ensure the correct balancing of short term price competition and long term innovation in the pharmaceutical sector is that pharmaceutical R&D is extremely expensive. The research and development involved in the creation of a new drug is usually significant, both in terms of time and cost, while the marginal cost of production (and of ‘copying’) is typically low.<sup>42</sup> This is the main reason why patents are so important in the pharmaceutical industry,<sup>43</sup> and why regulators and antitrust

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2016. The importance of a competitive pharmaceutical market has been recently emphasized by the European Commissioner for Competition Margrethe Vestager, who noted that “*there can be times when prices get so high that they just can’t be justified. After all, people rely on these medicines for their health, even their lives.*” (M. Vestager, Protecting consumers from exploitation, 21 November 2016, available at [https://ec.europa.eu/commission/2014-2019/vestager/announcements/protecting-consumers-exploitation\\_en](https://ec.europa.eu/commission/2014-2019/vestager/announcements/protecting-consumers-exploitation_en), accessed on 11 December 2016)

<sup>39</sup> This is due to the fact that “*health-related spending generally increases with the age of a person and the prevalence of chronic diseases like diabetes or dementia will rise with an ageing population*” (Commission Staff Working Document, Pharmaceutical Industry: A Strategic Sector For The European Economy, SWD(2014) 216 final/2, 1 July 2014, p. 3).

<sup>40</sup> Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States (2016/C 269/06), 23 July 2016, par. 48, available at [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XG0723\(03\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XG0723(03)), accessed on 11 December 2016.

<sup>41</sup> The in-depth report is available at: <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>, accessed on 6 August 2016.

<sup>42</sup> Generic drugs are much easier and cheaper to develop than brand-name ones. The involved R&D is minimal, as is the risk of unsuccessful attempts. The same goes for the time and cost of obtaining the marketing authorization, since generic manufacturers can usually rely on the results of the clinical test conducted by the originator (provided they demonstrate bioequivalence).

<sup>43</sup> “*The pharmaceutical industry is a textbook example of a science based sector characterised by high R&D costs, uncertainty and spill overs, for which patent protection assures appropriable, thus providing incentives for innovation*” (L. Magazinni, F. Pammolli, M. Riccaboni, M.A. Rossi, Patent Disclosure and R&D Competition in Pharmaceuticals, 18 Economics of Innovation and New Technology, 2009, p. 467).

enforcement agencies should be careful in their activity, not only to avoid diminishing the incentives to invest, but also to actively promote investments in more advanced and affordable drugs. As Professor Merges points out:

*“[T]here is one consistent finding across all the empirical literature on patents, one canonical truth that has been repeatedly established and confirmed beyond a peradventure of doubt: the pharmaceutical industry needs patents to survive. [...] If there is one industry where the conventional ‘incentive theory’ of patents is actually true, it is the pharmaceutical industry. As a result, it is equally well understood that eliminating or weakening patent protection in this industry would significantly reduce the volume of R&D and consequently the supply of new drugs”*.<sup>44</sup>

The importance of patent protection is emphasized also by Professors Boldrin and Levine, who identified the pharmaceutical industry as *“the poster-child of every intellectual monopoly supporter. It is the vivid example that, without the sheltering patents provide inventors with, the outpouring of new wonder drugs we have grown accustomed to would have not materialized, our life expectancies would be a lot shorter, and millions of people would have died of the diseases Big Pharma has instead managed to cure”*.<sup>45</sup>

The patent system balances the interest of the inventor to recoup the investments necessary to bring a new drug to the market, with the broader interest of society to have access to new and improved cures at affordable prices. Without a patent system, generic manufacturers would “free-ride” on the originator’s R&D expense,<sup>46</sup> investments in the development of new drugs would not guarantee adequate returns, and investors would put their money in more lucrative activities. The result would be suboptimal level of new drugs creation to the detriment of society.<sup>47</sup>

Although originators are very cautious in disclosing data regarding the cost of developing a new active principle,<sup>48</sup> it has been estimated that the costs of bringing a “breakthrough” invention, often called New Molecular Entity (NME), to the market have increased substantially over the years. While in 1975 development costs have been estimated in \$149 million (in year 2000 prices), in 2000 development costs had increased to more than

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<sup>44</sup> R.P. Merges, *Justifying Intellectual Property*, Harvard University Press, 2011, p. 289.

<sup>45</sup> M. Boldrin, D.K. Levine, *Against Intellectual Monopoly*, Cambridge University Press, 2010, p. 242.

<sup>46</sup> *“Given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation”* (EFPIA, *Intellectual Property and Pharmaceuticals*, 2008, p. 15, available at: [http://www.efpia.eu/uploads/Modules/Documents/efpia-ipr\\_annex-20080616.pdf](http://www.efpia.eu/uploads/Modules/Documents/efpia-ipr_annex-20080616.pdf), accessed on 6 August 2016). See also Council Directive 2004/48/EC of 29 April, 2004 on the enforcement of intellectual property rights, OJ L 195/16–25, Recital 3 (*“[W]ithout effective means of enforcing intellectual property rights, innovation and creativity are discouraged and investment diminished.”*)

<sup>47</sup> See C. Bohannon, H.J. Hovenkamp, *IP and Antitrust: Reformation and Harm*, 51 *Boston College Law Review*, 2010, p. 922 (*“[M]arket failure is the starting point for IP laws, and it is market failure that gives rise to the need for legal entitlements.”*).

<sup>48</sup> As reported by Professor Abbott, *“[t]he cost of researching and developing originator pharmaceutical products is deliberately shrouded in mystery. The originator pharmaceutical industry has aggressively resisted providing data regarding its R&D costs. This resistance traces back as early as 1950s U.S. Senate investigations into pharmaceutical pricing in the United States, has manifested itself in litigation in countries as diverse as South Africa and India, and continues to this day as reflected in Gilead’s refusal to provide R&D data to the U.S. Senate in response to request from the Finance Committee.”* (F.M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6(3) *UC Irvine Law Review*, forthcoming Spring 2017, p. 20, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095), accessed on 6 August 2016)

\$800 million.<sup>49</sup> From 2010 to 2015, the cost of bringing a new active ingredient from discovery to launch has been estimated as still on the rise, from \$1.2 billion in 2010 to \$1.6 billion in 2016.<sup>50</sup> As noted, “[w]ith R&D costs of such magnitude, it seems impossible to even dream of a pharmaceutical industry that could properly function and innovate in the absence of a very strong patent protection.”<sup>51</sup>

Costs take into consideration also the R&D costs of failed attempts, which in the pharmaceutical industry are substantial. The success rate for the development of a new drug is very low – typically less than 1% of the molecules discovered in pre-clinical tests enter the clinical trial stage,<sup>52</sup> and only 16% of those survive the process of human clinical trials and gain drug approval.<sup>53</sup>

The development of a new drug is not only expensive, it is also time-consuming. As explained by the European Commission in the final report of its Pharmaceutical Sector

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<sup>49</sup> J.A. DiMasi, R.W. Hansen, H.G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 *J. Health Econ.*, 2003; C.P. Adams, V. van Brantner, *Estimating The Cost Of New Drug Development: Is It Really \$802 Million?*, 25 *Health Affairs*, 2006; C.P. Adams, V. van Brantner, *Spending on new drug development*, 19 *Health Economics*, 2010. Cost includes R&D, formulation and testing, animal studies, human clinical trials, failed attempts, opportunity cost of capital, and authorization procedure.

<sup>50</sup> Deloitte, *Measuring the return from Pharmaceutical innovation, 2015*, available at <http://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html>, accessed on 6 August 2016. Different results have been reached in 2014 by the Tufts Center for the Study of Drug Development, summarized at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf), accessed on 6 August 2016. Tufts estimated that the cost per new prescription drug approval (inclusive of failures and capital costs) in 2013 was \$2.558 billion. The cost was \$1.395 billion out-of-pocket (*i.e.* not capitalized). These figures have been heavily criticized *inter alia* by Doctors without Borders that observed that new drugs can be developed for \$50 million, or up to \$186 million taking failures into account, and Tufts’s figures were “nowhere near what the industry claims is the cost” (Rohi Malpani, *R&D Cost Estimates: MSF Response to Tufts CSDD Study on Cost to Develop a New Drug*, 18 November 2014, available at <http://www.doctorswithoutborders.org/article/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug>, accessed on 6 August 2016).

<sup>51</sup> M. Boldrin, D.K. Levine, *Against Intellectual Monopoly*, Cambridge University Press, 2010, p. 244.

<sup>52</sup> H. Grabowski, *Patents, innovation and access to new pharmaceuticals*, 5 *Journal of International Economic Law*, 2002, p. 851.

<sup>53</sup> J.A. DiMasi and others, *Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs*, 87 *Clinical Pharmacology & Therapeutics*, 2010, 272. In the words of R. Jacob, Judge of the Court of Appeal of England and Wales, “*the nature of the investment is risky. Most research leads nowhere. The few winners must pay for all the losers. And in recent years the number of really important drugs coming forward seems to be diminishing. It is in the nature of investors – human that they are – that the higher the risk the more reward is needed to persuade them to put their money up.*” (R. Jacob (Rt. Hon. Sir), *Patents and Pharmaceuticals*, paper given on 29th November at the Presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-Sector Inquiry, 27 September 2011, par. 6, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf>, accessed on 6 August 2016). As Professor Korah explains, “*most attempts to find a cure for particular problems by the pharmaceutical companies do not work. Of those that do, many never get far through their safety trials. So a small loss is made on most drugs. A few almost get to the market, but then some side effect appears and those cost the inventor a great deal. Only a few drugs are successful and the company must make a large profit on these to make up for the losses on the other, or R&D will not be worthwhile*” (V. Korah, *Merck v. Primecrown – The Exhaustion of Patents by Sale in a Member State where a Monopoly Profit Could not be Earned*, 4 *ECLR*, 1997, 273).

Inquiry, the life cycle of a medicine starts with the so-called “basic research”, where the molecular targets of a disease are identified and promising molecules, which interact with the targets, are determined. This phase is usually 6 month to 2-3 years long and includes, in its last part, the application for patent protection. The development phase follows and is usually divided into two stages: the pre-clinical tests, consisting of laboratory and animal tests, and the clinical trials, comprising three distinct clinical phases (so-called Phase I, II and III) directed towards progressively larger groups of patients, in which the efficacy of the drug is investigated. The most significant costs are concentrated in Phase III which alone accounts on average for 60% of the total R&D budget. The basic research and pre-clinical phase combined account only for 8% of the total expenditure, while the remaining 32% goes into Phase I and Phase II (12% and 20% respectively).<sup>54</sup>

Once all phases have been completed, and delivered consistent results in terms of safety and efficacy, the company applies for a marketing authorization to launch the drug on the market. From discovery of a new chemical compound, and correlated patent application, to the final market approval and product launch, the process has been estimated to last on average 12 to 13 years,<sup>55</sup> during a big part of which patent protection is running.

Originators apply for patent protection early in the research phase, several years before product launch. While a patent lasts twenty years, due to the lengthy gap between discovery and approval of a new drug, the effective monopoly protection is estimated to last only 10 to 12 years – plus 3 to 5 years of extension. The European Commission estimated that in 2007 the effective protection period from the date of launch of the pharmaceutical product to the first generic launch was approximately 14 years. In 2000 the figure stood at 10.5 years.<sup>56</sup>

The need for patent protection in the pharmaceutical industry is obviously not disputed by this work, quite the contrary. The development of a new drug, or its improvement, is immensely beneficial to society and should be incentivized. The cost and time needed and the risks involved in developing a new drug make it very important that successful inventors (and investors) recoup all expenses and foregone investment opportunities, and are rewarded for their results. The patent system is extremely beneficial to pharmaceutical R&D, and R&D is in turn indispensable to the discovery of new drugs, the cure of diseases, and ultimately the benefit of society. As originators are profit-driven companies, it is the profits they make on new drugs that incentivize new investments in R&D and in turn translates into the creation of new, more beneficial, drugs. As eloquently stated by Abraham Lincoln almost 160 years ago,

*“Next came the Patent laws. [...] Before then, any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby*

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<sup>54</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, pp. 50-63, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf), accessed on 6 August 2016.

<sup>55</sup> EFPIA, The Pharmaceutical Industry in Figures, Key Data, 2014, available at: [http://www.efpia.eu/uploads/Figures\\_2014\\_Final.pdf](http://www.efpia.eu/uploads/Figures_2014_Final.pdf), accessed on 6 August 2016, p. 6.

<sup>56</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 164.

*added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.*<sup>57</sup>

## 1.7. Innovation in the Pharmaceutical Industry

We saw that the cost and time necessary to develop new drugs are significant. The capital necessary to be able to sustain research, development and marketing of new drugs, including failed attempts, influence the composition of the market, characterized by the presence of a relatively small group of very big companies,<sup>58</sup> whose blockbuster drugs ensure them massive profits.<sup>59</sup> The industry is indeed operating on a “blockbuster drug” business model.<sup>60</sup> As noted by the European Commission, “*some blockbusters account for a very large share of total turnover of the companies concerned (up to 55%). On average the most important blockbusters [...] generate 19% of the total global turnover of the originator companies concerned.*”<sup>61</sup>

A blockbuster drug is defined as a drug that “*achieves annual revenues of over US\$1 billion at a global level*”<sup>62</sup>. Blockbuster drugs are often very innovative products that treat pathology not previously curable or represent a leap forward in terms of reduced side effects, overall effectiveness, or new pharmaceutical action. Innovative products comprise new active ingredients, often called NME (new molecular entities). NMEs are the substance for which pre-clinical test and clinical trials must be conducted, and which are given an International Non-proprietary Name (INN), which will define that active ingredient globally. Recent years have seen a sharp decline in the number of approvals of NMEs. The Commission reported that between 1994 and 1999 an average of 40 NMEs were launched every year. The number dropped to 27 per year between 2000 and 2007.<sup>63</sup>

This decrease in the number of NMEs is not necessarily problematic since follow-on and incremental innovation, *i.e.* further development of known substances, is as valuable and important, and may result in decisive improvements to the drug’s effectiveness.<sup>64</sup> In the

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<sup>57</sup> A. Lincoln, Lecture on Discoveries and Inventions, 1858, available at <http://www.abrahamlincolnonline.org/lincoln/speeches/discoveries.htm>, accessed on 6 August 2016.

<sup>58</sup> As we saw *supra*, the top-ten companies accounted in 2014 for more than 1/3 of total worldwide sales.

<sup>59</sup> See *supra*. The Commission explains: “*the revenues from these products are often the backbone of many originator companies*” (European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 26).

<sup>60</sup> L.E. Battaglia, Drug Reformulation Regulatory Gaming: Enforcement and Innovation Implications, 7 European Competition Journal, 2011, p. 381.

<sup>61</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 67.

<sup>62</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, p. 6.

<sup>63</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, p. 33.

<sup>64</sup> “[P]harmaceutical innovation is almost invariably incremental in nature, with most therapeutic advances building upon what has gone before. Systems that seek only to reward “breakthrough” innovations therefore risk undervaluing the great majority of innovations, which although incremental may represent real improvements in efficacy and/or reductions in side effects.” (Lundbeck, Pharmaceutical Pricing and Market Access, 2014, available at <https://www.lundbeck.com/global/CSR/positions/pricing-and-market-access>, accessed on 6 August 2016) See also Glaxosmithkline, GSK Public policy positions. Incremental Innovation, April 2014, available at <https://www.gsk.com/media/280854/incremental-innovation-policy.pdf>, accessed on 6 August 2016 (“*most pharmaceutical R&D is incremental – indeed, incremental innovation is the key to most major advances in the treatment and prevention of disease.*”). On the nature of innovation in the

words of Sir Isaac Newton, it could be said that modern pharmaceutical research is “*standing on the shoulders of giants*”.<sup>65</sup>

The structure of the industry and the reliance on blockbuster drugs may however lead originators to put all their efforts into protecting revenues flowing from their most successful products, rather than seriously improving them (or replacing them with a radically different, more effective, drug) to the benefit of consumers. Second generation products of questionable value are developed as a way to extend or strengthen patent protection on blockbuster drugs, with the sole purpose of keeping generics and competing originators out of the market.

## 1.8. Marketing and Promotional Activities

In an ideal world, companies would invest in R&D (and every other activity necessary to bring new drugs to the market), obtain patent protection and marketing authorization, market their drugs and, thanks to the success of their most innovative cures, make sufficient profits to fund new R&D projects. Unfortunately the picture’s colors are much less bright and defined. In addition to the cumulative innovation conundrum discussed above, an interesting aspect of the pharmaceutical industry is the role of marketing initiatives.

Although the pharmaceutical industry is one of the sectors with the highest ratio of R&D investments to net sales, having spent 14.4% of net sales on research and trials in 2012,<sup>66</sup> pharmaceutical companies spend more on marketing and sales than on R&D.<sup>67</sup> The Commission estimated that European originator companies spent on average 23% of their global turnover in the period 2000-2007 on marketing and promotional activities (and 17%

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pharmaceutical sector, see C.M. Correa, Ownership of knowledge. The role of patents in pharmaceutical R&D, 82 Bulletin of the World Health Organization, 2004, p. 785 (“*Innovation in pharmaceuticals relies increasingly on the knowledge gleaned from preceding innovations and on generally available techniques [...]. Innovation in this sector follows, therefore, an essentially “cumulative” model of innovation, as opposed to the “discrete” model, where the prospects of variations and improvements of inventions are substantially bounded*”).

<sup>65</sup> Letter from Isaac Newton to Robert Hooke (5 February 1676) (“*What Descartes did was a good step. You have added much several ways, and especially in taking the colours of thin plates into philosophical consideration. If I have seen a little further it is by standing on the shoulders of Giants*”). As explained by Prof Shapiro, “*The essence of science is cumulative investigation combined with hypothesis testing. The notion of “cumulative innovation,” each discovery building on many previous findings, is central to the scientific method. Indeed, no respectable scientist would fail to recognize and acknowledge the crucial role played by his or her predecessors in establishing a foundation from which progress could be made. [...] Most basic and applied researchers are effectively standing on top of a huge pyramid, not just on one set of shoulders. Of course, a pyramid can rise to far greater heights than could any one person, especially if the foundation is strong and broad. But what happens if in order to scale the pyramid and place a new block on the top, a researcher must gain the permission of each person who previously placed a block in the pyramid, perhaps paying a royalty or tax to gain such permission? Would this system of intellectual property rights slow down the construction of the pyramid or limit its height?*” (C. Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, in A.B. Jaffe, J. Lerner, S. Stern, Innovation Policy and the Economy, MIT Press, 2001, pp. 119-120).

<sup>66</sup> EFPIA, The Pharmaceutical Industry in Figures, Key Data, 2014, available at: [http://www.efpia.eu/uploads/Figures\\_2014\\_Final.pdf](http://www.efpia.eu/uploads/Figures_2014_Final.pdf), accessed on 6 August 2016, p. 10.

<sup>67</sup> Drugs sold on prescription cannot be advertised directly to consumers in the EEA. Originators can however advertise them to doctors through the so-called detailing, *i.e.* visits by medical sales representatives (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2140).

on R&D).<sup>68</sup>

Looking at the 2015 annual report of Novartis,<sup>69</sup> the ratio between R&D and Marketing and Sales expenses, around 0.7 to 1, is in line with the European Commission's findings.<sup>70</sup>

Expenses in marketing and sales might be of concern not only because they might be a way to disguise payments to doctors to favor certain drugs in their prescriptions,<sup>71</sup> but also because they might be used by originators to persuade doctors, pharmacists, hospitals, and therefore consumers (patients, whose decisions are heavily influenced by doctors and pharmacists), to prefer their drug, notwithstanding the existence of more effective, or as effective and cheaper, alternatives (*e.g.*, generics).

The information asymmetry existing in the pharmaceutical industry makes consumers (and even doctors) particularly vulnerable to aggressive marketing and sales tactics, and over-investment in marketing, as opposed to R&D, should not be in any way incentivized. The same reasoning applies to legal expenses.<sup>72</sup>

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<sup>68</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, paras. 72 and 74. In addition, at paras. 76-77, the Commission reports that “*the number of employees in marketing and sales departments is twice the number of those working in R&D. In some companies, this ratio can reach even one employee in R&D to three in marketing.*” See also S.O. Schweitzer, *Pharmaceutical Economics and Policy*, Oxford University Press, 2006, p. 82 (“*While the R&D expenses varied between 11% and 15% of annual sales for [originators], marketing and promotional expenses ranged from 21% to 40% of annual sales.*”).

<sup>69</sup> Available at <https://www.novartis.com/investors/financial-data/annual-results>, accessed on 6 August 2016.

<sup>70</sup> These numbers seem even too generous. Professors Boldrin and Levine found that “*the top 30 firms spend about twice as much in promotion and advertising as they do in R&D; and the top 30 are where private R&D expenditure is carried out, in the industry.*” (M. Boldrin, D.K. Levine, *Against Intellectual Monopoly*, Cambridge University Press, 2010, pp. 255-257, who continues, “*no more than 1/3 – more likely 1/4 – of new drug approvals are considered by the FDA to have therapeutic benefit over existing treatments, implying that, under the most generous hypotheses, only 25-30% of the total R&D expenditure goes toward new drugs. The rest [...] goes toward the so called “me-too” drugs.*”). Me-too drugs, are those “*structurally similar to – and that largely duplicate the action of – already patented medicines.*” (European Commission, *Pharmaceutical Sector Inquiry, Preliminary Report*, 28 November 2008, par 212, available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, accessed on 6 August 2016). In other words, me-too products are usually based on new active substances – thus NMEs – but are launched on the market only after an innovative product was disclosed to the public. Me-too products do not usually entail a genuine therapeutic progress and provide little added value in comparison to the rival’s successful drug, ultimately representing an emulation exercise (for which marketing expenses are much more important than R&D)(C.M. Correa, *Ownership of knowledge. The role of patents in pharmaceutical R&D*, 82 *Bulletin of the World Health Organization*, 2004, p. 785).

<sup>71</sup> In 2011, the Fair Trade Commission of the Republic of Korea imposed corrective orders and fines against six drug manufacturers for offering economic incentives to doctors, clinics and hospitals to increase the prescription of their drugs. Such incentives included seminars, conferences, golf outings, lectures and consultancy fees. Similarly, in September 2014, the National Development and Reform Commission of China fined GlaxoSmithKline \$490 million for having bribed hospitals and doctors. (UNCTAD Secretariat (note by), *The Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers*, UN Conference on Trade and Development, 27 April 2015, paras. 58-59).

<sup>72</sup> “[Pharmaceutical] *Companies today have found that the return on investment for legal tactics is a lot higher than the return on investment for R&D,*” says Sharon Levine, the associate executive director of the HMO

## 1.9. The Conducts

It is clear from the above that pharmaceutical research and development is costly, risky and lengthy but, when it leads to the discovery of new or better cures, is beneficial to consumers and should be incentivized.

Unfortunately, an increase in investments in research does not equal more or better drugs nor an increase in profits. R&D costs nearly doubled in the past 20 years without a corresponding increase in the discovery of NMEs (rather, regulatory authorities around the world observed a decrease in the rate of new drug submissions), many key blockbuster drugs are falling off the cliff of loss of exclusivity and revolutionary and wildly successful drugs are becoming rarer and rarer.

To face the increased competition from new entrants and generics, and the slowdown of breakthrough discoveries, originators started to be more concerned about ensuring that their old goose (blockbuster drug) keeps on laying golden eggs than to breed new ones. Pharmaceutical companies have thus a strong incentive to concentrate their investments in protecting product exclusivity for as long as possible, instead of trying to innovate. To do this, originators employ various techniques that extend the profitability of their commercially successful drugs and restrict or delay generic market entry, to the detriment of consumers. Patent protection thus becomes an end in itself.<sup>73</sup>

A slowdown in the transition from the protected status of a proprietary medicine to the status of generic products, manufactured and distributed in open competition, does not simply decrease static efficiency, *i.e.* consumers' short-run well-being in terms of lower prices and increased access to drugs. Rather, it might be the reason – and simultaneously the consequence – of a progressive decline in innovation, as it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate.<sup>74</sup>

To better understand the value (and cost) of delaying generic entry, noteworthy is a statement made by the CEO of Cephalon, a large U.S. biopharmaceutical company, in relation to a pay for delay settlement with 4 generic companies: “*We were able to get six more years of patent protection. That’s \$4 billion in sales that no one expected.*”<sup>75</sup>

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*Kaiser Permanente. “Consumers today are paying an inordinate premium under the guise of the creating the stream of innovation in the future. But it’s actually funding lawyers.”* (M. Boldrin, D.K. Levine, *Against Intellectual Monopoly*, Cambridge University Press, 2010, p. 263).

<sup>73</sup> “*To confront generics upon expiry of the compound patent, originators often put in place strategies to create and enforce a comprehensive set of additional patents protecting other aspects of the product (production process, forms, formulations etc.)*.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1127).

<sup>74</sup> As discussed, not only generic competition helps patients to have access to affordable healthcare and public health systems to remain economically sustainable, it also stimulates pharmaceutical companies to continue investing in research and develop innovative treatments, as they cannot rely forever on their blockbuster products.

<sup>75</sup> *FTC v. Cephalon, Inc. No. 08-cv-2141: Complaint for injunctive relief*, 13 February 2008, p. 4, available at <http://www.ftc.gov/enforcement/cases-proceedings/061-0182/cephalon-inc>, accessed on 6 August 2016. The FTC settled its suit against Cephalon in May 2015 for injunctive relief and \$1.2 billion. On 4 August 2016, Cephalon reached a \$125 million settlement agreement to end a 48-U.S. States investigation. Cephalon allegedly defrauded the Patent and Trademark office to secure an additional patent and then concluded pay for delay agreements that delayed generic entry for nearly six years.

The pharmaceutical industry has been a central focus in the debate over the appropriate balance between patents and antitrust. The general perception is that there is an inherent tension between the two, one granting the right to exclude and the other condemning exclusionary practices. Their interaction, however, often seen as problematic, is instead beneficial when long-term consumer welfare is put back in its rightful central position. The complementarity between the two bodies of laws, and the ability they have to strengthen each other, has been highlighted on both sides of the Atlantic. In Europe, Mario Monti, at the time Commissioner for Competition, famously referred to innovation as the bride and competition as the groom:

*“It is of course a longstanding topic of debate in economic and legal circles how to marry the innovation bride and the competition groom. In the past some have argued that such a marriage will unavoidably lead to divorce because of conflicting aims of IPR law and competition law. But I think that by now most will agree that for a dynamic and prosperous society we need both innovation and competition. Contrary to what some might think, competition is a necessary stimulus for innovation. IPR law and competition law have a complementary role to play in promoting innovation to the benefit of consumers. I therefore firmly believe in this marriage and, like in all good marriages, the real question is how to achieve a good balance between both policies.”*<sup>76</sup>

In the U.S., Professor Hovenkamp underlined the coincidence between the two regulations’ objectives and the central role played by antitrust in promoting innovation:

*“Antitrust policy and the IP laws are both concerned with practices that restrain competition unnecessarily by reducing the size of the public domain beyond that which the Constitution contemplates or as Congress intended for them to be expanded. In fact, antitrust has a dual role as promoter of competition in IP-intensive markets. It regulates both restraints on competition and restraints on innovation.”*<sup>77</sup>

The patent system and competition law are interacting components of the market, into which they must both be active and coordinate to limit consumer welfare losses. There is no reason why antitrust should be deferential to IP, and the instrumental use of the patent system can and should be addressed by competition law.<sup>78</sup> At the same time, competition

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<sup>76</sup> M. Monti, The New EU Policy on Technology Transfer Agreements, Paris, 16 January 2004, available at [http://europa.eu/rapid/press-release\\_SPEECH-04-19\\_en.htm?locale=en](http://europa.eu/rapid/press-release_SPEECH-04-19_en.htm?locale=en), accessed on 6 August 2016.

<sup>77</sup> H.J. Hovenkamp, Innovation and the Domain of Competition Policy, 60 Alabama Law Review, 2008, p. 106.

<sup>78</sup> In the EU, the Commission and the EU Courts have shown little deference towards IP rights. The special responsibility incumbent upon dominant firms not to impair competition has resulted in the Commission aggressively enforcing competition rules under Article 102 TFEU, including in those areas of intersection between competition rules and IPR. In the U.S., antitrust enforcement agencies and courts have traditionally applied the principle of symmetry under which antitrust rules are applied to IPRs exactly the same way as to other property rights. The U.S. system however evolved in recent years “towards a more interventionist approach, possibly under the influence of some distinguished scholars who have started to challenge the idea of IP rights’ untouchability and parity with other property rights. First, it has been argued, IPRs are probabilistic in nature, i.e. they contain a strong element of uncertainty; many rest on shaky grounds, are issued after a limited examination process and would not stand scrutiny if litigated. Second, IPRs cannot be treated like other property rights since the former may in some circumstances confer market power, sometimes even extraordinary market power. Accordingly, strong antitrust enforcement is needed in presence of strong IPRs.” (M. Todino, Antitrust Rules and Intellectual Property Rights in the EU and the US, 1(2) Italian Antitrust Review, 2014, pp. 28-29). The US Supreme Court ruling in Actavis confirmed the departure

enforcement should not be concerned only about prices, but also about innovation, and aim at striking the right balance between short-term and long-term consumer welfare.<sup>79</sup>

Patent law is the starting point. (One of) The rationale of the patent system is exactly the renounce to some short-term price competition in exchange for long-term innovation. Society agrees to potentially paying higher prices for a defined period of time in exchange for the introduction of new or improved products. The balance between price competition and innovation has thus been struck by society in adopting patent law.

Patent law has however to be interpreted and applied. It is the interpretation and application of patent law, or better the conducts originators claim to be within their patent rights, that this work is investigating. While potentially within the letter of patent law, most of the conducts scrutinized by antitrust agencies around the globe are not within the purpose, the *ratio*, of patent law (*rectius*, they are contrary to its *ratio*) and are therefore forbidden by patent law itself, in addition to be antitrust violations. The role of antitrust is however decisive when it comes to deterring these conducts. As much as IP law is premised on a market failure, antitrust intervention in the IP world is premised on a failure of the IP system to detect and deter conducts contrary to its purpose. Patent law is (ab)used to achieve objectives that are diametrically opposed to those pursued by patent law itself, and upset the balance between short-term competition and long-term innovation on which patent law is premised.<sup>80</sup>

The European Commission's pharmaceutical sector inquiry identified a "toolbox" of unlawful practices ascribed to originators to delay or block the entry of generic drugs. The final report made reference to (i) patenting strategies of originators; (ii) patent settlements and other agreements between originator and generic companies; (iii) promotional activities; (iv) strategic launching of second generation and follow-on products; and (v) aggressive patent litigation, opposition procedures and appeals before patent offices and interventions before marketing authorities and pricing reimbursement authorities.<sup>81</sup>

These practices take advantage of patent laws and healthcare regulation thereby disrupting the necessary balance between incentives to innovate and access to affordable

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from the traditional symmetry principle and recognized that IPRs may deserve special antitrust attention due to their features and strength.

<sup>79</sup> T. Curzon Price, M. Walker, Incentives to Innovate v Short-term Price Effects in Antitrust Analysis, *Journal of European Competition Law & Practice*, 2016, p. 5: [T]here is a trade-off, and it is unlikely to be socially optimal to maximise rewards from innovation. [...] 'Maximising innovation' is very unlikely to equate to the 'highest possible rewards for innovation' because of the rent-protecting behaviour that will thereby be induced. Competition authorities therefore need to be aware that protecting dynamic incentives may incentivise dynamically inefficient rent-seeking behaviour." See also p. 8: "the goal of competition policy should [not] be simply to maximise innovation. There is no economic theory that says that maximising innovation maximises social welfare. It may lead to over-rapid redundancy of past innovations. Furthermore, maximising the rents flowing from innovation is likely to incentivise wasteful activity to protect those rents".

<sup>80</sup> In the words of the former European Competition Commissioner Joaquin Almunia: "Companies should spend their time innovating and competing on the merits of the products they offer – not misusing their intellectual property rights to hold up competitors to the detriment of innovation and consumer choice." (J. Almunia, Antitrust: Commission sends Statement of Objections to Motorola Mobility on potential misuse of mobile phone standard-essential patents, IP/13/406, 6 May 2013, available at [http://europa.eu/rapid/press-release\\_IP-13-406\\_en.htm](http://europa.eu/rapid/press-release_IP-13-406_en.htm), accessed on 6 August 2016).

<sup>81</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 24.

drugs. Indeed, an element to be always kept in mind when it comes to the pharmaceutical industry is that the society's interest in this field is not limited to competition and innovation, but includes also public health, product safety and access to drugs.

In recent years, the pharmaceutical industry has been a central element in the agenda of several antitrust authorities around the world. This renewed interest may be motivated, on one side, by the protection of public health and public finances (made critical by the prolonged period of economic crisis), and, on the other side, by the explosion of allegedly anticompetitive practices, maybe motivated by the expiration of patent protection of a large number of blockbuster drugs in a narrow time frame, the so-called "patent cliff",<sup>82</sup> coupled with a decrease in the number of NMEs discovered.

## 2. Patent Regulation

As anticipated, the starting point is patent law. This chapter analyzes the patent system, focusing on the legal instruments put in place to ensure proportionality of patent rights. This introduction on patent regulation has the purpose of providing all the necessary background to determine the objective of patent law and how to best reach it.

Patents for pharmaceuticals can be of three kinds: product, process, and medical use.<sup>83</sup>

Product patents are those protecting the chemical compound. They include patents on the active ingredient as well as on salts, esters, enantiomers, combinations and other derivatives of a known active ingredient. Generally speaking, compound patents have to clearly state at least one medical use for the compound. The first compound patent for a new active substance is usually very broad, potentially covering several alternative compounds depending on the displacement of the specific chemical groups in the molecular structure.<sup>84</sup>

Process patents "*protect the way in which a technical result is obtained, and not the result as such*"<sup>85</sup>. As it can be inferred from Article 64(2) EPC,<sup>86</sup> the resulting product is protected by the process patent only in so far as it has been realized using that process. In the case of pharmaceuticals, due to the fact that there are indefinite chemical reactions and processes through which the drug can be manufactured, a process patent is normally considered much weaker than a product patent and usually cannot by itself keep generics out of the market.

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<sup>82</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 165.

<sup>83</sup> A. Kur., T. Dreier, *European Intellectual Property Law: Text, Cases and Materials*, Edward Elgar, 2013, p. 109.

<sup>84</sup> C.M. Correa, *Efforts to Raise the Bar in Patent Examination Need to Be Supported*, 43(7) *International Review of Intellectual Property*, 2012, p. 749. See also B. Domeij, *Patent Claim Scope: Initial and Follow-on Pharmaceutical Inventions in Europe*, 23(7) *European Intellectual Property Review*, 2001, p. 326. The EPO considers the so-called *Markush* type claim (a chemical formula grouping hundreds or even thousands of alternative compounds) acceptable and compliant with the principle of unity of the invention when all alternatives indicated have common properties and share a common structure (EPO, *Guidelines for Examination, Markush grouping*, November 2015, available at: [http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f\\_v\\_5.htm](http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_v_5.htm), accessed on 6 August 2016).

<sup>85</sup> A. Kur., T. Dreier, *European Intellectual Property Law: Text, Cases and Materials*, Edward Elgar, 2013, p. 109.

<sup>86</sup> "*If the subject matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process*".

Indeed, generic manufacturers can enter the market as long as they employ a different (and non-protected) process.

Finally, medical use patents refer to the patentability of the therapeutic/medical use of a previously known, and potentially patented, substance.<sup>87</sup>

## 2.1. International Patent Law

The patent regulation is very fragmented and several layers of legislation exist. The first layer is represented by the international regulations, in particular the Paris Convention<sup>88</sup> and the TRIPS agreement.

The most important provision of the Paris Convention for the purposes of this work is Article 5A. In particular, Article 5A(2) authorizes the use of compulsory licensing to prevent “abuses” which might result from the exercise of the exclusive rights conferred by the patent (of which failure to work is mentioned as an example).<sup>89</sup> This provision is interesting not only for its wording, which brings into the patent regulation the concept of abuse,<sup>90</sup> but also for its genesis. It seems that British proponents of the “abuse” language, introduced in 1925 by The Hague Convention, suggested it be understood as a reflection of the then-existing British law on the abuse of monopoly rights.<sup>91</sup> This provision of the Paris Convention is evidence of the fact that the anti-monopolistic rationale is not an antitrust exclusive and is inherently present in the patent system as well.

In the past decades, the enforcement of patents has been further globalized, mainly through the agreement on Trade-Related Aspects of Intellectual Property Rights (so-called, TRIPS agreement). The TRIPS agreement, which entered into force on 1 January 1995, contains provisions reaching broadly into substantive and procedural aspects of intellectual

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<sup>87</sup> Article 54(5) of the European Patent Convention establishes “*patentability of any substance or composition [...] for any specific use [...], provided that such use is not comprised in the state of the art.*” A famous example of second medical use for medicinal products having multiple therapeutic effects is Viagra, originally developed to cure angina pectoris (A. Kur., T. Dreier, *European Intellectual Property Law: Text, Cases and Materials*, Edward Elgar, 2013, p. 110).

<sup>88</sup> The Paris Convention for the Protection of Industrial Property was concluded in 1883 and revised periodically thereafter. This Convention has been for over a hundred years the foundational instrument for discussions on international standards in patent regulation and remains to this day relevant in international intellectual property policy.

<sup>89</sup> Article 5A(2) states: “*Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.*” Article 5A(3) expresses a bias favoring compulsory licensing over patent forfeiture or revocation: “*Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.*”

<sup>90</sup> The Paris Convention does not limit the national legislature’s freedom to determine what use or conduct by right holders shall constitute an “abuse”.

<sup>91</sup> U.K. Patent and Designs Act of 1907, par. 27, as revised by U.K. Patent and Designs Act of 1919 (9 & 10 Geo. V., c. 80), cited in S.P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection*, Harvard University Press, 1975, p. 278. See also R.M. Hilty, *Legal Remedies Against Abuse, Misuse, and Other Forms of Inappropriate Conduct of IP Right Holders*, in R.M. Hilty, K.-C. Liu (eds.), *Compulsory Licensing*, Springer, 2015, p. 385 (“*the Paris Convention historically responded to far-reaching provisions in national legislations which were related in particular to a “patent abuse” in terms of non-working of the invention. Such conduct of the patent holder quite often led to the forfeiture of the patent in question (e.g., Austria and Belgium, both laws from the 1850s).*”

property law.<sup>92</sup> As to the relation between the TRIPS agreement and the Paris Convention, Article 2 TRIPS establishes that the latter, and in particular its Art. 5, continues to apply.<sup>93</sup>

On the purpose of IP, Article 7 TRIPS, in line with the premises of this work, establishes that the protection and enforcement of IPRs “*should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*”

Article 8(2), in line with Article 5 of the Paris Convention, recognizes the power of the WTO Member States to take appropriate measures to prevent the “*abuse of intellectual property rights*” by right holders.<sup>94</sup> The TRIPS agreement thus offers a legal basis to justify, from an international law perspective, a restriction of patent rights in case of abusive behavior to the detriment of innovation and consumer welfare.<sup>95</sup>

With respect to access to drugs, the TRIPS agreement was clarified by the Doha Declaration on the TRIPS agreement and public health of 14 November 2001. The Doha

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<sup>92</sup> As far as general rules on patent go, Article 27 requires the signatory States, *i.e.* all members of the World Trade Organization (WTO), to make sure patents are “*available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.*” Note 5 of the agreement further specifies that “[f]or the purposes of [Art. 27], the terms “*inventive step*” and “*capable of industrial application*” may be deemed by a Member to be synonymous with the terms “*non-obvious*” and “*useful*” respectively”. According to Article 28, patents confer general rights to exclude third parties from, in case the subject matter of the patent is a product, manufacturing, using, marketing, or importing for such purposes the product; in case the patent concerns a process, third parties are precluded from using the process, and using, selling or importing the product obtained directly by that process. Patents grants also positive rights to their holders. Patent owners can assign, or transfer by succession, the patent and conclude licensing agreements.

<sup>93</sup> Article 2 TRIPS establishes that: “*In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967). Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.*”

<sup>94</sup> Article 40 states that “*Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology*” and nothing prevents States from “*specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.*” In turn, Article 48 TRIPS allows Member States (but does not oblige them) to “*order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse*”. Article 67 requires developed countries to assist developing and least-developed countries in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse. With respect to patent protection of pharmaceutical products in developing countries, although Article 41 of the TRIPS agreement requires the members of the WTO to “*ensure that enforcement procedures [...] are available under their law so as to permit effective action against any act of infringement of intellectual property rights*”, WTO members granted these countries a transition period, recently extended to 2033. (WTO members agree to extend drug patent exemption for poorest members, 6 November 2015, available at [https://www.wto.org/english/news\\_e/news15\\_e/trip\\_06nov15\\_e.htm](https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm), accessed on 6 August 2016.)

<sup>95</sup> See Article 30 TRIPS (“*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*”)

Declaration is the result of demands by developing countries, increasingly concerned over the prohibitive cost of essential patented drugs.<sup>96</sup> The aim of the Doha declaration was to strike a balance between the protection of IP and the protection of public health and the way to achieve it has been to limit IP rights in order to favor access to drugs.<sup>97</sup>

## 2.2. United States

Having introduced the patent rules at the international level, it is now appropriate to briefly consider regulations at the regional/national level, in particular those at the U.S. and EU level.

To ensure the correct balancing between stimulating innovation by protecting inventors and limiting secondary innovation and price competition by granting undeserved and/or overly broad patents, the patent system is premised on the review of the inventor's application by the patent office to determine whether the claimed invention respect the standard of patentability (and thus justifies the social cost of granting a patent).<sup>98</sup> To be patentable, an invention must meet all the statutory requirements for patentability.<sup>99</sup>

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<sup>96</sup> In response to such demands, the Doha declaration embraces a doctrine of "flexibility". This way, WTO members can be compliant with the TRIPS agreement, but at the same time guarantee respect of public health and improve access to drugs, by counting on flexibilities such as parallel imports, compulsory license and exceptions to patent rights. The declaration states that WTO members "*recognize the gravity of the public health problems afflicting many developing and least-developed countries*" and "*recognize that intellectual property protection is important for the development of new medicines [and] the concerns about its effects on prices*". The Declaration, at paragraph 4, clarifies that: "*the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, [...] the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*" As noted by Professor Petit, "*This shift in legal policy entitled developing countries to issue compulsory licenses. The FCL doctrine was turned into practice in Africa, Asia and India, where compulsory licenses were issued over anti-retroviral drugs useful for the treatment of HIV/AIDS*" (N. Petit, "Stealth Licensing" - Or Antitrust Law and Trade Regulation Squeezing Patent Rights, *Revue du Droit des Industries de Réseau*, 2014, p. 7-8).

<sup>97</sup> Within the flexibilities at the States disposal to ensure the protection of public health and, in particular, to promote access to medicines for all, competition law (whose importance is recognized inter alia by Article 31(k) TRIPS on compulsory license) and IP law (whose limitations are permitted under Article 30 TRIPS) are the focus of this work. Countries like India, which has taken advantage of the flexibilities provided for by the TRIPS agreement, enjoy up to 41 times cheaper drugs than countries not making use of those flexibilities (C.M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Zed Books, 2002, 35).

<sup>98</sup> As explained by the Federal Circuit, the government-granted monopoly "*is not a disbursement of governmental largesse and thus not a 'gift'; rather, the government grant of a property right, namely the right to exclude for a limited time, is conditioned on the creation and public disclosure of a new and useful invention*" (*Xechem Int'l, Inc. v. Univ. Of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d, Fed. Cir., 2004, p. 1331). See also *In re '318 Patent Infringement Litigation*, 583 F.3d, Fed. Cir., 2007, 1324, where it can be read, a "*patent is not a hunting license; it is not a reward for the search, but compensation for its successful conclusion*".

<sup>99</sup> One of the requirements, enablement (Section 112 of the Patent Act), relates more directly to the invention description and claims than to the patent subject matter. Enablement serves the purpose of enabling third parties to make and use the invention, once the patent is expired, and to let the public know the outer limits of the patent (thus encouraging innovation). Enablement ensures that the scope of the patent is proportional to the inventor's disclosure – a patent can claim only as much as it teaches. The description has to be sufficiently clear and complete (i) that those skilled in the art will be able to make, use, and understand the invention, and (ii) "*to enable others to discern the*

The first requirement of patentability is utility, *i.e.*, as indicated by Section 101 of the Patent Act, the invention has to be “useful”. This requirement is potentially extremely important to avoid patents being granted before a new technology has been adequately described or understood. In this sense, its aim is to optimize the timing of the award and prevent rent seeking.<sup>100</sup>

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*boundaries beyond which experimentation and invention are undertaken at the risk of infringement.”* (Eli Lilly and Co. v. Premo Pharmaceutical Labs., 630 F. 2d, 3rd.Cir., 1980, p. 120). Professor Merges describes the characteristics of a patent application as follows: “*A patent application has two main parts. The first is a specification of the invention, which is written like a brief science or engineering article describing the problem the inventor faced and the steps she took to solve it. It also provides a precise characterization of the “best mode” of solving the problem. The second part of the patent application is a set of claims, which usually encompass more than the material set out in the specification. Claims define what the inventor considers to be the scope of her invention, the technological territory she claims is hers to control by suing for infringement. [...] [A] patent’s specification need not point out precisely how to make every device that would fall within its claims. Disclosure of an inventive concept or principle, whose precise contours are defined by the claims, is enough.*” (R.P. Merges, R.R. Nelson, On the Complex Economics of Patent Scope, 90 Columbia Law Review, 1990, pp. 844, 846) Another requirement is that the subject matter needs to be patentable. The U.S. Patent Act, Section 101, provides: “*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.*” Justice Breyer explains clearly the rationale of the limits to the patentable subject matter: “[I]he reason for the exclusion is that sometimes too much patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection. U. S. Const., Art. I, §8, cl. 8. The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so. Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others.” (Laboratory Corp. Of America Holdings V. Metabolite Laboratories, Inc., 548 U. S. (2006), Breyer J. dissenting)

<sup>100</sup> See *Brenner v. Manson*, 383 U.S. 519, 1966 (“*Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.*”) Utility weeds out patents with no practical application, used only to game the system to the benefit of rent-seekers and to the detriment of consumers. “*Investment and effort are therefore directed toward the socially useful goal of developing the technology, rather than simply racing to the patent office.*” (R.P. Merges, *The Trouble with Trolls Innovation Rent-Seeking and Patent Law*, 24(4) Berkeley Technology Law Journal, 2009, pp. 1588-1590) The utility requirement has however been interpreted quite broadly and does not often entail a stringent verification. The pharmaceutical industry might be the exception and the practical use of the chemical compound should be stated by the applicant and is carefully scrutinized by the office. “*Only if an invention has absolutely no “practical utility” will a patent be denied. The only exception is inventions pertaining to pharmaceuticals, where some cases question whether laboratory promise is enough to establish utility in treating human patients.*” (R.P. Merges, P.S. Menell, M.A. Lemley, *Intellectual Property in the New Technological Age*, Aspen Publishers, 2012, p. 129). See also R.P. Merges, *Commercial Success and Patent Standards Economic Perspectives*, 76(4) California Law Review, 1988, pp. 811-812 (“*The second requirement “utility,” has devolved over the years into a rather minimal obstacle to obtaining a patent. Today, a patent will not be withheld even though the invention works only in an experimental setting, and has no proven use in the field or factory [...] In chemical patent cases, however, the courts*

Second, the invention has to be novel. This is also called the first-to-invent requirement and refers to the need for the invention to be the first of its kind, not previously known, used, patented, or described in a printed publication.<sup>101</sup> The novelty requirement ensures that information in the public domain remains public and can be used freely by consumers, competing companies and inventors (standing on the shoulders of the public domain giant). If the information is already in the public domain, society has no interest in, nor benefit from, granting a patent.<sup>102</sup>

The third requirement is non-obviousness. The invention has to be a nontrivial step forward in what is already known, *i.e.* it has to entail a degree of skill and ingenuity. The grant of a patent is thus excluded under Section 103 of the Patent Act when “*the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.*”<sup>103</sup> As emphasized by Professor Merges,

“*The statutory nonobviousness test serves a gatekeeping function; it seeks to reward inventions that, viewed prospectively, have a low probability of success. [...] The standard insists that only the results from uncertain research should be rewarded with a patent. Research which overcomes uncertainty is precisely the sort society values, and hence rewards with a patent. [...] [T]he job of nonobviousness is to encourage invention while not over-rewarding it.*”<sup>104</sup>

Exactly as the novelty requirement, also non-obviousness aims at limiting the publicly-available information sacrificed in the name of innovation. Countless inventors draw from the stock of publicly-available resources and price competition depends on it.<sup>105</sup> A

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*have consistently held that a chemical compound claimed in a patent application must have some known, practical use. [...]”).*”

<sup>101</sup> Section 102 of the Patent Act. “*Lack of novelty may bar the claimed invention from being patentable either because it was made before; it was sold more than a year before a patent application was filed; or it was otherwise subject to prior use or knowledge*” (R.P. Merges, Commercial Success and Patent Standards Economic Perspectives, 76(4) California Law Review, 1988, p. 811).

<sup>102</sup> “[Jefferson] viewed a grant of patent rights in an idea already disclosed to the public as akin to an *ex post facto* law, obstruct[ing] others in the use of what they possessed before. [...] Sections 102(a) and (b) operate in tandem to exclude from consideration for patent protection knowledge that is already available to the public. They express a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use.” (Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 1989). See also Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 1966, (“*The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. [...] Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.*”)

<sup>103</sup> “*The nonobviousness requirement extends the field of unpatentable material beyond that which is known to the public under Section 102, to include that which could readily be deduced from publicly available material by a person of ordinary skill in the pertinent field of endeavor. See Graham, 383 U.S., at 15.*” (Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 1989) As explained by the Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 1966, “*the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.*” To verify whether an invention is non-obvious, courts have to presume that the reasonably skilled inventor knows everything (public) in the prior art. Although not realistic, this presumption ensures objectiveness, administrative efficiency and reduces the risk of conflicting decisions.

<sup>104</sup> R.P. Merges, Uncertainty and the Standard of Patentability, 7 Berkeley Technology Law Journal, 1992, pp. 2-3.

<sup>105</sup> “*“Obvious” patents harm consumers by creating exclusive rights in things that would otherwise sell*

patent should be granted only when a person of ordinary skill in the art would have excluded reasonable chance of success for the experiment leading to the invention.<sup>106</sup> Non-obviousness must be defined narrowly because patent law does not leave room for independent invention – a patent can be infringed unknowingly.<sup>107</sup>

The difference between novelty and nonobviousness is that to verify the first it is necessary to look back, asking whether something in the prior art anticipates all of the elements of a patent claim; to verify the second it is necessary to look into the future and consider whether a person skilled in the art would be likely to have come up with the same invention on his own.<sup>108</sup> As highlighted by the U.S. Supreme Court,

*“Taken together, the novelty and nonobviousness requirements express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of either that which is already available to the public or that which may be readily discerned from publicly available material.”*<sup>109</sup>

Ensuring the correct application of the novelty and non-obviousness requirements is potentially a solution (or at least a serious complicating factor) to several of the abusive practices analyzed below. An originator would not be able to obtain patents on a chemical component of the drug, a changed form or an altered salt, for the sole purpose of extending exclusivity and preventing generic substitution.<sup>110</sup> Two potentially abusive practices that would be made difficult, harmless, or in some cases impossible, by the strict interpretation of

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*competitively. The deadweight loss of obvious patents is high. As the previous discussion suggests, it tends to be higher in markets that are already noncompetitive to begin with, because marginal consumers in those markets have more consumers’ surplus to lose. Many pharmaceutical extension patents very likely fall into this category.”* (H.J. Hovenkamp, *Consumer Welfare in Competition and Intellectual Property Law*, 9 *Competition Policy International*, 2014, pp. 60-61)

<sup>106</sup> To determine nonobviousness, the case law recognized the importance of objective factors such as *“the commercial success of the invention (which I have criticized), the failure of competitors to make the invention (which I have suggested ought to be the major objective factor), a long-felt need in the industry for an invention, and recognition in the industry of a notable achievement.”* (R.P. Merges, *Uncertainty and the Standard of Patentability*, 7 *Berkeley Technology Law Journal*, 1992, p. 35). The Supreme Court clarified in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 1989, that *“[e]ven if a particular combination of elements is “novel” in the literal sense of the term, it will not qualify for federal patent protection if its contours are so traced by the existing technology in the field that the “improvement is the work of the skillful mechanic, not that of the inventor.”* *Hotchkiss v. Greenwood*, 11 *How.* 248, 267 (1851).”

<sup>107</sup> *“If we are going to be in the business of condemning innocent discoverers for patent infringement then we must make sure that patents are granted only for things that are sufficiently nonobvious that there won’t be a large number of innocent discoverers. Otherwise we create monopoly rights in pedestrian changes.”* (H.J. Hovenkamp, *Institutional Advantage in Competition and Innovation Policy*, University of Iowa Legal Studies Research Paper No. 13-43, 2013, p. 4)

<sup>108</sup> *“Determining nonobvious subject matter requires going beyond what the prior art actually contains in order to assess whether someone of “ordinary” skill and who is acquainted with the prior art in that field would be likely to come up with the invention independently. In the patent granting process nonobviousness queries typically involve situations where there are multiple pieces of prior art but no single piece fully anticipates a particular patent claim; or where the invention is anticipated in a different market, or “field of endeavor,” but not in the one where the patent is sought.”* (H.J. Hovenkamp, *Consumer Welfare in Competition and Intellectual Property Law*, 9 *Competition Policy International* 53, 2014, pp. 63-64)

<sup>109</sup> *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 1989.

<sup>110</sup> The so-called evergreening, a strategy consisting in patenting the metabolite of a drug when its patent is close to expiration to prevent generic substitution, was ended in the U.S. by deeming the metabolite “inherent” in the original drug and thus not novel. See *Schering Corp. v. Geneva, Inc.*, 339 F.3d, Fed. Cir., 2003, p. 1373.

the novelty and non-obviousness requirements are the creation of patent clusters<sup>111</sup> and product hopping.

### 2.3. European Union

The most notable difference between the U.S. and EU patent laws is the absence, at least for now, of a unitary patent protection system in the European Union. When the Treaty of Rome was first drafted in 1957 no provision was set forth to unify intellectual property law and IP rights protection. The Treaty of Lisbon introduced an extremely important innovation in this respect with Article 118 of the Treaty on the Functioning of the European Union (TFEU). This Article grants the European Parliament and the Council the power to “*establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.*” The European Parliament acted on this power and a Unitary patent, valid and enforceable in the entire EU, is close to becoming a reality.

Despite the patent system not being completely harmonized within the EU, it is a fair assumption for the purposes of this work to consider the patent systems of the EU Member States roughly aligned. Indeed, the TRIPS agreement and the European Patent Convention (EPC) helped in the process of bringing Member States’ IP legislations closer together and most national provisions have substantially identical wording. Given the harmonizing effect of the EPC, this work will focus on its provisions and on the most recent evolutions that interested the protection of patents at the EU level.

On 5 October 1973, in Munich, several western European nations entered into a treaty (the EPC) establishing, as Article 1 states, a “*system of law, common to the Contracting States, for the grant of patents for invention*”. The EPC is an international treaty binding on all EU Member States as well as some other European countries (such as Switzerland, Liechtenstein, Monaco, Turkey, Norway, Macedonia, San Marino, Albania, and Serbia), establishing a common system of law for the grant of patents. The EPC created the European Patent Office (EPO), in charge of the examination of patent applications in accordance with the substantive principles established by the Convention. Although commonly referred to as “European” patents, the patents granted under the European Patent Convention have a hybrid character: they are granted under common rules by the EPO, a central, European, authority but, once granted, they instantly transmogrify into a bundle of national patents, governed by the national law of each of the Member States for which they are granted.<sup>112</sup> Therefore, a European patent has the same effect and confers the same rights, subject to the

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<sup>111</sup> See I. Lianos, R.C. Dreyfuss, *New Challenges in the Intersection of Intellectual Property Rights with Competition Law*, 4 CLES Working Paper Series, 2013, p. 16 (“*The United States Court of Appeals for the Federal Circuit, the court that hears all patent appeals, at one time set the level of nonobviousness very low. As a result, patent thickets developed and it became increasingly difficult to determine freedom to operate.*”)

<sup>112</sup> Article 2(2) EPC states: “*The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State*”. See also Article 64 EPC which establishes that the patents granted by the EPO confer on its holder, “*in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State*” (Article 64 EPC). Patent protection lasts 20 years from the date of filing of the application (Article 63 EPC).

same conditions, as a national patent and must be enforced or challenged before national courts.<sup>113</sup>

Not differently from the U.S. system (and from most of the legal systems around the world), Article 52 EPC establishes three main requirements for an invention to be patentable.<sup>114</sup>

The invention needs to be new, *i.e.* not part of the “state of the art”, which includes everything made available to the public before the filing of the patent application.<sup>115</sup> An invention will thus be new only when it is objectively different from any other known technical solutions, with no geographic or other delimitation.<sup>116</sup>

Second, the invention has to involve an inventive step. This can be considered the alter ego of the non-obviousness requirement in the U.S., *i.e.* the invention needs to be not obvious to a person skilled in the art.<sup>117</sup> As explained by the European Commission, to determine whether this requirement is respected, “*the EPO follows the “problem-solution approach”, consisting of three stages of analysis. First, the closest prior art is determined. (The closest prior art is the combination of already known features which constitutes the most promising starting point for development leading to the claimed invention.) Then the objective technical problem to be solved is established, based on the difference between the claimed invention and the closest prior art. Finally, the EPO considers whether the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to a skilled person.*”<sup>118</sup>

Finally, the invention has to be susceptible of industrial application, *i.e.* it can be made or used in any kind of industry.<sup>119</sup> The term “industry” has to be interpreted broadly and includes any physical activity of “*technical character, i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts*”.<sup>120</sup>

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<sup>113</sup> Article 64(3) provides: “*Any infringement of a European patent shall be dealt with by national law.*” After the European patent has been granted, it needs to be validated in each Member State for which it was requested. The patent needs to be translated in case it is not in one of the official languages of the Member State. The success of the EPC is probably due to its hybrid nature. While its introduction allowed inventors to overcome the costs and problems connected with multiple national applications, Member States maintain their sovereignty on “national” patents granted thereunder.

<sup>114</sup> According to Article 52 of the EPC, “*European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.*”

<sup>115</sup> “*An invention shall be considered to be new if it does not form part of the state of the art. The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application*” (Article 54 EPC).

<sup>116</sup> Not every element of the invention needs to be never heard of – it is sufficient that at least one essential technical feature cannot be found in the prior art. In the pharmaceutical field, the novelty requirement tends to be relative easy to fulfil. As Professor Domeij explains: “[d]ue to the precision with which a substance can be defined structurally in chemistry, the novelty requirement in connection with product patents tends to become an assessment of the identity of two substances: if there is the slightest difference, the novelty requirement is satisfied.” (B. Domeij, *Pharmaceutical Patents in Europe*, Kluwer and Nordstedts Juridik, 2000, p. 92)

<sup>117</sup> “*An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art*” (Article 56 EPC).

<sup>118</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 67.

<sup>119</sup> “*An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture*” (Article 57 EPC).

<sup>120</sup> EPO, *Guidelines for Examination*, part G, Ch., III, 3.1.

Noteworthy is the fact that, in its final report on the pharmaceutical sector inquiry, the European Commission reported critics on the thoroughness of the EPO process. “Generic companies suggested that in particular in such situations of relatively minor modifications to already patented products, the EPO should examine the patent application very closely before granting it. At present, it was felt by many respondents that the novelty and the inventive step requirements for such patent applications were at times too easily considered as being met, partly because the EPO sometimes overlooked prior art and partly because the EPO sometimes accepted, as part of their “problem-and-solution approach” to inventive step, claims from applicants regarding non-existent or obvious problems.”<sup>121</sup>

An additional requirement for a valid patent application is the unity of the invention. Article 82 EPC states that a European patent application “shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept”. The applicant can overcome an objection of lack of unity raised by the EPO by simply filing one or more divisional applications for each separate inventive concept.<sup>122</sup> A divisional application can be filed also

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<sup>121</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 1316.

<sup>122</sup> Divisional applications ensure that the patentee pays the appropriate patenting fee for each invention, make the research for prior art easier, and divide stronger from contestable claims. Divisional applications are regulated by Article 76 EPC that provides: “A European divisional application shall be filed directly with the European Patent Office in accordance with the Implementing Regulations.” The crucial substantive requirement is that the divisional application is “filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed; in so far as this requirement is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority.” Although a violation of the EPC may be corrected by way of amendments, allowing the applicant to radically amend its request and maintain the original priority date, Article 123(2) and (3) EPC establishes that “the European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. The European patent may not be amended in such a way as to extend the protection it confers.” An alarming, and increasingly frequent, practice in the area of divisional applications is the so-called double patenting, *i.e.* the filing of divisional application(s) whose subject matter is literally or substantially identical to the parent application or patent. If granted, the same invention would thus be protected by two patents. Such a practice is used as a precautionary measure against final rejection or revocation. At present, while double patenting is generally recognized as a problematic aspect of the system, there is no specific legal basis in the EPC for its prohibition. The recently updated EPC Guidelines, however, provide that: “The EPC does not deal explicitly with the case of co-pending European applications of the same effective date filed by the same applicant. However, it is an accepted principle in most patent systems that two patents cannot be granted to the same applicant for one invention. The Enlarged Board of Appeal has accepted *obiter dictum* that the principle of the prohibition on double patenting is based on the notion that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter if he already possesses one granted patent for that subject-matter (see G 1/05, and G 1/06). It is permissible to allow an applicant to proceed with two applications having the same description which do not claim the same subject-matter (see also T 2461/10). The applicant may, for example, be interested in obtaining a first quicker protection for a preferred embodiment and pursue the general teaching in a divisional application (see G 2/10). However, in the rare case in which there are two or more European applications from the same applicant definitively designating the same State or States (by confirming the designation through payment of the relevant designation fee) and the claims of those applications have the same filing or priority date and relate to the same invention, the applicant should be told that he must either amend one or more of the applications in such a manner that the subject-matter of the claims of the applications is not identical, or choose which one of those applications he wishes to proceed to grant. If he does not do so, once one of the applications is granted, the other(s) will be refused under Art. 97(2) in conjunction with Art. 125. If the claims of those applications are merely partially overlapping, no objection should be raised (see T 877/06).” (Guidelines for Examination in the European Patent Office, G, IV, 5.4 Double patenting, November 2015) The scope for a double patenting objections is however rather limited. The EPO jurisprudence has progressively restricted the interpretation of “same invention” to the point that objections of double patenting are upheld

voluntarily by the applicant. On the procedural side, a divisional patent can be filed with the EPO for as long as the “earlier” European patent application is still pending.<sup>123</sup> This, and the lack of an explicit prohibition in Article 76 EPC, led the Enlarged Board of Appeal of the EPO to deem sequences of divisional applications (*i.e.* a divisional application of a divisional application) acceptable.<sup>124</sup> This means that as long as there is a pending patent application (even if it is a divisional of a divisional) it is possible to file an additional divisional application. Applicants can thus continuously file divisional applications throughout the entire patent term.<sup>125</sup>

Although divisional applications are not unique to the pharmaceutical industry, the subject matter of a new drug is often particularly suitable to be divided into several patent applications. This characteristic of the pharmaceutical subject matter leads to the frequent use (and occasional abuse) of voluntary divisional applications by originators. The strategic use of this tool to the detriment of consumer welfare will be analyzed below.

As a final remark on the EPO procedure, the validity of a European patent can be challenged in an opposition and appeal procedure before the EPO without any presumption regarding its status. An EPO decision is retro-actively effective in all States where the opposed patent has been validated.

### 2.3.1. SPC

Specific to the pharmaceutical industry is another regulatory instrument created to recoup a portion of the time elapsed between the filing of the patent application for a new drug and the grant of the marketing authorization. It is the so-called Supplementary Protection Certificates (SPC).<sup>126</sup> The SPC compensates companies for the period of patent exclusivity they could not (potentially) profit from due to the time necessary to obtain the

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only when there is no practical difference between the claims of two applications. Applications broader or narrower in scope as well as partially overlapping are considered acceptable.

<sup>123</sup> Article 36 of the Implementing Regulations to the Convention on the Grant of European Patents states: “*The applicant may file a divisional application relating to any pending earlier European patent application.*”

<sup>124</sup> See case G-1/06, Sequences of divisionals/SEIKO, 28 June 2007. See also Guidelines for Examination in the European Patent Office, A, IV, 1.1.2 Sequences of divisional applications, November 2015 (“*A divisional application can also be an earlier application in the sense of Art. 76(1) for the purposes of one or more further divisional applications. The characterising feature of a sequence of divisional applications each divided out from its predecessor is that each member of the sequence claims as date of filing the date of the root application in which the subject-matter divided out in sequences of divisional applications was first disclosed (G 1/05, G 1/06). In a sequence of divisional applications, a first-generation divisional application is a divisional application based on an application which is not itself a divisional application, i.e. the root application. A second-generation divisional application is a divisional application based on a first-generation divisional application; and so on.*”)

<sup>125</sup> G. Ghidini, G. Cavani, P.F. Pisera’, Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 259, footnote 30, note that “*the ‘cascading’ fragmentation of an original patent through a succession of divisional applications, one based on the other, has the substantial effect of disorienting one’s competitors and augmenting their uncertainty in relation to the scope of the patent right.*”

<sup>126</sup> In the U.S., it is the Hatch-Waxman Act that, to compensate for the time that lapsed during the FDA regulatory process, grants originators the possibility to extend their exclusivity beyond the standard 20-year patent term for a period of up to five years, and an additional six-month of “paediatric exclusivity” if the manufacturer conducts certain paediatric studies.

authorization to market the drug. The SPC has been introduced by Council Regulation 1768/92<sup>127</sup> in response to the perceived insufficiency, for the amortization of investments, of the period of market exclusivity left after the marketing authorization is obtained. Recitals 2 and 3 of the Regulation explain its purpose:

*“[M]edicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research [...] [A]t the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.”*

The application must be lodged with the competent patent office of the Member State that granted the basic patent.<sup>128</sup> According to Article 3 of Regulation 469/2009, for the grant of the certificate, the drug shall be protected by a basic patent in force in a Member State at the time of the application and a valid marketing authorization has been granted to place that product on the market. The application needs to be lodged within six months of the date on which the marketing authorization in that particular Member State was granted.

The SPC confers the same rights as conferred by the basic patent and extends the term of the basic patent for a period equal to the time between the date on which the application for the basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by five years.<sup>129</sup> However, the SPC cannot be granted for a period exceeding five years and the combined patent and SPC exclusivity cannot exceed 15 years from the first marketing authorization. It is evident that if the basic patent is revoked or limited, the certificate will consequently become invalid.

As we will see in greater details below, the SPC regulation has been at the center of attention in one of the most important cases of abuse of dominance in the pharmaceutical sector, the European Commission decision (and the following EU Courts judgments) in *AstraZeneca*. In this case, the submission of false or inaccurate statements, capable of effectively misleading public authorities, has been deemed in violation of competition law. The SPC had a role also in the Italian *Pfizer* case, in which the Italian Competition Authority sanctioned a non-misleading request of an SPC because it was deemed part of a complex strategy aimed at delaying generic entry.

### **2.3.2. Pediatric Extension**

In addition to the SPC, the originator may obtain also a so-called “pediatric extension”. Regulation 1901/2006 requires that a pediatric investigation plan is established and results are submitted to the European Medicines Agency to obtain the marketing authorization, unless the EMA decides to waive this requirement either independently or

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<sup>127</sup> The SPC is now regulated by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ 2009, L152.

<sup>128</sup> Article 9 of Regulation 469/2009.

<sup>129</sup> Article 13 of Regulation 469/2009. To avoid disparities and obstacles to the common market, the SPC is calculated on the basis of the first marketing authorization and will thus have equal expiration date in every Member State.

upon request from the applicant.<sup>130</sup> As compensation for conducting the pediatric studies, the patent holder which obtained an SPC is entitled to an automatic 6-month extension of the exclusivity period.

This extension was introduced to incentivize the pediatric research since a relevant number of drugs used on children were not studied nor authorized for that purpose. As analyzed below in discussing *Pfizer*, given its purpose, the regulation on the pediatric extension may be considered abused where, for drugs that will not be used in the treatment of children, the originator, instead of asking for a waiver, conducts the pediatric investigation with no other purpose than to obtain the extension.

### 2.3.3. Unitary Patent and Unified Patent Court

Although not yet in force, it is worth mentioning the most recent (successful, at least for now) attempt at a unitary patent for the whole (or almost whole) EU. The proposal to create an EU patent system, under which a central granting authority (the EPO) would grant EU-wide patent rights, is long-standing. As of 2009,<sup>131</sup> the interest in creating a European patent with unitary effect has strengthen and in 2012, in the context of the so-called “enhanced cooperation” procedure (under which a group of Member States can proceed without the others),<sup>132</sup> the relevant regulations laying the foundation for a unitary patent protection were adopted.<sup>133</sup> In addition, in February 2013, 25 European Countries (excluding Croatia, Poland, and Spain) reached an agreement on the creation of a Unified Patent Court (UPC), which will have exclusive jurisdiction for the enforcement of European patents with unitary effect and supplementary protection certificates issued for a product covered by such patents. Therefore, *e.g.*, a single injunction will be obtainable through the Unified Patent Court for all States having ratified the UPC Agreement. The UPC will also have non-exclusive competence over non-unitary European patents in participating states, which will become exclusive after an extendable seven year transition period (if the patentee has not opted out by notifying the Registry of the Court).

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<sup>130</sup> Typical reason for a waiver is the fact that the disease the drug cures only occurs in the adult population.

