

# The Role of Article 102 in European Pharmaceutical Sector

**Hazal Basarik\***

*Article 102 enforcement in pharmaceutical sector, in which competition law interferes with intellectual property rights, is one of the most complex competition analysis. Complications of the sector, namely its importance for public health, dependency on costly R&D and to be subject to divergent regulations around the EU, are considered to clarify more Article 102 enforcement in the sector. In regard to influence of the sector on public health and vague boundaries between IP law and Competition Law, more circumspect enforcement is suggested. In addition, this article argues that non-harmonised regulation scheme of the sector is one of the main hurdles of Article 102 enforcement. Therefore, harmonisation in the sector regulations as well as IP laws of the EU is advised. Moreover, based on the fact that there is a lack of substantial case law about Article 102 enforcement in the sector, there is a need for more clarified case law and explanatory guidelines. In this respect, prospected forms of abuses in the sector are analysed in this research.*

## **I. INTRODUCTION**

Pharmaceutical sector is one of the most strategic sectors of European economy due to its impact on public health, economic growth, trade and science. According to the European Commission ('Commission'), the pharmaceutical sector produced € 220 billion amount of output to the economy in the European Union ('EU') in 2012.<sup>1</sup> Approximately eight per cent of EU's Gross domestic

---

\* I graduated from double major on Law and Economics in Koc University, Turkey. After that I completed my LL.M. on Law and Economics in Queen Mary University of London. I am also a qualified lawyer in Turkey.

<sup>1</sup> Commission, 'Pharmaceutical Industry: A Strategic Sector for the European Economy' (Staff Working Document) COM (2014) 216 final/2.

product ('GDP') is dedicated to healthcare expenditure; this number is also subject to growth.<sup>2</sup> Moreover, pursuant to IMS Health Report<sup>3</sup>, the EU is one of the major traders in global pharmaceutical sector. Particularly France, Germany, Italy, Spain and the UK, shared fifteen per cent of global pharmaceutical spending in 2012. Even though the Commission's report states that this proportion is expected to decrease to thirteen per cent due to austerity measures, it is still substantial compared to the rest of the world. Therefore, not only the pharmaceutical sector itself is essential for the EU economy, but also the EU economy itself has an influential importance for global pharmaceutical sector.

In light of the pharmaceutical sector's significance for the EU economy, relevant authorities have endeavoured to achieve effective competition in the sector in order to encourage reforms and to promote innovation. Indeed, four per cent of the EU antitrust decisions are related to this sector.<sup>45</sup> The Commission had issued some decisions related to '*parallel trade*' in this sector.<sup>6</sup> Contrary to substantial case law related to parallel trade, Article 102 of the Treaty of Functioning of the European Union ('TFEU') enforcement in the sector has started to be developed after the Commission's decision on *Astra Zeneca*<sup>7</sup>. In that case, possession of intellectual property rights ('IPR') is recognized as an influential factor of dominance determination. According to the Opinion of Advocate General Mazak in *Astra Zeneca*<sup>8</sup>, IPR possession does not necessarily lead to dominant position for a company; however that possession may be backbone factor in determining dominance. In this regard, the Commission's sector inquiry and the relative Final Report<sup>9</sup> on the EU pharmaceutical market is also notable. This inquiry has been launched in January 15, 2008 to investigate the obstacles to market entry in pharmaceutical sector caused by originator companies. Accordingly, the Final Report

---

<sup>2</sup> Eurostat Health Database, Healthcare expenditure by all financing agents. Based on the average of 22 Member States in 2008.

<sup>3</sup> IMS Institute for Healthcare Informatics, The Global Use of Medicines: Outlook through 2017 (2013) <[www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global\\_Use\\_of\\_Meds\\_Outlook\\_2017/IIHI\\_Global\\_Use\\_of\\_Meds\\_Report\\_2013.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global_Use_of_Meds_Outlook_2017/IIHI_Global_Use_of_Meds_Report_2013.pdf)> accessed 5 August 2015.

<sup>4</sup> Commission, Ten Years of Antitrust Enforcement under Regulation 1/2003: Achievements and Future Perspective, (Staff Working Document) COM (2014) 230 final.

<sup>5</sup> Pharmaceutical sector composes of pharmaceuticals, medical devices, other health products and health care services in regard to this article.

<sup>6</sup> Joined Cases C-2/01 P and C-3/01 P *BAI and Commission v Bayer* [2004] ECR I-00023.

<sup>7</sup> *AstraZeneca* (Case COMP/A 37.507/F3) Commission Decision (2006/857/EC) [2005] OJ L 332/24.

<sup>8</sup> C-457/10 *AstraZeneca v Commission* [2012] ECR I-00000, Opinion of AG Mazák, para 131.

<sup>9</sup> Commission, 'Pharmaceutical Sector Inquiry Final Report' (2009).

(‘FRSI’) mainly focused on company behaviours which delay or prevent new market entries and the impacts of regulatory framework on such delays. In the FRSI, the Commission highlighted that IPRs play a vital role for pharmaceutical sector. However, it is noted that some originator companies may take an advantage of their IPRs by using them strategically to foreclose their competitors from the market or to delay them to enter into the market. In light of the FRSI, regulatory reforms have been made in both communal and national levels. Regulation 536/2014, which aimed to achieve a uniformed framework for authorisation of clinical trials and asked for a more transparent disclosure mechanism for the clinical trial data,<sup>10</sup> is only one of these regulatory reforms.<sup>11</sup>

The case law is also developed as regards abuse of dominance in the pharmaceutical sector. In this sense, *Astra Zeneca* constitutes the first, but not the last case. Recently, another Commission decision is released about *Servier*<sup>12</sup> condemning that Servier has abused its dominant position which is generated mostly based on its IPR possession. There are also plenty of “abuse of dominance” decisions in pharmaceutical sector by the national authorities. For an illustration, Italian Competition Authority decided in January 11, 2012 that Pfizer had infringed Article 102 with its exclusionary conducts based on the patent system and its decision is upheld by the judgement of the Council of State<sup>13</sup>. Another example is the French Competition Authority’s (‘FCA’) *Sanofi-Aventis*<sup>14</sup> decision in May 14, 2013. The FCA fined Sanofi-Aventis by stating that Sanofi-Aventis has abused its dominant position by denigrating its competitors which are operating in the same market of cardiovascular drugs. In 2013, the Office of Fair Trade (‘OFT’)<sup>15</sup> issued a complaint about *GlaxoSmithKline* (‘GSK’)<sup>16</sup> alleging that GSK had caused delay in the market due to its ‘pay-for-delay’ agreements.

---

<sup>10</sup> Timo Minssen, ‘A More Transparent System for Clinical Trials Data in Europe-Mind the Gaps!’(2014) Harvard Law <<http://blogs.law.harvard.edu/billofhealth/2014/05/01/a-more-transparent-system-for-clinical-trials-data-in-europe-mind-the-gaps/>> accessed 30 July 2015.

<sup>11</sup> Council Regulation (EC) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158/1.

<sup>12</sup> *Perindopril (Servier)* (CASE AT.39612) Commission Decision (2014) 4955 final, Provisional Version.

<sup>13</sup> Italian Council of State, No 693/2014 (2014).

<sup>14</sup> The Autorité de la Concurrence, Décision 13-d-11 (2013) available at <[http://ec.europa.eu/competition/ecn/brief/03\\_2013/fr\\_sanofi.pdf](http://ec.europa.eu/competition/ecn/brief/03_2013/fr_sanofi.pdf)> accessed 16 August 2015.

<sup>15</sup> It is transformed to Competition and Markets Authority (‘CMA’).

<sup>16</sup> Ben Hirschler, ‘OFT accuses GSK over "pay-for-delay" drug deals’, *Reuters*, (London, 19 April 2013).

All those recent developments and cases revealed a question of the role of abuse of dominance in pharmaceutical sector. This essay, thus, concerns with three main issues. Firstly, vague definition of the characteristics of pharmaceutical sector and non-harmonised regulations over the EU, makes the Article 102 enforcement complicated in the sector EU. Secondly, pharmaceutical sector is mainly based on IPRs, therefore it aggravates to draw the boundaries between competition law and IP law. Lastly, since the established enforcement of Article 102 is few and new, there is uncertainty on the forms of abuse of dominance in the sector.

Therefore, this article aims to analyse the abovementioned issues and contribute to clarification of the role of abuse of dominance in the EU pharmaceutical sector which is inherently related to law and economics. The analysis will include three main chapters. Firstly, specific features of pharmaceutical sector which affect the role of abuse of dominance will be defined. In this chapter both the features of pharmaceutical sector in general and specifically in the EU market will be examined. Secondly, boundaries between competition law and IP law will be analysed with a comparative study between the interests of consumers and companies. Following the analysis, the actual and potential forms of abuse of dominance will be questioned under the third chapter. For purpose of this article, available statistical data, relative case law and literature will be used. As a result of the research, based on the importance and complication of the sector, more intensive harmonization in the relevant laws (i.e. competition law, patent law, and pricing and reimbursement procedures) will be proposed. It is believed that such harmonization will clarify the Article 102 enforcement in the sector, thereby it will increase dynamic efficiency of the market by reducing unpredictable costs of pharmaceutical companies. In addition to that, this article will highlight that the authorities should be more transparent and circumspective while enforcing the competition laws for the sake of the interest of both consumers and customers and predictability of the system. Therefore, it is believed with this article to contribute to the EU pharmaceutical sector in general, to the relevant literature and to the jurisdictions in which the EU legislation sets a pace.

## **II. SPECIFIC FEATURES OF THE EU PHARMACEUTICAL SECTOR**

### **1. Importance for Healthcare**

Healthcare service is one of the pivotal policies of countries. Pharmaceutical sector, in this sense, is a dimension- of healthcare expenditures along with hospital care, physicians, clinical services and health insurance mechanism. Pharmaceutical sector's role is pointed out in various platforms. Pursuant to the report of the World Health Organization ('WHO'), an effective healthcare system calls for an equitable access to pharmaceutical products (i.e. drugs or vaccines).<sup>17</sup> The sector fundamentally contributes to effective healthcare system by providing essential medicines and vaccines.<sup>18</sup> Accordingly, pharmaceutical sector does not only supply medicines but also it undertakes clinical trials to develop new medicines and vaccines to save more lives of patients. The International Federation of Pharmaceutical Manufacturers and Associations' ('FPMA') report also states that an efficient healthcare system should enable accessibility of pharmaceutical products in good quality which is generally prescribed by professionals, with an effective distribution mechanism.

Frech and Miller stated that there is a significantly positive relationship between pharmaceutical expenditures and life expectancy at the ages of 40 and 60.<sup>19</sup> In addition, Lichtenberg also clarifies with his empirical study that pharmaceutical innovation increases average life time of the society.<sup>20</sup> All those experimental studies highlight the impact of pharmaceutical sector on the public health.

The mentioned fundamental role of the sector for public health leads to two conclusions. First of all, its essentiality on human health makes all issues in the relevant topic more sensitive. In other words, to achieve an effective competition in the sector and to prevent any abuses become more important. Secondly, because of its vital role for healthcare, pharmaceutical sector itself, and the pharmaceutical companies in particular become inevitable for governments. This reduces the bargaining power of governments while participating pricing and reimbursement negotiations with pharmaceutical companies.

---

<sup>17</sup> WHO, *Everybody's business: Strengthening health systems to improve health outcomes*, (2007) p3 <[www.who.int/healthsystems/strategy/everybodys\\_business.pdf](http://www.who.int/healthsystems/strategy/everybodys_business.pdf)> accessed 15 July 2015.

