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## **Patenting Strategies of the EU Pharmaceutical Industry – Crossroad between Patent Law and Competition Policy**

Nicoleta Tuominen<sup>(\*)</sup>

### **Introduction**

The pharmaceutical sector inquiry carried out by the European Commission in 2008 provides a useful framework for assessing the relationship between the patent system on the one hand and competition policy and law on the other hand. The pharmaceutical market is not only specifically regulated. It is also influenced by the special characteristics of the patent system which enables pharmaceutical companies engaged in research activities to enter into additional arrangements to cope with the competitive pressures of early patent application and the delays in drug approval. Patents appear difficult to reconcile with the need for sufficient and adequate access to medicines, which is why competition expectations imposed on the pharmaceutical sector are very high. The patent system and competition law are interacting components of the market, into which they must both be integrated. This can result in competition law taking a very strict view on the pharmaceutical industry by establishing strict functional performance standards for the reliance on intellectual property rights protection granted by patent law. This is in particular because in this sector the potential welfare losses are not likely to be of only monetary nature. In brief, the more inefficiencies the patent system produces, the greater the risk of an expansive application of competition law in this field.

The aim of the present study is to offer a critical and objective view on the use or abuse of patents and defensive strategies in the pharmaceutical industry. It shall also seek to establish whether patents as presently regulated offer an appropriate degree of protection of intellectual property held by the economic operators in the pharmaceutical sector and whether there is a need or, for that matter, scope for improvement.

A useful starting point for the present study is provided by the pharmaceutical sector competition inquiry (hereafter “the sector inquiry”) carried out by the European Commission during the first half of 2008. On 8 July 2008, the Commission adopted its Final Report pursuant to Article 17 of Regulation 1/2003 EC, revealing a series of “antitrust shortcomings” that would require further investigation<sup>1</sup>.

### **I. The Unique Nature of the European Pharmaceutical Industry**

The findings of the Commission sector inquiry as presented in the Final Report have been subject to strong criticism notably on the part of the industry but also by academics and other commentators. To better understand those arguments it would seem helpful to begin

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<sup>1</sup> European Commission Press Release of 8.07.2009, IP/09/1098. Available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1098&format=HTML&aged=0&language=EN&guiLanguage=en>, accessed on 18 March 2011.

with a brief overview of the basic features that influence and make the sector in the European Union so unique. In legal literature those features have been identified to include: “(...) i) *the need for a strong pharmaceutical sector in Europe*; ii) *the need for the industry to be able to fund research and development independently*; iii) *price controls and purchase arrangements maintained by the Member States*; iv) *failure to appreciate that the pharmaceutical industry is in business*; v) *realising the single market*; and vi) *the Community competition rules*.”<sup>2</sup>

The process behind the discovery, production and ultimately the distribution of drugs differentiates the pharmaceutical sectors from any other industry<sup>3</sup>. As concluded in the Single Market Law Review on the pharmaceutical sector in the European Union<sup>4</sup>, the pharmaceutical market is a highly fragmented one, where specific conditions are treated with specific medicine and where individual products hold very little market share on national markets; similar medicine is used in most Member States, especially for serious diseases to the extent that a potentially pan-European market in medicine has emerged; the industry engages in innovation, production, marketing and distribution, it comprises companies of various sizes<sup>5</sup>, of which the large ones are engaged in R&D and have extended their business operations to cover also markets outside the European Union.

## 1. The Market

The global pharmaceutical market accounted for an estimated € 484,130 million (\$ 663,500 million) at ex-factory prices in 2007, the North American market (USA & Canada) remaining the largest market with a 45.9% share, while Europe covered 31.1% of the market.<sup>6</sup> Distribution margins and VAT rates differ considerably between Member States (the rate of VAT on medicine is 3% in Luxemburg as compared with 25 % in Norway, Denmark and Sweden) and approximately 36% of the retail price of medicine returns to the distributors and the State.<sup>7</sup> According to the European Commission’s Final Report of the Pharmaceutical Sector Inquiry, “in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices”<sup>8</sup>, which makes it significantly more profitable than any other sector of the manufacturing industry.

<sup>2</sup> Russell Graeme Hunter, *The Pharmaceutical Sector in the European Union: Intellectual Property Rights, Parallel Trade and Community Competition Law*, Juristförlaget, Stockholm, 2001, p. 5.

<sup>3</sup> Subseries I: Impact on Manufacturing, Vol. 2: Pharmaceutical Products, ‘The Pharmaceutical Sector in the EU’, (1997), *The Single Market Review*, p. 99.

<sup>4</sup> *Ibid.*

<sup>5</sup> *Ibid.*, p. 103.

<sup>6</sup> European Federation of Pharmaceutical Industries and Associations, (EFPIA hereafter), *The Pharmaceutical Industry in Figures*, Edition 2009, p. 14, EFPIA Publication. Available at: <http://www.efpia.eu/content/default.asp?PageID=559&DocID=4883>, accessed on 18 April 2010.

<sup>7</sup> *Ibid.*

<sup>8</sup> Commission Communication, of 8 July 2008, *Executive Summary of the Pharmaceutical Sector Inquiry Report*, p. 1. Available at: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf), accessed on 23 April 2010.

Manufacturers of “generics”<sup>9</sup> can play an important role on the European pharmaceuticals markets albeit geographically their market shares vary considerably from one country to another. The market share of generics is for instance as high as 74% in Croatia and as little as 7.2 % in Spain and in general it would seem that their market shares tend to be higher in new EU Member States, which is mostly due to the formerly low levels of intellectual property protection in those Member States<sup>10</sup>. Delays in generic entry have a significant economic impact as prices for generics are on average 25% lower than prices of originator medicines before patent expiry<sup>11</sup>.

## 2. Major Issue: Research and Development

Before being fit for marketing, medicine requires intense investments on the part of the pharmaceutical companies. *“The latest study released (...) estimated the average cost of researching and developing a new chemical or biological entity at €1,059 million.”*<sup>12</sup>

Almost all R&D costs are financed from the industry’s own resources. As the Commission observed<sup>13</sup>, 90% of R&D is industry-financed and, that is an ability that should be preserved due to the risks inherent in such high investments. Moreover, the R&D costs constitute a high entry barrier. Companies are indeed difficult to replace if they disappeared from the market<sup>14</sup> and fewer pharmaceutical companies translates in fewer new products being developed in the future.