<sup>131</sup> Noteworthy is the fact that the final report of the European Commission pharmaceutical sector inquiry specifically recommended the creation of an EU patent and unified patent court to limit the risk of conflicting judgments and the obstacles to the Common Market created by national patents, as well as national patent systems. As pointed out by G. Muscolo, Abuse of Litigation, Abuse of Patent and Abuse of Dominance: Where Do We Stand?, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 119, the Commission’s report “*confirms the lack of consistency in EU case law and the consequent uncertainty in the pharmaceutical patent situation derived from the absence of a unified patent judiciary. The creation of a Unified Patent and of a Unified Patent Court has finally filled the gap; moreover, a branch of the Court of First Instance, dealing with cases on pharmaceutical and bio-technologic patents, has been recently established in London.*”

<sup>132</sup> Croatia, Italy, and Spain did not participate at the beginning, but in September 2015 Italy joined the Unitary Patent and became the 26th member of the enhanced cooperation.

<sup>133</sup> Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (Article 15 expressly states that the Regulation “*shall be without prejudice to the application of competition law and the law relating to unfair competition*”) and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation requirement.

The two regulations entered into force on 20 January 2013 but will apply only after the entry into force of the UPC Agreement. As to the UPC Agreement, it will enter into force the first day of the fourth month after it has been ratified by 13 participating States, including the three most patent intensive Member States (Germany, France and the United Kingdom). Eleven states have ratified the UPC Agreement so far, namely Austria, Belgium, Bulgaria, Denmark, France, Luxembourg, Malta, the Netherlands, Portugal, Sweden and Finland.<sup>134</sup>

Under Article 3(2) of Regulation 1257/2012: “[a] *European patent with unitary effect shall have a unitary character. It shall provide uniform protection and shall have equal effect in all the participating Member States. It may only be limited, transferred or revoked, or lapse, in respect of all the participating Member States. It may be licensed in respect of the whole or part of the territories of the participating Member States.*”<sup>135</sup> The European patent with unitary effect will be granted by the EPO under the rules and procedures laid down by the European Patent Convention (EPC). Regulation 1257/2012 defines the conditions and the scope of the unitary effect, while the EPC establishes the relevant criteria under which the patent is granted. Therefore, nothing substantially changes in the pre-grant phase.<sup>136</sup> After the grant of a European patent, the patentee has the opportunity, within one month from the publication in the European Patent Bulletin, to file a request for unitary effect and, if the formal requirements are met, benefit from such uniform protection and equal effect in all participating States.

As to the enforcement system, the UPC will be divided into a Court of First Instance (CFI) and a Court of Appeal. The UPC-CFI will be one court with several divisions. The central division will be seated in Paris (with local (or regional) divisions in individual member

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<sup>134</sup> The list is constantly updated at this address <http://www.consilium.europa.eu/en/documents-publications/agreements-conventions/agreement/?aid=2013001>, accessed on 11 December 2016. In addition, the legislation enabling Italy’s ratification and implementation of the UPC Agreement came into force on 25 November 2016. The Law also provides for the implementation of the UPC agreement in three ways: (i) excluding UPC disputes from the competence of national IP specialized courts; (ii) amending Article 66 of the Industrial Property Code to introduce provisions on indirect patent infringement (currently acknowledged only by the case law); (iii) authorizing the required budgetary changes for Italy’s participation in the new UPC system (Italy’s local division of the UPC in Milan should be ready to function by June 2017).

<sup>135</sup> Article 7 of Regulation 1257/2012 provides that: “[a] *European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect and in which, according to the European Patent Register: (a) the applicant had his residence or principal place of business on the date of filing of the application for the European patent; or (b) where point (a) does not apply, the applicant had a place of business on the date of filing of the application for the European patent. 2. Where two or more persons are entered in the European Patent Register as joint applicants, point (a) of paragraph 1 shall apply to the joint applicant indicated first. Where this is not possible, point (a) of paragraph 1 shall apply to the next joint applicant indicated in the order of entry. Where point (a) of paragraph 1 does not apply to any of the joint applicants, point (b) of paragraph 1 shall apply accordingly. 3. Where no applicant had his residence, principal place of business or place of business in a participating Member State in which that patent has unitary effect for the purposes of paragraphs 1 or 2, the European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the State where the European Patent Organisation has its headquarters in accordance with Article 6(1) of the EPC.*”

<sup>136</sup> The application can be filed in any language and prosecuted in English, French or German. Before the grant, the EPO requires the patent specification to be translated into English, where the EPO prosecution was in French or German, or into any other official language of an EU member state, where the EPO prosecution was in English.

states),<sup>137</sup> with sections in London and Munich dealing with cases concerning specific patent classifications.<sup>138</sup> The UPC Court of Appeal will be located in Luxembourg and will hear all appeals. All the panels of both Courts (of three and five judges respectively) will have a multinational composition and operate under the Rules of Procedure of the UPC. The decisions of the UPC-CFI and of the UPC Court of Appeal will be immediately enforceable in any contracting State.

### 3. Objective of IP and Scope of the Patent

After this brief introduction on patent law, it is now time to determine its rationale. Often laws are considered a given and interpretation and enforcement take the letter of the law as the starting (and sometimes ending) point. The risk with this approach is that a law created to accomplish a specific result might be (ab)used to achieve unforeseen and often undesirable consequences, sometimes diametrically opposed to those behind the same existence of the law.

Patent law, as any other law, has been created for a reason, to pursue a specific objective. A conduct that, by using the means provided by patent law, aims at achieving patent law's objective should not be the object of criticism by antitrust authorities. In deciding whether to adopt a patent law, and how to structure it, regulators balance the different interests coming into play (on one hand, the need to encourage innovation; on the other hand, the avoidance of monopolies), and this balancing should not be questioned by antitrust authorities.<sup>139</sup> To the contrary, when the conduct, although formally compliant with

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<sup>137</sup> Actions for revocation must be brought in the Central Division. The same applies to actions for non-infringement. In this case, however, if a corresponding action for infringement is brought within three months, the Central Division must stay the non-infringement proceeding. Actions for infringement shall in general be brought before the Local (or Regional) Division (1) where the infringement has occurred or is threatened, or (2) where the defendant (or one of the defendants) has his residence or place of business. In cases where the defendants are not EU-based or the country under (1) or (2) does not participate in a Local or Regional Division (as is the case for Luxembourg and Malta), the case can again be brought in the Central Division. In the event the defendant present a counterclaim for revocation, the Local or Regional Division hearing the infringement action can (i) proceed with the infringement and revocation proceedings together; (ii) proceed with the infringement proceedings and send the counterclaim for revocation to the Central Division (so-called "bifurcation"); (iii) send the counterclaim to the Central Division and stay the infringement proceedings until a decision on the revocation. If the parties agree, it is also possible for the infringement action and revocation counterclaim to be both heard by the Central Division.

<sup>138</sup> London: patents in the IPC (International Patent Classification) classifications A and C (chemistry, pharmaceuticals, biotechnology and also human necessities, including medical devices); Munich: IPC classification F (mechanical engineering). Other matters, *i.e.* classifications B, D, E, G and H, including electronics, software and physics, will be heard in Paris. After the British referendum to exit the EU (Brexit), the issue of whether the UK will remain part of the UPC system has been widely discussed and a final position is yet to be expressed. While it is likely that the UK will remain part of the UPC system (though Brexit will probably delay the implementation of the Unitary patent), certain steps to address the participation of a non-Member State will need to be taken.

<sup>139</sup> "The tradeoff between static welfare loss from short-run supra-competitive pricing and dynamic efficiency gains from more abundant innovation over time is said to be implicitly struck by Congress when it set the length and breadth of patent rights." (I. Cheng, Putting Innovation Incentives Back in the Patent-Antitrust Interface, 11(5) *Northwestern Journal of Technology and Intellectual Property*, 2013, p. 390). See also A. Chowdhury; A. Gaigl, *The Economics of Competition Law and of Pharmaceutical Patents*, in G.

the letter of the law, goes against the principles and objectives of patent law, not only antitrust has a role to play, but the same patent law will be central in sanctioning its abuse and ensuring that its purpose is not frustrated. Indeed, to determine whether a right has been abused it is necessary to determine whether it has been used in a way contrary to the objective for which it was granted. The notion of abuse is symbiotically linked to the very objectives that the law sets for the patent.

The patent holder's conduct should thus always be tested against the objective of IP law in general, and of patent law in particular, to determine whether it is in line or in conflict with it. When a conduct involving the use of a patent conflicts with the reason why the patent was granted, it may be abusive both under patent law and antitrust law.<sup>140</sup> As briefly expressed by the former European Commissioner for Competition, Joaquin Almunia:

*“a healthy system for the protection of intellectual property creates incentives for researchers and inventors granting them exclusive rights – within certain limits – for the commercial exploitation of their findings. But the system can be abused, which can be particularly harmful for the economy. This is why we want to prevent the trend we can observe in certain industries toward the strategic use of patents as a means to block competition”*.<sup>141</sup>

As said, the abuse of a patent may be understood as the use of patent rights to hinder the achievement of the objective for which the rights were granted. To determine what an abuse is, it is therefore necessary to determine the objective pursued by patent law in granting exclusive rights. The same conduct may also restrain third parties from competing with the patentee, which strengthens the harmfulness of the conduct and may lead to the intervention of antitrust authorities.

The basis for the introduction of patent law in the United States is article I, § 8, cl. 8, of the U.S. Constitution, which gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Patent rights thus stem from a specific constitutional provision which authorizes Congress to grant exclusive rights, for limited times, “[t]o promote the Progress of Science”. What is clear from this clause is that the power granted to Congress is limited and conditioned by a specific aim, the promotion of advances in science and the useful arts.<sup>142</sup> As

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Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 11 (“First, it is important to acknowledge that patents indeed do account for (at least, to some extent) the trade-off between static and dynamic welfare through the consideration of parameters such as the patent length/term (or, maximum patent duration) and the scope/breadth of the patent (i.e., the extent to which substitute products will be considered to be infringing on the patent). As such, an optimal patent design, specified by the length and breadth of a patent, is one that aims to strike the balance between providing sufficient monopoly profits to recoup the investment cost of the innovation and reducing the welfare loss due to the monopoly.”)

<sup>140</sup> This work is premised on the idea that creator's rights are not absolute and society can, under certain circumstance, be worse off by the granting and use of a patent (even when the patent was the reason the invention was disclosed in the first place). On this idea, see W. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 *Yale Law Journal*, 1993, p. 1533.

<sup>141</sup> J. Almunia, *Antitrust enforcement: Challenges old and new*, 8 June 2012, available at [http://europa.eu/rapid/press-release\\_SPEECH-12-428\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-12-428_en.htm), accessed on 6 August 2016.

<sup>142</sup> See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 1966. See also *United States v. Singer Mfg.*, 374 U.S., 1963, p. 199 (“There is a public interest here which the parties have subordinated to their private ends—the public interest in granting patent monopolies only when the progress of the useful arts and of science will be furthered because as the consideration for its grant the public is given a novel and useful invention”).

clearly expressed by the Supreme Court:

*“The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society – at odds with the inherent free nature of disclosed ideas – and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. [Thomas] Jefferson [author of the 1793 Patent Act] did not believe in granting patents for small details, obvious improvements, or frivolous devices. His writings evidence his insistence upon a high level of patentability.”*<sup>143</sup>

The exclusivity right on the invention granted by the patent is thus not an end in itself.<sup>144</sup> The purpose of a patent is not to exclude others. That is a means to achieve the purpose of promoting total welfare.<sup>145</sup> A patent is the price society agrees to pay as a consideration for a useful, novel and non-obvious invention, to incentivize the inventor to

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<sup>143</sup> Graham v. John Deere Co. of Kansas City, 383 U.S., 1966, p. 9 (Patents reduce competition by creating temporary monopolies to reward inventors who invent “*things which are worth to the public the embarrassment of an exclusive patent.*”). It is noteworthy that Jefferson had an instinctive aversion to monopolies. Initially he argued against the need for limited monopoly to incite “*ingenuity*”, since “*the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression,*” (V Writings of Thomas Jefferson, 47, Ford ed., 1895). His position changed when in a letter to Madison in August 1789 he stated that he would have welcome a provision to this effect: “*Art. 9. Monopolies may be allowed to persons for their own productions in literature & their own inventions in the arts, for a term [...] but for no longer term & no other purpose.*” Jefferson believed that the exclusive right on the invention is not a natural right, but it is granted for the benefit of society. His view that the public interest is inherent in patent law is shared by the Supreme Court. See also Diamond v. Chakrabarty, 447 U.S., 1980, p. 315 (“*The [...] provisions of patent law have been cast [...] to fulfill the constitutional and statutory goal of promoting ‘the Progress of Science and the useful Arts’ with all that means for social and economic benefits envisioned by Jefferson.*”), and Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S., 1989, p. 146 (“*the Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’*”)

<sup>144</sup> As Professor Lemley clearly puts it, IP “*intervenes in the market to interfere with the freedom of others to do what they want in hopes of achieving the end of encouraging creativity. If we take that purpose out of the equation, we are left with a belief system that says the government should restrict your speech and freedom of action in favor of mine, not because doing so will improve the world, but simply because I spoke first. But why do we think there is some entitlement to be the only one allowed to say a particular thing, or to make a particular product, simply because I did so first? Why not give the right instead to the last person to do so, or the person with the longest last name, or with the longest eyelashes? Most often, the answer turns out to be a utilitarian one—because we believe that doing so privileges creativity and therefore encourages someone to strive to be first. But that is an empirical prediction, not one we can simply assume to be true.*” (M.A. Lemley, Faith-Based Intellectual Property, 62 UCLA Law Review, 2015, pp. 1339-1340)

<sup>145</sup> “*The patent system recognizes the exclusionary power of the patentee not as an end in itself but as a means to an end – in short, that of promoting greater overall welfare by stimulating technological innovation and its dissemination. A clear confirmation of this is the obligation imposed by many legislations on the patent holder to implement the invention to an extent that is not disproportionate to the needs of the country (in Italy, see Art. 70 of Industrial Property Code, IPC), except in the case where non-implementation is due to causes beyond the control of the owner. This principle finds a precedent in the first international Convention on industrial property, the Paris Union Convention of 1883: Art. 5 is clearly and precisely aimed at avoiding the emulative practice, for mere exclusionary purposes, of patent applications.*” (G. Ghidini, G. Cavani, P.F. Pisera, Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 261, footnote 37)

make the productive effort.<sup>146</sup> In short, “a patent, is at once the equivalent given by the public for benefits bestowed by the genius and meditations and skill of individuals, and the incentive to further efforts for the same important objects”.<sup>147</sup>

Looking at the EU, the European Commission recently confirmed that granting to the patentee the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time is aimed at rewarding “the creative effort of the inventor”.<sup>148</sup>

As a creation of society and an exception to the inherent free nature of disclosed ideas,<sup>149</sup> the scope of patent rules needs to be interpreted narrowly,<sup>150</sup> to avoid society being overcharged.<sup>151</sup> This might happen in two cases: first, the patent grant is too broad, keeping

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<sup>146</sup> Kewanee Oil Co. v. Bicron Corp., 416 U.S., 1974, p. 480. See also, for an EU perspective, A. Leonard, Abuse of Rights in Belgian and French Patent Law – A Case Law Analysis, Jipitec, 2016, p. 46 (“Connections with the “right-function” criterion of abuse can be established considering the goals of patent law. Patents represent incentive to innovate, encompassing the promotion of the development of products and services for consumers.”)

<sup>147</sup> Fox Film Corp. v. Doyal, 286 U. S., 1932, pp. 127-128.

<sup>148</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1120, citing Court of Justice, 15/74, Centrafarm BV and Others v Sterling Drug, 31 October 1974, par. 9. In the FAQ on the Pharmaceutical Sector Inquiry, p. 5, the European Commission expressly states: “Patents are essential for protecting intellectual property rights of inventors so that they can make a profit on their innovation and will continue to invest and work in the field.” At the international level, as seen above, Article 7 TRIPS states that: “[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

<sup>149</sup> “Patents and copyrights are legal monopolies, as this term has been used since at least the sixteenth century. That is, they are statutory grants that restrain people from doing things that they would otherwise be free to do under the common law. Because patents and copyrights give their owners power over the exercise of the common law rights of others, their exclusionary power must not only be grounded in a recognized legal rule, but also be bounded by law. Thus, determining the scope of IP rights and the limitations on their exercise involves more than balancing economic interests, and ultimately relies on the general principles of the rule of law.” (Katz A., Intellectual Property, Antitrust, and the Rule of Law: Between Private Power and State Power, 17 Theoretical Inquiries in Law, 2016, pp. 635-636)

<sup>150</sup> See, e.g., Diamond v. Chakrabarty, 447 U.S., 1980, p. 315 (“Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available”). See also Deepsouth Packing Co. v. Laitram Corp., 406 U.S., 1972, p. 531 (“in light of this Nation’s historical antipathy to monopoly [...] [w]e would require a clear and certain signal from Congress before approving the position of a litigant who [...] argues that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought”).

<sup>151</sup> “Empirical evidence indicates that whatever the total social cost of a patent, it is not, on average, zero” (R.P. Merges, Uncertainty and the Standard of Patentability, 7 High Technology Law Journal, 1992, p. 30). A balance has to be found between over-protection and under protection of inventions. Under-protection may discourage R&D and investment in innovation. Over-protection may discourage follow-on innovation and harm competition and consumer welfare. Indeed, granting inventors the right to exclude limits the diffusion of ideas and prevents people (both consumers that cannot pay the supracompetitive price, if that is the case, and other inventors, that have the same idea, or a dependent idea) from fully benefiting from them. Although one might think that the dependent invention would not exist without the first, this does not take into consideration that patent holders have the right to sue also those that developed the same invention independently, without even knowing it was patented. Therefore, the price society is “paying” to grant a patent has to be

out of the public domain too big of a portion or being used to achieve results that exceed the need to promote further innovation, or too long, extending the exclusivity beyond the patent term; second, the invention might not be of a sufficient value to justify a patent grant as consideration.<sup>152</sup> Overcompensating the patentees disrupts the incentive system and results in inefficiency, reduced innovation and competition, and unjustifiably high prices.

Both the value of the invention and the balancing exercise between the scope of the patent and the consideration paid by society has to be determined in an objective way. The minimum value of an invention to be worth a patent simply coincides with the patentability requirements. If those requirements are met, society considers the invention valuable and worth paying for with the grant of exclusive rights. For this reason the patent office, as a representative of society in concluding the social contract with the inventor,<sup>153</sup> should carefully review the invention<sup>154</sup> and verify that it meets all the patentability requirements.<sup>155</sup>

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outbalanced by the benefit in terms of creation and dissemination of new works. When patentees are overcompensated, the incentive system is disrupted and the result is inefficiency and reduced output.

<sup>152</sup> Judge Kozinski, dissenting from denial of rehearing en banc in *White v. Samsung Elecs. Am., Inc.*, 989 F.2d 1512, 9th Cir., 1993, noted: “*Overprotecting intellectual property is as harmful as underprotecting it. Culture is impossible without a rich public domain. Nothing today, likely nothing since we tamed fire, is genuinely new. Culture, like science and technology, grows by accretion, each new creator building on the works of those who came before. Overprotection stifles the very creative forces it’s supposed to nurture. [...] Intellectual property rights aren’t free. They’re imposed at the expense of future creators and of the public at large. [...] This is why intellectual property law is full of careful balances between what’s set aside for the owner and what’s left in the public domain for the rest of us [...] All of these diminish an intellectual property owner’s rights. All let the public use something created by someone else. But all are necessary to maintain a free environment in which creative genius can flourish.*”

<sup>153</sup> A patent does not derive from natural law, but from an act of State, which grants the patentee an exclusivity right on the invention. The patent system can be viewed as a contract between the inventor and society (see, e.g., *Century Elec. Co. v. Westinghouse*, 191 F. 350, 8th Cir., 1911, and *Syndicate Sales, Inc. v. Floral Innovations, Inc.*, U.S. Dist. LEXIS 140345, 2012 (S.D. Ind. Sept. 28, 2012) “*A patent is, therefore, appropriately viewed as a contract between the patentee and the public.*”) under which a patent is a consideration for the disclosure and the enabling of the innovation by the inventor (See A. Musso, *Del Diritto di Brevetto per Invenzioni Industriali*, in *Commentario del Codice Civile Scialoja-Branca*, Zanichelli, 2012, pp. 541-543; V. Falce, *Sulle Fondazioni Filosofiche delle Moderne Dottrine Economiche dell’innovazione*, *Rivista di Diritto Industriale*, 2004, p. 125). Society renounces to the free exploitation of the invention, granting an exclusive right (limited in time) to the inventor; the inventor creates and discloses its invention, new and useful to society, in the pursuit of an increase in consumer welfare. This incentive rationale has at its core the societal benefits of the invention.

<sup>154</sup> The concern that, due to budget constraints and record numbers of new applications, patent offices cannot reliably and efficiently render complex patentability judgments is widespread. See, e.g., C.S. Hemphill, B.N. Sampat, *When Do Generics Challenge Drug Patents?*, *Journal of Empirical Legal Studies*, 2011, p. 6 (“*The lightness of review ex ante might be a rational response given the substantial cost entailed in reviewing each patent. Such “rational ignorance” is costeffective provided that most patents have little economic importance, and the set of important patents cannot be identified early, but can be identified later.*”). See also F. Jenny, *Anticompetitive Abuses of Patent Systems and the Role of Competition Authorities*, *Concurrences*, 2013, p. 31 (“*possibly because they are overworked or possibly because patent examiners are rewarded for patents granted, some patent offices have granted weak patents, i.e. patents which do not meet the criteria of “utility” “novelty” or “non-obviousness” and would be invalidated if challenged, but the court proceedings to establish the invalidity of such patents is long and costly*”).

<sup>155</sup> “*It makes sense to view the Patent Office’s job not as an assessment of the possible value of the invention in action, but instead as an evaluation of the significance of the inventor’s contribution to technical knowledge. [...] [T]he role of the Patent Office is to police the “contract” between society and the inventor. [...] The Patent Office is then in a sense acting to insure the adequacy of the inventor’s contribution-guaranteeing that the inventor is providing sufficient consideration for the contract. The Patent Office thus acts as society’s agent in negotiating a disclosure*

If this does not happen, not only society (over)pays for something that it does not want, but it risks missing the opportunity to get something it does want (another invention blocked by the undeserved patent).

Allowing inventors to harvest the benefits deriving from their work by granting them exclusivity for a limited period of time must be in the interest of society in general, *i.e.* lead to the creation of a valuable innovation that would not have been developed without the granting of a patent.<sup>156</sup>

The balancing exercise between rewarding inventors and promoting competition and access to innovation informs the grant of the patent as much as the scope of the patent once it is granted. Specifically, the scope of the patent must coincide with its purpose. The only conducts falling within the scope of the patent's exclusivity rights are conducts that are in line with the purpose of the patent, *i.e.* the enhancement of long-term consumer welfare<sup>157</sup> by incentivizing innovation.<sup>158</sup> Patent regulation should thus be interpreted in line with its ultimate aim, increase consumer welfare.<sup>159</sup>

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*agreement with an inventor. And nonobviousness is the standard society has given the Patent Office in evaluating which "deals" it considers worth making.*" (R.P. Merges, Uncertainty and the Standard of Patentability, 7 High Technology Law Journal, 1992, pp. 68-69 (although the author is describing the disclosure theory, the same principles are applicable, *mutatis mutandis*, to the position taken by this work))

<sup>156</sup> See S.C. Gilfillan, The Root of Patents, or Squaring Patents by their Roots, 31 Journal of the Patent Office Society, 1949, p. 611 ("*A patent is helpful and proper when it rewards sufficiently useful creative work which might not have been done without that prospective reward. And conversely a patent is unnecessary, and wrongly gives away the people's freedom, to a merely lucky, adventitious monopolist, when it gives him the ownership of an invention that would have been made without a patent reward, nearly as soon, either by him or by someone else somewhere in the world. This principle has always been the basis for granting patents for inventions won by genius or luck, and denying them for inventions that could have been made by anyone skilled in the art, or inventions that follow logically from already known principles.*")

<sup>157</sup> According to some authors, whose opinion is shared by this work, maximizing consumer welfare is the high road to total welfare maximization. See J. Farrell, M.L. Katz, The Economics of Welfare Standards in Antitrust, 2(2) Competition Policy International; and S. Martin, The Goals of Antitrust and Competition Policy, CIBER Working Papers, July 2007.

<sup>158</sup> "*From a utilitarian point of view, the objective of intellectual property protection is to secure long-term public interest by providing exclusive rights to right holders for a limited duration of time to incentivize certain desirable behaviour.*" (M. Lorenz, P. Chrocziel, et al. (eds), Intellectual Property and Competition Law, Kluwer, 2016, p. 8). At pp. 3-6, the authors list four theories, or points of view, that have been developed over time to justify the granting of a patent: the natural rights theory, the reward theory, the utilitarian-based incentive theory, and the disclosure theory. As it can be inferred from this work, while recognizing the importance and relevance of all of these theories, this author takes a position that, with the necessary caveats, is most in line with the utilitarian-based incentive theory.

<sup>159</sup> As Professor Anderman explains it: "*The contribution of IPRs to "consumer welfare," by stimulating innovative efficiencies [...] cannot be measured solely by the benefits of first inventor incentives, it must also take into account the potential consumer harms caused by practices such as "blocking" patents, unwarranted higher prices and the enforcement of unused patented inventions which are used to prevent follow on and cumulative innovation.*" (S. Anderman, The "Accommodation" of EU Competition Law with Intellectual Property Law, p. 6, available at <http://www.agcm.it/component/joomdoc/eventi/Anderman.pdf/download.html>, accessed on 6 August 2016). See also See, *e.g.*, M. Franzosi, The New Unified European Patent Court and a New Patent Law: When a KU is Not a KU, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 182 ("*It seems to me the patent system has to be conceived and administered as a tool to promote, not only (a) the progress of science and useful arts, but also (b) the best allocation of the market and at the end (c) the welfare of society. At least three, and not one, are the goals of the system. And the solutions, in the day by day judicial practice, should be influenced by the vision of these three goals.*")

*“Consumer interests should be just as central to intellectual property law as they are to antitrust. Just as in antitrust, consumers have the correct set of incentives. They tend to profit from a well-functioning patent system, furthering innovation that expands output and increases quality and variety, while reducing costs. More generally, consumers profit from economic growth, and innovation is growth’s largest driver.”*<sup>160</sup>

Patent rights are not absolute,<sup>161</sup> the exclusive right to exploit an invention does not exist in *rerum natura* and it is thus created and granted by a public authority, with a precise social function. Limits and exceptions to patents are thus inherent to the rights themselves and arise directly from the same reason the rights were granted.

*“A patent right cannot be viewed as a title giving (almost) complete freedom of action but rather as temporary permit to exploit monopoly rights under fair and reasonable conditions, in other words, as a duty-bearing privilege.”*<sup>162</sup>

The same position has been taken by the U.S. Supreme Court when it affirmed that a patent is a privilege because it is conditioned by a public purpose.<sup>163</sup> The right to exclude is thus granted for, and as long as it is, fostering innovation and long-term consumer welfare. As Professor Hovenkamp explains:

*“The constitutional mandate to Congress to create intellectual property regimes in order to “promote the Progress of Science and useful Arts” is expressly tied to creating incentives to innovate. Indeed, the IP Clause is the only place where the Constitution expressly links the scope of a property right to the incentive to develop it. An optimal IP policy creates just enough incentive to cause creative people to innovate at the optimal level, but not so much as to restrain excessively others who want to build on*

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<sup>160</sup> H.J. Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 485.

<sup>161</sup> *“The Court’s decision in Actavis reaffirmed the conclusions of circuit courts that a patent does not confer upon the patent holder an “absolute and unfettered right to use its intellectual property as it wishes,” Microsoft, 253 F.3d at 63, and “[i]ntellectual property rights do not confer a privilege to violate the antitrust laws,” In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000).”* (State of New York v. Actavis, No. 14-4624, 2d Cir., 2015, p. 52) In its judgment in *Scarlet Extended* (C-70/10, 24 November 2011, par. 43), the Court of Justice of the EU expressly stated that *“The protection of the right to intellectual property is indeed enshrined in Article 17(2) of the Charter of Fundamental Rights of the European Union (‘the Charter’). There is, however, nothing whatsoever in the wording of that provision or in the Court’s case-law to suggest that that right is inviolable and must for that reason be absolutely protected.”*

<sup>162</sup> G. Van Overwalle, *Fair Use: A Workable Concept in European Patent Law?*, in R.M. Hilty, K.-C. Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward*, Springer, 2014, pp. 425-426. The author cites in particular P. Drahos, *A Philosophy of Intellectual Property*, Dartmouth, 1996, pp. 220-223, where it can be read: *“If the purpose in creating the privilege [i.e. the patent] is to fulfil some approved goal then it should also follow that the [patent] holder is subject to duties not to exercise the [patent rights] in a way that defeats the purpose for which the [patent] was granted. [...] Holders of intellectual property privileges are subject to those duties that maximize the probability that the purpose for which the privilege was first created is achieved. [...] The grant of these monopolies would be tied to the idea of duty. Duty-bearing privileges would form the heart of an instrumentalism of intellectual property”*. See also A. Musso, *Del Diritto di Brevetto per Invenzioni Industriali*, in *Commentario del Codice Civile Scialoja-Branca*, Zanichelli, 2012, pp. 541-545.

<sup>163</sup> *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S., 1971, p. 313. *“It is a mistake [...] to conceive of a patent as but another form of private property. The patent is a privilege conditioned by a public purpose.”* (*Special Equip. Co. v. Coe*, 324 U.S., 1945, pp. 380-84, Justice Douglas dissenting)

*their work.*<sup>164</sup>

The mentioned balancing between returns to the patent holder (increasing its incentive to create socially valuable invention) and the public losses from patent exclusion is reflected in the scope and duration of a patent. The balancing as regards duration has been legislatively addressed by establishing a limited duration of exclusivity ending 20 years from the date on which the application for the patent was filed. The patent's scope, instead, is being constantly defined by courts, within the limits of the law, in every decision involving directly (*e.g.*, when deciding questions of patent infringement) or indirectly (*e.g.*, in antitrust cases) a patent.

As emphasized, *inter alia*, by Professor Hovenkamp, the scope of the patent rights should be tailored to the objective to achieve which the patent was granted. The patent rights should thus encompass as much as necessary to spur consumer welfare-enhancing innovation, but nothing more. Too narrow patents would not provide incentive enough to innovate, while overly broad patents would discourage much useful research and competition.<sup>165</sup>

To conclude and recap, patent rights are neither unlimited nor unconditioned. If the patent holder's behavior does not fall within the perimeter of the patent, as interpreted on the basis of the purpose for which it was granted, it cannot be considered within its rights. If the

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<sup>164</sup> H.J. Hovenkamp, *Innovation and the Domain of Competition Policy*, 60 *Alabama Law Review*, 2008, p. 107.

<sup>165</sup> "This raises the issue of how much patent protection is necessary to spur innovation. For example, if the duration of patents were too limited, inventors might not be able to charge a supracompetitive price long enough to recoup their research costs and earn a sufficient profit to make their efforts worthwhile. Similarly, if the bundle of exclusionary rights were somehow inadequate, the value of patents would decrease and diminish the rewards to inventors. In short, weak patent protection reduces the incentive to research and innovate. While it is easy to see how insufficient rewards may hurt innovation, less obvious is the fact that overly strong patent protection also hurts innovation. Innovation is a cumulative process in which today's inventors build on the ideas of yesterday's creators." (C.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1261). Prof. Anderman clarifies: "a wide patent grant runs the risk that the social and economic costs of IP protection will exceed the innovative value of the grant by foreclosing too many avenues to future improvements by later innovators." (S. Anderman, *Overplaying the innovation card: The stronger intellectual property rights and competition law*, in P. Drahos, G. Ghidini, H. Ullrich (eds.), *Kritika: Essays on Intellectual Property*, 2015, p. 24). See also R.P. Merges, R.R. Nelson, *On the Complex Economics of Patent Scope*, 90 *Columbia Law Review*, 1990, pp. 874, 877, 916 ("The real problem is not controlling overfishing, but preventing underfishing after exclusive rights have been granted. The only way to find out what works and what does not is to let a variety of minds try. If a property right on a basic invention covers a host of potential improvements, the property right holder can be expected to develop the basic invention and some of the improvements. But we would expect a single rightholder to underdevelop – or even ignore totally – many of the potential improvements encompassed by their broad property right. [...] [W]e have little faith in the imagination and willingness of a "prospect" holder to develop that prospect as energetically or creatively as she would when engaged in competition. We are also skeptical about her ability to orchestrate development. Given the way humans and organizations think and behave, we believe we are much better off with considerable rivalry in invention than with too little. [...] When a broad patent is granted [...] its scope diminishes incentives for others to stay in the invention game, compared with a patent whose claims are trimmed more closely to the inventor's actual results. This would not be undesirable if the evidence indicated that control of subsequent developments by one party made subsequent inventive effort more effective. But the evidence, we think, points the other way."). Another explanation has been provided by Professor Hovenkamp: "[a]s patent protection is greater, measured by either duration or breadth, the incentive to obtain patents increases but the dissemination of knowledge decreases. Economic growth depends both on sufficient incentives to innovate plus the effective dissemination of innovation through the economy" (H.J. Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 508).

patent holder uses its patent right to achieve results that exceed or run counter to the purpose of the patent (which is, as we saw, the enhancement of long-term consumer welfare by incentivizing investments in innovation)<sup>166</sup> and can thus lead to limitations to the patent right and, as discussed in further details below, even be considered abusive either under patent law or antitrust law.

With regards to the limitation of patent rights to what is necessary to ensure and realize the purpose of the patent, the U.S. Supreme Court expressed an opinion that perfectly summarizes the position taken by this work in the *eBay* case.<sup>167</sup> This case recognized the threat to innovation of overreaching patent protection and provided a considered approach to limiting patent rights and maintaining incentives to innovate. In its concurring opinion, Justice Kennedy, joined by three judges, warned lower courts about the use of patents “*not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees. [A]n injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest. [...] The equitable discretion over injunctions, granted by the Patent Act, is well suited to allow courts to adapt to the rapid technological and legal developments in the patent system.*”

The Supreme Court thus limited the extent of the patent rights by limiting the scope of the remedies for its violation,<sup>168</sup> in case the patent is not used “*as a basis for producing and selling goods*” and the remedy “[does] *not serve the public interest*”. In particular, the Supreme Court directed trial courts to abandon the automatic injunction rule and instead rely on a flexible test, based on the traditional principles of fairness, to determine whether an injunction can be granted or the patent right should be limited to legal damages.<sup>169-170</sup> As

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<sup>166</sup> Noteworthy is the fact that conducts that exceed the perimeter of the patent often run counter its purpose (and vice versa). This is clearly explained by the fact that a patent-related conduct that is not within the perimeter of the patent can’t but represent the appropriation of part of the public domain or of the public welfare that was not part of the original deal and is thus contrary to the enhancement of both short- and long-term consumer welfare.

<sup>167</sup> *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 2006.

<sup>168</sup> The limitation of the right to get an injunction has effects that do not substantially differ from the grant of a compulsory license. “[T]he court’s denial is equivalent to the grant of a compulsory license under the patent. A compulsory license is also among the range of remedies that may result from the assertion of a successful patent-related antitrust claim. Accordingly, after *eBay*, patent infringers may be expected to argue against permanent injunctions using the same or similar arguments that previously may have served as the basis for *Sherman Act* § 2 claims.” (H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law, Aspen, 2014, p. 2-50). See also I. Lianos, R.C. Dreyfuss, New Challenges in the Intersection of Intellectual Property Rights with Competition Law, CLEAS Working Paper Series, 2013, p. 29 (“*Refusing to grant injunctions (and instead requiring the payment of royalties) is, in some ways, the functional equivalent of compulsory licensing. Knowing that an injunction will not be awarded, patentees will be more likely to negotiate deals on their own rather than have the court calculate royalties.*”)

<sup>169</sup> The Supreme Court held that: “*According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury;*[(In *Paice v. Toyota Motor Corp.*, 504 F.3d 1 293, Fed. Cir., 2007, the Federal Circuit upheld the denial of injunctive relief by the district court, based on the rejection of Paice’s arguments regarding irreparable harm. The district court concluded that “*the absence of an injunction would not adversely affect Paice’s ability to license its technology, and would not adversely affect*

clearly explained by Professor Peritz:

*“eBay’s distinction between property rights and property remedies should be understood as harboring a patent policy to promote competition, an equitable doctrine that allows infringers to compete against the owners with the patent in suit unless extraordinary circumstances warrant an injunction.”*<sup>171</sup>

This limitation is perfectly in line with the discussed provision in the U.S. Constitution on the basis of which the exception to the inherent free nature of disclosed ideas has been introduced “[t]o promote the Progress of Science and useful Arts”. Exclusive rights are thus granted by society to inventors for a purpose, and charging exorbitant fees falls outside of that

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*Paice’s reputation or market share (because Paice was not manufacturing goods under the patent). In addition, Paice had offered a license to Toyota.”* (H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law, Aspen, 2014, p. 2-49).)] (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;[(“An ongoing royalty payment or damage award will typically be more than adequate to compensate the patentee. This is best demonstrated by the fact that so many patentees routinely accept a running royalty for all users of a standard.” (R.P. Merges, J.M. Kuhn, An Estoppel Doctrine for Patented Standards, 97 California Law Review, 2009, p. 28))] (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted;[(In Verizon Services Corp. v. Vonage Holding Corp., 503 F.3d I 295, Fed. Cir., 2007, the Federal Circuit noted that in balancing the harms, an important factor is whether the infringer would have the time to implement an alternative solution.)] and (4) that the public interest would not be disserved by a permanent injunction.[(The Court thus explicitly refers to the need to strike a balance between the interests of the patentee, the infringer and the public, the latter being the ultimate purpose of patent law)]”

<sup>170</sup> In this author’s opinion, also the district court’s position in *eBay*, which the Supreme Court rejected as “expansive” since “traditional equitable principles do not permit such broad classifications”, in reality falls within the four-factor test coined by the Supreme Court. As summarized by the Supreme Court, the District Court “concluded that a “plaintiff’s willingness to license its patents” and “its lack of commercial activity in practicing the patents” would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue”. The Supreme Court criticized the district court’s decision because it did not take into account the reasonable preference by some patent holders to “license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market”. This critic, although correct, should not lead to reject the district court reasoning *tout court*. The district court’s reference to the “lack of commercial activity in practicing the patents” should be understood as encompassing both the marketing of the patented product and the licensing of the patent (which is a commercial activity as much as product sales). Lacking both, and in case the plaintiff is willing to license its patents, an injunction should not be issued. None of the factors identified by the Supreme Court as necessary for an injunctive relief to be granted can be considered present. In particular, it would be quite difficult to demonstrate that the patent holder would suffer an irreparable injury that monetary damages are inadequate to compensate when (i) it has a patent, (ii) it is not practicing it (either commercializing a product or licensing it), but (iii) it is willing to license it. While the first two elements would not be sufficient, under U.S. law (the reasoning would be much different under most European patent laws, which provides for a compulsory license in case of patent non-use), to deny a motion for injunctive relief (in line with the right not to use the patent as enshrined in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 1908, “which rejected the contention that a court of equity has no jurisdiction to grant injunctive relief to a patent holder who has unreasonably declined to use the patent.” The right not to use the patent is, in this author’s opinion, contrary to the public interest (the fundamental purpose of the patent system) and the Supreme Court could have taken this occasion to definitively reject it, at least with regards to the possibility to be granted an injunctions (since, as the Supreme Court noted in *eBay*, “the creation of a right is distinct from the provision of remedies for violations of that right”). The willingness to license its patents, however, should tip the balance in favor of the infringer and lead to the conclusion that an injunction would not serve the public interest.

<sup>171</sup> R. Peritz, *The Competition Question Unmasked in Actavis: What Is the Scope of the Patent Right to Exclude?*, 28 *Antitrust*, 2013, p. 48.

purpose and therefore of the perimeter of the patent.

Having analyzed a way to limit patent rights to what is necessary to ensure and realize the purpose of the patent, we can now consider the other measures applicable under patent law and antitrust law to patent holders using their patent rights to achieve results that exceed or run counter to the purpose of the patent. Both IP and antitrust are indeed indispensable instruments *ex post* grant to (re)balance patent rights and make sure that the general aims of patent protection are not lost in an enforcement of patent rights that undermine, instead of enhancing, consumer welfare.

#### 4. Patent Misuse

Starting from patent law, the doctrines analyzed by this and the following chapters are the American doctrine of patent misuse and the European abuse of rights doctrine. The principles behind these two doctrines are not only in large part coincident, but they are also common to antitrust law. This was noted recently by the Italian Council of State in its judgment confirming the Italian Competition Authority decision fining Pfizer (on which, see below chapter 11.2).

With respect to patent misuse, the doctrine originated in the U.S. and its purpose is to “prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right.”<sup>172</sup> Patent misuse is an equitable defense available for defendants in patent infringement cases. The doctrine finds its origins in the equitable doctrine of unclean hands, “whereby a court of equity will not lend its support to enforcement of a patent that has been misused.”<sup>173</sup> Patent misuse was born and raised by judicial practice<sup>174</sup> to restrain patentees from adopting conducts that, while formally adhering to the letter of the law, unduly attempt to expand exclusive rights beyond the invention.<sup>175</sup> An alleged infringer may assert misuse where the

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<sup>172</sup> Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d, Fed. Cir., 1992, p. 704.

<sup>173</sup> B. Braun Med, Inc. v. Abbot Labs., 124 F.3d, Fed. Cir., 1997, p. 1427. Judges invoke equity to guide the case to an outcome that is fair and just to all the parties involved as well as to the public at large. See also U.S. Gypsum Co. v. Nat'l Gypsum Co., 352 U.S., 1957, pp. 465-66 (“*It is now, of course, familiar law that the courts will not aid a patent owner who has misused his patents to recover any of their emoluments accruing during the period of misuse or thereafter until the effects of such misuse have been dissipated, or ‘purged’ as the conventional saying goes. [...] The rule is an extension of the equitable doctrine of “unclean hands” to the patent field.*”) See also Morton Salt Co. v. G. S. Suppiger Co., 314 U.S. 488, 1942 (“[i]t is a principle of general application that courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest.”)

<sup>174</sup> Congress upheld the judicial creation of patent misuse, while restraining its application. 35 U.S.C. Section 271(d), as amended in 1988, sets forth the conducts which may not provide the basis for finding misuse, including refusal to license.

<sup>175</sup> The successful assertion of patent misuse “requires that the alleged infringer show that the patentee has impermissibly broadened the ‘physical or temporal scope’ of the patent grant with anti-competitive effect”. (Virginia Panel Corp. v. MAC Panel. Co., 133 F.3d 860, Fed. Cir., 1997, p. 869). “A patent is, therefore, appropriately viewed as a contract between the patentee and the public. Patent misuse occurs when the scope of an otherwise valid patent monopoly extends beyond the prescribed boundaries of the patentee’s control” (Syndicate Sales, Inc. v. Floral Innovations, Inc., U.S. Dist. LEXIS 140345, 2012 (S.D. Ind. Sept. 28, 2012). Misuse therefore delineates the limit beyond which the patent grant becomes “more embarrassment than advantage to society.” (Letter from Thomas Jefferson to Isaac McPherson (13 August 1813), available at [http://press-pubs.uchicago.edu/founders/documents/a1\\_8\\_8s12.html](http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html), accessed on 6 August 2016). As explained by Professor Lim, “misuse serves as an insurance policy against unanticipated roughish behavior from

patentee attempts to enforce its patent in a manner foreclosing “*competition, future innovation, or access to public domain*”.<sup>176</sup> As explained by Professor Lim,

“[I]f the entire basis for misuse is directed toward the goal of ensuring that patentees obtain a right commensurate, and not more than, the services they render. [...] Misuse imposes a duty on patentees to conduct themselves so that they further (or at least refrain from contravening) the patent and antitrust policies embodied in the grant of patent rights. And where the equities favor neither party, the law is clear that the balance should be struck in favor of a broader rather than a narrow use of that technology, or in other words, the policy of public use should outweigh the monopolistic privilege of a patentee.”<sup>177</sup>

As a result of the misuse, the patent is unenforceable until the effects of the misuse have been purged.<sup>178</sup> Purging means for the patentee to show that it abandoned the misconduct and “*the baleful effects of the misuse have been fully dissipated*”.<sup>179</sup>

Infringers asserting misuse need not to prove market power<sup>180</sup> or show evidence of an

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patentees. A number of interviewees, notably judges, observed that they had no problems with the inherent vagueness of misuse. Interviewees opined that vague formulations are to be expected when dealing with equity. Doctrines meant to cover situations not defined in advance had no way but to be vague. The ingenuity of patentees to devise ways of abusing their patent rights is matched only by the potential malleability of patent misuse.” (D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Edward Elgar, 2013, p. 160). As stated by Marshall Leaffer, “[o]f course equitable doctrines, like patent misuse, are messy by their very nature. However, they do allow for a needed flexibility for judicial determination.” (M. Leaffer, *Patent Misuse and Innovation*, 10 *Journal High Tech. Law*, 2010, p. 157). On the vagueness of patent misuse, Professor Merges notes that, “[n]ot only is [it] a notoriously difficult standard for an antitrust plaintiff to meet, it is also a standard that is very difficult to apply. Thus it is ironic indeed that advocates of greater certainty in the law of patent misuse would propose a unified rule of reason approach when this is arguably one of the least certain legal rules ever propounded”. (R.P. Merges, *Reflections on Current Legislation Affecting Patent Misuse*, 70 *Journal of the Patent & Trademark Office Society*, 1988, p. 794)

<sup>176</sup> C. Bohannon, *IP Misuse as Foreclosure*, 96 *Iowa Law Review*, 2011, p. 478. Referring to the Supreme Court’s eBay decision, as providing an important rationale for rethinking misuse, Professor Hovenkamp notes that “[t]he courts have a legitimate role in policing conduct that is not expressly authorized by the Patent Act and that serves to restrain innovation, sequesters the public domain, imposes competitive harm disproportionate to innovation effects, or that involves improprieties in the patent procurement process.” (H.J. Hovenkamp, *Antitrust and the Patent System. A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 564)

<sup>177</sup> D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Edward Elgar, 2013, p. 170. At p. 162, Professor Lim indicates that *one approach to determine misuse* “is to require the defendant to show cognizable harm either to the competitive process or to incentives to innovation under the general analysis that animates patent law cases.” The burden should then “shift to the patent owner to demonstrate a business justification for having insisted on [...] a strategic use of the patent grant exceeding its scope and contrary to patent policy.” (M. Leaffer, *Patent Misuse and Innovation*, 10 *Journal of High Technology Law*, 2010, p. 159)

<sup>178</sup> *Morton Salt Co. v. G. S. Suppiger Co.*, 314 U.S., 1942, p. 492.

<sup>179</sup> See *U.S. Gypsum Co. v. Nat’l Gypsum Co.*, 352 U.S., 1957, pp. 594-95. See also *Ansul Co. v. Uniroyal, Inc.*, 306 F. Supp. 541, S.D.N.Y., 1969, p. 560 (“*What conduct constitutes a “purge” depends upon the nature and extent of the misuse. Where the misuse [...] consists of extensive and aggravated misconduct over a period of several years, which has substantially rigidified the price structure of an entire market and suppressed competition over a wide area, affirmative action may be essential effectively to dispel the consequences of the unlawful conduct.*”)

<sup>180</sup> “*A finding of market power is not required under traditional patent misuse doctrine, but it is required for establishing an antitrust violation. Thus, a finding of patent misuse does not necessarily mean that the patent holder has committed an antitrust violation*” (R. Feldman, *Rethinking Patent Law*, Harvard University Press, 2012, p. 139).

antitrust injury<sup>181</sup> but if successful will not be awarded damages, let alone treble damages as in antitrust cases. Misuse may result only in the unenforceability of the patent.

These differences, in conjunction with the fact that misuse is an affirmative defense and antitrust is a cause of action, justify the existence of the doctrine.<sup>182</sup> Other than that, the differences between the conducts condemned as misuse of patents (or, as we will see, abuse of rights)<sup>183</sup> and the anticompetitive conducts violating antitrust are not significant.<sup>184</sup> This does not entail, as many seem to argue, a limitation of the reach of patent misuse. It is antitrust that should reappropriate its position of ultimate watchdog of consumer welfare and

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<sup>181</sup> An antitrust plaintiff needs to show that the patentee has caused injury “of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants’ acts unlawful.” (Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S., 1986, p. 109)

<sup>182</sup> Patent misuse can thus be a useful response to practices in conflict with the purpose of the patent system, but falling outside the reach of antitrust. See *Smithkline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, N.D. Ill., 2003, p. 1047 “When the advance of science [...] enables a form of patent misuse that is new but is well within the conceptual heartland of the doctrine, the boundaries of the doctrine can expand modestly to encompass it. [...] It would be inappropriate to confine patent misuse, as is sometimes suggested, to practices that violate antitrust law, for in that event the doctrine would be superfluous”. See also, D.L. Burk, M.A. Lemley, *Biotechnology’s Uncertainty Principle*, 54 Case Western Reserve Law Review, 2004, p. 741 (“The patent misuse doctrine can play a powerful role in deterring anticompetitive efforts to extend patent rights beyond the scope a rational pharmaceutical patent policy would give”). Professor Thomas Cotter explains: the “reasons to have a misuse doctrine in addition to antitrust law, if the substantive content of the two is the same”: “(1) to permit someone who does not have antitrust standing or cannot prove antitrust injury to challenge the conduct at issue, or (2) to create an additional penalty (such as unenforceability of the IPR) in addition to the antitrust sanction” (T.F. Cotter, *Misuse*, 44 *Houston Law Review*, 2007, p. 935).

<sup>183</sup> See C. Osti, *What Is in a Name: The Concept of Abuse in Sui Generis Abuse*, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 99 (“Now, if you consider just these two elements [of the abuse of rights], i.e., the distortion of the rule’s function (such theory in fact deriving from a conspicuous creation of the French *droit administratif*, i.e., the theory of *détournement de pouvoir*) and the gross unbalance between the interest satisfied and the one oppressed by the abusive conduct, it is not hard to see how basically all of the above [antitrust] cases [of abuse] would fall in either category, if not in both.”)

<sup>184</sup> Judge Posner in particular argued that patent misuse principles should be completely aligned with antitrust principles. “The [misuse] doctrine arose before there was any significant body of federal antitrust law, and reached maturity long before that law (a product very largely of free interpretation of unclear statutory language) attained its present broad scope. Since the antitrust laws as currently interpreted reach every practice that could impair competition substantially, it is not easy to define a separate role for a doctrine also designed to prevent an anticompetitive practice – the abuse of a patent monopoly. [...] [T]here is increasing convergence of patent-misuse analysis with standard antitrust analysis. See, e.g., *Carter-Wallace, Inc. v. United States*, 449 F.2d 1374, 1378-82 (Ct.Cl.1971); *Congoleum Indus., Inc. v. Armstrong Cork Co.*, 366 F.Supp. 220, 227-32 (E.D.Pa.1973), *aff’d*, 510 F.2d 334 (3d Cir.1975); *SCM Corp. v. Xerox Corp.*, 463 F.Supp. 983, 997-98 (D.Conn.1978) (the lengthy subsequent history of this case is irrelevant). One still finds plenty of statements in judicial opinions that less evidence of anticompetitive effect is required in a misuse case than in an antitrust case. See, e.g., *Transitron Electronic Corp. v. Hughes Aircraft Co.*, 487 F.Supp. 885, 892-93 (D.Mass.1980), *aff’d*, 649 F.2d 871 (1st Cir.1981). But apart from the conventional applications of the doctrine we have found no cases where standards different from those of antitrust law were actually applied to yield different results. [...] If misuse claims are not tested by conventional antitrust principles, by what principles shall they be tested? Our law is not rich in alternative concepts of monopolistic abuse; and it is rather late in the day to try to develop one without in the process subjecting the rights of patent holders to debilitating uncertainty. Cf. *Hensley Equipment Co. v. Esco Corp.*, 383 F.2d 252, 261-62 n. 19, *amended*, 386 F.2d 442 (5th Cir.1967).” (*USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505, 7th Cir., 1982). See also *Linzer Prods. Corp. v. Chandra Sekar*, 499 F. Supp. 2d 540, S.D.N.Y., 2007, p. 552 (“Patent misuse, which developed long before the advent of antitrust law, has largely merged with antitrust law. Misuse is closely intertwined with antitrust law, and most findings of misuse are conditioned on conduct that would also violate the antitrust laws’ (Herbert Hovenkamp, *Mark D. Janis & Mark A. Lemley, IP and Antitrust* § 3.1 (2002 & 2007 Supp.))”).

intervene when this is frustrated by the (dominant) patentees' anticompetitive conducts contrary to the purpose of the patent system. Professors Areeda and Hovenkamp observed this shortcoming of current antitrust enforcement in noting that:

“[Misuse] has additional concerns that antitrust does not capture, or at least that it does not capture very effectively. One of these concerns is with protection of the public domain, even if nonmonopolistic. Another is with practices that restrain rather than promote innovation. Of course, one might say that “foreclosure” of the public domain is an antitrust concern. Further, antitrust is also concerned as much with dynamic as with static competition, and thus innovation is always important to its analysis. While both of these things are true, antitrust takes a much more cautious and restrictive approach to these problems than IP policy does”.<sup>185</sup>

The misuse doctrine, although not completely disappeared, is playing a very minor role in patent-related litigation in the U.S. and was featured in only 20 appellate level cases between 1991 and 2012.<sup>186</sup> The decline in the reference to patent misuse is a lost opportunity to find in patent law itself the solution “to make the system more consistent with its underlying goals.”<sup>187</sup>

This is one of the principles on which this work is premised. Patent law can cure itself by turning to its roots, its *rationale*, the objective it pursues.<sup>188</sup> The doctrines of patent misuse and abuse of rights define the scope of the patent in line with the patent law's very own purpose, promoting innovation.<sup>189</sup> These doctrines go beyond the letter of the law to find and protect its *raison d'être*. The opportunity however is not lost forever and courts are continuously presented with the possibility to take an important stand in (what this author thinks is) the right direction (the eBay decision being the perfect example).

## 5. Abuse of Rights

The general doctrine of abuse of rights, as that of patent misuse, is the main weapon to strike down harmful conducts by patentees using their statutory rights in a manner that is contrary to their purpose. As anticipated, the application of patent misuse has been limited to

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<sup>185</sup> P.E. Areeda, H.J. Hovenkamp, *Antitrust Law: an Analysis of Antitrust Principles and Their Application*, Aspen, 2004, par. 178 (as cited in D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Edward Elgar, 2013, p. 27).

<sup>186</sup> D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Edward Elgar, 2013, pp. 28-29 (“To give some context to this figure, it is useful to consider another equitable defense-inequitable conduct. Inequitable conduct featured in about 300 appellate level cases in the same period. (Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 *BERKELEY TECH. L.J.* 1329, 1333 (2009) (“The Federal Circuit has issued over 600 cases since 1983 that mention ‘inequitable conduct.’ Over 300 of those cases substantively address, and contain a ruling on, an issue of inequitable conduct” [citations omitted]). [...] “Since the facts that give rise to inequitable conduct also give rise to misuse, it is surprising that misuse is not alleged every time an allegation of inequitable conduct is raised.”)

<sup>187</sup> H.J. Hovenkamp, *Antitrust and the Patent System. A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 561.

<sup>188</sup> Indeed, the doctrine of patent misuse captures all of the anti-competitive (and, as we saw, anti-innovation) practices that increase the scope of the patent.

<sup>189</sup> “A patentee, as the beneficiary of a public policy “to promote the Progress of Science and useful Arts”, does not have the right to use the special privilege of a patent monopoly to secure rights not granted by the patent and that are contrary to public policy” (*Windsurfing International, Inc. v. Fred Ostermann GmbH*, 613 F. Supp., S.D.N.Y., 1985, p. 952).

the United States while in Europe the so-called abuse of rights doctrine found application. Exactly as patent misuse, the abuse of rights doctrine is essentially a jurisprudential construction (in some country then codified, expressly or implicitly by the legislator) where judges found themselves empty-handed when faced with conducts permitted by the law but contrary to its purpose.<sup>190</sup> At the outset, it is noteworthy that the abuse of rights doctrine is applicable to every field of the law,<sup>191</sup> and is not therefore confined to patent law (one of the fields in which it had the most success is undoubtedly tax law). The patentee's abuse of its rights may be split into two broad categories:

- a) abuse with antitrust relevance, in which the patentee holds a dominant position in the relevant market for the patented product, and the abuse qualifies as an abuse of dominance;
- b) abuse without antitrust relevance, in which the patent does not grant its holder significant market power (*e.g.* due to the presence of substitutes), and therefore the abuse can be dealt with only by referring to other provisions or to the general principles of patent law.

The abuse of rights doctrine does not have a widespread application, however, mainly due to the existence (and wide application) of rules protecting consumers, as well as rules punishing unfair competition, often sufficient to address patent abuses that do not fall within the realm of EU antitrust (which has already a much wider reach than in the U.S.). The relevance of the abuse of rights doctrine is however not limited to its potential application, it is also useful to determine the boundaries of antitrust. Indeed, conducts constituting an abuse not only are not covered by the patent rights but run counter to the very purpose of the patent system which, as seen and will be discussed in further details below, converge with the antitrust purpose in the protection and enhancement of (long-term) consumer welfare.

A (patent) right can be considered abused when, notwithstanding its formal adherence

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<sup>190</sup> Interestingly enough, Article 7 of the preliminary project for the Italian Civil Code of 1942 provided that “*nobody can exercise its right in a way inconsistent with the purpose for which the right was granted*”. This provision was taken out in the final version of the Code due to concerns on the excessive powers that such a general clause left to judges (see Italian Supreme Court, 18 September 2009, n. 20106).

<sup>191</sup> A. Lenaerts, The relationship between the principles of *fraus omnia corrumpit* and of the prohibition of abuse of rights in the case law of the European Court of Justice, 25 Common Market Law Review, 2011, pp. 1703-1718. See, *e.g.*, G. Ghidini, G. Cavani, P.F. Pisera, Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 259 (“*The Italian courts have [...] expressly enforced the abuse of rights relating to tax, corporate, civil and civil-procedural matters, identifying – on the basis of the ruling given by the European Court of Justice in Halifax (Court of Justice, 21 Feb. 2006, Case C-255/2002, Halifax plc et al. c. Commissioners of Customs & Excise, ECR 2006, I-1655.) – its characteristic features, such as in particular: (i) the entitlement to a subjective right; (ii) the possibility that such right may be actually exercised according to an undefined set of procedures; (iii) the fact that such an exercise is carried out in compliance with the laws governing it; (iv) the occurrence of an unjustified disproportion between the benefit achieved by the holder of the right and the sacrifice to which the counterpart is subject.*”) See also C. Osti, What Is in a Name: The Concept of Abuse in Sui Generis Abuse, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 100 (“*It is a rather well known fact that the European courts have made ample use of the theory of abuse of rights in such distant areas as tax law, civil procedure, freedom of establishment and free circulation of people and services, and even State Aid law.*”)

to the conditions laid down by the law,<sup>192</sup> the patentee's conduct does not achieve the purpose of the law, and the patentee's intention is to obtain an improper and undeserved advantage (with a corresponding unjustified and unproportioned sacrifice by the other party which, in the case of patents, is society as a whole).<sup>193</sup> As clearly explained by Professors Ghidini and Cavani, "*the use of subjective rights intended to achieve purposes to the detriment of third parties for purposes other than those for which they were conferred is to be considered contra ius.*"<sup>194</sup> Advocate General Maduro explained in *Halifax* that:

*"there is a Community law principle of interpretation prohibiting the abuse of Community provisions [...]. According to that principle, the provisions [...] must be interpreted as not conferring the rights that might appear to be available by virtue of their literal meaning, when two objective elements are found to be present. First, that the aims and results pursued by the legal provisions formally giving rise to the [...] advantage invoked would be frustrated if that right were conferred. Second, that the right invoked derives from economic activities for which there is objectively no other explanation than the creation of the right claimed."*<sup>195</sup>

Maduro's interpretation, upheld by the Court of Justice in its final decision,<sup>196</sup> focuses

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<sup>192</sup> As observed by Leonard, "[t]he principle rejects a rigid adherence to the letter of the law in the evaluation of an individual exercise of rights. In light of the creativity of right holders and their ability to circumvent rules, the principle of AoR proves to be a necessary complement to the principle of formal legality." (A. Leonard, *Abuse of Rights in Belgian and French Patent Law – A Case Law Analysis*, Jipitec, 2016, p. 32).

<sup>193</sup> "[A] finding of an abuse requires, first, a combination of objective circumstances in which, despite formal observance of the conditions laid down by the Community rules, the purpose of those rules has not been achieved. It requires, second, a subjective element consisting in the intention to obtain an advantage from the Community rules by creating artificially the conditions laid down for obtaining it." (Court of Justice, C-110/99, *Emsland-Stärke*, 2000, par. 5153) See also Opinion of Advocate General Tizzano, C-200/02, *Man Lavette Chen*, 18 May 2004, paras. 114-115 ("For it to be possible to speak of an abuse of law, there must [...] also be an underlying 'combination of objective circumstances' in which 'despite formal observance of the conditions laid down by the Community rules, the purpose of those rules has not been achieved'. [...] In other words, it must be ascertained whether the person concerned, by invoking the Community provision which grants the right in question, is betraying its spirit and scope. The test is therefore, essentially, whether or not there has been a distortion of the purposes and objectives of the Community provision which grants the right in question.") To be able to leverage the patent right in order to obtain an undue advantage it is usually necessary to be in a position of market power. This means that the abuse of patent rights is often interconnected with (and absorbed by) the abuse of dominance. Indeed, some of the most relevant cases in which an abuse of IP rights has been found, both in the U.S. and in the EU, are related to undertakings in a dominant position.

<sup>194</sup> G. Ghidini, G. Cavani, P.F. Pisera', Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 259.

<sup>195</sup> Opinion of Advocate General Poiares Maduro, C-255/02, *Halifax*, 7 April 2005, par. 91.

<sup>196</sup> See Court of Justice, C-255/02, *Halifax*, 7 April 2005, paras. 68-69, 74-75 ("according to settled case-law, Community law cannot be relied on for abusive or fraudulent ends (see, in particular Case C-367/96 *Kefalas and Others* [1998] ECR I-2843, paragraph 20; Case C-373/97 *Diamantis* [2000] ECR I-1705, paragraph 33; and Case C-32/03 *Fini H* [2005] ECR I-1599, paragraph 32). The application of Community legislation cannot be extended to cover abusive practices by economic operators, that is to say transactions carried out not in the context of normal commercial operations, but solely for the purpose of wrongfully obtaining advantages provided for by Community law (see, to that effect, Case 125/76 *Cremer* [1977] ECR 1593, paragraph 21; Case C-8/92 *General Milk Products* [1993] ECR I-779, paragraph 21; and *Emsland-Stärke*, paragraph 51). [...] In view of the foregoing considerations, it would appear that [...] an abusive practice can be found to exist only if, first, the [conduct] concerned, notwithstanding formal application of the conditions laid down by the relevant provisions [...], result in the accrual of a [...] advantage the grant of which would be contrary to the purpose of those provisions. Second, it must also be apparent from a number of objective factors that the essential aim of the [conduct] concerned is to obtain

more on the objective nature of the abuse of rights than on the subjective intention of the patentee.<sup>197</sup> The test to determine an abuse has thus two prongs: (i) the purpose and results pursued by the legal provision whose application has been distorted would be frustrated if the right was conferred; (ii) the right invoked derives from activities which have no other explanation than the creation of the undue right. This is however not necessarily in contrast with the interpretation given by the Court of Justice in *Emsland*. The subjective element of the patentee's intention to obtain an undeserved advantage should indeed be objectivized to the criteria of "no other explanation" for the patentee's conduct other than an intention contrary to the purpose of the law. This is indeed the position taken by Advocate General Maduro who explains:

*"What appears to be a decisive factor in affirming the existence of an abuse is the teleological scope of the Community rules invoked, which must be defined in order to establish whether the right claimed is, in effect, conferred by such provisions, to the extent to which it does not manifestly fall outside their scope. [...] When the Court takes the view that an abuse exists whenever the activity at issue cannot possibly have any other purpose or justification than to trigger the application of Community law provisions in a manner contrary to their purpose, that is tantamount, in my view, to adopting an objective criterion for the assessment of the abuse. It is true that those objective elements will reveal that the person or persons engaged in that activity had, most likely, the intention of abusing Community law. But it is not that intention that is decisive for the assessment of the abuse. It is instead the activity itself, objectively considered. [...] What matters is not the actual state of mind [...], but the fact that the activity, objectively speaking, has no other explanation but to [abuse the law]."*<sup>198</sup>

Civil law in several of the EU Member States has crafted a coherent doctrine of abuse of rights, which applies in general to every kind of rights, including patents. Central principle of such a doctrine is that there will be an abuse whenever the exercise of a right goes against the (social) purpose that animated the legislator in granting that right.<sup>199</sup> According to this principle (the so-called right-function principle), the legislator confers rights upon individuals to realize specific social aims. A patent right is thus the means to achieve the (social) end. The enforcement and exercise of patent rights by the patent holder must respect and further these ends. In case it does not, and rights are instead exercised to achieve objectives that are contrary to the ends for which they were granted, an abuse takes place.<sup>200</sup>

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*[the] advantage. As the Advocate General observed in point 89 of his Opinion, the prohibition of abuse is not relevant where the economic activity carried out may have some explanation other than the mere attainment of [the] advantages."*

<sup>197</sup> As explained by Maduro, "what is referred to in *Emsland* as the subjective element of the abuse does not affect the interpretative nature of the Community law notion of abuse. In *Emsland* the Court linked that subjective element to the finding that the situation giving rise to the application of a certain Community rule was purely artificial. In my view, that finding of artificiality should not be based on an assessment of the subjective intentions of those claiming the Community right. The artificial nature of certain events or transactions must certainly be determined on the basis of a set of objective circumstances verified in each individual case. This is, furthermore, in line with the Court's reference, again in *Emsland*, to the 'sole purpose' of an activity or behaviour as a central element supporting the conclusion that there has been an abuse of Community law." (Opinion of Advocate General Poiares Maduro, C-255/02, Halifax, 7 April 2005, par. 70).

<sup>198</sup> Opinion of Advocate General Poiares Maduro, C-255/02, Halifax, 7 April 2005, par. 70.

<sup>199</sup> P. Van Ommeslaghe, *Abus de droit, fraude aux droits des tiers et fraude à la loi* note sous Cass., 10 sept. 1971, R.C.J.B., 1976, pp. 303 et seq.

<sup>200</sup> See, in general, S. Herman, *Classical social theories and the doctrine of 'abuse of*

Whenever an abuse of rights takes place, the sanction is often not the forfeiture of the right but its unenforceability in the manner considered improper by the judge. The abuse of patent rights (exactly as patent misuse) is thus a shield more than a sword and has the objective of re-establishing the victim in the state it would have been had the abuse never occurred.

## 6. Marketing Authorization

Before moving to antitrust, and to the intersection between patent law and antitrust law, it seems appropriate to briefly discuss about a regulation specific to the pharmaceutical sector, the marketing authorization. The importance of this regulation is two-fold, on one side it is obviously an element to take into consideration when assessing the patentees' conducts in the pharmaceutical sector, on the other side patentees may abuse patent law as much as the regulation governing marketing authorization, with not very dissimilar results.

Entry into pharmaceutical markets is heavily regulated, to protect consumers from the risks of harm to their health, and both consumers and States from excessive prices and ineffective products. Pharmaceutical products must thus meet strict regulatory requirements as a condition to access the market. Agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require that all new drugs undergo specific laboratory, animal and human testing in controlled clinical trials, to provide evidence of safety and efficacy.

Clinical trials typically take 4 to 6 years, and regulatory review adds an additional 1 to 2 years. This leads to a more limited duration in time of patent protection – the effective monopoly protection is estimated to last about 10 to 12 years – plus a 3 to 5 year extension.

### 6.1. United States

In the United States, the relevant regulation is the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.<sup>201</sup> The Act provides for two different procedures for originators and generics to facilitate the latter's entry and thus competition from lower priced generic drugs, while maintaining incentives for originators to invest in developing new drugs.

An originator company seeking to market a new drug must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"), demonstrating the safety and efficacy of the drug, which inevitably requires "*a long, comprehensive, and costly*

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rights', 37 Louisiana Law Review, 1977. An additional or alternative element that may lead to a finding of abuse is the disproportion between the harm caused to the other party and the utility brought to the right holder by the use of the right. "*This prong was inspired by a famous case of the French Court of Appeals of Colmar, which Josseland himself considers as a first inroad in the theory of abuse of rights: a case where the court found for limiting the property right of an owner who intended to build a false chimney on his house roof essentially for the purpose of blocking his neighbour's view. Such action having been considered devoid of a 'serious and legitimate interest.'*" (C. Osti, What Is in a Name: The Concept of Abuse in Sui Generis Abuse, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 99)

<sup>201</sup> The Act has been amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2), 355(j) and 35 U.S.C. § 271(e).

testing process.”<sup>202</sup> NDA-based drugs are referred to as “brand-name drugs”.

The FDA requires also originators to identify the patents covering the drug and publishes a list of the approved drugs and their related patents on the so-called “Orange Book”, a publicly available database of the Approved Drug Products with Therapeutic Equivalence Evaluations. The Orange Book is a comprehensive database containing indications on the drug’s patent protection, which encompasses every patent in which at least one claim cover the drug’s active ingredient, formulation, or medical use.

The marketing authorization of generic drugs is less burdensome. Generic drugs are defined as “copies of brand-name drugs [...] in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.”<sup>203</sup> As seen in the introductory chapter, market entry of generics leads to significant savings both for consumers and States. In the words of the then President Ronald Reagan, the Hatch-Waxman Act was introduced in the U.S. specifically to enable “the Federal Government, the largest single consumer of drugs, [...] to purchase generic drugs at significantly lower cost.”<sup>204</sup> The Supreme Court recently confirmed that the Hatch-Waxman Act’s purpose was to “speed the introduction of low-cost generic drugs to market, thereby furthering drug competition.”<sup>205</sup> Before the Act, generics had to repeat the tests already performed by originators.<sup>206</sup> Due to the cost and time required, generic entry was often delayed and not cost-effective, resulting in a *de facto* extension of the patent monopoly. Congress therefore sought to increase the availability of generic substitutes following the loss of exclusivity and reduce both healthcare costs and the individual expenditure on pharmaceuticals. To promote price competition, the Act established a swifter regulatory approval process for generic products, the Abbreviated New Drug Application (ANDA). A generic manufacturer who wishes to market a generic version of a brand-name drug may seek FDA approval by filing an ANDA. The ANDA allows the generic manufacturer to avoid having to conduct detailed studies to demonstrate efficacy and safety of the drug, granting it the possibility to “piggyback” on the originator’s studies submitted in connection with the already-approved

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<sup>202</sup> FTC v. Actavis, Inc., 133 S. Ct., 2013, p. 2228.