<sup>18</sup> IFPMA, *The Pharmaceutical Industry and Global Health: Facts and Figures* (2014) <[www.lif.se/globalassets/pdf/rapporter-externa/ifpma-facts-and-figures-2014.pdf](http://www.lif.se/globalassets/pdf/rapporter-externa/ifpma-facts-and-figures-2014.pdf)> accessed 1 July August 2015.

<sup>19</sup>H. E. Frech and Richard D. Jr. Miller, 'The Productivity of Health Care and Pharmaceuticals: An International Comparison' (1996) Research Program in Pharmaceutical Economics and Policy, UCLA.

<sup>20</sup> Frank R. Lichtenberg, 'Pharmaceutical Innovation, Mortality Reduction, and Economic Growth' (1999) 29 <<http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf>> accessed 16 July 2015.

## 2. R&D Based Nature and the Rationale of IPR

R&D investments and innovations are a kind of fixture of public health.<sup>21</sup> Particularly, pharmaceutical sector is mostly based on R&D developments. Lichtenberg's empirical study suggests that pharmaceutical innovations lengthen the life time of the society.<sup>22</sup> Available data states that global R&D investment in pharmaceutical sector in 2014 is around \$ 142 billion.<sup>23</sup> According to Tufts University's research, the average cost of developing a new drug is approximately \$ 1.2 billion which is subject to changes due to where the R&D takes place.<sup>24</sup> Therefore, these inevitable R&D costs are very high for the innovators.

Pharmaceutical sector mainly involves two types of companies; originator and generic. The R&D investments are mostly undertaken by originator companies. They develop the new therapeutic products and supply them under the protection of patents. Generic companies, on the other hand, manufacture the drugs which have the same therapeutic effect as originator companies' products, following the patent expiry of the branded products. Originator companies usually rely on their blockbuster medicines which enable them to generate the most of their revenues. Due to the high proportion of R&D investments in the turnovers of the companies, the FRSI<sup>25</sup> states that if those costly R&D investments are ended up successfully, they enable the companies –originator companies in particular- to generate high profits. On the contrary, following patent expiration, the generated revenue from the blockbusters is expected to be dropped dramatically.<sup>26</sup> In addition to that, there is also a risk of getting

---

<sup>21</sup> WHO (n 17).

<sup>22</sup> Frank R. Lichtenberg, 'Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003' (2009) 31 <[www.ncbi.nlm.nih.gov/pubmed/18634121](http://www.ncbi.nlm.nih.gov/pubmed/18634121)> accessed 13 August 2015.

<sup>23</sup> <[www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/](http://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/)> accessed 26 July 2015.

<sup>24</sup> The data: <[http://csdd.tufts.edu/news/complete\\_story/pr\\_tufts\\_csdd\\_2014\\_cost\\_study](http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study)>; the comment of *Economist*: <[www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure](http://www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure)> accessed 02 August 2015.

<sup>25</sup> See *ibid* Table 3-4.

<sup>26</sup> Frech and Miller (n 19).

nothing from the investment unless the research is ended up successfully. In other words, since the top selling prescription medicines (i.e. blockbusters) constitute very big proportion of the originator companies` turnover, the originator companies need to invest million dollars for new molecular innovations or developments by taking the risk of getting nothing from the investment. Therefore, they fairly expect to recoup at least their expenses with a reasonable profit margin (i.e. expected value) in response to their successful R&D works. In this respect, granted supplying monopoly for a certain period of time with IPR entitlement aims to fulfil such recoupment and profit margin expectation of pharmaceutical companies.

Despite of the highlighted importance of R&D investments for the sake of the pharmaceutical sector and public health in general, acceleration of pharmaceutical innovations in the EU is low. Pharmaceutical and Biotechnology R&D growth performance is the second lowest dimension in the patent/R&D ratio with the level of 0.9 per cent.<sup>27</sup> Accordingly, restrictive sector regulations and requirements are one of the reasons of the given fact.<sup>28</sup> Therefore, the entitled authorities should balance the necessary actions to strengthen dynamic efficiency of the market by considering the requirement for the pharmaceutical R&D investments and fair expectancy of the pharmaceutical companies.

### **3. Non-Harmonized Regulation Framework**

In response to its vital role for the society, pharmaceutical sector is one of the most regulated sectors in all around the world. As part of healthcare policy, almost each step in pharmaceutical sector such as initiation of R&D investments, marketing authorisations, patent expirations, prescribing doctors, insurance, prices, reimbursements so and so forth are regulated by governments.<sup>29</sup>

This divergent and highly regulated trend applies to the EU too. Each Member State has its own competence regarding to healthcare polices under Article 168 (7) of the TFEUEU Pharmaceutical Legislation<sup>30</sup>, in this sense, plays a complementary role with respect to national health care policies.

---

<sup>27</sup> Commission, 'EU R&D Scoreboard' COM (2014) 5.

<sup>28</sup> Ibid 40.

<sup>29</sup> Alberto Heimler, 'The Pharmaceutical Industry & Parallel Trade', WTO - Home Page, accessed 12 August 2015.

<sup>30</sup> <[http://ec.europa.eu/health/documents/eudralex/index\\_en.htm](http://ec.europa.eu/health/documents/eudralex/index_en.htm)> accessed 12 August 2015.

In this respect, Member States are fully entitled to negotiate with the pharmaceutical companies, to arrange their own pricing and reimbursement schemes as well as to form their own national prescribing procedure. This leads various applications in different Member States. For example, pharmaceutical expenditure is mostly private in some Member States such as Belgium, Finland, Greece and Italy while in some other Member States, the governments themselves undertake the most part of the pharmaceutical expenditure like in Netherlands and Switzerland.<sup>31</sup> Some Member States may charge the patients for their pharmaceutical expenses while some others may provide a large scale of exemptions from user charges.<sup>32</sup> Similarly, Member States may require different conditions on pharmaceutical companies to enter into their market. This may lead divergent selling prices for the same pharmaceutical products in different Member States. These varied national regulations lead the pharmaceutical companies to implement different business strategies in different Member States.

Pharmaceutical sector in the EU is subject to various strict regulations almost in each Member States. Governments aim to control their healthcare expenses and to attain more effective healthcare system by regulating the sector; on the other hand strict regulations adversely affect pharmaceutical innovations by increasing the innovation costs.<sup>33</sup> Similarly, various legal requirements in the Common market also increase the marketing expenses of pharmaceutical companies since they have to fulfil different conditions in different Member States. In addition, it is hard to claim that free market conditions, which are prerequisite for competition, are perfectly applicable under this type of strong regulation tradition. Considering these adverse effects, a harmonised regulation and enforcement at least in some branches of law are desirable not only for the sector but also for a proper Article 102 application. A harmonised system would help to decrease innovation and marketing costs of pharmaceutical companies as well as various transactional costs all around the EU. In addition to that, harmonisation in the mentioned below fields would provide an effective healthcare system for all the Common Market by saving the regulation costs of individual states. Moreover, harmonisation in the

---

<sup>31</sup> OECD, Health Data (2011, Paris).

<sup>32</sup> Elias Mossialos and Sarah Thomson, 'Access to Health Care in the European Union: the impact of user charges and voluntary health insurance' in Martin Gulliford and Myfanwy Morgan (eds), *Access to health care* (Routledge, 2003).

<sup>33</sup> Henry G. Grabowski, John M. Vernon and Lacy Glenn Thomas, 'Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry' (1978) 21/1 *Journal of Law and Economics* <<http://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/2648/GrabowskiVernonandThomas.pdf?sequence=1>> accessed 1 August 2015.

sector may contribute to free market conditions by decreasing the number of restrictions or divergent enforcement in different Member States.

**a. Patents**

Patent is a type of IPRs which provides its owner an exclusive right for a certain period of time to prevent the third parties from making, using or selling the patented invention without any permission. Hence, patent rights provide its inventor patent monopoly to recoup the creative expenses and to underpin its forthcoming inventions.

The EU patent system provides maximum 20 years of protection for inventions.<sup>34</sup> Nevertheless, IPRs are generally related with national laws because IPR law in the EU has not been harmonized yet. An inventor may apply either to each national patent office separately to issue national patents or to the European Patent Office ('EPO') to issue European patent for the entire internal market. The EPO's centralised system seems to be preferable to national patents due to economise opportunity from transaction costs. However, the European patents require validation in most of the Member States depending on their national regulations. In this sense, European patent which is just a bundle of national patent rights also constitutes high business risk for pharmaceutical companies due to potential divergent outcomes in different Member States about either validity or enforcement of patents.

In addition to non-harmonised patent procedure, pharmaceutical companies in the EU may suffer from the length of the procedure. The patent grant process in the EU takes 5 years approximately<sup>35</sup>; therefore pharmaceutical companies generally apply for patents during their R&D developments. It leads a significant gap between the time of filing of application and the product launch into the market.<sup>36</sup> As a result, pharmaceutical companies may miss out a considerable part of their recoupment opportunity. These adverse effects are highlighted in the FRSI and harmonisation on the topic is recommended.<sup>37</sup>

---

<sup>34</sup> European Patent Convention, Article 63.

<sup>35</sup> OECD, 'Pharmaceutical Pricing Policies in a Global Market' (2008).

<sup>36</sup> FRSI (n 10) 49.

<sup>37</sup> Ibid 114, 441.

## **b. Market Authorisation System**

Market authorisation is granted to pharmaceutical products which are compatible with the EU standards. In other words, market authorisation is a scientific test<sup>38</sup> which verifies safety, effectiveness and quality of pharmaceutical products. Both originator and generic companies are required to apply for market authorisation in a certain time period and they need to achieve market authorisation to be able to enter into the EU market.<sup>39</sup> On the other hand, originator companies need to submit more expanded and detailed documentation whereas it is sufficient for generic companies to prove bio-equivalency between their products and previously authorised products (abridged application). Market authorisations are challengeable and may be withdrawn due to the owners' request.

According to the relative EC regulations, both national authorities and the European Medicines Agency ('EMA') are entitled to issue market authorisation. In contrast with patent procedure, centralised procedure is established with respect to market authorisation under Regulation 726/2004. Accordingly, authorised products, either by national authority or the EMA, are eligible to be put into the entire EU market.<sup>40</sup> However, market authorisation may be subject to Article 102 analysis when it is used out of its merits.

## **c. Supplementary Protection Certificate ('SPC')**

Pharmaceutical products pass through three main stages basically; the pre-launch period in which R&D and approvals take place, the marketing and sales period in which pharmaceutical companies have an opportunity to recoup their R&D costs along with other transactional costs, and the last period in which competition with generic entries takes place.<sup>41</sup> Due to the abovementioned length of patent procedure, pharmaceutical companies may not be able to recoup their expenses fairly. SPCs, in this sense, are designed under Council Regulation No 1768/92, to compensate possible missed out recoupments by providing an additional exclusivity for the products concerned.<sup>42</sup> Pharmaceutical

---

<sup>38</sup> Ibid 131.

<sup>39</sup> Ibid 54.

<sup>40</sup> Ibid 54.

<sup>41</sup> Ibid 49.

<sup>42</sup> Ibid 53.

companies should apply to each Member State concerned for SPC in following 6 months of the date of market authorisation issuance.<sup>43</sup> Accordingly, eligible pharmaceutical products may benefit maximum 5 years extension of protection with SPC. In addition, maximum 15 years effective protection is envisaged for a pharmaceutical company which holds both patent and SPC.<sup>44</sup> SPCs are patent-likely right. Therefore, it may be relevant in Article 102 analysis if it is used out of its merits.