Chances of isolating a substance with therapeutic value are relatively small, with several estimates ranging from 1 in 5,000 to 1 in 10,000<sup>15</sup>. As Valentine Korah expressed it: *“(...) most attempts to find a cure for particular problems by the pharmaceutical companies do not work. Of those that do, many never get far through their safety trials. So a small loss is made on most drugs. A few almost get to the market, but then some side effect appears and those cost the inventor a great deal. Only a few drugs are successful and the company must make a large profit on these to make up for the losses on the other, or R&D will not be worthwhile”*.<sup>16</sup>

Thus not every attempt to develop a new medicine turns out to be a commercial success such as Prozac. Sometimes there are tragedies like Thalidomide<sup>17</sup> and numerous

<sup>9</sup> “Generics are usually produced by a manufacturer who is not the inventor of the original product, and are marketed when intellectual property protection rights are exhausted. *“The Pharmaceutical Industry in Figures...” supra* note 6, p. 17.

<sup>10</sup> *Ibid.*

<sup>11</sup> Commission Communication, *supra* note 8, p. 9.

<sup>12</sup> EFPIA, *A highly regulated industry*, Available at: <http://www.efpia.org/content/Default.asp?PageID=361>, accessed on 18 March 2011.

<sup>13</sup> Communication from the Commission to the Council and the European Parliament on the Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community, COM (93) 718 final (Brussels, 02.03.1994), p. 5.

<sup>14</sup> Alfonso Gamarrella, Luigi Orsenigo, Fabio Pammolli, *Global Competitiveness in Pharmaceuticals: A European Perspective*, November, 2000, p. 16. Available at: [www.pharmacos.eudra.org](http://www.pharmacos.eudra.org), 18 March 2011.

<sup>15</sup> EFPIA, *supra* note 13.

<sup>16</sup> Valentine Korah, “Merck v. Primecrown – The Exhaustion of Patents by Sale in a Member State where a Monopoly Profit Could not be Earned”, (1997) 4 *ECLR* 273.

<sup>17</sup> Wikipedia, *Thalidomide*, Available at: <http://fr.wikipedia.org/wiki/Thalidomide>, accessed on 18 March 2011.

drugs turn out to be of no therapeutic value after having exhausted important R&D resources.<sup>18</sup>

The process of bringing a new medicine on the market is estimated to take on an average 10-13 years. While 5000 molecules are initially tested, 250 will enter into preclinical testing, 10 into clinical development and only 1 will be approved by the regulatory authorities and released on the market, where only 3 out of 10 medicines produce revenues matching or exceeding R&D costs before patent expiry<sup>19</sup> and intense generic competition.

However the business activities of pharmaceutical companies remain extremely profitable<sup>20</sup> and it would seem that in the pursuit of those profits they are not exhausting all their resources in R&D. It is indeed interesting to note that at least in the case of some products R&D expenses incurred by the industry are exceeded by their marketing costs.<sup>21</sup>

### 3. Price Controls and Purchase Arrangements

The pharmaceutical sector is one where clients can impose their will, given that the most significant customers consist in the national healthcare systems of the Member States. Price controls limiting the emerging of a fully competitive market in pharmaceuticals are therefore a common feature and a frequently used instrument in this field.<sup>22</sup>

The Treaty on the Functioning of the European Union provides that: “*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*”<sup>23</sup>

A provision like that begs the question as to whether such an objective can coexist with the governments endeavour to reduce public spending as their recourses are often on short supply. From this perspective, price controls and purchase arrangements do seem as very tempting tools and not entirely objectionable.

Obviously, market-based pricing for reimbursed pharmaceuticals would be the industry’s favourite solution. Nevertheless, close collaboration between governments and the industry might deliver the much expected change towards enhanced competitiveness, which would lead to more efficiency in the healthcare systems.<sup>24</sup>

Pharmaceutical companies require that the price society is prepared to pay for an innovative medicine “*should reflect the value it delivers to patients, healthcare systems, and society at large.*”<sup>25</sup> However, this argument is untenable, since the value of a patent consists

<sup>18</sup> Stephen Kon, Fiona Schaeffer, “Parallel Imports of Pharmaceutical Products: A New Realism, or Back to Basics”, (1997) 3 *ECLR* 124.

<sup>19</sup> EFPIA, *supra* note 13.

<sup>20</sup> Carinne Bruneton, [e-med] *Industrie Pharmaceutique: Protéger ses profits*. Available at : <http://www.essentialdrugs.org/emed/archive/200410/msg00053.php>, accessed on 18 March 2011.

<sup>21</sup> Barry Bleidt, “Recent Issues and Concerns about Pharmaceutical Industry Promotional Efforts”, (1992) Vol. 22, No. 2, *Journal of Drug Issues*, pp. 413-414.

<sup>22</sup> Hunter, *supra* note 2, p. 10.

<sup>23</sup> Article 168 (1) TFEU (ex 152 EC).

<sup>24</sup> EFPIA, *Policy Principles for a Competitive Healthcare Environment*, p. 1. Available at : <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=3826>, accessed on 18 March 2011.

<sup>25</sup> *Ibid*, p. 4.

of that what the market is willing to pay for it<sup>26</sup>. Nevertheless, if governments negotiated only for the prices of medicine they will purchase or reimburse, allowing for sales outside the state reimbursement system to be subjected to the normal market rules, this could solve to some extent the problems of market distortion.<sup>27</sup>

Another conflict is the one between the Commission's objectives of finalising the Single Market for pharmaceuticals and the exclusive right of Member States to determine their own healthcare policies<sup>28</sup>. The conflict could be solved if Member States would agree on a complete harmonisation of prices at the EU level, although this might jeopardise the increase in social welfare through price discrimination<sup>29</sup>. Pharmaceutical price policies should also be assessed with due consideration to the effectiveness of the patent system in general<sup>30</sup>. The value of a patent should be determined by what the market would be willing to pay for the medicines, which is why pricing policies inevitably diminish the value of patents.