<sup>203</sup> FDA, Understanding Generic Drugs, available at <http://www.fda.gov/Drugs/%20ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/>, accessed on 6 August 2016.

<sup>204</sup> R. Reagan, Public Papers of the Presidents of the United States: Ronald Reagan, 1984, p. 1362.

<sup>205</sup> FTC v. Actavis, Inc., 133 S. Ct., 2013, p. 2228. The Act aimed at balancing the interests of originators, thus encourage innovation, and of generic manufacturers and the public (short-term), thus promote price competition between brand-name and generic drugs. To promote innovation, the new law introduced the possibility for originators to apply for an extension of the patent term to make up for the time lost in the marketing authorization process. To promote competition, the Act introduced a less burdensome and time-consuming process to authorize marketing of generics. In the words of David Balto, former Policy Director of the Bureau of Competition of the FTC, “the added protections and exclusivity term for innovator firms have accompanied a tremendous increase both in the investment in, and the success of, pharmaceutical innovation. [...] [At the same time], [t]he industry also has seen an increase in the percentage of brand-name drugs that have a generic competitor on the market. Today, nearly 100% of the top-selling drugs with expired patents have generic versions available, versus only thirty-six percent in 1983.” (D. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks, 55 Food and Drug Law Journal, 2000, pp. 324-325)

<sup>206</sup> At the time of the introduction of the Hatch–Waxman Act in 1984, generic firms had to undertake lengthy and expensive trials to demonstrate safety and effectiveness. Approval by the U.S. FDA took years, and because the required tests constituted infringement, generic manufacturer could not begin the process before the expiration of the patent.

brand-name drug's NDA. The only requirement for the generic manufacturer is to demonstrate bioequivalence.<sup>207</sup> The generic applicant must demonstrate that its proposed drug is bioequivalent to the brand-name drug, *i.e.* that the rate and extent of absorption of the active ingredient is the same.<sup>208</sup> In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient into a patient's bloodstream over the same amount of time.

When a brand-name drug is covered by one or more patents listed in the Orange Book, before entering the market a generic must provide one of four certifications for each patent listed in the Orange Book.<sup>209</sup> Three out of the four possible certifications – no listed patent on the drug, any relevant patent has expired, and a promise to wait until any still-in-force patent expires – do not result in periods of exclusivity. The fourth, instead, results in a 180-day exclusivity period. A company that intends to market a generic version of a drug prior to expiration of the patents covering it must make a 'paragraph IV certification', certifying that the originator's patents are "*invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug.*"<sup>210</sup>

In almost all cases, a Paragraph IV certification provokes patent infringement litigation by the originator because the certification is an act of constructive infringement.<sup>211</sup> By certifying in the ANDA application that a patent is "*invalid or will not be infringed*", the generic manufacturer infringes the patent without having to actually produce and market the drug.

If a company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA must stay the ANDA application for a 30-month period, while the parties litigate patent validity and infringement in court. If the court decides the matter within that period, the FDA follows that determination; if 30 months pass with no decision, the FDA may decide to go forward and give approval to

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<sup>207</sup> 21 U.S.C. Sec. 355(j).

<sup>208</sup> 21 U.S.C. Sec. 355(j)(8)(B)(i).

<sup>209</sup> 21 U.S.C. Sec. 355(j)(2)(A)(vii).

<sup>210</sup> 21 U.S.C. Sec. 355(j)(2)(A)(vii)(IV). See C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, p. 952 ("*This pattern—launch, challenge, sue—is frequent for major drugs, and it has become the norm for the top-selling drugs. Litigation raises the expense of a Paragraph IV challenge to \$10 million or more.*") See also C.S. Hemphill, B.N. Sampat, Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals, Columbia Law and Economics Working Paper No. 399, 2012, pp. 13-14 ("*The likelihood that an ANDA includes a patent challenge increases sharply with drug sales. While generic entrants challenge patents for just 29 percent of drugs in the bottom quintile of sales, they do so for 96 percent of drugs in the top quintile (p-value < .01). The likelihood that a drug will be challenged "early," within five years of launch, is also increasing with sales. With the exception of the bottom quintile of sales (where the profitability of early generic entry and thus patent challenges would be lowest) effective market life is stable over the sales distribution. By contrast, nominal patent term increases sharply with sales, with the top sales quintile having almost four years more patent term than the bottom (p-value < .01). [...] For drugs that are challenged, the mean decrement to nominal patent term resulting from challenges is 6.4 years (median = 6.2 years). The drugs that were challenged had aggregate sales of over \$81 billion in the year prior to challenge. Given the large difference between brand and generic prices, the static welfare gains to consumers as a result of these challenges is likely large.*")

<sup>211</sup> 35 U.S.C. Sec. 271(e)(2)(A).

market the generic product.<sup>212</sup> As Professor Hovenkamp et al. pointed out,

*“In effect, the FDA acts as though the patent were conclusively presumed valid unless the Federal Circuit instructs it otherwise. The effect of this rather remarkable rule is to delay drug price competition for several years even where a patent is clearly invalid, by granting what is akin to an automatic preliminary injunction whenever a pharmaceutical patent owner files suit against a generic manufacturer.”*<sup>213</sup>

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<sup>212</sup> 21 U.S.C. Sec. 355(j)(5)(B)(iii)(I).

<sup>213</sup> H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law, Aspen, 2014, p. 15-68. See also p. 15-25 (“[U]ntil 2004 the Hatch-Waxman provisions created the potential for a pioneer to invoke multiple 30-month stays by successively listing new patent information in the Orange Book relevant to a given drug product. The prospect of multiple 30-month stays presented an opportunity for “evergreening,” a form of anticompetitive behavior that does not exist in ordinary patent infringement litigation. Regulatory and legislative changes effective in 2004 deal effectively with the problem of multiple 30-month stays, both by giving a generic ANDA applicant sued for patent infringement the right to assert a counterclaim challenging the listing of information in the Orange Book and by limiting patentees to a single 30-month stay for any given drug, regardless of the number of patents listed as covering that drug.”) The concern highlighted by Professor Hovenkamp directly relates to the so-called “patent linkage”, introduced in the U.S. by the Hatch-Waxman Act as a compromise between the interest of originators to obtain early adjudication of their patent rights, and the interest of generic manufacturers for an early and safe (from liability) entry. Patent linkage consists in the practice of linking the grant of the marketing authorization (the pricing and reimbursement status or any regulatory approval) of a generic drug to the status of the patent(s) covering the originator's drug. Patent linkage thus prevents marketing approval of a generic before adjudication of the brand-name drug's patent(s). The patents covering the brand-name drug are normally listed in a government registry (the Orange book in the U.S.) to provide notice to potential generics manufacturers. Whenever submitting an application for the marketing of a generic drug, generics manufacturers must notify the originator to allow it the opportunity to seek enforcement of its patent rights. If a patent infringement lawsuit is filed, the health agency refrains from approving the generics drug for a reasonable period of time to allow for resolution of the dispute. Patent linkage exists in Canada (as well as, e.g., in China, Singapore and South Korea), but it is rare in Europe (as well as, e.g., in India and Japan). In these latter countries, the marketing approval of generics does not require a verification of the status of the patent on the brand-name drug. One of few exceptions in the EU is Italy, where a patent linkage system has been (re)introduced by Article 11 of Law 8 November 2012, n. 189. The possibility to get rid of patent linkage in Italy has been recently discussed (and rejected) by the Senate, following a position paper of 12 November 2015 by the generic manufacturers' association Assogenerici (available at [https://www.senato.it/application/xmanager/projects/leg17/attachments/documento\\_evento\\_procedura\\_commissione/files/000/003/259/2015\\_11\\_12\\_-\\_Assogenerici\\_-\\_Position\\_paper.pdf](https://www.senato.it/application/xmanager/projects/leg17/attachments/documento_evento_procedura_commissione/files/000/003/259/2015_11_12_-_Assogenerici_-_Position_paper.pdf), accessed on 6 August 2016), and several statements by the Italian Antitrust Authority, but it may be discussed again as part of a wider reform of the rules on pharmaceutical products in September 2016. The provision of patent linkage in Italy runs counter EU law. The European Commission indicated that “[u]nder EU law, it is not allowed to link marketing authorisation to the patent status of the originator reference product. Article 81 of the Regulation [2004/726/EC] and Article 126 of the Directive [2001/83/EC] provide that authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. Since the status of a patent (application) is not included in the grounds set out in the Regulation and in the Directive, it cannot be used as an argument for refusing, suspending or revoking [marketing authorization].” (European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 336) Patent linkage often leads to delays in market entry of generic drugs, increasing cost and time necessary to obtain the marketing authorization. Patent linkage provides originators with an additional opportunity to game the system and create barriers to generic entry, particularly by aggravating the effect of patent clusters (as new patents are listed as covering the brand-name drug). As it has been noted, “the linkage regime provides a highly flexible tool in the hands of sophisticated pharmaceutical firms. The number and array of patent types, the speed of patent listing, the automatic injunction, and the low relevance

The first successful ANDA filer obtains a 180-day exclusivity period during which other generic challengers are not permitted to market their drug.<sup>214</sup> The purpose of this provision was to create an incentive for generic manufacturers to challenge patents that may be invalid, not infringed, or unenforceable, or invent around them, and accordingly get generic drugs on the market as early as possible for consumers to enjoy lower drug prices.<sup>215</sup>

The 180-day exclusivity period has however been exploited to delay generic entry instead of speeding it up. The Hatch-Waxman Act has been interpreted to grant 180 days of generic exclusivity to the first generic company to file for FDA approval, regardless of whether or not it succeeds in invalidating the patent or finding a way to avoid infringement. The originator can therefore “pay-off” the first generic “entrant” to convince it not to market its drug, without having to worry about any other generic manufacturer for at least 180 days. Even worse, generic exclusivity begins on the first day of commercialization of the drug and can thus be stipulated in the settlement. This may thus ultimately lead to the foreclosure of the market for as long as the period of generic exclusivity has not expired. As Professor Hovenkamp et al. clearly illustrate:

*“most grants of 180-day exclusivity today come not from successful challenges to patents but from generic companies that obtain entry rights through settlements, often settlements with cash payments attached. The 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with an exclusion payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market. Until 2004, such an agreement could keep out other generics indefinitely, because until the first generic actually entered the market no others would have the right to do so. Congress changed the law effective in 2004 to provide that the first generic to file an ANDA is entitled to only 180 days of generic exclusivity and forfeits that exclusivity if it fails to enter the market within a reasonable time. This new provision reduces, but certainly does not eliminate, the gains from anticompetitive settlements. Agreements that exclude generic competitors since that time can still delay generic entry, either directly (if the first ANDA filer*

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*requirement for listing combined with low evidentiary requirements for new and follow-on drug development enable pharmaceutical firms to rapidly identify attractive drug targets for legal protection both during and after regulatory approval”* (cfr. R. Bouchard, R. Hawkins, R. Clark, R. Hagtvedt, J. Sawani, Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals, 8(2) Northwestern Journal of Technology and Intellectual Property, 2010, p. 226).

<sup>214</sup> 21 U.S.C. Sec. 355(j)(5)(B)(iii)(IV). Under Sec. 355(j)(5)(D), the 180 days of exclusivity may be forfeited by 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.

<sup>215</sup> Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd., 527 F.3d, Fed. Cir., 2008, p. 1283; Teva Pharm. Indus. v. Crawford, 410 F.3d, D.C. Cir., 2005, pp. 53–54; Sandoz, Inc. v. FDA, 439 F. Supp. 2d, D.D.C., 2006, pp. 33–34. The 180-day exclusivity period is extremely valuable for generic manufacturers. The vast majority of their potential profits materialize during such exclusivity period. These profits come at the expense of consumers that, during the exclusivity period, have to pay higher prices, very close to those they were paying before the entry of the first generic. As it has been pointed out, “[t]he FDA has estimated an average price discount of just 6 percent when there is only one generic manufacturer competing with the brand-name firm. In the case of Zocor, the difference in retail prices between the brand-name drug and the exclusive generic was about 10 percent. The entry of additional competitors reduces the price sharply, and the more generic competitors, the lower the price.” (C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, p. 954)

*agrees to an entry date and therefore can still obtain its generic exclusivity) or because the FDA approval process takes time, so that other generics will not be able to enter as quickly.*<sup>216</sup>

During the exclusivity period, the generic manufacturer has to face competition not only from the brand-name drug, but potentially also from a generic version of the drug produced by the originator, known as authorized generic (“AG”). Indeed, the originator is permitted to market a generic version of its brand-name drug during the first filer’s exclusivity period under its NDA. Once an ANDA filer enters the market, an authorized generic may become an attractive choice as a means of recouping some of the revenue the originator would otherwise lose to the generic. Competition between the first generic entrant and an authorized generic often drives down both retail and wholesale generic drug prices.<sup>217</sup> The entry of an authorized generic thus has an impact on the first generic entrant both in terms of sales and margins.

## 6.2. European Union

Also at the EU level rules on market access of pharmaceutical products are common across States.<sup>218</sup> Drugs may only be placed on the market after they have obtained a

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<sup>216</sup> H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen, 2014, pp. 15-29 – 15-30. The first-filer generic must enter the market within the later of (i) 75 days after FDA approval; and (ii) 75 days after an appellate court decision finding invalidity or non-infringement of the originator’s patent (21 U.S.C. § 355(j)(5)(D)(i))(it is thus not sufficient a later filer obtains a declaration of invalidity by a district court), otherwise it forfeits its exclusivity and the exclusivity passes to the next generic in line. If there is no generic in line, the exclusivity is forfeited and any generic can enter. Professors Hemphill and Lemley notes how “[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.” (C.S. Hemphill, M.A. Lemley, *Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act*, 77 *Antitrust Law Journal*, 2011, p. 964) As noted by Professor Carrier, however, “appellate court decisions typically are not issued until years after a lawsuit challenging settlement is filed. For example, appellate rulings have come 6, 8, 11, and 13 years after settlement. As a result, the forfeiture provisions do not typically apply.” (M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, p. 15) In addition, Professors Hemphill and Lemley highlight an additional profile of complexity involved in the entry of later filers. Indeed, the analysis above “presumes that there is a patent lawsuit between the brandname firm and the later filer. Often, that cannot be taken for granted because the brand-name firm declines to sue the later filer, even if it sued the first filer. Without a suit, the later filer is bottled up behind the first filer, unable to secure FDA approval. In response, some generic firms file declaratory judgment suits in an effort to trigger (eventually) the first filer’s use-it-or-lose-it obligation. A declaratory judgment action, however, is a chancy thing, because there is often a dispute about whether the generic firm has standing to bring its suit. That complication makes this route an even more time-consuming, costly, and uncertain affair.” (C.S. Hemphill, M.A. Lemley, *Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act*, 77 *Antitrust Law Journal*, 2011, p. 964)

<sup>217</sup> FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, 2011, pp. 41-48, available at <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>, accessed on 6 August 2016.

<sup>218</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67-128), as amended, and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004). The Directive harmonizes national procedures and requirements for the authorisation, while the Regulation establishes the centralised procedure to obtain a marketing authorization with validity for the entire EEA.

marketing authorization, which ensures quality, efficacy and safety of medicinal product.<sup>219</sup> For new drugs, detailed results of pharmaceutical (physiochemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests and clinical trials must be submitted with the application for a marketing authorization.

A centralized marketing authorization procedure led by the European Medicines Agency (EMA), in charge of the scientific evaluation, is available for new drugs. The procedure takes at least 210 days (although it is possible to conduct an accelerated assessment in 150 days),<sup>220</sup> and the marketing authorization is granted by the European Commission for the entire EEA. In the alternative, it is possible to obtain the recognition in other Member States of the authorization issued on a national basis.<sup>221</sup> Since Directive 2001/83/EC harmonized the substantive requirements to obtain a marketing authorization, this procedure relies on the mutual recognition of national authorizations. Pursuant to Article 28 of Directive 2001/83/EC, companies can submit parallel national applications based on the decentralized procedure, which substantially coincides with the recognition procedure but applies to drugs which have not yet been granted a national marketing authorization at the time of application. The application is simultaneously submitted to several Member States, one of which is selected as Reference Member State and coordinates the procedure

As in the U.S., the marketing authorization for generics is easier and quicker to obtain. Generics are defined as products with the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the brand-name drug, and whose bioequivalence has been demonstrated by appropriate bioavailability studies.<sup>222</sup> Differences in salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and efficacy. In such cases, additional information providing proof of safety and efficacy must be supplied by the applicant. If these conditions are met, the competent authority can rely on the proof of safety and efficacy submitted in the marketing authorization application for the brand-name drug (the “reference product”) and a generic applicant is thus exempted from having to provide the results of pre-clinical tests and clinical trials. This is the so-called abridged application.<sup>223</sup> Using the brand-name’s dossier in

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<sup>219</sup> Directive 2001/83/EC provides that: “no medicinal product for human use may be placed on a market in the EEA unless a marketing authorisation has been issued for it”.

<sup>220</sup> The Committee for Medicinal Products for Human Use (CHMP) within the EMA prepares an opinion on whether the application should be granted or not and send it to the European Commission.

<sup>221</sup> As explained by the European Commission, “[t]he Member State that has already authorised the product (known as the Reference Member State (“RMS”)) submits an evaluation of the product to other Member State/s (known as Concerned Member States (“CMS”)) which are asked to mutually recognise the [marketing authorization] of the RMS. The CMS will then issue a [marketing authorization] permitting the marketing of the product in their territory.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 72)

<sup>222</sup> Article 10 of Directive 2001/83/EC.

<sup>223</sup> The generic manufacturer has to demonstrate that its drug has (i) the same qualitative and quantitative composition in active substances and (ii) the same pharmaceutical form as the reference drug and (iii) to show bioequivalence with it, by conducting bioavailability studies. According to the so-called “Bolar provision”, introduced in 2004, conducting the necessary studies and trials with a view to obtaining a generic marketing authorization “shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products” (Article 10(6) of Directive 2001/83/EC).

an abridged application for marketing authorization saves generic manufacturers time and money.<sup>224</sup> Once a generic has obtained a marketing authorization it can enter the market, provided that other national legal requirements, such as obtaining price approval and reimbursement status, have been satisfied.<sup>225</sup>

Since 2005, a generic entrant can benefit from the abridged procedure also if the reference product is not on the market anymore or the marketing authorization has been withdrawn. The inability to prevent generic entry by withdrawing the marketing authorization or discontinuing the product makes it more important for originators to switch patients to second generation (patent-protected) drugs before the patent on the first generation product expires. (Almost) Every prescription for the old drug not switched at the time of generic entry will, due to the rules on generic substitution, automatically be fulfilled with the cheapest available generic.

## 7. Generic Substitution

The last piece of regulation to take into consideration to assess conducts by pharmaceutical companies relates to generic substitution. This regulation is relevant for this work because originators' abusive conducts are often immediately aimed at disrupting the functioning of generic substitution. This is achieved either by blocking generic entry *tout court* or by switching patients to second generation (patent-protected) products that cannot be substituted for the generic version of the first generation brand-name drug. When assessing a conduct, the rules on substitution should thus always be kept in mind.

Rules on generic substitution may apply to doctors (in the form of guidelines recommending the prescription of generics when available) or pharmacists (in the form of mandatory generic substitution if the patient does not specifically need the more expensive brand-name drug, and thus the prescription specifies "non-substitutable"). Through prescription guidelines and pharmacy substitution, governments promote the use of generics (medically equivalent to brand-name drugs).

Drug substitution laws are designed to address the price disconnect between prescribing doctors, who choose the drug but do not pay for it, and insurers, consumers and States, who do not choose, but pay for the prescribed drug. The purpose of generic

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<sup>224</sup> Generic manufacturers are allowed to apply for a marketing authorization when the originator's product is still protected by exclusive rights. However, an abridged application can be submitted only upon expiry of the originator's eight-year period of data exclusivity on pharmacological and toxicological tests, as well as clinical studies, collected and submitted to the relevant authorities to demonstrate safety and efficacy of the brand-name drug (Directive 2004/27/EC and Regulation 2004/726/EC). In addition to data exclusivity, marketing exclusivity grants the originator two more years of protection from generic competitors, during which the drug, even if approved for marketing, cannot enter the market. Marketing exclusivity can be extended by one additional year, thus bringing the total to 11 years, if the originator, during the eight years of data exclusivity, obtains marketing authorization for one or more new therapeutic indications with significant clinical benefit. Data exclusivity and marketing exclusivity apply to both patent law and SPC protection.

<sup>225</sup> *"In principle, a generic company can decide to launch its generic product without waiting for the originator's relevant patents to expire or attempting to invalidate them. It is in these cases that one generally speaks of launch 'at risk' as the generic may still be prevented from entering the market or may subsequently have to be withdrawn pursuant to a court order/injunction, if it infringes a valid patent."*(European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 75)

substitution is thus to cancel out certain prescribing habits of physicians, which have little incentive to consider price when deciding which drug to prescribe, by shifting drug selection, between brand-name and their corresponding generics, from doctors to pharmacists and patients, who have greater financial incentives to choose the most cost-effective solution.

In addition, doctors are subject to incessant drug promotion, including detailing (sales calls and visits to doctors' offices), direct mailings, free drug samples, sponsored continuing medical education programs and media advertising.<sup>226</sup> In many countries, doctors do not have a thorough knowledge of medicines and get most of their knowledge (or at least updates) from pharmaceutical companies' visits and material.<sup>227</sup> Drug promotion tends to determine a brand-name recall in doctors and potentially distrust against generics, which result in the diffusion of prescriptions of brand-name drugs, instead of using their International Nonproprietary Names (INN). Generic substitution tries to counter also this effect.

In the U.S., all 50 States and the District of Columbia have drug substitution laws to encourage generic competition.<sup>228</sup> Although the specific provisions may vary, drug substitution laws either permit or require pharmacists to fulfill the prescription with a therapeutically equivalent,<sup>229</sup> lower-cost generic drug in place of the brand-name drug, absent express direction otherwise from the physician (*i.e.* when the prescription is marked "dispense-as-written").

Within the EU, the regulation on drug substitution is national. For example, in France pharmacists have the right to substitute brand-name drugs with their generic

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<sup>226</sup> S.O. Schweitzer, *Pharmaceutical Economics and Policy*, Oxford University Press, 2006, p. 87.

<sup>227</sup> As noted by the President of the French Competition Authority, "*the general reluctance toward generic is partly the side effect of the poor knowledge of the pharmacopoeia by many players within the health system, most notably by doctors themselves, who are also largely unaware of the legal framework applicable to the market entry and distribution of pharmaceuticals. Only a small minority of doctors in France write their prescriptions using the INN for drugs. The social affairs committee of the National Assembly noted in 2011 that pharmacology is hardly taught either in medical school or during continuing professional education. Hence doctors are highly receptive to the information brought to them by so-called 'medical visitors' who represent the pharmaceutical companies' interests.*" (B. Lasserre, France – Raising Artificial Barriers against Generic Entry: The French Experience, in in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 193-194)

<sup>228</sup> M.A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 *Florida Law Review*, 2010, p. 1017.

<sup>229</sup> Most States adopt the FDA's definition of therapeutically equivalent and allow generic substitution only if the FDA designates the generic as "AB-rated" in the Orange Book. To be AB-rated, a generic must not only be bioequivalent (*i.e.* it exhibits a similar rate and extent of absorption) but therapeutically equivalent to the brand-name drug, meaning it must have the same active ingredient, dosage, form, strength, and route of administration. As the court summarized in *Abbot Labs.*: "[t]herefore an approved generic drug that is not AB-rated against a currently available branded drug, because, for example, the drugs have different formulations or dosages, may not be substituted for the branded drug and may only be sold, if at all, as a separately branded, rather than generic, drug" (*Abbott Labs. v. Teva Pharmaceuticals USA, Inc.*, 432 F.Supp.2d, 2006, p. 415). Due to the narrowness of this criteria, originators can game the system by changing the form of the brand-name drug to avoid generic-substitution. See also the Orange Book Preface, available at <http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm>, accessed on 6 August 2016.

equivalent, provided it is on the generic list<sup>230</sup> (which is rather narrow in France compared to other countries like the UK or Germany).<sup>231</sup> However, substitution can be prevented by doctors if they indicate “non-substitutable” on the prescription.

## 8. Antitrust

### 8.1. United States

To better understand the intersection between IP and antitrust, and the principles expressed by courts and agencies, a brief introduction on the relevant provisions of antitrust law is opportune.

As a general note, antitrust provisions tend to be vague. In the U.S., this has been linked to the fact that “*Congress apparently did not want to get involved in articulating a specific definition of competition or in determining which practices might promote or undermine it. Rather it enacted a few general principles derived from the common law, and left it largely to the courts to determine what practices violate them.*”<sup>232</sup> The principles underlying the adoption of the antitrust law are thus very similar to those governing patent misuse and abuse of rights: general principles and a delegation to the courts for the case-by-case enactment.

The fundamental provisions of the U.S. antitrust laws for our purposes are Section 1

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<sup>230</sup> “*A statute law of 1998 and ensuing decrees introduced in France a right for pharmacists, when delivering prescription medicines, to substitute a generic for the [brand-name drug]. In order to encourage pharmacists to carry out this substitution, they were granted a legal guarantee that they would make the same margin rate for the sale of any medicine within a group of generics, i.e., that they would earn as much by selling a generic as they would the corresponding originator medicine, although the price of the latter is generally higher than that of the former. In the same vein, a statute law of 2003 ruled that, when doctors write their prescriptions using the International Nonproprietary Names (INN) for pharmaceutical substances rather than the brand-name, pharmacists may only deliver the originator medicine insofar as its final cost for the State Healthcare system does not exceed that of the most expensive generic. Only if the prescribing doctor expressly indicates that the prescribed, brand-name medicine is ‘not substitutable’ is the pharmacist barred from substituting a generic for its originator. [...] [F]or a pharmacist to be able to substitute a generic for an original medicine, the former must be listed in the repertoire of generics kept by health authorities.*” (B. Lasserre, France – Raising Artificial Barriers against Generic Entry: The French Experience, in in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 189-190)

<sup>231</sup> “*Paracetamol or aspirin-based medicines, for example are not included in the generics list, even if these drugs are frequently used by consumers. There are many manufacturers of paracetamol or aspirin that can be bought without prescription, but because consumers are not aware of the generic versions, they tend to buy the branded version. One of the paracetamol brands is the fifth most reimbursed drug by the public health insurance system in France, so this subject is an important one in terms of the financing of the public health system.*” (OECD Competition Committee, Summary Record of the Discussion on Competition and Generic Pharmaceuticals, DAF/COMP/M(2014)2/ANN3/FINAL, 6 November 2014, p. 5, available at [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M\(2014\)2/ANN3/FINAL&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M(2014)2/ANN3/FINAL&doclanguage=en), accessed on 6 August 2016) See also B. Lasserre, France – Raising Artificial Barriers against Generic Entry: The French Experience, in in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 187-188 (“*the market share of generic drugs in France does not exceed a quarter (by volume) of the total quantity of reimbursable drugs, whereas this proportion reaches about two-thirds in Germany and in the United Kingdom and three-quarters in the USA – despite the fact that, since the mid 1990s, a public policy in favour of generic medicines has been consistently and actively pursued, with the aim of controlling health expenditure.*”)

<sup>232</sup> C. Bohannon, H.J. Hovenkamp, *Creation without Restraint: Promoting Liberty and Rivalry in Innovation*, Oxford University Press, 2012, p. 43.

and Section 2 of the Sherman Act and Section 5 of the FTC Act.

Section 1 of the Sherman Act (15 U.S.C. Sec. 1) prohibits “[e]very contract, combination [...] or conspiracy, in restraint of trade [...]”. This provision has been interpreted as prohibiting “*virtually any practice that has the effect of reducing output and raising price – or those activities that are ‘anticompetitive’ under the ordinary definitions of neoclassical economics.*”<sup>233</sup>

Section 2 of the Sherman Act (15 U.S.C. Sec. 2) prohibits monopolization, or attempted monopolization. The offense of monopolization has two elements: “(1) *the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.*”<sup>234</sup> The court has thus to determine whether the firm possesses monopoly power and acquired, enlarged or maintained its monopoly power through exclusionary conduct. In *Aspen Skiing*, the Supreme Court clarified that a conduct may be exclusionary when it “(1) *tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way.*”<sup>235</sup> To be condemned for monopolization, the conduct of a firm having market power must have anticompetitive effect, and no procompetitive justification<sup>236</sup> that outweighs the anticompetitive harm.<sup>237</sup> Focus is thus on the effects of the conduct, while evidence of the intent behind it is only relevant to interpret facts and predict the likely consequences of the monopolist’s conduct.<sup>238</sup> To show attempted monopolization, instead, the plaintiff must prove: “(1) *that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.*”<sup>239</sup> Attempted monopolization, contrary to monopolization, requires a specific finding of intent.<sup>240</sup>

To conclude, Section 5 of the FTC Act allows the FTC to intervene when it has reason to believe that an “unfair method of competition” is likely to cause competitive harm. Section 5 enables the FTC to address conducts covered by the letter and the spirit of both Section 1 and Section 2 of the Sherman Act. Due to its open formulation, Section 5 of the FTC Act is potentially able to reach more broadly than the Sherman Act and address most if not all of the patentees’ abusive conducts discussed in this work, even before they produce

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<sup>233</sup> H.J. Hovenkamp, *The Federal Trade Commission and the Sherman Act*, 62 *Florida Law Review*, 2010, p. 874.

<sup>234</sup> *United States v. Grinnell Corp.*, 384 U.S., 1966, pp. 570-571.

<sup>235</sup> *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S., 1985, pp. 595-596.

<sup>236</sup> A procompetitive justification consists in “*a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal*” (*United States v. Microsoft*, 253 F.3d, D.C. Cir., 2001, p. 59). See also *LePage’s v. 3M*, 324 F.3d, p. 152 (“[A] monopolist will be found to violate § 2 of the Sherman Act if it engages in exclusionary or predatory conduct without a valid business justification.”).

<sup>237</sup> It is thus necessary to determine whether a conduct preventing actual or potential rivals from competing, or impairing their opportunities to do so effectively, does not benefit consumers at all, or is unnecessarily restrictive for the consumer benefits that it produces.

<sup>238</sup> See, e.g., *Chicago Board of Trade v. United States*, 246 U.S. 231, 238, 38 S.Ct. 242, 62 L.Ed. 683, 1918. Evidence that the conduct is “*not related to any apparent efficiency*” may constitute proof of specific intent to monopolize. (*Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S., 1995, p. 608)

<sup>239</sup> *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 1993, p. 456.

<sup>240</sup> See, e.g., *Delaware & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d, 2d Cir., 1990, p. 180.

any competitive harm.<sup>241</sup>

## 8.2. European Union

Contrary to patent law,<sup>242</sup> a common EU antitrust law exists, is applicable in every Member State and is enforced by a central authority, the European Commission, as well as by national competition authorities.

EU antitrust law stands on two main provisions (for our purposes), Article 101 and Article 102 of the Treaty on the Functioning of the European Union (TFEU).

Article 101 prohibits all agreements between undertakings and concerted practices “*which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market*”.<sup>243</sup> The main objective of this norm

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<sup>241</sup> In *FTC v. Brown Shoe Co. Inc.*, the Supreme Court allowed the FTC to apply Section 5 so as to “*arrest trade restraints in their incipency*”, without the need to show competitive harm. The Supreme Court held that Section 5 reaches “*practices which conflict with the basic policies*” underlying antitrust law, as well as incipient violations (*FTC v. Brown Shoe Co.*, 384 U.S., 1966, p. 321-322). See also *FTC v. Indiana Federation of Dentists*, 476 U.S., 1986, p. 454 (stating that Section 5 covers “*not only practices that violate the Sherman Act and the other antitrust laws but also practices that the Commission determines are against public policy for other reasons*”); *FTC v. Sperry & Hutchinson Co.*, 405 U.S., 1972, p. 244 (noting that FTC must “*consider [...] public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws*”). See W.E. Kovacic, M. Winerman, *Competition Policy and the Application of Section 5 of the Federal Trade Commission Act*, 76 *Antitrust Law Journal*, 2010, pp. 930-931 (“*Congress intended Section 5 to be a mechanism for upgrading the U.S. system of competition law by permitting the FTC to reach behavior not necessarily proscribed by the other U.S. competition statutes, including the 1890 Sherman Act and the Clayton Act.*”) *Contra*, see R.A. Posner, *The Federal Trade Commission: A Retrospective*, 72 *Antitrust Law Journal*, 2005, p. 766, that rejects the idea that the FTC Act’s prohibitions are broader than those of the Sherman Act, but expresses the view that “*the Sherman and Clayton Acts have been interpreted so broadly that they no longer contain gaps that a broad interpretation of Section 5 of the FTC Act might be needed to fill.*” Posner’s position is criticized by Professors Hemphill and Lemley who explain: “*We have no doubt that antitrust at one time was skewed toward over-enforcement, but today if there is any bias it is in the opposite direction. The Supreme Court in the last two decades decided seventeen antitrust cases in a row in favor of defendants. Only once in the last eighteen years has an antitrust plaintiff won in the Supreme Court. [...] [I]t does not suggest that as they are currently interpreted the Sherman and Clayton Act cover everything that might possibly be anticompetitive flies in the face of the realities of modern antitrust. Nonequivalence, in short, has its uses. That is particularly true if the prospect of treble damages leads courts to constrict the scope of liability in private plaintiff cases. Even if it is appropriate for courts to limit liability to compensate for the heightened false-positive risk created by treble damages, it does not follow that the FTC must adhere to the same path. The FTC seeks injunctive relief, not treble damages. That difference reduces concerns about false positives and overdeterrence. Put another way, the FTC’s optimal scope of liability may well be broader than the courts’. Nonequivalence allows the FTC to take advantage of that difference, while the Sherman Act applies a harsher penalty to a narrower class of activity.*” (C.S. Hemphill, M.A. Lemley, *Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act*, 77 *Antitrust Law Journal*, 2011, pp. 974-975)

<sup>242</sup> As seen, although there is no EU patent law (yet), legislations are largely harmonized, thanks to international treaties, EU regulations and directives, and the few differences are (for our purposes) mostly formal rather than substantial.

<sup>243</sup> The requirement that the agreement may affect trade between Member States is the jurisdictional threshold for the application of EU antitrust law (the same limit is provided for by Article 102 TFEU). To fulfil this requirement, it is sufficient the probability to influence, directly or indirectly, actually or potentially, the trade between Member States. This includes agreements limited to a single Member State, or relating to trade outside of the EU, if they have the potential to restrict imports or exports of otherwise affect the European internal market. Agreements explicitly prohibited by Article 101(1) include those which “*(a) directly or indirectly fix purchase or selling prices or any*

is to ensure that each undertaking determines its business conduct independently. Article 101 is applicable only in case of agreements or concerted practices within the meaning of antitrust law. To be in an agreement, the undertakings must have expressed their joint intention to conduct themselves on the market in a specific way.<sup>244</sup> An agreement can be considered concluded where “*there is a concurrence of wills on the very principle of a restriction of competition*”.<sup>245</sup> The concept of concerted practice, instead, refers to “*a form of coordination between undertakings which, without being taken to the stage where an agreement properly so called has been concluded, knowingly substitutes for the risks of competition practical cooperation between them*”.<sup>246</sup> The second element necessary for Article 101 to be applicable is the anticompetitive object<sup>247</sup> or effect.<sup>248-249</sup> Also

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*other trading conditions; (b) limit or control production, markets, technical development, or investment; (c) share markets or sources of supply; (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”* Agreements caught by Article 101(1) TFEU shall not be prohibited if they satisfy the four cumulative conditions of Article 101(3) TFEU: “[i] *the agreement must contribute to improving the production or distribution of products or contribute to promoting technical or economic progress, that is to say, lead to efficiency gains; [(ii)] the restrictions must be indispensable to the attainment of those objectives, that is to say, the efficiency gains; [(iii)] consumers must receive a fair share of the resulting benefits, that is to say, the efficiency gains, including qualitative efficiency gains, attained by the indispensable restrictions must be sufficiently passed on to consumers so that they are at least compensated for the restrictive effects of the agreement [...]; and [(iv)] the agreement must not afford the parties the possibility of eliminating competition in respect of a substantial part of the products in question.”* (European Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, 2011/C 11/01, 14 January 2011, par. 49)

<sup>244</sup> General Court, T-7/89, *Hercules Chemicals v Commission*, 17 December 1991, par. 256; General Court, T-9/99, *HFB and Others v Commission*, 20 March 2002, par. 199.

<sup>245</sup> European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 1105. In the case at stake, the Commission took the position that: “*The agreements that are subject to this Decision clearly constitute agreements in the sense of Article 101(1) of the Treaty and they contain a concurrence of wills with respect to the future commercial behaviour of the generic undertaking in question. As the analysis of each of the agreements will show, the obligations which the generic undertaking accepted in each of the agreements restricted their ability to enter the market and thereby their autonomy of decision-making, and eliminated or substantially reduced commercial uncertainty for [the originator] with respect to the future competitive behaviour of the generic undertaking for the duration of the agreement in question.*” (see par. 1108)

<sup>246</sup> European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 1105.

<sup>247</sup> “Restrictions “by object” are those which, “by their very nature”, can be regarded as being injurious to the proper functioning of normal competition. In order for an agreement to be regarded as having an anti-competitive object, it is sufficient that it has the potential to have a negative impact on competition. In other words, the agreement must simply be capable in an individual case, having regard to the specific legal and economic context, of resulting in the prevention, restriction or distortion of competition within the internal market. [...] [T]he anti-competitive object of an agreement may be deduced not only from the content of its clauses but also from the intention of the parties as it arises from the “genesis” of the agreement and/or manifests itself in the “circumstances in which it was implemented” and in the “conduct” of the companies concerned. [...] [T]he fact that an agreement may also have had other, entirely legitimate objectives does not bar the possibility of finding a restriction by object.” (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, paras. 1110-1111, 1113-1114, and references thereof) See also General Court, T-472/13, *Lundbeck v Commission*, 8 September 2016, paras. 339-341 (“*certain types of coordination between undertakings reveal a sufficient degree of harm to competition for the examination of their effects to be considered unnecessary [...] That case-law arises from the fact that certain forms of coordination between undertakings can be regarded, by their very nature, as being injurious to the proper functioning of normal competition [...] Consequently, it is established that certain collusive behaviour, such as that leading to horizontal price-fixing by cartels or consisting in the exclusion of some competitors from the market, may be considered so likely to have negative effects, in particular on the price, quantity or quality of the goods and services, that it may be considered redundant, for the purposes of applying Article 101(1) TFEU, to prove that they have actual effects on the market. Experience shows*

the effect on potential competition from new entrant, in our case generics, is relevant in determining the effects of the agreement.<sup>250</sup> As regards the intention of the parties to the agreement, the case law recognizes its importance in establishing the existence of a restriction by object.<sup>251</sup> Finally, with regards to the applicability of Article 101 to agreements concerning IP rights, the European Commission has recently noted that “[t]here are various [...] examples of cases in which the Courts of the European Union considered that agreements concerning intellectual or industrial property rights are subject to Union competition law and may infringe Article 101(1) of the Treaty.”<sup>252</sup> The General Court further explained that, “[a]lthough the rights recognized under the industrial property legislation of a Member State are not affected by Article 101 TFEU, the circumstances in which they are exercised may nevertheless fall within the scope of the prohibitions laid down in that article. This may be the case whenever the exercise of such a right appears to be the object, the means or the consequence of an agreement”.<sup>253</sup>

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that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers”).

<sup>248</sup> “For an agreement to have restrictive effects on competition within the meaning of Article 101(1) it must have, or be likely to have, an appreciable adverse impact on at least one of the parameters of competition on the market, such as price, output, product quality, product variety or innovation. Agreements can have such effects by appreciably reducing competition between the parties to the agreement or between any one of them and third parties. This means that the agreement must reduce the parties’ decision-making independence, either due to obligations contained in the agreement which regulate the market conduct of at least one of the parties or by influencing the market conduct of at least one of the parties by causing a change in its incentives.” (European Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, 2011/C 11/01, 14 January 2011, par. 27). “The assessment of whether a horizontal co-operation agreement has restrictive effects on competition within the meaning of Article 101(1) must be made in comparison to the actual legal and economic context in which competition would occur in the absence of the agreement with all of its alleged restrictions (that is to say, in the absence of the agreement as it stands (if already implemented) or as envisaged (if not yet implemented) at the time of assessment). Hence, in order to prove actual or potential restrictive effects on competition, it is necessary to take into account competition between the parties and competition from third parties, in particular actual or potential competition that would have existed in the absence of the agreement.” (par. 29).

<sup>249</sup> To determine the impact of the agreement on competition it is necessary to take into consideration not only “existing competition between undertakings already present on the relevant market but also [...] potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to penetrate the relevant market and compete with the undertakings already established” (General Court, T-374/94, T-375/94, T-384/94 and T-388/94, European Night Services and Others v Commission, 15 September 1998, par. 137).

<sup>250</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 1163, 1165. The Commission continues at paras. 1169 and 1181: “In any event as amply shown by the number of oppositions, revocation actions and counterclaims of invalidity either launched or envisaged by the generics in this case, the validity of a patent may be challenged. In addition, the burden to prove infringement rests with the patent holder. There is no presumption that a particular product is manufactured with a particular process that infringes a given patent. In the Commission’s view, nothing prevents the possibility that an invoked patent is found invalid or not infringed and thus incapable of blocking a generic product. [...] The absence of a marketing authorisation does not suggest that the product was not capable of reaching the market, as long as the generic was pursuing its efforts to obtain regulatory approval and such attempts did not run into objectively insurmountable problems.”

<sup>251</sup> General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 523.

<sup>252</sup> “[C]rucial aspect in demonstrating potential competition is the ability to enter a market. The perception of the incumbent [...] and of other [potential entrants] will also be taken into account. [T]he Court of Justice considers that in the pharmaceutical sector potential competition on the compound can and is likely to exist already well before the expiry of a basic, compound, patent, even if process or other patents may still be in force.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1120)

<sup>253</sup> General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 486.

The second relevant provision is Article 102 TFEU, which forbids “*any abuse by one or more undertakings of a dominant position [...] in so far as it may affect trade between Member States.*”<sup>254</sup> Article 102 TFEU is the provision dealing with unilateral abusive conducts in EU antitrust law as much as Section 2 of the Sherman Act does so in U.S. antitrust law. As Professor Arezzo argued, “*they are both meant to prohibit unilateral conduct which influences a certain market, and have the effect of impairing trade between member States [and in] both cases the conduct becomes relevant when a certain degree of economic power is involved.*”<sup>255</sup>

To assess whether a conduct falls under Article 102 TFEU, it is necessary to determine whether the conduct constitutes an abuse and whether it has been undertaken by a firm in a dominant position.<sup>256</sup> Starting with the concept of abuse, Article 102 TFEU imposes on an undertaking in a dominant position, irrespective of how it achieved such position, a “*special responsibility not to allow its conduct to impair genuine undistorted competition on the common market.*”<sup>257</sup> This is one of the main differences with the U.S. system, which takes a different view of the role of antitrust. In the U.S., preference is to tolerate questionable

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<sup>254</sup> Within the practices expressly forbidden, Article 102 lists: “*(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; (b) limiting production, markets or technical development to the prejudice of consumers; (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.*” The categories of abuses condemned under EU antitrust law are broader than those illicit under U.S. law. While in the U.S. only exclusionary practices fall under the reach of antitrust, in the EU also exploitative abuses are forbidden. Exclusionary abuses are, directly or indirectly, attempts to exclude from the market competitors or undertakings active on a related (upstream or downstream) market and “*cause consumers harm through their impact on competition*” (Court of Justice, C-209/10, Post Danmark, 27 March 2012, par. 20). Exploitative abuses are conducts essentially directed at customers or suppliers “*whereby the dominant undertaking takes advantage of its market power to exploit its trading partners (consumers)*” (A. Jones, B. Sufrin, *EU Competition Law: Text, Cases, and Materials*, Oxford University Press, 2014, p. 367) and extract supracompetitive gains. The main difference between exclusionary and exploitative abuses is that, in the first case customers and consumer are harmed indirectly, by harming the competitive process, in the second case the harm is direct. This work agrees with the European Commission cautious approach (sometimes even too cautious) in addressing exploitative abuses, and takes the view that relying exclusively on the market to get rid of exploitative practices is ill-advised. The non-interventionist approach does not take into consideration the fact that certain markets are unable to self-correct (due to, *e.g.*, non-transitory barriers) and, even when they are, self-correction may take so long that consumers are significantly affected by the abuse.

<sup>255</sup> E. Arezzo, *Intellectual Property Rights at the Crossroad between Monopolization and Abuse of Dominant Position: American and European Approaches Compared*, 24(3) *John Marshall Journal of Computer & Information Law*, 2006, p. 455.

<sup>256</sup> Only abuses that may affect trade between Member States are prohibited by Article 102 TFEU. Abuses can be considered to affect trade when they have an impact on the competitive structure in more than one Member State. It is sufficient that the abuse “*may affect trade*”, *i.e.* it is probable that the conduct affects (in any way, not necessary reducing it) the patterns of trade, based on an objective assessment (taking nonetheless any subjective element into consideration). The effect on trade has to be appreciable, or better, not insignificant, and this is assessed primarily by referring to the position of the undertaking on the market for the product concerned.

<sup>257</sup> Court of Justice, 322/81, *Michelin v Commission*, 9 November 1983, par. 57. See also Court of Justice, C-209/10, *Post Danmark*, 27 March 2012, par. 23. A dominant undertaking is thus barred from conducts that, notwithstanding the fact that they are aimed at protecting its own commercial interests, have the purpose of strengthening its dominant position or abuse it (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2762).

conducts (Type II errors) rather than prohibit innocuous (and potentially beneficial) ones (Type I errors). Premise of the U.S. approach is that markets, and thus Type II errors, are self-correcting (in the long-run) and the government should thus limit its intervention to avoid imposing duties on competitors and costumers that may undercut their incentives to invest and invent. EU antitrust takes a different position in this regard, often linked to ordo-liberalism.<sup>258</sup> In the EU, dominant firms are under a positive obligation to refrain from any form of competition other than performance competition. In other words, dominant undertakings have an obligation to behave as if they did not have market power. The difference between the U.S. and the EU approaches can thus be summarized in their faith in the market's ability to self-correct. At the EU level, faith in self-correction is limited, risk of Type I errors is perceived as manageable, and the cost of Type II errors is deemed substantial. For this reason, the "special responsibility" shifts the burden of enforcement to firms, which are deemed to be better placed to assess the compatibility of their conduct with the enhancement of consumer welfare. The U.S. approach (at the Supreme Court level at least) is diametrically opposed and is premised on avoiding, as much as possible, to restrict the firms' commercial freedom. The burden is thus on the agencies to show, in exceptional circumstances, that the firm's conduct is exclusionary and in breach of antitrust law.<sup>259</sup>

To determine whether a conduct can be considered abusive, the European Commission refers to the same principle as Section 2 of the Sherman Act, competition on the merits.<sup>260</sup> The behavior of a dominant undertaking is thus legitimate as long as it is

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<sup>258</sup> While preferring a market economy to central planning, ordo-liberalism is much less confident in the market's ability to self-correct, especially in terms of avoiding the concentration of economic power in private hands, which is considered the main threat to economic freedom. Ordo-liberalism takes the position that economic players should not be coerced into their choices and the only acceptable form of competition should be competition on the merits.

<sup>259</sup> As eloquently summarized by Professor Fox, "*A significant portion of U.S. and EU law on abuse of dominance and monopolization corresponds. In particular, monopolistic conduct prohibited by section 2 of the Sherman Act is likely to constitute an abuse of dominance under TFEU Article 102, although not vice versa. [...] The Competition Directorate in Europe faces a highest court that applies the Treaties' values of openness and access, often engages in formal legalistic analysis, and sometimes applies rules of fairness. Accordingly, the Court's pronouncements tend to proscribe more than the Competition Directorate's guidance would. The U.S. agencies face a highest court that tends to apply values of trust in the market and deep respect for the business judgment of even dominant firms, expecting thereby to maximize innovation, efficiency, and a notion of freedom. The Supreme Court's holdings proscribe less conduct than most current U.S. agency officials deem anticompetitive. Thus we see more administrative-level convergence and more judicial-level divergence.*" From this, it follows that, "*the EU perspective on abuse of dominance at the Court of Justice level stresses the process of competition, seeking to enable all market actors to compete on their merits, particularly efficient and potentially efficient competitors. The U.S. law of monopolization at the Supreme Court level stresses the costs of antitrust intervention, tending toward per se legality in a number of situations and otherwise imposing considerable burdens on plaintiffs to show how the particular conduct will increase market power and harm consumers and that the finding of a violation would not compromise low prices and incentives to innovate.*" (E.M. Fox, *Monopolization and Abuse of Dominance: Why Europe is Different*, 59(1) *The Antitrust Bulletin*, Spring 2014, pp. 150-151, and p. 143). See also P. Larouche, M.P. Schinkel, *Continental Drift in the Treatment of Dominant Firms: Article 102 TFEU in contrast to Section 2 Sherman Act*, TILEC Discussion Paper DP 2013-020, May 2013, p. 7 ("*Eleanor Fox suggests that, beyond the rhetoric, the difference between US and EU law relates to the grey zone of conduct which is not clearly output-limiting but nevertheless would injure the competitive process. US antitrust law does not thread into that grey zone, for fear of error, which would lead to prohibiting pro-competitive conduct. Under EU competition law, in contrast, authorities do not hesitate to prosecute conduct falling into that grey zone, despite the error risk.*")

<sup>260</sup> "[A]n undertaking in a dominant position has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market [...]. An undertaking in a dominant position cannot

“performance-based”, pursuing the undertaking’s legitimate commercial interests, to the benefit of consumers.<sup>261</sup> The European Commission defines competition on the merits as “*competition on product quality, strength of the patented technologies and similar.*”<sup>262</sup> As explained by the Court of Justice:

*“The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.”*<sup>263</sup>

The illegality of a conduct under Article 102 TFEU is unrelated to its compliance or non-compliance with other legal rules. Indeed, in the majority of cases, abuses of dominant positions consist of conducts otherwise (formally) lawful under branches of law other than antitrust.<sup>264</sup>

As far as intent goes, although not necessary for the purposes of identifying an abuse of dominant position, it constitutes a relevant factor in the Commission’s analysis<sup>265</sup> to

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*have recourse to means other than those within the scope of competition on the merits (Irish Sugar v Commission, cited at paragraph 54 above, paragraph 111).”* (General Court, T-203/01, Michelin, 30 September 2003, par. 97)

<sup>261</sup> See C. Osti, What Is in a Name: The Concept of Abuse in Sui Generis Abuse, in G. Muscolo, G. Pitruzzella, (eds.) Competition and Patent Law in the Pharmaceutical Sector. An International Perspective, Kluwer, 2016, p. 96 (“Often the Court couples [competition on the merits] with the one of ‘competition based on performance’, a clear reference to the German theory of *Leistungswettbewerb* (literally, performance competition)(See, e.g., Case C-280/08 P, Deutsche Telekom AG v. European Commission and others[2010] ECR I-9555, paras 174-177) Such theory was developed with reference to unfair competition law (a not insignificant detail, as we shall see), in order to distinguish ‘fair’ from ‘unfair’ competitive conduct. Conduct (or competition) based on performance was considered such as to allow a firm to prevail on a competitor (possibly, even to eliminate it from the market) as a result of a choice made by the customer, who considered that the products or services offered by such competitor would be superior in quality, or in price, etc. Contrast this with conduct based on ‘impediment’, where, e.g., the competitor would be falsely denigrated, or boycotted, or its products or brand slavishly imitated, its merits appropriated, etc. (H.C. Nipperdey, *Wettbewerb und Existenzvernichtung. Eine Grundfrage des Wettbewerbsrechts* (Heymann, Berlin, 1930), see in particular, 19)”)

<sup>262</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2766.

<sup>263</sup> Court of Justice, 85/76, Hoffmann-La Roche, 13 February 1979, par. 91. See also Court of Justice, 322/81, Michelin, 9 November 1983, par. 70 (“Article [102] covers practices which are likely to affect the structure of a market where, as a direct result of the presence of the undertaking in question, competition has already been weakened and which, through recourse to methods different from those governing normal competition in products or services based on traders’ performance, have the effect of hindering the maintenance or development of the level of competition still existing on the market.”) and Court of Justice, C-27/76, United Brands, 14 February 1978, par. 249 (“It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.”) More recently, see Court of Justice, C-209/10, Post Danmark, 27 March 2012, paras. 22-24 (“Competition on the merits may, by definition, lead to the departure from the market or the marginalisation of competitors that are less efficient and so less attractive to consumers from the point of view of, among other things, price, choice, quality or innovation. [...] Article [102 TFEU] applies, in particular, to the conduct of a dominant undertaking that, through recourse to methods different from those governing normal competition on the basis of the performance of commercial operators, has the effect, to the detriment of consumers, of hindering the maintenance of the degree of competition existing in the market or the growth of that competition”).

<sup>264</sup> Court of Justice, C-457/10 P, AstraZeneca, 6 December 2012, par. 132.

<sup>265</sup> General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 359 (“although

determine whether a conduct has an abusive nature. In its Guidance paper on Article 102 TFEU,<sup>266</sup> the European Commission lists among the factors generally relevant to assess whether the allegedly abusive conduct is likely to lead to anti-competitive foreclosure, “*internal documents which contain direct evidence of a strategy to exclude competitors, such as a detailed plan to engage in certain conduct in order to exclude a competitor, to prevent entry or to pre-empt the emergence of a market [...] Such direct evidence may be helpful in interpreting the dominant undertaking’s conduct.*”<sup>267</sup> Evidence of an exclusionary strategy can thus support the finding of an abuse, but it cannot serve as a conclusive factor. Intent is an important element to cross check the conduct, and verify whether it represents competition on the merits, but elements to “objectify” the conduct need to be present as well.<sup>268</sup>

As to the effects of the conduct, the Court of Justice explicitly stated: “*although the*

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*proof of the deliberate nature of conduct liable to deceive the public authorities is not necessary for the purposes of identifying an abuse of a dominant position, intention none the less also constitutes a relevant factor which may, should the case arise, be taken into consideration by the Commission. The fact, relied upon by the applicants, that the concept of abuse of a dominant position is an objective concept and implies no intention to cause harm [...] does not lead to the conclusion that the intention to resort to practices falling outside the scope of competition on the merits is in all events irrelevant, since that intention can still be taken into account to support the conclusion that the undertaking concerned abused a dominant position, even if that conclusion should primarily be based on an objective finding that the abusive conduct actually took place.”)*

<sup>266</sup> Communication from the Commission – Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, 2009/C 45/02, 24 February 2009, par. 20.

<sup>267</sup> In the specific case of creation of patent clusters, the purpose for which the application was filed is a relevant element for identifying whether the patent strategy can be construed as competition on the merits or not. “[B]oth patent clusters and divisionals seemingly serve to prevent or delay generic entry. While this, during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters. (During the public consultation the EPO has rightly pointed out that the purpose for which an application has been filed is not relevant to the decision-making process within the European patent system and that this should remain so. The EPO would have neither a mandate nor the resources to analyse such intentions. It goes however, without saying that the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments.)” (European Commission, Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, par. 523)

<sup>268</sup> The finding of an anticompetitive intent will often be objective as well, inferred from the objective characteristics of the undertaking, its conduct and effect, the market structure, and the absence of (credible) pro-competitive reason for the adoption of an exclusionary (or exploitative) behavior (on this last point, see M.A. Carrier, N.L. Levidow, A.S. Kesselheim, Using Antitrust Law to Challenge Turing’s Daraprim Price Increase, 31 Berkeley Technology Law Journal, forthcoming 2016, p. 11, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2724604](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2724604), accessed on 6 August 2016, “The Court found that the monopolist was guilty of anticompetitive conduct because it was willing to forego ticket sales and sacrifice profits to harm its smaller competitor. ([Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S., 1995.] at 608) As applied by commentators, this profit-sacrifice test offers a defendant-friendly approach that only punishes activity that has no justifiable reason other than harming competitors. (E.g., A. Douglas Melamed, Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?, 73 ANTITRUST L.J. 375, 392 (2006) (“anticompetitive intent” of firm willing to sacrifice profits can be “unambiguously inferred”); Gregory J. Werden, Identifying Exclusionary Conduct Under Section 2: The “No Economic Sense” Test, 73 ANTITRUST L.J. 413, 415 (2006) (the test’s application “could not be simpler if . . . the conduct cannot possibly confer an economic benefit on the defendant other than by eliminating competition”); Steve Shadown et al., Anticompetitive Product Changes in the Pharmaceutical Industry, 41 RUTGERS L.J. 1, 75-76 (2009) (profit sacrifice leads to natural inference that actor “was aware of and motivated solely to achieve that reduction”).”)

*practice of an undertaking in a dominant position cannot be characterised as abusive in the absence of any anti-competitive effect on the market, such an effect does not necessarily have to be concrete, and it is sufficient to demonstrate that there is a potential anti-competitive effect*<sup>269</sup> Although not excluding the necessity to demonstrate anticompetitive effects, the Court only requires the Commission to demonstrate that the conduct concerned is capable of having anticompetitive effects.<sup>270</sup> The analysis of anticompetitiveness of the conduct is *ex ante*, on the basis of the situation at the time when the conduct was undertaken.<sup>271</sup>

Exactly as in the U.S., also in the EU the dominant undertaking whose conduct is under scrutiny can provide justification for its conduct by demonstrating either that the conduct was objectively necessary, or that the exclusionary effect might be counterbalanced, or outweighed, by “*advantages in terms of efficiency that also benefit consumers*”<sup>272</sup>

### 8.3. Market Definition in the Pharmaceutical Industry

As seen, to be held liable for monopolization or abuse of dominance, the investigated firm has to possess a certain degree of market power. The first element to take into consideration in establishing market power is the definition of the market in which the firm is active.<sup>273</sup> The topic is of particular relevance for this work due to the fact that market definition is specific to each industry and often, in the pharmaceutical industry in particular, defining a broader or narrower market is what distinguishes dominance (or even monopoly) from effective competition.

The main purpose of market definition is to identify products regarded as substitutable by consumers, by reason of their characteristics, prices and intended use, and

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<sup>269</sup> Court of Justice, C-457/10 P, AstraZeneca, 6 December 2012, par. 112. See also Court of Justice, C-52/09, Konkurrensverket v TeliaSonera, 17 February 2011, par. 64.

<sup>270</sup> This does not mean that the European Commission is free to assert potential effects in any case. As explained by Advocate General Mazak, “[i]t must [...] be demonstrated that it is plausible that the practice harms or will harm competition. Abstract, purely hypothetical or remote assertions or theories of harm, which are not linked to the specificities of the case at hand, will thus not suffice.” (Opinion of Advocate General Mazak, C-457/10 P, AstraZeneca, par. 63).

<sup>271</sup> Court of Justice, C-457/10 P, AstraZeneca, 6 December 2012, par. 110. As explained by the European Commission, “[t]he assessment thus not only looks at what existed at the time of the acquisition but also takes into account what could reasonably be expected” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2812).

<sup>272</sup> Court of Justice, C-209/10, Post Danmark, 27 March 2012, paras. 41-42 (“[I]t is for the dominant undertaking to show that the efficiency gains likely to result from the conduct under consideration counteract any likely negative effects on competition and consumer welfare in the affected markets, that those gains have been, or are likely to be, brought about as a result of that conduct, that such conduct is necessary for the achievement of those gains in efficiency and that it does not eliminate effective competition, by removing all or most existing sources of actual or potential competition.”)

<sup>273</sup> Both in the U.S. and in the EU, market definition has a product and a geographic element. The European Commission has invariably found pharmaceutical markets to be national in scope due to a number of factors: “*different price and reimbursement rules [...], differences between national rules on incentives for cheaper generic [...], as well as different brand and packing strategies [...], different distribution and certain, however in the present case minor, differences in prescribing habits of doctors*”. (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2547) Although drugs and pharmaceutical companies are substantially identical throughout the EU, the pharmaceuticals markets remain fragmented along national borders. This is true both looking at the largely national (though harmonized) patenting regimes as well as at the pricing and reimbursement levels.

thus the competitive constraints faced by the undertaking.<sup>274</sup> Product market definition relies primarily on demand-side substitutability, *i.e.* on the identification of the products customers see as substitutes for that of the company under scrutiny.<sup>275</sup> To measure demand-side substitutability, reference is usually made to the SSNIP (Small but Significant Nontransitory Increase in Price) test.<sup>276</sup> If a 5 to 10% increase in price would lead a significant portion of customers switching to the lower-priced product, the products can be considered in competition between each other. The presence of the other product in the market acts as a constraint on the ability of the manufacturer of the first product to profitably raise prices, since a price increase would cause consumers to stop buying its product and switch to its competitor's. If this is the case, both products should be included in the same relevant market.<sup>277</sup> In the specific case of pharmaceuticals, when drugs “*can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated*”.<sup>278</sup> In addition, the market functioning needs to be taken into account in defining the relevant market. Most of the prescription drugs are indeed covered by either public or private health insurance, which provides financial protection to consumers and makes their demand inelastic. Insensitivity to increases in prices creates incentives for originators to charge much higher prices than they would on the sole basis of patent exclusivity. Another factor contributing to the general inelasticity of demand (and thus to a rather narrow market definition, often coinciding with the single drug on which the patent

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<sup>274</sup> According to settled case law, “*it is necessary first to define the products which, although not capable of being substituted for other products, are sufficiently interchangeable with its products, not only in terms of the objective characteristics of those products, by virtue of which they are particularly suitable for satisfying constant needs, but also in terms of the competitive conditions and the structure of supply and demand on the market*” (General Court, T-83/91, Tetra Pak, 6 October 1994, par. 63). See also General Court, T-504/93, Tiercé Ladbroke v Commission, 12 June 1997, par. 81. In this regards, the European Commission noted, “[h]owever, functional interchangeability and similarity in characteristics are insufficient to determine whether two products are demand substitutes, because the responsiveness of customers to changes in price is also determined by how customers value different characteristics. It must be recalled that the relevant market is not determined on the basis that certain products competed against each other in a broad sense but on the basis of whether such products were sufficiently substitutable to significantly constrain each other's market power, in particular as regards pricing. Moreover, a properly defined market does not need to include all functionally interchangeable products, as such interchangeability between products normally only defines the outer boundaries of a product market but may not be a decisive criterion. [...] A relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2417)

<sup>275</sup> The Court of Justice stated that: “*It is settled case law that, for the purposes of applying Article [102] of the Treaty, the market for the product or service in question comprises all the products or services which in view of their characteristics are particularly suited to satisfy constant needs and are only to a limited extent interchangeable with other products or services*”. (C-7/97, Oscar Bronner, 26 November 1998, par. 33) See also Commission Notice on the definition of relevant market for the purposes of Community competition law, 97/C 372/03, paras. 13 ff.

<sup>276</sup> The SSNIP test measures the elasticity of demand, *i.e.* the way the market responds to changes in price. If a small but significant increase in price triggers a significant reduction in demand, demand for the product is said to be elastic.

<sup>277</sup> The type of evidence relevant to assess whether two products are demand substitutes includes: “*evidence of substitution in the recent past*”. When available, “*this sort of information will normally be fundamental for market definition. If there have been changes in relative prices in the past (all else being equal), the reactions in terms of quantities demanded will be determinant in establishing substitutability*.” (Commission Notice on the definition of relevant market for the purposes of Community competition law, 97/C 372/03, par. 38)

<sup>278</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2417.

grants a monopoly) is the fact that the choice of which (prescribed) drug to buy is not taken by the ultimate consumer (the patient, who lacks the necessary medical expertise to determine the appropriate treatment) or the insurer/State (either, or both, potentially sensitive to increases in prices) but by doctors, who may not know, or care about, the price of the prescribed drug and generally have no incentive to take drug prices into account.<sup>279</sup> The doctors' experience in prescribing a specific drug with good results and their knowledge of drugs, heavily influenced by originators through literature, seminars and continuing medical education programs, as well as marketing efforts (including samples, mailing, detailing), plays a role in narrowing down the number of drugs that each doctor is ready to prescribe to his patients, and therefore the drugs actually competing in the relevant market. Once the doctor has become familiar with the brand-name drug, due to brand loyalty, risk aversion or else he will be likely to keep on prescribing it by name, even following patent expiration and generics entry (of which the doctor might not even be aware).<sup>280</sup> This well-known phenomenon is often referred to as "doctors' inertia".<sup>281</sup>

To define the relevant product market in the pharmaceutical sector, the European Commission has strongly relied in its merger control practice on the Anatomical Therapeutic Chemical Classification ("ATC"), devised by the European Pharmaceutical Marketing Research Association. The third level of the ATC classification, referred to as ATC3, which groups medicines that have the same therapeutic indication(s) (*i.e.* the same intended medical use), has been generally taken as a starting point for the selection of candidate products. However, under specific circumstances, the Commission found it more appropriate to look also at ATC4 or the molecule level.<sup>282</sup> To define the relevant market in each specific case, the

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<sup>279</sup> "Physician agency for patients in deciding whether/which drugs to prescribe tends to make demand more inelastic, because physicians are unaware of drug prices, and such price-insensitivity is rational if the patient-principals are also price-insensitive due to insurance. Given the high margin of price over marginal cost for originator drugs, originator manufacturers invest heavily in promotion to physicians. This promotion focuses solely on brand and clinical benefits of the drug, not the price, and the same is true of direct-to-consumer advertising in the US. The fact that promotion is often more important than price in determining market shares, because consumer demand is price-insensitive due to insurance, is important for antitrust approaches to market definition that rely on price elasticity." (P.M. Danzon, Competition and Antitrust Issues in the Pharmaceutical Industry, on file with the author, p. 11) The U.S. FTC explained: "[t]he basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescription". (FTC, Bureau of Consumer Protection, Drug Product Selection, January 1979, pp. 2-3, available at <https://babel.hathitrust.org/cgi/pt?id=mdp.39015008517792>, accessed on 6 August 2016)

<sup>280</sup> D.A. Lundin, Moral Hazard in Physician Prescription Behavior, 19(5) Journal of Health Economics, 2000, p. 639 ff.

<sup>281</sup> The General Court referred to "the specific features of the markets for pharmaceutical products, which are characterised by 'inertia' on the part of prescribing doctors" (General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 278). In the *Servier* case, the European Commission notes: "In the case of perindopril, decreases in the prices of other medicines that may have well been intended for the same use did not negatively affect the sales of perindopril. The reasons for this are the doctors' general disregard towards prices and the price rigidities induced by regulatory frameworks. Prices still mattered, sometimes because of incentives being gradually built in for doctors to prescribe cheaper medicines and sometimes because of payments by patients, however, not to a sufficient extent. Perindopril was virtually immune to changes in relative prices. There were also no other means to adequately replace competition in prices. Once the continued-use patients were known to dominate the patient base, and the doctors' inertia was established, other forms of competition, such as promotional efforts, could have, at best, a limited impact on the existing sales of perindopril." (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2544)

<sup>282</sup> European Commission, COMP/M.5661, Abbott/Solvay Pharmaceuticals, 2

Commission thus uses the ATC level as a starting point but takes also into account “*the case-specific evidence relating to the relative strength of the intra-class constraints faced by [the drug][...]. As a matter of principle, if constraints from other products are gauged insufficient, those other products cannot belong to the same relevant market.*”<sup>283</sup>

When the patentee’s conduct is aimed at blocking or delaying generic entry, the competitive constrain coming from generics is central in the relevant product market definition. The fact that “*the generic constraint outweighs by an order of magnitude all other potential constraints [would] naturally [lead] to the finding of a narrow market comprising only the medicine in question.*”<sup>284</sup>

#### 8.4. Market Power

As anticipated, market definition aims at determining whether the undertaking holds a position of market power, relevant for the application of antitrust rules to unilateral conducts. At the EU level, dominance (threshold for the application of Article 102 TFEU) has been defined as “*a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.*”<sup>285</sup>

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November 2010, paras. 8-9. The General Court recognized that taking into account the ATC level is only a preliminary step in the Commission’s analysis (General Court, T-321/05, AstraZeneca, 1 July 2010, paras. 154-155).

<sup>283</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, footnote 3215. In the recent *Servier* case, the Commission noted: “*certain functional similarities are not sufficient to establish that [...] other medicines represented sufficiently close substitutes to constrain [the originator’s] behavior. [...] [F]or any new patient, only an initially unknown subset of available medicines will be compatible. As soon as it is discovered that a given medicine alone, or in combination, adequately treats the patient’s condition without side effects, the doctor is unlikely to risk provoking side-effects by deciding to switch this patient to another treatment. A doctor would be unlikely to risk her patient’s well-being for a few euros of savings in the monthly treatment cost. [...] The health risks related to switching of successfully treated patients will generally lead to a relatively low propensity to switch for so-called continued-use patients. For first time patients, [...] [t]he doctors are surely aware of the broad choice of therapies, but they naturally tend to prescribe new patients with the medicines which have shown to be good for their previous patients. This well-known phenomenon is often referred to as “the doctors’ inertia”. The degree of substitutability of a given molecule with other molecules will therefore depend, among other things, on the degree of doctors’ inertia and on the relative proportion of continued-use patients out of all patients treated with a given medicine. [...] The combination of the aforementioned factors, the ex ante uncertain effects of treatments and the doctors’ personal experience, effectively [restrict] the substitutability between available therapies.*” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 1230-1235)

<sup>284</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1240.