#### **d. Pricing and Reimbursement Mechanisms & Demand Features**

As part of healthcare policies, Member States have competence to implement their own pricing and reimbursement mechanism regarding to pharmaceutical product concerned as long as it is compatible with the EU transparency conditions established under Directive 89/105/EEC.<sup>45</sup> Governments take into account supply and demand-side effects while determining price and reimbursement levels. The cost of pharmaceutical companies to develop the product and the reserved budget of governments for the products are taken into account as part of supply side effects; whereas doctors' and pharmacists' attitudes towards the products in question regarding to their uses and effects, constitute demand-side effects.<sup>46</sup> It is worth to note that demand feature for pharmaceutical sector is also sector specific. Consumers have not got sufficient knowledge to decide on the product. Therefore, due to patients' lack of information, product decisions and the method of usage are made by doctors or professionals instead of consumers themselves.<sup>47</sup> This leads difficulties to determine and analyse demand profile of products and it may direct pharmaceutical companies to focus on doctors and professionals instead of patients' needs.

Regarding to Article 102 analysis, state governed price and reimbursement mechanism has three main consequences. Firstly, price discrimination, which is indeed a pricing strategy to increase profits by discriminating demand profiles, in the EU pharmaceutical market may be a direct result of different price policies of Member States themselves. Despite cross-border referencing system which states

---

<sup>43</sup> Ibid 113.

<sup>44</sup> Ibid 112-113.

<sup>45</sup> Ibid 132.

<sup>46</sup> Ibid 133.

<sup>47</sup> Grabowski, Vernon and Thomas (n 33).

that Member States may refer to other Member States' price levels, price discrimination between the Member States is still considerable. Therefore, it should be taken into account during Article 102 analysis when it comes to price discrimination. Secondly, due to different regulated price levels in the internal market, it is hardly to state that perfect competition conditions are met in this sector. Prices are determined initially by governments in the most of the Member States. Pharmaceutical companies are only able to set their prices freely in few Member States such as Malta, Sweden and the UK. In addition to initial price settlements, subsequent rebates and discounts which may significantly affect market prices may also be applicable in the Member State concerned.<sup>48</sup> As a result of the process, pharmaceutical companies should deal with governments to negotiate initial prices, health insurance companies or funding agencies to agree upon reimbursement mechanisms. Therefore, they do not have much of control over their market prices. However, pharmaceutical companies may set their quantity according to market conditions; therefore they can compete based on their quantity, which is called Cournot Competition, as much as possible in the market. Within this respect non-pricing strategies should be more relevant than pricing strategies in competition scrutinises in the pharmaceutical sector.. Lastly, bargaining power balance between governments and pharmaceutical companies should be taken into account in Article 102 analysis. Even though the governments seem to be the decisive authorities on price levels, they negotiate with pharmaceutical companies on pricing levels. The state tries to achieve the widest market access as much as possible for its patients whereas the companies try to achieve higher pricing offers and stronger exclusive rights. Pharmaceutical companies need to agree with governments to get into the market whereas governments also need to agree with pharmaceutical companies to improve their healthcare efficiently. Therefore, their needs are reciprocal and none of them can leave the negotiation easily. Even though that bargaining balance depends on products and the state concerned, it may be claimed that both parties have their own bargaining power to agree upon a fair price level. Therefore, pharmaceutical companies' claims that they do not have any control their market prices should be analysed deliberately since they have a chance to affect the price level.

---

<sup>48</sup> FRSI (n 10) 149.

### III. BOUNDARIES BETWEEN COMPETITION AND IP LAW

Boundaries between IPRs and economically inspired competition law have been discussed for a long time in law and economics literature.<sup>49</sup> There is an inherent conflict between IP law and competition law because of their aims. This is more visible in pharmaceutical sector due to the impact of the sector on society. Boundaries between IP and competition law will be analysed considering their aims, conflict theories and solutions respectively.

#### 1. The Aims of Competition Law

Competition law, which has both economic and social objectives,<sup>50</sup> briefly, aims at lower prices with better quality and more choices due to innovation in the market. Competition law takes into account allocative efficiency together with dynamic efficiency. However, allocative efficiency has more imminent impact on consumer welfare. Therefore, in most instances dynamic efficiency may be placed to secondary position in case of any conflict between allocative and dynamic efficiency. This reflects the theory in the literature that competition law concerns more with the short-term effects whereas IP law concerns more with the long-term benefits.<sup>51</sup> Nevertheless, it does not mean that competition law ignores the long-term benefits of dynamic efficiency.<sup>52</sup> On the contrary, competition enforcement recognises IPRs' importance and reinforces innovation; however at the same time, it counterbalances IPRs by preventing IPR holders' anti-competitive behaviours.<sup>53</sup>

In principle, both competition and IP law aim at economic welfare; therefore there is not any conflict in principle. However, although competition law recognises existence of IPRs<sup>54</sup>, it prevents improper

---

<sup>49</sup> Ioannis Lianos and Rochelle C. Dreyfuss, 'New Challenges in the Intersection of Intellectual Property Rights with Competition Law A View from Europe and the United States' (2013) Centre for Law, Economics and Society Working Paper Series 4/2013 132 <[www.ucl.ac.uk/cles/research-paper-series/index/edit/research-papers/cles-4-2013](http://www.ucl.ac.uk/cles/research-paper-series/index/edit/research-papers/cles-4-2013)> accessed 15 July 2015.

<sup>50</sup> Maher M. Dabbah, *EC and UK Competition Law, Commentary, Cases and Materials* (Cambridge Press, 2004) 6.

<sup>51</sup> Lianos and Dreyfuss (n 50) 39.

<sup>52</sup> Commission Notice- *Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements* [2004] OJ C 101/2.

<sup>53</sup> Lianos and Dreyfuss (n 50) 7.

<sup>54</sup> Joint Cases C-56 and C-58/64 *Etablissements Consten SARL and Grunding-Verkaufs-GmbH v Commission* [1966] ECR 299, para166-173.

use of such rights. Therefore, the main conflicts arise from the exercise of IPRs in such a way to exclude competitors and to harm consumers.<sup>55</sup>

## **2. The Aims of IP Law**

The main idea behind IPR entitlement is to give an opportunity to innovators to recover their costs and to underpin their further innovative incentives. In other words, IP law intends to strengthen dynamic efficiency by appreciating the efforts of innovators for their present inventions and also by offering exclusivity for further innovations.

From this perspective, expected revenue of innovator should exceed at least the total costs of invention including fixed and variable costs. The fixed costs are considerably high in response to low marginal costs of manufacturing. Fixed costs of an innovator, includes R&D investments, including cost of failed projects, as well as cost of obtaining and maintaining IPRs. Due to significant fixed costs, an inventor needs to set the price above the marginal cost level to be able to earn a competitive return from the market.<sup>56</sup> In this respect, the existence of IPR confers the holder to raise prices accordingly.<sup>57</sup> Therefore, a firm's incentive to innovate and its willingness to hold IPR by spending such costs, depends on how much additional or extra profit can be earned due to the exclusivity. If the market is not capable to offer a sufficient profit margin for a firm as an incentive, it follows that firms will not undertake all mentioned costs.

Relying on exclusivity, innovator company reduces its level of output to increase prices and, thereby its profits. This leads to a loss in the consumers' side since the level of output of the particular product will be less and its price will be higher than it would have been the case in the absence of an exclusive right. The interference between IP and competition law arises in this point; competition law aims to maximize consumer welfare, even by limiting welfare transfer from the consumers to the IPR holders in some cases, whereas IP law aims to protect and to underpin innovative efforts. However, the existence of innovated product is pre-condition for the existence of such consumer welfare in

---

<sup>55</sup> Lianos and Dreyfuss (n 50) 38.

<sup>56</sup> Ibid 34.

<sup>57</sup> Ibid 45.

question.<sup>58</sup> Moreover, as explained, dynamic efficiency is also one of the goals of competition law. Therefore, a fair balance between competition law and presence of IPR requires more deliberate examination. Presence of IPR should give inventor an opportunity to recover its losses along with a fair profit. On the other hand, IPRs should not be used out of its merits such as a way of bonanza.

### 3. Interface Between Competition Law and IP Law

IPRs are defined as a property, therefore owner of that property, ideally, supposed to have the rights of *usus*, *fructus* and *abusus* the property. However, based on its immaterial feature, it may not provide the exact rights of material property.<sup>59</sup>

Despite of its distinct characters, IPRs are distinguished property right under almost each jurisdiction. In *Microsoft* decision, it is stated that, apart from its distinct impacts of IPRs on different legal fields, they are entirely a type of property right<sup>60</sup> which is protected by not only the first additional Protocol of the European Convention of Human Rights ('ECHR') but also by the national constitutions of Member States. Therefore, IPRs' property right character gives itself a constitutional value.<sup>61</sup>

On the other hand, IPRs' property character is not an absolute right; therefore it does not provide the holders immunity from competition law. According to the EU law, property rights may be restricted proportionally for the purpose of public interest without infringing their substance.<sup>62</sup> Apart from other legal fields, competition law may constrain the scope of property rights due to its established general interest objective.<sup>63</sup> In this sense, not the existence of IPRs but how it is exercised may be restricted if such exercise constitutes an infringement of competition law.<sup>64</sup>

With respect to IPR holders' incentive to misuse their exclusivity, Lianos and Dreyfuss<sup>65</sup> argues that normally innovators themselves also take benefit of dynamically efficient markets because

---

<sup>58</sup> Ibid 38.

<sup>59</sup> Hardy Boillon, 'A Note on Intellectual Property and Externalities' in Jörg Guido Hülsmann and Stephan Kinsella (eds), *Property, Freedom and Society, Essays in Honour of Hans-Hermann Hoppe*, Ludwig Von Mises Institute (2009) 159.

<sup>60</sup> Case T-167/08 *Microsoft v Commission* [2012] ECR II-000 paras 148-155.

<sup>61</sup> Lianos and Dreyfuss (n 50) 48.

<sup>62</sup> Case 265/87 *Herman Schröder HS Kraftfutter GmbH v Hauptzollamt Gronau* [1989] ECR 2237 para 15.

<sup>63</sup> *FAG-Flughafen Frankfurt/Main AG* Case 98/190 Commission Decision OJ [1998] L 72/30 para90 and Case C-344/98 *Masterfoods Ltd. v HB Ice Cream Ltd.* [2000] ECR I-11369, Opinion of AG George Cosmas.

<sup>64</sup> Lianos and Dreyfuss (n 50) 49.

<sup>65</sup> Ibid 60.

dynamically efficient market extends downstream market for innovators and it enhances the innovators' opportunity to increase profits. However, in some cases, IPR holders may have an interest to hinder dynamic innovation which will repeal their present innovation.<sup>66</sup> Exercise of IPRs, in this sense may constitute an infringement of competition law. Some theories are suggested in literature to conceptualize these infringements. The leverage theory, essential facilities doctrine, raising rivals' costs, maintenance of monopoly will be briefly examined respectively.

The leverage theory establishes that in case of an existence of related upstream and downstream markets, upstream incumbent may refuse to license its IPR to downstream companies in order to reserve downstream markets for itself.<sup>67</sup> Thereby, an upstream company leverages its power in the downstream market through its monopoly in the upstream market.<sup>68</sup> The upstream incumbent may tie its upstream and downstream products together, if it is possible, to prevent the downstream competitors' market expansion.<sup>69</sup> This may infringe competition law by either foreclosing existing competitors or increase the entry barriers. This theory is also supported by Choi and Stefanadis's empirical model.<sup>70</sup> The theory is challenged by Chicago School's single monopoly profit theorem.<sup>71</sup> Accordingly, a monopolist has already have capacity to earn the same amount without implying leveraging strategies. However, this theorem is implied by the Commission in *Microsoft* case.<sup>72</sup>

The essential facilities doctrine is a US-based doctrine<sup>73</sup> states that IPR holder may extend its monopoly power in one production stage to another if the IPR in question constitutes an essential facility (or bottleneck) for the market concerned or the downstream market. In this sense, to prevent either downstream or upstream competitors' access to the IPR in question constitute an infringement

---

<sup>66</sup> Dennis W Carlton and Robert H Gertner 'Intellectual Property, Antitrust and Strategic Behavior' (2002) NBER Working Paper Series 8976 <[www.nber.org/papers/w8976](http://www.nber.org/papers/w8976)> accessed 28 July 2015.