#### 4. Conflicting Interests in the Pharmaceutical Sector

Another defining feature of the pharmaceutical sector is that there are conflicting interests between the industry and those empowered to regulate the market. Whereas originator companies strive for longer patent exclusivity the European Commission and National Competition authorities tend to prioritise compliance with Community and national competition rules over IPR.

Intellectual property rights undoubtedly play an important role in fostering medical and scientific progress. According to the originator companies<sup>31</sup>, IPR only enable them to recoup their R&D investment and compensate for the risks they have assumed<sup>32</sup>. In this regard, the industry argues that "the patent system balances the interests of the inventor with the broader interests of society at large,"<sup>33</sup> since they are a means for the inventor to eliminate "free riders" and for the society to increase its knowledge base<sup>34</sup>.

In addition, because of long clinical testing, registration process and market access delays, instead of the full lifetime of a patent which on average is 20 years, medicines only enjoy roughly from 8 to 10 years effective protection,<sup>35</sup> since normally patent applications are

<sup>26</sup> Hans Ullrich, "Lizenzkartellrecht auf dem Weg zur Mitte", (1996), *GRUR Int.*, p. 564.

<sup>27</sup> EFPIA, Policy Principles, *supra* note 25, p. 5.

<sup>28</sup> Klaus Stegemann, "International Price Discrimination and Market Segmentation for Patented Pharmaceuticals in the EU. A Social Welfare Analysis", in Inge Govaere, Hanns Ullrich (eds.), *Intellectual Property, Public Policy and International Trade*, "College of Europe Series" No 6, Brussels, P.I.E. Peter Lang, 2007, p. 167.

<sup>29</sup> *Ibid.*

<sup>30</sup> Carsten Fink, "International Price Discrimination and Market Segmentation for Patented Pharmaceuticals in the EU. A Social Welfare Analysis – A Comment", in Inge Govaere, Hanns Ullrich (eds.), *Intellectual Property, Public Policy and International Trade*, "College of Europe Series" No 6, Brussels, P.I.E. Peter Lang, 2007, p. 171.

<sup>31</sup> EFPIA, *Competition occurs through successful R&D*. Available at: <http://www.efpia.org/Content/Default.asp?PageID=538>, accessed on 18 March 2011.

<sup>32</sup> EFPIA, *FACTSHEET: Understanding patents and their vital role in medicine discovery*, p. 1. Available at: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=5348>, accessed on 18 March 2011.

<sup>33</sup> *Ibid.*

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

<sup>35</sup> EFPIA, *supra* note 32.

filled early in the research phase. Although most profits from a branded pharmaceutical are derived during the first five- to eight-years of market exclusivity<sup>36</sup> the relatively short period of legal protection may diminish originator companies' possibilities of receiving an adequate return on their investments. The EU has to some extent acknowledged this problem and introduced a Supplementary Protection Certificate, ensuring a maximum of 15 years market exclusivity for new products<sup>37</sup>.

Another reason why originators require longer exclusivity is the threat of generics. Whatever the exact cost of an originator product market entry might be, *"the cost to a generic of obtaining approval is orders of magnitude below that needed to bring an innovative product to market. Further, as a general rule, it is technically easy for a generic company to copy an innovative small molecule product"*.<sup>38</sup>

More compelling than the high difference in market entry costs between originator products and generics, is the fact that while innovator companies incur high R&D risks, the generic manufactures assume little or no risk at all. The regulatory approval is not difficult to obtain since the product will be entering an already existing market<sup>39</sup>.

It is therefore evident that IP exclusivity is necessary in order for companies to be interested in pursuing innovation.

Even the EC legislator has stated: *"without effective means of enforcing intellectual property rights, innovation and creativity are discouraged and investment diminished."*<sup>40</sup>

The Directorate General for Enterprise and Industry of the European Commission considers that the European pharmaceutical sector is at a competitive disadvantage compared to the American pharmaceuticals producers and suggests that measures should be taken to strengthen the position of European producers<sup>41</sup>. The relevant question in this context is "what type of competition"<sup>42</sup> would be to the benefit of consumers. Given the unique nature of the pharmaceutical industry it may be argued that the Commission should apply competition rules in a manner that differs from the way they are applied to undertakings in other sectors. This view appears to be accepted by the Commission, which in its *Lederle-*

<sup>36</sup> Robin Daly, Mick Kolassa, *Start Early, Sell More, Sell Longer*, (2004), Pharma Exec., pp. 8-20, as cited by Robin Mitchell, Debra Bingham, in *Rules to Live or Die By For Life Cycle Management*. Available at: <http://www.pharmaquality.com/ME2/Audiences/dirmod.asp?sid=325598564E8C4B3EB736C7159241312D&nm=Browse+Articles&type=Publishing&mod=Publications%3A%3AArticle&mid=D3E3C719D8D44216836DCA4F4144BEC4&AudID=5648A5C28C97462DBBDB309539B820EF&tier=4&id=2482698BE7B7474F8A875B62C100DD58>, 18 March 2011.

<sup>37</sup> EFPIA FACTSHEET, *supra* note 31.

<sup>38</sup> EFPIA, *Intellectual Property and Pharmaceuticals*, p. 15. Available at: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4901>, accessed on 18 March 2011.

<sup>39</sup> *Ibid.*

<sup>40</sup> Council Directive 2004/48/EC, of 29 April, 2004, on the enforcement of intellectual property rights, Recital 3, OJ L 195/16–25.

<sup>41</sup> Hunter, *supra* note 2, p. 13.

<sup>42</sup> *Ibid.*, p. 14.

*Praxis Biologicals* decision<sup>43</sup> refused to apply the general rule on compulsory licensing as established in *Magill*<sup>44</sup> to the pharmaceutical sector exactly because of its special nature.

In *Lederle-Praxis Biologicals*, the Commission held that: “(...) *at the current stage of Competition law, it is highly doubtful whether one could impose an obligation upon a dominant form remedy to ensure the maintenance of effective competition in the national ... markets, to share its intellectual property rights with third parties to allow them to develop, produce and market the same products...which the alleged dominant firm is also seeking to develop, produce and market. This was judged to be all the more precarious in sectors such as the vaccine sector where R&D requires high investment. Even a simple refusal to supply could not be considered as an abuse as Lederle was not an existing customer that had found itself in a situation of factual dependence.*”<sup>45</sup>

However, the Commission is not always consistent in this view, as evidenced by the *Bayer-Adalat* decision<sup>46</sup>, where the Commission appeared to be encouraging parallel trade to the detriment of originators. Such lack of consistency together with other market distorting factors does seem to offer a potential justification for the industry to engage in defensive strategies<sup>47</sup>.