<sup>285</sup> Court of Justice, C-27/76, United Brands, 14 February 1978, par. 65. See also Communication from the Commission – Guidance on the Commission’s enforcement priorities in applying Article 82 to abusive exclusionary conduct by dominant undertakings, 2009/C 45/02, 24 February 2009, par. 8. As noted by Professor Ullrich, “*All in all, it has to be determined whether a firm’s conduct is sufficiently controlled by competition or needs to be controlled by law.*” (H. Ullrich, Mandatory Licensing Under Patent Law and Competition Law: Different Concerns, Complementary Roles, in R.M. Hilty, K.-C. Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward*, Springer, 2014, p. 361) See also E. Arezzo, Intellectual Property Rights at the Crossroad between Monopolization and Abuse of Dominant Position: American and European Approaches Compared, 24(3) *John Marshall Journal of Computer and Information Law*, 2006, pp. 490-491. The European Commission further explained that “[s]uch a position does not preclude some competition but enables the undertaking which profits from it, if not to determine, at least to have an appreciable influence on the conditions under which competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment. The notion of

In the U.S., the Supreme Court defined monopoly power (threshold for the application of Section 2 of the Sherman Act) as “*the power to control prices or exclude competition.*”<sup>286</sup> DOJ and FTC explained that: “[m]arket power is the ability profitably to maintain prices above, or output below, competitive levels for a significant period of time.”<sup>287</sup>

Market power can be proven directly by demonstrating that the originator has the ability to “*maintain the price of [the brand-name drug] at supracompetitive levels without losing substantial sales*”,<sup>288</sup> or indirectly, by referring to the originator’s market share. While not definitive in itself to assert dominance, market share represents a useful first indication of the market structure and of the undertakings’ relative position. In the European Commission’s practice, “*market shares of more than 50% constitute very large market shares and are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position, and that market shares of between 70% and 80% are a clear indication of the existence of a dominant position.*”<sup>289</sup> Market shares are used as a proxy also in the U.S.<sup>290</sup> As far as percentages go, in the U.S. as well courts have not drawn a bright-line for determining the market share sufficient to infer monopoly power. Reference is usually made to Judge Hand’s decision in *Alcoa* where he suggested 90% as the threshold for certain dominance, doubtful above 60% and certainly excluded below 33%.<sup>291</sup> Several U.S. courts found 75% to be sufficient.<sup>292</sup>

In some cases the product market can be defined so narrowly that it coincides with the patented product. Being a “one-product” market, a finding of dominance is rather obvious. Once the market is narrowly defined, the conclusion that a (strong) patent confers significant market power to its holder tends to follow inevitably. In such a situation, the assessment of dominance is pre-determined by the definition of the relevant market and mere ownership of a patent may be sufficient to confer dominance. This is however an exception (although quite common in the pharmaceutical industry) and holding a patent does not necessarily confer market power in the antitrust sense.<sup>293</sup> Patent holders have to compete on

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*independence which is the special feature of dominance is related to the level of competitive constraints facing the undertaking in question. Such power may involve the ability to eliminate or seriously weaken existing competition or to create barriers to entry for potential competitors.”* (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2552)

<sup>286</sup> United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 76 S.Ct. 994, 1956, p. 391.

<sup>287</sup> U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, 6 April 1995, par. 2.2. See also *In Ball Memorial Hospital, Inc. v. Mutual Hospital Insurance, Inc.*, 784 F.2d, 7th Cir., 1986, p. 1335, market power was defined as “*the ability to cut back the market’s total output and so raise price*”.

<sup>288</sup> *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, D. Mass., 2013. See also *In re Aggrenox Antitrust Litig.*, 94 F.Supp.3d, D.Conn., 2015.

<sup>289</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2561.

<sup>290</sup> See *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d, 2d Cir. 2004, p. 500 (monopoly power can be “*inferred from a firm’s large percentage share of the relevant market*”).

<sup>291</sup> *United States v. Alcoa*, 148 F.2d 416, 2d Cir., 1945.

<sup>292</sup> H.J. Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, West, 2016, p. 357.

<sup>293</sup> In the EU this principle has been recognized long ago. See Court of Justice, C-241/91 P and C-242/91 P, RTE and ITP (“Magill”), 6 April 1995, par. 46 (“*So far as dominant position is concerned, it is to be remembered at the outset that mere ownership of an intellectual property right cannot confer such a position.*”). See also Court of Justice, C-457/10 P, *AstraZeneca*, 6 December 2012, par. 186 (“*although the mere possession of intellectual property rights cannot be considered to confer such a position, their possession is none the less capable, in certain circumstances, of creating a dominant position, in particular by enabling an undertaking to*

the market with providers of products or technology that (do not imitate but) can substitute their patented ones (competition by innovation).<sup>294</sup> The degree of market power granted by a patent is thus inversely proportioned to the number of existing substitutes for the product. In a one-product market, the number of (successful) substitutes is the lowest possible (zero; this is the case when no other cure exists to treat a certain disease) and the market power is at the highest level (monopoly, protected from imitation by the patent). Increasing the number of substitutes decreases the degree of market power.<sup>295</sup> Therefore, as explained by Professor Ghidini,

*“[i]n a correct systemic perspective, patents’ institutional mission is to grant inventors a micro-monopoly (i.e., on the given specific technological solution they developed), not a macro-monopoly (on the industrial sector or niche to which that solution belongs). This assumption is backed by the indisputable principle that patents cannot prevent competitors from developing and marketing (and indeed patenting, if novel and inventive) any different competitive solution aimed at the same function: even if the first patented solution had happened to be, at the date of filing, the first and only to satisfy that specific function/usefulness.”*<sup>296</sup>

On the relevance of IP rights in assessing market dominance, patents are not the only to consider. Synergies between trademarks and patents, particularly in the pharmaceutical industry, should not be underestimated. As noted by Professor Ghidini, the commercial success and appeal of a trademark is *“enhanced by the exclusive presence of the product on the market for 20 years. Now the appeal acquired by such a trademark can prolong the ‘monopolistic’ effect of the patent, or rather the owner’s dominant position beyond the patent’s expiration (save for cases of vulgarization).*

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*prevent effective competition on the market”*). In the U.S. the presumption of market power was recently rejected by the Supreme Court in *Illinois Tool Works v. Independent Ink, Inc.*, 547 U.S., 2006, pp. 42-43. See also *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F.Supp.2d, N.D.Ill., 2003, p. 995 (*“patent confers a monopoly in the sense of a right to exclude others from selling the patented product. But if there are close substitutes for the patented product, the patent “monopoly” is not a monopoly in a sense relevant to antitrust law”*). Before, see U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, 6 April 1995, par. 2.2. (*“The Agencies will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner. Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power.”*)

<sup>294</sup> See J. Drexler, *The Relationship between the Legal Exclusivity and Economic Market Power: Links and Limits*, in I. Govaere, H. Ullrich (eds.), *Intellectual Property, Market Power and the Public Interest*, P.I.E. Peter Lang, 2008, p. 16: *“[I]ntellectual property rights only prevent competitors from imitating the subject matter of protection (“competition by imitation”). They do not exclude competitors from offering better products (“competition by substitution”). Hence, legal exclusivity by itself does not lead to an economic monopoly. [...] However, exclusivity may well produce such effects in specific cases, for instance as a consequence of the market circumstances”*.

<sup>295</sup> Although not necessarily decisive, patent rights have a very important role to play in determining market power and should always be part of the assessment. The General Court stated that *“[w]hen granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking’s ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right.”* (General Court, T-321/05, *AstraZeneca*, 1 July 2010, par. 362) The European Commission added, *“[t]he notion of barriers to entry does not require that barriers are absolute in order to include them in the assessment of dominance. The analysis of barriers to entry includes factors affecting timely and sufficient entry.”* (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2571)

<sup>296</sup> G. Ghidini, *The Bride and the Groom. On the Intersection between Intellectual Property and Antitrust Law*, in G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition Law and Intellectual Property: a European Perspective*, Kluwer, 2012, pp. 37-38.

*Opening the market to competitors does not prevent consumers, attached to the trademark which has accompanied the product for 20 years, from preferring to remain loyal to the latter, and thus from being locked-in even after the patent expires.*<sup>297</sup> The appeal acquired by a trademark on a blockbuster drug is further strengthened by the doctors' inertia discussed above. Without (generics and) rules on generic substitution, the risk of a monopoly of indefinite duration on the drug (and, if no alternative is found, on the cure) would be a real possibility.

Factors taken into account to establish dominance in the pharmaceutical industry are obviously market shares, but also barriers to entry in terms of R&D and regulatory cost, drug patent protection (number and type of patents, covering the compound, process, salts, crystalline form, etc., their strength and scope)<sup>298</sup> and the existence of other IP rights (such as a trademarks),<sup>299</sup> product differentiation and lack of effective substitutes for the patented drug, drug price above competitive level, lock-in effects (switching time, cost, and risk involved), doctors' inertia, price disconnect, and inelasticity of demand.<sup>300</sup>

## 9. Antitrust and IP: Friends or Foes?

Contrary to the analysis conducted with respect to patent law, the objective of antitrust law is not analyzed as a baseline to define its abuse. This chapter is focused on demonstrating that the objective of antitrust<sup>301</sup> does not clash with that of IP (and thus, to

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<sup>297</sup> G. Ghidini, *The Bride and the Groom. On the Intersection between Intellectual Property and Antitrust Law*, in G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition Law and Intellectual Property: a European Perspective*, Kluwer, 2012, pp. 41-42.

<sup>298</sup> See e.g. Court of Justice, C-457/10, *AstraZeneca*, 6 December 2012, par. 187 (“*Lossec, as the first PPI to be introduced on the market, enjoyed particularly strong patent protection, on the basis of which AZ brought a series of legal actions which enabled it to impose significant constraints on its competitors and to dictate to a large extent market-entry terms to them.*”)

<sup>299</sup> The European Commission notes: “*Indeed, an OECD report cites some evidence to the effect that, generally speaking, ‘intellectual property rights, in the form of patents and trademarks are relatively more important in the pharmaceutical industry than in other sectors’ and refers, in this connection, to ‘one survey of several industries which ranks the pharmaceutical industry the highest in its reliance on patent protection’. Similar rights derived from pharmaceutical law also effectively result in barriers to entry into the pharmaceutical sector. In particular, until the expiry of data exclusivity applications for market authorisation need to rely on costly and lengthy preclinical and clinical trials. In addition, one study of pharmaceutical firms’ decisions to launch new pharmaceutical products in a large number of OECD countries identifies national market authorisation and price approval rules and bodies as barriers to entry. Such rules, many of which remain national, entail costs and often long delays before a pharmaceutical product can be actually marketed*” (European Commission, COMP/A.37507/F3, *AstraZeneca*, 15 June 2005, par. 518).

<sup>300</sup> The Commission listed almost all of these factors in European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2405 (“*(a) active product differentiation, (b) perindopril being an experience good, (c) presence of the lock-in effects with respect to the bulk of perindopril prescriptions, (d) presence of loyal prescribers, (e) general price insensitivity observed with respect to both the prescribers and the patients, and (f) the regulatory frameworks that shielded Servier’s perindopril from price constraints from other molecules. Cumulatively all those elements enabled Servier to operate on the market for perindopril in a largely unconstrained manner.*”)

<sup>301</sup> As clearly put by the U.S. Seventh Circuit, “[i]f no consumer interest can be discerned even remotely in a suit brought by a competitor—if [...] a victory [...] can confer no benefit, certain or probable, present or future, on consumers—a court is entitled to question whether a violation of antitrust law is being charged.” (*Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d, 7th Cir., 1984, pp. 266–67) Even the three dissenting judges in *Actavis* acknowledged that “*the point of antitrust law is to encourage competitive markets to promote consumer welfare.*” (*FTC v. Actavis, Inc.* 133 S.Ct., 2013, par. 2238) See also Court of Justice, C-52/09, *TeliaSonera Sverige*, 17 February 2011, par. 22 (“*The function of [competition] rules is [...] to prevent competition from being distorted to the detriment of the public interest, individual undertakings and consumers, thereby*

realize one, the other does not need to be at least partially sacrificed). As this work aims to show, the objectives coincide on the maximization of consumer welfare in the long run, by promoting competition on the merits and innovation.<sup>302</sup> What differs between the two disciplines are the means to achieve the common objective – IP and Antitrust are thus convergent in objectives and complementary in means.<sup>303</sup>

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ensuring the well-being of the European Union”).

<sup>302</sup> “The ultimate goal of the competition rules is simple: to ensure that consumers benefit from new and improved products and lower prices.” (M. Monti, Competition and Information Technologies, Brussels, 18 September 2000, p. 2, available at [http://europa.eu/rapid/press-release\\_SPEECH-00-315\\_en.htm?locale=en](http://europa.eu/rapid/press-release_SPEECH-00-315_en.htm?locale=en), accessed on 6 August 2016) See also I. Lianos, Competition law, intellectual property rights and dynamic analysis: towards a new institutional “equilibrium?”, *Concurrences*, 2013, par. 8 (“Although there is some disagreement over the adequate methodologies to be followed for the incorporation of innovation and “dynamic competition” in competition law analysis, most competition scholars would agree that competition law should not only focus on static welfare effects and that it should also take a more dynamic approach.”); and J. Drexler, *Research Handbook on Intellectual Property and Competition Law*, Edward Elgar, 2008, p. 4 (“[w]hereas in the past intellectual property and competition were mostly considered as contradictory concepts, it is today widely admitted that both fields of law, [...] are meant to promote complementary goals, namely innovation based on dynamic concepts of competition”). In the U.S.; see C.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1267 (“Like patent policy, antitrust law attempts to strike the proper balance between under and over-enforcement. Overly aggressive antitrust enforcement could chill innovation. In addition to affirmatively trying to encourage innovation, antitrust policy avoids pursuing competition in a manner that unnecessarily stifles innovation.”); and T. Cheng, *Putting Innovation Incentives Back in the Patent-Antitrust Interface*, 11(5) *Northwestern Journal of Technology and Intellectual Property*, 2013, p. 390 (“Consumer welfare is enhanced when consumers are able to obtain the same good at a lower price or obtain a higher-quality good at the same price. Consumer welfare is also improved when consumer choice is widened. In economic parlance, antitrust is principally concerned with static efficiency – the allocation of goods and services over the short run. Dynamic efficiency, which refers to the ability of a market or an economy to produce innovation, is also important to antitrust. [...] Like patent law, antitrust is concerned with dynamic efficiency. This concern is motivated by the fact that in the long run, the greatest enhancement to consumer welfare comes not from lower prices obtained from static competition, but from the emergence of new technology and new products.”) In the economic literature, see L. Battaglia, P. Larouche, and M. Negrinotti, *Does Europe have an Innovation Policy? The Case of EU Economic Law*, Discussion Paper No. 8481, Centre for Economic Policy Research, July 2011, p. 22 (“[G]eneric competition is viewed as being an essential source of pressure to drive originators back to competition in innovation post-patent lapse. [...] [A]ctions which interfere with the standard model of upfront patent protection for novel medicines followed by vigorous competition by generics post-patent lapse to drive prices down, will be viewed with a healthy dose of skepticism.”); and C. Shapiro, *Antitrust, Innovation, and Intellectual Property*. Testimony Before the Antitrust Modernization Commission, 8 November 2005. Available at <http://faculty.haas.berkeley.edu/shapiro/amcinnovation.pdf>, accessed on 6 August 2016.

<sup>303</sup> See *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d, Fed. Cir., 1990, p. 1576 (“[T]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.”) and *Intergraph Corp. v. Intel Corp.*, 195 F.3d, Fed. Cir., 1999, p. 1362 (“The patent and antitrust laws are complementary, the patent system serving to encourage invention and the bringing of new products to market by adjusting investment-based risk, and the antitrust laws serving to foster industrial competition.”). See also U.S. Department of Justice and Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights. Promoting Innovation and Competition*, April 2007, pp. 1-2 (“Over the past several decades, antitrust enforcers and the courts have come to recognize that intellectual property laws and antitrust laws share the same fundamental goals of enhancing consumer welfare and promoting innovation. [...] Modern understanding of these two disciplines is that intellectual property and antitrust laws work in tandem to bring new and better technologies, products, and services to consumers at lower prices. [...] [A]ntitrust and intellectual property are properly perceived as complementary bodies of law that work together to bring innovation to consumers: antitrust laws protect robust competition in the marketplace, while intellectual property laws protect the ability to earn a return on the investments

*“At the highest level of analysis IPR and competition law are complementary because they both aim at promoting consumer welfare. The objective of IPR laws is to promote technical progress to the ultimate benefit of the consumers. This is done by striking the right balance between over- and under-protection of innovators’ efforts. The aim is not to promote the individual innovator’s welfare. The property right provided by IPR laws is awarded to try to ensure a sufficient reward for the innovator to elicit its creative or inventive effort while not delaying follow-on innovation or leading to unnecessary long periods of high prices for the consumers. [...] Competition policy aims at promoting consumer welfare by protecting competition as the driving force of efficient markets, providing the best quality products at the lowest prices. The relevant question is therefore not one of conflict but of complementarity and possibly adjustment in the individual case. To what extent should competition policy intervene and try to improve the balance produced by IPR law [...] There is [...] agreement that competition policy has to play its normal role where IPR rights are used to produce an anti-competitive effect beyond the exploitation of the IPR rights. [...] There is also general agreement that in such cases competition policy must take account of specific IPR characteristics in order to properly protect dynamic efficiency.”<sup>304</sup>*

The European Commission guidelines on the application of Article 101 to technology transfer agreements seem to be inspired by this same principle of complementarity.

*“The fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention. [...] Nor does it imply that there is an inherent conflict between intellectual property rights and the Union competition rules. Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation*

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*necessary to innovate. Both spur competition among rivals to be the first to enter the marketplace with a desirable technology, product, or service.”); and H.J. Hovenkamp, Antitrust and the Patent System. A Reexamination, 76(3) Ohio State Law Journal, 2015, p. 471 (“Both antitrust policy and patent policy are properly concerned with economic welfare, although the concerns are articulated more clearly in antitrust than in patent law. At the atmospheric level, antitrust focuses on the short run, including such things as immediate pricing and output, while patent law is concerned with long run issues relating to innovation. But upon inspection this dichotomy quickly breaks down. In fact, antitrust policy has always been concerned with performance over both the short and long runs and often considers effects on innovation.”)*

<sup>304</sup> European Commission evaluation report on the transfer of technology block exemption regulation N° 240/96, Technology transfer agreements under article 81, /\* COM/2001/0786 final \*/ , paras. 29-34. See also the U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, 6 April 1995, par. 1 (an update of the antitrust guidelines is currently under discussion, but this provision was not subject to any revision, see <https://www.ftc.gov/reports/antitrust-guidelines-licensing-intellectual-property-proposed-update-1995-guidelines-issued>, accessed on 19 August 2016)(“*The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare. The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without compensation. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers. The antitrust laws promote innovation and consumer welfare by prohibiting certain actions that may harm competition with respect to either existing or new ways of serving consumers.*”)

thereof.”<sup>305</sup>

From this it follows that competition authorities can and should intervene only when the conduct of a patentee is likely to deter consumer welfare (*i.e.* when the patent-related conduct is also contrary to the purpose patent law aims to achieve). Antitrust and patent laws thus complement and strengthen each other in the pursuit of the same objective. In the words of Professor Leslie,

*“Antitrust and patents are not merely complementary in that they pursue the goal of innovation; instead, they affirmatively depend on each other. Both are necessary; neither is sufficient. They are components of an overall innovation policy that maximizes both static and dynamic competition.”*<sup>306</sup>

Scenarios in which IP and antitrust are allegedly in tension are those in which the patentee’s conduct leads to less rather than more innovation, to the detriment of consumer welfare. In these cases, however, the conduct contrasts with the very aim of patent law as much as it does with antitrust.<sup>307</sup> In such cases, a limit to the rights alleged by the patentee is warranted to rectify, to the benefit of consumers, the imbalance that would otherwise result.<sup>308</sup> Antitrust complements patent law when IP rights are exercised to the detriment of consumer welfare. This is the position recently taken by the European Commission in the words of its Competition Commissioner Margrethe Vestager:

*“Without effective competition rules, there would be higher risks that today’s innovators might stifle those of tomorrow, or that consumers might not benefit from fair access to those innovations. Our*

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<sup>305</sup> European Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, 2014/C 89/03, 28 March 2014, par. 7.

<sup>306</sup> C.R. Leslie, Antitrust and Patent Law as Component Parts of Innovation Policy, 34(4) The Journal of Corporation Law, 2009, p. 1260.

<sup>307</sup> “As far as the patent-antitrust interface is concerned, the two paramount considerations for antitrust are the consumer harm resulting from restrictive patent exploitation practices and foreclosure of innovation opportunities by a dominant patentee against rival technology developers.” (I. Cheng, Putting Innovation Incentives Back in the Patent-Antitrust Interface, 11(5) Northwestern Journal of Technology and Intellectual Property, 2013, p. 391)

<sup>308</sup> “Defendants also argue that antitrust law is not a vehicle for enforcing the “spirit” of drug laws. Defs. Br. at 46. But the Supreme Court has made clear that “[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue.” *Trinko*, 540 U.S. at 411. Leading antitrust authorities have encouraged courts to acknowledge market defects, such as a price disconnect and the exclusivity of patents, in their antitrust analysis. And in other *Hatch-Waxman* contexts, this court has recognized that efforts to manipulate aspects of the *Hatch-Waxman* incentive structure to exclude competition could state an antitrust claim. See, e.g., *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 106 (2d Cir. 2010) [...] Therefore, we conclude that the district court appropriately considered the unique market characteristics of the pharmaceutical industry in concluding that antitrust law “requires [Defendants] to allow generic competitors a fair opportunity to compete using state substitution laws.” (*State of New York v. Actavis*, No. 14-4624, 2d Cir., 2015, pp. 46-47) *Standard Sanitary Mfg. Co. v. United States*, 226 U.S., 1912, p. 49 (“Rights conferred by patents are indeed very definite and extensive, but they do not give any more than other rights a universal license against positive prohibitions. The Sherman law is a limitation of rights -- rights which may be pushed to evil consequences, and therefore restrained.”) *FTC v. Actavis, Inc.*, 570 U.S., 2013, par. II.A ([R]ather than measure the length or amount of a restriction solely against the length of the patent’s term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents. See Part II–B, *infra*. Whether a particular restraint lies “beyond the limits of the patent monopoly” is a conclusion that flows from that analysis and not, as The Chief Justice suggests, its starting point.”)

*task in this regard is to find the right balance between the interests of distributors, artists, inventors and creators and the interests of consumers. [...] Competition policy should therefore work hand in hand with intellectual property policy to achieve common goals. [...] [They] must work hand in glove in order to promote economic growth while ensuring consumers gain access to a wide range of innovative and creative goods and services at reasonable prices.”*<sup>309</sup>

This is the so-called dialectical interplay between the two disciplines “*that works to eliminate situations which would obstruct both innovation and competitive dynamics*” – as noted by Professor Ghidini – “*Through such dialectical exchange, each discipline, by fulfilling its function, can also indirectly serve the aims of the other.*”<sup>310</sup> In the words of the former European Commissioner for Competition, Joaquim Almunia,

*“When addressing the role of competition policy in supporting innovation, one must deal with the seeming conflict between competition and the protection of intellectual property rights. In fact there is no such conflict. IPR policy and antitrust are complementary. Antitrust enforcement does not question the use of IPR but it must fight the abuse of IPR.”*<sup>311</sup>

In light of the above, the optimal level of intervention of antitrust authorities in case of patent-related conducts should be based on the maximization of consumer welfare from an innovation and competition perspective. To achieve this, competition law should aim at finding a balance between free competition and the provision of sufficient incentive for research and development. This balancing exercise should be carried out by determining whether the patent right has been exercised to pursue an aim falling outside of the essential function and purpose of patent law, the only potentially justifying encroachments on competition law.<sup>312</sup> In this analysis, the behavior of the patentee is an important indicator, thus intent can and should be taken into account in determining whether a patent-related conduct may be abusive. The conclusion reached so far is adequately summarized by the words of Professor Leslie: IP and antitrust “*are interdependent*”.

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<sup>309</sup> M. Vestager, Intellectual Property and Competition, 11 September 2015, available at [https://ec.europa.eu/commission/2014-2019/vestager/announcements/intellectual-property-and-competition\\_en](https://ec.europa.eu/commission/2014-2019/vestager/announcements/intellectual-property-and-competition_en), accessed on 6 August 2016.

<sup>310</sup> G. Ghidini, The Bride and the Groom. On the Intersection between Intellectual Property and Antitrust Law, in G. Caggiano, G. Muscolo, M. Tavassi (eds.), Competition Law and Intellectual Property: a European Perspective, Kluwer, 2012, pp. 28-29.

<sup>311</sup> J. Almunia, Competition Policy in Times of Restructuring, 22 June 2012, available at [http://europa.eu/rapid/press-release\\_SPEECH-12-487\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-12-487_en.htm), accessed on 6 August 2016. See also J. Almunia, Intellectual Property and Competition Policy, 9 December 2013, available at [http://europa.eu/rapid/press-release\\_SPEECH-13-1042\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-13-1042_en.htm), accessed on 6 August 2016 (“*In their different ways, both the patent system and the system that enforces competition law in the EU pursue common goals. A well-functioning IPR system can in fact promote competition by encouraging firms to invest in innovation. And both competition policy and the intellectual-property protection system do contribute to create the right framework for innovators. As a competition authority, we intervene only when the IP rights are abused or used as a cover-up for anti-competitive practices – which is clearly the exception, not the rule.*”)

<sup>312</sup> “*The Commission regards dynamic competition in R&D as an important mechanism of economic growth. This mechanism requires that the market power needed to attract innovation is restricted in time and in scope as foreseen in the applicable legislative framework. These restrictions are necessary in order to keep incentives for the undertaking enjoying temporary market power to further develop through genuine innovation and avoid being overtaken by competitors. Prohibition of the abuse of a dominant position is only aimed at the attempts of circumventing the existing restrictions of market power that originate from the mechanism of dynamic competition and not at its exercise in terms of collecting the economic rents during the legitimate period of legal protection.*” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2578)

*“On the one hand, antitrust law needs patent law to maximize innovation. Unrestricted competition creates insufficient incentives for innovation. Competitive markets without any protection for intellectual property would be less likely to see profit-maximizing firms investing in research that could easily be copied and used by competitors without restriction. Patent law also needs antitrust law in order to maximize innovation. In the same way that overly strong patent rights can reduce innovation, misconduct by patentees in procuring, enforcing, and using their patents can also be anticompetitive in a manner that stifles innovation. Yet the patent system is not designed to truly punish—let alone deter—patent abuses. Antitrust law is better equipped to punish and deter patent misconduct that may prove to reduce innovation.”*<sup>313</sup>

To reach the IP and antitrust’s common objective of enhancing consumer welfare, their enforcement needs to be coordinated so as to make sure that their means are not frustrated or weakened. To improve their interaction, antitrust enforcement should internalize IP values, such as the promotion of incentives to innovate. In the IP field, a rebirth (or resurrection) of the often forgotten doctrines of patent misuse and abuse of rights may help bring the patent’s purpose back at the center of attention and with it the enhancement of consumer welfare.<sup>314</sup>

## 10. Abuses: Introduction

In this and the following chapters we put the theory into practice. We saw in the introduction that IP is often more concerned about dynamic efficiency and antitrust about static efficiency. However, not only both regulations leave room to (or even explicitly pursue, or would be able to pursue) competition and innovation respectively, but dynamic and static efficiency are not necessarily at odds, and measures that foster one will often improve the other as well.<sup>315</sup>

Abusive behavior in the pharmaceutical industry has taken several different forms and have been scrutinized by authorities all over the world. It does not come as a surprise that most of the relevant cases concern unilateral practices by companies having a strong position

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<sup>313</sup> C.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1269.

<sup>314</sup> As noted by Professor Lianos, “[t]hese recommendations insist on the importance of trans-disciplinary links between IP and competition law and confirm the thesis that intellectual property and competition law have become or are in the process of becoming a “unified field.”” (I. Lianos, *Competition law, intellectual property rights and dynamic analysis: towards a new institutional “equilibrium?”*, *Concurrences*, 2013, par. 12, citing W.K. Tom, J.A. Newberg, *Antitrust and Intellectual Property: From Separate Spheres to Unified Field*, 66 *Antitrust Law Journal*, 1997)

<sup>315</sup> “What really matters in such cases is that markets remain contestable in terms of firms having both the ability and the incentive to innovate. [...] [T]he vast majority of abuse of dominance cases in Europe relate to exclusionary abuses. By definition, these have adverse effects on dynamic efficiency. Cartels are another area where there is not a trade-off. Cartels are generally set up in relatively tight oligopolies. By ensuring that all the firms in the cartel have a stake in the status quo, they are likely to undermine incentives to innovate” (T. Curzon Price, M. Walker, *Incentives to Innovate v Short-term Price Effects in Antitrust Analysis*, *Journal of European Competition Law & Practice*, 2016, pp. 6-7, who continues, “[s]ome mergers can harm both static and dynamic efficiency. For instance, mergers where a large incumbent buys a small recent entrant might reduce static efficiency but might also be aimed at removing the dynamic threat offered by the new entrant [...]. More directly, mergers involving firms that compete in innovation may have both static and dynamic adverse effects. For example, pre-merger, firms may have incentives to try to enter each other’s markets with innovations, while post-merger, cannibalisation of revenue streams might dampen such innovative efforts.”)

in their relevant market. These conducts fit under the so-called “product lifecycle management”, strategies aimed at delaying, preventing, foreclosing, or rendering ineffective generic competition (by increasing the uncertainty, the cost or the hurdles faced by generic companies), and thus extend the period of exclusivity as much as possible.

The conducts scrutinized include filing multiple patents on variants of the same drug (patent clusters or thickets), starting baseless litigation to delay or prevent generic entry (sham litigation), withdrawing the first-generation drug from the market to switch patients to a new, patent-protected, version (product hopping), denigrating generics, providing misleading information to the patent office, and paying generics to stay out of the market (pay for delay patent settlements). Excessive pricing, an exploitative abuse, prohibited in the EU (and at the Member States level) but not in the U.S., will be analyzed as well.

## 11. Patent Clusters and Acquisition of Competing Patents

The first abuse analyzed directly relates to the functioning of the patent system and patent’s quality.<sup>316</sup> In light of the indulgent approach of most patent offices in verifying the respect of the patentability requirements, originators often file a multitude of patent applications (including divisional),<sup>317</sup> on manufacturing process, reformulations, dosage

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<sup>316</sup> The idea that too many patents with insignificant value are awarded is more than a century old. Already in the late 1800s, David Brewer, Supreme Court Justice, suggested that patents were far too many, many of which with no value. (D.J. Brewer, *The Patent System*, 3 *Yale Law Journal*, 1894, p. 151) More recently, see OECD, *Policy Roundtable on Competition, Patents and Innovation*, DAF/COMP(2007)40, 8 January 2008, pp. 21-23 (“*In recent years, a number of commentators have expressed concern that too many patents are being issued, their scope is becoming too broad, they are too easy to obtain, and the legal rights attached to them have become too powerful. Some observers believe that these developments have changed patents from being innovation facilitators to being innovation retardants. [...] [T]he easier it is to obtain patents and the broader they are, the more of them will tend to be issued and the more comprehensive they will be (up to a saturation point). That, in turn, can lead to five types of costs. First, static inefficiencies increase because more patents and greater patent breadth make monopolisation and its attendant deadweight losses more likely. Second, dynamic inefficiencies increase because it will become more difficult for others to invent without infringing someone else’s patent. Third, a greater number of broader patents will encourage socially wasteful rent-seeking behaviour, such as patent trolling. Fourth, enforcement costs will be higher since there will be more to enforce. Finally, it is possible that overbroad patent rights and easier patentability will lead to inefficient overinvestment in R&D. Some believe that when patents are awarded too easily, or are allowed to protect very broad claims, a vicious cycle arises that deters innovation. This happens because the body of issued patents eventually covers so much substantive territory that companies are forced to recognise a substantial likelihood that their innovations will lead to accusations of infringement by other companies. To reduce their risk, businesses amass larger and larger patent portfolios in a kind of IP arms race in which patents are collected mainly for use as bargaining chips in the event of an infringement problem. But of course the act of building up those portfolios adds to that problem. With so many patents already granted and more being issued all the time, it becomes harder and harder to know who is likely to sue, to feel confident about one’s chances of successfully fending off an infringement suit, and to negotiate and pay for the licenses deemed to be necessary. [...] Consider the comments of an executive from Texas Instruments: ‘TI has something like 8000 patents in the United States that are active patents, and for us to know what’s in that portfolio, we think, is just a mind-boggling, budget-busting exercise to try to figure that out with any degree of accuracy at all.’ If a company with the resources of Texas Instruments cannot afford to know even what it has in its own patent portfolio, one can imagine how hard it could be for small potential entrants to determine their risks of triggering a patent infringement lawsuit.”)*

<sup>317</sup> While divisional applications have the same priority and expiration date as the parent patent, and thus cannot add any extra-time to the patent protection, strategic use of divisionals can create uncertainty as to the final extent of the patent, which in turn might cause delays to generic entry. Divisionals may be also used by originators to extend the overall time of patent examination (a

regimes, new uses, as well as salts, metabolites, polymorphic forms, particles, solvates and hydrates, to protect the drug from generics and expand the reach of exclusivity of the patent on the main active ingredient.<sup>318</sup> In other words, the originator<sup>319</sup> “stockpiles” patent protection by obtaining separate patents relating to the same drug<sup>320</sup> with the aim of creating several layers of defense.<sup>321</sup> This is often referred to as a patent cluster or patent thicket. As

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sequence of divisional applications might allow an invalid submission to survive several years of examination) thus prolonging the period of legal uncertainty for generic companies. The effect is further exacerbated by the divisionals’ independence (which leave them unaffected by the successful challenge of a parent application) and the possibility to use sequences of intertwined divisionals.

<sup>318</sup> This phenomenon is widespread in the pharmaceutical industry. As noted by C.S. Hemphill, B.N. Sampat, *When Do Generics Challenge Drug Patents?*, *Journal of Empirical Legal Studies*, 2011, p. 11, “*Drugs approved between 1985 and 1987, have an average of 1.9 patents per drug. In the final (2000 to 2002) cohort, the mean slightly more than doubles to 3.9 patents per drug. The median increases from 1.5 to 2.5 patents per drug. [...] In other words, the top twenty-five percent of patent portfolios, among drug approvals in the first several years of the Act, had two or more patents per drug, while the top portfolios fifteen years later were more than double that size.*” Professors Boldrin and Levine indicate that: “[t]he National Institutes of Health Care Management reveals that over the period 1989-2000, 54% of FDA-approved drug applications involved drugs that contained active ingredients already in the market. Hence, the novelty was in dosage form, route of administration, or combination with other ingredients. Of the new drug approvals, 35% were products with new active ingredients, but only a portion of these drugs were judged to have sufficient clinical improvements over existing treatments to be granted priority status. In fact, only 238 out of 1035 drugs approved by the FDA contained new active ingredients and were given priority ratings on the base of their clinical performances. In other words, about 77% percent of what the FDA approves is “redundant” from the strictly medical point of view.” (M. Boldrin, D.K. Levine, *Against Intellectual Monopoly*, Cambridge University Press, 2010, pp. 260-261)

<sup>319</sup> Not only incumbent firms protecting their profits are often less likely to innovate (see K. Arrow, *Economic Welfare and the Allocation of Resources to Invention*, in NBER, *The Rate and Direction of Inventive Activity*, Princeton University Press, 1962), but they also have an incentive to block their (potential) competitors from innovating. This is usually achieved by creating barriers to entry, including by obtaining or acquiring blocking patents, able to extend and strengthen protection from the same thing IP is supposed to incentivize, innovation.

<sup>320</sup> Patents in a cluster concern innovations that the originator has no intention of developing further or making use of, other than for reserving the domain and eliminating potential competition. This strategy is called “defensive patenting” and consists in inventions “*which the applying company considers to have little or no prospect of being developed and/or commercialised and/or which, once granted, the company holds primarily to protect itself against actual or potential competition.*” (European Commission, *Pharmaceutical Sector Inquiry: Final Report*, 8 July 2009, par. 1118)

<sup>321</sup> The validity of these patents is usually doubtful. As noted by the European Commission, “*the final outcome in 60 % of opposition and appeal procedures against originator company’s patents examined in this report was a revocation of the disputed patent. In addition to this, the scope of the patents was reduced in another 15%. These procedures almost exclusively concerned secondary patents. Furthermore in 55 % of the patent litigation cases between originator and generic companies that involved a question of the disputed patent’s validity and that reached a final judgement, the patents were annulled (43 of 78 cases).*” (European Commission, *Pharmaceutical Sector Inquiry: Final Report*, 8 July 2009, par. 501) The numbers vary, although they are not far from EU levels, in the U.S. The success rate of generic manufacturers’ challenges to originators’ patents has been demonstrated by the FTC in 2002 to be at more than 70% (FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002, available at <http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>, accessed on 6 August 2016). Professors Lemley and Shapiro found in 2005 that 50% of all litigated patents are declared invalid. (M.A. Lemley, C. Shapiro, *Probabilistic Patents*, 19 *Journal of Economic Perspectives*, 2005, p. 76) Similar results are cited by Professor Hovenkamp: “*litigated patents are found to be invalid anywhere from one-third to one-half of the time*” (Hovenkamp H.J., *Consumer Welfare in Competition and Intellectual Property Law*, 9 *Competition Policy International*, 2014, p. 11, citing W.M. Landes, R.A. Posner, *The Economic Structure of Intellectual Property Law*, Belknap, 2003, p. 338). In a more recent study, Professors Hemphill and Lemley refer to RBC Capital Markets,

defined by Professor Shapiro, a patent cluster is “*a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.*”<sup>322</sup>

The denser the cluster, the more difficult it is for generic manufacturers to determine if they could develop a generic version of the brand-name drug without infringing one of the originator’s patents. In this sense, this practice raises legal uncertainty as to whether generic manufacturers can enter the market, as they are not able to properly assess the scope of the originator’s patent portfolio. As explained by the European Commission, “*where generic companies might manage to invalidate the base patent before its regular expiry they still cannot enter the market, if the originator company has succeeded in creating what some originator companies call “a multilayered defence” by other patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations.*”<sup>323</sup>

Although the generic manufacturer knows that only a limited number of the myriad of patents allegedly covering the brand-name drug might be infringed by the generic version, and an even smaller number might be valid, it is extremely costly and time consuming to reach the necessary level of certainty prior to launch.<sup>324</sup> In other words, although the main patent protecting the brand-name drug (*i.e.* the one on the basic compound) may have expired, generic entry might be delayed by uncertainty on whether the generic version infringes one of the multiple patents surrounding it.<sup>325</sup>

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Pharmaceuticals: Analyzing Litigation Success Rates, 15 January 2010, concluding that generic manufacturers won only about half of the cases that reached judgment between 2000 and 2009. They however note that “[t]he drop in the generic win rate is likely traceable to two changes we think occurred in challenge and settlement practice. The first is an increase in settlements in weak-patent cases [...]. The second is an increase in the filing of weak generic claims, motivated in part by the prospect of a future settlement payoff.” As Professors S. Hemphill and Sampat reports “*each drug has 2.7 patents on average (with a median of two patents), which yield an average nominal patent term of 15.9 years. By comparison, average effective life is 12.2 years, a difference of nearly four years. [...] The key difference between effective life and nominal term is patent challenges by the generic firm.*” (C.S. Hemphill, B.N. Sampat, Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals, Columbia Law and Economics Working Paper No. 399, 2012, p. 12)

<sup>322</sup> C. Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, in A.B. Jaffe, J. Lerner, S. Stern, Innovation Policy and the Economy, MIT Press, 2001, p. 119.

<sup>323</sup> European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 476.

<sup>324</sup> “*Despite their often dubious strength in eventual invalidity procedures, the mere existence of ‘evergreening’ patents will first discourage generic competitors from entering the market. At the very least, it will delay entry.*” (M. Temmerman, The Legal Notion of Abuse of Patent Rights, Working Paper No 2011/23, nccr trade regulation, p. 24) See also K.S. Gaudry, Evergreening: A Common Practice to Protect New Drugs, 29 Nature Biotechnology, 2011, p. 876 (“*Under the practice of “evergreening”, a company may attempt to extend its total monopoly by securing a number of monopolies – each beginning and ending at different times. For example, a company may file a first patent application claiming a new chemical compound. Several years later, the company may file a second patent application claiming a use of the compound to treat a condition. Later yet, the company may file a third patent application claiming a particular formulation of the compound. [...] [A] patent arising from third patent application would likely expire years after [the first patent]. Though the latter part of the monopoly would likely cover a narrower concept, the protection may be sufficient to deter competitors from attempting to design-around the patent.*”)

<sup>325</sup> “*This can occur either because patents cover all economically interesting or viable salt forms, enantiomers or formulations of the compound or all efficient ways of its manufacturing. In other words patent clusters and divisionals seem to be aimed at creating legal uncertainty for generic competitors*” (European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 525). See also J. Drexler, AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?, in J. Drexler, L. Nari

The creation of a patent cluster is thus used to expand the scope of the exclusivity both objectively (protecting the drug from competing products that are not infringing the main patent) and temporally (extending the duration of the exclusivity on the drug beyond the 20 years granted by the main patent),<sup>326</sup> creating uncertainty for potential competitors (generic and not).<sup>327</sup> Under certain circumstances, this strategy might be pursued to facilitate the switch to second generation products, which will be analyzed in more detail in the chapter dedicated to product hopping.

Directly connected with the creation of patent clusters is their enforcement through litigation. Indeed, patent clusters represent a valuable asset for originators to engage in patent litigation, whose simple threat may be sufficient to deter generic companies from entering the market. Enforcement of worthless, invalid or non-infringed patents creates unjustified obstacles to generic entry (in terms of legal cost, risk of interim injunctions and damages). Only larger generic companies may have the financial resources to identify potentially infringed patents, determine their validity and undertake long and costly litigation.<sup>328</sup>

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(eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Edward Elgar, 2013, p. 308 (“[P]harmaceutical companies [...] apply [...] for a number of secondary patents, such as for processes or re-formulations, in addition to the base patent in order to extend the exclusivity beyond the expiry of the protection period of the base patent. If this happens towards the end of the term of protection of the base patent – a strategy that is generally termed ‘evergreening of patents’ – this will cause the most delay to the market entry of generics.”)

<sup>326</sup> This is the case when originators submit, as innovative, inherent characteristics of the brand-name drug whose main patent is about to expire. See, e.g., European Commission, AT.39226, Lundbeck, 19 June 2013, par. 627 (“the crystallisation patent, on which Lundbeck heavily relied to deter generic entry, [...] was analysed by Lundbeck’s “enemies” as “high school chemistry” and not novel, meaning that parties realised that this patent could very well be held partially or entirely invalid by a court, a national patent office or the EPO.”) and par. 1026 (“Alpharma shared this basic assessment of the vulnerability of Lundbeck’s crystallisation patent. [...] “My personal opinion, regarding the patent in question [that is to say Lundbeck’s crystallisation patent], is that we shall go ahead and market our product. The patent is not likely to pass scrutiny on novelty and inventive step. I expect that they will end up, either with no patent or a very limited and narrow patent, which should not cause us problems. We do however need the supportive opinions of [external lawyers]. If they coincide, then I would recommend a “go ahead”. We might lose and have to pay a limited damage fee, but not entering the market, could also lead to a significant loss.””)

<sup>327</sup> Generic manufacturers and other originators tend to respect the patents granted and, instead of challenging their validity, they may simply abstain from bringing generics to the market and redirect their investments. Indeed, the creation of a patent cluster may prevent the creation of substitutable products (such as me-too products) by interfering with the R&D path of rival companies, thus impairing both price and dynamic competition. As illustrated by Professor Hovenkamp, “[o]ne consequence of ineffectual opposition is that fields become very crowded with patents whose technological contributions are minimal or nonexistent. Nevertheless, the cost of challenging or avoiding them is very high. As a result, they can deter competitive entry and innovation even if they do little to promote long run technical progress. [...] In such cases there is no innovation–competition “tradeoff” because there is no innovation to trade off.” (H.J. Hovenkamp, *Antitrust and the Patent System. A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 483-484)

<sup>328</sup> “Litigation costs deter innovation because a firm looking to invest in innovation will consider the risk that the innovation will inadvertently expose it to a patent infringement lawsuit. Recognizing these costs, firms [...] will refrain from entering or continuing with a particular field of research that such patents appear to cover. Such effects deter market entry and follow-on innovation by competitors and increase the potential for the holder of a questionable patent to suppress competition. The anticompetitive effect is particularly strong for small innovative firms that lack the resources to challenge such patents. [...] The presence of any patent serves as a scarecrow that may keep competitors out of a particular field. Patentees initiate and threaten litigation based on suspect patents. Litigation costs associated with defending an infringement suit are high. And that is just the litigation costs; the potential liability costs can be staggering. Further, if the competitor knows about the patent and infringes anyway, the court may consider the

This first type of conduct, which has been the object of a number of antitrust cases, can be considered first and foremost an abuse of rights,<sup>329</sup> as patent rights are used by originators to impede, rather than incentivize, innovation. The excessive proliferation of patents raises transaction costs, constrains R&D, and exposes firms to ex-post holdup through patent litigation.<sup>330</sup>

Issues connected to patent clusters should ideally be tackled by patent offices by

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*infringement willful and award treble damages and attorneys' fees. Even if a competitor believes the patent is invalid, the costs of being wrong – or having the judge get it wrong – are too high. Investigating patent validity takes time and money.”* (C.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, pp. 1271-1273)

<sup>329</sup> “[I]nvalid patents upset the balance between encouraging innovation and suppressing competition because we pay the cost of reduced competition without receiving the benefit of increased innovation.” (C.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1270) “It is not appropriate to defend such a broad fence of defence by means of unused patents on the ground that in patent law there is no obligation to use the protected invention. Firstly, such an obligation indeed exists, only that it is sanctioned merely by the imperfect instrument of the imposition of compulsory licences.” (H. Ullrich, *Strategic patenting by the Pharmaceutical Industry: Towards a Concept of Abusive Practices of Protection*, in J. Drexler, L. Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Edward Elgar, 2013, p. 244)

<sup>330</sup> To explain the issues potentially arising from defensive patenting and the creation of patent clusters from an IP perspective, we can refer to two compelling analogies, with blackmail and kidnapping, proposed by Professor Merges and Professor Abbot respectively. What Professor Merges explains is that, “for an economist, the puzzling aspect of blackmail is that it involves a voluntary and seemingly Pareto-satisfying exchange. The blackmailer has information the blackmailee wants; they agree to a price; and the deal is done. From the point of view of libertarian theory, if not pure market exchange, what’s not to like? After some discussion of these issues, the answer came clear enough to Ronald Coase when he wrote about blackmail in 1984. He emphasized the social wastefulness of blackmail transactions: “Blackmail involves the expenditure of resources in the collection of information which, on payment of blackmail, will be suppressed. It would be better if this information were not collected and the resources were used to produce something of value.” [...] Blackmail is part of a broader pattern in which the legal system sorts out which voluntary transactions ought to be enforced. Where [...] there is no social welfare gain possible [...], and especially where enforcement encourages wasteful expenditures (again from the perspective of social welfare), there is good reason not to promote voluntary exchange.” (R.P. Merges, *The Trouble with Trolls Innovation Rent-Seeking and Patent Law*, 24(4) *Berkeley Technology Law Journal*, 2009, pp. 1600-1601). It is difficult not to see a parallelism with patents unrelated to actual innovation, i.e. patents obtained and enforced with the sole purpose of blocking innovation from other originators, delaying generic entry or extracting undue and excessive benefits from a product whose patent is expired or would have a much more limited reach. Patentees who employ patents not only not to benefit social welfare, but to its detriment, can be said to engage in a form of extortion. (R.P. Merges, *The Trouble with Trolls Innovation Rent-Seeking and Patent Law*, 24(4) *Berkeley Technology Law Journal*, 2009, p. 1603) In the same vein, Professor Abbot offers a parallelism with kidnapping. See F.M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6(3) *UC Irvine Law Review*, forthcoming Spring 2017, p. 19, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095), accessed on 6 August 2016. (“The pharmaceutical industry prefers that discussions about price be based on the “value” to healthcare systems in terms of alternatives. For example, without treatment by a new drug a patient would develop symptoms, visit doctors, be subject to tests, be admitted to a hospital(s), become disabled and potentially die. The cost of hospitalization can be quite high, and the price of hospitalization for an extended period can run into the millions of dollars. Therefore, in “value” terms based on alternatives, even a high-priced medicine may be a “bargain”. This type of value assessment is essentially a “hostage” bargaining model. The drug is under the control of the monopoly patent owner, and the price of ransoming the drug is whatever the party seeking to obtain it can pay. If the ransom is not paid the consequences may be terrible, and in that regard the ransom can be characterized as a bargain. But it is only a bargain because of the threat. A similar “value proposition” could be worked out for virtually any essential product.”)

simply not granting unmeritorious patents.<sup>331</sup> This would avoid at least the legal cost and uncertainty of litigation (where the decision is left to legally trained judges instead of scientifically trained patent examiners), and would limit the negative effects that the existence (and abstract enforceability) of invalid patents have on incentives to innovate.<sup>332</sup>

In determining whether the originator's conduct (*i.e.* filing the patent application) is abusive, the key criterion is whether the originator has any interest in developing and bringing the patented invention to the market.<sup>333</sup> To determine the originator's intent, which, while irrelevant for the grant of a patent, can be taken into account in the antitrust assessment, objective factor may provide some indication. If the only justification for patenting around the main patent is to impede competition on innovation from originators<sup>334</sup> and price competition from generic manufacturers<sup>335</sup> (evidence of which can be the fact that this

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<sup>331</sup> “[P]atent offices are much better placed to detect weak patents. Hence, the problem of unjustified secondary patents is a topic that should primarily be addressed in the context of patent law and policies. Accordingly, the appropriate question to ask is not whether competition law should be applied to patent filings at all, but, from an institutional perspective, whether specific competition policy concerns can be better taken account of in the framework of patent or competition law. It is hoped that the patent offices will defend the patent system at their best by maintaining a high level of patent quality and, thereby, convince the competition agencies that intervention is not needed.” (J. Drexl, AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?, in J. Drexl, L. Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Edward Elgar, 2013, p. 319) See also C.S. Hemphill, M.A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 *Antitrust Law Journal*, 2011, pp. 967-968 (“Patents are not carefully scrutinized by the Patent Office before they are issued. That default could be altered for drug patents, for example, by providing for reexamination of every patent that receives a Paragraph IV certification, or even every patent in the Orange Book. Reexamination has the advantage that, unlike a private suit, it cannot be settled once it has begun. And this additional scrutiny would be consistent with proposals that the PTO focus more attention on the most important patents. But it cannot solve the whole problem. The PTO is oriented towards granting, not denying, patents.”) The number of hours spent on each application is limited, the application can be closed only if the patent is approved, the examiner is required to write an explanation for patent rejections, and bonuses are often based on productivity (in terms of patents examined or approved). See M.A. Lemley, *Rational Ignorance at the Patent Office*, 95 *Northwestern University Law Review*, 2001, p. 149, and R.P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 *Berkeley Technology Law Journal*, 1999, p. 609.

<sup>332</sup> Litigation fears may induce generics and rival originators to “avoid market or research activities out of recognition of the vagaries of litigation results and the possibility of infringement liability”. (J.R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, *University of Illinois Law Review*, 2001, p. 319) Indeed, “[o]nly 1.5% of patents are ever litigated, and only .1% make it to trial.” (M.A. Lemley, C. Shapiro, *Probabilistic Patents*, 19 *Journal of Economic Perspectives*, 2005, p. 75)

<sup>333</sup> “[I]n some case both patent clusters and divisionals seemingly serve to prevent or delay generic entry. While this, during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters. [...] the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments.” (European Commission, *Pharmaceutical Sector Inquiry: Final Report*, 8 July 2009, par. 523. See also par. 1122)

<sup>334</sup> “Competitors will face a difficult choice: either they will have to litigate the validity of the patents, or they will have to accept a license and pay the fee, or finally they will have to design their products “around the patent”. All these practices will increase their costs, reduce their incentives to innovate and facilitate collusive practices as, in most cases, the dispute will lead to an anticompetitive patent settlement or a cross-licensing scheme.” (I. Lianos, R.C. Dreyfuss, *New Challenges in the Intersection of Intellectual Property Rights with Competition Law*, *CLEAS Working Paper Series*, 2013, pp. 43-44)

<sup>335</sup> As anticipated, the immediate consequence of patent clusters is the creation of

happened close to the main patent expiry),<sup>336</sup> than there is strong case in favor of finding an abuse. This is the case when the dominant originator knew, or should have known, that its application did not respect the patentability requirements, and the filing was thus aimed solely at obtaining an unmeritorious patent. It is the complete lack of pro-innovation justification that leads to a finding of abuse, both under antitrust and patent law.

This position is not shared by the U.S. Supreme Court. In *Continental Paper Bag*,<sup>337</sup> the circuit court found that “*the complainant, so to speak, locked up its patent. It has never attempted to make any practical use of it, either itself or through licenses, and apparently its proposed policy has been to avoid this. [...] [C]omplainant stands in the common class of manufacturers who accumulate patents merely for the purpose of protecting their general industries and shutting out competitors.*” The Supreme Court however concluded “[a]s to the suggestion that competitors were excluded from the use of the new patent, we answer that such exclusion may be said to have been of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive. [...] In some foreign countries, the right granted to an inventor is affected by nonuse. This policy, we must assume, Congress has not been ignorant of, nor of its effects. It has nevertheless selected another policy; it has continued that policy through many years. We may assume that experience has demonstrated its wisdom and beneficial effect upon the arts and sciences.”

This is clearly in contrast with the position expressed by this work. What the U.S. Supreme Court does is erroneously equating patent non-use in general to the abusive use of the patent system, aimed at preventing competition and deterring innovation through the creation of patent clusters. Not only, the Supreme Court’s opinion should be read in light of the eBay opinion discussed above. Doing so would, in this author’s view, lead to a similar position to that expressed by Justice Douglas in (his dissenting opinion in) *Special Equipment*.<sup>338</sup>

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uncertainty as to the subject matter protected and thus the increase of the originator’s rivals’ costs and risks. Even after the main patent expired, a generic manufacturer might stay out of the market fearing infringement of one of the multiple patents surrounding it.

<sup>336</sup> This is the case of “last-minute” or “just in time” inventions. Even when the filing was not close to expiration of the main patent, the fact that it has been made much later than the conclusion of R&D is a strong indication of abusive intent.

<sup>337</sup> *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S., 1908, pp. 428-430.

<sup>338</sup> *Special Equipment Co. v. Coe*, 324 U.S., 1945, pp. 381-384 (“*The right of suppression of a patent came into the law over a century after the first patent act was passed. In 1886, Judge Blodgett had ruled that a patentee “is bound either to use the patent himself or allow others to use it on reasonable or equitable terms.” Hoe v. Knap*, 27 F. 204, 212. In 1896, that rule was repudiated [...] [T]he court stated that a patentee’s “title is exclusive, and so clearly within the constitutional provisions in respect of private property that he is neither bound to use his discovery himself, nor permit others to use it.” That theory was adopted by this Court in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U. S. 405, decided in 1908. [...] I think it is time to be rid of that rule. It is inconsistent with the Constitution and the patent legislation which Congress has enacted. [...] “The Congress is given no general power to issue letters patent or to reward inventors as it will. [...] The purpose “to promote the Progress of Science and useful Arts” accordingly provides the standards for the exercise of the power and sets the limits beyond which it may not go. That purpose also provides the guide for the interpretation of patent laws enacted pursuant to that power. [...] The patent is a privilege “conditioned by a public purpose.” *Mercoid Corp. v. Mid-Continent Co.*, 320 U. S. 661, 320 U. S. 666. The public purpose is “to promote the Progress of Science and useful Arts.” The exclusive right of the inventor is but the means to that end. That was early recognized by this Court. See *Pennock v. Dialogue*, 2 Pet. 1, 27 U. S. 19; *Kendall v. Winsor*, 21 How. 322, 62 U. S. 327-328; *Seymour v. Osborne*, 11 Wall. 516, 78 U. S. 533-534. But the Paper Bag case marked a radical departure from that theory. It treated the “exclusive” right of the inventor as something akin to an “absolute” right. It subordinated the public purpose of the grant to the self-interest of the patentee. The result is that suppression of patents has become commonplace. Patents are multiplied to protect an economic barony or empire, not to put new discoveries to use for the common good. “It is common practice to make an

*“the Court sits as a court of equity. It should withhold its aid from a patentee who has employed or plans to employ the patent not to exploit the invention, but to suppress it in order to protect another patent or otherwise. [...] If that purpose were clear, a patent should not issue in the first instance. If it has been issued and not cancelled and the patent has been suppressed, anyone should be permitted to use it, at least on payment of reasonable royalties. In that way, the constitutional objective will be more nearly realized -- the product of the inventive genius of the human mind will be put to work in the economy.”*

It is not necessary to file multiple applications to stockpile patents and create a patent cluster, originators can simply (and more easily) buy someone's patent (or even patent application) on a competing product or process, and suppress it.<sup>339</sup> While this might seem counterintuitive to some, the reason why a (potential) competitor would sell its innovation to a competing originator is the fact that it might earn more with lower risk from splitting monopoly profits than from competing. This is the economic theory behind the prohibition of cartels. Selling at agreed upon monopoly prices (and thus acting as one single undertaking in a monopolistic position) enhances the undertakings' profits to the detriment of consumers.

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*invention and to secure a patent to block off a competitor's progress. By studying his ware and developing an improvement upon it, a concern may 'fence in' its rival; by a series of such moves, it may pin the trade enemy within a technology which rapidly becomes obsolete. As often as not, such maneuvers retard, rather than promote, the progress of the useful arts. Invariably their effect is to enlarge and to prolong personal privilege within the public domain.”* Hamilton, *op. cit. supra*, p. 161. *One patent is used merely to protect another. The use of a new patent is suppressed so as to preclude experimentation which might result in further invention by competitors. A whole technology is blocked off. The result is a clog to our economic machine and a barrier to an economy of abundance. It is difficult to see how that use of patents can be reconciled with the purpose of the Constitution “to promote the Progress of Science and the useful Arts.” Can the suppression of patents which arrests the progress of technology be said to promote that progress? It is likewise difficult to see how suppression of patents can be reconciled with the provision of the statute which authorizes a grant of the “exclusive right to make, use, and vend the invention or discovery.”* Rev.Stat. § 4884, 35 U.S.C. § 40. *How may the words “to make, use, and vend” be read to mean “not to make, not to use, and not to vend”? Take the case of an invention or discovery which unlocks the doors of science and reveals the secrets of a dread disease. Is it possible that a patentee could be permitted to suppress that invention for [...] the term of the letters patent [...] and withhold from humanity the benefits of the cure? But there is no difference in principle between that case and any case where a patent is suppressed because of some immediate advantage to the patentee. I think it is time to return to the earlier, and I think the true, philosophy of the patent system. We should not pass on to Congress the duty to remove the private perquisites which we have engrafted on the patent laws. This Court was responsible for their creation. This Court should take the responsibility for their removal.”*

<sup>339</sup> “[S]uppose the patent monopolist of widgets pursues a course of buying up exclusive licenses to all patents pertaining to the production of widgets. If the monopolist finds the patent useful to its own widget-production process, it employs the patent; if not, it simply “inventories” the patent, refusing to license it to any other. Thus the monopolist's strategy continuously denies to potential rivals the patents needed to engage in widget production. Should this form of nonuse violate the antitrust laws? Condemnation of such nonuse is unnecessary if the courts are steadfast in enforcing a rule that a monopolist may not lawfully acquire exclusive rights in “related” patents as a general matter. In that case, the widget monopolist's mere acquisition of alternative widget patents developed by others constitutes the violation, and no additional showing of nonuse is necessary. We would permit the monopolist to acquire a nonexclusive license, but such a license would not deny the technology to others, and thus the acquirer's refusal to license becomes unimportant.” (H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen, 2014, p. 14-32) See also p. 2-49 (“[S]uch a strategy may constitute an antitrust violation, possibly leading to the grant of a court-ordered license under the patents. Suppose that the patent holder sues a third party would-be licensee for producing widgets in defiance of the patents, and the patent holder proves infringement. At the remedy stage, the third party may well present its antitrust arguments as equitable arguments under the eBay test against a permanent injunction. If the court declines a permanent injunction, the third party will have gained a compulsory license, quite possibly without ever actually litigating the antitrust claim. Even where competition-related arguments may have failed under antitrust law, courts might well decide that those arguments contribute to an overall equitable showing under eBay that disfavors the grant of an injunction.”)

The same can be said here. Acquiring patents on competing technologies, at an embryonic stage (when merger control may not apply),<sup>340</sup> allows the incumbent originator to use its monopoly profit to “buy-off” its closest (potential) competitors to stay out of the market, by purchasing their innovative product or technology for a much higher price than it would be valued if the market was competitive. To put it in economic terms, the incumbent originator pays with consumer welfare to suppress competition and innovation. The incentive to sell is particularly strong, not only because of the amount offered (usually higher than what the market values the invention), but also for the costs involved in developing and marketing a competing drug and/or process (often prohibitive for small and medium enterprises), and the risk it will not be successful (due to doctors’ inertia, marketing and distribution cost and effectiveness, infringement litigation from the originator, etc.).<sup>341</sup>

This behavior runs counter to the patent’s purpose (which is certainly not to be piled up to prevent competition by innovation, quite the contrary) and is detrimental to consumer welfare. It should thus be prohibited, both under antitrust and patent law.

### 11.1. Servier (EU)

Due to the position taken by the Supreme Court, there have been no cases in the U.S. prohibiting patent clusters and the acquisition of competing patents under the rules of monopolization (and/or patent misuse). We thus have to look at the EU, and at the individual EU Member States, to find precedents on patent clusters. The two cases analyzed

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<sup>340</sup> It is noteworthy that the European Competition Commissioner recently stressed the importance of protecting competing innovations in the context of mergers. In her words, “[o]ne of the simplest defences against innovation is to buy up rivals that create innovative products. [...] Last year, we looked at a merger between the drug company Pfizer and its rival, Hospira. We only approved the deal after Pfizer agreed to sell the European rights to an arthritis drug it was developing. One concern was that Hospira already had a competing drug on the market, and we thought Pfizer might stop work on its own drug if the deal went ahead as planned. Which would have meant less of the innovation that we depend on as patients. So protecting innovation is important in our merger policy. So important, in fact, that we’re considering whether to change our rules to do it more effectively. Our rules decide which mergers need to be notified to us based on the turnover of the companies involved. So when someone buys up an innovator, with a lot of good ideas but not yet much in the way of sales, we might not even have the chance to look at whether that merger will be bad for innovation. That’s why I announced last month that we’re looking at whether to change the thresholds for notification, to make sure we get a look at this type of merger.” (M. Vestager, Competition: the mother of invention, 18 April 2016, available at [https://ec.europa.eu/commission/2014-2019/vestager/announcements/competition-mother-invention\\_da](https://ec.europa.eu/commission/2014-2019/vestager/announcements/competition-mother-invention_da), accessed on 6 August 2016). The existence of a gap in merger control rules has been acknowledged by both national competition authorities and the European Commission. Already in 2014, the German Monopolies Commission (GMC) recommended “*additional notification requirements based on the transaction volume*”. The GMC noted that purchase price may be a more appropriate criterion to determine the economic impact of a transaction. On 1 July 2016, the German Ministry for Economic Affairs published a draft of the ninth amendment to the German Act against Restraints of Competition, *inter alia*, to introduce an additional threshold for concentrations valued in excess of EUR 50 million. At the EU level, on 7 October 2016 the European Commission launched a public consultation on the evaluation of procedural and jurisdictional aspects of EU merger control. The consultation is aimed, *inter alia*, at determining whether a reform is necessary to allow the Commission to capture all transactions that have the potential to affect competition in Europe. Particularly, the Commission is considering whether the current turnover-based thresholds should be complemented by a value-based threshold.

<sup>341</sup> This whole analysis applies specifically to innovation aimed at competing with, and not replacing, the current drug or process to manufacture it. The effects, value and incentives relating to an innovation that could replace the incumbent’s would be much more uncertain and complicated to assess.

by this work, *Servier* at the EU level and *Pfizer* at the Member State level are two of the most controversial cases recently decided.

In *Servier*,<sup>342</sup> the European Commission found a combination of infringements of both Article 101 and Article 102 TFEU by the French originator Servier in relation to the blood pressure control drug Perindopril. Under Article 102, the Commission found that Servier purchased the main viable competing delivery technology, not to improve its own production process (as there was evidence that Servier did not use the technology), but to foreclose competitors from having access to the market. This acquisition was used by Servier to reinforce the patent thicket it had created around the compound.<sup>343</sup> Faced with the expiry of the compound patent, Servier created a cluster of blocking patents around it. These patents, however, did not afford absolute protection against generic entry as alternative processes to manufacture the drug could be developed. Therefore, Servier put in place and rigorously pursued a comprehensive strategy to protect perindopril by amassing process patents. As the Commission puts it, Servier “relied on the creation of a “maze of patents”, and influenc[ed] regulatory standards so that they would, for example, “lead to the use of [Servier’s] protected processes” and thus influenced the parameters for viable market entry by generic perindopril. Within that broader context, Servier pursued a targeted exclusionary strategy [...] to remove, before market entry, all close sources of competitive threats on the up- and down-stream markets for perindopril with the potential to overcome notably the patent and regulatory barriers.”<sup>344</sup>

Two of Servier’s strategies are discussed in this chapter. The first one is the acquisition of the most advanced alternative technologies for the production of perindopril. Every time Servier learned that a producer of active pharmaceutical ingredients (“API”) had found an alternative (non-infringing and thus potentially competing) method, it acquired the technology and removed it as a competitive threat from the market. This way, Servier strengthened the defense mechanism for its drug<sup>345</sup> and prevented generic companies from being able to develop non-infringing perindopril formulations.<sup>346</sup> “Through these acquisitions, Servier not only eliminated direct competition from the patent holders themselves but also removed them as a

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<sup>342</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014.

<sup>343</sup> See T. Curzon Price, M. Walker, Incentives to Innovate v Short-term Price Effects in Antitrust Analysis, *Journal of European Competition Law & Practice*, 2016, p. 6 (“there were valuable primary patents that had run out. The EC argued that the firms involved attempted to extend the rents from those primary patents by protecting their market positions with secondary patents of dubious validity. If the Commission’s argument is correct, then these cases are examples of precisely the type of rent-seeking behaviour that competition authorities need to be aware of within a context of protecting dynamic efficiency.”)

<sup>344</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2793.

<sup>345</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2776 (“Servier’s interest in the acquisition of the Azad technology was not to improve its production processes (as stated ex post facto in the context of the present investigation), but to add the Azad patent application to its “defense mechanism” which can only have been designed to defend against generic entry. There is also evidence that Servier did not put to use the purchased technology [...]. In addition, Servier’s list of patents qualified as protective measures against generics later contained an explicit reference to the patent application for delta and epsilon polymorphs acquired from Azad. This again confirmed that the Azad technology was effectively added to the “blocking patents.”)

<sup>346</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 142 (“the generic companies perceived Servier as acquiring all alternative supply sources, which rendered market entry difficult. Generic companies also recommended to each other not to disclose their respective API sources to Servier. Another internal Ivax/Teva email of 10 August 2005 states: “In any conversations with Servier, it is important that they are not given the name of our APIs supplier. The general Industry consensus is that Servier will attempt to take out API sources.”)

source of essential inputs (notably supplies of API, and licences) for other potential generic entrants. The generic companies noted on this practice: “once an API manufacturer has got around the process patents, Servier has bought the company, sourcing API has been very difficult”.<sup>347</sup>

The second abusive conduct by Servier consisted in the application for, and obtainment, an array of patents on process to manufacture and synthesize the drug, as well as on its crystalline alpha form (the “947” patent), with the aim of creating a patent cluster (a “maze of patents”) protecting different aspects of the drug. “[O]f the 33 process patents (mostly patents for synthesis routes), 21 were described by Servier internally as “blocking” patents or “paper patent”. Three of these 21 process patents were in addition characterised as involving “zero inventive step”. These patents were, however, granted by the EPO.”<sup>348</sup> The 947 patent was declared invalid by the UK High Court for lacking novelty. In confirming the High Court’s decision, the Court of Appeal, in the person of Lord Justice Jacob, explained: “as the Judge held and we confirm, it is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. But this is not one of them. For simply comparing the cited prior art (341) with the patent would not reveal lack of novelty and probably not obviousness. You need the technical input of experts [...] and some experimental evidence in order to see just how specious the application for the patent was. The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest. It is right to observe that nothing Servier did was unlawful. It is the court’s job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably”.<sup>349</sup>

This passage of the judgment is very insightful. It highlights the shortcomings of the patent office examination, noting how difficult it is to address them. It explains how applying and obtaining unmeritorious patents harm the public interest and how the solution is to get rid of them. It makes a parallelism between the lack of patentability requirements and a potential antitrust violation, (indirectly) underlining how the latter can be more effective in deterring these conducts (by imposing a fine rather than simply invalidating the patent and awarding costs).

With respect to technology acquisitions, they are considered to deviate from competition on the merits, and be thus capable of producing foreclosure effects and infringe Article 102 TFEU, when: (i) the acquired technology was a source of competition to the originator and (ii) was effectively removed from the market (*i.e.* the transferor could not use it or license it to others and the transferee was not willing and/or able to license it to others), and (iii) the acquisition “was “capable of making more difficult, or impossible the entry” and thus to

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<sup>347</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 6.

<sup>348</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 122. See also par. 123 (“Furthermore, minutes of one of Servier’s internal meetings held on 22 January 2003, show that Servier continued throughout the lifecycle of perindopril to develop and file patent applications which were themselves considered internally as “blocking” patents. The minutes categorise as such 31 synthesis process patent applications. For those patent applications Servier proposes filing with the EPO as a purely editorial task – *i.e.* without conducting any patentability studies or any laboratory trials.”).