<sup>67</sup> Louis Kaplow 'Extension of Monopoly Power through Leverage' (1985) 85 Columbia Law Review 515.

<sup>68</sup> Ibid 516.

<sup>69</sup> Michael D Whinston, 'Tying, Foreclosure and Exclusion' (1990) 80 American Economic Review 837.

<sup>70</sup> Jay P Choi, 'Preemptive R&D, Rent Dissipation and the 'Leverage Theory' (1996) 110 Quarterly Journal of Economics, 1153. Jay P Choi and C. Stefanadis 'Tying, Investment, and the Dynamic Leverage Theory' (2001) 32 Rand Journal of Economics 52.

<sup>71</sup> Ward Bowman 'Tying Arrangements and the Leverage Problem' (1957) 67 Yale Law Journal 19 and Richard Posner, *Antitrust Law* (University of Chicago Press, 2<sup>nd</sup> ed, 2001) 198-200.

<sup>72</sup> *Microsoft* (n 61).

<sup>73</sup> *United States v Terminal R.R. Ass'n* 224 US 383 (1912); *Associated Press v United States*, 326 US 1 (1945); *Otter Tail Power Co. v United States*, 410 US 366 (1973).

of competition law. Therefore, in these occasions, the IPR holder may be forced to share its input which is protected under IP law with its competitors.<sup>74</sup>

Validity of the doctrine is criticised by the US literature<sup>75</sup>; however it had been used by the Commission to justify interim measures.<sup>76</sup> In 1998, the doctrine is examined by the Court of Justice of the European Union (CJEU) in *Oscar Brunner* case. The Court highlighted that essentiality (or indispensability) of the refused facility is not sufficient to prove abuse of dominance, but some other conditions which will be analyzed below should be fulfilled.<sup>77</sup>

According to the raising rivals' costs theory, which is quite similar to leveraging theory, a dominant IPR holder may use its exclusivity as an entry barrier towards its competitors by raising the competitors' costs.<sup>78</sup> However, in this theory, dominant firm focuses on to raise the costs of its competitors instead of leveraging its monopoly power into another market. Raising rivals' cost may be a consequence of various strategies. For example, this may be the case if a technology of dominant company which protected under IP law may be used to raise rivals' costs by preventing access to such technology.<sup>79</sup> In addition to that, IPR holders may abuse their portfolio power to create a "patent thicket" which is a dozen of patents with small differences from the present technology. As a result of patent thicket applications of dominant firm, its competitors will have only two choices. Firstly, they may litigate the validity of patents which is very costly and time consuming. Alternatively, they need to handle with the presence of such patent thickets either by accepting the offered licensing agreements of dominant firm<sup>80</sup> or by manufacturing their products in line with the patent thickets.<sup>81</sup>

---

<sup>74</sup> *MCI Communications Corp. v AT&T*, 708 F.2d 1081 1132-1133 (7th Cir. 1983).

<sup>75</sup> Abbott B Lipsky and Gregory J Sidak 'Essential Facilities' (1999) 51 Stanford Law Review 1187-1192.

<sup>76</sup> *Containers v Stena Sealink* (Case IV/34.689) Commission Decision 94/19/EC [1994] OJ L15/8; *B&I Line plc v Sealink Harbours Ltd and Sealink Stena Ltd* (Case IV/34.174) Commission Decision [1992] OJ L378.

<sup>77</sup> Case C-7/97 *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co KG* [1998] ECR I-7791

<sup>78</sup> Thomas G Krattenmaker and Steven C Salop 'Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price' (1986) 96 Yale Law Journal 209.

<sup>79</sup> Lianos and Dreyfuss (n 50) 43.

<sup>80</sup> Herbert Hovenkamp, Mark D Janis and Mark A Lemley 'Anticompetitive Settlement of Intellectual Property Disputes' (2003) 87 Minnesota Law Review 1719.

<sup>81</sup> Daniel L Rubinfeld and Robert Maness 'The Strategic Use of Patents: Implications for Antitrust' in Lévêque and Shelanski (eds) 97; Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, 'Unilateral Refusals to License in the US' in François Lévêque and Howard Shelanski (eds), *Antitrust, Patents and Copyright - EU and US Perspectives* (Edward Elgar, 2005) 12-18.

Another example of raising cost strategy is a bundle of licensing agreements offered by dominant firms. Competitors, in this case, need to accept the whole bundle which involves unneeded agreements and need to pay more than that they would have paid for the only ones that they need.<sup>82</sup> Consequently, all these strategies of dominant firm may limit the choices of competitors and it may lead to foreclosure of existing competitors by increasing their costs or to prevent new entries due to entry barriers.

On the other hand, monopoly maintenance theory refers to strategies of dominant firms towards to their competitors in another market to prevent them to enter into the primary market in which the incumbent has dominance. In this respect, a potential competitor in another market needs to invest its occurred profits from complementary sector into the primary market to compete with the dominant firm. However, a dominant firm may bundle its products, thereby reduce competitors' profits in complementary market to prevent competitors to enter into the primary market.<sup>83</sup> This may lead an infringement of competition since it will prevent new entry and new innovations overall in the market.

84

All these theories reflect dominant firms' incentive to abuse their dominance arising from IPRs. However, the theories are not distinct to each other, they may overlap in some circumstances. In the light of discussed theories, the EU's approach for balancing application of Article 102 with IP law will be examined.

#### **4. The Enforcement of Article 102 on IPRs**

At the outset, it should be noted again that the EU case law is very clear on that a mere IPR ownership cannot be challenged by competition law. However, improper exercises of such rights are prohibited under the EC law.<sup>85</sup> Moreover, presence of IPR does not lead necessarily dominance in the market;

---

<sup>82</sup> Lianos and Dreyfuss (n 50) 44.

<sup>83</sup> Ibid (n71); Dennis W Carlton and Michael Waldman 'The Strategic Use of Tying to Preserve and Create market Power in Evolving Industries' (2002) 33 Rand Journal of Economics 194 and Jay P Choi and C. Stefanadis 'Tying, Investment, and the Dynamic Leverage Theory' (2001) 32 Rand Journal of Economics 52.

<sup>84</sup> Lianos and Dreyfuss (n 50) 45.

<sup>85</sup> Case 24/67 *Parke, Davis & Co v Probel* [1968] ECR 55.

however it may be an effective factor of dominance determination. Based on the given principles of EU case law, Article 102 enforcement may interfere with IPRs mainly in three points.<sup>86</sup>

First issue is dominant company's refusal to licence its IPRs. As it has been argued in essential facilities doctrine, in some circumstances a dominant company may have an incentive to refuse license requests of competitors for the protected products. The European Courts follows formalistic view on this issue by defining the scope of the IPR concerned. The scope of IPR is called as 'specific subject matter' and it is defined by the Court as "the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time (...) as well as the right to oppose infringements".<sup>87</sup> Moreover, the Court added that the existence of IPR provides its owner a right to be the sole producer of the protected products, in other words, manufacturing of such product is a part of subject matter of IPR.<sup>88</sup> Therefore, any refusal of license which is covered by the specific subject matter of the IPR concerned would not constitute an abuse of dominance. Based upon this principle, the Court highlighted that a refusal of license is not itself an abusive conduct as long as the special circumstances rendered otherwise.<sup>89</sup>

Pursuant to the Guidance<sup>90</sup>, these special circumstances occur when the product or service which is refused to be licensed constitutes an objective necessity to operate effectively in downstream market, and/or such a refusal is likely to eliminate effective competition and/or such refusal is likely to harm consumers.<sup>91</sup> The specific circumstances are conceptualised by the EU case law. The Court of First Instance (currently the General Court) pointed out in its *Magill* decision that refusal of license may infringe Article 102 in three illustrations; first there would be no other actual or potential substitute for the product which is refused to license<sup>92</sup> (in other words, the product which is refused to license should be indispensable), secondly there would not be an objective justification for such refusal and thirdly dominant company would have an intention to reserve the secondary market for itself by

---

<sup>86</sup> Kevin Coates, Lars Kjølbye and Luc Peeperkorn, 'Intellectual Property' in Jonathan Faull and Ali Nikpay (eds), *Faull & Nikpay The EC Law of Competition* (OUP, 2nd Edition, 2007) 1293–1302.

<sup>87</sup> Case 15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* [1974] ECR 1147.

<sup>88</sup> Case 238/87 *AB Volvo v Erik Veng (UK) Ltd* [1988] ECR 621.

<sup>89</sup> *Ibid* para 9.

<sup>90</sup> Commission, *Guidance on Article 102 Enforcement Priorities*, OJ [2009] C45/7.

<sup>91</sup> *Ibid* paras 174-177.

<sup>92</sup> Joined Cases C-241/91P and C-242/91P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission* [1995] ECR I-74, para 49.

refusing licensing.<sup>93</sup> *Magill* case seems to create a limited obligation to license if such IPR is indispensable to create a new product with a consumer demand. *Magill* criteria are confirmed by the Court in its *IMS Health*<sup>94</sup> decision. The Court stated in its *IMS Health* decision that any refusal of licence, which intend to offer new products or services with potential demand into the market, would infringe Article 102 as long as it is not justified objectively.

To sum up, refusal of licensing itself is not prohibited under the EU competition law. However, if the product or service which is refused to licence is indispensable for downstream company to produce a new product which has potential demand; and if the dominant company has no objective justification for its refusal; and if such a conduct leads elimination of competition in the market or a substantial part of it as well as affecting trade between Member States, that refusal would infringe to Article 102.

Second issue is dominant company's arbitrary refusals of licensing. As it is explained in raise rivals' costs theory, a dominant company which holds IPR may have an incentive to discriminate its competitors, which constitute a risk of being potential competitor, while licensing its products or services. This discriminatory licensing may infringe Article 102 if it affects competition in the market. A dominant company, in this sense, who asked its competitors for excessive royalties without any objective justification, can be fined for infringing of Article 102.<sup>95</sup>

The third issue is misuse of regulatory process to extend monopoly power. This issue is implied recently in *Astra Zeneca* case by the General Court. The General Court stated in paragraph 355 of its decision 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.”

---

<sup>93</sup> *Volvo* (n 89) paras 55-56.

<sup>94</sup> Case T-184/01 *IMS Health Inc v Commission* [2001] ECR II-3193 para 106.

<sup>95</sup> Case 402/85 *Basset v SACEM* [1987] ECR 1747 para19; Case 395/87 *Ministere Public v Tournies* [1989] ECR 2521 para 38.

As a result, Astra Zeneca is fined for misusing both market authorisation and SPC procedure to delay generic market entries. Special responsibility of dominant company is also stressed out by the General Court.<sup>96</sup> With respect to Astra Zeneca's counter claims about its non-willingness to misuse the regulatory procedure, the General Court clarified that abuse is an objective concept and there is no need to prove bad faith or intention of dominant company for the purpose of identifying an abuse of dominant position, though it is clear that Astra Zeneca deliberately intended to mislead the authorities.<sup>97</sup>

Another version of misuse of regulatory scheme may be seen as a vexatious behaviour<sup>98</sup> as it is examined under raising rivals' costs theory. A dominant company may have an incentive to apply for various patents or to engage in litigation procedure with an aim of to prevent its competitors by raising their costs. This strategy may constitute an infringement of competition law if it affects competition in the market. These strategies may be used in various forms in different sectors. In this sense, pharmaceutical sector will be analysed below.