A constructive approach to remedying the competitiveness deficit within the pharmaceutical sector could be found through ensuring an adequate level of IP protection rather than by promoting parallel trade over originator producers.<sup>48</sup> As Russell G. Hunter concluded: “*This [the pharmaceutical industry] is an environment typified by imperfect competition, where the legislative and judicial organs of the Community must maintain a balance between realising the Single Market while respecting the function and integrity of IP rights, as well as ensuring the social element of the pharmaceutical industry is not sacrificed on the altar of the Single Market. Unlike other sectors, the barriers to entry are such as to naturally exclude new entrants – for the pharmaceutical industry requires huge sums to be invested with no guarantee of any return and high risk of failure. There is no scope for pursuing the wrong economic policy in a market in which the chances of success are between 0.02 and 0.03% of a successful new discovery.*”<sup>49</sup>

## II. Legal Tools for Protecting IP for Pharmaceuticals

In the pharmaceutical sector in the European Union, the industry has the following legal instruments at its disposal for intellectual property rights protection: patents, supplementary protection certificates, regulatory data protection and a 10-year market

<sup>43</sup> Commission Decision 94/770/EC, of 6 October 1994, relating to a proceeding pursuant to Article 85 of the EC Treaty (now Article 101 TFEU) and Article 53 of the EEA Agreement (IV/34.776 – Pasteur Merieux – Merck), 1994, OJ L309/94, pp. 1-23.

<sup>44</sup> Joined Cases C-241 & C-242/91 P, RTE and ITP v Commission, [1995] ECR I-00743.

<sup>45</sup> Cited in See Hunter, *supra* note 2, p. 15.

<sup>46</sup> Commission Decision 96/478/EC, of 10 January 1996, relating to a proceeding under Article 85 of the EC Treaty (now 101 TFEU), OJ L201/96, pp. 1-77.

<sup>47</sup> Hunter, *supra* note 2, p. 15.

<sup>48</sup> *Ibid.*

<sup>49</sup> *Ibid.*, p. 16.

exclusivity for orphan drugs (drugs used for the treatment of rare conditions)<sup>50</sup>. As regards the latter, the European legislator has explicitly recognised the need to encourage the research also in drugs of little demand, stating that in the case of extremely rare conditions, which would not allow for the R&D costs to be recouped by the expected sales, a special level of protection would be justified.<sup>51</sup>

## 1. Patents

Despite the fact that the patent system is not completely harmonised within the EU, it is a fair assumption that the patent systems of the Member States are roughly similar<sup>52</sup>. This is because of the harmonising effect of the TRIPS Agreement, Member States are parties to the European Patent Convention 2000<sup>53</sup> and the fact that Member States have adopted some key provisions of the Community Patent Convention.

The EPO grants patents only if the invention is patentable<sup>54</sup>, i.e. the invention is novel<sup>55</sup>, inventive<sup>56</sup> and susceptible of industrial application<sup>57</sup>. Patent claims can be filed either with the national patent offices or with EPO, in which case, the patent will “confer on its proprietor from the date of publication of the mention of its grant, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State”.<sup>58</sup> The period of protection is 20 years from the date of the filing<sup>59</sup>.

According to Art. 28 of the TRIPs Agreement<sup>60</sup>, patents create a general negative obligation by which third parties are forbidden to manufacture, market or import for such purposes the product, and if the patent concerns a process, third parties are precluded from using or marketing that process. Patents also create rights for their holders. They can assign,

<sup>50</sup> Council Regulation 141/2000, of 16 December 1999, on Orphan Medicinal Products, [22. 1. 2000], OJ L 18/1.

<sup>51</sup> *Ibid*, paras. 1-2.

<sup>52</sup> EFPIA, *Intellectual Property and Pharmaceuticals*, p. 16. Available at: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4901>, accessed on 19 April 2010.

<sup>53</sup> Convention on the Grant of European Patents (European Patent Convention), of 5 October 1973, as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998 and 27 October 2005 and comprising the provisionally applicable provisions of the act revising the EPC of 29 November 2000.

<sup>54</sup> Art. 52 (EPC) – Patentable inventions: “1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.”

<sup>55</sup> Article 54 (EPC) – Novelty: “(1) An invention shall be considered to be new if it does not form part of the state of the art. (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.”

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

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

<sup>58</sup> See Art. 64 of the EPC.

<sup>59</sup> See Art. 63 of the EPC.

<sup>60</sup> Article 28 of TRIPS: “1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.”

transfer by succession or conclude licensing agreements. However, such right can be enforced only by the holder of the patent (or by an exclusive licensee) in legal infringement proceeding and to the extent that the patent is valid<sup>61</sup>.

In the pharmaceutical sector, patent applications are filed very early in the R&D process, which diminishes considerably the 20-year protection period.

Most patent filing by European pharmaceutical companies are made in accordance with the Patent Cooperation Treaty (PCT), because it gives the possibility of designating almost 140 countries. Some are filed with the EPO and others with the Member States' patent offices<sup>62</sup>.

When filing with the EPO, the patent application undergoes a thorough examination, which is why patents approved by EPO are considered to be of a very high quality.<sup>63</sup> Applicants can put forward arguments in support of the patentability of their inventions, which can consist of technical data and expert reports.<sup>64</sup> Third parties can, also anonymously, file observations against patent application<sup>65</sup>, to which the applicant has the opportunity to respond.<sup>66</sup> If an application is rejected, the applicant can lodge an appeal, which is then decided by the Appeal Board<sup>67</sup>.