<sup>349</sup> Judgment [2008] EWCA Civ 445, Case No A3/2007/1715, paragraphs 9 and 10, as cited by European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 187.

significantly delay generic competitors trying to enter the perindopril market”.<sup>350</sup> The specificities of the pharmaceutical market have obviously to be taken into account in conducting this assessment.<sup>351</sup> In the specific case of Servier, the Commission concluded that, “[u]nlike many other technology acquisitions, the Azad Technology Acquisition deviated from competition on the merits in that it consisted, as part of a broader strategy to eliminate competitive threats, in the acquisition by a dominant undertaking of scarce potentially viable technology liable to enable early entry by interested generic companies, which it acknowledged did not infringe its patents and with the stated purpose of strengthening the defence mechanism for these patents, and its branded product.”<sup>352</sup> “Azad technology was not excluded from the market because Servier’s technology was superior, but because Servier, seeking to strengthen its protection against generic entry, removed this independent source of competition by means of an acquisition. This was capable of restricting competition not only because it made generic entry more remote, as a number of generic development projects needed to be discontinued, but because it was capable of delaying generic entry.”<sup>353</sup> Therefore the acquisition represented an “abusive behaviour, contributing to Servier’s overall single and continuous exclusionary strategy which the Commission considers an infringement of Article 102”<sup>354</sup>

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<sup>350</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2800. At par. 2802, the Commission refers to previous case law (specifically 31.043, Tetra Pak, 26 July 1988, in which an exclusive license was acquired) on which its test is based. In that case “acquisition of exclusive rights can, in specific circumstances where this acquisition strengthens the dominant position and prevents or considerably delays the entry of competitors on the market, constitute an abuse under Article 102 of the Treaty.” At par. 2804, the European Commission summarizes its findings in Tetra Pak as follows: “Tetra Pak’s acquisition of the exclusive license had two consequences. First, it “strengthened Tetra’s very considerable dominance” compared to its actual competitor in the relevant market, PKL, “by reinforcing its technical advantages vis-à-vis the minimal competition that remains”. Second, the exclusive license “had the effect of preventing, or at the very least considerably delaying, the entry of a new competitor into a market where very little if any competition is found”. [...] The Commission thus concluded that the exclusive license had “The effect of blocking or delaying the entry of a new competitor”.” As explained by the General Court in AstraZeneca (T-321/05, AstraZeneca, 1 July 2010, par. 365), in the appeal of the Commission decision in Tetra Pak, “the Court merely approved the Commission’s assessment that, in the case before it, Article [102 TFEU] did not allow the undertaking in a dominant position, by acquiring an exclusive licence, to strengthen its [already] very considerable’ dominance and to prevent or considerably delay ‘the entry of a new competitor into a market where very little if any competition [was] found’ (paragraph 23 of [T-51/89, Tetra Pak v Commission, 10 July 1990]).” At par. 2854 of its decision, the Commission indicates the elements it will take into account in the assessment of the effects of the Azad acquisition: “(i) the anticompetitive effects the acquisition was capable of producing in view of the alternative potentially enabling sources of API technology able to constrain Servier in the absence of Azad (ex ante perspective), and (ii) the consequences of the acquisition on Servier’s position on the API technology market and the final product market for perindopril formulations.”

<sup>351</sup> Particularly, “(a) API is an indispensable input into final formulation; (b) generic entry requires several years of multifaceted development work (vertically integrated, or in cooperation on one or more levels) on the API, the formulation, distribution, taking into account regulatory and patent law requirements; and any disruption of this process is liable to cause significant delays (for example because both the work on the API and the formulation may need to be restarted if a source of API is lost); (c) any delay in generic entry, from the end of the patent term, causes significant consumer harm both for patients and for social security systems; (d) the demand is fairly price-inelastic prior to generic entry; (e) the price difference between a monopolised market and a market with just two (or more) competitors is often very large – sometimes a factor of ten to one.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2801)

<sup>352</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2917.

<sup>353</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2881.

<sup>354</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2917. The Commission cautions on extending the significance of the decision to other cases and explicitly state that “the finding in this case with regard to the technology acquisition is limited to the circumstances of this case and should not be construed as a general prohibition of technology acquisitions by dominant undertakings.”

The effects of the technology acquisition cannot thus be isolated from the other conducts (in this case, the reverse payment patent settlement, which is analyzed below) with which the originator pursued the same objective of delaying generic entry. As the Commission explains:

*“[T]he acquisition of Azad’s patent application and related know-how by Servier (“Azad Technology Acquisition”) and the reverse payment patent settlements can be seen to form a single and continuous exclusionary strategy by Servier. There are essentially two ways to viably launch a generic product where the market is still protected by patent barriers. The first one is to invent around the remaining patents and develop a non-infringing product. The second one is to challenge the relevant patent situation, either by directly seeking a finding of invalidity or non-infringement of the patents or by entering at risk. Any strategy to successfully delay generic entry, would have to address both types of generic threats, as illustrated by the above-mentioned documents from Servier and generic companies, which advocate the use of both acquisition of novel, non-infringing, technology and settlements to end litigation on the relevant patents. This is why the Azad Technology Acquisition, targeting an independent non-infringing technology to produce perindopril API, was a necessary complement to the patent settlement agreements with generic companies which threatened to invalidate the ‘947 patent in legal proceedings.”<sup>355</sup>*

## **11.2. Pfizer (Italy)**

One of the most recent and meaningful cases assessing the potential antitrust concerns arising from patent clusters has been decided at the national level. *Pfizer*<sup>356</sup> is one of the most controversial decisions on the intersection between IP and antitrust in the pharmaceutical sector and, as we delve into it, it will become evident how important it is for this work.

The facts of the case are as follows. In 1989, Pharmacia, a Swedish originator, filed a European patent application for latanoprost, a drug aimed at curing ocular glaucoma. The brand-name given to the product was Xalatan. The patent was granted in 1994 and was due to expire in September 2009 (20 years after the application). In 1997, Pharmacia filed SPC applications in several European countries, but not in Italy. The SPC was granted and extended the patent protection in selected countries up to 17 July 2011. In Italy the expiration of the patent protection remained 2009 and the term to submit the SPC application expired.

The conduct analyzed by the Italian Competition Authority (ICA) consisted in the attempt by Pfizer (that had acquired Pharmacia) to close the gap between the protection of Xalatan in Italy and in other European countries. In 2002 – 7 years before the expiration of its patent in Italy – Pfizer filed a European voluntary sub-divisional application with the European Patent Office (EPO) to obtain a divisional patent on a specific dosage regime of Xalatan. The divisional patent was granted at the beginning of 2009, six month before

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<sup>355</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 2794-2795.

<sup>356</sup> Italian Competition Authority (ICA), A431, Ratiopharm/Pfizer, prov. no. 23194, 11 January 2012. The decision was annulled by the first instance administrative tribunal and confirmed by the Council of State (Consiglio di Stato), in *AGCM v. Pfizer Italia s.r.l., Pfizer Health Ab and Pfizer Inc.*, 12 February 2014, no. 693.

expiration of the main patent,<sup>357</sup> and validated by Pfizer exclusively in Italy, Spain and Luxembourg. No new product was introduced on the market. Based on this divisional patent, Pfizer requested in April 2009 and obtained in June 2009, from the Italian Patent and Trademark Office (UIBM), an SPC covering Italy, moving the loss of exclusivity on Xalatan to July 2011, thus realigning the patent duration in Italy with that of the other European countries.<sup>358</sup> Pfizer requested and was granted also a supplementary six months extension of the SPC, until January 2012, as part of an approved pediatric investigation plan.

At this point, Pfizer started an aggressive campaign against the generic manufacturers to make them ‘cease and desist’ from entering the market.<sup>359</sup> Pfizer put pressure also on the Italian pharmaceutical regulatory body (AIFA) in an attempt to dissuade it from granting marketing authorizations to the generic versions of Xalatan. When the AIFA granted the authorization to launch the generics, Pfizer immediately appealed the decision and was granted an interim injunction in the first instance in June 2010. The Council of State (CoS) however repealed the judgment of the lower court in July 2010 and generics were able to effectively enter the market. In addition to the appeal proceedings against the AIFA decision, Pfizer also sued generic manufacturers for patent infringement, asking for damages.

In October 2010, the ICA, following a complaint from Ratiopharm (a generic manufacturer), opened a formal investigation into Pfizer’s conduct, shortly after the General Court’s ruling in AstraZeneca. The ICA’s investigation regarded in particular the belated divisional patent applications, filed at the EPO in 2002, and the SPC requested on the basis of that patent in 2009, which effectively delayed generic entry. Pfizer’s letters to Ratiopharm asking to confirm that it would respect Pfizer’s exclusive right under the SPC was also taken into account.

In the ICA’s view, the purpose pursued with the divisional patent application was not the preservation of the unity of the patent or the protection of a new invention (the dosage regime), but the correction of Pfizer’s past negligence and obtain an SPC in Italy, notwithstanding the abundant expiry of the time limit to request it on the basis of the main patent.<sup>360</sup>

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<sup>357</sup> During the seven years of examination by the EPO, Pfizer repeatedly amended its claims and the scope of the divisional patent as ultimately granted had very little in common with the application as originally filed.

<sup>358</sup> As said, Pfizer would have been too late to request an SPC based on the main patent and was able to do it only because it requested and obtained a divisional patent (on whose basis it requested the SPC).

<sup>359</sup> The situation described above had already led to a climate of “*deep uncertainty among generic drug manufacturers – which had relied on the expiry of the main patent protection, in Italy, in September 2009 – about whether or not the generic version of the original drug could be marketed. As a result, [generic manufacturers] decided to postpone their entry into the market, discouraged also by the several warnings with which Pfizer threatened to take legal action.*” (G. Ghidini, G. Cavani, P.F. Pisera’, Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 256)

<sup>360</sup> The ICA thus recognized a specific relevance to the exclusionary intent of the divisional application, namely the extension beyond its term of the patent protection. This conclusion was based not only on the fact that Pfizer did not launch any new product, but also on the timing of the divisional application (thirteen years after the main patent application) and on the fact that the divisional was validated only in certain countries. As noted by Stefano Grassani, “*Competition on the merits holds that a dominant company cannot be allowed to indirectly and subtly seek for such additional patent*

The ICA concluded that the use of a divisional application as a pretext to obtain an artificial extension of the exclusivity granted by the main patent (through the request of an SPC based on such divisional) constituted an abuse of dominance, as well as an abuse of rights. While Pfizer was formally entitled to request and obtain a divisional patent, use the divisional patent to obtain the SPC, and request and obtain such SPC, these rights were granted with and for a specific purpose, foster innovation and consumer welfare, and using them in a specious way, not coherent with their purpose, runs counter the very reason they were granted and thus represents an abuse of rights, punishable under both patent and antitrust laws.

*“In other words, the abuse of rights does not suppose a formal infringement of laws, but the distorted exercise of the granted rights, for purposes different from those meant by the legislator.”*<sup>361</sup>

The immediate purpose of a patent is to protect a new product (broadly speaking) or process. In this case, the patent was granted for the optimal dosage of the active ingredient covered by the main patent and Pfizer was thus requested to demonstrate that, following the grant of the patent, a new product was launched or any other activity was carried out under the protection of the new patent (*i.e.* the patent was commercially exploited in any way). In these regards, the ICA (and on appeal the CoS) concluded that the evidence collected proved that no real and concrete use of such divisional patent was made, other than for the purpose of prolonging the duration of the exclusion of competitors by discouraging generic entry through the creation of legal uncertainty on the date of expiration of Xalatan’s patent protection. Pfizer’s divisional patent was thus considered a case of defensive patenting,<sup>362</sup> as no new product was covered, other the one already protected and produced under the main patent.

In the ICA’s view, the use of administrative procedures with the sole purpose of

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*protection by resorting to tactics which, ultimately, have a purely foreclosing object; regardless of whether such tactics are formally lawful under IP law.”* (S. Grassani, *Evolution or Revolution? The Italian Competition Authority and the Pfizer Decision: A Reply to Thomas Graf*, 7 February 2012, available at <http://kluwercompetitionlawblog.com/2012/02/07/evolution-or-revolution-the-italian-competition-authority-and-the-pfizer-decision-a-reply-to-thomas-graf/>, accessed on 6 August 2016)

<sup>361</sup> C. D’Amore, *The Administrative Supreme Court Confirms the ICA’s Decision to Condemn Pfizer for Abuse of Dominant Position*, *Italian Antitrust Review*, 2014, p. 80 (citing Council of State, III, decision No. 2857, dated 17 May 2012). See also UNCTAD Secretariat (note by), *The Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers*, UN Conference on Trade and Development, 27 April 2015, p. 13 (“*Therefore, besides the legitimate nature of the right, the purpose to grant such legal right by the legislator shall be taken into account with more proportion when weighing the pros and cons in making a decision on the abuse of intellectual property rights.*”)

<sup>362</sup> The EPO Board of Appeal denied the existence of double patenting and approved the divisional patent because the optimal dosage of the active ingredient in Xalatan had not been claimed by, nor could be inferred from the description of, the original patent application. This however brings about another issue, the legitimacy of the divisional. As explained by G. Ghidini, G. Cavani, P.F. Pisera’, *Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case*, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 266-267, “*by inserting in the divisional of such ‘further’ claim with respect to the parent patent [...], an extension of the inventive material covered by the main application was implemented, thus running counter to the principle that the divisional application may involve only ‘elements that do not extend beyond the content of the initial application’, and that, after having been originally ‘packed’ in the only parental patent, they were then removed from the latter and inserted in the divisional (only). [...] In this perspective, it is all the more doubtful that the divisional application was filed strictly for the purpose of splitting what was reasonably considered compatible with the principle of ‘unity of invention’ (Article 82 EPC).*”

excluding competitors, with no benefit to innovation and consumer welfare other than those already achieved by the main patent, might constitute an abuse of rights as well as an abuse of a dominant position if it restricts competition. In *Pfizer*, the ICA found that the originator purposefully adopted a complex strategy to create a climate of legal uncertainty in respect of the possibility to commercialize the generic version of Xalatan. Pfizer's conduct with respect to the filing of a divisional patent application (without any new product or new version being introduced or even the patent being validated in more than just the countries in which Pfizer needed an SPC) and application for the related SPC and extension for pediatric trial, were further aggravated by the submission of numerous formal warning letters to generic manufacturers intimating them not to enter the market prior to the loss of exclusivity. The cease-and-desist letters were followed by civil lawsuit against alleged infringers to prevent, discourage or raise costs of generic entry. Finally, Pfizer tried to prevent AIFA from granting marketing authorization to generic manufacturers and include the generic versions of Xalatan in the list of generic medicines available on the market (so-called "transparency list"). As a result of these actions, competition was significantly restricted as the first market entry was in May 2010.<sup>363</sup>

On this basis, the ICA reached the conclusion that, even though Pfizer's conduct was in the abstract compliant with patent law, it integrated "a single and complex exclusionary strategy" in violation of Article 102 TFEU.<sup>364</sup> Accordingly, the ICA imposed on Pfizer a fine for abuse of dominant position amounting to €10.6 million.

The most interesting element of this case is the fact that the ICA (and on appeal the CoS) expressly identified the abuse of a dominant position as a *species* of the *genus* abuse of rights, which is what this work is premised upon. In the case at stake, Pfizer abused two "*distinct, although teleologically convergent rights.*"

*"The first one is the right of – rectius: to – the patent, (Needless to say, 'patent right' and 'right to the patent' are not synonymous. The former refers to the complex of exclusive rights that the law grants to the holder after the patent has been awarded, particularly: the right to put into effect, use and make a profit from the invention. The latter refers to the right and corresponding conditions, to apply for and obtain a valid patent entitlement) where the abuse lies in the unlawful mode of*

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<sup>363</sup> "According to industry data presented by Pfizer itself, the delayed entry of the manufacturers of generics gained the company a seven-month extension of its monopolistic profits, which amounted to approximately 17 million euros (based on the market share gained by generic manufacturers during the first seven months of market entry). Thanks to its strategy, Pfizer managed to: 1) increase the effective market entry costs for the manufacturers of generic drugs; 2) delay the market entry of Xalatan-equivalent specialty drugs by at least 7 months; 3) maintain the de facto exclusive commercialization of medicines based on latanoprost even after patent coverage had expired; 4) cause an estimated 14 million euros in lost savings by the NHS. These elements led the Authority to classify the sanctioned competitive violation as very serious." (ICA, Press Release. Pfizer sanctioned with 10.6 million euro fine for abuse of dominant position, 17 January 2012, available at <http://www.agcm.it/en/newsroom/press-releases/1986-pfizer-sanctioned-with-106-million-euro-fine-for-abuse-of-dominant-position.html>, accessed on 6 August 2016)

<sup>364</sup> In defining the relevant market, the ICA followed the method adopted by the European Commission and referred to the ATC4 level, limiting it to prostaglandin-analogous products (due to the different modes of action of prostaglandins and beta-blockers, and the different effectiveness to treat specific pathologies, the two types of products were not considered substitutable). Pfizer was found dominant in light of (i) high market share (Xalatan was the de facto standard in the prostaglandin market), (ii) scarce competition by substitution and absence of competition by imitation (generics), (iii) high barriers to entry before and after patent expiry.

*application: in Pfizer, for obtaining an extension of the exclusive right thanks to a SPC of a divisional patent (in fact, note: a divisional of a previous divisional, in turn obtained from the main patent), in contrast with the principle known as unity of invention (Articles 82 EPC, Rule 44 EPC's Executive Regulation). The aim and effect of the foregoing was to exclude others from gaining access to an active ingredient, adopted as the de facto standard, which the competitors legitimately expected as forthcoming off patent due to the imminent expiry of the 'parental' patent. (The filing of divisional applications for exclusionary purposes was analysed by the European Commission which revealed how this practice – an example of strategic patenting – creates uncertainty as to the scope and duration of the patent right. In fact, until such time as the European Patent Office finally rules on the grant of the right, the party filing the patent is entitled to the early protection recognized by Art. 67, subs. 1, of the European Patent Convention. This applies even if the parent patent has been invalidated (or where the application is still pending). Therefore, the applicant of an original patent (until the original patent has not yet been granted) who subsequently files a series of divisional applications related to one or more 'portions' of the original application, may benefit from 'consolidated' protection. [...]) The second form of abuse is the right to appeal to the Courts, which consists – from an antitrust perspective of the sham litigation – in the launch, under the exclusive right artfully achieved, of a judicial and para-judicial intimidation campaign. [...] [I]his aspect seems to be assessed not as an autonomous exclusionary conduct, but rather as an additional element of 'circumstantial' evidence of the abusive form of strategic patenting committed by the dominant undertaking.*<sup>365</sup>

In *Pfizer*, the finding of an abuse of rights (basis for the finding of an abuse of dominance) arose from the nature of Pfizer's conduct, aimed at delaying and preventing generic entry, to the detriment of consumers. To assess the originator's behavior, the ICA and the CoS looked at: (i) the timing of the divisional application, more than 10 years after the parent patent application and just in time to obtain the SPC; (ii) the non-use of the divisional, which did not lead to the introduction of a new drug or a version of the already marketed drug and was validated only in Italy, Spain and Luxembourg, which were the only countries in which Pfizer did not apply for an SPC in time; (iii) the de facto extension of the exclusivity on the brand-name drug (and not merely on the "innovation" covered by the divisional) thanks to the SPC and pediatric extension application based on a divisional of a divisional of the patent on the main compound. Based on the foregoing, the ICA's and CoS's conclusion can be summarized in the words of Professors Ghidini and Cavani: "*the divisional patent [...] was requested and obtained for a purpose other than the one assumed by the law. This is not only because the divisional application had been filed thirteen years after the 'grand-parent' patent application without any objective justification for such abnormal delay; but also and especially because such a late request appeared to be aimed strictly at enabling the period in which Pfizer could request and obtain that SPC that it had forgotten to timely request in Italy and Spain, as had instead been done in many other countries, 'to start to run afresh'.*"<sup>366</sup>

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<sup>365</sup> G. Ghidini, G. Cavani, P.F. Pisera', Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 259-260.

<sup>366</sup> G. Ghidini, G. Cavani, P.F. Pisera', Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 265 (at footnote 54, the authors note: "*What was questioned, rather, was the abusive nature, in this case, of the procedure followed to obtain the result and the fact that, in doing so, the patent holder thwarted the legitimate expectations of the competitors to*

In its analysis of Pfizer's conduct, the ICA took into account, not only the objective factors mentioned above, but also Pfizer's intention deemed "*the binding agent of an anticompetitive strategy*". Although the abuse of dominance is an objective concept, intent can still be relevant in determining the anticompetitive nature of the conduct. For this reason, the ICA referred to several excerpts from internal communications that confirmed the fact that Pfizer was aware of the fact that its application was baseless and feared antitrust enforcement.

Pfizer was thus sanctioned for its antitrust violation and appealed the ICA decision before the administrative court (of first instance) of Lazio, which overturned it in its judgment of 3 September 2012. The court took the position, awfully similar to that of the dissenting opinion in the U.S. Actavis case (discussed below), that Pfizer's conduct could not be abusive as the originator simply pursued its legitimate interests, by lawfully exercising its rights under the (patent) law. According to the administrative court, Pfizer's applications for the divisional patent, the SPC and the pediatric extension were perfectly legal and Pfizer's enforcement strategy was simply a legitimate way to protect its intellectual property rights from infringement. The ICA lodged an appeal against the judgment of the administrative court of first instance before the CoS, which reinstated the ICA decision on 12 February 2014. This judgment is the most innovative part of the case as the Council of State expressly stated the position taken by this work: the abuse of dominance is a *species* of the wider *genus* of abuse of (patent) rights.<sup>367</sup> In the words of the Court:<sup>368</sup>

*"the abuse of a dominant position, attributed to Pfizer, is nothing more than a specification of the broader category of abuse of right, of which a condition is precisely the existence of a right, exercised in a distorted way, inconsistent with the purpose for which it was provided for by the legal system: in this case, the exclusion of competitors from the market."*

And again:

*"The considerations discussed above can be summarized in the sense that, while representing, and indeed precisely because, in theory, they represent, if taken individually, the exercise of rights conferred in the abstract by the legal system, [...] the conduct and actions undertaken by Pfizer resulted in a complex and comprehensive behavior not wrongly defined by the Authority in terms of abuse of right and, particularly, anticompetitive."*

The ICA and the CoS have thus taken the position (shared by this author) that an

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*enter the market on the twentieth year, nullifying, or at least compromising, their projects and investments. In this sense, it must be said that the end (the obtaining of an extension of the twenty-year term, in itself abstractly legitimate from the point of view of the patent system) did not justify the means, since through this distorted modus procedendi Pfizer had obtained a more advantageous and additional result compared to the standard exclusionary effect typical of patent protection: i.e., paralyzing, in a way not foreseen or foreseeable, the competitive activity of generic manufacturers already operating in the market. Pfizer brought about an unexpected extension of the patent protection similar to that established in certain cases by patent law itself."*

<sup>367</sup> In the words of the CoS, "*the constituting elements of the abuse of rights are [...] the existence of a right [...]; the possibility that the right can be actually exercised in a variety of non rigidly predetermined manners; the fact that the actual exercise of the right, although formally compliant with the law conferring it, is performed in a reprehensible manner [...]; the fact that, due to the manner in which it was exercised, it resulted in an unjustified disproportion between the benefit to the right holder and the harm to the other party; therefore the abuse of rights, far from requiring a formal breach of the law, entails the distorted use of the legal framework, aimed at pursuing objectives which go both further and are different from those indicated by the legislator*".

<sup>368</sup> Council of State (Consiglio di Stato), AGCM v. Pfizer Italia s.r.l., Pfizer Health Ab and Pfizer Inc., 12 February 2014, no. 693.

antitrust violation (particularly an abuse of dominance) is an abuse of rights with a plus factor, the anticompetitiveness. The abuse of dominance thus belongs to the broader category of abuse of rights which encompasses all the conducts formally permitted by the law but contrary to its purpose (as they create an unjustifiable disproportion between the benefit of the right-holder, in this case the patentee, and the harm caused to its counterparty, in this case society) and thus unlawful under the same law. Therefore, the fact that a conduct is legitimate under the language of the law is irrelevant for the application of antitrust law, not only because the violation of antitrust does not require the formal violation of any other law (as the violation of another law is dealt directly by the provisions of that law), but also because formal compliance does not exclude the abuse of right, on which an antitrust infringement is premised. While the abuse of rights conferred by a specific law could be addressed through the doctrine of abuse or misuse of rights by the law itself, the antitrust intervention (which is not coextensive with the abuse of right as it requires a plus factor) is sometimes necessary to correct the effects of the conduct and deter the patentee (and any other) from adopting the same abusive behavior.

In this case, the CoS concluded that the ICA was right in holding that, although Pfizer's request for a divisional patent (and subsequent request for an SPC) was formally legitimate under patent law, Pfizer exercised its right not for the purposes for which it was provided (protecting a new invention), but with the sole aim of extending the exclusivity on the brand-name drug beyond its term, and thus delay generic entry.

## 12. Sham litigation

As we saw, the creation of a patent cluster (as well as most of the other abusive techniques discussed by this work) is often coupled with a lawsuit (or the threat of one). Indeed, for its conduct to be as effective as possible (and thus keep generic manufacturers and other competitors out of the market), the originator has to enforce its rights against potential infringers. This is of course not unlawful per se, the enforcement of lawfully obtained rights is fundamental to the well-functioning of any legal system and has positive effects on the overall, as well as consumer, welfare. Concerns however arise when the right of access to court is abused and litigation is used to reinforce the effects of another anticompetitive practice, *e.g.*, of patent clusters and defensive patents (by increasing legal (un)certainly regarding the patent protection of the brand-name drug and discouraging generic entry), of fraudulently obtained patents, and as a way to reach a reverse payment patent settlement. Litigation may also be abusive when it is an end in itself, *i.e.* the originator has no interest in the results of the litigation and promotes a lawsuit solely to harass the generic manufacturer or other (actual or potential) competitor and cause them damage, this way preventing, delaying or making less effective generic (or other competing product) entry.<sup>369</sup> In short, sham litigation can be defined as “*predatory or abusive litigation before administrative or judicial courts by firms that have no reasonable grounds for their claims, but anticipate that the costs of litigation will be lower in relation to the benefits to be obtained from the delay of the entrance of a*

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<sup>369</sup> “[T]he plaintiff wants to hurt a competitor not by getting a judgment against him, which would be a proper objective, but just by the maintenance of the suit, regardless of its outcome.” (Professional Real Estate Investors, Inc., v. Columbia Pictures, 508 U.S., 1993)

*competing product on the market during the period of litigation*".<sup>370</sup>

The prospect of lengthy and costly litigation might deter smaller generic companies (as well as competing originators), without the necessary financial resources, from developing or launching their product in competition with that of the originator (particularly in cases where the originator may be granted a preliminary injunction and the generic would thus be unable to sell its products on the market, while the originator will continue to collect revenues).<sup>371</sup> As the European Commission notes in the executive summary of its Pharmaceutical Sector Inquiry,

*"Enforcing patent rights in court is legitimate and a fundamental right guaranteed by the European Convention on Human Rights: it is an effective means of ensuring that patents are respected. [H]owever, [...] litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants. [...] The vast majority of disputes were initiated by the originator companies, which most often invoked their primary patents, e.g. by sending warning letters."*<sup>372</sup>

What is most concerning is the fact that "[i]n contrast to the primary patents invoked in the pre-litigation phase, originator companies mainly invoked secondary patents during litigation",<sup>373</sup> which may indicate that the patents invoked in the warning letters were expired, invalid or unenforceable and/or that the originator have a significant amount of patents covering the same drug (patent cluster) used as means to start litigation against generic manufacturers and delay or block their entry. Equally concerning is the fact that "[w]ilst the originator companies initiated the majority of the cases, generic companies won 62% of [them]" and "[t]he average duration of the court proceedings was 2.8 years, but varied considerably between Member States, from just over six months to sometimes more than six years."<sup>374</sup>

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<sup>370</sup> V. Guimarães de Lima e Silva, *Sham Litigation in the Pharmaceutical Sector*, 7(3) *European Competition Journal*, 2011, p. 455.

<sup>371</sup> The European Commission goes into much more details in its *Pharmaceutical Sector Inquiry: Final Report*, 8 July 2009, par. 583 ("*Patent litigation can influence the commercial decisions of generic companies. In particular, the threat of lengthy and costly patent litigation across EU Member States can dissuade smaller generic companies from launching a competing product, hence avoiding burdensome court procedures, before patent expiry, even if they consider the patent to be invalid or not to have been infringed. Even if generic companies are not put off by patent litigation and are willing to go to court, litigation can have an impact on bringing to market a generic version of the originator product. Most importantly, interim injunctions can oblige generic companies to withdraw their product from the market and refrain from further production and commercialisation until the main action is decided. It goes without saying that interim injunctions can also be a necessary and legitimate tool allowing patent-holders to effectively enforce their patent rights. However, the grant of interim injunctions can become particularly relevant when examined in the light of originator companies' overall patent and life cycle strategies which are aimed at maximising profit and shielding their products from competition.*")

<sup>372</sup> European Commission, *Communication - Executive Summary of the Pharmaceutical Sector Inquiry Report*, SEC(2009) 952 COM(2009) 351 final, 8 July 2009, p. 12.

<sup>373</sup> European Commission, *Communication - Executive Summary of the Pharmaceutical Sector Inquiry Report*, SEC(2009) 952 COM(2009) 351 final, 8 July 2009, p. 13.

<sup>374</sup> European Commission, *Communication - Executive Summary of the Pharmaceutical Sector Inquiry Report*, SEC(2009) 952 COM(2009) 351 final, 8 July 2009, p. 12. At p. 13, the Commission notes also that "[i]n 30% of the cases litigation was initiated between the same parties in more than one Member State with respect to the same medicine. In 11% of the final judgments reported, two or more different courts in different EU Member States gave conflicting final judgments on the same issue of patent validity or infringement." See also European Commission, *Pharmaceutical Sector Inquiry: Final Report*, 8 July

To recap, most lawsuits are brought by originators on the basis of secondary patents and the absolute majority of those that reach judgment are decided in favor of the generic manufacturer. The generic manufacturer has however to spend serious amounts<sup>375</sup> and wait from six months to six years (the proceedings last on average 2.8 years) to be able to have legal certainty that its product does not infringe the originator's patents (and thus that it does not risk liability for damages marketing it). In the course of the proceedings, originators are granted injunctions lasting on average 18 months in half of the cases, but almost half of these cases end in a way favorable to the generic manufacturer.<sup>376</sup>

As for the other abuses of dominance, also sham litigation is primarily an abuse of rights (to access to court)<sup>377</sup> and becomes also an abuse of dominance when coupled with (potential) anticompetitive effects (and is undertaken by a company with significant market power). The abuse of right is particularly evident when litigation is based on double patenting, defensive patenting or patent clusters (e.g. using divisional and divisional of divisional), where the originator attempts to keep generics "busy" with the litigation for as long as possible.<sup>378</sup> To determine whether litigation can be qualified as abusive, the originator's intention to harm<sup>379</sup> and knowledge of the harassing nature of its action (due to

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2009, par. 501, and the other sources mentioned *supra* at footnote 320.

<sup>375</sup> The Commission reports that "[t]he total cost of patent litigation in the EU relating to the 68 medicines on which litigation was reported for the period 2000 – 2007, is estimated to exceed € 420 million, of which a significant proportion could have been saved, if the cross-border duplication of cases linked to the absence of a Community patent and a specialised patent litigation system could have been avoided." (European Commission, Communication - Executive Summary of the Pharmaceutical Sector Inquiry Report, SEC(2009) 952 COM(2009) 351 final, 8 July 2009, p. 13)

<sup>376</sup> Indeed, originators "asked for interim injunctions in 255 cases, and were granted such injunctions in 112 cases. The average duration of the interim injunctions granted was 18 months. In 46% of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favourable to the generic company, or settlements which appear to be favourable to the generic company as they allowed early entry for the generic company and/or foresaw a value transfer to it. In addition there were a number of further patent settlements, for which a final classification (i.e. favourable to the generic or the originator company) was not possible." (European Commission, Communication - Executive Summary of the Pharmaceutical Sector Inquiry Report, SEC(2009) 952 COM(2009) 351 final, 8 July 2009, p. 13)

<sup>377</sup> As noted by G. Ghidini, G. Cavani, P.F. Pisera', Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 269, "even in the absence of a dominant position in the strict sense, [sham litigation can] be qualified, as confirmed by the case law, as an act of unfair competition. See, for example, *Supreme Court of Cassation (Civil) Section I*, 26 Nov. 1997, no. 11859 and *Milan Court*, 29 Mar. 2007, in *G.A.D.I.*, 2007, 304, according to which 'the transmission of a letter demanding that a product not be brought to market could be considered in the context of Art. 2598, no. 3, of the Civil Code, given that the threat of legal proceedings made culpably or in bad faith – ignoring the obvious invalidity of the patent – constitutes an inappropriate market disturbance'. See also T. Ascarelli, *Teoria della concorrenza e dei beni immateriali [Theory of Competition and Intangible Goods]*, Milan, 1960, p. 262".

<sup>378</sup> See e.g. *Rb. Brussel (kort geding)* 26 Oct. 2004, *Medinol Ltd. c. Janssen Pharmaceutica, Johnson & Johnson Medical, Cordis Holding Belgium (Johnson & Johnson Group)* (04/607/C), as cited by A. Leonard, *Abuse of Rights in Belgian and French Patent Law – A Case Law Analysis*, Jipitec, 2016, pp. 44-45.

<sup>379</sup> See, e.g., with respect to Belgium and France, A. Leonard, *Abuse of Rights in Belgian and French Patent Law – A Case Law Analysis*, Jipitec, 2016, p. 35 ("It is worth noting that prior to 2003, the intention to harm criterion played a predominant role in the evaluation of AoR in the course of litigation. However, in a landmark decision regarding procedural abuses, the Belgian *Cour de cassation/Hof van cassatie* clarified that this criterion was not unique, and that manifest excesses in the exercise of a right can turn a procedure into a vexatious litigation [...]. Similarly [...], the French *Cour de cassation* has also declared that procedural abuse does not require an

the invalidity of the patent or lack of infringement)<sup>380</sup> are the key elements.<sup>381</sup> These elements are common to both an abuse or misuse of rights and an antitrust violation.<sup>382</sup> For instance, in the U.S., the Federal Circuit explained that “[t]he bringing of a lawsuit to enforce legal rights does not of itself constitute violation of the antitrust laws or patent misuse; there must be bad faith and improper purpose in bringing the suit, in implementation of an illegal restraint of trade. See *American Tobacco Co. v. United States*, 328 U.S. 781, 809, 66 S.Ct. 1125, 1138, 90 L.Ed. 1575 (1946) (otherwise lawful acts, when done to give effect to conspiracy to restrain trade, are forbidden); *Grip-Pak, Inc. v. Illinois Tool Works, Inc.*, 694 F.2d 466, 472 (7th Cir.1982) (even if a lawsuit has a colorable basis, it can violate the antitrust laws if filed for an improper purpose), cert. denied, 461 U.S. 958, 103 S.Ct. 2430, 77 L.Ed.2d 1317 (1983). A purpose is improper if its goal is not to win a favorable judgment, but to harass a competitor and deter others from competition, by engaging the litigation process itself, regardless of the outcome.”<sup>383</sup>

In the U.S., two are the most important cases when it comes to sham litigation, *Noerr* (which establishes an immunity from antitrust liability for “petitioning the government”, including filing a lawsuit)<sup>384</sup> and *PREI*.<sup>385</sup> On the basis of these precedents, a patentee is

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*intentional element. Specifically, it was deemed sufficient to demonstrate that the right had been used for another purpose than its social goal [N. Cayrol (n.27). The plaintiff does not act to restore justice, but merely to pressure the defendant.] or that the right holder acted with frivolousness?”* See also p. 38 (“As with the difficulty to prove the knowledge of the patent holder, it is quite clear from the cases analysed that, for the argument of abuse to succeed, it is necessary to demonstrate a manifest intention to harm or to clearly objectify this intention by relying on the particular circumstances of the case.”)

<sup>380</sup> A. Leonard, Abuse of Rights in Belgian and French Patent Law – A Case Law Analysis, Jipitec, 2016, p. 41 (“This combination was at the heart of a 2003 French Supreme Court case. [...] [I]t was manifestly abusive for a patent holder to enforce a patent for which he/she could not have misunderstood, in good faith, the extent of its scope (i.e. the knowledge of the patent holder). Therefore, a patent holder could not have initiated an infringement action when he/she knew, or should have known, that its patent was actually not infringed upon. To do so could only have been explained by the intention to intimidate a competitor and to drive them out of the market (i.e. unfair competition practices).”)

<sup>381</sup> A. Leonard, Abuse of Rights in Belgian and French Patent Law – A Case Law Analysis, Jipitec, 2016, p. 34 (“Therefore, when litigants institute legal procedures – or persevere in a legal action – with the sole purpose of harming the defendant (the intention to harm criterion), in a disproportionate manner (the proportionality criterion) or with a particular objective not intended by the legislator (the right-function criterion), it can become abusive. An action is considered vexatious when a litigant uses the procedure to (intentionally/maliciously) hinder or harm third parties. In short, there will be an AoR in the course of litigation when the right holder exercises his/her rights with either, the intention to harm or when he/she is inexcusably negligent, frivolous or indifferent to the consequences of this exercise.”)

<sup>382</sup> “Vexatious litigation under patent misuse is similar to sham litigation under the antitrust laws in that the theory of misconduct flows from patentees coercing and intimidating defendants into submission despite having weak or invalid patents by saddling defendants with litigation costs. (See Guido Calabresi, *The Costs of Accidents: A Legal And Economic Analysis* 26, 135-73 (1970) (arguing that imposing liability on the party best able to choose between accident and safety costs maximizes the efficiency in accident cost reduction).) One court has treated misuse based on vexatious litigation similarly to sham litigation. (*Moore U.S.A., Inc. v. Standard Register Co.*, 139 F. Supp.2d 348, 362 (W.D.N.Y., 2001) (“it appears that SRC can state a patent misuse claim to the extent that it alleges that Moore NA, Toppan Printing and Moore Canada have engaged in sham litigation. In other words, the same facts that could support a finding of sham litigation (and an antitrust violation) could also support a finding of patent misuse [...]. In light of the Federal Circuit’s decision in *Galverbel*, SRC’s ninth counterclaim survives this motion to dismiss for the same reasons that SRC’s antitrust counterclaims survived”).” (D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Edward Elgar, 2013, p. 137)

<sup>383</sup> *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d, Fed. Cir., 1995, p. 1558.

<sup>384</sup> *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S., 1961, p. 144

<sup>385</sup> *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 1993.

presumptively entitled to immunity for filing a lawsuit – a finding of misuse, as well as of an antitrust violation (if the underlying elements of an antitrust violation are present), requires two elements: objective and subjective baselessness. First, the claim must be objectively baseless, *i.e.* no reasonable litigant could realistically expect success on the merits (because the patent is invalid or not infringed). Second, if the objective element is established,<sup>386</sup> it must be demonstrated that “*the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor, through the use of the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon.*”<sup>387</sup> This second prong protects litigants that filed an objectively baseless suit in good faith. Indeed, negligence or recklessness are not sufficient to establish an antitrust violation, and a knowledge of the meritlessness of the suit or, more likely, the specific intention to harass a competitor is required.<sup>388</sup> In *Abbott v. Teva*,<sup>389</sup> the district court denied motion to dismiss because it recognized that Abbott’s infringement lawsuits could constitute sham litigation. The court’s finding was based on the two prong-test outlined above. First, as to the objective baselessness, before bringing the lawsuit the patentee did not investigate (by obtaining the infringing product and conducting a good faith comparison) whether the generic actually infringed its patents. Second, subjectively, the originator was perfectly aware of the fact that the allegedly infringed patents were unenforceable due to inequitable conduct before the Patent Office.

At the EU level, as seen above, the European Commission expressly recognized as a fundamental right guaranteed by the European Convention on Human Rights the right to effective remedies and a fair trial to ensure the respect of patent rights. The requirements for a finding of sham litigation are thus not very different from the U.S. The leading case decided by European Commission (rejecting IIT Promedia’s complaint) and General Court (confirming the Commission’s decision) is *IIT Promedia*.<sup>390</sup> In this case, while confirming that entering into litigation is expression of the fundamental right of access to justice and could not be considered abusive in itself,<sup>391</sup> the Court conceded that an antitrust violation can be exceptionally envisaged when the action brought by the dominant firm fulfills two criteria: (i) is objectively manifestly unfounded (*i.e.* it “*cannot reasonably be considered as an attempt to establish [the plaintiff’s] rights and can therefore only serve to harass the opposite party*”) and (ii) is “*conceived in the framework of a plan whose goal is to eliminate competition*”.<sup>392</sup> Both criteria must be fulfilled to

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<sup>386</sup> Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S., 1993, p. 60 (“*Only if the challenged litigation is objectively meritless may a court examine the litigant’s subjective motivation.*”)

<sup>387</sup> Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S., 1993, p. 62. See, with specific reference to patent misuse, *In re Indep. Serv. Org.*, 85 F. Supp. 2d, D. Kan., 2000, p. 1169. See also H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen, 2014, p. 11-26 (“*The Supreme Court relied extensively on the existence of “probable cause” to bring the underlying lawsuit, as the standard established and defined in the context of the tort of malicious prosecution. In the words of the Court, “a proper probable cause determination irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to Noerr immunity.*”)

<sup>388</sup> H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen, 2014, p. 11-30.

<sup>389</sup> *Teva Pharmaceuticals USA, v. Abbott Laboratories*, 580 F. Supp.2d, D. Del., 2008.

<sup>390</sup> General Court, T-111/96, *IIT Promedia v Commission*, 17 July 1998.

<sup>391</sup> General Court, T-111/96, *IIT Promedia v Commission*, 17 July 1998, par. 60.

<sup>392</sup> General Court, T-111/96, *IIT Promedia v Commission*, 17 July 1998, par. 55.

establish an abuse,<sup>393</sup> and the second (subjective criteria) may be considered only after the first has been satisfied.<sup>394</sup>

### 13. Product Hopping

Another abuse of market power involving patents is the so-called product hopping. This abuse has been dealt with by authorities and courts in the U.S., EU, and individual Member States.

Product hopping (or product switching) is one of the most popular tactics used by originators to extend the period of exclusivity over a cure.<sup>395</sup> It consists in modifying certain characteristics of the drug, *e.g.*, dosage; means of administering the drug: such as tablet (extended release, orally dissolving, or chewable), capsule, injectable, solution, suspension, syrup; and addition, removal or combination of active compounds; to qualify for a new patent, or at least prevent generic substitution,<sup>396</sup> shortly before the patent on the older version of the drug expires, and then withdrawing the older drug from the market.<sup>397</sup>

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<sup>393</sup> General Court, T-111/96, IIT Promedia v Commission, 17 July 1998, par. 56 (“*The fact that unmeritorious litigation is instituted does not in itself constitute an infringement of Article 86 of the Treaty unless it has an anti-competitive object. Equally, litigation which may reasonably be regarded as an attempt to assert rights vis-à-vis competitors is not abusive, irrespective of the fact that it may be part of a plan to eliminate competition.*”)

<sup>394</sup> General Court, T-111/96, IIT Promedia v Commission, 17 July 1998, par. 59.

<sup>395</sup> The European Commission found that “*originator companies [tried to switch patients of their medicine facing imminent loss of exclusivity to a so-called second generation, or follow-on, medicine] in relation to 40% of the medicines in the sample selected for in-depth investigation, which had lost exclusivity between 2000 and 2007.*” (European Commission, Pharmaceutical Sector Inquiry, Preliminary Report, Fact Sheet “Originator-Generic competition”, p. 4)

<sup>396</sup> As noted by Professors S. Hemphill and Lemley, “*Another tactic is to execute multiple switches, for example, from a capsule form to a tablet form, and then a second switch—as the generic firm again closes in on approval—to a third, slightly different tablet form.*” (C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, p. 961)

<sup>397</sup> Timing is of the essence for a successful product switch. As the Commission explains in its sector inquiry report, “[*t*iming the launch of a follow-on product is crucial for originator companies. If cheaper, generic versions of the first product come on the market before or simultaneously with the switch to the follow-on product, the originator company may incur considerable value losses both in terms of smaller volumes and reduced prices. Therefore, it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity. This means that very often accompanying measures are taken by the originator company to facilitate the switch. Such measures typically aim at effective channeling of demand from the first product to the follow-on product, but may in certain cases also attempt to delay or prevent generic entry for the sensitive period of the product switch.” (European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, paras. 1010-1011) In the fact sheet, the Commission notes that, “[*o*n average, the launch took place one year and five months before loss of exclusivity of the first generation medicine. In some cases, the first medicine was withdrawn from the market some months after the launch of the second generation medicine. If originator companies succeed in switching patients by that point, the probability that generic companies will be able to gain a significant share of the market decreases significantly. If, on the other hand, generic companies enter the market before the patients are switched, originator companies have difficulties in convincing doctors to prescribe their second generation medicine and/or obtain a high price for it.” (European Commission, Pharmaceutical Sector Inquiry, Preliminary Report, Fact Sheet “Originator-Generic competition”, pp. 4-5) The same conclusion is reached in the U.S. by M.A. Carrier, A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping, in 62 Florida Law Review, 2010, p. 1020 (“*Several examples demonstrate the crucial role played by timing. In the TriCor case, one document demonstrated the different projected sales based on timing. The brand firm, Abbott, predicted that if it launched its reformulated version before generic entry, sales would rise from 161*

This conduct is aimed at steering doctors and pharmacists to the new patent-protected version of the brand-name drug and avoiding generic competition, thus prolonging exclusivity for another patent term.<sup>398</sup> By withdrawing the previous product from the market and switching patients to the new drug, the originator hampers generic competition, as generic manufacturers cannot rely on substitution rules (that allow pharmacists to fulfill the prescription for a brand-name drug with its generic version) to make up for the significant entry barriers represented by the prolonged exclusivity granted by the patent (on the main active substance) and the originator's investment in marketing (over the life of the drug), particularly vis-à-vis doctors.<sup>399</sup>

*“When the brand name manufacturer kills demand for its old formulation, demand for rival generics dies with it”.*<sup>400</sup>

From launch of the reformulated drug, originators undertake intensive marketing efforts to convince doctors to migrate their patients to the new drug. If the old drug is still on the market, doctors are presented with a choice between two brand-name drugs, one of which is presented as an improvement to the other, for a price that is often slightly lower. In addition to the significant marketing efforts on the second-generation product, highlighting the advantages of the new product compared to the old, the originator often stops at the

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*million Euros in 2004 to 269 million Euros in 2008. But if the reformulation did not reach the market before the generic, sales would only reach 35 million Euros in 2004 and 15 million Euros in 2008. In other words, in 2008, sales would be more than 17 times greater if Abbott introduced the new version before generic entry”).* Indeed, as the European Commission highlights quoting statements from originators: *“once generics are on the market, it becomes more difficult to switch patients to second generation products, [...] “If [generics] come together with or prior to [second generation product] the switch rate is dramatically reduced. [...] Once [generics] come in it becomes more difficult to get switches from [old original product]”*; and *“Originator companies are aware of their competitive advantage if they manage to switch patients to the second generation product before loss of exclusivity for the first product: “The launch of [our second generation product] is a challenge, not experienced until now, as generics firms, [...] press onto the market with all force and as we have to fear the loss of our patent [...]. This means each patient that is not switched quickly enough to [our second generation product] is forever lost to the generics. Once the patient is switched to [our second generation product] the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!?”* (European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, paras. 1025 and 1028)

<sup>398</sup> As Professor Domeij explains: *“The originator company has in the switching context clearly done some innovative work, because the follow-on product has been awarded a patent. However, patentability requirements are low. The technical and therapeutic results when reformulating a known pharmaceutical are unpredictable to a degree, even for a person skilled in the art, which may be enough to make the reformulation patentable. With the patent, the follow-on product is shielded from direct copying. The available generics will be identical with the first generation product but, crucially, not with the second generation product. This will be enough to prevent generic substitution if physicians prescribe the follow-on product.”* (B. Domeij, Anticompetitive marketing in the context of pharmaceutical switching in Europe, in J. Drexl, N. Lee (eds.), *Pharmaceutical Innovation, Competition and Patent Law*, Edward Elgar, 2013, p. 273)

<sup>399</sup> See *State of New York v. Actavis*, No. 14-4624, 2d Cir., 2015 (*“Competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers. (The district court found that the regulatory context makes it impractical and uneconomical for generic manufacturers to market their products to doctors or pharmacists because, among other reasons, marketing costs severely impact generic manufacturers’ ability to offer the lower prices upon which they compete.)”*)

<sup>400</sup> J. Cheng, Note: An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry, 108 *Columbia Law Review*, 2008, p. 1488. See also European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, par. 1028, quoting an originator's document (*“Once the patient is switched to [our second generation product] the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!?”*)

same time any promotional activity on the first generation drug, thus limiting the opportunity for doctors and patients to compare the two.<sup>401</sup>

If doctors stop writing prescriptions for the older drug, either because it is not on the market anymore (although the patent is still enforceable) or convinced by the originator's marketing efforts, and prescribe instead the newly introduced drug; once the generic version is finally able to enter the market the patient base will be almost entirely gone. Indeed, if switching is successful, after patent expiry the use of generics will be limited to the very narrow share of the market that has not switched. Doctors and patients are unlikely to switch back after generic entry, both because of lack of marketing efforts on the first generation product and because of the doctors' inertia (and risk-aversion).<sup>402</sup>

To be substitutable with the newly prescribed drug, generics have to be equivalent, including in terms of form and dosage.<sup>403</sup> Limited reformulations, coupled with withdrawal of the first brand-name drug from the market, de-registration of the market authorization and

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<sup>401</sup> On the originators' marketing efforts, Professor Domeij notes: "*it is too simplistic to assume that the 'launch' of a new product merely entails passively making the product available for consumers. In almost all cases marketing is necessary and competition law scrutiny could be focused on this, rather than on the originator's technical product development. Even a small modicum of product improvement is beneficial for someone, but marketing is, from a competition and economic perspective, a more ambivalent practice and an easier target for scrutiny. [...] Certain specific and well-defined marketing efforts abuse a dominant position in the special context of the pharmaceutical field. Marketing will prevent the up-take of generics and constitute deviations from competition on the merits. For a host of reasons, it is evidently important with high standards concerning marketing of pharmaceuticals, but from a competition perspective this is especially true in the time-span between the launch of the follow-on product and the loss of exclusivity for the first generation medicine (typically a period of one year and five months).*" (B. Domeij, Anticompetitive marketing in the context of pharmaceutical switching in Europe, in J. Drexler, N. Lee (eds.), *Pharmaceutical Innovation, Competition and Patent Law*, Edward Elgar, 2013, p. 285-286)

<sup>402</sup> Generic companies have no resources nor incentive to invest in marketing since the cost would be borne by one manufacturer and the resulting benefits would be shared by all generic manufacturers (*i.e.* the other manufacturers would free-ride on one's marketing efforts because pharmacist may substitute any generic for any other). Generics' sole method of competition is price (and investments in marketing would make them much less competitive on price). Indeed, "*costs incurred to encourage a doctor to write a prescription for one's product would be squandered because the pharmacist could fill the prescription with a competitor's AB-rated product. As Namenda concluded, "additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors."* (787 F.3d at 656) *The inability of generics to profitably market to doctors is desirable. If a generic could do so, this would reintroduce the price-disconnect failure.*" (M.A. Carrier, *Product Hopping: A New Framework*, 91 *Notre Dame Law Review*, forthcoming 2016, p. 33) This however leads to doctors having access (pre-generic entry) only to the bias point of view of the originator on the relative merits of the drugs (both brand-name and generics). Once generics enter, originators almost always stop promoting their drug.

<sup>403</sup> Even without new patent, originators may delay generic entry by reformulating the drug because, for their product to be substitutable for the reformulated drug, generic manufacturers must obtain a new market authorization, which faces the same lengthy review as the first one. In the U.S., substitution in most States is possible only if the generic is 'AB-rated' by the FDA. "*To receive an AB rating, a generic drug must be pharmaceutically equivalent (having the same active ingredient, form, dosage, strength, safety, and efficacy) and bioequivalent (absorbed in the body at roughly the same rate). The concern when a brand reformulates its drug is that the generic version of the original product is not bioequivalent or pharmaceutically equivalent to the reformulated product. And while the generic may eventually demonstrate equivalence, such a showing likely will not occur for years as the generic reformulates its product, seeks FDA approval, and awaits the expiration of the brand's thirty month stay of FDA approval.*" (M.A. Carrier, *United States. Pharmaceutical Antitrust Law in the United States*, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 480).

changes to the reference code of the first generation product to “obsolete” (or de-listing of the product from the prescribing software) may be sufficient to impair the functioning of the drug’s substitutability mechanism and thus limit generic competition.

The legality of product hopping (any version thereof) would have a negative impact also on the originators’ incentive to invest in R&D. Investments in incremental improvements of existing blockbuster drugs would be highly encouraged and originators would concentrate their efforts on switching demand to trivial or minor reformulations instead of developing innovative, more socially valuable, but costly and of uncertain success, new drugs.

Obviously the introduction of a new formulation of a drug does not constitute an abuse in itself and can generate significant therapeutic benefits. This is the case when the follow-on drug is a real improvement over the original version, and its introduction is not primarily aimed at delaying generic entry. In these cases, however, there is no reason, other than to damage consumers and foreclose competitors, for the originator to wait until (close to) patent expiry of the first drug to release the new version, denigrate the first drug (and consequently its generic versions) as compared to the new, and/or withdraw the first drug from the market. If the follow-on drug is a real improvement over the original, consumers will switch regardless of the presence of generics in the market. This can be regarded as a good indicator of the level of improvement of the follow-on drug over the original, as consumers “vote with their feet” which drug is most beneficial to them. The originator’s conduct will thus have to be assessed in light of the innovative content of the new drug only as an indication of the anticompetitive intent (when the reformulation has no or negative impact on consumer welfare), which is not the end, but only an element, of the antitrust assessment.

To get more into detail, the switch characterizing product hopping may take two different forms: hard and soft. The soft switch consists in the differential promotion of the two drugs (favorable comparison of the new product to the old one, “denigration” of the old drug potentially highlighting risks to the patient’s health and side effects, aggressive promotion of the new drug, including pressure on doctors, hospitals and insurance companies, and complete halt of any promotion of the previous version)<sup>404</sup> and differential price (raising the price of the old drug and selling the new one at a sensibly lower price or with heavy discounts, increasing with the quantity purchased). It is evident how doctors and patients, in a situation in which there are no generics on the market (and there will not be for some time as the patent on the old drug is not expired yet), the new drug is described as the “*panacea*” and the old as a seriously lacking cure (to which generic manufacturers cannot respond adequately), and the price differential between the two is in favor of the new drug, may be persuaded to switch. By the time generic approval has been obtained, the market has already moved on to the new, patent-protected, drug. As described above, switching back patients and doctors once generics enter the market is extremely difficult given the characteristics of the pharmaceutical market.<sup>405</sup>

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<sup>404</sup> This strategy, substantially addressed against the originator’s own old drug has been defined “*cannibalizing*” (S.D. Shadowen, K.B. Leffler, J.T. Lukens, *Anticompetitive product changes in the pharmaceutical industry*, 41 *Rutgers Law Journal*, 2009, p. 45).

<sup>405</sup> In certain cases, such as *Namenda*’s discussed below, the specific characteristics of the drug or of the patients make switching back even less likely (in *Namenda* this was due to the high

The soft switch has not been considered in breach of antitrust (in the U.S.),<sup>406</sup> although denigration of generic drugs has been (in France, see below). This author agrees with the finding that soft switch is not anticompetitive when it happens once the patent on the old drug has expired and generics could (and did) enter the market.<sup>407</sup> If the conducts described above are undertaken before loss of exclusivity on the first drug, however, both patients and doctors can be easily misled and the originator's behavior cannot be qualified as competition on the merits. It would thus depend on how serious the effort to mislead doctors and consumers is. If it is significant and unjustified by the objective difference between old and new drug, it would not fit under competition on the merits and would thus constitute a breach of antitrust rules.<sup>408</sup> As clearly explained by Professor Domeij:

*“A dominant firm’s price or quality comparisons between its first and second generation pharmaceutical in a marketing context should be deemed abusive as long as the first generation product is still benefitting from exclusivity. In effect, negative statements concerning the first generation product are in this period statements directed at soon to be launched generic products. It is not obvious, but in the switching window any marketing messages formally directed at the first generation product are in practice concerned with competitors’ future generic products. This is a direct consequence of the rules on generic substitution. Negative statements are likely to be misleading about the relative value of the soon to be launched generics, due to generic companies’ inability to respond. During exclusivity generics may not legally be marketed due to the patent on the first generation product. After patent expiry generics cannot realistically be market for economic consequences flowing from the rules on generic substitution. Another rationale for not accepting negative statements concerning the first generation product as competition on the merits, is that resulting patient migration is not profit maximizing for the originator absent the competitive changes that will arise in the near future for the first and second generation products. When the comparative advertisement is made the second generation product is normally no more profitable than the first generation product for the originator. The marketing is only profit-maximizing because switched patients will after migration be mostly captured, that is not exposed to pending generic competition. They are locked in due to a lack of marketing funds for generics and rigidities in physicians prescribing practices. Negative messages in general about the first generation product and comparisons with the second generation product in*

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transaction costs associated with changing Alzheimer patients’ prescriptions).

<sup>406</sup> In the U.S., the Second Circuit stated: “As long as Defendants sought to persuade patients and their doctors to switch from [Product A] to [Product B] while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.” (New York v. Actavis plc, No. 14-4624, 2nd Cir., 22 May 2015). See also Walgreen Co. v. AstraZeneca Pharms., 534 F. Supp. 2d, D.D.C., 2008.

<sup>407</sup> The importance of timing for (a successfully anticompetitive) product hopping is underlined by M.A. Carrier, Product Hopping: A New Framework, 91 Notre Dame Law Review, forthcoming 2016, p. 10 (“Stated most simply, the brand firm will be much more successful in forestalling generic competition if it can switch the market to the reformulated drug before a generic of the original product enters the market. Without a generic on the market, the brand’s heavy promotion and marketing artillery can convince doctors to prescribe the reformulated drug. If the brand successfully switches the market to the reformulated product before the generic enters, the generic entry is of no practical significance: there are few or no prescriptions for the original product for which the generic can be substituted.”)

<sup>408</sup> See G. Ghidini, Profili Evolutivi del Diritto Industriale, Profili evolutivi del diritto industriale: innovazione, concorrenza, benessere dei consumatori, accesso alle informazioni, Giuffrè, 2015, Ch. V, par. 9, who would not condemn product hopping before having verified whether the new product represents a “cosmetic” bluff and nothing more or an actual (incremental) innovation.

*particular, are not profit-maximizing for the originator in the short time frame, but will be when competition develops differently in the near future for the first and second generation products.”*<sup>409</sup>

The hard switch involves, often in addition to the practices qualified as soft switch, the discontinuation of the old drug.<sup>410</sup> Contrary to the soft switch, the hard switch is not limited to trying to persuade (more or less aggressively) doctors and patients to switch, it actually forces them to do so (since they cannot, even if they wanted to, buy the old, and withdrawn, drug). Discouraging or impeding generic competition without an objective and legitimate business justification is considered in violation of competition law.<sup>411</sup>

In both cases of hard and soft switch, the test developed by courts in relation to anticompetitive product redesign should be applied. First, it is for the authority/plaintiff to demonstrate that the switch has anticompetitive effects, *i.e.* it coerces consumers and impedes competition.<sup>412</sup> Once this has been demonstrated, the originator must present a

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<sup>409</sup> B. Domeij, Anticompetitive marketing in the context of pharmaceutical switching in Europe, in J. Drexler, N. Lee (eds.), *Pharmaceutical Innovation, Competition and Patent Law*, Edward Elgar, 2013, pp. 286-287.

<sup>410</sup> “[T]he withdrawal of a product/registration, and/or its replacement with another that is functionally equivalent [...] in order to preclude or obstruct generic competition, can be characterised as such conduct” (R. O’Donoghue, J. Padilla, *The Law and Economics of Article 102*, Hart, 2013, p. 669). “Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, *id.* at 287, and to impede competition, *id.* at 274-75, its actions are anticompetitive under the *Sherman Act*. (Several other courts have held that product redesign violates § 2 when combined with other conduct and the combined effect is anticompetitive or exclusionary. See *Allied Orthopedic*, 592 F.3d at 1000 (explaining that § 2 is violated when “some conduct of the monopolist associated with its introduction of a new and improved product design constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market” (internal quotation marks omitted)))” (*State of New York v. Actavis*, No. 14-4624, 2d Cir., 2015).

<sup>411</sup> See also H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen, 2014, pp. 15-78.3 - 15-79 (“From an antitrust perspective, product hopping to ward off generic competition is precisely the sort of behavior the *Sherman Act* condemns. While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition. And while distinguishing between the two can be tricky, courts have proven themselves up to the task, even in cases involving product design. It makes no sense to immunize patently anticompetitive behavior because of the risk that some cases might prove tough to decide. The proper standard requires deference to innovation, but not complete abdication.”) and P.R. Malone, J. Pearlman, M. Rietfors, Brief for Intellectual Property and Antitrust Professors as Amicus Curiae in Support of Plaintiff-Appellee, *State of New York v. Actavis*, No. 14-4624, 2d Cir., 2015, pp. 3-4 (“Because product hopping typically exploits the *Hatch-Waxman* framework to restrain generic competition and cause anticompetitive effects with no countervailing procompetitive justification, it can constitute illegal exclusionary conduct under Section 2 of the *Sherman Act*. The type of product hopping at issue in this case – withdrawing drugs from the market and forced-switches to new versions – undermines the generic entry and competition intended and facilitated by the operation of *Hatch-Waxman* and state drug substitution laws. This exclusionary conduct can violate Section 2 by foreclosing competition and reducing consumer choice when it is undertaken without a purpose other than eliminating competition or when its anticompetitive effect outweighs any business purpose.”)

<sup>412</sup> See also P.R. Malone, J. Pearlman, M. Rietfors, Brief for Intellectual Property and Antitrust Professors as Amicus Curiae in Support of Plaintiff-Appellee, 14-4624, in *People of the State of New York v. Actavis*, 2<sup>nd</sup> Circuit, 2015, pp. 28-29 (“The anticompetitive effects of product hopping can be particularly pronounced when the conduct includes, as in this case, changes timed to occur before generic entry, proffered justifications for the changes that are pretextual or lacking in evidentiary support, “smoking gun” documents that demonstrate the actual intent and effect of the product switch are to protect monopoly revenue from generic competition, rather than a legitimate business purpose, or other evidence demonstrating an exclusionary objective and impact.”)

procompetitive justification for its conduct, *i.e.* that its conduct is indeed a form of competition on the merits. The burden of proof moves then back on the authority/plaintiff that has to rebut the procompetitive justification or demonstrate that it is outweighed by the anticompetitive effects of the originator's conduct.<sup>413</sup>

This conduct as well has been considered to run against the very purpose of the patent system and thus represents an abuse of rights “[i] *in view of the rationale of the patent right and the patent system (by re-claiming 20 years of protection without having innovated); and [(ii)] also against higher ends, because the society as whole would not benefit from that patent anymore. We think in particular of access to medicines and the human right to health. Both are reportedly favoured and hindered by the grant of patents, yet this balance may shift the wrong way if patent protection goes up to 40 years.*”<sup>414</sup>

### 13.1. United States

#### 13.1.1. Namenda (U.S.)

Product hopping has been the object of more than one decision, at the U.S., EU, and Member States level. Starting with the U.S., the first case analyzed is the one involving the Alzheimer's treatment Namenda.

The issue arose from the decision taken by Actavis, the originator manufacturing Namenda, to switch patients from an immediate release (IR) version of the drug onto a sustained release version (Namenda XR). Namenda IR and Namenda XR had the same active ingredient and the same therapeutic effect, but they were not therapeutically equivalent. The main difference between the two drugs was in the dosage regimen, and thus in the strength, from the two tablets a day of the IR (immediately released into the bloodstream) to one of the XR (released gradually)(in addition, the IR was marketed in tablet form, the XR in capsule form). Due to these differences, the generic version of the IR would not be AB-rated to the XR and pharmacist would not be permitted to substitute the generic IR for a Namenda XR prescription.

Actavis planned to withdraw the IR version near the end of its patent term (the XR version was brought to market in 2013, three years after it was approved and two years before patent expiry of the IR), and migrate patients to the newly introduced XR, in order to force patients to switch before generic entry. The patents on XR ensured exclusivity, and thus prevented generic competition, until 2029. Actavis's conduct was described as “*“product extension” strategies to convert patients from Namenda IR to Namenda XR and, thus, to avoid the patent cliff. Initially, Defendants sold both Namenda IR and XR but stopped actively marketing IR. During that time, they spent substantial sums of money promoting XR to doctors, caregivers, patients, and pharmacists. They also sold XR at a discounted rate, making it considerably less expensive than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR. The parties have referred to Defendants' efforts to transition patients to XR while IR was still on the*

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<sup>413</sup> See, inter alia, in the U.S., *United States v Microsoft*, 253 F.3d, D.C. Cir., 2001, pp. 58-64 (where, the court held that, when an alleged monopolist introduces a new product, the question is whether it is “*engaging in exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident*” and that “[j]udicial deference to product innovation [...] does not mean that a monopolist's product design decisions are *per se* lawful”); *Trans Sport, Inc. v. Starter Sportswear, Inc.*, 964 F.2d, 2d Cir. 1992, pp. 188-89.

<sup>414</sup> M. Temmerman, *The Legal Notion of Abuse of Patent Rights*, Working Paper No 2011/23, nccr trade regulation, p. 23.

market as the “soft switch,” [...]. In early 2014, Defendants decided on a more direct approach. They were concerned that they would be unable to convert a significant percentage of Alzheimer’s patients dependent upon memantine therapy from IR to XR prior to the entry of generic IR. Defendants’ internal projections estimated that only 30% of Namenda IR users would voluntarily switch prior to July 2015. On February 14, 2014, Defendants publicly announced that they would discontinue Namenda IR on August 15, 2014, notified the FDA of their plans to discontinue Namenda IR, and published letters on their websites urging caregivers and healthcare providers to “discuss switching to Namenda XR” with their patients. Defendants also sought to convert Namenda IR’s largest customer base, Medicare patients, to XR by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it.”<sup>415</sup>

Therefore, Actavis first tried a soft switch, keeping both IR and XR on the market. Failed this (*i.e.* only a small part of the patients switched to the new drug before loss of exclusivity, probably due to the transaction costs involved in changing the medications taken by Alzheimer patients); Actavis changed its strategy and announced (and prepared for) a hard switch (*i.e.* the withdrawal of Namenda IR from the market). The hard switch was not put into effect because Actavis agreed to a standstill during the litigation proceedings and the Court ultimately decided not to allow Actavis to implement it, by granting a preliminary injunction barring Actavis from restricting access to Namenda IR prior to generic IR entry. However, as noted by the Second Circuit, “[b]ecause a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.”<sup>416</sup>

A particularity of the case is the fact that Namenda is a drug for Alzheimer patients. Doctors’ inertia was therefore multiplied in this case by the type of patients. Indeed, it is very complicated to change drugs that treat long-term or chronic condition, above all in cases where the patient population is represented by Alzheimer’s patients with moderate-to-severe dementia. The friction was thus significant when trying to move doctors and patients from one drug to another (which is probably the reason why the soft switch was not successful), but once the switch is completed, it will be likely permanent. While in theory doctors would be free to switch their patients back once the generics enter in the market, in practice they, the patients and their families would be reluctant to do so (due to routine and risk-aversion), notwithstanding the price difference.

As to the effects, the district court found that “consumers would pay almost \$300 million more and third-party payors would pay almost \$1.4 billion more for memantine therapy if Defendants were permitted to switch patients to Namenda XR before generic IR entry. And HHS reports that Defendants’ withdrawal of Namenda IR prior to generic entry would cost Medicare and its beneficiaries a minimum of \$6 billion over the next ten years.”<sup>417</sup>

In deciding that Actavis was liable of antitrust infringement, the Court noted that neither the introduction of a new, arguably superior, drug nor the withdrawal of an old one are anticompetitive *per se*. They might however be when they are carried out in combination, with substantially coercive effects on doctors and patients. The Court concluded:

“In withdrawing Namenda IR from the market, Defendants’ explicit purpose was to impede generic

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<sup>415</sup> State of New York v. Actavis, No. 14-4624, 2d Cir., 2015, pp. 18-20.

<sup>416</sup> State of New York v. Actavis, No. 14-4624, 2d Cir., 2015, p. 21.

<sup>417</sup> State of New York v. Actavis, No. 14-4624, 2d Cir., 2015, p. 56.

*competition and to avoid the patent cliff—which occurs at the end of a drug’s exclusivity period when generics gain market share through state substitution laws. [...] Defendants’ hard switch crosses the line from persuasion to coercion and is anticompetitive. [...] By effectively withdrawing Namenda IR prior to generic entry, Defendants forced patients to switch from Namenda IR to XR—the only other memantine drug on the market. [...] Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of Berkey Photo’s basic tenets: the market can determine whether one product is superior to another only “so long as the free choice of consumers is preserved.” 603 F.2d at 287. Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer’s patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice. In this way, Defendants could avoid competing against lower-cost generics based on the merits of their redesigned drug by forcing Alzheimer’s patients to take XR, with the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely. [...] While introducing Namenda XR may be procompetitive, that argument provides no procompetitive justification for withdrawing Namenda IR. [...] [I]n deciding to take IR off the market, Defendants were willing to give up profits they would have made selling IR—Forest’s bestselling drug. This “willingness to forsake short-term profits to achieve an anticompetitive end” is indicative of anticompetitive behavior. In re Adderall, 754 F.3d at 135 (internal quotation marks omitted).”<sup>418</sup>*

### 13.1.2. TriCor (U.S.)

In *TriCor*,<sup>419</sup> another U.S. case, Abbot Labs changed multiple times the dosage strength of its brand-name drug and the dosage form, from a capsule to a tablet (the FDA considered all of the formulations bioequivalent: from a medical perspective they were thus substitutable, but they were not from a regulatory one). Once obtained the NDA for the tablet formulation, Abbot stopped selling the old product in capsules, purchasing back existing supplies from pharmacies, and changed the code of the capsules in the database used by pharmacies for automatic substitution purposes (the National Drug Data File) to “obsolete” (which prevented pharmacies to fill prescriptions for the new formulation with a generic capsule formulation).