#### **IV. ANALYSIS OF ABUSE OF DOMINANCE IN THE EU PHARMACEUTICAL SECTOR AND PREDICTIONS**

In light of high upfront costs of developing pharmaceutical products, pharmaceutical sector needs patent exclusivity.<sup>99</sup> Indeed, empirical studies described pharmaceutical sector as a sector in which particularly originator companies mostly rely on patent law to capture their expenses and revenues.<sup>100</sup> However, obtaining patent rights is time-consuming for pharmaceutical companies, thereby underpins transactional costs. The average time for patent review process for pharmaceutical products

---

<sup>96</sup> Case T-321/05 *Astra Zeneca v Commission* [2010] ECR II-02805 para 358.

<sup>97</sup> *Ibid* para 356, 493 and 814.

<sup>98</sup> Richard Wish and David Bailey, *Competition Law* (7<sup>th</sup> ed, OUP, 2012), 805.

<sup>99</sup> Richard Posner, 'Why There are Too Many Patents in America', *The Atlantic* (12 July 2012) <[www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/](http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/)> accessed 10 August 2015.

<sup>100</sup> Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32 *Management Science* 173 and Andrés López, 'Innovation and Appropriability, Empirical Evidence and Research Agenda' in *The Economics of Innovation* (WIPO 2009) <[www.wipo.int/ipdevelopment/en/economics/pdf/wo\\_1012\\_e\\_ch\\_1.pdf](http://www.wipo.int/ipdevelopment/en/economics/pdf/wo_1012_e_ch_1.pdf)> accessed 10 August 2015.

is 44 months in the EU.<sup>101</sup> In this respect, life-cycle of pharmaceuticals, which consists of three phases, should be taken into account. The first phase is for R&D and regulatory approvals. In this phase, pharmaceutical companies mostly invest for their R&D and transactional costs incur; therefore they do not have any opportunity to capture their expenses in this phase. The most valuable phase for the pharmaceutical companies is the second phase, in which originator companies do marketing and selling. Pharmaceutical companies enjoy the exclusivity rights to recoup their expenses which occurred in the first phase. They need to recover their investments, including the cost of failed R&Ds, as much as possible in this phase because in the last phase, generic companies may enter into the market due to the loss of exclusivity. In the third phase, therefore originator companies are confronted with more intense competition.<sup>102</sup> Therefore, enforcement mechanism of competition law, which may constrain exercise of patent rights and result an increase of business risks and costs, has a crucial influence on pharmaceutical companies' expected revenue from the second phase.

Application of Article 102, which prohibits abusive conducts of dominant firms by exercising<sup>103</sup> IPRs is already a controversial issue<sup>104</sup> and its application into pharmaceutical sector is far more complicated not only because of the sector's specificities but also because of lack of steady case law on the topic. Therefore, as Baker suggests, it is better to apply industry-specific approach while enforcing competition law to some certain sectors<sup>105</sup>, such as pharmaceutical sector which is strongly based on R&D and subject to strict regulatory intervention. Indeed, even though the Commission has recently fined Servier allegedly abusing of its dominance, it has not been decided yet by upper courts. In this regard, *Astra Zeneca* constitutes the sole Article 102 enforcement in pharmaceutical sector yet which has been upheld by the CJEU. On the other hand, following the FRSI, scrutinizes are increased in both national and the EU level. This fact provides, on the one hand, an opportunity to clarify competition enforcement in the sector based upon further decisions. On the other hand, it increases pharmaceutical companies' fears from any potential scrutiny due to remaining ambiguous

---

<sup>101</sup> Intellectual Property Patents: The vehicle for innovation, <[www.efpia.eu/topics/innovation/intellectual-property](http://www.efpia.eu/topics/innovation/intellectual-property)> accessed 10 August 2015.

<sup>102</sup> FRSI (n 10) 49.

<sup>103</sup> Paul Lugard, 'European Union: assessment of IP licensing agreements under EU competition law' (Baker Botts LLP, 2014) <[www.lexology.com/library/detail.aspx?g=7d121141-f763-470b-bb04-20454fa881bf](http://www.lexology.com/library/detail.aspx?g=7d121141-f763-470b-bb04-20454fa881bf)> accessed 12 August 2015.

<sup>104</sup> Nikpay (n 87) 1296.

<sup>105</sup> Jonathan Baker, 'Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation' (2007) 74(3) Antitrust Law Journal 575.

competition enforcement. Therefore, recent and potential anticompetitive behaviours under Article 102 will be analysed in this chapter along with the influential issues for the topic.

### **1. Market Definition for the Purpose of the Enforcement of Article 102 TFEU**

The one of the most debated parts of competition assessment is market definition which is the first step of EU competition analysis. Market definition has basically two main elements; relevant product market and relevant geographical market. Pursuant to the Notice<sup>106</sup>, economic tools are used to define the relevant markets. Accordingly, demand and supply substitution, potential competition and competitive constraints are taken into account while defining the relevant product market. Following the relevant market definition, the Commission evaluates whether the company –or companies- under the scrutiny has market power in the defined market. If the concerned company has an ability to raise prices over time, or to behave independently from its competitors and customers,<sup>107</sup> then it would have a market power.

Due to pharmaceutical sector's complications and the pivotal role of market definition with respect to Article 102 assessment, the relevant market should be defined deliberately. In the pharmaceutical sector, the main conflict is the definition of relevant product market, rather than relevant geographic market. If the relevant market is defined too narrow than it should have been, then it may end up with finding of dominance. On the contrary, too wide market definition may mislead the Commission to notice the existence of dominance and the corresponding potential abuses.

IPRs presence may lead narrower definition in pharmaceutical sector as it is discussed in *Astra Zeneca* case.<sup>108</sup> Astra Zeneca asked the Commission a wider market definition by stating that histamine receptor antagonists ('H2 blockers') should also be considered in the same medicinal market with proton pump inhibitors ('PPI') which is produced by Astra Zeneca under the label of Losec. Accordingly, Astra Zeneca complained that neither the Commission nor the General Court examined

---

<sup>106</sup> Commission, *Notice on the Definition of Relevant Market for The Purposes of Community Competition Law* (1997) OJ C 372 .

<sup>107</sup> William Landes and Richard Posner, 'Market Power in Antitrust Cases' (1981) 94 Harvard Law Review 937 <[http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=2551&context=journal\\_articles](http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=2551&context=journal_articles)> accessed in 26 July 2015.

<sup>108</sup> C-457/10 *AstraZeneca v Commission* [2012] ECR I-00000 paras 36-50.

sufficiently the gradual increase of PPI sales. Astra Zeneca asserted that since PPI has considerable side-effects which are considered in prescription process and since H2 blockers constitute a significant competitive constraint for PPI in the market; PPI sales increased slower than it would have been in the absence of H2 blockers. In addition, Astra Zeneca claimed that development of the competitive relationship between these two medicinal products during the relevant infringement period should also have been taken into account. Moreover, Astra Zeneca complained that the Commission focused on the identical period of treatment to compare the costs of medicines; however the required dosage of medicines for the same impact should have been focused. In response to Astra Zeneca's arguments, the CJEU confirmed that the developments during the relevant breaches may be taken into account to define the market<sup>109</sup> even though it rejected the rest of the appeal grounds stating that H2 Blockers and PPI have their own differentiated markets. This case law illustrates how difficult it could be to define the relevant product market properly. Even though there are only four components of market definition; namely, demand and supply substitutions, competitive constraints and potential competition; other factors such as side-effects of medicines, attitude of prescribing doctors, gradual sales regression line of products, cost-effectiveness of production or required dosage of products for the diseases may be relevant to market definition.

More recently, Servier, which has been dealt with the Commission's fining decision in 2014, complained about the market definition of the Commission. The spokesman of Servier stated that the relevant market should not be limited to perindopril while the treatments of hypertension contain more than a bunch of other products.<sup>110</sup> In this regard, European Federation of Pharmaceutical Industries and Association ('EFPIA') commented that the authorities should be circumspect while defining the market which means that substitutes in the same therapy class and competitive constraints should also be considered.<sup>111</sup> One can argue that the EFPIA has reason on its claims. Due to the complications of the pharmaceutical sector, the relevant market definition requires more intense and sector specific expertise. Therefore, cooperation between the authorities would contribute to

---

<sup>109</sup> Ibid paras 30-31.

<sup>110</sup> Servier Communication Department (2014) <[www.servier.com/content/european-commission-limits-legitimate-exercise-intellectual-property-rights-and-thus-weakens](http://www.servier.com/content/european-commission-limits-legitimate-exercise-intellectual-property-rights-and-thus-weakens)> accessed 10 August 2015.

<sup>111</sup> EFPIA, Home Page, <[www.efpia.eu/documents/116/48/EFPIA-Reaction-to-European-Commission-Decision-of-9-July-2014-condemning-Servier-patent-settlement-agreements-and-commercial-conduct-as-abusive](http://www.efpia.eu/documents/116/48/EFPIA-Reaction-to-European-Commission-Decision-of-9-July-2014-condemning-Servier-patent-settlement-agreements-and-commercial-conduct-as-abusive)> accessed 10 August 2015.

proper market definition. In addition, it is not reasonable to seek a perfect substitution to widen the relevant product market since almost each product -even the generic products- has its own specificity which differentiates itself in the market. Otherwise, the sole existence of IP protected product will lead dominance. It is undisputable that a pharmaceutical company under Article 102 scrutiny would prefer a wider market definition to not to be in a dominant position. However, the entitled authorities approach should point out the most appropriate market definition to be able to improve and promote competition.

## 2. Determining Dominance in the EU

Dominance is defined under the case law, as an economic strength of firm(s), in the internal market or a substantial part of it, which gives ability to the firm(s) to behave independently on an appreciable extent of its competitors, customers and consumers.<sup>112</sup> Apart from market share level, in its assessment, the Commission also considers entry barriers and customers' capacity to react. The CJEU stated that IPR possession<sup>113</sup>, especially when it protects essential facility for other products, or superior technology of firm(s)<sup>114</sup> may also be taken into account while determining dominance. Indeed, there is no presumption that IPR possession endows with market power, however such possession may reinforce finding of dominance if the holder enjoys a high market share along with its IPR.<sup>115</sup> In case of IPR presence, dominance determination does not depend on existence of such right *per se*, but depends on whether that protected product has any other substitute in the market.<sup>116</sup> As a result, the sole existence of IPR does not refer to dominance or monopoly of the holders, but the actual and potential substitutes of the protected product in the market should be analysed deliberately.<sup>117</sup> Especially in pharmaceutical sector in which even the new ways of producing active

---

<sup>112</sup> Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 461, para38; Case 27/76, *United Brands v Commission* [1978] ECR 207 para65 and John Vickers, 'Market Power in Competition Cases' (2006) 2 *European Competition Journal*, 3 <[http://heinonline.org/HOL/Page?handle=hein.journals/eurcompet2&div=3&g\\_sent=1&collection=journals](http://heinonline.org/HOL/Page?handle=hein.journals/eurcompet2&div=3&g_sent=1&collection=journals)> accessed 03 April 2015

<sup>113</sup> Case 53/92 P *Hilti AF v Commission* [1994] ECR I-667 para93; Case L 78/43 *Magill TV Guide/ITP, BBC and RTE* OJ (1989) 4 CMLR 757 paras 46-47.

<sup>114</sup> *United Brands* (n 113) paras 82-84; Case 322/81 *Michelin v Commission* (1983) ECR 3461.

<sup>115</sup> *Hoffmann-La-Roche* (n112), paras42-48; Case T-51/89 *Tetra Pak Rausing S.A. v Commission* [1990] ECR II-309 para 23.

<sup>116</sup> *Nikpay* (n 87) 1298.