## 2. Supplementary Protection Certificates

In response to the perceived insufficiency of the period of protection offered by patents, the Council of Ministers made an effort to bring about a remedy by adopting its Regulation 1768/92<sup>68</sup> which introduced the Supplementary Protection Certificate. The recitals 2 and 3 of the Regulation state that: *"[M]edicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research ... [A]t the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research."*

In terms of its effects the certificate functions much like a regular patent<sup>69</sup> as it extends the initial patent protection by up to 5 years<sup>70</sup>. However, the patent holder cannot enjoy more than 15 years of combined patent and SPS exclusivity from the first authorisation

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<sup>61</sup> EFPIA., *supra* note 53, p. 17.

<sup>62</sup> *Ibid.*

<sup>63</sup> *Ibid.*, p. 18.

<sup>64</sup> *Ibid.*

<sup>65</sup> In 2006, 5.4% of applications have been opposed to. See European Patent Office Annual Report 2006. Available at <http://www.epo.org/about-us/office/annual-reports.html>, accessed on 18 March 2011.

<sup>66</sup> EFPIA, *supra* note 53, p. 19.

<sup>67</sup> *Ibid.*

<sup>68</sup> Council Regulation 1768/92, of 18 June 1992, concerning the creation of a supplementary protection certificate for medicinal products, [2.7.1992] OJ L 182.

<sup>69</sup> See Art. 5 of the Council Regulation 1768/92.

<sup>70</sup> See Art. 13 of the Council Regulation 1768/92.

in the Community<sup>71</sup>. The certificate can be given in respect of products already enjoying the protection of a valid patent<sup>72</sup> and if different parties hold patents relating to the same product, each of them is entitled to a separate SPC<sup>73</sup>.

In *Novartis AG and others v. Comptroller-General of Patents Designs and Trade Marks for the United Kingdom*, and *Ministre de l'Économie v Millennium Pharmaceuticals Inc.*,<sup>74</sup> the ECJ held that the SPC for medical products “is to take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the territory of one of the States covered by the EEA Agreement, reduced by a period of five years.”<sup>75</sup>

Additional IP protection for exclusive rights against imitation is granted through Regulation EC 1901/2006<sup>76</sup>. This Regulation requires for the release of a marketing authorisation relating to the use of a product on children (unless a waiver or deferral is granted), that a paediatric investigation plan is established and data is submitted to the European Medicines Agency<sup>77</sup>. As compensation for conducting the paediatric research, the patent holder which qualifies for an SPC or the holder of an SPS is entitled to a 6-month extension of the protection period<sup>78</sup>.

### 3. Regulatory Data Protection

“Regulatory data protection (“RDP”) is a form of exclusive right enforced through the marketing authorisation procedure.”<sup>79</sup> An originator company when releasing a new medicine on the market must provide vast amount of information on its product<sup>80</sup> in order to obtain the necessary market authorisation<sup>81</sup>. However, in order for a subsequent generic manufacturer to bring the same product on the market it must either generate its own data or wait a certain

<sup>71</sup> See Recital 8 of the Council Regulation 1768/92.

<sup>72</sup> See Art. 4 of the Council Regulation 1768/92.

<sup>73</sup> See Article 3(2) of Regulation 1610/96, of 23 July 1996, concerning the creation of a supplementary protection certificate for plant protection products, [8.8.1996], OJ L 198, According to the Recitals of Regulation 1610/96, the provisions of Article 3(2) are for the interpretation of Article 3 of Regulation 1768/92.

<sup>74</sup> Cases C-207/03 *Novartis v. Comptroller General* and C-252/03 *Ministre de l'Economie v Millenium Pharmaceuticals*, [2005] RPC 33.

<sup>75</sup> *Ibid.*, para. 26.

<sup>76</sup> Council Regulation 1901/2006, of 12 December 2006, on medicinal products for paediatric use, amending Regulation (EEC) 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) 726/2004, [27.12.2006] OJ L 378.

<sup>77</sup> See Art. 15 of Regulation 1901/2006.

<sup>78</sup> EFPIA, *supra* note 53, p. 20.

<sup>79</sup> *Ibid.*

<sup>80</sup> *Ibid.*

<sup>81</sup> See Art. 6(1) of Council Directive 2001/83/EC, of 6 November 2001, on the Community Code Relating to Medicinal Products for Human Use, (28/11/2004) OJ L–311, as amended by Directive 2002/98/EC, of the European Parliament and of the Council, of 27 January 2003, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, (08/02/2003), OJ L–33, by Directive 2004/24/EC of the European Parliament and the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use, (30/04/2004) OJ L–136, and by Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004, (30/04/2004) OJ L–136.

period until it would be permitted to rely on the data provided by the innovator<sup>82</sup>. Such an approach seems to be in compliance with Article 39(3) of TRIPs which states: “*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*”

The generic manufacturer’s application for authorisation can be described as “abridged” and can only be used after defined periods of time<sup>83</sup>: firstly, no valid application using the abridged procedure can be made in the first 8 years from the date of first authorisation in the Community, after the initial 8 years, requests for generic authorisation can be made, but actual marketing cannot take place before 10 years from the first Community authorisation have elapsed. An additional delay of generic entry exists if the originator obtains approval of new therapeutic indications.

However, in practice the exclusivity rendered by the RDP is weak because of several reasons<sup>84</sup>. For instance, the RDP period overlaps with any patents or SPCs and is very likely to expire before them. In addition, once the RDP period expires, manufacturers of generics can seek approval to launch their products, independently of existing patent, in which case the patent holder is entitled to initiate infringement proceedings, but only after the generic product has been placed on the market. In conclusion, RDP would only be relevant if there was no other IP protection.

### III. Strategic Patenting of Pharmaceuticals in the European Union

#### 1. Introduction to ‘Evergreening’

In the final report of the European Commission’s sector inquiry<sup>85</sup>, the Commission identifies a series of originator patent strategies, which it describes as aiming “to extend the breadth and duration of their patent protection”<sup>86</sup> and “to delay or block the market entry of generic medicines”<sup>87</sup>. Such strategies are: patent thickets/ clusters, secondary or follow-on-patents and defensive patenting. At the same time, the Commission recognises that “patents are key in the pharmaceutical sector, as they allow companies to recoup their often very considerable investments and to be rewarded for their innovative efforts”<sup>88</sup>, which is why

<sup>82</sup> See Art. 10 of Directive 2001/83/EC.

<sup>83</sup> *Ibid.*

<sup>84</sup> EFPIA, *supra* note 53, p. 21.