Generic manufacturers then developed equivalents to the new tablet formulation and submitted ANDAs. Abbot filed lawsuits against these manufacturers alleging infringements of its patents. While the litigation was pending, Abbott submitted an NDA for a new dosage strength of its drug in the form of nanoparticulate tablets. And, as before, the originator stopped selling the old version and removed the drug from the database to prevent generic substitution.

Through the reformulations of TriCor (which could be considered very close to mere repackaging of the chemical compound), Abbot managed to hold off generics for over a decade (after they had successfully challenged the patents), and thus prevented consumer choice. Abbot manipulated the pharmaceutical regulatory framework to block generic entry.<sup>420</sup> By eliminating the most cost-efficient means of generic competition, *i.e.*

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<sup>418</sup> State of New York v. Actavis, No. 14-4624, 2d Cir., 2015, pp. 23, 37-38, 49.

<sup>419</sup> Abbott Labs v. Teva, 432 F. Supp. 2d, D. Del., 2006.

<sup>420</sup> “[W]hile a monopolist may compete and is not required to aid its competitors, see, e.g.,

substitution,<sup>421</sup> Abbot prevented consumers from being able to choose freely among competing products. As the Court stated: “[t]he nature of the pharmaceutical drug market, as described in Plaintiffs’ allegations, persuades me that the rule of reason approach should be applied here as well. [...] Consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations. Hence, an inquiry into the effect of Defendants’ formulation changes, following the rule of reason approach, is justified. [...] Therefore, in this case, an antitrust inquiry into the benefits provided by Defendants’ product changes is appropriate. Contrary to Defendants’ assertion, Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.”<sup>422</sup> On the basis of the above, the District Court denied the motion to dismiss. The case settled shortly before trial. Two class action lawsuits were also brought against Abbot and were settled. The lawsuit by the direct purchasers with a payment of \$184 million, the one with the indirect purchasers with the payment of \$65.7 million. 25 States and the District of Columbia sued Abbot as well complaining that it violated antitrust law by obtaining multiple patents through inequitable conduct, reformulating TriCor with only minor changes to its form and strength and creating artificial product differentiation to persuade doctors to switch to new formulations. The case was settled in January 2010 with Abbott agreeing to pay \$22.5 million. As noted by Shannon Gibson, “[a]lthough the above settlement amounts are significant, [...] Abbott unquestionably still came out ahead, especially considering that since 2006, TriCor has generated more than \$1 billion in annual sales in the U.S. and is one of the top 30 selling drugs in the country.”<sup>423</sup>

### 13.1.3. Doryx (U.S.)

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*Microsoft*, 253 F.3d at 58, “a monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist’s behavior.” *LePage’s Inc. v. 3M*, 324 F.3d 141, 151-52 (3d Cir.2003) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601-04, 105 S.Ct. 2847, 86 L.Ed.2d 467 (1985)). Contrary to Defendants’ assertion (D.I. 384 at 15), Plaintiffs allege harm to competition rather than simply harm to Teva and Impax. By removing the old products from the market and changing the NDDF code, Defendants allegedly suppressed competition by blocking the introduction of generic fenofibrate. The Court in *Berkey Photo* noted that such conduct, which results in consumer coercion, is potentially anticompetitive. See 603 F.2d at 287 & n. 39 (finding no liability but stating that “the situation might be completely different” if the defendant stopped producing old products or removed them from the market). Thus, the allegations of product removal and NDDF code changes, like the allegations related to the product changes themselves, support Plaintiffs’ antitrust claims.” (Abbott Labs v. Teva, 432 F. Supp. 2d, D. Del., 2006, p. 424)

<sup>421</sup> “To show that conduct has an anticompetitive effect, “it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market’s ambit.” *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 191 (3d Cir.2005). Competitors need not be barred “from all means of distribution,” if they are barred “from the cost-efficient ones.” *Microsoft*, 253 F.3d at 64. Here, while Teva and Impax may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants’ allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.” (Abbott Labs v. Teva, 432 F. Supp. 2d, D. Del., 2006, p. 423)

<sup>422</sup> Abbott Labs v. Teva, 432 F.Supp. 2d, D. Del., 2006, p. 422.

<sup>423</sup> S. Gibson, The Use and Abuse of Drug Reformulation in Pharmaceutical Life Cycle Management, 20 Health Law Journal, 2013, p. 118.

U.S. courts discussed again product hopping in a case involving Warner Chilcott and its drug Doryx.<sup>424</sup> In July 2012, Warner Chilcott was sued by Mylan, a generic manufacturer, under the accusation of having engaged in product hopping to prevent or delay generic competition for its drug Doryx, used to treat acne. This is the first product hopping case in which the FTC intervened filing an amicus brief.

The conduct contested to Warner Chilcott consisted in at least three distinct changes to Doryx with little to no therapeutic benefit: (i) from capsule to tablet; (ii) from 75 mg and 100 mg tablets to a single 150 mg; (iii) from a single-scored version of the 150 mg tablet to a dual-scored version. Warner Chilcott ceased marketing of the old versions of Doryx and eventually discontinued its sales, asking major customers to return inventory.

Warner Chilcott argued that originators do not have a duty to continue promoting outdated drugs to permit generic competitors to take advantage of automatic substitution laws. This is most certainly the case, but it obviously does not cover drug withdrawal. The public relies on the functioning of the system devised by the Hatch-Waxman Act and State substitution laws to expedite generic entry and the originator's regulatory gaming goes in the opposite direction. What some companies qualified as generics' free-riding is what the Hatch-Waxman is premised on, *i.e.* allowing *"the generic manufacturer [to] obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval "for a pioneer drug." See Eli Lilly & Co. v. Medtronic, Inc., 496 U. S. 661,676 (1990). The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, "speed[s] the introduction of low-cost generic drugs to market," [...] thereby furthering drug competition."*<sup>425</sup> In its amicus brief, the FTC emphasized that *"[w]hatever 'free-riding' occurs is the intended result of the legislative framework of the Hatch-Waxman Act and the state substitution laws."* In other words, patent protection, marketing authorization and piggy-backing go hand in hand. The originator cannot get one without allowing the other.

In the case at stake, however, Doryx capsules have been available without patent protection for almost 20 years before Sandoz and Mylan introduced the generic version. Mylan launched also its own generic 75 and 100 mg Doryx tablets after Warner Chilcott had introduced them and was thus already in the market when Warner Chilcott introduced a new dosage and discontinued the old drug. Therefore, *"doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug."*<sup>426</sup> Citing Microsoft, the Court thus concluded that Mylan *"failed to produce initial evidence of anticompetitive conduct [and] thus need not proceed with the burden-shifting framework and determine whether Defendants have proffered nonpretextual, procompetitive justifications for their product changes, whether Mylan has rebutted those justifications, or whether the product changes were, on balance, procompetitive or anticompetitive."* On 28 September 2016, the Third Circuit confirmed the Eastern District of Pennsylvania's holding that Warner Chilcott's conduct did not violate antitrust. In its opinion, the Third Circuit indicated that, while in *Namenda* the originator's reformulation extended the period of patent exclusivity and served to *"completely bar generics from entering the market"*, in *Doryx* *"there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral*

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<sup>424</sup> Mylan Pharm. Inc. v. Warner Chilcott PLC et al., No. Civ. 12-3824, 2015 WL 1736957, E.D. Pa., 16 April 2015.

<sup>425</sup> FTC v. Actavis, Inc. 570 U.S., 2013, par. I.A.

<sup>426</sup> Mylan Pharm. Inc. v. Warner Chilcott PLC et al., No. Civ. 12-3824, 2015 WL 1736957, E.D. Pa., 16 April 2015.

tetracycline market.”<sup>427</sup>

#### 13.1.4. Suboxone (U.S.)

The last U.S. product hopping case analyzed by this work relates to Suboxone and is instructive of the importance of consumers’ freedom of choice in determining the anticompetitiveness of product hopping.<sup>428</sup> In this case, the Court denied motion to dismiss (concluding that the plaintiff had “*plausibly pleaded exclusionary conduct, as required for an antitrust claim*”) on grounds that the originator, after having developed a new, patent-protected, version of the drug (changing the administration form from tablets to film), launched a marketing campaign against its previous tablet version, warning doctors of allegedly fabricated safety concerns, and announced the withdrawal of the tablet version (soon to lose patent exclusivity).<sup>429</sup>

The court noted that, “*what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market’s ambit. This analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind*”<sup>430</sup> The specific conduct undertaken by the originator (Reckitt Benckiser, now Indivior) was ultimately found potentially anticompetitive because “[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film. A patient that preferred the tablets despite the safety concerns might be further persuaded to switch to the film, believing that their favored product would soon be removed from the market”<sup>431</sup> On 4 October 2016, 35 States and the District of Columbia filed a federal lawsuit against the originator alleging that it engaged in an illegal scheme to block generic entry and cause purchasers to pay artificially high prices.

### 13.2. European Union

#### 13.2.1. Pharmaceutical Sector Inquiry

Having concluded the analysis of the U.S. case law, it is now time to look at the

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<sup>427</sup> Mylan Pharms. Inc. v. Warner Chilcott Pub. Co., No. 15-2236, 3rd Cir., 28 September 2016, p. 38.

<sup>428</sup> In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-MD-2445, 2014 WL 6792663, E.D. Pa., 3 December 2014.

<sup>429</sup> In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-MD-2445, 2014 WL 6792663, E.D. Pa., 3 December 2014, p. 9 (“*the facts presented sufficiently allege that the disparagement of Suboxone tablets took place alongside ‘coercive’ measures. The threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film. A patient that preferred the tablets despite the safety concerns might be further persuaded to switch to the film, believing that their favored product would soon be removed from the market.*”)

<sup>430</sup> In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-MD-2445, 2014 WL 6792663, E.D. Pa., 3 December 2014, p. 10.

<sup>431</sup> In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-MD-2445, 2014 WL 6792663, E.D. Pa., 3 December 2014, p. 12. The Court stated that: “*While Reckitt did not repurchase existing supplies held by pharmacies or change the NDDF code on the tablets to obsolete, the withdrawal of Suboxone tablets is alleged to have created a similar effect of reducing consumer choice. While Plaintiffs acknowledge that the Generics have not been completely foreclosed from the market, neither were the generics in [Abbott]. [...] [C]omplete foreclosure is not the standard [...] for establishing anticompetitive conduct.*”

decisions adopted at the EU and Member States level. As is in the U.S., product hopping is contrary to antitrust rules in the EU as well. In its pharmaceutical sector inquiry, while recognizing the importance of incremental research “*as it can lead to significant improvements of existing products, also from the perspective of the patients [the Commission emphasized the fact that] for 40% of the medicines in the sample selected for in depth investigation, which had lost exclusivity between 2000 and 2007, originator companies launched second generation or follow-on medicines. Nearly 60% of the patent related litigation cases between originator and generic companies examined in the context of the inquiry concern medicines that moved from first to second generation products. The launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product. The companies have an incentive to do so in order to avoid generic exposure for the second generation product. In this respect the inquiry indicates that in order to successfully launch a second generation medicine, originator companies undertake intensive marketing efforts with the aim of switching a substantial number of the patients to the new medicine prior to the market entry of a generic version of the first generation product. If they succeed, the probability that generic companies will be able to gain a significant share of the market decreases significantly. If on the other hand generic companies enter the market before the patients are switched, originator companies may have difficulties in convincing doctors to prescribe their second generation product or in obtaining a high price for the second generation product. On average the launch took place one year and five months before loss of exclusivity of the first generation product. In some cases the first medicine was withdrawn from the market some months after the launch of the second generation medicine.*”<sup>432</sup>

### 13.2.2. AstraZeneca (EU)

The first case in which product hopping was sanctioned by the European Commission is *AstraZeneca*.<sup>433</sup> In this case, the first European patent application for omeprazole (brand-name Losec) was filed in 1979 (thus set to expire in 1999) and designated nine EPO Member States. In 1998, AstraZeneca introduced a new version of Losec, which consisted in a repackaging of the original drug in a different pharmaceutical form, from capsules to tablets (only the means of delivery changed, while the active ingredient remained the same).<sup>434</sup> The old version of Losec was withdrawn from the market and replaced by the new Losec MUPS (Multi-Unit Pellet System). AstraZeneca also deregistered the marketing authorization for the capsule formulation in Denmark, Norway and Sweden.<sup>435</sup> In 2000,

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<sup>432</sup> European Commission, Communication - Executive Summary of the Pharmaceutical Sector Inquiry Report, SEC(2009) 952 COM(2009) 351 final, 8 July 2009, pp. 15-16.

<sup>433</sup> European Commission, COMP/A.37.507/F3, AstraZeneca, 15 June 2005.

<sup>434</sup> As in the U.S., “*the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers. [...] [T]he fact that an undertaking in a dominant position is under no obligation to protect the interests of competitors does not make practices implemented solely to exclude competitors compatible with Article 82 EC. The mere desire of an undertaking in a dominant position to protect its own commercial interests and to guard against competition from generic products and parallel imports does not justify recourse to practices falling outside the scope of competition on the merits.*” (General Court, T-321/05, AstraZeneca, 1 July 2010, paras. 804, 816)

<sup>435</sup> The strategy relied on loopholes, now closed, in the marketing authorization system for generic products. At the time, generic companies could not rely on the originator’s clinical trials and necessary scientific literature if the marketing authorization was not in force on the date on which the generic abridged drug application was filed. With the deregistration of the marketing authorisation, AstraZeneca prevented generic manufacturers from using the abridged procedure and

AstraZeneca launched a second-generation product, the esomeprazole (brand-name Nexium), a single isomer version of omeprazole and the successor of Losec capsules and Losec MUPS.

Assessing the anticompetitiveness of AstraZeneca's conduct, the General Court expressly excluded that launching Losec MUPS or withdrawing Losec capsules from the market represented a breach of competition law, since those acts were not such as to raise legal barriers to entry, capable of delaying or preventing the introduction of generic products. The Court however confirmed the Commission's conclusion that the deregistration of Losec capsule's marketing authorization could not be considered competition on the merits, and as such constituted an abuse.<sup>436</sup> The Court confirmed also the Commission's finding that the purpose of the deregistration was to create obstacles to the market entry of generic products in Denmark, Norway and Sweden.<sup>437</sup> "[I]t is quite clear from the documents on which the Commission relied that AZ intended, by means of those deregistrations, to obstruct the introduction of generic products and parallel imports. [...] AZ was aware of the utility that the deregistration of the Losec capsule marketing authorisations might have for the purposes of raising barriers to entry of a regulatory nature, with regard both to the introduction on the market of generic products and to parallel imports."<sup>438</sup> The General Court thus concluded that, "in the absence of grounds connected with the legitimate interests of an undertaking engaged in competition on the merits and in the absence of objective justification, an undertaking in a dominant position cannot use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market."<sup>439</sup>

What the Court found abusive in this case is thus the fact that the conduct had no

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thus delayed generic entry and increased the generic manufacturers' costs. Council Directive 65/65/EEC has been since repealed by Council Directive 2001/83/EEC, amended by Directive 2004/27/EEC. According to Art. 10, the deregistration of a marketing authorisation can no longer prevent generic applicant from relying on the originator's application.

<sup>436</sup> "[T]hat conduct was not based on the legitimate protection of an investment designed to contribute to competition on the merits, since AZ no longer had the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials. Furthermore, the applicants adduce no evidence to permit the inference that those deregistrations were necessary, or even useful, for the introduction on the market of Losec MUPS, or for the conversion of sales of Losec capsules to Losec MUPS. Thus, [...] the deregistration of the Losec capsule marketing authorisations was the sole aspect of the conduct identified by the Commission which would be capable of creating obstacles to the market entry of generic products and to parallel imports." (General Court, T-321/05, AstraZeneca, 1 July 2010, par. 812).

<sup>437</sup> See also par. 901 ("With respect to the second abuse of a dominant position, it is also established that the purpose of the deregistrations of the marketing authorisations was to create obstacles to the market entry of generic products in Denmark, Norway and Sweden and to parallel imports in Sweden, thus resulting in partitioning of the common market.") The Court of Justice confirmed the General Court's findings in these regards (Court of Justice, C-457/10, AstraZeneca, 6 December 2012, paras. 130-131, "conduct like that impugned in the context of the second abuse – consisting in the deregistration, without objective justification and after the expiry of the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials [...], by which AZ intended [...] to hinder the introduction of generic products and parallel imports – does not come within the scope of competition on the merits. [...] [A]fter the expiry of the period of exclusivity [...], conduct designed, inter alia, to prevent manufacturers of generic products from making use of their right to benefit from those results was not based in any way on the legitimate protection of an investment which came within the scope of competition on the merits?").

<sup>438</sup> General Court, T-321/05, AstraZeneca, 1 July 2010, par. 814.

<sup>439</sup> General Court, T-321/05, AstraZeneca, 1 July 2010, par. 817. This statement was repeated almost *verbatim* by Court of Justice, C-457/12, AstraZeneca, 6 December 2012, par. 134 ("It is important to point out, in this context, that an undertaking which holds a dominant position has a special responsibility [...] [and] it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.").

reason to be undertaken other than to exclude rivals. The subjective intention to harm rivals is objectivized by inferring it from the way in which the conduct was designed (*i.e.* from the fact that the conduct was designed to achieve an anticompetitive effect) and thus its objective justification (or lack thereof).<sup>440</sup>

### 13.2.3. Servier (EU)

The second case of product hopping decided at the EU level is *Servier*.<sup>441</sup> This case has been already analyzed in the context of patent clusters and patent acquisition and will be discussed again in the chapter on pay for delay agreements.

Servier had developed a second generation product, bioequivalent to the original, but based on a new salt (arginine instead of erbumine),<sup>442</sup> for which it received a patent,<sup>443</sup> and sold in different dosages (due to the different molecular weight of the new salt). The second generation product was considered to have no therapeutic advantages for patients over the first generation product.<sup>444</sup>

As in the cases discussed above, Servier's strategy was to withdraw the first generation product from the market before generic entry in order to switch patients to its second generation, patent-protected, drug. In an internal document mentioned by the European Commission in its decision, Servier described the purpose of its strategy as threefold: (i) extend the duration of protection of Coversyl, (ii) replace Coversyl immediately, (iii) prevent substitution by generics.<sup>445</sup> As the Commission explains, "*Servier put significant effort and resources*

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<sup>440</sup> See, *e.g.*, C. Osti, What Is in a Name: The Concept of Abuse in Sui Generis Abuse, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 95.

<sup>441</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014. A similar case of product hopping (as well as patent cluster and pay-for-delay agreement) has been decided a year before by the European Commission. The Commission however did not subject the originator's patenting activity and switching tactics to direct antitrust assessment and the decision will thus be discussed below in the chapter dedicated to pay for delay (see European Commission, AT.39226, Lundbeck, 19 June 2013).

<sup>442</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 231 ("*With regard to the [marketing authorization], the registration of perindopril arginine was based on bioequivalence studies with perindopril erbumine [...] Servier relied on clinical and pre-clinical data from the perindopril erbumine marketing dossier. The procedure started with an abridged submission in France [...]. The fact that Servier used the abridged application route is evidence that Servier considers perindopril erbumine and arginine as bioequivalent. In other words, perindopril arginine can be linked to a generic version of perindopril erbumine.*")

<sup>443</sup> "*In France and in Poland, where Servier successfully shifted the existing patient base to the arginine salt, the relevant patents protecting that salt constituted an additional barrier to expansion for the generic producers offering the products based on the erbumine salt of perindopril. [...] The patents relating to the arginine salt must be viewed as barriers to expansion whenever Servier was successful in carrying out its switching strategy.*" (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 2572, 2574)

<sup>444</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 8. At par. 225, the European Commission states: "*It is evident that Servier was aware of the lack of added therapeutic benefits of the new product and that it would not bring any cost savings to the state. An undated internal Servier presentation refers to perindopril arginine as a "New form without IMSP [Improvement in the Medical Service Provided] (expected saving compared with the existing form)" which is, however, "likely to impede or block generic entry (generic price applied on the outgoing patent of the existing form)"*"

<sup>445</sup> "*Servier explicitly lists as one advantage of the salt switch that "Pharmacist's substitution of one salt by another one is currently not permitted in a certain number of countries". More specifically, Servier explains that generic substitution at the pharmacy level is hindered due to the new dosages (rather than the salt switch in itself): "[...] However we are not completely protected from generics. The launch of Coversyl arginine will protect us against the*

into the switch from erbumine to arginine. The timing of the switch (between 2006 and 2008) and the withdrawal of perindopril erbumine were often described as crucial, complemented by aggressive detailing as described in internal documents. From the beginning, the strategic goal of quickly replacing perindopril erbumine with arginine appears to have been an important element in the action plan to prolong the lifecycle of perindopril.”<sup>446</sup>

The timing of the hop was carefully planned. The first marketing authorization for the arginine salt was obtained much before it was actually commercialized. Commercialization was delayed until the time “generic entry of perindopril erbumine occurred (or was imminent) [...] [T]he development of perindopril arginine was pursued with the objective to find “the immediate replacement (annuls and replaces) while retaining all the therapeutic indications”.”<sup>447</sup>

In light of all the above considerations, the Commission concluded that “the main objective of the introduction of perindopril arginine was to deny generic substitution due to the different dosages of the new product”<sup>448</sup> and was therefore anticompetitive. With regards to the effects, the Commission calculated that, “where generic perindopril was eventually launched, average price reductions for all perindopril products (i.e. also including Servier’s perindopril) ranged from around 18% in Poland (where Servier successfully switched to perindopril arginine and limited generic penetration) to 90% in the United Kingdom (where, following the annulment of the ‘947 patent, there was considerable generic entry) compared to Servier’s prevailing prices prior to generic entry.”<sup>449</sup>

#### 13.2.4. Gaviscon (UK)

To conclude, also the UK OFT decided a case of product hopping. In *Gaviscon*,<sup>450</sup> Reckitt Benckiser delisted its brand-name drug Gaviscon, before a generic name was created for it (which happens as soon as the drug comes off-patent), from the NHS software which enables doctors to search for originators’ drugs and their generic equivalent. As a result, doctors looking for Gaviscon could find neither it nor any generic equivalent. They could however find the patent-protected second-generation drug named Gaviscon Advance Liquid, which obviously had no generic alternative. Since a generic name for the first generation drug did not exist, doctors started writing prescriptions for the second-generation drug, Gaviscon Advance. These prescriptions did not allow substitution by pharmacists.

The UK OFT issued a Statement of Objections alleging Reckitt Benckiser abused its dominant position by deleting Gaviscon from the NHS prescription list and qualified such conduct as falling outside the scope of “normal competition” or “competition on the merits”. The OFT took the position that, while “an intention to convert sales of GL to GA may be consistent

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potential generics of Covercyl because pharmacists cannot substitute medicines with different dosages.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 234) See also par. 2971 (“Whether generic entry was eventually successful also depended on whether Servier had been able to switch prescriptions from perindopril erbumine to perindopril arginine. In certain Member States, where substitution between perindopril erbumine and arginine was not automatically possible due to the difference in dosages (e.g. France, Belgium, Italy, Ireland), generic versions of perindopril erbumine could not be dispensed when Servier’s perindopril arginine was prescribed. Thus, in France, the anticompetitive foreclosure was capable of having effects even after the patent and regulatory barriers had been overcome successfully by generic companies.”)

<sup>446</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 235.

<sup>447</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2156.

<sup>448</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 242.

<sup>449</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2912.

<sup>450</sup> OFT, CE/8931/08, Reckitt Benckiser, decision no. CA98/02/2011, 12 April 2011.

with a ‘normal lifecycle management strategy’, achieving that strategy by the Withdrawal cannot itself be regarded as part of a ‘normal lifecycle management strategy’. While there is no accepted definition of a ‘normal lifecycle management strategy’ in the pharmaceutical sector, the OFT considers that in this context a ‘normal lifecycle management strategy’ would involve a pharmaceutical manufacturer choosing to replace an existing product with one that incorporates innovations that are valued by clinicians and patients alike, such that it can make commercial sense (irrespective of any gains from hindering the development of full generic competition) to withdraw the original product for which there may then be no (or only limited) residual demand”<sup>451</sup>

Central in the OFT’s finding that the withdrawal did not form part of a normal lifecycle management strategy, was the fact that it “was motivated by a desire to hinder the development of full generic competition in the relevant market [and, given the significant demand for the first generation product at the time of withdrawal, it] would have been commercially irrational were it not for the anticipated benefits to RB of hindering the development of full generic competition.”<sup>452</sup> As far as effects go, the OFT considered reasonable to expect that the delisting would restrict competition by hindering generic competition, or was at least capable of such effect. Ultimately, Reckitt Benckiser admitted having infringed UK and EU antitrust and was fined 10.1 million pound.

## 14. Denigration

As seen in the chapter above, a soft switch may consist in the favorable comparison of the new product to the old one, potentially highlighting risks to the patient’s health and side effects of the old drug, and putting pressure on doctors, hospitals and insurance companies to prefer the new. This behavior may be used by the originator to migrate patients from the old drug (whose patent is expiring) to the newly introduced, patent-protected, drug. This same behavior, in the form of negative comparison of generics to the brand-name drug, used to prevent patients from switching once generics become available, has been addressed and sanctioned by the French Competition Authority (FCA) in two different cases, *Sanofi* and *Schering*. As illustrated by the President of the FCA, Bruno Lasserre,

*“The Autorité refers to denigration as situations where an originator manufacturer communicates on a group of generics so as to discredit them, at a time when the rival medicine is about to enter the market, thereby seeking to bar or delay such entry [...]. The aim for the originator laboratory is to put forward to the target audience false, unverified or/and misleading information that will instill or reinforce distrust on the part of health professionals vis-à-vis the group of generics concerned, a feeling that is then passed on to patients and in turn makes these professionals wary of prescribing or*

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<sup>451</sup> OFT, CE/8931/08, Reckitt Benckiser, decision no. CA98/02/2011, 12 April 2011, pp. 277-278. In an internal document, Reckitt Benckiser stated: “Our understanding is that removal from the NHS lists of an apparently effective market leading product which is trusted by GP’s and patients alike is a very unusual, if not unique, course of action... Given that GA has been on the market since 1997 RB cannot claim that the switch is simply to a new improved version, and indeed if that were the case one assumes that the withdrawal of liquid would have been phased.” The OFT thus took the view that “[t]he documents described above demonstrate that neither RB nor its advisors were of the view that the decision to carry out the Withdrawal was in any way ‘normal’ or typical of the pharmaceutical industry. Rather, the decision to withdraw RB’s leading product was described by RB as being ‘unique’, ‘high risk’ and as an ‘industry first’.” (pp. 279-280)

<sup>452</sup> OFT, CE/8931/08, Reckitt Benckiser, decision no. CA98/02/2011, 12 April 2011, p. 253.

*delivering the generic drug.*<sup>453</sup>

Both the *Sanofi* and *Schering* cases were opened following complaints from generic manufacturers (Teva in *Sanofi* and Arrow in *Schering*) that originators had denigrated quality, efficacy, and/or bioequivalence of their products with the aim of stopping doctors and pharmacists from substituting the brand-name drug for the generic.

The originators' practices included warnings to pharmacists and doctors and in general alarming and negative messages, as well as baseless accusations, against generics, spread by medical visitors and pharmaceutical representatives.

Several were the FCA's concerns in these cases: (i) the originator is often considered a credible and reliable source of information on drugs, particularly on its drug and relative generic version; (ii) doctors have relatively limited information on drugs and most of them comes (directly and indirectly) from the originator – doctor's prescription practice is thus influenced by the originator's promotional efforts and information provided; (iii) doctors are reluctant to change their prescribing habits and are risk averse, they thus tend to favor products they know, especially between brand-name and generics;<sup>454</sup> (iv) the warnings the originator spread about generics were considered by the FCA inaccurate, misleading and/or unsubstantiated.

In *Sanofi*,<sup>455</sup> the originator Sanofi-Aventis adopted a denigration strategy against generic version of its brand-name drug Plavix. The strategy was aimed at doctors and pharmacists and had the objective of limiting the entry of competing generics in favor of Plavix and Sanofi's own generic Clopidogrel Winthrop. Focus of the practice was a type of salt (hydrogen sulfate) on which Sanofi-Aventis had a patent still in effect at the time of loss of exclusivity on the main active substance. Therefore, only Plavix and Sanofi's generic could use this salt while competing generics had to choose a different one to avoid patent infringement.<sup>456</sup> The FCA, supported by the French pharmaceutical regulatory body

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<sup>453</sup> B. Lasserre, France – Raising Artificial Barriers against Generic Entry: The French Experience, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 193 (who continues “*The denigration of generics can have powerful effects. In the long term, it raises barriers to innovation, because the savings made on the greater use of generics are a means for the State Healthcare system to free up funding to allocate to truly innovative drugs. In the short run, the effect of denigration – as actually intended by the perpetrator – is a decrease in both the prescriptions by doctors of the generics concerned and a lower rate of substitution by dispensing chemists in favour of these. The IGAS report of 2012 identified denigration as one of the factors accounting for the slow growth of the proportion of generics in the general consumption of medicines in France and noted that, according to a survey conducted in early 2012, 89% of dispensing chemists but only a mere 43% of doctors believed that generics met the same requirements as originator drugs.*”

<sup>454</sup> As noted by the FCA, “*in general, healthcare professionals are weary of new medicinal products for which insufficient time was available for evaluation*” and “*there remains, moreover, among healthcare professionals, some reluctance towards generic medicines; it can be explained in particular by their ignorance of MA procedures, by their wrong appreciation of the regulatory framework on substitution and by their will to protect themselves from being held liable, in either civil or criminal terms.*” (FCA, Press release of 14 May 2013: Medicinal products, The Autorité de la concurrence fines Sanofi-Aventis a total of €40.6 million for disparaging the generic versions of Plavix®, one of the world's best-selling medicines, available at [http://www.autoritedelaconurrence.fr/user/standard.php?id\\_rub=483&id\\_article=2091](http://www.autoritedelaconurrence.fr/user/standard.php?id_rub=483&id_article=2091), accessed on 6 August 2016)

<sup>455</sup> FCA, 13-D-11, Décision du 14 mai 2013 relative à des pratiques mises en oeuvre dans le secteur pharmaceutique.

<sup>456</sup> In addition, generics could not claim a specific therapeutic indication for the

(Afssaps), took the view that “[t]he variations in salts and therapeutic indications of Plavix®’s generic competitors, only due to intellectual property issues rather than to specific chemical or medical characteristics, have no impact on the bioequivalence and substitutability of these medicines; this goes for all pathologies treated by Plavix®”.<sup>457</sup> The different salt was considered as safe and effective as the one used by Sanofi, and the generics were thus perfectly substitutable for Sanofi’s product.

To avoid generic substitution, Sanofi put in place a communication strategy, at the exact time when specialty generic competitors were introduced in the market, aimed at influencing doctors and pharmacists. Sanofi tried to convince doctors to use the indication “non substitutable” in their prescriptions and pharmacists to substitute Plavix only with Sanofi’s generic. Sanofi used its medical visitors and pharmaceutical representatives to systematically denigrate and discourage the use of competing generics by spreading inaccurate statements as to their efficacy and safety, and claiming doctors’ and pharmacists’ liability in case of medical issues arising from the prescription or substitution of Plavix for a competing generic using a different salt.<sup>458</sup> The FCA received substantial feedback indicating that doctors and pharmacists were greatly influenced by Sanofi’s strategy, which influenced both prescription and substitution practices.<sup>459</sup> This is also due to the fact that Plavix was used to treat very serious cardio-vascular conditions (life-threatening illnesses) and the risks involved in the choice of treatment were substantial. Sanofi’s campaign was so extensive and persuasive that two pharmacists’ associations had to distribute circulars to their members to

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treatment of acute coronary syndrome, which involved the use of Plavix in combination with aspirin.

<sup>457</sup> FCA, Press release of 14 May 2013.

<sup>458</sup> Sanofi prepared and distributed to its representatives a set of Q&As to help them persuade doctors that it was safer to prescribe the brand-name drug and explicitly mention “not to be substituted” in the prescription.

<sup>459</sup> “In the Champagne-Ardenne area: “antigeneric communication from MV [medical visitor] to pharmacies with an aim to prevent the substitution of Plavix®, unless the generic medicine should be Wintrop. A communication that was sometimes aggressive: such substitution (except in the case of the Wintrop generic medicine marketed by the same brand) would be a « murderous » behaviour. Main argument: the salt difference. Communication of the MV to doctors in order to encourage “NS” [non-substitution]. Death cases linked to Plavix® substitution were mentioned by the MV [...]” (paragraph 183 of the decision). In the Nord-Pas-de-Calais area, the speeches identified mentioned in particular an “endangerment of patients if plavix or its generic from the same brand is not prescribed”, and a “defamation of other generic medicines by insisting on the pharmacist’s liability in a case a patient suffered complications following the substitution” (paragraph 186 of the decision). In the Rhône-Alpes area, “pharmacies notice numerous “NS” indications on the medical prescriptions for clopidogrel (50% of medical prescriptions, because labs “terrorised” doctors with their speeches) and voice their discontent: ‘we must fight the disinformation spread by the labs every time a generic products enters the market’” (paragraph 247 of the decision). In the Centre area, cardiologists “systematically add on to their prescription the indication “non substitutable”. In the Midi-Pyrénées area, “both general practitioners and pharmacists do not wish to take any risks by prescribing or selling the generic product because there are doubts regarding the therapeutic efficiency of the generic products marketed (doubts on efficiency, concerns over medical consequences). Doctors therefore add the indication “non substitutable” on the prescriptions and chemists do not substitute or they reference the generic produced by Sanofi-Aventis, Wintrop”. (paragraph 500 of the decision) In the Picardie area, “general practitioners and cardiologists do not wish to take any risks; consequently, more and more do the indications “PLAVIX NS”, even sometime “CLOPIDOGREL WINTHROP NS”, appear on prescriptions.” (paragraph 501 of the decision). Likewise, numerous pharmacists reported that they chose to order the generic medicine marketed by Sanofi-Aventis, Clopidogrel Wintrop®, to avoid being held liable. Among the many examples identified, here is a testimony of a retail pharmacist located in Pierrelatte: “We sell the generic medicine of the Wintrop labs because it is made with the same salt as Plavix and we do not want to be held liable if we associated with the Kardegic. On this subject, the pharmacy’s employees were very convinced by the SANOFI labs’ discourse on the concept of liability upon delivery, in resulting cases of strokes and heart attacks (there are risks involved when mixing kardegic and a generic medicine other than wintrop)” (paragraph 494 of the decision).” (FCA, Press release of 14 May 2013)

counter the misinformation and restore scientific facts.<sup>460</sup>

The campaign significantly slowed the expected rate of generic substitution.<sup>461</sup> Generics represented less than 65% of the market by the end of 2010 (Sanofi's own generic having 34%, about four times greater than the average),<sup>462</sup> against the expected 75%. According to the FCA, this has cost the national health system (Assurance Maladie) €38 million in expected savings between January 2010 and August 2011.

Sanofi tried to justify its communications by arguing that the difference in salts raised issues regarding competing generics' efficacy and safety. The FCA however noted that Sanofi had access to marketing authorizations confirming bioequivalence and substitutability of competing generics (despite the use of a different salt), against which Sanofi did not file any appeal. Sanofi received also a letter from French public authorities confirming the inaccuracy of its insinuations. The FCA indicated: "*Sanofi-Aventis was free to submit to the healthcare authorities any information it had relating to the safety and efficiency of the Plavix® generics, not only within the framework of MA procedures, but also within that of pharmacovigilance. But it did not bring to the attention of the healthcare authorities, after conclusion of the scientific debate before them, any argument that would allow for uncertainty about the quality and innocuousness of the Plavix® generics.*"<sup>463</sup>

The FCA defined the relevant market by looking at substitutability between drugs included in the relevant ATC4 category, and ultimately narrowed it down to Clopidogrel, for which it concluded there were no close substitutes (considering also the importance of the Plavix brand, which meant that doctors and patients would not take into consideration other drugs). On this basis, the FCA found that Sanofi was dominant in the French market for Clopidogrel sold in pharmacies, in which it had a market share of about 60% between its brand-name drug Plavix and its own generic Winthrop. As to the abuse of such dominance, the FCA found that Sanofi's communication plan created uncertainty about the quality and safety of generic substitutes, without any evidence to base it on. Sanofi's statements were inaccurate and, as seen above, had the effect of maintaining or strengthening its dominant position by reducing the substitution rate. The FCA thus concluded that Sanofi had abused its dominant position in the French market for Clopidogrel and imposed a fine of €40.6 million.

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<sup>460</sup> The FCA referred to the following extracts: "*The salt used in the medicine is not critical element of its efficiency*"; "*The absence of a specific therapeutic indication (i.e. certain combinations with salicylic acid) is not due to a possible lack of efficiency of generics, but to the fact that they were patented at a later date than the other therapeutic indications*". (paragraph 195 of the decision) "*Sanofi tried to do with the "salts" what it had done with the "Excipients known to have a recognised action". Let's be objective: we understand Sanofi's motives (see above) when opposing generic medicines for its flagship product. However, today, Afssaps did not hold the difference in salts to be a valid argument to prohibit Plavix's generic medicines, and it referenced the molecule in the generics directory. The influence of the salts is becoming a non-argument, which chemists cannot be fooled by: no serious publication can justify Winthrop's position*". (paragraph 197 of the decision)" (FCA, Press release of 14 May 2013)

<sup>461</sup> "*Case documents show that the substitution rate for Plavix® follows a very atypical pattern. Indeed, despite great volumes and turnover, as well as numerous generic labs operating in the market, this rate, after it soared when generic were introduced, then experienced a steady decline for numerous months; no other similar molecule experienced such a pattern.*" (FCA, Press release of 14 May 2013)

<sup>462</sup> "*The practice at stake also resulted in an exceptional penetration rate for Sanofi-Aventis' own generic medicine, Clopidogrel Winthrop® (now called Clopidogrel Zentiva®). This product enjoys a market share of over 34% in the clopidogrel generics segment; in other words its market share is four times greater than the one usually held by Sanofi-Aventis in the French generic medicine market.*" (FCA, Press release of 14 May 2013)

<sup>463</sup> FCA, Press release of 14 May 2013.

The FCA decision was appealed by Sanofi that argued that it has, as an originator, a duty to provide complete and precise information on the characteristics of its product to doctors and pharmacists, and that its communication plan simply fulfilled this obligation. The Paris Court of Appeal<sup>464</sup> rejected this argument, focusing on the way in which Sanofi communicated the information. According to the Court, Sanofi highlighted differences between its products and the competing generics that had no impact on their efficacy or substitutability and simply resulted from Sanofi's patent portfolio. With its communication plan, Sanofi implied that the difference in salts could affect efficacy or safety of competing generics, which in turn created uncertainty in doctors and pharmacists as to the substitutability of Plavix with its competing generics. Sanofi's medical representatives encouraged doctors to indicate "non-substitutable" on their prescriptions and directed pharmacists to substitute Plavix only with Sanofi's generic. The Court thus confirmed that spreading incomplete, ambiguous or misleading information on generics that creates unsubstantiated uncertainty about their quality and discourages doctors and pharmacists from generic substitution constitutes an abuse of dominance. An appeal was lodged against the Court of Appeals decision and is now pending before the *Cour de cassation*.

As anticipated, the FCA decided another case of denigration in the pharmaceutical industry, *Schering*.<sup>465</sup> The case started with a complaint from a generic (Arrow) and ended with a fine imposed on Schering-Plough of €15.3 million for the disparagement of Arrow's generic and the granting of loyalty discounts to pharmacists to block generic entry.<sup>466</sup> In this case, contrary to *Sanofi*, the FCA ordered Schering, by way of an injunction at the very beginning of the investigation, to publish a statement in the specialized press reminding doctors and pharmacists of the strict bioequivalence between its brand-name drug Subutex and its generic version, and of the absence of health risks from generic substitution.

As in *Sanofi*, also in *Schering* the FCA found that the originator adopted a communication plan focusing on lack of bioequivalence and health risks of generic substitutes, aimed at delaying generic entry and discouraging substitution. Referring to differences in appearance, dissolution and excipients, the originator's purpose was to create uncertainty in doctors and pharmacists about the risk of psychiatric instability of patients and misuse and trafficking of the generic versions of Subutex.<sup>467</sup> To carry out its communication

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<sup>464</sup> Paris Court of Appeal, 2013/12370, 18 December 2014.

<sup>465</sup> FCA, 13-D-21, Décision du 18 décembre 2013 relative à des pratiques mises en œuvre sur le marché français de la buprénorphine haut dosage commercialisée en ville.

<sup>466</sup> See B. Lasserre, France – Raising Artificial Barriers against Generic Entry: The French Experience, in in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 194-195 (the FCA "recommended that visits made to doctors by sales representatives on their behalf should come under tighter control and sanctions. The [...] [FCA] negotiated and obtained from infringing pharmaceutical companies a commitment to avoid in the future such denigration practices within their ranks, by incorporating preventive measures within their corporate compliance programmes. It would be advisable that all manufacturers take similar initiatives and train their staff, especially within the marketing department, in order to raise their awareness of competition, in anticipation of the patent expiry on the originator medicine and the entry of generics.)

<sup>467</sup> The content of the message changed before and after generic entry. Before, the plan focused on the alleged greater risk of misuse by patients, due to the fact that the generic was easier to dissolve and it was thus claimed that more patients could inject the product. After generic entry, the communication was based on the alleged negative consequences for patients of the difference in excipients, and the consequent risk of liability for doctors of a prescription that allowed substitution. None of the allegations were substantiated by studies.

plan, “Schering-Plough organised seminars and telephone meetings and prepared sales pitch templates for its medical and pharmaceutical representatives so that they could disseminate an alarmist message to doctors and pharmacists on the risks of prescribing or dispensing the Arrow generic, even though it did not have access to any specific medical study to justify such a position.”<sup>468</sup>

The plan was complemented by the offer of considerable discounts to pharmacists on the Subutex purchased, to “saturate their aisles” before generic entry, and minimize generics market penetration. The commercial policy was to favor large orders by setting increasing volume discounts (in the form of vouchers in exchange for additional services supposedly rendered by pharmacists) for the purchase of significant quantities of Subutex, and extended payment deadlines. By using this strategy, Schering aimed at making pharmacists store up to three months of supply.

Schering’s plan was very effective.<sup>469</sup> It significantly increased the number of “non-substitutable” prescriptions (67% of the total) and pharmacists’ reluctance in substituting Subutex when this reference was not included. This affected the substitution rate and the generic version had a market share “twice as low as the average for molecules in the same therapeutic category one year after the entry of the first generic.” The effects on the national health system were significant with several million euros per year of unrealized savings.

While the FCA’s decisions are certainly questionable, they highlight the fact that the pharmaceutical industry has characteristics (both in terms of structure and players) that make certain abusive conducts more effective (and concerning). The wording and interpretation of Article 102 TFEU (and Section 2 of the Sherman Act, if not Section 5 of the FTC Act)<sup>470</sup> are broad enough to address these practices when they fall outside of competition on the merits and a certain degree of market power is involved.<sup>471</sup> The question here (as well as above with

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<sup>468</sup> FCA, Press release of 19 December 2013: Medicinal Products, The Autorité de la concurrence fines the Schering-Plough pharmaceutical laboratory a total of 15.3 million euro for hindering entry onto the market of the generic of its originator medicinal product Subutex®, available at [http://www.autoritedelaconcurrence.fr/user/standard.php?id\\_rub=483&id\\_article=2325](http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=483&id_article=2325), accessed on 6 August 2016. As in *Sanofi*, the FCA indicated specific examples in its press release: “during a training seminar for medical representatives, they were asked to “instil certain “doubts” in the minds of pharmacists regarding change” (“2006 pharmacy strategy - Communicate information on the specificities of drug addicts, and the specific nature of care: instil certain “doubts” regarding change (psyc. comorbidities, risk of misuse and trafficking)/paragraph 369 of the decision. Schering-Plough’s CEO reproduced the speech delivered by a medical representative to a pharmacist that he wished to be disseminated due to its effectiveness: “1) The excipients are not the same (talc + silica) 2) no-one knows what would happen if injected 3) indeed, initial problems with generic products have arisen in Beziers”/paragraph 375 of the decision”.

<sup>469</sup> The FCA referred to a regional manager of Schering prasing the job done by their “drug addiction specialists. It quoted “I believe that their actions have greatly curbed the establishment of the generic product. Every day I meet pharmacists in the field who tell me that had the drug addiction specialists not been there, they would have immediately ordered the generic product (the same is true for doctors’ prescriptions). (...) I believe that given the penetration rate of the generic, they are performing exceptionally well” (FCA, Press release of 19 December 2013).

<sup>470</sup> Section 5 of the FTC Act authorizes the FTC to intervene prosecute “unfair method of competition”, including deceptive acts or practices. A conduct may be considered deceptive when it involves representation, omission, or practice likely to mislead customers affecting their conduct or decision-making (See, e.g., FTC Policy Statement on Deception, 14 October 1983, available at <https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception>, accessed on 6 August 2016).

<sup>471</sup> As stated by the Court of Justice, “the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from

regards to the “soft switch” in product hopping cases) is: why authorities should not scrutinize (and, if found anticompetitive, sanction) conducts by dominant undertakings aimed at, and having the effect of, foreclosing competitors (and ultimately consumers) by means other than competition on the merits? This type of conduct is not only premised on inaccurate and misleading statements, but takes also advantage of information asymmetries, regulatory framework (both patent- and health- related), market structure, price disconnect and doctor’s inertia. It is thus not simply the mendacity of the conduct to be of concern, but the (ab)use of a position in which the originator is not only for its commercial success, but also thanks to a regulatory framework aimed at protecting consumers and enhancing consumer welfare. Misinformation by originators is thus particularly troubling in the pharmaceutical industry, especially if part of a plan to prevent or delay generic substitution. As recapped by David Tayar, “*the FCA seems to impose a duty of candor in such a situation, leaving little room for ambiguity. Thus, to be considered lawful, a promotional campaign would likely need to focus on differences that are therapeutically relevant and backed by scientific studies (alternatively, if the differences in question have no therapeutic relevance, the originator company would need to expressly say so, which would likely diminish the impact of its promotional campaign). Also, merely questioning (even implicitly) the efficacy and safety of approved generics is likely to be found abusive.*”<sup>472</sup>

## 15. Provision of Misleading Information to the Patent Office

We discussed how the number of patents keeps on increasing and how the grant of patents not respecting the patentability requirements may prevent competition and slow down innovation. The malfunctioning of the patent system cannot be attributed solely to a somewhat lenient and precipitous<sup>473</sup> review (and an incentive towards the granting of patents) by patent examiners. Also the way in which the patent system is devised and the patent applicants’ conducts play their part. With regards to the patent system, the confidentiality that characterizes much of the application process, and the limited to no participation of third parties in the decision to grant a patent (which can be challenged only *ex-post* grant), exclude a significant help from interested third parties to the patent office in weeding out the applications that do not meet the patent requirements. The patent system (and the patent office review) is heavily reliant on the applicants’ honesty, candor, good faith and cooperation. To ensure celerity of the review, examiners rely on the patent applicants being truthful in their statements and disclosing prior art and every other relevant information they are aware of that may exclude patentability. This grants the patent applicant the ability to influence the outcome of such decisions, *e.g.*, by withholding information that might prevent it from getting a patent.<sup>474</sup>

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*generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.”* (Court of Justice, C-457/10, AstraZeneca, 6 December 2012, par. 129)

<sup>472</sup> D. Tayar, Spreading Misleading Information on a Competitor’s Product as an Abuse of a Dominant Position: a French Pharmaceutical Story?, 5(9) Journal of European Competition Law & Practice, 2014, p. 634.

<sup>473</sup> As noted by H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law, Aspen, 2014, p. 11-5, “[p]atent examiners spend very little time with each application – only 18 hours per patent on average over the course of three years.”

<sup>474</sup> In *Analytichem Int’l, Inc. v. Har-Len Assoc., Inc.*, 490 F. Supp., W.D. Pa., 1980, p.

Although the patent system includes remedies in case of improper conduct, these consist mainly in the declaration of invalidity or unenforceability of the patent. As noted by the General Court, “*the existence of specific remedies which make it possible to rectify, or even annul, patents and SPCs granted unlawfully [does not limit the] application of the competition rules [...]. Where behaviour falls within the scope of the competition rules, those rules apply irrespective of whether that behaviour may also be caught by other rules, of national origin or otherwise, which pursue separate objectives. Similarly, the existence of remedies specific to the patent system is not capable of altering the conditions of application of the prohibitions laid down in competition law and, in particular, of requiring, in cases of behaviour such as that at issue in the present case, proof of the anticompetitive effects produced by such behaviour.*”<sup>475</sup>

Professor Hovenkamp perfectly explained why the antitrust intervention is important even when the patent system has the means (directly or through inequitable conduct, patent misuse or abuse of rights) to address the applicant’s conduct (but not to remedy nor to deter it):

*“a mere declaration of invalidity as punishment on a patent that was invalid to begin with is not really a punishment at all. For example, if a patent would not be issued if the true facts were known, then an applicant has every incentive to hide an essential fact when the probability of detection is less than 100% and the only penalty is that the patent is unenforceable. [...] It is the rough equivalent*

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275, the Court qualified as “*abuse of a patent [...] seeking economic gain by persuading or coercing the purchasing public to believe that a patent right exists when in fact and in truth it does not. The situation is akin to a private individual, like the legendary Captain from Kopenick, pretending to be a tax collector authorized by law to exact tribute when in fact he is an impostor without authority*”. It is the applicants’ ability and incentive to withhold potentially deleterious information that led to the introduction of the concept of inequitable conduct in the U.S. Under inequitable conduct, failure to disclose material information or provision of false information to the patent office, to mislead or deceive the examiner, determines unenforceability of the entire resulting patent (even in cases where the withheld information, while material, would not have prevented the grant of the patent if disclosed). As explained by Professor Leslie, “[f]rom a patentee’s perspective, the legal ramifications of inequitable conduct are sweeping: the entire patent is rendered unenforceable, even those patent claims that are not the root of the inequitable conduct. This may seem punitive, or at least sufficiently far-reaching, to deter deception. In some circumstances, however, this patent remedy may be inadequate to ensure candor. First, some inequitable conduct permeates the entire patent and not merely individual claims. [...] Second, the claims that are not directly the target of the inequitable conduct may not be particularly valuable. [...] The fact that the applicant attaches the valid claims to the invalid claim, and thereby puts the valid claims at risk, suggests that the valid claims had a significantly lower expected value than the claim for which the applicant committed inequitable conduct.” (C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1282) The doctrine of inequitable conduct essentially operates as a defense in infringement lawsuits. The defendants arguing that a patent is unenforceable must show by clear and convincing evidence that the patentee breached its duty of candor to the patent office. If the inequitable conduct defense is successful, the defendant is not liable for infringement. See D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Edward Elgar, 2013, p. 130, citing *Landers v. Sideways, LLC*, No. 4: OOCV-35-M, 2004 WL 5569335, W.D. Ky., 2004, p. 23 (“*To successfully assert a breach of the duty of candor, otherwise known as inequitable conduct, based on a patent applicant’s submission of untrue statements to the PTO, the person making the allegations must ‘demonstrate by clear and convincing evidence that (1) the false information was material to the patent examiner’s decision to issue the patent; and (2) the patentee intended to mislead the examiner’*”). In *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d, Fed. Cir., 2011, pp. 1290-92, the Federal Circuit raised the standard of proof for inequitable conduct requiring the demonstration of “but for” materiality and specific intent to deceive (except in cases of affirmative egregious conduct). After *Therasense*, the Federal Circuit expressly stated in *Transweb, LLC v. 3M Innovative Props. Co.*, 812 F.3d, Fed. Cir., 2016, p. 1307, that “*the showing required for proving inequitable conduct and the showing required for proving the fraud component of Walker Process liability may be nearly identical*”.

<sup>475</sup>

General Court, T-321/05, *AstraZeneca v Commission*, 1 July 2010, par. 366.

*of a criminal rule for theft that required as its only penalty that the thief return the stolen good.*<sup>476</sup>

The lack of a serious and in-depth evaluation of the merits of a patent application, as well as the lack of discretion by the patent office, has been considered an important element in determining the anticompetitiveness of a practice. In particular, the intervention of the patent office or of any other regulatory agency does not protect the undertaking from responsibility when no (or a very superficial) analysis has been conducted and/or when the office had no discretion in deciding whether to grant the request.

Antitrust is thus concerned as much as patent law about the grant of unmeritorious patents as a result of inaccurate or misleading representations to the patent office. This conduct may constitute patent misuse/abuse of rights as well as abuse of a dominant position or illegal monopolization and trigger antitrust intervention. In the U.S., the Supreme Court expressed this concept in *Walker Process* by stating that, “[t]o permit recovery of treble damages for the fraudulent procurement of the patent coupled with violations of § 2 [...] would also promote the purposes so well expressed in *Precision Instrument*, [...]: ‘A patent by its very nature is affected with a public interest. \* \* \* (It) is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.’<sup>477</sup>

In the EU, the General Court expressly recognized the harm to the public interest of misleading representations to the patent office to obtain patents to which the undertaking is not entitled, or to which it is entitled for a shorter period. This conduct is “*contrary to the public*

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<sup>476</sup> H.J. Hovenkamp, *Antitrust and the Patent System. A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 548. See also C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, pp. 1280-1281. Unenforceability or invalidity of the patent “*is hardly sufficient to right the wrong that the patentee has committed. The competitors should never have been sued for infringement in the first place – and should never have had to worry about an infringement suit when deciding to enter the market – because no patent should have issued. The unenforceable patent necessarily complicated – and probably delayed – market entry. Furthermore, the competitors had to endure the cost, diversion of resources, and distraction of defending themselves against a lawsuit that should have never been brought. [...] [C]ompetitors who stayed out of the market for fear of drawing an infringement lawsuit could now safely enter the market. But those competitors that had previously been excluded from the market did not have a cause of action for lost profits: Patent law creates no affirmative rights for non-patentees injured by invalid or unenforceable patents. In addition to the competitors, consumers also suffer damages caused by applicant misdeeds. For example, in Walker Process, even though its patent was invalid, FMC was able to use it to deter market entry for almost the entire life of the patent. Yet once the patent expired, the market price fell from \$150 per unit to \$50. Because of the patent fraud, the patentee was able to charge consumers three times the market price. Consumers who paid supracompetitive prices – designed to reward inventors with valid patents – would not be able to recover for the overcharge because inequitable conduct does nothing to compensate victims of the patentee’s deception. In sum, if consumers and competitors can only look to the patent system for relief, they will not be compensated for their injuries caused by the patentee’s misconduct. [...] [T]he reliance on patent law to the exclusion of antitrust remedies risks making applicant misconduct cost-beneficial. The facts of Walker Process itself also show why antitrust law is a better vehicle to punish and deter patent fraud, and to remedy the anticompetitive and anti-innovative effects of patent fraud. [...] Although Walker Process did argue an inequitable conduct defense, this alone would have been inadequate to right FMC’s wrong. FMC had already charged the monopoly price for the life of the patent; rendering the patent unenforceable would have been meaningless because the patent expired before the litigation finished. Patent law could not disgorge the ill-gotten gains, but antitrust law could. Even if a patent is invalidated, it would not disgorge the ill-gotten gains from the patent’s effective exclusion of competitors. This failure to disgorge makes the misconduct profitable.*”

<sup>477</sup> *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S., 1965, p. 177.

*interest, as weighed up and applied by the legislator. As the Commission observes, such misuse of the patent system potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator.*<sup>478</sup>

In the U.S., in addition to the patentee's market power, for a finding of an antitrust violation it is required to demonstrate that the misrepresentation has been deliberately carried out (*i.e.* deceptive intent) and had, or may have had, anticompetitive effects. Under *Walker Process*, a patentee might violate antitrust if (i) it made a material omission or misstatement to the Patent Office with a specific intent to deceive the examiner,<sup>479</sup> (ii) the patent would not have been granted but for the misrepresentation or omission,<sup>480</sup> (iii) it acquired or maintained a monopoly through patent fraud,<sup>481</sup> and (iv) the plaintiff has suffered antitrust injury as a result.<sup>482</sup>

As seen, antitrust intervention is not barred by the existence of rules concerning

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<sup>478</sup> General Court, T-321/05, *AstraZeneca v Commission*, 1 July 2010, par. 367.

<sup>479</sup> Fraud in the procurement of the patent, which has to be intentional, material (*i.e.* on facts), and can consist in misrepresentation or omission, is defined by the Court as “*knowingly and willfully misrepresenting facts to the Patent Office*” (see also *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d, 9th Cir., 1979, p. 996, “[t]he road to the Patent Office is so tortuous and patent litigation is usually so complex, that ‘knowing and willful fraud’ as the term is used in *Walker* can mean no less than clear, convincing proof of intentional fraud involving affirmative dishonesty, ‘a deliberately planned and carefully executed scheme to defraud the Patent Office.’ [...] Patent fraud cases prior to *Walker* required a rigorous standard of deceit [...] *Walker* requires no less.”).

<sup>480</sup> “*Fraud on the PTO cannot produce such an anticompetitive market effect unless the PTO would not have issued the patent but for the patentee’s misrepresentation or omission. The cases are unanimously in accord with this higher standard of causation. As the Eight Circuit has explained, where the patent would have issued even absent the fraud, the patentee does not receive any legal right he would not have received anyway. It makes little sense to hold him liable for enforcing the patent in such a circumstance*” (H.J. Hovenkamp, M.D. Janis, M.A. Lemley, C.R. Leslie, M.A. Carrier, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen, 2014, p. 11-17).

<sup>481</sup> The relation between the tort of fraud and antitrust violation is that from genus to species. As explained by the Federal Circuit: “[t]he tort of fraud requires that there was a successful deception, and action taken by the person deceived that would not have otherwise been taken. Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable”. To find an antitrust violation, the elements above have to be accompanied by market power, anticompetitive effects and “a greater showing of scienter and materiality” than when seeking unenforceability based on conduct before the Patent Office (*C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d, Fed. Cir., 1998, p. 1364).

<sup>482</sup> It is required a minimum level of enforcement of the fraudulently procured patent to find antitrust liability. Patent enforcement may take several forms, it is obviously satisfied in case the patentee starts an infringement lawsuit, but it is equally present when the patentee threatened to sue the antitrust plaintiff (*Unitherm Food Systems v. Swift-Eckrich*, 2004 WL 1543286, Fed. Cir., 2004) or third parties, such as the plaintiff's customers (*Hydril Co. LP v. Grant Prideco LP*, 474 F.3d, 2007). “*In the pharmaceutical context, the requirement that the patent be enforced is typically met by listing the patent in the FDA’s Orange Book and filing an infringement lawsuit that triggers a 30-month stay. However, the Federal Circuit has held that defending a patent in a declaratory judgment action is also sufficient to establish enforcement for purposes of a Walker Process claim. Courts have not expressly addressed whether a mere Orange Book listing, without filing for a patent infringement suit, constitutes enforcement of a patent under Walker Process*” (*American Bar Association, Pharmaceutical Industry Antitrust Handbook*, 2009, p. 314) The Federal Circuit stated that: “*antitrust liability under Section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition.*” (*C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d, Fed. Cir., 1998, p. 1364)

annulment of patents. In case antitrust liability is raised, “[w]hile one of its elements is the fraudulent procurement of a patent, the action does not directly seek the patent’s annulment. [...] [The patentee] must answer [...] in treble damages to those injured by any monopolistic action taken under the fraudulent patent claim. Nor can the interest in protecting patentees from “innumerable vexatious suits” be used to frustrate the assertion of rights conferred by the antitrust laws. It must be remembered that we deal only with a special class of patents, i.e., those procured by intentional fraud.”<sup>483</sup>

Both the European Commission and the EU Courts dealt with the provision of misleading information in the obtainment of a patent in the already mentioned *AstraZeneca* case.<sup>484</sup> The General Court observed that:

*“the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market”*.<sup>485</sup>

To be in breach of antitrust, the misleading nature of the representations made to public authorities for the purposes of improperly obtaining exclusive rights must be assessed *in concreto*, on the basis of objective factors and circumstances of each case. What needs to be determined is whether the conduct in question was such as to lead the authorities wrongly to grant exclusive rights to the dominant undertaking.<sup>486</sup> There is no need to show proof of the

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<sup>483</sup> Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S., 1965, p. 176.

<sup>484</sup> The case originated from the adoption by AstraZeneca of a favorable interpretation of the regulation governing the grant of an SPC. AstraZeneca took the view that the date of the first marketing authorization, on which the duration of an SPC is based, was not the date of the grant of the marketing authorization but the date on which the authorization was effective, *i.e.* after other types of authorisations and decisions, such as those relating to pricing or reimbursement (this interpretation was definitely rejected by the Court of Justice only in December 2003, C-127/00, Hässle AB v Ratiopharm GmbH, thus after AstraZeneca’s conduct). It thus submitted its applications using this later date, without making it clear to the authorities (which relied on the applicant to supply all the necessary information, without verifying the submission independently) that that was not the date on which the authorization was granted (and concealing information about certain relatively early marketing authorizations). The Commission excluded any relevance of AstraZeneca’s alleged good faith interpretation of the law and sanctioned its misleading and opaque representations to the public authorities. As the General Court summarized it, “AZ adopted a consistent and linear course of conduct, characterised by the communication to the patent offices of misleading representations for the purposes of obtaining the issue of SPCs to which it was not entitled (Germany, Finland, Denmark and Norway), or to which it was entitled for a shorter period (Austria, Belgium, Luxembourg, Ireland and the Netherlands.” (General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 598) Indeed, according to the transitional provisions under Art. 19(1) of Regulation 1786/92 (introducing the SPC), it was possible to apply for an SPC for products that obtained the first marketing authorisation after 1 January 1985, whereas for Germany and Denmark this date was 1 January 1988. Since the first technical marketing authorisation for omeprazole was obtained in France on 15 April 1987, according to the transitional provisions AstraZeneca could not have applied for an SPC in Germany and Denmark. AstraZeneca thus communicated to the patent offices March 1988, *i.e.* the date when the drug’s prices were published in Luxembourg, as the date of the first marketing authorization.

<sup>485</sup> General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 355.

<sup>486</sup> As seen, “the limited discretion of public authorities or the absence of any obligation on their part to

deliberate nature of the patentee's deceiving conduct or bad faith<sup>487</sup> to identify an abuse of dominance, "*intention none the less also constitutes a relevant factor which may, should the case arise, be taken into consideration by the Commission.*"<sup>488</sup> There is also no need for the fraudulently procured patent to be enforced for a finding of an abuse. "*The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right.*"<sup>489</sup> In synthesis, "*the submission to the patent offices of objectively misleading representations by an undertaking in a dominant position which are of such a nature as to lead those offices to grant it [a patent] to which it is not entitled or to which it is entitled for a shorter period, thus resulting in a restriction or elimination of competition, constitute[s] an abuse of that position.*"<sup>490</sup>

As anticipated, there is no need to show either deliberate intent or actual enforcement of the wrongfully obtained patent, only that the exclusive right has been granted on the basis of false or inaccurate information. The U.S. and the EU approaches thus diverge, with the U.S. much more oriented towards non-intervention. While in the U.S. specific intent and enforcement of the fraudulently obtained exclusive right are required, this is not the case in the EU.

In AstraZeneca, the Court of Justice confirmed the Commission decision and concluded: "*AZ's consistent and linear conduct [...] characterised by the notification to the patent offices of*

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*verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to raise regulatory obstacles to competition.*" (General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 357) In the case at stake, the transitional rules governing the grant of an SPC did not leave the patent office any scope for discretion. At the following paragraph, the General Court specifies that: "*in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility not to impair, by methods falling outside the scope of competition on the merits, genuine undistorted competition in the common market requires it, at the very least, to inform the public authorities of this so as enable them to rectify those irregularities.*" In the case at stake, at par. 493, the Court found that, "*in view of the context in which [...] representations to the patent attorneys and patent offices were made, AZ could not reasonably be unaware that, in the absence of an express disclosure of the interpretation that it intended to adopt [...] the patent offices would be prompted to construe those representations as indicating that the first technical marketing authorisation in the Community had been issued in Luxembourg in 'March 1988'. Thus, there was no need for the Commission to demonstrate AZ's bad faith or positively fraudulent intent on its part, it being sufficient to note that such conduct, characterised by a manifest lack of transparency, is contrary to the special responsibility of an undertaking in a dominant position*".

<sup>487</sup> General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 494 ("*the applicants' multiple arguments based on the alleged absence of bad faith on the part of AZ, as regards both the interpretation that it chose to adopt of Regulation No 1768/92 and the manner in which the SPC applications were presented, or the significance that it attached to the Luxembourg list, cannot constitute objective justification for the absence of proactive disclosure of the nature of the dates mentioned in relation to the Luxembourg and French marketing authorisations, on the one hand, and of the interpretation of Regulation No 1768/92 which led to the choice of those dates, on the other.*")

<sup>488</sup> General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 359 ("*[I]ntention can [...] be taken into account to support the conclusion that the undertaking concerned abused a dominant position, even if that conclusion should primarily be based on an objective finding that the abusive conduct actually took place.*").

<sup>489</sup> General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 362 (the Court continues: "*Furthermore, to the extent that the applicants argue that an intellectual property right must have been exercised in legal proceedings, that argument would tend to make the application of Article [102 TFEU] conditional on the contravention by competitors of the public regulations by their infringing the exclusive right of an undertaking; that argument must be rejected. Moreover, third parties seldom have information enabling them to know whether an exclusive right has been unlawfully granted.*").

<sup>490</sup> General Court, T-321/05, AstraZeneca v Commission, 1 July 2010, par. 361.

*highly misleading representations and by a manifest lack of transparency [...] by which AZ deliberately attempted to mislead the patent offices and judicial authorities in order to keep for as long as possible its monopoly on the PPI market, fell outside the scope of competition on the merits.*<sup>491</sup>

The position taken by EU Courts has been recently criticized by Professor Podszun as potentially resulting in “*far-reaching obligations*.”<sup>492</sup> This critic, however, fails to recognize the importance of an *in concreto* assessment. What makes transparency relevant in *AstraZeneca* is not only nor mainly the patentees’ dominant position; it is the limited discretion of public authorities and/or the absence of any obligation on their part to verify the accuracy of the information received (as well as the lack of a third party *ex ante* review of the application). One could thus answer to the critic by noting that, yes, a dominant undertaking has a duty of candor vis-à-vis public authorities but only when they heavily rely on the undertaking’s information to make their assessment, because they have no discretion in their decision-making, they do not review in depth the application and/or they cannot ask third parties for their views.

## 16. Excessive Pricing

Although not exclusive to drugs, excessive pricing has a relevant role to play in the pharmaceutical industry, at least in the countries that recognize it as a competition law violation. As seen above, the creation of a new drug is lengthy, costly, and risky. A limited number of new drugs reaches the market and an even smaller number has sufficient success to justify the continuing investments in their manufacturing, distribution and marketing.

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<sup>491</sup> Court of Justice, C-457/12, *AstraZeneca*, 6 December 2012, par. 93. See also paras. 95-96: “*the onus was on AZ to disclose to the patent offices all the relevant information and in particular the existence of that French technical authorisation in order to allow them to decide, with full knowledge of the facts, which of those authorisations they wished to accept for the purposes of issuing the SPC. Thus, by making misleading representations to those patent offices, by concealing the existence of that French technical authorisation and deliberately leading them to believe that the date of 21 March 1988 corresponded to the Luxembourg technical authorisation and that that latter was the first MA in the Community, AZ knowingly accepted that those offices granted it SPCs which they would not have issued had they known of the existence of the French technical authorisation and which would have been shown to be unlawful in the event that the alternative interpretation proposed by AZ was not followed by the national courts or the Court of Justice.*” To conclude, at par. 99 the Court of Justice clarified that “*contrary to what the EFPIA submits, the General Court did not hold that undertakings in a dominant position had to be infallible in their dealings with regulatory authorities and that each objectively wrong representation made by such an undertaking constituted an abuse of that position, even where the error was made unintentionally and immediately rectified. It is sufficient to note in this connection that, first, that example is radically different from AZ’s conduct in the present case, and that, secondly, the General Court pointed out [...] that the assessment of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made in concreto and may vary according to the specific circumstances of each case. It thus cannot be inferred from that judgment that any patent application made by such an undertaking which is rejected on the ground that it does not satisfy the patentability criteria automatically gives rise to liability under Article [102 TFEU].*”

<sup>492</sup> “*Imagine the case of a trademark to be registered with the Office for Harmonization in the Internal Market. Does a dominant undertaking need to disclose concerns it has that the new trademark could interfere with the rights of other trademark-holders? Does the undertaking need to disclose legal opinions of its in-house legal team, which may have seen difficulties with some requirements of the Trade Mark Regulation? Or think of the notification of a merger to the European Commission: does a dominant undertaking act abusively if it omits certain facts that the Commission deems relevant for assessing the case, even if it is not clear law that these facts need to be presented? Should the undertaking disclose unfavourable market definitions that had been contemplated before?*” (R. Podszun, *Can competition law repair patent law and administrative procedures? AstraZeneca*, 51(1) *Common Market Law Review*, 2014, p. 289)

Even those that are successfully marketed have to (potentially) face competition from other drugs curing the same disease. There is however a limited number of drugs that makes it all worth it, the blockbusters. These are usually leap forward in the cure of certain diseases and often enjoy very strong patent protection and limited to no competition. Most if not all of the drugs discussed in this work are blockbusters as they grant their originator a monopoly (or quasi-monopoly) and thus the power to abuse it.<sup>493</sup>

While profit maximization is a legitimate commercial objective, fundamental to recoup R&D costs across products (by charging more for the small number of successful drugs), indiscriminate freedom to set prices in a heavily patent-protected industry (where the patients' health, and the State's finances, are at stake) might lead to excess. Since the ability to charge inflated prices is often connected with the grant of a patent (without a patent, a new drug would be easily and inexpensively copied and sold at a price close to its marginal cost), it is necessary to determine whether charging excessive prices can be considered to fall within the purpose of patent law or it constitutes an abuse.