<sup>117</sup> Ioannis Lianos 'Competition Law and Intellectual Property Rights: Is the Property Rights' Approach Right?' in John Bell and Claire Kilpatrick (eds) 8 *The Cambridge Yearbook of European Legal Studies* (Hart Publishing 2006) 153.

ingredients are patentable<sup>118</sup>, intense expertise assistance is required for substitution analysis. In this sense, authorities' cooperation, i.e. the Commission, the EPO and the EFPIA would contribute to dominance determination.

Establishment of dominance lays a burden on dominant firms a special responsibility<sup>119</sup> of not to distort competition in the market. That is to say that some conducts, which will not be considered as anticompetitive if it has been undertaken by a non-dominant company, may constitute an infringement if it is undertaken by a dominant company. For example, Astra Zeneca applied for SPCs in various Member States by submitting its patents' expiration date wrong. It argued that its conduct has no intention, but it was only a misinterpretation of law. The CJEU clarified that even though it seems like Astra Zeneca intended to mislead the patent offices,<sup>120</sup> abuse is an objective concept in any case.<sup>121</sup> Therefore, the appellant's intention does not need to be established. Moreover, the CJEU confirmed that due to its dominant position, Astra Zeneca has a special responsibility which leads its conducts to be considered an abuse.<sup>122</sup> This means that a dominant company may be fined because of its misunderstanding about the procedure whereas the non-dominant companies would not be fined for the same conduct. However, this article argues that, based on the abovementioned complications of patent procedure in the EU, this special responsibility may lay a larger burden on dominant companies in pharmaceutical sector than it would have been in any other sector. Therefore, even though it is reasonable to expect dominant companies to behave more responsibly; such responsibility should not put an extra obstacle to pharmaceutical companies. A pharmaceutical company which holds dominant position may also stumbled over the patent procedure without any intention, just because of complications of patent procedure. This is because of the non-harmonised procedure. Therefore, it is better to take necessary steps for patent and SPC system harmonisation in the EU to clarify the practice and to increase predictability of the procedure.

### **3. Finding of Abuse**

---

<sup>118</sup> *FRSI* (n 10) para 259.

<sup>119</sup> *Michelin* (n 115) para 7 and Case C-202/07 P *France Telecom v Commission* [2009] ECR I-2369 para 105.

<sup>120</sup> *Astra Zeneca* (n 109) para 66.

<sup>121</sup> *Ibid* paras 74-106.

<sup>122</sup> *Ibid* para 134.

According to Article 102, any abuse of dominance within the common market or a substantial part of it is an infringement of competition law as long as such conduct is not justified objectively. A dominant company may objectively justify its conduct by proving that the conduct resulted or likely to result efficiencies in the market, and such conduct is the least anticompetitive way of achieving such efficiency, and such efficiencies outweighed any actual or potential anticompetitive effects of the conduct, and such conduct does not eliminate effective competition in the market.<sup>123</sup> In this sense, for example preserve IPR by refusing supply to reserve the innovative incentives is not accounted as objective justification.<sup>124</sup> According to the Commission, IPRs do not constitute self-evident objective justification.<sup>125</sup> Therefore, objective justification should be more definite, concurrent and conduct specific.

Abuse of dominance in the EU pharmaceutical sector is very recent topic; therefore there is a poverty of substantial case law on the topic. Nevertheless, the Commission pointed out its main concerns in the FRSI. Accordingly, late generic entry and low R&D momentum are two main concerns. Therefore, all cases should be interpreted by considering the fact that innovation is a common objective of both IP and competition law as confirmed by the Commission<sup>126</sup> especially in pharmaceutical sector in which abuse of right concept<sup>127</sup> is not likely to be the focus.

Following the FRSI, developed case law illustrated the fact that various types of abuses, which had never been interpreted by the EU Courts, may arise in the sector. For example, in *Astra Zeneca* case, the Court defined to submit misleading information to national patent authorities to attain SPC and withdrawal requests for market authorisation of products of which patent expiration is in the near future, as abusive. The Court stated that all these conducts may lead or they are likely to lead delay of generic entry. This was the first case in which the Court interpreted misleading regulatory procedures as abusive. Another example is from France for Sanofi- Aventis.<sup>128</sup> French Competition Authority decided that Sanofi abused its dominant position by denigrating its generic competitors’

---

<sup>123</sup> Commission, *Guidance on Article 102 Enforcement Priorities* (n 90) para30.

<sup>124</sup> *Microsoft* (Case COMP/C-3/37.792) Commission Decision (2004) para 711.

<sup>125</sup> *Ibid* paras 710-783.

<sup>126</sup> *Ibid* para 712.

<sup>127</sup> Case C-255/02 *Halifax plc, Leeds Permanent Development Services Ltd and County Wide Property Investments Ltd v Commissioners of Customs & Excise* [2006] ECR I-1609.

<sup>128</sup> *Sanofi-Aventis* (n 15).

products. In *Sanofi*, denigration has been interpreted firstly as an abusive conduct in the pharmaceutical sector. Therefore, apart from the non-exhaustive anticompetitive behaviour examples of Article 102, it seems like pharmaceutical sector will face more divergent types of abuses. As a consequence, all the recent abuse decisions and predicted forms of abuse in the pharmaceutical sector will be examined below.

#### **a. Strategic Use of Patents**

Strategic use of patents is one of the most usual conducts of dominant companies in pharmaceutical sector to delay market entries. Especially, originator companies which hold dominant position may intend to use their IPRs improperly to delay generic entries. Such conducts are outside of the competition merits. Therefore, they may be considered abusive with respect to Article 102 in the absence of objective justification.

Strategic use of patents which aimed to expand and extend the duration of IPRs is represented in the FRSI as an important tool of originator companies to delay generic entries.<sup>129</sup> This tool is defined as ‘patent clusters’. Accordingly, originator companies may apply for various patents, as well as secondary patents, with a sole aim of delaying generic entries. Since generic companies can enter into the market only after the patent expirations, they need to wait the consequence of the originator companies’ such applications. As a result, generic entry into the market will be delayed. Strategic use of patents may also apply to the competition between originator companies. Within this regard, the Commission pointed out ‘defensive patenting’ strategy of originator companies.<sup>130</sup> Defensive patenting is a patent of which sole intention is to prevent the competitors to operate in patented field. An originator company may apply for a patent in a close field to other competitors’ operating field rather than its own field by aiming to prevent its competitors’ expansion.<sup>131</sup> These two; patent clusters and defensive patents, are the examples of abuse of rights which are highlighted in the FRSI. However, these examples are not exhaustive and there may be other types of abusive use of IPR in pharmaceutical sector which has not been interpreted by the EU Courts yet. However, very recently,

---

<sup>129</sup> FRSI (n10) 183-200.

<sup>130</sup> Ibid 380-395.

<sup>131</sup> See for a brief presentation, Commission, sector inquiry, <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/si.pdf>> accessed 15 July 2015.

the Italian Supreme Administrative Court ('ISAC') has fined Pfizer by interpreting its divisional patent request and subsequent SPC requests for Xalatan as an abuse of IPR.<sup>132</sup> Accordingly, the ISAC asserted that even though Pfizer has a legitimate right to request for a divisional patent and SPC, it exercised its right improperly to prevent generic entry. According to the ISAC, patent applications of Pfizer created uncertainty for generic companies related to expiration date of patent protection of Xalatan. Moreover, the ISAC emphasised Pfizer's aim to delay generic entry by creating a complex patenting strategy based on the lack of any marketed product on the basis of the entitled divisional patent, by applying for patent extension for paediatric trials and by requesting injunction to prevent generic entries.

Based upon the lack of any other EU Courts' interpretation, the ISAC's interpretation is very valuable to interpret the abuse of right concept as a mere final judgment even in a Member State. Pursuant to the ISAC, there are some conditions for an abuse of rights<sup>133</sup>; firstly there should be a right which can be used in several ways, secondly, even if such right is formally legitimate, the exercise of such right should be eligible to be challenged on either legal or non-legal basis, and finally the consequence of such exercise should provide unjustified and unreasonable benefits to the IPRs holders while costing to either actual/potential competitors or customers.<sup>134</sup>

The ISAC's conclusion is important to remark the fact that even though a conduct is legitimate under other areas of law, it may be, however, challenged by competition law if such conduct is outside of the scope of competition on the merits. It is also asserted in *Astra Zeneca* case by the General Court<sup>135</sup> and confirmed by the CJEU<sup>136</sup> stating that infringement of competition law is not related to legality of the conducts position according to other law branches. This perspective points out that any conduct, whether legal or illegal, may be considered an infringement of competition law. Therefore, since

---

<sup>132</sup> Italian Supreme Administrative Court (n 14).

<sup>133</sup> Ibid.

<sup>134</sup> Miranda Cole, Andrea Zulli, 'European Union: Pharmaceuticals', *The European Antitrust Review* 2016, (2015), <<http://globalcompetitionreview.com/reviews/72/sections/239/chapters/2898/european-union-pharmaceuticals/>> accessed 06 August 2015.

<sup>135</sup> *Astra Zeneca* (n 97) para 677.

<sup>136</sup> Ibid para 127.

pharmaceutical companies cannot rely on the legality of their IPRs, they should be more careful about their conducts.

The ISAC's interpretation has another dimension which deserves attention, the impact of intention on abuse decisions. The ISAC mainly based its abuse decision on to Pfizer's intention to delay generic entries. This issue is interpreted under the EU case law too. Accordingly abuse is an objective concept; therefore an intention of dominant firm is expected to be irrelevant for abuse decision. However, although abuse is an objective concept, the intention of a firm may influence the decision. Indeed, objectiveness of abuse is widely interpreted in the case law. That is to say that an intention of a dominant company to distort competition does not have to be established for abuse decision; however, a deliberate intention to distort competition will influence the abuse decision. This interpretation is established also recently by the Advocate General of Mazak<sup>137</sup> and it is confirmed by the CJEU<sup>138</sup> in *Astra Zeneca* case. However, it is argued that this interpretation sets the bar very low<sup>139</sup> and creates uncertainty with respect to Article 102 enforcement by adding subjectivity into the assessment. That criticism may have reason because of following arguments.

First of all, to focus on the intention, is one of the established standards to balance IP and competition law in the FRSI<sup>140</sup>, case law<sup>141142</sup> and the literature.<sup>143</sup> On the other hand, intention is very vague concept due to its subjectivity. For example, an originator company precisely would like to prevent competition which may decrease its profits. Moreover, the increased number of IP litigation in pharmaceutical sector, may also lead the patent holders to employ divergent strategies to prevent or delay market entries.<sup>144</sup> In this sense, intention of such company is inherent. Moreover, it should be

---

<sup>137</sup> AG Mazak (n 8) para 50.

<sup>138</sup> *Astra Zeneca*, (n 109) para 63.

<sup>139</sup> Gavin Bushell, 'AstraZeneca v Commission, Advocate-General Mazak's Opinion of 15 May 2012' (2012) Kluwer Competition Law Blog <<http://kluwercompetitionlawblog.com/2012/06/11/astrazeneca-v-commission-advocate-general-mazaks-opinion-of-15-may-2012/>> accessed 12 August 2015.

<sup>140</sup> FRSI (n 10) footnotes 375 and 376.

<sup>141</sup> Case T-69/89 *RTE v Commission* [1991] ECR II-485; Case T-70/89 *British Broadcasting Corporation and BBC Enterprises Ltd v. Commission* [1991] ECR II-535 para58 and Case T-76/89 *ITP v Commission* [1991] ECR II-575

<sup>142</sup> *AstraZeneca* (n97) para 334.

<sup>143</sup> Michael Carrier 'Resolving the Patent-Antitrust Paradox Through Tripartite Innovation' (2003) 56 Vanderbilt Law Review 1047 793.