<sup>85</sup> European Commission, *Communication from the Commission - Executive Summary of the Pharmaceutical Sector Inquiry Report*. Available at:

<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, accessed on 18 March 2011.

<sup>86</sup> Commission Communication, *supra* note 87, p. 11.

<sup>87</sup> *Ibid.*

<sup>88</sup> European Commission, *Pharmaceutical Sector Inquiry Preliminary Report (DG Competition Staff Working Paper)*, of 28 November 2008, p. 5. Available at:

competition rules should not be applied in the same manner as they would in other technology areas<sup>89</sup>.

As discussed in Section III, a patent is an exclusive right given to the inventor or his licensee, for a period of 20 years, in exchange of having disclosed the invention. It is the reward for enlarging the knowledge base of mankind. However, some innovator companies seek to extend this period of patent protection. For this purpose, they make use of a practice called 'evergreening', which is defined as follows: *"Evergreening' refers to different ways wherein patent owners take undue advantage of the law and associated regulatory process to extend their IP monopoly particularly over highly lucrative 'blockbuster drugs' by filing disguised/ artful patents on an already patent-protected invention shortly after expiry of the 'parent' patent. These artful patents tend to protect delivery profiles, packaging, derivatives, and isomeric forms, mechanism of action, dosing regimen, and dosing rage, and dosing route, different methods of treatment, combinations, screening methods, biological targets and field of use for the same old molecule."*<sup>90</sup>

'Evergreening' raises numerous fundamental questions. It allows innovator companies to recover high R&D costs and provides an instrument for innovators to obtain legal protection for any improvements that they may have made to their inventions<sup>91</sup>. At the same time, multiple patents on the same product can prolong the exclusivity that the patentee enjoys<sup>92</sup> and, organising entire patent portfolios on the basis of what is commonly termed as "lucrative molecules" can result in potential loss to competitors, as their market entry would be delayed or completely blocked<sup>93</sup>. Although 'evergreening' can occur in any industry, it is said to be more frequent in the pharmaceutical sector where "patents cover such aspects of drugs as their active ingredient, formulations, methods of medical treatment, method of manufacturing, and chemical intermediates"<sup>94</sup>.

## 2. Innovator Product vs. Generic - Extended Patents

In relation to generic manufacturers, originators use patenting practices, aiming at replacing the original preparation by similar follow-on-products through simple proprietary modifications and / or name changes, and subsequently placing them on the market just before the expiry of the exclusivity so that they can assume the economic role of the original

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[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary\\_report.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf), accessed on 18 March 2011.

<sup>89</sup> Stephen Mavroghenis, *Article 82 EC and Strategic Patenting – Patent Thickets, Defensive Patents, and Follow-on Patents*, p. 4. Available at: [http://www.droit.ulg.ac.be/ieje/fileadmin/IEJE/Pdf/Mavroghenis\\_Strategic\\_Patenting\\_and\\_Article\\_82\\_EC.pdf](http://www.droit.ulg.ac.be/ieje/fileadmin/IEJE/Pdf/Mavroghenis_Strategic_Patenting_and_Article_82_EC.pdf), accessed on 18 March 2011.

<sup>90</sup> Inderjit Singh Bansal, Deeptymaya Sahu, Gautam Bakshi, Sukhjeet Singh, "Evergreening – A Controversial Issue in the Pharma Milieu", (2009) Vol. 14 *Journal of International Property Rights*, p. 299.

<sup>91</sup> GlaxoSmithKline Briefings, *Evergreening*. Available at: <http://www.gsk.com/policies/GSK-and-evergreening.pdf>, accessed on 18 March 2011.

<sup>92</sup> See Sarah Beth Myers, "A Healthy Solution for Patients and Patents: How India's Legal Victory Against A Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights," (2008), 10 *Vanderbilt Journal of Entertainment and Technology Law*. 763.

<sup>93</sup> Bansal, *supra* note 90, p. 2.

<sup>94</sup> John R. Thomas, *Patent "Evergreening": Issues in Innovation and Competition*, p. 4. Available at: [http://ipmall.info/hosted\\_resources/crs/R40917\\_091113.pdf](http://ipmall.info/hosted_resources/crs/R40917_091113.pdf), accessed on 18 March 2011.

specimen<sup>95</sup>. The manufacturer of the original product seems less interested in obtaining the broadest possible patent basis for his first generation drug, than in the further course of product's life cycle, i.e. he tries to develop innovative patentable variations which will enable him to extend the first product life cycles<sup>96</sup>.

After patent expiry, generic manufacturers can file an application for an equivalent innovator drug. However, this also means that "a prodigious amount of investment is at risk for innovator companies"<sup>97</sup>. To protect their interests, as previously stated, originator companies engage in 'evergreening' strategies. While such defensive strategies are frequently used in the pharmaceutical sector, comparable practices of patent applications are not unprecedented in other industries either.

## 2.1. Patent "thickets" or "clusters"

Patent 'thickets' or patent 'clusters' are formed when "originators file numerous broad and 'weak' patents around the original molecule patent."<sup>98</sup> Divisional patent applications split parent patent application into one or several narrower patent applications<sup>99</sup>.

Clusters and thickets have the effect of increasing the uncertainty of the generic manufacturer regarding the originator's IP rights when it attempts to enter the market<sup>100</sup>, because it cannot properly assess the scope of the innovator's IP portfolio. Generics are left with two options: either to wait until all the patents forming the patent family have expired, or to apply for a marketing authorisation and run the risk of litigation<sup>101</sup>. Hence, such practices can have the effect of limiting competition, which raises the question as to whether they might contravene the relevant provisions of TFEU? The answer to such a question will obviously depend on the particular facts and circumstances present in each case. However, there are some general arguments and considerations to be borne in mind in this context.

It has been suggested that when clusters serve the sole purpose of eliminating potential competition, "this is not in line with the underlying objectives of the patent system and is anti-competitive"<sup>102</sup>. The European Commission in its turn seems to take the view that legitimate business practices cannot become illegitimate simply by their cumulative application<sup>103</sup>, but that there clearly is a problem if permissible patenting and enforcement practices can be used in cases where there is little or no legal justification for them<sup>104</sup>.