To encourage investments in innovation to the benefit of consumers, patent rights are intended to give their holder the ability to charge prices above marginal cost. This ensures the originator that its investment will be repaid if the product is successful and thus incentivizes investments that would not be otherwise made due to the risk of free-riding by generic manufacturers. The power to charge monopoly prices is thus one of the means devised by the patent system to reach its purpose. Without the power to charge monopoly prices, certain life-saving drugs would not be developed. It is thus better to pay higher prices in exchange for a new and improved drug, instead of not having it at all.

While prices above marginal costs may be considered a key element in reaching the patent's purpose (and thus stimulate innovation and the introduction of new drugs), this does not mean that originators in a dominant position should be left free to charge any price they want for the entire duration of their public-granted monopoly. In exchange for the creation of an innovative drug, society pays a consideration to the originator, the grant of a patent. This consideration, however, cannot be unlimited and should be proportioned to what is necessary to achieve the society's purpose.

Exclusivity is not granted for the originator to maximize the return on its investment, it is granted to maximize society's interest in long-term consumer welfare. If the originator uses the patent in a way contrary to the enhancement of consumer welfare, *i.e.* in a way that

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<sup>493</sup> As explained in details by Professor Abbot, “[a]s a consequence of exclusive marketing rights (whether through patent or regulatory exclusivity), the originator pharmaceutical product is not subject to competition from the “same product” (from a juridical standpoint) during the term of protection. In principle, this enables the originator to charge whatever price it decides upon without fear of competition. In practice, there are potential constraints on pricing. First, there may be pharmaceutical products that are reasonable substitutes (even if not “the same”), and this introduces the element of potential price competition. Second, the price that the originator can charge will depend on demand for the product, which is influenced by the degree to which it is required by patient/consumers, and ultimately by the amount the patient/consumers can afford to pay. The maximum pricing power for the originator is manifest when it owns exclusive marketing rights for a unique (or breakthrough) therapy for a life-saving pharmaceutical product. If there is no reasonable substitute product, pricing power is effectively constrained only by the capacity of the patient/health provider to pay.” (F.M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health, 6(3) UC Irvine Law Review, forthcoming Spring 2017, p. 4, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095), accessed on 6 August 2016)

make the consideration paid by society excessive, its behavior can be deemed abusive. As Professor Cotter points out:

*“Even if patents are necessary to stimulate the invention of drugs and other health-related subject matter, this does not necessarily mean that the optimal policy is, always and everywhere, to permit patent owners to charge whatever the market will bear. Public utility monopolies are regulated, after all; and in theory there is no obvious reason why monopolies based on patents could not be too, as they are in countries that regulate drug prices.”*<sup>494</sup>

The monopoly rests on a patent granted by the public and is limited by the public interest. Social costs and social benefits of a patent should be kept aligned and this is what the prohibition of excessive pricing do. Intervention is thus based on the idea that the self-correcting capacity of excessive prices, *i.e.* stimulating entry of competing products, is neither sufficient nor optimal to enhance consumer welfare, in particular when patents and drugs are involved.

As explained by economists, it is post-entry prices that attract entry, rather than pre-entry prices. Since competition would significantly lower prices (particularly in the pharmaceutical industry), originators have much higher incentives to concentrate the significant investments necessary to discover and bring a new drug to the market in the development of drugs for which a rival is not already on the market.<sup>495</sup>

In the U.S., the non-interventionist school has gained the upper hand and excessive prices are not subject to antitrust intervention.<sup>496</sup> The idea is that new entrants will challenge

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<sup>494</sup> T.F. Cotter, Patents, Antitrust, and the High Cost of Health Care, *The Antitrust Source*, April 2014, p. 3.

<sup>495</sup> M. Motta, A. de Streel, Exploitative and Exclusionary Excessive Prices in EU Law, in C.-D. Ehlermann, I. Atanasiu (eds.), *European Competition Law Annual 2003: What Is an Abuse of a Dominant Position?*, Hart, 2006, p. 49.

<sup>496</sup> In *Verizon Communications Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S., 2004, p. 407, the Supreme Court noted that “[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.” (see also *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d, 2d Cir., 1979, p. 297, “[a] pristine monopolist [...] may charge as high a rate as the market will bear”; and *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d, 7th Cir., 1995, p. 1413, “[a] natural monopolist that acquired and maintained its monopoly without excluding competitors by improper means is not guilty of ‘monopolizing’ in violation of the Sherman Act [...] and can therefore charge any price that it wants, [...] for the antitrust laws are not a price-control statute or a public utility or common-carrier rate-regulation statute.”) B. Baer, Reflections on the Role of Competition Agencies When Patents Become Essential, Remarks at the 19th Annual International Bar Association Competition Conference, 11 September 2015, available at <https://www.justice.gov/opa/speech/assistant-attorney-general-bill-baer-delivers-remarks-19th-annual-international-bar>, accessed on 6 August 2016, explained that: “We don’t use antitrust enforcement to regulate royalties. That notion of price controls interferes with free market competition and blunts incentives to innovate. For this reason, U.S. antitrust law does not bar ‘excessive pricing’ in and of itself. Rather, lawful monopolists are perfectly free to charge monopoly prices if they choose to do so. This approach promotes innovation from rivals or new entrants drawn by the lure of large rewards. In this regard, we make common cause with our European enforcement colleagues. Even though Article 102 of the Treaty on the Functioning of the European Union (TFEU) authorizes actions against excessive pricing, the European Commission has said that “addressing excessive prices is an area of antitrust where limited and very cautious intervention is warranted.”” See also D. Lim, Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives, Edward Elgar, 2013, pp. 122-124 (“Even in the heyday of vigorous enforcement, case law made it clear that “[a] patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly.” (*Brulotte v. Thys*

the incumbent and excessive prices will not be upheld on a long-term basis. Intervention would lower prices and increase consumer welfare in the short-run, but new competitors would be less likely to enter the market, the incumbent would not be able to maximize its profits and investments in innovation would be disincentivized.<sup>497</sup>

While the non-interventionist stance has compelling arguments,<sup>498</sup> this works takes the view that, especially in the pharmaceutical sector, a careful intervention in cases of blatantly excessive prices has positive effects on consumer welfare (both in the short and in the long

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*Co., 379 U.S. 29, 33 (1964)) Indeed, royalty rates well of up to 30 percent have been upheld. (See, e.g., W. L. Gore & Assocs., Inc. v. Carlisle Co., 529 F.2d 614, 623 (3d Cir. 1976) (30% Royalty).) [...] One reason for this approach is simply that parties should be free to decide what the value of the deal is worth to them. Thus under antitrust law, the position has been that prices are not subject to regulatory oversight. Another reason for the reluctance of courts to intervene is that it is too complicated and speculative a venture.”)*

<sup>497</sup> The U.S. non-interventionist stance does not seem to reason well anymore with a long list of U.S. politicians. On 22 August 2016, U.S. senator Amy Klobuchar wrote a letter to the FTC to urge it to investigate the almost 500% price increase over a less than 10-year period of EpiPen, the dominant drug-filled injectable device used to counter potentially deadly allergic reactions (with a market share close to 90%). The Senator noted that “[a]lthough the antitrust laws do not prohibit price gouging, regardless of how unseemly it may be, they do prohibit the use of unreasonable restraints of trade to facilitate or protect a price increase.” What is interesting about this letter is that it specifically refers to the fact that “there does not appear to be any justification for the continual price increases of EpiPen. Manufacturing costs for the product have been stable and Mylan does not need to recover the product’s research and development costs” and qualify the lack of prohibition of excessive pricing as “unseemly”. The Senator’s letter refers to two other cases that have recently shaken the public opinion, 5,500% price increase of Daraprim by Turing Pharmaceuticals and the 525 and 212% increase in Nitropress and Isuprel’s prices by Valeant Pharmaceuticals. Not much different has been the response of the former Secretary of State Hillary Clinton, who recently stated “I’ve put forward a plan to address exorbitant drug price hikes like these. As part of my plan, I’ve made clear that pharmaceutical manufacturers should be required to explain significant price increases, and prove that any additional costs are linked to additional patient benefits and better value. Since there is no apparent justification in this case, I am calling on Mylan to immediately reduce the price of EpiPens.” (<https://www.hillaryclinton.com/briefing/statements/2016/08/24/hillary-clinton-statement-on-epipen-pricing/>) The EpiPen scandal is being addressed from different perspectives. The New York Attorney General is investigating contracts between Mylan and schools, apparently providing for an exclusivity obligation (*i.e.* a requirement not to purchase competitors’ epinephrine injectors for a year). If confirmed, Mylan may be found in breach of antitrust law as its conduct effectively excluded rivals from the market for the sale of epinephrine auto-injectors to schools, in which Mylan is dominant. The West Virginia Attorney General has taken a different approach, opening an investigation of Mylan’s “pay-for-delay” patent settlement with Teva, which prevented the latter from introducing its generic version of EpiPen, as well as of rebates paid under West Virginia’s Medicaid program. Other actions have been brought alleging breach of consumer protection laws rather than antitrust. The grounds on which some of these actions are based tend to coincide with those typical of excessive pricing. Particularly, a class action filed in Ohio alleges that Mylan “has a legal duty and obligation to set a fair, affordable, and reasonable Price and not hold consumers hostage by forcing them to pay exorbitant prices for its medically necessary product.” (*Linda Bates vs Mylan Pharmaceuticals, Inc.*, Court of Common Pleas Hamilton County Ohio, Civil Consumer Class Action Complaint, p. 5) While the EpiPen case is likely to be ultimately closed on grounds other than excessive pricing, having Mylan apparently engaged also in exclusive dealing, sham litigation (including the filing of a sham citizen petition at the FDA) and other potentially exclusionary practices, the positions repeatedly taken by influential U.S. politicians against price gouging may be an indication that it is now time for U.S. antitrust to cautiously move towards a more interventionist approach.

<sup>498</sup> The non-interventionists often indicate the difficulty in determining when a price is excessive and the fact that courts are not price regulators as the main arguments in favor of their approach.

run).<sup>499</sup> The desirability of this approach is confirmed by the case of Sovaldi, the revolutionary drug treating chronic hepatitis C introduced by Gilead, in respect of which neither the U.S. nor the EU agencies<sup>500</sup> have opened any investigation.<sup>501</sup>

Having taken an interventionist stance, the first (and biggest) issue is defining the limit

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<sup>499</sup> A similar position has been taken by Professor Abbot, who states: “[t]he arguments against application of excessive pricing doctrine are essentially arguments against government interference in the free market. But, no market is “less free” than the pharmaceutical market. It is regulated every step of the way. Except, in the United States, with respect to prices. And it is somewhat odd to argue that patent owners protected by legislative monopolies are pricing in a freely competitive market. It is obvious that they are not. [...] This is not an argument against patents. It is an argument against using patents as a basis for charging of excessive prices. It is an argument that even in the context of patent protected pharmaceuticals there is such thing as a “reasonable price”, and conversely an “excessive price”. It is an argument in favor of returning to the original objective of the Sherman Act: protection of the public.” (F.M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6(3) UC Irvine Law Review, forthcoming Spring 2017, pp. 17-18, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095), accessed on 6 August 2016.)

<sup>500</sup> Notwithstanding the more interventionist approach, the European Commission expressly stated with regards to cure for hepatitis C that: “[r]egarding the proposal to open an investigation into the possible violation of EU rules on competition [...] by the high prices of new drugs against hepatitis C, on the basis of the information currently available, the nature of the market appears to be dynamic with several new entrants and more products in advanced stages of development. There is therefore a limited likelihood that the Commission may find an infringement of the EU competition rules, in particular Article 102 TFEU prohibiting the abuse of a dominant position.” (Commission reply of 8 February 2016 to Petition No 0058/2015, available at <http://www.europarl.europa.eu/sides/getDoc.do?type=COMPART&reference=PE-576.836&format=PDF&language=EN&secondRef=01>, accessed on 6 August 2016). See also D.W. Hull, M.J. Clancy, *The Application of EU Competition Law in the Pharmaceutical Sector*, 7(2) *Journal of European Competition Law & Practice*, 2016, p. 156, “in December 2014, the European Commission declined to open an investigation into allegations of excessive prices for Hepatitis C drugs, despite pressure from members of the European Parliament. In response to two parliamentary questions, the Commission noted that Member States have both economic bargaining power and regulatory powers to control the prices of pharmaceutical products, and that such powers were being used to limit the prices of the Hepatitis C drugs. (European Commission, *Response to Parliamentary Question P-008636/2014*, 22 December 2014, and *Response to Parliamentary Question E-000261-15 (31 March 2015)*)”.

<sup>501</sup> The effects of this decision have been explained by Professor Abbot. “When Sovaldi was introduced in late 2013, it was a unique therapy successful in the treatment of hepatitis C. There was tremendous pent-up patient demand for the product. Gilead, with the advice of a team of investment bankers and pharmaceutical market specialists, took advantage of the situation to set a price of \$84,000 for a 12 week course of treatment, and earned over US\$14 billion in the first year of sales. Gilead did not develop Sovaldi. The drug was initially developed by a smaller biotechnology company, Pharmasset, which was purchased by Gilead for \$11 billion in 2011. [...] The process by which the price of Sovaldi was set by Gilead makes for chilling reading from a public health standpoint. The executives at Gilead essentially set out to determine what would be the maximum price that would stress the limits of political and public opinion, but not quite break it. This was with a clear understanding that the pricing of the drug would severely undermine state public health procurement budgets. Gilead has refused to furnish Congress with direct information regarding its cost of bringing the product to market, despite being requested to do so. When Gilead introduced Sovaldi it had strong reason to believe that reasonably comparable alternative treatments would be approved by the FDA and introduced by other originators within a year or two. In other words, there would be a temporal limit to its unconstrained pricing power. In fact, such products were introduced and, approximately 1.5 years following the introduction of Sovaldi, Gilead was forced to reduce the price significantly. While it may be suggested that this demonstrates that market forces will act to constrain pricing power, it remains that Gilead charged an excessive price when it introduced the product and for more than one year, and that even with the introduction of competition, the price for hepatitis C treatments offered by originators is very high and continues to threaten public health budgets.” (F.M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6(3) UC Irvine Law Review, forthcoming Spring 2017, pp. 4-5, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095), accessed on 6 August 2016)

over which a price is considered excessive. Authorities are generally reluctant to investigate potential cases of excessive pricing due to the risk of setting the threshold too low, thus reducing incentives to innovate.<sup>502</sup>

At the EU level, Article 102(a) TFEU expressly includes in the non-exhaustive list of abuses of dominance: “*directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions*”. The Court of Justice observed that this provision could be invoked where a dominant undertaking charged “*a price which is excessive because it had no reasonable relation to the economic value of the product supplied.*”<sup>503</sup>

The demonstration that a price is excessive requires evidence that (i) the difference between the costs actually incurred to bring the product to the market<sup>504</sup> and the price actually charged for it is excessive (the Court refers to cost of production,<sup>505</sup> selling price and profit margin),<sup>506</sup> and if it is, (ii) the price imposed is either unfair in itself or when compared to competing products.<sup>507</sup> These two conditions are cumulative. Neither an excessive profit margin nor an unfair price are sufficient by themselves to prove an abuse, both need to be present. As summarized by the European Commission, “[t]he *United Brands test* implies in essence that prices are only excessive if the profit margin is excessive and this is not the result of superior efficiency but

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<sup>502</sup> This trade-off has been recently recognized by the European Commissioner for Competition Margrethe Vestager, who noted: “*if we want businesses to invest in coming up with those new ideas, then of course we need to make sure that innovation brings rewards. So when we do take action against excessive prices, we need to make sure we’re not taking away the rewards that encourage businesses to innovate. Because we need the innovation.*” (M. Vestager, Protecting consumers from exploitation, 21 November 2016, available at [https://ec.europa.eu/commission/2014-2019/vestager/announcements/protecting-consumers-exploitation\\_en](https://ec.europa.eu/commission/2014-2019/vestager/announcements/protecting-consumers-exploitation_en), accessed on 11 December 2016)

<sup>503</sup> Court of Justice, C-27/76, *United Brands v Commission*, 14 February 1978, par. 250.

<sup>504</sup> Which should include R&D and any fixed cost and take into account the cross-subsidization between successful and unsuccessful projects.

<sup>505</sup> In the case of drugs, the cost includes R&D (taking into account failures) and clinical testing, as well as any other expense incurred to secure marketing approval and bring the new drug to the market. “*In other words, the cost of developing and approving a new product must include a risk factor.*” (F.M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health, 6(3) UC Irvine Law Review, forthcoming Spring 2017, p. 18, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095), accessed on 6 August 2016)

<sup>506</sup> In *United Brands*, the Court of Justice concluded that a profit margin of 7% is not excessive.

<sup>507</sup> Court of Justice, C-27/76, *United Brands v Commission*, 14 February 1978, paras. 249-252 (“*It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition. In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse. This excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin [...]. The questions therefore to be determined are 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.*”) The European Commission explained that “[i]n the case law the *United Brands test* has a central place, even though the Court has stressed that it is not the only way to assess excessive prices. In particular, the case law shows that, depending on the circumstances of the case, the assessment focuses more on the second limb of the test, especially where it is obvious that the dominant firm is not providing a superior product.” (OECD Roundtable on Excessive Prices, European Union, 17 October 2011, par. 62, available at [http://ec.europa.eu/competition/international/multilateral/2011\\_oct\\_excessive\\_prices.pdf](http://ec.europa.eu/competition/international/multilateral/2011_oct_excessive_prices.pdf), accessed on 6 August 2016)

of the exercise of durable market power.”<sup>508</sup>

The European Commission is often more hesitant<sup>509</sup> than national authorities when it comes to excessive pricing. As indicated by David Hull and Michael Clancy, “Pricing is likely to continue to be a focus of enforcement activity. While the European Commission does not seem inclined to intervene as it sees pricing in this sector as primarily a national issue, it would not be surprising to see continued activity at the national level in light of the increasing concern over the impact of high-priced drugs on national healthcare budgets.”<sup>510</sup> While most certainly right on the enforcement at the national level, the two authors may be wrong on the approach that will be taken by the European Commission. In a recent speech, the European Commissioner for Competition Margrethe Vestager opened the door to a more interventionist approach on excessive pricing. She stated that the European Commission is “bound to come across cases where competition hasn’t been enough to provide a real choice. Where dominant businesses are exploiting their customers, by charging excessive prices or imposing unfair terms. We have to be careful [...] that we don’t end up with competition authorities taking the place of the market. The last thing we should be doing is to set ourselves up as a regulator, deciding on the right price. But there can still be times when we need to intervene.”<sup>511</sup> She then proceeded to mention

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<sup>508</sup> OECD Roundtable on Excessive Prices, European Union, 17 October 2011, par. 63, available at [http://ec.europa.eu/competition/international/multilateral/2011\\_oct\\_excessive\\_prices.pdf](http://ec.europa.eu/competition/international/multilateral/2011_oct_excessive_prices.pdf), accessed on 6 August 2016. The Commission went on to say that “The case law described above seems sometimes to indicate that any appreciable deviation from competitive levels could be deemed excessive. To the extent that cases are only pursued in markets where high prices and profits have lost their signalling function to attract entry, it could be argued that such a clear but strict comparator is not inappropriate. The enforcement practice indicates that generally only cases concerning large deviations from competitive levels are pursued. In view of the complexity of excessive pricing cases this is arguably a wise use of enforcement resources.”

<sup>509</sup> The European Commission explained its cautious and restrained approach as follows: “It seems that enforcement action against excessive prices has only been considered as a last resort, in markets where high prices and high profits do not have their usual signalling function to attract entry and expansion because of very high and long lasting barriers to entry and expansion. This recognises that even though in many markets prices may be temporarily high, due to a mismatch of demand and supply or the exercise of market power, it is preferable to give market forces the time to play out and entry and expansion to take place, thereby bringing prices back to more normal levels. We have not seen enforcement activity in such markets, recognising that it would be unwise to run the risk of taking a wrong decision and furthermore spend enforcement resources on solving a problem that would solve itself over time anyway. This is so even in markets characterised by sufficient entry barriers where there can be dominant firms. Of course, it may be that a dominant firm tries to prevent this process of entry and expansion taking place by artificially raising entry barriers. However, in such a situation it is more efficient for the competition authority to tackle the raising of these entry barriers directly since this will likely amount to an exclusionary abuse. If, however, the market is characterized by such entry barriers that it is unlikely that market forces over time will bring prices down, enforcement actions aimed directly against excessive prices may indeed be appropriate.” As the European Commission itself noted, “the relatively small number of cases that we have been able to deal with, may already indicate that addressing excessive prices is an area of antitrust where limited and very cautious intervention is warranted. Indeed, the case law indicates that enforcement against excessive prices is generally only contemplated in markets with an entrenched dominant position where entry and expansion of competitors can not be expected to ensure effective competition in the foreseeable future, that is markets where high prices and high profits do not have their usual signalling function to attract entry and expansion.” (OECD Roundtable on Excessive Prices, European Union, 17 October 2011, paras. 42, 60-61, available at [http://ec.europa.eu/competition/international/multilateral/2011\\_oct\\_excessive\\_prices.pdf](http://ec.europa.eu/competition/international/multilateral/2011_oct_excessive_prices.pdf), accessed on 6 August 2016)

<sup>510</sup> D.W. Hull, M.J. Clancy, The Application of EU Competition Law in the Pharmaceutical Sector, 7(2) Journal of European Competition Law & Practice, 2016, pp. 160-161

<sup>511</sup> M. Vestager, Protecting consumers from exploitation, 21 November 2016, available at <https://ec.europa.eu/commission/2014-2019/vestager/announcements/protecting-consumers->

three examples, one of which is the pharmaceutical industry.

*“Often people’s health relies on drugs that are sold by just one company. That can be because the company has a patent. But it can also be that no one else is interested in coming in to the market, because there isn’t enough demand for the drug to make it worth their while. That isn’t a problem in itself, if prices stay at a reasonable level. But there can be times when prices get so high that they just can’t be justified. After all, people rely on these medicines for their health, even their lives. The best answer is often to adjust regulation, or to give the health systems that buy those medicines better bargaining power. But as the recent action by the British and Italian competition authorities shows, there can be times when competition rules need to do their bit to deal with excessive prices.”*

In conclusion,

*“we need to act carefully when we deal with excessive prices. The best defence against exploitation remains the ability to walk away. So we can often protect consumers just by stopping powerful companies from driving their rivals out of the market. But we still have the option of acting directly against excessive prices. Because we have a responsibility to the public. And we should be willing to use every means we have to fulfill that responsibility.”<sup>512</sup>*

At the Member States level, in November 2014 the Italian competition authority (ICA) launched an investigation into the prices charged by Aspen Pharma for its life-saving and irreplaceable drugs used in the treatment of certain forms of cancer.<sup>513</sup> On 29 September 2016, the ICA imposed a fine in excess of EUR 5 million on Aspen for unfair and excessive prices (in violation of Art. 102(a) of the TFEU). After purchasing the marketing rights from GlaxoSmithKline – whose patent expired decades before – Aspen started negotiating with the Italian pharmaceutical regulatory body (AIFA) to obtain a significant price increase, in the absence of economic justifications. To obtain such an increase, which ultimately ranged between 300% and 1500% of the initial prices, Aspen threatened to interrupt the direct (and indirect through parallel trade) supply of the drugs to the Italian market. The ICA’s investigation on the unfair practice was carried out through a two-phase test that measured the disproportion between prices and costs. The unreasonableness of this disproportion was the basis for a finding of unfair prices also in the light of specific context and behavioral factors, such as: the absence of economic justifications for the increase, the absence of any extra-economic benefits for patients, and the damage caused to the National Health System (Sistema Sanitario Nazionale – SSN).

In the UK, the Competition and Markets Authority (CMA) dealt with excessive pricing in a case involving Pfizer and Flynn Pharma.<sup>514</sup> A Statement of Objections was issued

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exploitation\_en, accessed on 11 December 2016. The fact that the Commission should not act as a price regulator does not imply it should not intervene. Indeed, as national authorities did, the Commission will likely limit its intervention to the determination that the price charged is unlawful and order that the price be adjusted to a reasonable level. Provide guidance on this point may be difficult, but should be a considered a priority.

<sup>512</sup> Ibid.

<sup>513</sup> ICA, A480, Price Increase of Aspen’s Drugs (<http://www.agcm.it/concorrenza/concorrenza-delibere/open/41256297003874BD/5D5033789DE6406AC1258051003331BE.html>, accessed on 11 December 2016).

<sup>514</sup> CMA, CE/9742-13, Phenytoin sodium capsules: suspected unfair pricing, 1 May 2013 (<https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products>, accessed on 11 December 2016).

on 6 August 2015 alleging that these companies abused their dominant positions in the markets for the manufacture and supply of phenytoin sodium capsules (an anti-epilepsy drug)<sup>515</sup> respectively, by charging excessive and unfair prices in the UK. On 7 December 2016, the CMA concluded the investigation and imposed a record fine of GBP 84.2 million on Pfizer and GBP 5.2 million on Flynn Pharma. The CMA also ordered the two companies to reduce their prices. Prices can be profitable, but must not be excessive and unfair. The CMA found that, prior to September 2012, Pfizer manufactured and sold phenytoin sodium capsules under the brand name Epanutin and the prices were regulated. In September 2012, Pfizer sold the distribution rights for the UK to Flynn Pharma, which de-branded the drug, making it no longer subject to price regulation. Pfizer kept on manufacturing the drug, but started supplying it to Flynn Pharma at prices significantly higher than those at which it previously sold Epanutin in the UK – between 780% and 1,600% higher. Flynn Pharma then distributed the drug to UK wholesalers and pharmacies at prices between 2,300% and 2,600% higher than those previously charged by Pfizer. The CMA found that the amount paid by the NHS for 100mg packs of the drug increased from GBP 2.83 to more than GBP 50. As a result of the price increases, the CMA estimated that the NHS expenditure on phenytoin sodium capsules increased from GBP 2 million a year prior to September 2012 to approximately GBP 50 million in 2013. Ann Pope, CMA Senior Director of Antitrust Enforcement, commented:

*“While businesses are generally free to set prices as they see fit, those that hold a dominant position have a special responsibility to ensure that their conduct does not impair genuine competition and that their prices are not excessive and unfair. The prices that the CMA is concerned about in this case are very high compared to those prices previously charged and have led to a big increase in the total NHS drug bill for what is a very important drug for tens of thousands of patients.”*<sup>516</sup>

In the same vein, Philip Marsden, Chairman of the Case Decision Group for the CMA’s investigation, emphasized that:

*“There is no justification for such rises when phenytoin sodium capsules are a very old drug for which there has been no recent innovation or significant investment. This is the highest fine the CMA has imposed and it sends out a clear message to the sector that we are determined to crack down on such behaviour and to protect customers, including the NHS, and taxpayers from being exploited.”*<sup>517</sup>

An almost identical case of excessive pricing, in which the originator removed the drug from price regulation and significantly increased prices, has been opened by the CMA against Actavis. On 16 December 2016, the CMA issued a statement of objections alleging that Actavis broke competition law by debranding its hydrocortisone tables (used to treat a life threatening condition) and increasing prices by between 9,500% and 12,000% compared

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<sup>515</sup> Noteworthy is the fact, mentioned by the CMA, that switching epilepsy patients already taking phenytoin sodium capsules to other products, including other versions of the same product, involved risk of loss of seizure control, with potentially serious health consequences. This acted as a constraint on NHS, which had no alternative to paying the increased price.

<sup>516</sup> CMA issues statement of objections to Pfizer and Flynn Pharma in anti-epilepsy drug investigation, 6 August 2015, available at <https://www.gov.uk/government/news/cma-issues-statement-of-objections-to-pfizer-and-flynn-pharma-in-anti-epilepsy-drug-investigation>, accessed on 6 August 2016.

<sup>517</sup> CMA fines Pfizer and Flynn £90 million for drug price hike to NHS, 7 December 2016, available at <https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs>, accessed on 11 December 2016.

to the branded version of the drug (prices deemed by the CMA excessive and unfair). The CMA found that prior to April 2008 the NHS spent approximately GBP 522,000 a year on hydrocortisone tablets. Spend that had risen to GBP 70 million a year by 2015.<sup>518</sup>

## 17. Pay for Delay

The last type of antitrust breach analyzed by this work is also one of the most discussed at the U.S. and EU level,<sup>519</sup> and the only one that does not consist in a purely unilateral conduct but involves an agreement between originator and generic manufacturers. As indicated in the introduction, consumers heavily benefit from competition between the brand-name drug and generics. The reason is that generics enter the market at a price significantly lower than the brand-name drug and, thanks to the rules on generic substitution, they keep on increasing their market share and decreasing their prices. Economically, generic entry means that the originator surplus and the deadweight loss decrease in favor of an increase of consumer surplus (and overall economic welfare). Not only the originator's surplus decreases in favor of consumers, but the originator has to share its reduced surplus with generic manufacturers. This means that, with the entry of generics, the overall producers' surplus decreases as well as the individual producers' share of it (given that products are homogeneous). The profit that the generic manufacturer anticipates to make is thus much lower than the profit the originator will lose from the same sales. This is because the generic manufacture sells at a significant discount. The difference between the originator's loss and the generic manufacturers' gain is what consumers save. If the originator could prevent the shrinking of its surplus while ensuring that generic manufacturers receive part of it, the result would be a win-win for originator and generic manufacturers as each of

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<sup>518</sup> Pharmaceutical company accused of overcharging NHS, 16 December 2016, available at <https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs>, accessed on 18 December 2016.

<sup>519</sup> “For more than 15 years, one of the FTC’s top priorities has been to put an end to anticompetitive reverse-payment settlements between brand-name drug makers and their potential generic rivals. [...] FTC economists estimate that these agreements cost consumers, insurers, and taxpayers billions of dollars each year in higher drug costs. Moreover, they undermine the regulatory framework of the Hatch-Waxman Act, which was intended to speed the entry of generic drugs and stimulate innovation by research-based pharmaceutical companies.” (J. Towey, Quo Vadis Post-Actavis?, 30 Mar 2016, available at <https://www.ftc.gov/news-events/blogs/competition-matters/2016/03/quo-vadis-post-actavis>, accessed on 6 August 2016) “A top priority for the Commission for nearly 20 years has been stopping anticompetitive reverse-payment settlements of patent litigation in which the brand-name drug firm pays its potential generic rival to abandon a patent challenge and delay entering the market with a lower cost, generic product.” (E. Ramirez, Oversight of the Enforcement of the Antitrust Laws, speech before the U.S. Senate, 9 March 2016, available at [https://www.ftc.gov/system/files/documents/public\\_statements/934563/160309enforcementantitrustlawstest.pdf](https://www.ftc.gov/system/files/documents/public_statements/934563/160309enforcementantitrustlawstest.pdf), accessed on 6 August 2016. At the EU level, the Commissioner for Competition repeated several times the importance of preserving competition in the pharmaceutical sector, identifying antitrust enforcement in this sector as a top priority. Opening proceedings to assess whether a contractual arrangement between the originator Johnson & Johnson and the generic Novartis may have had the object or effect of hindering generic entry, the at-the-time Commissioner for Competition Joaquín Almunia said: “I regard this sector as a priority in terms of enforcement of competition rules given its importance for consumers and for governments’ finances, [...] Pharmaceutical companies are already rewarded for their innovation efforts by the patents they are granted. Paying a competitor to stay out of the market is a restriction of competition that the Commission will not tolerate.” (Antitrust: Commission opens proceedings against Johnson & Johnson and Novartis, available at [http://europa.eu/rapid/press-release\\_IP-11-1228\\_en.htm](http://europa.eu/rapid/press-release_IP-11-1228_en.htm), accessed on 6 August 2016)

their surplus would be either the same or bigger than in a competitive scenario.<sup>520</sup> It is obviously not a win for consumers that keep on paying monopoly prices even after patent expiry (or notwithstanding patent invalidity).<sup>521</sup> Pay-for-delay agreements are essentially agreements concluded at the expense of a third party, the consumer (as well as health insurance and national health systems), who is not a party to them.<sup>522</sup> Their purpose is to keep the originator's surplus high (and consequently the consumers' surplus low) and share the resulting benefit with potential generic entrant (by paying them to stay out of the market).<sup>523</sup> In return for a value transfer from the originator, the generic manufacturer agrees not to enter the market before a certain date. The patent-holder spends less than the profits it would lose in case of generic entry and the generic manufacturer earns more by staying out of the market than entering it (as its entry would reduce the margins on the drug). Thus, their incentives are aligned against consumers, as they share in the benefits from delaying

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<sup>520</sup> “The price and output determined by a well-functioning cartel is identical to the price and output that a monopolist would determine.” (H.J. Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 492) For a thoughtful economic analysis of pay for delay agreements, see W. Choi, B. Den Uyl, M. Hughes, *Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and Others*, 5(1) *Journal of European Competition Law & Practice*, 2014, pp. 46-48, 50-51.

<sup>521</sup> “By eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. Although both the brand-name and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry [...]. Instead, consumers pay higher prices because such early generic entry is delayed” (United States, 121st meeting of OECD Competition Committee, *Generic Pharmaceuticals*, DAF/COMP/WD(2014)51, 19 June 2014, par. 15). See also M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, p. 15 (“Because the brand makes more by keeping the generic out of the market than the brand and generic would receive in total by competing in the market, they have an incentive to cede the market to the brand and split the monopoly profits. The brand then can use a portion of this additional profit from delayed competition to pay the generic to stay out of the market. In an extreme case [...] the brand could even pay more than the generic would have received by competing on the market after winning its patent challenge. Consumers, on the other hand, suffer by paying higher prices and forgoing access to needed medicines from the quashing of challenges to patents that often are invalid or not infringed.”)

<sup>522</sup> “It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices.” (J. Almunia, *Antitrust: Commission Fines Lundbeck and other Pharma Companies for Delaying Market Entry of Generic Medicines*, Press Release IP/13/563, 19 June, 2013, available at [http://europa.eu/rapid/press-release\\_IP-13-563\\_en.htm](http://europa.eu/rapid/press-release_IP-13-563_en.htm), accessed on 6 August 2016) “Consumer harm from pay for delay settlements is significant. In 2010, the FTC estimated that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from a ban on such settlements would be approximately \$3.5 billion.” (United States, 121st meeting of OECD Competition Committee, *Generic Pharmaceuticals*, DAF/COMP/WD(2014)51, 19 June 2014, par. 16)

<sup>523</sup> The European Commission offered a clear analogy, later confirmed by the General Court, between pay for delay agreements and the market sharing agreement in the *BIDS* case. As summarized by the General Court, “the undertakings active in the beef processing market in Ireland had created a mechanism by which some undertakings agreed to stay out of that market for two years in exchange for payments from the undertakings that stayed in the market. A similar dynamic arose in the present case through the conclusion of [pay for delay] agreements [...], pursuant to which [the originator], which was the principal, or even the only, undertaking on the market in the countries concerned by those agreements, paid the generic undertakings, which were potential competitors, so that they would stay out of the market for a certain period. It follows that both the case that gave rise to the *BIDS* judgment [...] and the present case concern agreements that limited the ability of competing economic operators to determine independently the policy that they intended to adopt on the market, by preventing the normal operation of the competitive process” (General Court, T-472/13, *Lundbeck v Commission*, 8 September 2016, paras. 423-425).

competition.

Having a patent on the brand-name drug is not what determines the exclusionary nature of these agreements. Generic exclusion is caused by the value transfer rather than the existence of a patent. “*Would not that ‘pay-for-delay’ practice violate antitrust rules even if the agreement took place between two producers of generics, or between two holders of patents for the same therapeutic purpose?*”<sup>524</sup> As Professor Carrier puts it: “*agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, in which the parties reserve for themselves particular territories, they allocate time. The brand and generic, in other words, agree that the brand will not be subject to competition for a period of time, thereby dividing the market and preventing competition. Market division is particularly concerning because it restricts all competition between the parties on all grounds.*”<sup>525</sup> Patents however play an important role in complicating the antitrust intervention since these agreements are often concluded to settle a patent infringement lawsuit started by the originator against one or more generic manufacturers (this is the reason why they are often called pay-for-delay patent settlement agreements).<sup>526</sup> The originator sues the generic manufacturer for infringement of a patent protecting the brand-name drug and the lawsuit is settled with a payment from the originator to the generic and the agreement that the generic will not enter the market before a certain date.<sup>527</sup> The peculiarity of these settlements is the “wrong direction” of the payment (which is

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<sup>524</sup> G. Ghidini, *The Bride and the Groom. On the Intersection between Intellectual Property and Antitrust Law*, in G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition Law and Intellectual Property: a European Perspective*, Kluwer, 2012, p. 27.

<sup>525</sup> M.A. Carrier, *Payment after Actavis*, 100(7) *Iowa Law Review*, 2014, p. 14.

<sup>526</sup> “*Patent settlement agreements [...] are commercial agreements to settle patent-related disputes, e.g. questions of patent infringement or patent validity. They are concluded in the context of patent disputes, opposition procedures or litigation where no final adjudication has been handed down. Although the content of individual settlements will vary according to the circumstances of the case, the common aim of a settlement is to end the disagreement.*” (European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 2, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report7\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report7_en.pdf), accessed on 14 December 2016) As noted by the European Commission, “[p]atent settlements often benefit both the parties to the dispute and, more generally, society, by allowing for a more efficient allocation of resources than if litigation were to be pursued to judgement. The vast majority of patent settlement agreements between competitors do not raise antitrust concerns. There is no presumption that patent settlements between competitors are antitrust infringements.” (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 1102). See also European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 3 (“*As in any other area of commercial disagreement, the parties concerned have a legitimate interest in finding a mutually acceptable compromise. In particular the parties may prefer to discontinue the dispute or litigation because it is too costly, time-consuming and/or risky as regards its outcome. Settlements are thus a generally accepted, legitimate way of ending private disagreements. They can also save courts and/or competent administrative bodies such as patent offices time and effort. Therefore, they can have some positive impact in the interest of society.*” However, there is also no presumption of validity of patent settlement agreements between actual or potential competitors. “[S]uch agreements do not provide immunity from competition law because they concern a patent or the settlement of a dispute.” (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 1122) The European Commission refers also to the fact that “*The Court of Justice has also recognised that agreements to settle patent litigation can fall within the prohibition of Article 101(1) of the Treaty: ‘In its prohibition of certain ‘agreements’ between undertakings, Article [101](1) makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.’” Par. 1123 further confirms that “while undertakings who are actual or potential competitors may reach agreement on their patent disputes just as they may conclude other kinds of agreements, in doing so they must respect Union competition law.”*)

<sup>527</sup> “[A] generic company’s ability to enter the market can be limited in several ways. The most straightforward limitation occurs when the settlement agreement contains a clause explicitly stating that the generic

the reason why these agreements are sometimes called reverse-payment settlements).<sup>528</sup> Instead of the generic manufacturer paying damages and litigation cost to the originator, it is the latter that pays the generic. Assuming the patent is valid, enforceable and infringed, a value transfer from the originator to the generic would not be necessary to keep it out of the market. Nothing more than the enforcement of the patent would be needed to achieve the exclusion of the infringing undertaking.<sup>529</sup> If the patent is not valid, not enforceable or not infringed, there is no possible justification for the generic to stay out of the market other than the payment. The payment is thus unjustified if one were to assume the patent is valid and infringed, and anticompetitive (as its purpose and effect is to keep a potential competitor out of the market) if the patent is invalid or not infringed.<sup>530</sup> This is the reason why authorities do

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*company will refrain from challenging the validity of the originator company's patent(s) ("non-challenge clause") and/or refrains from entering the market until the patent(s) has(ve) expired ("non-compete clause"). [...] [A] licence granted by the originator company allowing market presence of the generic company is also categorised as limiting generic entry, if the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialisation of its product freely. Accordingly, the generic company's entry is at least partly controlled by the originator company through the terms of the licence agreement. Note though, that an exception applies in case of royalty free licences that allow generic companies to immediately launch their own product without any further constraints, i.e. concerning quantities, composition, pricing or other marketing conditions of their product. Hence, such licence agreements are not viewed as limiting generic entry. The same logic [...] applies to patent settlement agreements in which the parties agree that the generic company will be a distributor of the originator product concerned or if the generic company will source its supplies of the active pharmaceutical ingredient (API) from the originator company. Furthermore, agreements providing for an early entry of a generic medicine will be seen as limiting generic entry where entry is not immediate. It should be noted that the list of potential limitations is not exhaustive.” (European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, paras. 9-11)*

<sup>528</sup> M.A. Lemley, C. Shapiro, Probabilistic Patents, 19 *The Journal of Economic Perspectives*, 2005, p. 92. The Supreme Court observed that “*where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit.*” (*FTC v. Actavis*, 133 S. Ct., p. 2233)

<sup>529</sup> “[I]f a generic undertaking is paid by an originator undertaking to cease its independent efforts to enter the market with a potentially infringing product, the situation to be analysed under competition law is very different from that if the originator undertaking had succeeded in obtaining an infringement ruling from a court. If infringement is established by a court, the means used to achieve exclusion are the right to oppose based on the objective strength of the patent. Such means fall within the specific subject matter of the patent. If a settlement is agreed without any transfer of value, such an agreement is subject to the scrutiny of competition law, but is likely to be found in compliance therewith as long as the agreement has been reached based on each party’s competing assessment of the patent situation. But when the generic undertaking’s incentives to seek market entry are reduced or eliminated because of a transfer of value by the originator undertaking, the generic undertaking may willingly accept market exclusion which it would not accept without the inducement, and the result of market exclusion is therefore not achieved by the strength of the patent, but by the amount of the value transfer.” (European Commission, AT.39226, *Lundbeck*, 19 June 2013, par. 604)

<sup>530</sup> “When in a patent dispute or patent litigation, a settlement is reached on the basis of each party’s assessment of the patent case before them, such a patent settlement is unlikely to infringe competition law even though it may contain an obligation on the generic undertaking not to use the invention covered by the patent during the period of patent protection (e.g. a non-compete clause) and/or an obligation not to challenge the patent concerned in court (e.g. a non-challenge clause). Although in such a case certain limitations on the commercial behaviour of the generic undertaking are agreed between the parties to the patent dispute, they directly and exclusively result from the strength of the patent litigation case, as perceived by each party and are not the result of an additional transfer of value from the originator to the generic. The situation is very different when such a result is achieved where the generic parties’ incentives to independently compete have been affected by elements extraneous to the dispute/litigation. This is notably the case where the originator pays significant sums of money, or offers other compensation (for example, a market sharing arrangement), to the generic company as consideration for a significant restriction of the generic company’s commercial behaviour, limiting its independent efforts to enter one or more EU markets with a generic product (a “reverse payment” situation). This is not foreseen by the patent system. While a patent holder has the right to oppose possible infringement of its patent, patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to

not need to determine the validity, enforceability or infringement of the patent to assess whether a reverse payment is anticompetitive.<sup>531</sup> What is relevant is the effect of the agreement and the parties' *ex ante* expectations regarding the "strength" of the patent. As the European Commission explicitly stated:

*"[E]ven if the limitations included in the patent settlement remain within the scope of the patent, a settlement agreement may, under certain circumstances, have to be considered as contrary to competition law. [...] With respect to in-scope limitations obtained through transfers of value, it is not because the patent holder might (or might not) have obtained the same result by seeking an infringement ruling from a court that it must necessarily be free at a time when the outcome of a court ruling is unknown to achieve that same potential result in any other manner conceivable. The means used matter."*<sup>532</sup>

Patent settlements are of concern when they comprise a value transfer from the originator to the generic manufacturer, the effect of which is to keep in force potentially invalid and unenforceable patents<sup>533</sup> and/or to keep out of the market potentially non-infringing competitors for longer than, at least, the case in which the settlement did not include any transfer of value.<sup>534</sup>

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*refrain from challenging a patent prior to entering the market. The means used by patent holders to defend their rights matter. It is not because the patent, if valid and infringed, grants the patent holder certain rights to exclude that any means used to obtain the exclusionary result would necessarily be compatible with competition law. In particular, payments made by patent holders to generic challengers aimed at persuading them to stop or delay their independent efforts to enter the market may well, in certain specific circumstances, fall afoul of Union competition law. Indeed, even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they constitute a breach of Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market."* (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 1136-1137)

<sup>531</sup> *"A later finding of patent invalidity should not create antitrust liability for a settlement that was reasonably deemed lawful when created; nor should a later finding of validity serve to ratify an agreement reasonably regarded as anticompetitive. This is consistent with the general principle that economics takes an ex ante rather than ex post approach to decision making. Further, requiring judicial inquiries into patent validity and infringement in order to evaluate a settlement agreement brings back in the very questions that the disputing parties were seeking to avoid at the time of their settlement."* (H.J. Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76(3) *Ohio State Law Journal*, pp. 516-517)

<sup>532</sup> European Commission, AT.39226, Lundbeck, 19 June 2013, par. 603.

<sup>533</sup> *"Preventing patent challenges, whether in the form of pre-litigation disputes, court litigation, or opposition procedures may [...] seriously impact the competitive process as they are frequently the very expression of competition to enter the market with a cheaper, generic product. In Windsurfing International, the Court of Justice confirmed that "it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error"*" (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1132) See also General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 390 (*"the specific subject matter of the patent cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity, which may arise where a patent was granted in error"*) and European Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, 2014/C 89/03, par. 235 (*"it is in the general public interest to remove invalid intellectual property rights as an unmerited barrier to innovation and economic activity"*).

<sup>534</sup> *"[I]n the absence of the agreed inducement and hence based purely on its assessment of its chances to succeed in the patent dispute, i.e. on the merits of the patent case, the generic company as a reasonable economic operator would not accept the commercial limitations which are accepted in the settlement and instead act independently in keeping with its own specific competitive incentives and resort to more pro-competitive solutions (for example, continued litigation,*

Essentially, a settlement is contrary to antitrust when it substitutes (potential) competition for collusion. The European Commission explained that, “[b]y paying the generic undertaking to give up its competitive challenge, the originator undertaking obtains certainty that the generic undertaking will not enter the market for the period of the agreement [...]. From the perspective of the originator undertaking, it is the uncertainty of possible generic market entry, including through patent litigation, which reflects potential competition. This potential competition is eliminated through the transfer of value and transformed into the certainty of no competition. This is in particular the case when the amount of the value transfer matches the profit that the generic producer would have made if it had entered the market.”<sup>535</sup>

Through the value transfer to the generic manufacturer, the originator uses its monopoly profits to purchase protection from the risk of competition<sup>536</sup> from products that may not infringe its patent (or the patent risks being invalidated or rendered unenforceable).<sup>537</sup> A reverse payment patent settlement raises concerns if it distorts the incentives of the generic manufacturer who, no longer aims at an entry date as early as possible

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*acceptance of an early entry settlement). [...] [W]ithout the payment, litigation between the parties may have continued, or the generic could have insisted on less restrictive settlement conditions. In both cases, the degree of competition (actual or potential) would have been superior compared to the situation where the restrictions are leveraged by a reverse payment, or another value transfer to the generic company.”* (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 1138, 1142) See also par. 1102 (“*An infringement of Article 101 can be envisaged only where the transfer of value represents a significant inducement which substantially reduced the incentives of the generic undertaking to pursue its independent efforts to enter the market. Any finding of an antitrust infringement by a patent settlement depends on the specific circumstances of the case.*”)

<sup>535</sup> European Commission, AT.39226, Lundbeck, 19 June 2013, par. 604.

<sup>536</sup> Potential competition between the originator and the allegedly infringing (and settling upon payment) generic company is one of the main points of discussion in these cases. As recently explained by the General Court, “*the examination of conditions of competition on a given market must be based not only on existing competition between undertakings already present on the relevant market but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market and compete with established undertakings*” (General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 99). In case of pay for delay settlement agreements, what matters to determine potential competition is that the generic company “*had real concrete possibilities of entering the market at the time the agreements at issue were concluded [...], with the result that [it] exerted competitive pressure on the [originator]. That competitive pressure was eliminated for the term of the [settlement agreement], which constitutes, by itself, a restriction of competition by object, for the purpose of Article 101(1) TFEU.*” (Ibid., par. 474)

<sup>537</sup> “*The D.C. Circuit in United States v. Microsoft Corp. made clear that “the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant’s continued monopoly power.”* (United States v. Microsoft Corp., 253 F.3d 34, 79 (D.C. Cir. 2001)) In fact, “*it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will.*” Similarly, the leading antitrust treatise makes clear that “*the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition.*” (12 Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* 220 (3d ed. 2012))” (M.A. Carrier, Payment After Actavis, 100(7) Iowa Law Review, 2014, p. 14) As it has been explained by the General Court, “[w]hat matters [...] is that there was uncertainty, at the time the agreements at issue were concluded, as to the possibility, for the generic undertakings, of entering the market without being subject to injunctions or infringement actions, or of successfully challenging the validity of the applicants’ patents, and that those agreements had replaced that uncertainty, by means of significant reverse payments, with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue” (General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 369).

(i.e. what consumers, and the regulation, want),<sup>538</sup> but prefers instead to share in the originator's monopoly profits.<sup>539</sup>

A large and unexplained payment is of concerns not only due to its incentive-changing effect on generic manufacturers (effect that is obviously known and relied upon by the originator), but also as an indication of patent invalidity (the larger the payment, the lower the probability, in the originator's opinion, that the patent would be found valid and/or infringed),<sup>540</sup> market power (the larger the payment, the higher the monopoly profits that make it worthwhile),<sup>541</sup> and competitive harm (the larger the payment, the larger the expected savings consumers would gain from generic entry).<sup>542</sup>

A payment below the originator's expected litigation cost (avoided by the settlement) is often deemed legitimate (at least in the U.S., where each of plaintiff and defendant usually

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<sup>538</sup> “[P]rice cuts resulting from a regulatory intervention, in a context where the [product] patent has already expired, illustrate the balance which the Member States have struck between the protection afforded to the patent of the originator undertaking, on the one hand, and the savings for State budgets and for consumers achieved by the entry of generics to the market and the effects of competition, on the other.” (General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 385)

<sup>539</sup> “[B]oth the brand and the generic companies have an important incentive to prevail in the patent infringement suit. The brand can preserve its patent monopoly by proving the patent is valid, and the generic, if it proves the patent is invalid, can enter the market [...]. Both parties, however, also have a compelling reason to settle the patent infringement suit, in addition to avoiding the cost of prolonged litigation. By reaching a settlement agreement before the court might invalidate the patent, the patent continues to generate monopoly profits that the brand and the generic can divide between them.” (D. Geradin, D. Ginsburg, G. Safty, Reverse Payment Patent Settlements in the European Union and the United States, George Mason University Legal Studies Research Paper Series LS 15-22, 2015, p. 3) See also General Court, T-472/13, Lundbeck v Commission, 8 September 2016, par. 429, that eloquently explains: “In the present case, the parties to the agreements at issue preferred to replace the risks inherent in the normal competitive process and the state of uncertainty surrounding the validity of Lundbeck’s process patents and whether or not the products that the generic undertakings intended to market infringed those patents, with the certainty that those undertakings would not enter the market during the term of those agreements, in return for significant reverse payments which corresponded approximately to the profits that those undertakings would have made if they had entered the market. It is therefore irrelevant whether the undertakings would undoubtedly have entered the market during the term of the agreements at issue, since those agreements eliminated that very possibility, replacing it with the certainty that those undertakings would not enter the market with their products during that period. By doing so, the parties to the agreements at issue were able to share a part of the profits that Lundbeck continued to enjoy, to the detriment of consumers who continued to pay higher prices than those they would have paid if the generics had entered the market”.

<sup>540</sup> “In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.” (W. Choi, B. Den Uyl, M. Hughes, Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and Others, 5(1) Journal of European Competition Law & Practice, 2014, p. 48) “The assumption implicit [...] is that a generic would demand a “large” payment if it had a strong case, but would settle for a small payment if it was unlikely to prove the patent is invalid. A large payment therefore indicates a greater likelihood the generic would have prevailed and thereby made the market more competitive had it not settled the litigation.” (D. Geradin, D. Ginsburg, G. Safty, Reverse Payment Patent Settlements in the European Union and the United States, George Mason University Legal Studies Research Paper Series LS 15-22, 2015, p. 11)

<sup>541</sup> *FTC v. Actavis, Inc.*, 570 U.S., 2013. For instance, an originator’s willingness to pay 20% of its profits to keep a generic out of the market suggests that the originator’s profit-maximizing price is at least 20% above its costs.

<sup>542</sup> As M. Todino, Antitrust Rules and Intellectual Property Rights in the EU and the U.S., 1(2) Italian Antitrust Review, 2014, p. 35, has argued, at its extreme consequences, this series of presumptions “is tantamount to say that, once there is evidence of a large and unexplained payment, anticompetitive effects are somehow inherent to the settlement as such – which in turn is very close to endorse an analysis by object only [...] – in order to reverse the burden of proof upon the parties to the agreement.”

pay their own legal fees).<sup>543</sup> Patent litigation in the U.S. has been estimated to cost between \$2.6 and \$10 million.<sup>544</sup> A transfer of less than \$10 million would thus be abstractly attributable to covering the litigation costs. A payment in excess of the expected cost of litigation, instead, arguably raises concerns as it indicates that the originator and generic manufacturer thought it was at least possible that the patent would be deemed invalid or not infringed, and the originator paid the generic manufacturer to avoid such risk (of invalidity or non-infringement, and thus of generic entry).<sup>545</sup>

While a payment below saved litigation costs is often unproblematic, authorities and courts in the U.S. and EU indicated that a payment close to the amount the generic would

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<sup>543</sup> “If a brand’s payment to a generic is no higher than its future litigation costs, it is more likely to represent an objective assessment of patent validity. Once the brand sues the generic, each side must pay its litigation costs. An exclusion payment that does not exceed the brand’s future costs does not present significant concern since the brand would have been required to spend this money in any event.” (M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, p. 21)

<sup>544</sup> “For example, in its consent decree in *In re Bristol-Myers Squibb Co.*, the FTC did not prohibit settlements in which the value received by the generic was “the lesser of the [brand firm’s] expected future litigation costs...or \$2 million.” And in *In re Schering-Plough Corp.*, the FTC created an exception to its prohibition on settlements “for payments to the generic that are linked to litigation costs, up to \$2 million.” More recently, the Court in *Actavis* found that defendants could show “offsetting or redeeming virtues” justifying payment when the payment “amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement.” In such a case, “there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” Most generally, the concept of litigation costs encompasses expenditures incurred in conducting litigation. The most frequently cited survey of costs in intellectual property litigation is assembled every two years by the American Intellectual Property Law Association (“AIPLA”). The AIPLA defines litigation costs to include “outside legal and paralegal services, local counsel, associates, paralegals, travel and living expenses, fees and costs for court reporters, photocopies, courier services, exhibit preparation, analytical testing, expert witnesses, translators, surveys, jury advisors, and similar expenses.” The figures from the most recent AIPLA survey show that patent litigation in which there is more than \$1 million at risk costs \$2.6 to \$5.5 million on average. In *Hatch–Waxman* litigation in particular, the figures range from \$2.65 million to \$6 million. One study found that generics spent an average of \$10 million for each challenge to a brand’s patent.” (M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, p. 20) See also H.J. Hovenkamp, *Institutional Advantage in Competition and Innovation Policy*, University of Iowa Legal Studies Research Paper No. 13-43, 2013, p. 6: “Parties often pay settlements in order to avoid costly litigation. But anticipated litigation costs in infringement cases of this type typically run less than \$10 million. Settlements in gross excess of that amount suggest that something else must be going on.”

<sup>545</sup> The General Court clearly explained the reasoning that is often behind a pay for delay patent settlement and the reason it can be anticompetitive: “It is true that the asymmetry of the risks faced by the generic undertakings and the originator undertaking can partly explain why the latter may decide to grant significant reverse payments in order to avoid any risk, even small, that the generics might enter the market. [...] It must be recalled, however, that the fact that the adoption of anticompetitive behaviour may be the most cost-effective or least risky course of action for an undertaking in no way excludes the application of Article 101 TFEU [...], particularly if that behaviour consists in paying actual or potential competitors not to enter the market and sharing with those competitors the profits resulting from the absence of generic medicinal products on that market, to the detriment of consumers [...] [T]here was significant uncertainty, at the time the [pay for delay] agreements [...] were concluded, as regards the outcome of the potential patent litigation, and [...] that uncertainty was eliminated and replaced by the certainty that the generic undertakings would not enter the market during the term of those agreements. [...] Furthermore, the fact that a reverse payment may constitute the only means of reaching an agreement by ‘bridging the gap’ between the parties to that agreement, does not mean that such a payment constitutes a legitimate means of reaching such an agreement or that that agreement is exempt from the application of competition law, in particular in circumstances where (i) the amount of that payment appears to be linked to the profits expected by those generic undertakings if they had entered the market, (ii) the agreement does not enable the resolution of the underlying patent dispute and (iii) the agreement contains restrictions going beyond the scope of the originator undertaking’s patents” (General Court, T-472/13, *Lundbeck v Commission*, 8 September 2016, paras. 379-383).

have earned if it had entered the market would raise antitrust concerns.<sup>546</sup> The test is thus two-pronged: “a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim. [...] A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim.”<sup>547</sup>

In sum, a payment equal or below the originator’s litigation costs is unlikely to raise antitrust concerns and a payment (close,) equal or above the generic manufacturer’s expected profits is likely to raise concerns. The area in between is grey and authors have taken different positions as to the anticompetitiveness of these payments to settle a patent litigation.<sup>548</sup>

A payment for the purposes of determining the anticompetitiveness of reverse settlements can consist in a transfer other than monetary “and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement.”<sup>549</sup> From an antitrust perspective the form of the value transfer from the originator to the generic manufacturer is irrelevant. A value transfer may consist in “distribution agreements or a “side-deal” in which the originator company grants a commercial benefit to the generic company, for example by allowing it to enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company. A value transfer could furthermore consist in granting a licence to the generic company enabling it to enter the market.”<sup>550</sup>

The European Commission included in the value transfer potentially relevant to determine the anticompetitiveness of an agreement also “a non-assert clause whereby – even without a licence – the originator binds itself not to invoke the patent against the generic company, thereby allowing the

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<sup>546</sup> In a comparison between the U.S. Actavis and the EU Lundbeck decisions, the at-the-time Director General for Competition Alexander Italianer stated that “Supreme Court looked at the same factors [as the European Commission], in particular the size of the payment including as compared to the expected profits of the generic producer, and the lack of any other convincing justification.” (A. Italianer, Competitor Agreements under EU Competition Law, 26 September 2013, available at [http://ec.europa.eu/competition/speeches/text/sp2013\\_07\\_en.pdf](http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf), accessed on 6 August 2016)

<sup>547</sup> King Drug Co. of Florence, Inc. v Cephalon, Inc., 88 F.Supp.3d, E.D. Pennsylvania, 2015, p. 418 (“First, Actavis specifically instructs that an appropriate benchmark for the size of a reverse payment is “its scale in relation to the payor’s anticipated future litigation costs[.]” Id. at 2237. [...] Regarding the “inducement” prong, Actavis instructs that “there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market[.]” which “cannot in every case be supported by traditional settlement considerations.” Actavis, 133 S.Ct. at 2234-35. [...] As Actavis explains, the relevant inquiry is what would induce the generic to stay off of the market. Id. at 2235. [...] See Herbert Hovenkamp, Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision, 15 Minn. J.L. Sci. & Tech. 3, 12 (Winter 2014) (“Even if the generic believes there is a 100% likelihood that the patent will be found invalid, it may still be more valuable for the generic to share the monopoly returns”).”)

<sup>548</sup> E.g., A. Edlin, C.S. Hemphill, H.J. Hovenkamp, C. Shapiro, Activating Actavis, 28 Antitrust, 2013, p. 16, took the view that a payment exceeding the expected litigation cost can be considered “large and unjustified”, thus anticompetitive; while D. Geradin, D. Ginsburg, G. Safty, Reverse Payment Patent Settlements in the European Union and the United States, George Mason University Legal Studies Research Paper Series LS 15-22, pp. 11-12, took the opposite view.

<sup>549</sup> In re Aggrenox Antitrust Litig., 94 F.Supp.3d, D.Conn., 2015, p. 243.

<sup>550</sup> European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 12.

*generic medicine to come onto the market*”.<sup>551</sup> The Commission however notes that if the agreement concerns exclusively the determination of an early entry date, prior to the expiration of the patent, and the originator’s undertaking not to challenge it, *i.e.* no other limitations to the generic manufacturer stem from it, it is unlikely “*to attract the highest degree of antitrust scrutiny.*” If the settlement concerns exclusively the determination of the entry date, originator’s and generic manufacturer’s interests are opposed and the generic manufacturer will push for the most consumer enhancing solution it is able to get, *i.e.* enter the market as early as possible. This means that the agreed upon entry date reflects the parties’ view on the likely outcome of the litigation and validity or infringement of the patent.<sup>552</sup>

A peculiarity of the U.S. system when it comes to pharmaceuticals is the above-discussed 180-day exclusivity period (from the “first commercial marketing” of the generic) granted by the Hatch-Waxman Act to the first generic manufacturer to file an ANDA with a

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<sup>551</sup> European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 12.

<sup>552</sup> “*As a result, it is less likely that settlements involving only an entry date lead to a loss of consumer welfare.*” (G. Gurkaynak, A. Guner, J. Filson, *The Global Reach of FTC v. Actavis – Will Europe Differ from the US Approach to Pay-for-Delay Agreements?*, 45(2) *International Review of Intellectual Property and Competition Law*, 2014, p. 132) As thoroughly explained by Prof. Carrier (and by the cited authors, courts and agencies): “*The FTC explained that “[a] settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer’s patent.” (In re Schering-Plough Corp., 136 F.T.C. at 987) Rather, “[i]n light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations.*” Similarly, the Supreme Court in *Actavis* stated that settlement allowing entry before patent expiration could “bring about competition . . . to the consumer’s benefit.” (*FTC v. Actavis*, 133 S. Ct. 2223, 2234 (2013)) [...] *The parties’ compromise on the entry date reflects the odds of the parties’ success in patent litigation. (Herbert Hovenkamp et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 15.3 (2d ed. Supp. 2010); Robert D. Willig & John P. Bigelow, Antitrust Policy Toward Agreements that Settle Patent Litigation, 49 Antitrust Bull. 655, 660 (2004).) The greater the likelihood that the patent is valid and infringed, the later in the period generic entry would be expected. The lower the likelihood, the earlier entry would be expected: “By way of example, if there were ten years remaining in the patent term and the parties agreed there was a 60 percent chance that a court would uphold the patent’s validity [and find that it was infringed], the mean probable date of entry under litigation would occur in six years.” ([Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality, 108 MICH. L. REV. 37, 2009, p.] 75–76; see also Marc G. Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L.J. 1033, 1043–44 (2004).) In short, patent-term split agreements are based on the strength of the patent alone, (The strength of the patent includes the likelihood of infringement as certain patents may be valid but not infringed) not supplemented by payment from the brand to the generic. If the brand were to win its patent case, the generic would not be able to enter until the patent expired. But if the generic were successful in showing that the patent was invalid or not infringed, it could enter immediately. The settling parties’ selection of a date for generic entry that lies between immediate entry and patent expiration thus falls naturally within the potential range of litigation outcomes. [...] Where the generic has not entered at risk, the brand’s best-case scenario from litigation is to exclude the generic from the market for the duration of the patent term. And the best-case scenario for the generic is immediate entry. Under legitimate settlements based on the strength of the patent, then, generic entry would be anticipated at some point between immediate entry and the expiration of the patent term. As discussed above, the particular entry date within the allowable range would depend on the parties’ assessments of patent strength, with stronger patents resulting in later generic entry and weaker patents leading to earlier entry.” (M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, pp. 17-18, 28. The author continues: “*In contrast, where a generic that has not entered at risk receives a type of consideration other than entry, it cannot trace its bounty to its victory in patent litigation. For in this case, it receives a type of consideration that cannot be explained by patent litigation. In other words, the generic obtains something that would not be available even upon a resounding decision that the patent is invalid or not infringed. (In cases in which a generic has filed a counterclaim against a brand, the test is satisfied if the brand pays the generic an amount greater than the sum of litigation costs and the generic counterclaim.)*”)*

paragraph IV certification, if the patent is not declared valid and infringed.<sup>553</sup> This provision has a very important role to play in reverse payment settlements. On one side, the originator is risking its monopoly profits, which it would lose if the court declares the patent invalid (or non-infringed). A generic manufacturer is equally interested in not losing the patent suit as most of its profits come from the 180-day exclusivity period and it would lose it if the court finds in favor of the originator and decides that the patent is valid and infringed.<sup>554</sup> The generic manufacturer is therefore willing to exchange a later entry for the possibility to enjoy the exclusivity period.<sup>555</sup> Since both parties have to lose from an unfavorable decision and to gain from a settlement with retained exclusivity, they may agree for the generic manufacturer to delay triggering the 180-day exclusivity, and thus delay its entry and that of any other generic, while the originator pays it off (with cash or the transfer of other values, including an acceleration clause).<sup>556</sup> An acceleration clause gives the settling generic manufacturer the

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<sup>553</sup> As noted by Professors Hemphill and Lemley, “[i]n the early years of the Hatch-Waxman Act, [...] to win the bounty, a generic drug maker had to file a Paragraph IV certification, be sued by the brand-name firm, and win the subsequent suit. If the generic drug maker settled the case in a manner that delayed entry, or was never sued, no exclusivity was awarded. During this period, awards of exclusivity were rare. [...] In 1998, the courts rejected this limitation on generic exclusivity as an impermissible interpretation of the Act’s text, and the FDA changed its interpretation accordingly. Since 1998, a first-to-file generic drug maker has been eligible for the bounty provided that it does not lose the patent suit, even if it never actually wins the patent litigation. Indeed, it may earn the exclusivity even if it was never sued, so long as it was the first to file an ANDA.” (C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, pp. 954-955) See also pp. 956-957 (“we collected every instance in which 180-day exclusivity was awarded by the FDA and triggered by the generic firm over a four-year period between 2005 and 2009. [...] Almost half of the awards (23) are no-suit awards, meaning that the generic firm didn’t have to spend money on litigation or face uncertainty about the outcome of the suit. Indeed, in some cases the basis for the award was a patent that was arguably irrelevant to the product described in the ANDA, in which case little or no effort was needed to develop a legal or design-around strategy. Another nine are settlements. None of these settlements did anything to open up the market to other generic entrants. Eight more were launches at risk. Only nine included a win by the generic firm, all but one of which included an invalidation or unenforceability determination as to at least one brand-name patent. [...] For the 180-day awards on non-suit drugs, twelve blocked other generic approvals, with the effect of keeping prices high for longer than would otherwise be the case. Moreover, in most cases the award blocked approval of a large number of other generics, the earlier entry of which would have reduced prices even more. Five of the nine settlements also blocked subsequent approvals. In other words, when the exclusivity associated with the settling generic firm expired, there were immediate approvals of at least one other generic firm. Of the generic wins, five blocked subsequent generics. These results confirm the expectation that the exclusivity period does indeed impede subsequent entry.”)

<sup>554</sup> “Most of the profits are earned during the exclusivity period. As a result, the generic firm cares more about protecting its 180-day duopoly entitlement, and less about when exactly that entry occurs. It is therefore much more willing to accept a later entry date than it would be if settlement did not preserve exclusivity.” (C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, p. 965)

<sup>555</sup> “Elimination of the risk of losing by the generic company is not just a payment in and of itself, but the primary form of payment in Hatch-Waxman settlements.” (Statement of Bernard Sherman, CEO of the generic manufacturer Apotex, Inc., Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 111th Cong., 2009)

<sup>556</sup> “Both the brand-name drug maker and the generic firm gain by settling the pending patent litigation without resolving the status of either the patent or the generic exclusivity. The brand-name firm is much better off because it has eliminated a near-term threat to its monopoly. And because the FDA regulates entry without evaluating the scope or strength of the relevant patents, settling that suit will enable it to keep even a dubious patent intact for some period of time. The generic drug maker is also much better off. When it eventually enters the market, at a time set by mutual agreement of the drug makers, it will reap the 180-day bounty. Thanks to the lack of a successful defense requirement, the generic firm need not win a patent suit to receive the bounty. Consumers, however, suffer from the elimination of a

possibility to anticipate its entry, and still benefit from its 180-day period of exclusivity, in case another generic manufacturer is successful in challenging the originator's patent.<sup>557</sup> The effect of the acceleration clause is thus to reduce, if not to eliminate, the other generic manufacturers' incentive to challenge the originator's patent, as it ensures that no other generic manufacturer can enter the market before the settling generic manufacturer.<sup>558</sup> Acceleration clauses thus "*constitute exclusion payments*".<sup>559</sup>

The combined effect of the 180-day exclusivity and the acceleration clause is to incentivize reverse payment settlements. An originator that would be normally cautious in (over)paying to settle, as it risks encouraging other generic manufacturers to sue in the hope to be paid off, would not have this disincentive in the U.S. due to the first-to-file 180-day exclusivity period. Without this reward available, generic manufacturers other than the first filer have limited incentive to challenge the validity of the originator's patent, even in cases where the first filer received a substantial payment from the originator to settle (and stay out of the market).<sup>560</sup>

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*chance at early generic entry, as explained below, and from higher prices during the 180 days of generic exclusivity.*" (C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, p. 962)

<sup>557</sup> See, e.g., Brief of Apotex, Inc. as Amicus Curiae Supporting Petitioner, *FTC v. Watson Pharm., Inc.*, No. 12-416, 677 F.3d 1298, 11th Cir., 2012.