<sup>144</sup> Lianos and Dreyfuss (n 50) 117.

borne in mind that intention is neither a part of patent assessment<sup>145</sup> nor a part of abuse which is an objective concept; therefore it should be applied very carefully. It can be argued that if all the conditions of abuse is already fulfilled, such as an actual or potential distortion of competition, lack of objective justification and effect on trade between Member States; to include the intention of dominant company into interpretation is unnecessary. Apart from the concrete cases, intent of the IPR holder may be taken into account with a limited extent in abuse determinations.<sup>146</sup> Secondly, the non-harmonized patent system increases the dominant companies' eligibility to mislead various authorities. Therefore, to harmonise the patent system may contribute the issue more effectively rather than focus on intention. Thirdly, patent authorities' capacity to distinguish the aims and actual/potential economic consequences of patents is also important. If patent authorities are equipped with more economic experts along with competition expertises; dominant companies may be disqualified from exercising such patents in an anticompetitive way.

#### **b. Misuse of Market Authorisations**

Market authorisation is a scientific procedure which supposed to be irrelevant with both competition and IP law. Each pharmaceutical product, regardless to its production by originator or generic company, need to have market authorisation to be put into the market for the sake of public health. However, market authorisations may be abused by their holders to prevent the competitors to enter into the market based upon their market authorisations. The FRSI revealed that such strategies delay market entries approximately 4 months, and this delay significantly contributes to originator companies' revenue.<sup>147</sup>

Misuse of market authorisations is considered as an abuse in *Astra Zeneca* for the first time. Astra Zeneca applied to some Member State's authorities to withdraw its market authorisation for Losec capsules and deregistered market authorisation for Losec tablets. As a result of the conduct, generic companies would not be able to take benefit of abridge system for the product Losec capsule since its

---

<sup>145</sup> Similarly EPO's arguments: Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report (Communication) 7 <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)> accessed 10 August 2015.

<sup>146</sup> Case C-549/10 *Tomra Systems ASA and Others v Commission* ECR 2012 -00000 paras 19,21 and 22.

<sup>147</sup> *Lianos and Dreyfuss* (n 50) 113.

market authorisation is withdrawn. On the other hand they would need to wait until Losec tablet's patent expiration to be able to obtain market authorisation. The CJEU upheld the General Court's decision which stated that, even though Astra Zeneca had a legitimate right to ask for withdrawal, such conduct infringes competition law because of lack of objective justification for withdrawal and the aim was deliberately and solely to delay generic market entry by misleading the authorities.<sup>148</sup>

The Court focused on the dominant company's intention to abuse and highlighted special responsibility of dominant companies. However, an absence of concrete and harmonised system was the main resources of the issue. Regardless of intention of the company, a harmonised market authorisation procedure would prevent companies to abuse the procedure in such a way. Indeed, market authorisation system has been changed and centralized with Regulation (EC) No 726/2004.<sup>149</sup> Accordingly, there is a harmonised mechanism for market authorisations and pharmaceutical companies have to submit their justifications for withdrawal requests. Therefore, as argued by Fagerlund and Rasmussen, this type of abuse cannot be repeated again.<sup>150</sup>

### **c. Reverse Payment Agreements (Pay-for-delay)**

Settlement agreements are examined generally under Article 101.<sup>151</sup> However, in some circumstances –as it is analysed in ‘raising cost theory’-, generic companies may be obliged to engage in reverse payment agreements due to the originator companies' dominance. Pay-for-delay agreements are one type of these settlement agreements in which originator companies transfer their profits to generic companies in return of a statement to they will not to enter the market or delay their entries and/or they will not challenge to the originator company's patent rights. If a dominant company obtains an essential patent with respect to generic company, generic company may prefer settlement agreements which will provide at least a margin of revenue, instead of facing with the hurdles arising from exclusivity right of the dominant firm. Originators, on the other hand, may also have an incentive for such agreements because otherwise they need to sue the generic companies, and need to pay litigation

---

<sup>148</sup> *Astra Zeneca* (n109) para 135-149.

<sup>149</sup> (2004) OJ L 136/1.

<sup>150</sup> Niklas Fagerlund, Søren Bo Rasmussen, 'AstraZeneca: the first abuse case in the pharmaceutical sector' <[http://ec.europa.eu/competition/sectors/pharmaceuticals/cpn2005\\_3\\_54.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/cpn2005_3_54.pdf)> accessed 12 August 2015

<sup>151</sup> *Lunbeck* (Case AT.39226) Commission Decision (2013); *Fentanyl* (Case COMP/AT. 39685) Commission Decision (2013).

fees. Considering the fact that originator companies generally lose such litigations<sup>152</sup>, to conclude a settlement agreement is preferable if the costs of such settlement is less than expected loss of profits due to generic competition.<sup>153</sup> In this case, both originator and generic companies take benefits of such agreement while the consumers face with scarce of choice and high prices.

The FRSI highlighted possible anticompetitive impacts of such agreements. Accordingly, pay-for-delay agreements may be abusive if it leads market delays and thereby distorts the competition; therefore pay-for-delay agreements are one of the tools of originator companies to prevent generic competition in the market.<sup>154</sup> Moreover, according to the Commission's recent report on Settlement Agreements, the number of pay-for-delay agreements in the sector has been increased.<sup>155</sup> On the contrary, some originator companies argue that these agreements are legitimate considering the actual patent system and time-consuming and costly patent litigations.<sup>156</sup>

Very recently, the Commission fined Servier due to alleged competition infringements. The Commission based its decision on two arguments; firstly the patent settlement agreements with respect to perindopril market to delay generic entries and/or prevent any challenge towards Servier's patents; secondly unilateral act of Servier of acquiring technology, with an aim to prevent potential competition.<sup>157</sup> However, the Commission has interpreted abusive pay-for-delay agreements under Article 101 rather than Article 102 because of their bilateral character. Therefore, there has been no case law yet related to pay-for-delay agreement which is interpreted under Article 102 in the EU level. On the other hand, the UK competition authority, OFT's investigation to GSK based on allegations that GSK abused its market power in Serotax by keeping prices high with patent settlement

---

<sup>152</sup> Lianos and Dreyfuss (n 50) 119.

<sup>153</sup> Federal Trade Commission Staff Study, 'How Drug Company Pays-Offs Cost Consumers Billions' (2010) <[www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf](http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf)> accessed 18 July 2015.

<sup>154</sup> Commission, '5th Report on the Monitoring of Patent Settlements', COM (2014) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report5\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report5_en.pdf)> accessed 05 August 2015.

<sup>155</sup> Ibid.

<sup>156</sup> Lugard (n 105).

<sup>157</sup> *Servier* (n 14).

agreements is remarkable. Although, the CMA has not announced any corresponding fine to GSK, it is argued that the OFT considered such agreements also under Article 102.<sup>158</sup>

In conclusion, pay-for-delay agreements are generally interpreted under Article 101 rather than Article 102. However, there is not any precise statement that they are required to be interpreted under Article 101; therefore, even though it seems unlikely, they may also be considered under Article 102. In this case, to apply more economic approach would be reasonable. As Kaplow argues, economic approach may compare “the reward the patentee receives” and “the monopoly loss that results from such exploitation of the patent”.<sup>159</sup> In case of pay-for-delay agreements, authorities may evaluate effects by comparing the efficiency gains as a result of such agreements and corresponding consumer’s welfare loss.

#### **d. Vexatious Behaviour and Ever-greening**

Litigation process in pharmaceutical sector takes 2.8 years on average whereas interim injunction requests are finalized in 18 months approximately.<sup>160</sup> This duration may even go up to 6 years in some cases. As a result of length and non-harmonized patent feature of the market, cost of litigation is considerable. Based on given facts, dominant pharmaceutical companies may litigate their competitors alleging patent infringements just to increase their costs and to exclude them from the market. These actions generally restrain the generic companies’ ability to enter into the market. This is called ‘vexatious litigation’ in the EU law jargon and it may infringe Article 102 if the conditions are fulfilled.<sup>161</sup> First of all, the plaintiff, dominant company in this sense, should have a genuine interest in judicial relief.<sup>162</sup> Then as stated by the General Court,<sup>163</sup> such litigation constitutes an abuse if the conduct cannot be defined reasonable under the rights of company, and the conduct is just aimed to harass competitors or if the conduct is a part of competition elimination plan..

---

<sup>158</sup> Paul Gershlick, ‘Depressing and anxious time for GSK and three generics companies as CMA sends statement of objections over “pay for delay” settlement agreements’ (2014) MAB Law LLP <[www.mablaw.com/2014/11/paroxetine-gsk-pay-for-delay-agreement/](http://www.mablaw.com/2014/11/paroxetine-gsk-pay-for-delay-agreement/)> accessed 12 August 2015.

<sup>159</sup> Louis Kaplow, ‘The Patent-Antitrust Intersection: A Reappraisal’ (1984) 97 Harvard Law Review 1813-1816.

<sup>160</sup> FRSI (n10) 202-253 and 394-415.

<sup>161</sup> Case T-111/96 *ITT Promedia NV v Commission* (1998) ECR II-2937.

<sup>162</sup> Lianos and Dreyfuss (n 50) 83.

<sup>163</sup> *ITT Promedia* (n 163) paras 55-57.

Another abusive approach is ever-greening. Accordingly, dominant companies may supply their own generics to maintain their monopoly in the relevant market before any generic company had entered into market. This provides dominant companies a significant market share in the generic market, while distorting generic companies' incentive to enter into the relevant market. Moreover, dominant companies may also apply life cycle strategies for follow-on products to delay new entries.<sup>164</sup> Accordingly, a dominant company, which holds an IPR, may make minor changes on its product and then, apply for another patent for such product. Dominant firms aim to delay launch of generics with ever-greening, and thereby to maintain their monopolies on the relevant market. Therefore, they may distort competition by preventing new entries, and constitute an abuse.

This article argues that such vexatious behaviours and ever-greening strategies are one of the most serious types of abuse in pharmaceutical sector. First of all, since to bring litigation is a fundamental right, its restriction is really problematic. Secondly, such strategies not only distort competition in the market, but also lead misuse of administrative resources since their sole aim is to extend the monopoly in the market, not to protect their legitimate rights. On the other hand, the sources and parameters of such abusive conducts should be examined very carefully. For example, non-harmonized patent system underpins such conducts since it enables dominant companies to bring separate litigations in various Member States to prevent the generics on different basis. They may also apply for different types of patents in different Member States and they may use this opportunity strategically to exclude one specific generic company out of the market. Therefore, harmonisation or even centralization of EU patent law would relieve the vexatious behaviour problem. Moreover, it should be noted that these kind of strategies' viability is closely related with effectiveness of enforcement system. That is to say dominant companies take an advantage of long-drawn-out of litigation procedure while engaging in these strategies. On the contrary, the more effective and faster litigation process will make vexatious behaviours less profitable. In this sense, not only harmonised patent mechanism but also faster and effective enforcement mechanism may be recommended.

**e. Other Tools**

---

<sup>164</sup> FRSI (n 10) 351.

Abusive conducts are not exhaustive. In regard to its specific features, there may be more abusive strategies in pharmaceutical sector. Some of these strategies will be examined below.

**i. Denigration**

In 2013, FCA gave a very distinct decision for Sanofi Aventis<sup>165</sup> by considering its denigration as an abuse of dominance. Accordingly, FCA fined Sanofi Aventis deciding that Sanofi has abused its dominance position in Plavix product market by denigrating its competing generic products. The FCA stated that, after generic Plavix' entry into French market in 2009, Sanofi abused its dominant position by convincing prescribing doctors to state that Sanofi's Plavix products are not substitutable for the relevant generic products and by persuading pharmacists to sell Sanofi's own generic products instead of other generic products as a substitute of Plavix. As a result, it is argued that an abnormal decline is observed in sales of generic Pavix. Therefore, the FCA concluded that there is a considerable effect on competition as a result of denigration conducts. The case is upheld on the appeal; however it is pending before Court of Cassation.<sup>166</sup>

This distinguished interpretation has two consequences. First of all, this interpretation is a caveat for dominant pharmaceutical companies. They have to be very careful on the way of their promotion as they may be considered outside of competition on the merits if they disparage any other competing product without any proven evidence or lead doubt over the quality or safety of competing products. Secondly, this interpretation highlighted again that abusive strategies are not exhaustive. Therefore, dominant pharmaceutical companies should decide deliberately each of their conducts whether they would lead anticompetitive consequences.