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<sup>95</sup> Hanns Ullrich, "Wahrung von Wettbewerbsfreiäumen innerhalb der Schutzrechtsverwertung", *Die Sektoruntersuchung Pharma - kartellrechtliche Disziplinierung des Patentsystems? Symposium 17 Juli 2009 München - Vorträge und Materialien*, Bücher Carl Heymanns Verlag.

<sup>96</sup> *Ibid.*

<sup>97</sup> Bansal, *supra* note 90, p. 4.

<sup>98</sup> Mavroghenis, *supra* note 91, p. 5.

<sup>99</sup> *Idem*, p. 6.

<sup>100</sup> Mavroghenis, *supra* note 91, p. 7.

<sup>101</sup> European Generic Association, *Evergreening of Pharmaceutical Market Protection*. Available at: <http://www.egagenerics.com/gen-evergrn.htm>, accessed on 18 March 2011.

<sup>102</sup> Mavroghenis, *supra* note 91, p. 10.

<sup>103</sup> European Commission, Final Report, *supra* note 89, p. 16.

<sup>104</sup> *Ibid* p. 15.

Nevertheless, it has also concluded that “[s]trong patent protection promotes ex ante incentives to innovate. If the invention is new, involves an inventive step and is susceptible to industrial application it is patentable, [and] [c]ompetition law should not second guess.”<sup>105</sup>

## 2.2. Secondary Patent Applications

Another defensive strategy used by innovator companies is to file applications for secondary or follow-on-patents. Secondary or follow-on-patents, also called reformulations remain “the most popular and, arguably, the most effective way to prolong a product’s commercial life”<sup>106</sup>, since it can delay competition between products based on same original invention<sup>107</sup>. However, “patenting throughout life of a product is not novel and not restricted to the pharmaceutical sector”<sup>108</sup>. Moreover, if it can be confirmed that: “A follow-on inventor that has made a valuable further development is not usually seen as an infringer, because courts tend to narrow the technical scope of the patent or, at least they refrain from expanding it through the doctrine of equivalence. Extra incentives are made available for the radical improver, so as to prevent him being held up by an earlier patent,”<sup>109</sup> which raises the question why an innovator applying for a secondary patent should be treated less favourably. Yet, one of the main issues emphasised by the Commission in its Preliminary Report concerns the quality of such late secondary patents. In that regard, the Commission’s success statistics of the patent opposition and appeals between originator and generic manufacturers<sup>110</sup> raise doubts whether the expected quality and legal safeguards of the patenting process are always fully observed.

## 2.3. Reverse Payments

In order to prevent or delay market access, innovators occasionally conclude agreements with generic manufacturers, whereby, in exchange for delaying market entry, the generic companies accept compensation payments or other benefits from innovator companies<sup>111</sup> or enter into settlement agreements<sup>112</sup>. However, the settlement of patent infringement disputes is only to be considered under the ambit of cartel law in so far as the validity or the substantive scope of a property right is seriously in doubt<sup>113</sup>.

<sup>105</sup> *Ibid*, p. 11.

<sup>106</sup> Robin Mitchell, Debra Bingham, *Rules to Live or Die By For Life Cycle Management*. Available at: <http://www.pharmaquality.com/ME2/Audiences/dirmod.asp?sid=325598564E8C4B3EB736C7159241312D&nm=Browse+Articles&type=Publishing&mod=Publications%3A%3AArticle&mid=D3E3C719D8D44216836DCA4F4144BEC4&AudID=5648A5C28C97462DBBDB309539B820EF&tier=4&id=2482698BE7B7474F8A875B62C100DD58>.

<sup>107</sup> European Commission, Final Report, *supra* note 89.

<sup>108</sup> Mavroghenis, *supra* note 91, p. 7

<sup>109</sup> Bengt Domeij, *Patent Claim Scope: Initial and Follow-on Pharmaceutical Inventions in Europe*, p. 8. Available at: [https://www.kth.se/polopoly\\_fs/1.10601!initialfollow.pdf](https://www.kth.se/polopoly_fs/1.10601!initialfollow.pdf), accessed on 18 March 2011.

<sup>110</sup> Commission, Final Report, *supra* note 89, p. 13.

<sup>111</sup> Scott C. Hemphill, *Drug Patent Settlements between Rivals: A Survey*, 2007, pp. 1-49. Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=969492](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=969492), accessed on 18 March 2011.

<sup>112</sup> Commission, Final Report, *supra* note 89, p. 12.

<sup>113</sup> Hanns Ullrich, “VI Abschnitt. Kartellverfahrensverordnung” in Ulrich Immenga, Ernst-Joachim Mestmäcker, *Wettbewerbsrecht Kommentar zum Europäischen Kartellrecht*, 4. Auflage, München, Verlag C. H. Beck, 2007.

Such “reverse payments” are defined as “a variety of diverse agreements between patent owners and alleged infringers that involve a transfer of consideration from the patent owner to the alleged infringer”<sup>114</sup>. The mere presence or amount of reverse payments is not sufficient to conclude that patent settlements were illegal, nor do any estimates of an eventual outcome of a patent infringement dispute warrant such conclusion<sup>115</sup>. However, when competing manufacturers agree on restrictions that go beyond the exclusivity rendered normally by a patent, such a decision not to compete constitutes a hardcore restriction under Art. 4 (1) of the Technology Transfer Guidelines<sup>116</sup>.

Combe<sup>117</sup> describes yet another strategy of pharmaceutical companies, called “pseudo-generics” strategy. The primary patentee indirectly enters the generics market by launching himself a generic drug, but entrusts the distribution to another firm through a licensing agreement, without the prescriber or consumer being informed of the ties between the two companies<sup>118</sup>. At first glance, the pseudo-generics appear to have a pro-competitive effect, as new products are launched on the market. However, in comparative terms, the presence of pseudo-generics, sold at “too” low prices, may also limit the entry of “real” generics.

### 3. Competition between Originator Manufacturers

The pharmaceutical sector inquiry report identified a series of defensive practices between the research-based pharmaceutical companies as further possible causes for a falling rate of innovation<sup>119</sup>. In this regard, the report acknowledges that the originator manufacturers do need a wide exclusivity status for their R&D activities, but such an extent for IPR protection can lead to patent overlaps and conflicts<sup>120</sup>. In this respect it may be noted that where the between-patent competition is particularly fierce the duration of the patent protection may not have as significant an impact on the incentive to engage in R&D as it has in the case of within-patent competition<sup>121</sup>.