<sup>558</sup> On acceleration clauses (otherwise called "poison pills"), see M.A. Carrier, *Payment After Actavis*, 100(7) Iowa Law Review, 2014, pp. 37-41. At p. 40, the author states: "*if the surrogate loses, the settling generic still can exploit its 180-day period, which is delayed under the settlement. And if the surrogate wins, the settling generic can show up on the scene after the hard work has been done, claiming the 180-day period that the Hatch-Waxman Act reserves for first filers and that is triggered by the success of the litigating generic. The poison pill thus offers the settling first filer more than it could have gained by litigating, giving it the exclusivity period it could attain by winning the patent case while protecting it from one of the principal risks of losing – the risk that a second filer would enter before it does. Second, and relatedly, the settling generic increases its likelihood of enjoying the 180-day exclusivity period by reducing later-filing generics' incentives to pursue litigation challenging the brand's patent. Later filers cannot themselves use the valuable 180-day period reserved for the first filing generic. [...] In short, poison-pill clauses provide a type of consideration that the generic could never obtain as a result of winning a district court ruling that the patent is invalid or not infringed.*"

<sup>559</sup> M.A. Carrier, *Payment After Actavis*, 100(7) Iowa Law Review, 2014, p. 41.

<sup>560</sup> A solution to the concerns relating to the use of the 180-day exclusivity to further delay generic entry has been proposed by Professors Hemphill and Lemley. Their proposal consists in awarding the 180 days of exclusivity only if the generic manufacturer wins the lawsuit and invalidates the originator's patent or proves its drug does not infringe it; settle with immediate entry; or obtains FDA approval having never been sued. Their solution (to an antitrust concern) is, as this work deems opportune, based on the society-welfare-enhancing purpose of the regulation establishing the 180-day exclusivity, i.e. it encourages "*challenges to patents because the invalidation of bad patents benefits society as a whole. Society doesn't benefit from a private deal to drop a challenge that has the effect of limiting competition. [...] Litigating more cases to judgment is desirable. As noted above, both the Supreme Court and commentators have observed that the invalidation of patents is a public good: one party bears the costs of invalidation, but lots of others share in the benefits. And like most public goods, the invalidation of patents is likely to be undersupplied. Generic manufacturers that have evidence invalidating a patent are using that evidence to obtain a private sweetheart deal, rather than to benefit the world at large by invalidating the patent. Under earned exclusivity, some – though not all – of those patents will be invalidated. That invalidation provides a substantial social benefit. (While we discuss invalidity here, the same logic applies to a finding of noninfringement. A generic that succeeds in designing around a patent while making a bioequivalent drug has provided a public benefit, too.)*" (C.S. Hemphill, M.A. Lemley, *Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust Law Journal, 2011, p. 949, 978). The proposal "*could be implemented without any legislative action, for example, by the FDA in interpreting the Hatch-Waxman Act. The FDA took a similar view in the 1990s, under different statutory language, but the D.C.*

Directly related to the 180-day exclusivity period is the value transfer consisting in the originator's commitment not to launch its own authorized generic in return for delayed generic entry. An authorized generic is a generic version of the brand-name drug marketed by the originator (or, more commonly, by a licensed generic manufacturer) under its own patent(s) and FDA approval. The authorized generic is often identical to the brand-name drug both in active and inactive ingredients, the main difference being in the name and packaging. U.S. courts have consistently held that authorized generics can be marketed even during the 180-day exclusivity period,<sup>561</sup> which substantially lowers the first filer's sales and profit. According to the FTC's Authorized Generic Study, the generic manufacturer loses, on average, 25% of its market share. Retail generic prices are 4 to 8% lower and wholesale generic prices are 7 to 14% lower. Competition from an authorized generic reduces also the first-filer's revenues by 40 to 52% on average during the 180 days.<sup>562</sup> The "no authorized generic" commitment is thus very valuable to a prospective generic entrant and can be used instead of a cash payment to convince the generic manufacturer to delay its entry.<sup>563</sup>

After a period of uncertainty, U.S. Courts seem to have recognized the potential competitive concerns arising from patent litigation settlements involving the originator's commitment not to launch an authorized generic.<sup>564</sup>

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*Circuit held that the statute did not support it. It also could be implemented by the Federal Trade Commission using its enforcement powers under Section 5 of the FTC Act.” (Ibid., p. 950) The proposed solution would encourage generics to file only if and when they have a strong case, given that what counts is not to be the first to file, but the first to win. This would reduce litigation, thus litigation cost and uncertainty for originators, and increase the number of weak patents invalidated or invented around, with a clear benefit to consumers and generic manufacturers able to bring a strong challenge against the originator's patent. “A generic that rushes to file an ANDA without doing its research may actually have a weaker case than one that waits. For example, an early generic entrant may rush onto the market by copying the patentee's product exactly, relying only on the possibility of invalidating the patent or on long-shot claims like inequitable conduct. By contrast, a generic firm that spends the time to design around the patentee's drug, coming up with a bioequivalent drug that may not infringe the patent, may take longer to do so, but may also bring a stronger challenge. If earned exclusivity discourages the long-shot challenge because the challenger was simply hoping for a settlement, the result may be to give the second challenger – the one with a stronger case – more incentive to bring its challenge.” (C.S. Hemphill, M.A. Lemley, Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust Law Journal, 2011, pp. 983-984)*

<sup>561</sup> See, e.g., Mylan Pharm., Inc. v. FDA, 454 F.3d, 4th Cir., 2006, p. 271; Teva Pharm. Indus. v. FDA, 410 F.3d, D.C. Cir., 2005, p. 52.

<sup>562</sup> FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, 2011, pp. 57-62, available at <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>, accessed on 6 August 2016.

<sup>563</sup> Professor Hovenkamp illustrates why so-called “no-AG” agreements should be scrutinized and, if anticompetitive, sanctioned. “The patentee's promise not to enter with an authorized generic is very valuable [...] for the same reason that any cartel agreement can be valuable to participants: one cartel member promises to restrain its own output in order to get market prices up. A “no authorized generic” provision is actually more anticompetitive and harmful to consumers than a payment for delay. The payment for delay is merely a wealth transfer between the patentee and generic. By contrast, the “no authorized generic” agreement is not merely a wealth transfer, it is also a cartel agreement that serves to reduce market output and keep prices higher than they would otherwise be. As a result, agreements restraining authorized generic entry should be treated more harshly than pay-for-delay settlements.” (H.J. Hovenkamp, Antitrust and the Patent System: A Reexamination, 76(3) Ohio State Law Journal, pp. 498-499)

<sup>564</sup> King Drug Co. of Florence Inc. v. Smithkline Beecham Corp., 791 F.3d, 3d Cir., 2015, pp. 32-35 (“no-AG agreements are likely to present the same types of problems as reverse payments of cash. [...] In Actavis, the Supreme Court recognized generally that the 180-day exclusivity period is “possibly ‘worth several

The absence of the 180-day exclusivity period in the EU limits the risk and effectiveness of pay-for-delay settlements. Since paying off one generic manufacturer has the effect of “*putting blood in water where sharks are always near*”.<sup>565</sup> Indeed, for a pay for delay to be effective in the EU, the originator has to settle with multiple generic manufacturers to prevent entry, not only with the first filer. As we will see in further details below, this has been the case in the settlements sanctioned by the European Commission.

The U.S. agencies and the European Commission have not only enforced antitrust and fined originators and generic manufacturers that had concluded pay for delay settlement agreements; they are also actively monitoring them.

In the U.S., since 2004, originators and generic manufacturers are required to file certain agreements with the FTC and DOJ by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The FTC reviews these filings and issues an annual report summarizing the number of agreements filed and the incidence of certain potentially anticompetitive terms. In its latest report, the FTC noticed that, since the Actavis decision (discussed below), while the number of overall patent settlements filed increased, the percentage of settlements containing reverse payments appears to be declining.<sup>566</sup> In the

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*hundred million dollars,” and may be where the bulk of the first-filer’s profits lie. [...] At the same time, a brand’s commitment not to produce an authorized generic means that it must give up the valuable right to capture profits in the new two-tiered market. The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly. Thus, “the source of the benefit to the claimed infringer is something costly to the patentee.” Aaron Edlin et al., *Activating Actavis, Antitrust*, Fall 2013, at 16, n.22. Absent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand. For this reason, the fact that the brand promises not to launch an authorized generic (thereby giving up considerable value to the settling generic) makes the settlement something more than just an agreed-upon early entry: it “may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Actavis*, 133 S. Ct. at 2235. The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash. If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market). As with a reverse payment of cash, a brand agreeing not to produce an authorized generic may thereby have “avoid[ed] the risk of patent invalidation or a finding of noninfringement.” *Id.* at 2236. In addition, when the parties’ settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted. And during this time, the brand’s monopoly remains in force. Once the generic enters, moreover, it faces no competition with other generics at all.”) See also *In re Loestrin 24 FE Antitrust Litig.*, --- F. 3d. ---, 2016 WL 698077, 1st Cir., 2016; and *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, D. Mass., 2013. “*The Use of No-AG Commitments Appears to Be Declining—In FY 2012, almost half of the reverse-payment agreements filed with the FTC included a commitment by a brand company that it would not sell an authorized generic (AG) for some period of time, allowing the settling generic company to increase its sales volume, likely at prices greater than if the brand company sold an AG. [...] Starting in FY 2013, the number of no-AG commitments in pharmaceutical patents settlements has declined substantially, from nineteen in FY 2012 to four in FY 2013 and five in FY 2014.*” (J. Towey, B. Albert, *Is FTC v. Actavis Causing Pharma Companies to Change Their Behavior?*, 13 January 2016, available at <https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their>, accessed on 6 August 2016)*

<sup>565</sup> This language comes curiously from J. Robert’s dissenting opinion in *FTC v. Actavis, Inc.*, 570 U.S., 2013.

<sup>566</sup> “From FY 2005 to FY 2012, potential pay-for-delay agreements [...] increased steadily, from three in FY 2005 to 40 in FY 2012. But since early 2013, this trend seems to have reversed. For example, in FY 2014, 21 such reverse-payment agreements were filed with the Commission – a nearly 50% decline from the FY 2012 peak of 40 – while the number of final patent settlements went up. Also, almost half of the FY 2014 reverse-payment settlements involved cash payments to the generic company amounting to \$5 million or less. Such small cash payments

FTC's words: "[t]hese statistics confirm what the Supreme Court said in *Actavis*: "parties may well find ways to settle patent disputes without the use of reverse payments." The recent decline in settlements with reverse payments may signal that the Commission's commitment to combat anticompetitive agreements is finally paying off."<sup>567</sup>

In the EU as well, the European Commission monitors patent settlements in the pharmaceutical sector. Each year, originator and generic companies are required to submit copies of all the patent settlement agreements covering the EU/EEA. As in the previous reports, the Seventh Monitoring Report<sup>568</sup> discusses the main categories of settlements and provides statistics relating to the agreements concluded during the previous year. The categories identified by the Commission are 3: A, B.I and B.II. Settlements within the first two categories (A, allowing immediate generic entry, and B.I, involving no value transfer from originator to generic company) are considered unproblematic. These agreements represented 26% and 64% respectively of the settlements filed in 2015.<sup>569</sup> Category B.II contains the potentially problematic agreements, *i.e.* those that do not allow immediate generic entry and involve a value transfer from the originator to the generic company. They represented 10% of the settlements in 2015.<sup>570</sup> Only one of the B.II agreements in 2015 included a payment to the generic company and the percentage of agreements falling within this category has stabilized at a much lower level than in the period covered by the pharmaceutical sector inquiry.<sup>571</sup> As noted by David Hull and Michael Clancy, however, "[t]he problem with this category is that it includes almost every form of settlement that would seem to fall within the normal definition of the term and, thus, risks discouraging companies from entering into meaningful settlements at all, including those that would allow early entry. For example, this category includes a common form of settlement that would

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*might represent saved litigation costs, one of the few justifications the Supreme Court specifically identified in Actavis. [...] More final patent settlements were filed with the Commission in FY 2014 than in any previous year (160 final settlements, compared to the previous high of 156 in FY 2011), but in the vast majority—more than 80%—pharma companies settled without any compensation to the generic company.*" (J. Towey, B. Albert, *Is FTC v. Actavis Causing Pharma Companies to Change Their Behavior?*, 13 January 2016, available at <https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their>, accessed on 6 August 2016)

<sup>567</sup> J. Towey, *Quo Vadis Post-Actavis?*, 30 March 2016, available at <https://www.ftc.gov/news-events/blogs/competition-matters/2016/03/quo-vadis-post-actavis>, accessed on 6 August 2016. In a recent hearing held by the U.S. Congress to address pay for delay agreements, the FTC Chairwoman E. Ramirez indicated that despite the Supreme Court ruling, she continued to support legislation making pay for delay agreements presumptively illegal. The main reason given is that it would enhance clarity, create a stronger deterrent effect, and help the FTC intervene more quickly (United States, 121st meeting of OECD Competition Committee, *Generic Pharmaceuticals*, DAF/COMP/WD(2014)51, 19 June 2014, par. 40).

<sup>568</sup> European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 2, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report7\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report7_en.pdf), accessed on 14 December 2016.

<sup>569</sup> "[M]ost of the settlements (90% in 2015) fall into categories that *prima facie* raise no need for competition law scrutiny. Companies, in most cases, are able to solve their disputes in a manner that is typically considered unproblematic from a competition law perspective." (European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 50)

<sup>570</sup> European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 30.

<sup>571</sup> European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, Table 2 and paras. 46, 49.

*seem to be benign in most circumstances: early entry by the generic.*”<sup>572</sup> The total number of patent settlements increased through the years with a peak in 2012. After 2012, the number decreased in 2013 and 2014, but increased significantly in 2015.<sup>573</sup> Noteworthy is the percentage of originators and generic manufacturers that concluded a settlement agreement in 2015, 40% and 30% respectively. Both percentages are at their second to highest levels (only in 2011 the percentage of originators has been higher, at 44%, while the percentage of generic manufacturers has exceeded 30% only in 2013, reaching 35%).<sup>574</sup>

## 17.1. United States

### 17.1.1. Actavis (U.S.)

The first case that will be analyzed is also one of the, if not the, most important on pay-for-delay patent settlements. Across this work, three are the crucial cases that revolutionized the way in which the interface between IP and antitrust in the pharmaceutical industry is conceived: *AstraZeneca* in the EU, *Pfizer* in Italy and *Actavis* in the U.S.

The most important finding in *Actavis* is the definite rejection of the “scope of the patent” test to determine whether a conduct may fall within the reach of antitrust (this test provided that, if the effect of the agreement fell within the exclusionary effect of the patent, the agreement is immune from antitrust). This however should not lead to think that patent law and antitrust law are two different and completely independent disciplines, whose infringement should be assessed notwithstanding the other. As we saw, the two disciplines have overlapping goals and complementary means to achieve them. Their application should always go in parallel to avoid the risk of one undermining the other and reaching conflicting

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<sup>572</sup> D.W. Hull, M.J. Clancy, *The Application of EU Competition Law in the Pharmaceutical Sector*, 7(2) *Journal of European Competition Law & Practice*, 2016, p. 153. “*Of the 13 B.II agreements for the 2015 period, 5 (38%) enabled early entry without a licence or a distribution agreement, 6 (46%) combined early entry with a licence to the generic company, 1 (8%) only included a licence, and 1 (8%) included a payment to the generic company to compensate for damages.*” (European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 46) See also M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, p. 26 (“*the most expansive definition of an exclusion payment would encompass every settlement that involves the transfer of any consideration between the parties. Under this definition, an exclusion payment would be present when a brand conveys anything of value to a generic. This standard would be too broad. It is hornbook contract law that parties would not settle a case if they did not receive some consideration. The most frequently cited source for this proposition is Judge Richard Posner, sitting by designation in the Northern District of Illinois, in Asahi Glass Co. v. Pentech Pharmaceuticals, Inc. In granting defendants’ motion to dismiss, Judge Posner explained that “any settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement.” Judge Posner appropriately observed that settlements tend to give each of the settling parties something of benefit. For that reason, the standard for exclusion payments that violate the antitrust laws should not encompass the broadest conception of value transferred to the generic. Of particular concern, such a standard would ensnare settlements in which the brand and generic reach agreement solely on the date for generic entry. For these settlements allow the generic to obtain something of value: the right to enter before the end of the patent term.*”)

<sup>573</sup> The Commission thus notes that “[a]s with the former six exercises, the results of the seventh monitoring exercise show that the Commission’s announcement that it would continue scrutinizing B.II category settlements in the future has not hindered companies from concluding settlements in general.” (European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 48)

<sup>574</sup> European Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, par. 24.

results.<sup>575</sup> The correct test is thus to determine whether a conduct falls within the purpose of the patent, not its scope. If it is within the purpose to pursue which the right has been granted, the conduct is “shielded” from antitrust intervention, as it can be considered falling within the meaning of competition on the merits and is presumptively beneficial to consumer welfare. If the conduct falls outside of the purpose of the patent, *i.e.* it is neither aimed nor useful to achieve the purpose of patent law, or runs counter to it, it should be scrutinized and potentially prohibited and sanctioned. This way patent and antitrust works in tandem to define each other’s reach and better achieve their common purpose.

In *Actavis*, Solvay Pharmaceutical had filed an NDA for a brand-name drug called AndroGel in 1999, in 2000 the application was approved by the FDA, and in 2003 Solvay obtained the only patent protecting AndroGel (due to expire in August 2020). Later that same year, Actavis (at the time, Watson Pharmaceuticals) and, subsequently, Paddock Laboratories filed ANDAs with paragraph IV certifications (invalidity or non-infringement) for the generic version of AndroGel. Par Pharmaceutical did not file an application but joined forces with Paddock, sharing patent litigation costs and profits if Paddock obtained approval for its generic. Solvay sued Actavis and Paddock for patent infringement and the 30-month stay started running. Thirty months later, in early 2006, the FDA authorized the marketing of Actavis’ first-to-file generic. In 2006, however, the two patent litigations were settled. The settlement agreement with Actavis provided for: (i) a commitment by Actavis not to enter the market before 31 August 2015, 65 month before Solvay’s patent expiry (with an acceleration clause, *i.e.* the possibility to enter sooner in case some other generic was to enter the market), (ii) an obligation of Actavis to promote AndroGel to urologist, (iii) a payment by Solvay to Actavis. The settlement agreement with the other generic manufacturers had similar provisions. The payments by the originator Solvay to the generic manufacturers were as follows: \$12 million in total to Paddock; \$60 million in total to Par; and an estimated \$19 to \$30 million annually, for the time it agreed to stay out of the market (nine years), to Actavis.<sup>576</sup> Originator and generic manufacturers described these payments as compensation for the services provided by the generic manufacturers, whose value according to the FTC was very limited.

On 29 January 2009, the FTC filed a complaint against Solvay, Actavis, Paddock, and Par alleging that they violated Section 5 of the FTC Act<sup>577</sup> by agreeing to abandon their

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<sup>575</sup> “[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well. And indeed, contrary to the Circuit’s view that the only pertinent question is whether “the settlement agreement . . . fall[s] within” the legitimate “scope” of the patent’s “exclusionary potential,” 677 F. 3d, at 1309, 1312, this Court has indicated that patent and antitrust policies are both relevant in determining the “scope of the patent monopoly”—and consequently antitrust law immunity—that is conferred by a patent. Thus, the Court in *Line Material* explained that “the improper use of [a patent] monopoly,” is “invalid” under the antitrust laws and resolved the antitrust question in that case by seeking an accommodation “between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act.” 333 U. S., at 310. [...] It would be difficult to reconcile the proposed right [to pay a competitor to respect its patent and quit its patent invalidity or noninfringement suit] with the patent-related policy of eliminating unwarranted patent grants so the public will not “continually be required to pay tribute to would-be monopolists without need or justification.” *Lear, Inc. v. Adkins*, 395 U. S. 653, 670 (1969).” (FTC v. Actavis, Inc., 570 U.S., 2013, par. II.A)

<sup>576</sup> AndroGel was Solvay’s best-selling drug. In 2007 sales went beyond \$400 million, accounting for one-third of Solvay’s U.S. revenues.

<sup>577</sup> “The *Actavis* case was brought by the Federal Trade Commission under Section 5 of the FTC Act. However, the FTC often applies Sherman Act standards in such cases, and nothing in the Supreme Court’s opinion

lawsuits and delay their market entry in exchange for Solvay's payment. The District Court concluded that these allegations did not represent an antitrust violation and dismissed the FTC's complaint. The FTC appealed and the Court of Appeals for the Eleventh Circuit affirmed the District Court's opinion, confirming the "scope of the patent" test ("*absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.*")<sup>578</sup>

The Supreme Court's opinion, as anticipated, rejected the scope of the patent test, reversed the District Court decision, and remanded the case to the district court for trial.<sup>579</sup> The Supreme Court, while recognizing the value of settlements, concluded that this patent-related factor should not affect the FTC's opportunity to prove its antitrust claim. The Court listed five sets of considerations leading to this conclusion.

First, the Court recognized that pay for delay settlements have the potential for genuine adverse effects on competition (as requested for the application of Section 5 of the FTC Act). In particular, with the payment the patentee purchases "*the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.*"<sup>580</sup> While generic entry before patent expiry benefits consumers, the payment to delay generic entry keeps prices at monopoly levels while dividing that return between originator and generic manufacturers. In *Actavis*, generic manufacturers received a sum larger than what they would have gained if they won the litigation and entered the market. According to the Supreme Court, a payment this size cannot be explained by traditional settlement considerations and "*may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.*" The Court discussed also the fact that a high reverse payment may "*signal to other potential challengers that the patentee lacks confidence in its patent, thereby provoking additional challenges, perhaps too many for the patentee to buy off*". As we saw, this argument is weakened by two features of the U.S. system: the 180-day exclusivity granted to the first filer<sup>581</sup> and the 30-month stay before the FDA may approve the

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*suggests that the Court was applying a broader liability rule available only to the FTC under Section 5 of the FTC Act. This was, for all intents and purposes, a Sherman Act case. Thus, the inference and procedure [...] are also available to private plaintiffs.*" (A. Edlin, C.S. Hemphill, H.J. Hovenkamp, C. Shapiro, *Activating Actavis*, 28 *Antitrust*, 2013, p. 20)

<sup>578</sup> *FTC v. Watson Pharmaceuticals (now Actavis)*, 677 F. 3d, 2012, p. 1312. As the Supreme Court summarized it: "*The court recognized that "antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market." [...] But, the court found that "reverse payment settlements of patent litigation present atypical cases because one of the parties owns a patent.*" 677 F. 3d, at 1307 (internal quotation marks and second alteration omitted). Patent holders have a "*lawful right to exclude others from the market,*" *ibid.* (internal quotation marks omitted); thus a patent "*conveys the right to cripple competition.*" *Id.*, at 1310 (internal quotation marks omitted). The court recognized that, if the parties to this sort of case do not settle, a court might declare the patent invalid. *Id.*, at 1305. But, in light of the public policy favoring settlement of disputes (among other considerations) it held that the courts could not require the parties to continue to litigate in order to avoid antitrust liability. *Id.*, at 1313–1314." (*FTC v. Actavis, Inc.*, 570 U.S., 2013, par. I.B.2)

<sup>579</sup> "*Discovery in that case will close soon, and summary judgment motions are due early [2017]*" (J. Towey, *Quo Vadis Post-Actavis?*, 30 March 2016).

<sup>580</sup> *FTC v. Actavis, Inc.*, 570 U.S., 2013, par. II.B.

<sup>581</sup> "*Subsequent challengers cannot secure that exclusivity period, and thus stand to win significantly less than the first if they bring a successful paragraph IV challenge. That is, if subsequent litigation results in invalidation of the patent, or a ruling that the patent is not infringed, that litigation victory will free not just the challenger to compete, but all other potential competitors too (once they obtain FDA approval). The potential reward available to a subsequent*

second generic manufacturer's application. The Court thus concluded that: "*a reverse payment settlement with the first filer (or, as in this case, all of the initial filers) 'removes from consideration the most motivated challenger, and the one closest to introducing competition.'*"<sup>582</sup>

Second, the mentioned adverse effects on competition may prove unjustified. When confronted with a potentially anticompetitive settlement, courts will have to determine whether the virtues offset the vices. One of the virtues recognized by the Supreme Court is ending the litigation, and saving litigation costs. This may be the case when the payment is "*a rough approximation of the litigation expenses saved through the settlement*". Another potential justification for the payment is that it corresponds to the fair value of the services that the generic has promised to perform (mostly supply of raw material, distribution, marketing/co-promotion or backup manufacturing services).<sup>583</sup> If it is not to save on litigation costs or to buy legitimate services from the generic manufacturer, the payment has no other purpose than to delay generic entry relative to what originator and generic manufacturer would have expected absent the value transfer.

Third, the patentee must possess the market power to bring about the unjustified anticompetitive harm in practice; market power that may be inferred from the size of the payment. If the patentee were active in a competitive market, it would not pay (or be able to pay) to keep a rival out, as this would have a very limited impact on the drug prices, already close to marginal cost. The exact opposite is true for a firm with market power, which often enjoys high margins and has any interest in protecting them by excluding rivals. According to the Court, the "*size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power*"—namely, the power to charge prices higher than the competitive level. [...] *An important patent itself helps to assure such power. [A] firm without that power [is un]likely to pay "large*

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*challenger being significantly less, the patentee's payment to the initial challenger (in return for not pressing the patent challenge) will not necessarily provoke subsequent challenges.*" (FTC v. Actavis, Inc., 570 U.S., 2013, par. II)

<sup>582</sup> The Court continues by noting that "*scholars in the field tell us that 'where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit.'*" H.J. Hovenkamp, M. Janis, M. Lemley, & C. Leslie, *IP and Antitrust* §15.3, p. 15–45, n. 161 (2d ed. Supp. 2011). *It may well be that Hatch-Waxman's unique regulatory framework, including the special advantage that the 180-day exclusivity period gives to first filers, does much to explain why in this context, but not others, the patentee's ordinary incentives to resist paying off challengers (i.e., the fear of provoking myriad other challengers) appear to be more frequently overcome. See 12 Areeda ¶2046, at 341 (3d ed. 2010) (noting that these provisions, no doubt unintentionally, have created special incentives for collusion).*"

<sup>583</sup> Critic of the genuinity of these "side deals" is M.A. Carrier, *Payment After Actavis*, 100(7) *Iowa Law Review*, 2014, p. 23 ("*In most cases, brands are not interested in generic services outside the settlement context. Based on a review of settlements between 1993 and 2000, as well as settlements filed under the Medicare Modernization Act of 2003, former FTC Chairman Jon Leibowitz testified that "side deals" between brands and generics were "observed in settlements that restrained generic entry, but virtually never in settlements that did not."* Leibowitz observed that there had been only two exceptions to this pattern, one of which was then under investigation. *And he concluded that the side deals "may be serving as a vehicle to compensate a generic challenger for its agreement to a later entry date than the generic firm would otherwise accept."* Similarly, based on a review of the securities filings of brands and generics that have entered into settlements, Scott Hemphill has concluded that "[o]utside of settlement, brand-name firms seldom contract with generic firms for help with the activities that form the basis of side deals." In particular, Hemphill found that the 25 total combinations among five major brand firms and five major generic firms yielded only two minor business arrangements. *While the facts of individual settlements call for review, common sense calls for rigorous scrutiny. Do brands really need promotion by generics? As evidenced by armies of pharmaceutical sales representatives and commercials with wind-swept actors walking along the beach, brands tend not to be at a loss in marketing their drugs. And while brands sometimes rely on other brands for promotion, they do not use generics for this task outside the context of settlement.*")

*sums” to induce “others to stay out of its market.” [...] [R]everse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.”*

Fourth, there is no need to litigate neither the patent’s validity nor patent infringement to answer to the antitrust question.<sup>584</sup> The Supreme Court insightfully explained that: “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival. And that fact, in turn, suggests that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.”<sup>585</sup> The Court rejects also a risk-aversion defense by saying that payments to avoid even a small risk of competition are antitrust violations. “The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”

Fifth, the potential antitrust liability presumed in case of a large and unjustified reverse payment does not prevent litigating parties from settling their lawsuit in other ways, such as, by allowing the generic to enter prior to patent’s expiration, “without the patentee paying the challenger to stay out prior to that point”. As the Supreme Court concluded: “[a]lthough the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.”

## 17.2. European Union

While the most internationally well-known case of reverse payment is probably *Actavis*, the European Commission has studied and tackled pay-for-delay agreements as well.<sup>586</sup> As did the FTC and the U.S. Supreme Court, the Commission rejected the scope of

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<sup>584</sup> As the Supreme Court notes: “litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement [...] [would] prove time consuming, complex, and expensive. The antitrust game, the Circuit may believe, would not be worth that litigation candle.” (*FTC v. Actavis, Inc.*, 570 U.S., 2013, par. II.B)

<sup>585</sup> “[A] very large payment is strong evidence that the parties themselves think the patent is very weak or invalid. [...] That, incidentally, is a market based assessment of the patent’s strength, and as such it is very likely more reliable than a court’s determination. If the parties have calculated a, say, 70% likelihood that the patent will be invalid, given what they know about similar situations, that statistical assessment is more valid than the ultimate decision of the court, which could be wrong about half the time. Given the high likelihood of invalidity, the high payment then indicates that this generic is delaying or foregoing entry in order to maintain the high prices currently being charged.” (H.J. Hovenkamp, *Institutional Advantage in Competition and Innovation Policy*, University of Iowa Legal Studies Research Paper No. 13-43, 2013, p. 8)

<sup>586</sup> The European Commission’s reasoning as to why these agreements are concluded and why they are detrimental to consumer welfare is perfectly in line with the analysis conducted in the U.S.: “it may be in the interest of the originator undertaking to induce, with a significant value transfer, the generic undertaking to stay out of the market for a period of time and in the interest of the generic undertaking to agree to stay out of the market in exchange for that payment. In fact, both parties may do better with such an agreement than if they had continued their own independent commercial course and rivalry. The reason why both (potential) competitors can be better off at the same time is that the profits the generic undertaking could make from entering the market will be lower than the loss in profits that would likely result for the originator undertaking from generic entry. Therefore the originator can easily afford to pay-off one or several generics to prevent their entry. [...] [O]riginator’s losses from generic entry

the patent test<sup>587</sup> and ruled that reverse payment agreements should be considered restrictions “by object” (thus excluding the need to demonstrate their effects).<sup>588</sup> In the most recent case it decided, *Servier*, the Commission confirmed its previous finding that it is not necessary to show effects for a pay-for-delay agreement to be anticompetitive, but nevertheless assessed the effects of the agreement. This is not the only interesting element of *Servier*. In this case, the Commission introduced also another innovative element in the scrutiny of reverse payments, the unilateral perspective. Indeed, the agreement may be seen as part of the originator’s unilateral conduct aimed at inducing generic manufacturer to refrain from entering the market, rather than a common decision by originator and generic manufacturer(s). This perspective will be discussed in detail in the context of the *Servier* case.

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*exceed generic company’s expected gains from competing. The difference would accrue to the consumer. Therefore, if also consumers’ interest in lower, off-patent prices is taken into account, the originator’s interest in preserved product exclusivity is counterbalanced by both generics’ and consumers’ interest in generic competition. It can certainly make commercial sense for an originator company to simply pay the generic undertaking the money that it could hope to gain by entering the market, or more, on condition that the generic undertaking stays out of the market. The incentive to do so is even higher if the originator perceives an appreciable risk that its patent(s) will be held invalid and/or not infringed by a court. This does not imply that it is legitimate to avoid risks of competition by practical cooperation between the companies. (Judgment in Beef Industry Development and Barry Brother, C-209/07, EU:C:2008:643, paragraphs 33 to 35)” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 1146-1149).*

<sup>587</sup> As the European Commission notes in AT.39226, Lundbeck, 19 June 2013, par. 698, “[p]aying potential competitors not to try to enter the market at all is not based on any rights granted by patent law, nor is it based on the strength of the patent, nor is it one of the legitimate means society has provided for the defence of patent rights. In this sense, one could say that the agreements covered by this Decision fall outside of the “specific subject matter” of the patent, which includes the right to oppose, but not the right to buy off competition.” This position has been confirmed by the General Court, which affirmed that the European Commission rightly noted that the “scope of the patent test” is problematic from a competition law perspective as “it leads to a presumption that a generic medicinal product infringes the originator undertaking’s patent and thus allows the generic medicinal product to be excluded on that basis, when the question whether it infringes any patents is an unresolved issue. Secondly, it is based on the premiss that any patent invoked in the context of a settlement agreement will be held valid if its validity is challenged, although there is no basis in law or in practice for that outcome [...]. The ‘scope of the patent’ test is therefore based on a subjective assessment, by the applicants, of the scope of their patents and of their validity, whereas a national court or competent authority may have taken a different view. Moreover, the Supreme Court of the United States, concluding an intense debate on that issue, adopted the same approach by rejecting the ‘scope of the patent’ test [...] Whether or not a restriction falls within the scope of a patent is a conclusion that follows from an examination of the scope and validity of that patent and not, as the applicants suggest, the starting point of such an examination [...] Moreover, the fact that some restrictions contained in the [pay for delay] agreements [...] were considered by the Commission as potentially falling within the scope of [the originator’s] patents means only that the applicants could have obtained comparable restrictions through court rulings enforcing their patents, assuming that they succeeded in actions brought before the competent national courts. In that respect, even if the agreements at issue also contained restrictions potentially falling within the scope of the applicants’ patents, those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market” (General Court, T-472/13, Lundbeck v Commission, 8 September 2016, paras. 491-495).

<sup>588</sup> The European Commission’s position has been later confirmed by the General Court, which stated that: “the very existence of reverse payments and the disproportionate nature of those payments [are] relevant factors in establishing whether [pay for delay settlement] agreements [constitute] restrictions of competition ‘by object’ for the purpose of Article 101 TFEU in that, by those payments, the originator undertaking [provides] an incentive to the generic undertakings not to continue their independent efforts to enter the market. [...] [Pay for delay agreements are] comparable to market exclusion agreements, which are among the most serious restrictions of competition. The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production.” (General Court, T-472/13, Lundbeck v Commission, 8 September 2016, paras. 355 and 435)

As to the infringement of Article 101 TFEU, based on the Commission's practice so far, three are the basic criteria applied to determine whether an agreement is anticompetitive: (i) it has been concluded between (at least potential) competitors; (ii) it involves an unjustified transfer of value from the originator to the generic manufacturer; (iii) as a result of the agreement, the generic manufacturer's ability and incentives to independently compete with the originator are somehow limited (*i.e.* delayed entry, no-challenge or non-compete clauses, and/or market entry under license or distribution agreement with the originator).

Therefore, if (i) an originator and a generic manufacturer settle a patent litigation with the agreement that (ii) the originator gives something of value to the generic manufacturer with no other justification than to induce (iii) the generic manufacturer to delay its entry (or otherwise limit its efforts to compete), the patent is assumed to be "weak" (*i.e.* there is a high probability it is invalid or not infringed) and the agreement is considered a restriction by object contrary to Article 101 TFEU, with no need to prove effects.<sup>589</sup> As the Commission noted in *Servier*, "[t]he protection of rivalry, including through patent law challenges, relates to an important general principle underlying Article 101 of the Treaty, which is that each economic operator must determine independently the policy which it intends to adopt on the market."<sup>590</sup> Obviously a reverse payment

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<sup>589</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1144 ("If the generic company was an actual or potential competitor as it had a real concrete possibility to enter, or viably remain on, the market absent the settlement, the immediate and direct consequence of the reverse payment patent settlements as assessed in this Decision is to remove the possibility that the generic undertaking will enter or remain on the market. [F]or the purposes of competitive assessment (of restrictions by object) [w]hat matters is if a reverse payment patent settlement collusively removes a potential competitor and affects the structure of the market. [...] In this case, it is not only inappropriate, but also unnecessary for the Commission to rely on posterior patent court decisions or perform an own assessment of the likely outcome of the patent dispute/litigation. A reverse payment settlement may remove a potential competitor and distort the market structure, resulting in reduced risks from competition and the resulting market uncertainty, thus easing competitive pressure to the benefit of the originator.") See also European Commission, AT.39226, Lundbeck, 19 June 2013, paras. 638-640 ("When in a patent dispute a settlement is reached without inducement on the basis of each party's assessment of the probability of a patent being held valid and infringed by a court, such a patent settlement will normally not infringe Article 101(1) of the Treaty if the agreed limitations on the behaviour of the generic undertaking do not go beyond the rights granted by patent law. [...] [By contrast,] "when an agreement is concluded in which the generic undertaking accepts to exit or not to enter the market for a certain period of time [...] but instead the originator undertaking pays a considerable sum of money to the generic undertaking, then such an agreement, whether referred to as a patent settlement or not, merits the full scrutiny of competition law.")

<sup>590</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1139. The Commission continues with a pertinent parallelism with the Irish Beef case (Court of Justice, C-209/07, Beef Industry Development and Barry Brothers, 20 November 2008, paras. 33-34): "Irish Beef is of particular interest to the facts examined in this Decision. This case dealt with a mechanism, the so-called BIDS arrangements, to reduce perceived overcapacity in the Irish beef sector. As part of the BIDS arrangements, the undertakings that stayed in the market paid financial compensation to those who agreed to leave the market. The Court of Justice found that: "That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article 81(1) EC [now 101(1) of the Treaty] is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between undertakings for the risks of competition. In the context of competition, the undertakings which signed the BIDS arrangements would have, without such arrangements, no means of improving their profitability other than by intensifying their commercial rivalry or resorting to concentrations. With the BIDS arrangements it would be possible for them to avoid such a process and to share a large part of the costs involved in increasing the degree of market concentration...". The European Court of Justice in *Irish Beef* concluded that the arrangements in question, premised on exclusionary payments, were a restriction by object. Advocate General Trstenjak characterised the arrangement as "the 'buying off' of competition". This is close to how one of the settlements had been described internally, as well as by a third party, as the generic company "taking the money in exchange for being bought out" by *Servier*." (paras. 1139-1140)

agreement can still be exempted under Article 101(3) TFEU if the parties are able to rebut the illegality presumption and demonstrate that the efficiencies counterbalance the adverse impact on competition.

The European Commission's on pay-for-delay agreements have been taken one year apart, in 2013 and 2014, and concern brand-name drugs manufactured by Lundbeck and Servier. In *Lundbeck*, the Commission found that the agreements restricted competition by object and infringed Article 101 TFEU. In *Servier*, the Commission's analysis went further and found that the agreements restricted competition both by object and by effect and Servier's conduct violated both Article 101 and 102 TFEU.

### 17.2.1. Lundbeck (EU)

The 2013 Lundbeck decision is the first intervention by the European Commission on pay for delay agreements. The case concerned agreements between an originator (Lundbeck) and four generic manufacturers, involving a value transfer from the former to the latter. These agreements were not patent settlements as the most relevant patents on the brand-name drug (the antidepressant Citalopram) had already expired and the agreements were not concluded to resolve a patent dispute.<sup>591</sup> However, since several secondary process patents, e.g., on the means of delivery, were still in place, the Commission took the view that the agreements were “concluded in the context of at least a potential patent dispute”.<sup>592</sup>

In 2002, Lundbeck's best-selling drug Citalopram was near the end of its lifecycle. The product and process patents had been granted between 1977 and 1985 and were thus due to expire between the late nineties and the beginning of the year 2000. As the Commission's decision reports, “[b]etween 1997 and 1999, with the expiry of patent protection for the citalopram compound in many European countries looming, Lundbeck launched an avalanche of patent applications for all processes for manufacturing citalopram Lundbeck was able to identify.”<sup>593</sup> Lundbeck thus created a cluster of process patents at the time of the agreements to further delay generic entry and create a window of opportunity to switch patients to its second generation product Escitalopram.<sup>594</sup> However, due to the expiration of the main patents covering the original compound and some manufacturing processes, not all possible production methods were covered and generic manufacturers could enter the market with their drugs. Indeed, one of them started selling a generic version of Citalopram while others were preparing to launch theirs.

To avoid competition from generics, Lundbeck concluded pay-for-delay agreements with four generic manufacturers (Alpharma, Merck, Arrow and Ranbaxy) – Lundbeck would pay generic manufacturers tens of millions of euros (substantially the equivalent of what they

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<sup>591</sup> “The agreements in question did not resolve any patent dispute; they rather postponed the issues raised by potential generic market entry. It was also established that the agreements contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement. Finally, the agreements concerned obtained results for Lundbeck that Lundbeck could not have achieved by enforcing its process patents before the national courts. Each of the agreements in question prevented the generic company concerned from selling generic citalopram, irrespective of whether such citalopram would be produced in infringement of Lundbeck's process patents.” (European Commission, AT.39226, Lundbeck, 19 June 2013, par. 6)

<sup>592</sup> European Commission, AT.39226, Lundbeck, 19 June 2013, par. 4.

<sup>593</sup> European Commission, AT.39226, Lundbeck, 19 June 2013, par. 144.

<sup>594</sup> European Commission, AT.39226, Lundbeck, 19 June 2013, par. 133.

would have earned if they had entered the market) and the generic manufacturers would keep their generic version of Citalopram out of the market for the duration of the agreements. Lundbeck paid significant lump sums, purchased existing stocks of generics with the sole purpose of destroying them, and offered guaranteed profits via distribution agreements. What was peculiar about this case is that the agreement to delay generic entry was used by Lundbeck not only to keep Citalopram prices up,<sup>595</sup> but also to adopt a concurrent product switching strategy. While the agreements were in force, Lundbeck's strategy was to migrate patients to its second-generation patented drug, Escitalopram, whose success would have left no market for generic manufacturers to sell their generic product when they were finally able to enter.<sup>596</sup>

Based on the above, the Commission concluded that the pay-for-delay agreements between Lundbeck and the four generic manufacturers, violated Article 101 TFEU, and imposed fines amounting to €93.8 million on Lundbeck and €52.2 million in total on the generic manufacturers. In its decision, the Commission referred to the economic and legal context leading to each agreement, their content and objectives, and each party's subjective intention in concluding the agreement (to verify it matched the assessment based on objective elements). The anticompetitiveness of each agreement was based on the following findings: (i) Lundbeck and the four generic manufacturers were potential competitors; (ii) Lundbeck paid the generic manufacturers millions of euros, in different forms, to induce them not to independently pursue their efforts to enter the market; (iii) as a result, and for the duration of the agreement, the generic manufacturers' ability and incentives to compete were limited. In its press release, the European Commission expressly stated:

*“Paying competitors to stay out of the market at the expense of European citizens has nothing to do with the legitimate protection of intellectual property: it is an illegal practice and the Commission will fight against it.”*<sup>597</sup>

Lundbeck and the generic manufacturers have presented appeals to the General Court, which were recently rejected. Particularly, on 8 September 2016 the General Court upheld the European Commission's decision in its entirety, confirming the finding that

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<sup>595</sup> Patients were thus deprived of access to cheaper versions of Citalopram and public health systems had to bear the cost of the brand-name drug, one of the most widely prescribed antidepressants, for a much longer period than it would have been otherwise the case. The harm has been significant considering that, after generic entry in the UK, prices of generic citalopram “dropped 31% in just three months’ time. After seven months, prices of generic citalopram had dropped 69% and after 13 months they had dropped 90%.” (European Commission, AT.39226, Lundbeck, 19 June 2013, par. 726)

<sup>596</sup> In an internal document, Lundbeck described its strategy in the following way: “*It is like a poker game[.] We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards[.] But we have a large pile of \$\$\$ at our side[.] We call it – “the art of playing a losing hand slowly”[.] Our strategy[.] Our objective : To create a window of opportunity for the CipraleX switch[.] Focus on EU and particularly the northern European markets – the generic markets[.] Three main tactics: – Influencing the authorities[.] – Patent defence, mainly process patents[.] – Deal making”.* Lundbeck defined “window of opportunity” as “time difference from CipraleX launch to generic entry [on citalopram].” The same “Generic citalopram update 22 11 2002” also stated: “Value of delayed generic entry[.] Besides the value of “sales not lost to generics”[.] Additional value from impact on – CipraleX price[.] – CipraleX penetration![.] – Staff morale.” (European Commission, AT.39226, Lundbeck, 19 June 2013, paras. 131-132)

<sup>597</sup> J. Almunia, Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines, 19 June 2013, available at [http://europa.eu/rapid/press-release\\_SPEECH-13-553\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-13-553_en.htm), accessed on 6 August 2016.

Lundbeck's pay for delay settlement agreements are restrictions by object.<sup>598</sup>

### 17.2.2. Servier (EU)

The second European case analyzed by this chapter involved the originator Servier. This case has been discussed more than once in the chapters above, in relation to patent clusters and product hopping, and will be examined once more from the perspective of the pay-for-delay agreement concluded by Servier with a number of generic manufacturers.

As in *Lundbeck*, Servier's patent on the perindopril molecule had expired but several secondary patents were still in force, protecting the manufacturing processes and different forms of the drug. This protection was limited and generic manufacturers were thus preparing to enter the market. The technologies for the production of perindopril not covered by Servier's patents were however limited and Servier acquired the most advanced one, blocking several generic projects and delaying their market entry. Each time a generic company was about to enter the market (*e.g.*, it applied for a marketing authorization), Servier sent warning letters making reference to its patent cluster and started litigation to obtain injunctions. At the same time, generic producers challenged Servier's secondary patents.<sup>599</sup> It is in this context that Servier concluded five reverse payment settlement agreements with generic manufacturers, namely Niche/Unichem, Matrix, Teva, Krka and Lupin. The agreements imposed contractual limitations on the generic companies with regards to challenging Servier's patents and entering the market (typically in the form of non-challenge and non-compete obligations), and in exchange provided for a "reverse payment" from Servier in the form of actual monetary transfers or other inducements. The settlement with Krka and Lupin included also the transfer of certain of their patents to Servier. In total, Servier's payments to the generic companies exceeded €120 million.

The Commission's findings were that each of the five reverse payment patent settlements that Servier concluded with its generic competitors violated Article 101 TFEU.

First, the Commission applied the analytical framework applied in *Lundbeck* and concluded that the agreements restricted competition by object. In particular, (i) Servier and the generic manufacturers were at least potential competitors, (ii) the agreements involved a value transfer from Servier to the generic manufacturers as an inducement to reduce their ability and incentive to compete (the sum paid was based on the generic companies' expected profit in case of market entry),<sup>600</sup> and (iii) generic companies committed to delay their entry

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<sup>598</sup> General Court, T-472/13, *Lundbeck v Commission*, 8 September 2016.

<sup>599</sup> "During the period concerned, Servier sent warning letters to practically all generic challengers and entered into litigation in certain Member States with a number of generic companies that were preparing to launch generic versions of perindopril. In addition, Servier defended itself against several generic companies that had initiated opposition procedures before the EPO. The main subject matter of the litigation as well as the opposition procedure was the '947 patent. Litigation with Niche and Krka also related to Servier's process patents, '339, '340 and '341." (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 152)

<sup>600</sup> "Niche noted on the transfer: "Settlement was equivalent to over 10 year planned sales and 20 years planned gross profit"." (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 7) As the Commission explained: "Servier had considerable financial resources at its disposal because of the profits it had made as a result of the sales of perindopril. Servier used a portion of these rents to induce its competitors to enter into the successive reverse payment patent settlement agreements." (European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2929)

for the duration of the agreements.<sup>601</sup> In addition, the agreements did not restrict Servier's ability to sue the generic manufacturers for patent infringement (once they were able to enter the market) and the obligations imposed on some generic manufacturers were more restrictive than what Servier could have obtained successfully enforcing its patents.

Second, the European Commission went further than in *Lundbeck* and, although it deemed “unnecessary to analyse whether the effects of the said agreements were also restrictive of competition, [...] for the sake of completeness, the Commission [analyzed also] the likely restrictive effects of the agreements on competition.”<sup>602</sup> The Commission concluded that each of the agreements “appreciably restrict[ed] potential competition among Servier and generic companies and barred “real concrete possibilities” [...] to compete among themselves or “for a new competitor to penetrate the relevant market and compete with the undertakings already established”. [Furthermore, the] *Settlement Agreement* appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time, thereby avoiding the significant reduction of prices that would have ensued from timely and effective generic entry.”<sup>603</sup>

It is interesting to note that the Commission, not only rejected the parties' claimed efficiencies, as they did not (i) substantiate the alleged savings from avoided litigation, nor (ii) demonstrate the restrictions were indispensable to obtain them (and cash payment exceeded litigation costs), but it also noted that the parties should have demonstrated that “such cost reductions produce any pro-competitive effect on the market instead of just increasing the companies' profits?”. In particular, “litigation forms a key part of competition between originator and generic companies. Avoided litigation costs are basically savings achieved due to a reduction of output into (litigation) activity needed to possibly successfully challenge the patent and thus enable a viable generic entry into the market. The parties failed to show how such savings would lead to pro-competitive effects on the market.”<sup>604</sup> The Commission thus rejected the automatic procompetitiveness of savings on litigation costs, envisioning the possibility that even simply ending the litigation might have negative effects on competition.

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<sup>601</sup> “Servier used its financial resources to “pay off” the generic companies in question so they would not challenge Servier's patents and would not enter the market and therefore compete. [Servier paid] an amount which was equivalent to [...] years of profit expected by the generic compan[ies]. In exchange [the generic companies] needed to commit not to challenge Servier's patents concerning perindopril [...] and to restrict their ability to compete. [...] The generic companies cashed the expected profit without running the risk of competition. This clearly changed their incentives to enter the market. The amounts paid were self-financing since they enabled Servier to keep its rents for a longer time period.” (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, paras. 2937-2938)

<sup>602</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1213. “This new approach is not entirely surprising considering that one of the main criticisms made against the *Lundbeck* decision was that the “by object” restriction approach pursued by the Commission was inappropriate considering the complex nature of reverse-payment patent settlements. Unlike price-fixing cartels – whose negative effects on competition are clear and cannot be redeemed by efficiencies – the effects of reverse-payment patent settlements, which can vary a lot in scope and nature, are unlikely to be so clear cut and thus should be proven. In addition, in its *Cartes Bancaires* judgment adopted in September 2014, the Court of Justice of the EU ruled that the concept of restriction of competition “by object” (the equivalent of *per se* illegality under Article 101 TFEU) must be interpreted “restrictively” and “can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects, otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which are in no way established to be, by their very nature, harmful to the proper functioning of normal competition.” Thus, by showing the effects of reverse-payment patent settlements the Commission placed itself on safer grounds.” (D. Geradin, D. Ginsburg, G. Safty, *Reverse Payment Patent Settlements in the European Union and the United States*, George Mason University Legal Studies Research Paper Series LS 15-22, 2015, p. 23)

<sup>603</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 1659.

<sup>604</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2075.

The Commission ultimately imposed fines totaling €427.7 million on Servier, for its strategy aimed at excluding competitors and delaying generic entry, and on Servier and the five generic manufacturers for concluding a series of anticompetitive pay for delay settlement agreements.

Peculiar to this decision is the analysis on whether concluding reverse payment patent settlements can be considered a unilateral conduct in violation of Article 102 TFEU.<sup>605</sup> In particular, the Commission examined whether the five agreements concluded by Servier “constituted behaviour falling outside the scope of competition on the merits and was capable of contributing to the foreclosure effects of Servier’s single and continuous exclusionary strategy, that is to say rendering generic entry more difficult and/or delayed.”<sup>606</sup> Referring to *Continental Can*<sup>607</sup> and *TeliaSonera*,<sup>608</sup> the Commission pointed out that an “[a]buse may occur if any undertaking in a dominant position strengthens such a position in such a way that the degree of dominance reached substantially fetters competition [...] regardless of the means and procedure by which it is achieved.”<sup>609</sup> It then referred to *Hoffman-La Roche* to specify that the fact that the other parties to the agreement were powerful undertakings did not preclude the existence of an abuse. An undertaking may abuse its dominant position if it interferes with the structure of competition in a market in which the degree of competition has already been weakened by the very presence of the dominant undertaking.<sup>610</sup>

The unilateral behavior contested to Servier as part of its exclusionary strategy is the use of its market power to induce generic manufacturers to withdraw from competition, by offering to pay them a significant sum of money, or provide other commercial advantages.<sup>611</sup> The Commission concluded that “[t]he five agreements formed part of a continuous course of conduct by Servier whereby it used its market power in order to hinder effective competition on the market for perindopril. This behaviour by a dominant company falls outside the scope of competition on the merits.”<sup>612</sup> The reasons why Servier’s conduct cannot be qualified as competition on the merits are clearly articulated by the Commission. “*Servier’s strategy deviated from its special responsibility as a dominant company “not to allow its conduct to impair genuine undistorted competition on the common market” and constituted “recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators”. Servier did not exclude the operators representing a close competitive threat on the technology market or the final product market by outperforming them with the*

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<sup>605</sup> The European Commission refers to several cases in which the Court of Justice and General Court concluded that both Article 101 and 102 TFEU were applicable concurrently, provided that there is an additional and distinct unilateral aspect (Court of Justice, C-85/76, *Hoffman-La Roche*, 13 February 1979, par. 116; C-66/86, *Ahmed Saeed Flugreisen*, 11 April 1989, par. 37; T-83/91, *Tetra Pak*, T-83/91, 6 October 1994, paras. 21, 25 and 30; C-395/96 P, *Compagnie maritime belge transports*, 16 March 2000, par. 33. The parallel application of Articles 101 and 102 TFEU is foreseen also by the Commission’s Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements of 17 January 2011, par. 16.

<sup>606</sup> European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2920.

<sup>607</sup> Court of Justice, C-6/72, *Europemballage Corporation and Continental Can Company v Commission*, 21 February 1973.

<sup>608</sup> Court of Justice, C-52/09, *TeliaSonera Sverige*, 17 February 2011, paras. 26-27.

<sup>609</sup> European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2921.

<sup>610</sup> Court of Justice, C-85/76, *Hoffman-La Roche v Commission*, 13 February 1979, par. 120.

<sup>611</sup> European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2927.

<sup>612</sup> European Commission, AT.39612, *Perindopril (Servier)*, 9 July 2014, par. 2920. See also par. 2960.

*strength of its patent portfolio, quality of its products, or superior manufacturing efficiency, but by a series of direct transactions with these operators to effectively buy them out of the market by purchasing their technology or by providing inducements for them to accept restrictions of competition. Servier's conduct was capable of leading to "the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition".*"<sup>613</sup>

On the basis of this analysis, it is difficult to imagine a situation in which a pay-for-delay patent settlements violating Article 101 TFEU is not violating Article 102 TFEU as well (provided the originator is in a dominant position).<sup>614</sup> If the pay-for-delay violates Article 101 TFEU, it would be quite odd to qualify it as "competition on the merits". While it can be often expected to be part of a "single and continuous exclusionary strategy", as the creation of a patent cluster is a sensible antecedent and product hopping is a profit-maximizing subsequent, even by itself this conduct could be considered abusive.<sup>615</sup>

The question that is left to answer is, while in case of reverse payment settlements there is no 101 without 102, can there be 102 without 101? There could be situations in which the agreement is the outcome of pressure brought to bear by the originator on the generic manufacturer. Indeed, the context in which these agreements are concluded is most certainly not one in which the parties are free from pressure. While under certain circumstances it is the originator to be under pressure, due to the weakness of its patent and the concrete threat of generic entry, in other cases it is the generic manufacturer to enter into the agreement because the pressure exercised by the originator forced it. This may be the

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<sup>613</sup> European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2996.

<sup>614</sup> As for the dominant position, however, as explained above there cannot be a reverse payment patent settlement without the originator having significant market power. The Commission itself pointed out that, "[i]f the market for [the brand-name drug] was contested by generic entry or another significant competitive constraint, [the originator]'s ability to provide such significant inducements would have been undermined. In addition, in a competitive market, [the originator] would, as a reasonable economic operator, not have the incentive to hand out such inducements, as the restrictions imposed on a single generic company would be offset by remaining competition." (European Commission, AT.39612, Perindopril (Servier), 9 July 2014, par. 2938) See also par. 2933 ("Servier had a strategy of using all possible means to protect Coverisyl from the threat of generic entry, which included using part of the substantial profits that it was reaping from its sales of perindopril to fend off generic challengers. As the holder of the key patents protecting perindopril, only Servier could devise a strategy of different settlement agreements with the different generic challengers. Thus Servier was the counterparty in each of the agreements and could, through this situation, use its market power to induce generic companies to enter into reverse payment patent settlement agreements by paying in total more than EUR [80 - 95]\* million to the generic companies to keep them off the market. The chain of agreements was likely to have a cumulative and self-reinforcing effect, which was stronger than that of each agreement taken individually and sought to maximise the potential of perpetuating Servier's monopoly on the perindopril market.")

<sup>615</sup> Of the same opinion is S. Gallasch, A new dimension to EU pharma antitrust product hopping and unilateral pay for delay, 12 (1) European Competition Journal, 2016, p. 157 ("pay for delay settlements could be used as a means to an end for the brand company to succeed with a broader unilateral strategy, which would justify an investigation under Art. 102 TFEU. A pay for delay settlement could turn the general legitimate attempt of the brand company to switch consumers to a new follow-on drug into an anticompetitive conduct." At pp. 143-144, the author insightfully notes that: "Scrutinizing such unilateral conduct under Art. 102 TFEU would also have a further strategic advantage. In an investigation against a brand company regarding the alleged abuse of its dominant position, the European Commission is more likely to receive cooperation from the generic company that entered into the pay for delay settlement, as only the brand company is subject of the investigation. In fact, the European Commission could initiate proceedings under Art. 101 TFEU as well as under Art. 102 TFEU and could use its discretion to drop the Art. 101 TFEU proceedings against the generic company in return for their cooperation. This is also not likely to be an undue prioritization of the enforcement, as the investigated conduct is based on a unilateral strategy that has been facilitated by the agreement between the brand company and the generic company.")

case when the originator is much more economically powerful than the generic manufacturer and undertakes (or threatens to undertake) an exclusionary strategy including the creation of a patent cluster and vexatious litigation.<sup>616</sup> If this is the case, the generic manufacturer has two alternatives, either it accepts the (economically advantageous) offer to be bought off by the originator, or it starts an endless and economically extenuating fight only to get, in the best case scenario, the exact same (or worse) result than accepting the offer. Even in the best case scenario, a judge may award legal fees and damages to the originator as the generic manufacturer did not settle the litigation when offered to and brought it forward only to get the exact same (or worse) result in the end. Under procedural rules, this may qualify as harassment of the other party (*i.e.* vexatious litigation) and a waste of the court's time and resources, leading to the generic manufacturer's responsibility.

Generic manufacturers are profit-oriented companies, competing on price. They have neither aim nor prospect of inventing a disruptive new product that grants them monopoly profits, and can predict their likely revenues from market entry. If rational, they will thus accept the originator's offer both if induced<sup>617</sup> as well as forced. The difference between the two is however that in the second case it would be much more difficult to demonstrate the necessary meeting of the minds and the fact that the generic manufacturer had a concrete possibility to take an unfettered decision as to its market entry and conclusion of the settlement agreement.

## 18. Conclusion

The analysis of patent-related abusive conducts in the pharmaceutical industry confirmed that conducts sanctioned under antitrust law and conducts contrary to the purpose of patent law tend to coincide. Patent-related abuse of dominance is nothing more than a specification of the broader category of abuse of (patent) rights. When patents are involved, and directly relevant for the conduct, also concerted actions may fall within the definition of abuse of patent rights. As seen, the European Commission itself found that patent settlements may form part of a unilateral conduct falling outside the scope of competition on the merits and, as did the U.S. Supreme Court, excluded that paying generics to stay out of the market falls within the specific subject matter of the patent. This also means that, if the anticompetitive settlement is reached mainly thanks to the undue leverage of the market power conferred by the patent, an abuse of the patent right (often in the form of sham litigation) can be found.

If, as this work contends and doctrine and case law upheld, antitrust and patent law have the same ultimate purpose, why would we need both patent law and antitrust to address the same conduct, and what is their respective role? As said, antitrust and patent law are interdependent and complement each other. Both are needed to maximize consumer welfare as they focus on different aspects and use different means to reach their common purpose.

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<sup>616</sup> And here we can go back to the insightful parallelism discussed in the chapter dedicated to patent clusters that Professor Merger proposed with blackmail (see R.P. Merges, *The Trouble with Trolls Innovation Rent-Seeking and Patent Law*, 24(4) *Berkeley Technology Law Journal*, 2009, pp. 1600-1601).

<sup>617</sup> See General Court, T-472/13, *Lundbeck v Commission*, 8 September 2016, par. 391 (“*the reverse payments had induced the generic undertakings to accept the limitations on their autonomy laid down in the agreements at issue*”).

The limitations to unrestricted static competition coming from patent law incentivize innovation and dynamic competition. Innovation is an objective of antitrust as well, but patent law is undeniably better placed to achieve it. In the same way that lack of protection for new inventions is unlikely to lead firms to invest in research that could be easily copied, excessively pervasive patents and misconducts by patentees can stifle innovation (as well as price competition).

The two disciplines thus work together to strengthen and balance each other out, in the pursuit of the same overarching goal: “*maximize wealth by producing what consumers want at the lowest cost*”<sup>618</sup> and “*encourage[e] innovation, industry and competition*”.<sup>619</sup> Each controls the excess of the other and punishes its abuse. It is thanks to their teamwork that they can keep up with the constantly evolving industries and worldwide markets, as well as consumers’ needs and undertakings’ misconducts, with no need for the legislator to intervene.<sup>620</sup>

It is not only their focus (on price and innovation respectively, while not neglecting the other) that justifies the need for both to maximize consumer welfare, it is also their divergence in means. The patent system is not designed to truly punish, even less to deter, the abuse of patent rights. Antitrust fines, on the other hand, are calculated and imposed with the specific aim to punish and deter abusive conducts. Patent law focuses on relations between individuals and is designed to remedy wrongs committed against (or by, in the case of abuse) patent owners vis-à-vis alleged patent infringers. From this it follows that, while patent law is pursuing and protecting the public interest, its enforcement (also in the negative, when the patent right is abused or misused) is aimed at righting private wrongs. There is no public authority (as the FTC or the European Commission) that intervenes on its own motion once the patents have been granted, to ensure they are exercised (and protected) in compliance with the public interest. The abuse of patents may thus go unpunished and even when it does not (because consumers or other innovators invoke the abuse of patent rights or patent misuse doctrines), the solution provided by the patent system is often limited to the case at stake or inadequate to deter future misconducts by the same or other patentees. The means provided by the patent system alone are thus ineffective and insufficient to address all the patent-related conducts that may have a negative impact on consumer welfare.<sup>621</sup> To

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<sup>618</sup> W.S. Bowman, *Patent and Antitrust Law: A Legal and Economic Appraisal*, University of Chicago Press, 1973.

<sup>619</sup> *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d, Fed. Cir., 1990, p. 1576.

<sup>620</sup> “[I]ntellectual property laws and antitrust laws share the same fundamental goals of enhancing consumer welfare and promoting innovation. [...] Intellectual property and antitrust laws work in tandem to bring new and better technologies, products, and services to consumers at lower prices. Intellectual property laws create exclusive rights that provide incentives for innovation by “establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression.” [...] Antitrust laws, in turn, ensure that new proprietary technologies, products, and services are bought, sold, traded, and licensed in a competitive environment.” (U.S. Department of Justice and Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition*, April 2007, pp. 1-2) See also U.S. Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, 6 April 1995, par. 1.

<sup>621</sup> Both the abuse of rights and the abuse of dominance usually intervene once the patent has been granted. At this stage antitrust is undoubtedly more effective in punishing the patentee and deterring future abuses. Patent law has however a much bigger role to play at the stage of patent application. Indeed, a strict interpretation of the non-obviousness/inventiveness criteria would go a long way in preventing the issuance and validation of questionable patent, whose proliferation is one of the elements on which the abusive conducts are premised.

maximize innovation (as well as competition), the legal system needs to respond to abusive conducts by patentees that stifle innovation. In this sense, while the doctrines of abuse of rights and patent misuse may be sufficient (and most of the times even more effective than antitrust) to stop the misconduct (by making the patent unenforceable), antitrust intervention (which is not coextensive as it requires a *quid pluris*) is sometimes necessary to correct the deficiencies of these doctrines in terms of disgorging ill-gotten gains, deter future abuses and compensate the victim(s).<sup>622-623</sup>

Antitrust intervention strengthens the means provided for by patent law. Though requiring a showing of market power and anticompetitive effects (and often of anticompetitive intent, at least to confirm the objective evidence of abuse), antitrust remedies help the patents system to achieve its purpose (common to antitrust).<sup>624</sup> An interesting analogy to better understand the relative role of the two disciplines has been proposed by the U.S. Federal Circuit. The court likened the inequitable conduct doctrine (but the same can be said about the abuse of patent rights or patent misuse) to a shield, and antitrust to a sword. As explained by Professor Leslie, while the court “*seemed to think that applying these labels showed, ipso facto, that antitrust remedies were unnecessary [...] the court misconstrued the significance of its own analogy. A shield can stop an attack, but it cannot disgorge ill-gotten gains, deter future attacks, or compensate the victims of earlier attacks. Only a sword—an offensive weapon—can achieve these additional goals. In employing its analogy, the Federal Circuit failed to recognize that shields and swords are complements, not substitutes. Every well-prepared knight has both. So it is with innovation policy: patent*

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<sup>622</sup> “In most instances, patent law stops misconduct more easily than an antitrust approach can, because an antitrust claim requires the plaintiff to prove the components of the patent defenses as well as the elements of the antitrust cause of action, such as monopoly power for section 2 monopolization claims or specific intent to monopolize for attempted monopolization claims. The patent system, however, does not succeed in achieving the remaining three goals. It is not designed to disgorge, deter, and compensate.” (C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1286). See also H.J. Hovenkamp, *Antitrust and the Patent System. A Reexamination*, 76(3) *Ohio State Law Journal*, 2015, p. 548.

<sup>623</sup> When the patentee is not in a dominant position, however, patent misuse (and abuse of patent rights) is the only remedy available to impede the distorted use of patent rights to the detriment of competition and innovation. This doctrine does not require a demonstration of market power but simply refers to the responsibility of each patentee “*not to distort, to the detriment of third parties (i.e., to the detriment of freedom of competition) rights granted in the abstract, trying to obtain them in ways and/or for purposes other than those for which the law conferred them.*” (G. Ghidini, G. Cavani, P.F. Pisera’, *Italy – Abuse of Patent Rights and Abuse of Dominant Position: The Pfizer Case*, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, pp. 268-269). The authors continue: “[i]n our opinion, therefore, patent misuse can be enforced even in cases where it is not possible to establish a market power, that is, a ‘dominant position’ in the strict sense, so as to warrant the need for antitrust intervention.” The same authors refer also to the possibility to address these conducts under the rules of unfair competition: “*when the illegally obtained exclusive right is exercised to restrict the freedom of competition of one or more individual competitors’ the conduct of the owner may qualify as an act contrary to ‘honest business practices’, hence of unfair competition (Article 10bis of Paris Union Convention, PUC), and ensuing national legislations.*” While antitrust is more concerned about risks for competition and consumer welfare as such, trying to preserve an actually pluralistic market structure and the existence of alternative choices for consumers, unfair competition focus on the individual competitors and the conflicts between them.

<sup>624</sup> “The inadequacy of [patent law] remedies leads one to expect that the amount of deadweight loss caused by improper enforcement actions is significant, particularly where the probability of detection is low. This is the reason that antitrust law has a damages multiplier—designed to offset the fact that violations are difficult to detect and prove.” (Herbert Hovenkamp *Antitrust and the Patent System A Reexamination*, p. 550)

*and antitrust provide complementary responses to patent misconduct that threatens innovation. Those who take on perpetrators of patent misconduct need both the shield (patent law) and the sword (antitrust law).”*<sup>625</sup>

The two disciplines should thus work together, which means that both judges and antitrust agencies should always keep in mind both disciplines when deciding or bringing a case.<sup>626</sup> As the U.S. Supreme Court explained in *Actavis*, “*patent and antitrust policies are both relevant in determining the “scope of the patent monopoly” – and consequently antitrust law immunity – that is conferred by a patent.*”

Including both a patent and antitrust approach in deciding a case involving patent-related conducts increases the effectiveness of the response.<sup>627</sup> Patent law and antitrust law are not enemies but partners in the maximization of consumer welfare.<sup>628</sup> “*Antitrust and patent should be working together against their common enemies: invalidity, fraud, and tying.*”<sup>629</sup>

In conclusion, one cannot but hope for a rethinking of the intersection between patent and antitrust laws by some courts and practitioners, in line with the case law and doctrine mentioned in this work, to do justice to the profoundly connected and interdependent nature of these two disciplines. On one hand, the reach of antitrust should be limited by the need to achieve the purpose of patent law. Therefore, a conduct falling within the purpose (not the scope) for which the patent was granted could not be considered in breach of antitrust. On the other hand, a conduct contrary to the purpose of patent law cannot be considered competition on the merits and will be caught by patent law (as an abuse of rights) as well as antitrust (when the patentee is dominant and the conduct is anticompetitive). This joint intervention and reciprocal limitation is of particular importance in the pharmaceutical sector, where the need for incentives to innovate (due to significant R&D costs and ease of copying) and the risk of consumer harm (given the direct impact of abusive conducts on the fundamental right to health), are at the highest levels.

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<sup>625</sup> C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1286.

<sup>626</sup> “*Judges, however, sometimes go one step too far by conflating patents and innovation as if they are one and the same, instead of appreciating that patents are but one aspect of innovation policy. Judges should recognize that their goal should be to maximize innovation, not just patent rights, and that innovation cannot be maximized without taking antitrust principles into account. A strong antitrust system is an important component of a larger innovation policy because it provides a check on those forms of patent misconduct that also injure competition. Much of the conduct that antitrust law condemns in the context of patents – such as fraud and tying – is conduct that patent law itself often seeks to stop.*” (C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1288)

<sup>627</sup> “*In sum, to the extent that invalid and improperly procured patents stifle innovation, the exclusive use of patent law to address applicant misconduct constitutes inefficient innovation policy. Supplementing patent law with antitrust remedies provides a more effective legal response to the problem of invalid patents.*” (C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1283)

<sup>628</sup> “[C]ompetition law enforcement should not be perceived as a threat to IPR: intervention is limited to those specific cases in which pathological IPR-driven LCM strategies hamper the otherwise healthy relationship that exists between innovation and competition.” (G. Pitruzzella, *Life-Cycle Management Strategies in the Pharmaceutical Patent Sector*, in G. Muscolo, G. Pitruzzella, (eds.) *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, Kluwer, 2016, p. 84)

<sup>629</sup> C. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34(4) *The Journal of Corporation Law*, 2009, p. 1286.

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