**ii. Refuse to License & Supply**

Refusal of license is one of the most debated issues in the EU when it comes to intersection of IP and competition law after the decision of the CJEU in *Volvo v Vend and CICRA v Renault*.<sup>167</sup> As it is

---

<sup>165</sup> *Sanofi Aventis* (n 15). 'French Competition Authority fines Sanofi-Aventis for hindering the market entry of Plavix generic products' (King&Wood Mallesons, 17 May 2013) <[www.kwm.com/en/uk/knowledge/insights/french-competition-authority-fines-sanofi-aventis-for-hindering-the-market-entry-of-plavix-products-20130517](http://www.kwm.com/en/uk/knowledge/insights/french-competition-authority-fines-sanofi-aventis-for-hindering-the-market-entry-of-plavix-products-20130517)> accessed 12 August 2015.

<sup>166</sup> *Ibid.*

<sup>167</sup> Case 53/87 *CICRA v Renault* [1988] ECR 6039; *Volvo* (n 89).

examined previously, the EU's approach is quite flat though it seems like complicated. Overall, the Commission takes into account how important IPRs for innovation incentive and IPR holders cannot be obliged to license their rights in principle. However, mandatory licensing is possible in the 'exceptional circumstances'. These exceptional circumstances are standardized in *Magill* case.<sup>168</sup> Accordingly, (i) if the product which is refused to be licensed is indispensable for production of new product and<sup>169</sup>, (ii) if the refusal hinders production of new product which has already potential consumer demand and, (iii) if there is no objective justification of refusal; then such refusal constitutes an infringement of competition law.

In addition to pure refusals to license, some other certain abusive conducts established under the case law, such as arbitral refusals to supply, fixing prices at unreasonable levels, decisions to cease production of spare parts<sup>170</sup>, acquisition of patent of an alternative technology<sup>171</sup> or refusal to license with a pure aim of raising the rivals' costs and thereby maintain the remaining monopoly.<sup>172</sup>

In 2006, the Italian Competition Authority deemed that GSK had abused its dominant position in Italy by refusing Fabbrica Sintetici Italiana to grant licence of an active drug ingredient called Sumatriptan Succinato ('SS').<sup>173</sup> According to the Authority, GSK has dominant position in production and marketing of SS not only in Italy but also in Spain which is the sole opportunity for potential competitors to access to SS. Therefore, the Authority concluded that, due to lack of objective justification, such refusal of GSK is hampered competition by preventing potential competitors' access to SS<sup>174</sup> This application of Italian Authority illustrated a version of abusive refuse to license in pharmaceutical sector. However, there may be other forms of abuse which have not been interpreted yet. For example, originators data exclusivity which is protected under the law may be

---

<sup>168</sup> Joined Cases C-241/91 and C-242/91, *Radio Telefis Eireann v Commission* (Magill) ECR [1995] I-743.

<sup>169</sup> *Oscar Brunner* (n 78) para40 and *IMS Health* (n 95) paras 34-40.

<sup>170</sup> *Renault* (n 169) para 9.

<sup>171</sup> *Tetra Pak* (n 116).

<sup>172</sup> Case T-504/93 *Tiercé Ladbroke SA v. Commission* [1997] ECR II-923.

<sup>173</sup> Case A363 *Glaxo-Principi attivi*, Italian Competition Authority, No 15175 of 8 February 2006 published Bulletin 6/2006

<sup>174</sup> International Competition Network, 'Conduct Working Group Questionnaire' 3 <<http://www.internationalcompetitionnetwork.org/uploads/questionnaires/uc%20refusals/italy.pdf>> accessed 12 August 2015

subject to Article 102 assessment if they aimed purely to prevent generic products without any objective justification.

With respect to refusal of supply, the *Sot Lelos* case referral is remarkable. In this case GSK had ceased to supply to particular Greek wholesalers claiming that they were engaging in parallel trade. In response to Greek Authority's referral, Advocate General of *Syfait*<sup>175</sup> judgement highlighted special features of pharmaceutical sector and stated that a pressure on R&D due to actual parallel trade may be considered as an objective justification with respect to pharmaceutical sector.<sup>176</sup> On the other hand, Advocate General in the *Sot Lelos* case took an opposite view and stated that GSK could not prove a causal link between parallel trade and R&D.<sup>177</sup> Despite the fact that it stated pharmaceutical sector deserves a special attention due to its influence on public health, a dominant firm like GSK cannot cease supply to a customer as long as the such customer's orders is not extraordinary.<sup>178</sup> In response to conflict opinions of Advocate Generals, the CJEU<sup>179</sup> did not state about healthcare objectives of GSK in this sense.<sup>180</sup>

As a result of all these given case law illustrations, the first conclusion is lack of settled case law on the practices. This may lead uncertainty in the market considering the increased number of cases and scrutinises. Secondly, the specific features of the sector should be highlighted again. As it is stated by Advocate General in *Syfait*<sup>181</sup>, originator companies may be reluctant to engage R&D if they seriously doubt to cover their expenses. Indeed, particularly in pharmaceutical sector to be subject to internal patent exhaustion system in whole EU and to be subject to different pricing schemes may contribute this disincentive too. In this respect, sector specific regulations<sup>182</sup> and illustrative guidance may be helpful both for companies and decision authorities. Therefore, it is better for authorities to take into account the specific features of the sector and be circumspect while giving abuse decisions.

---

<sup>175</sup> Case C-53/03 *Syfait* [2005] ECR I-8089.

<sup>176</sup> *Ibid*, Opinion of AG Jacobs, paras 89–104.

<sup>177</sup> Joined cases C-468/06 to C-478/06 *Sot. Léllos kai Sia* ECR I-07139, Opinion of AG Ruiz-Jarabo Colome, para 119.

<sup>178</sup> *Ibid* para 49.

<sup>179</sup> Peter Turner-Kerr, 'Finally a bit of clarity for pharmaceutical companies; but uncertainties remain: Judgment of the CJEU in *Sot. Léllos Kai Sia EE v GlaxoSmithKline AVEE*' (2009) 30/2 *European Competition Law Review* 57

<sup>180</sup> *Ibid* 59.

<sup>181</sup> AG Jacobs (n178).

<sup>182</sup> Dan L Burk and Mark A Lemley, 'Policy Levers in Patent Law' (2003) 89 *Vanderbilt Law Review* 1575.

### iii. Price Discrimination

Due to divergent price regulations of Member States, same pharmaceutical products may have different prices around the EU. Therefore, price discrimination in pharmaceutical sector is not only a strategy of individual companies, which requires a substantial market analysis<sup>183</sup>, but also it is a consequence of the market regulations. However, in any case, discriminative prices should be appropriate for the relevant markets' competition conditions and regulatory frameworks.<sup>184</sup> Otherwise, it would be considered as an infringement of competition law.<sup>185</sup> Latvian Competition Authority's fine decision for AGA SIA for its price discrimination without any objective justification constitutes an illustration.<sup>186</sup> Though, there is not any relevant case law in the EU level which interprets merely price discrimination as an abuse yet. However, such price discriminations may lead parallel trade which is legitimate under EU law, in the internal market; and pharmaceutical companies' attempts to prevent such parallel trade are likely to be considered outside of competition on the merits.

### iv. Tying and Bundling

Tying and bundling strategies in pharmaceutical sector may be scrutinized under Article 102, although there is not such an illustration in the EU level. However, in the national level, the FCA's fine decision on Sandoz<sup>187</sup> is remarkable. The FCA stated that Sandoz abused its dominant position in cyclosporine market while supplying university hospitals two cyclosporin based products with a discount under a condition of purchase other Sandoz products. This case law illustrated that such mix bundling strategies may be considered as an infringement of competition law. However, for the rest of possible tying and bundling abuses, sector specific guidance would be helpful for both companies and jurisdictional authorities.

---

<sup>183</sup> Werner Z Hirsch, *Law and Economics, An Introductory Analysis*, (2<sup>nd</sup> ed. Academic Press 1988) 330.

<sup>184</sup> Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969 paras 177–178.

<sup>185</sup> *Astra Zeneca* (n 136).

<sup>186</sup> John Wileur, 'The Limits Imposed by EU Competition Law on Pricing by Dominant Firms in the Life Sciences Sector', (Inside EU Life Sciences, 18 June, 2013) <[www.insideeulifesciences.com/2013/06/18/the-limits-imposed-by-eu-competition-law-on-pricing-by-dominant-firms-in-the-life-sciences-sector-2/](http://www.insideeulifesciences.com/2013/06/18/the-limits-imposed-by-eu-competition-law-on-pricing-by-dominant-firms-in-the-life-sciences-sector-2/)> accessed 06 August 2015.

<sup>187</sup> *Ibid.*

## V. CONCLUSIONS

Boundaries between IP and competition law has been discussed for a long time. Pharmaceutical sector is one of the most debated sectors due to its essential role in health care policies and R&D based character. Following the FRSI, there has been a dramatic increase in the number of competition inquiries and related decisions and cases.

Even though both IP and competition law aim for dynamic efficiency, finding a competition infringement is not easy as it is analysed. Competition law is more sensitive about allocative efficiency in the short-run whereas IP law focus on innovative incentives. As a matter of this fact, the EU authorities lean to economic approach rather than the formalistic view which focus on the scope of IP rights. However, economic approach in the Article 102 enforcement is not always easy. It may lead to more favourable consequences for allocative efficiency which is more predictable than dynamic efficiency.<sup>188</sup> Pharmaceutical sector is mainly based on R&D; therefore competition enforcement in the sector is mainly related with the interface of IP and competition law. As a result, improper competition enforcements would be very costly to pharmaceutical companies, consumers and the states due its importance for healthcare. Therefore, Article 102 enforcement in pharmaceutical sector deserves more careful analysis. The relative market should be defined well as a sole presence of IPR should not constitute dominance. Due to the lack of settled case-law and complex nature of existing decisions; Article 102 enforcement in the sector should be clarified with relative guidance. Moreover, decisive authorities should be more circumspect while applying competition law in this sector.

Moreover, non-harmonised patent system in the EU complicates Article 102 enforcement in the sector. Non-harmonisation on the topic requires pharmaceutical companies to follow national healthcare regulations, pricing and reimbursement requirements as well as national IP laws; and at the same time to act on the merits of the EU competition law. As a result of non-harmonisation, pharmaceutical companies should devote additional expenses to their transactional costs because they are subject to different regulations in the same Common Market. Moreover, non-harmonisation also complicates competition law enforcement and decreases enforcement efficiency. Authorities should

---

<sup>188</sup> Lianos and Dreyfuss (n 50) 50.

take into account that pharmaceutical companies may be subject to different requirements in the defined relative product market. This may lengthen the competition analysis and increase the costs of the decisive authorities. Therefore, as it is pointed out in this article, harmonised patent law would contribute to overcome these efficiency problems. As a matter of fact, recent developments<sup>189</sup> to achieve unitary patent in the EU should be appreciated but should also be expedited.

---

<sup>189</sup> See for developments, Unitary patent: Protecting inventions in 25 countries, <[www.epo.org/news-issues/issues/unitary-patent.html](http://www.epo.org/news-issues/issues/unitary-patent.html)> accessed 12 August 2015.