<sup>114</sup> Christopher M. Holman, “Do Reverse Payment Settlements Violate the Antitrust Laws?”, (2007), Vol. 23, Santa Clara Computer & High Tech. L.J., p. 489. Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=989611](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=989611), accessed on 18 March 2011.

<sup>115</sup> *Ibid.*

<sup>116</sup> Richard Whish, *Competition Law*, Oxford, Oxford University Press, 2008, p. 786. See also COMMISSION NOTICE-Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements, [27.4.2004], O.J. 2004/C 101/02, para. 205: “The block exemption applies provided that the agreement does not contain any hardcore restrictions of competition as set out in Article 4 of the TTBER. The hardcore list of Article 4(1) may in particular apply where it was clear to the parties that no blocking position exists and that consequently they are competitors. In such cases the settlement is merely a means to restrict competition that existed in the absence of the agreement.”

<sup>117</sup> Emmanuel Combe, “Les laboratoires pharmaceutiques face à la concurrence des génériques : quels enjeux pour l’antitrust?”, N° 1-2006, *Concurrences. Revue des droits de la concurrence*, pp. 47-62.

<sup>118</sup> Abdelillah Hamdouch, Dominique Perrochon, “Formes d’engagement en R&D, processus d’innovation et modalités d’interaction entre firmes dans l’industrie pharmaceutique”, (2000) Vol. 93, *Revue d’économie industrielle*, p. 46

<sup>119</sup> European Commission, Final Report, *supra* note 89, p. 17.

<sup>120</sup> *Ibid.*

<sup>121</sup> Tomas J. Philipson, Carolanne Dai, “Between- vs. Within-Patent Competition”, (2003) Vol. 26, No. 3, *Regulation*, pp. 43-44. Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=511403](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=511403), accessed on 18 March 2011.

Defensive patenting takes place in order to block market access of competing products. It supposes that an innovator company files applications for or maintains patents in respect of innovations without any intention of developing them further or making use of them<sup>122</sup> other than for the sole purpose of reserving the domain and eliminating potential competitors. Such a definition comes close to the one used by the ECJ to define the criteria for “abuse of rights”<sup>123</sup>.

In its final report of the pharmaceutical sector inquiry the Commission observes that: “[T]he term “defensive” patents cannot be found in patent law and all patent applications need to be evaluated on the basis of the statutory patentability criteria, not on the basis of underlying intentions by the applicant. Also it is an inherent feature of a patent system to grant exclusive rights. The notion of “defensive patents” should therefore not be understood to mean that these patents are of a lower quality or value (...)”<sup>124</sup>

Patent applications are generally filed with the intent to gain legal protection for an innovation of which the patentee plans to make commercial use on the market. The defensive strategy appears to be a “secondary motivation” for a patent application<sup>125</sup>. The key criterion for defining defensive patenting centres on the intent of the innovator company for filing a patent application but the question is how to detect a defensive intent? In practice, to detect the intent of a company is inherently difficult. Objective factors may however provide some indications of its presence<sup>126</sup>. Is the intent to engage in defensive strategies for instance more likely to exist already during the R&D phase, or at the later stage of secondary patents? The second option seems more plausible and could be revealed by accumulation of patents of little or no use at all<sup>127</sup>.

#### 4. Scope for Applying Article 102 TFEU to Strategic Patenting

Paragraph seven of the Technology Transfer Guidelines<sup>128</sup> says: “Indeed, both bodies of law [competition law and IPR] share the same basic objective of promoting consumer welfare and an efficient allocation of resources..”<sup>129</sup>

<sup>122</sup> Mavroghenis, *supra* note 91, slide 8.

<sup>123</sup> In a different context, i.e. as regards rights conferred upon economic operators by Community law provisions, the ECJ has held that “...the scope of Community regulations must in no case be extended to cover abuses on the part of a trader” and that “[A] finding of an abuse requires, first, a combination of objective circumstances in which, despite formal observance of the conditions laid down by the Community rules, the purpose of those rules has not been achieved. It requires, second, a subjective element consisting in the intention to obtain an advantage from the Community rules by creating artificially the conditions laid down for obtaining it.”; Case C-110/99 *Emsland-Stärke* [2000] ECR I-11569, paras 51-53.

<sup>124</sup> European Commission, Final Report, *supra* note 89, p. 16.

<sup>125</sup> Ullrich, *Wahrung von Wettbewerbsfreiräumen*, *supra* note 95.

<sup>126</sup> In *Halifax* C-255/02 [2006] ECR I-1609 para 86, the ECJ seemed to suggest that the presence of the subjective element can be deduced from the objective factors at hand: “...it must also be apparent from a number of objective factors that the essential aim of the transactions concerned is to obtain a tax advantage.”

<sup>127</sup> Ullrich, *Wahrung von Wettbewerbsfreiräumen*, *supra* note 95.

<sup>128</sup> See *supra* note 116.

<sup>129</sup> European Commission’s Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements, [2004] C101/2.

Patents are granted in order to promote innovation, which is in the public interest. Obtaining a patent and exercising it against third parties does not turn the patentee into a monopolist, nor is it in principle abusive<sup>130</sup> and today's major challenge of competition law is to determine at what point if at all the exercise of IP rights becomes harmful to consumer welfare<sup>131</sup>.

In the Preliminary Report on the pharmaceutical sector inquiry the Commission seems to be taking a more critical view of conduct involving patenting, as it identifies a "tool box" of practices which in its view hamper market entry by generics and other innovators<sup>132</sup>. However, does the Commission have a case under Art. 102 TFEU?

Conditions for applying Article 102 TFEU to refusals to licence have been established in the *AB Volvo v. Erik Veng* case<sup>133</sup>, as being the following: there should be no substitute for the product or service refused; the licence should be indispensable to the exercise of a particular activity on a neighbouring market; the refusal must exclude effective competition on that neighbouring market where it would prevent either the appearance of a new product for which there is potential consumer demand or technological development to the detriment of consumers, and there should be no objective justification for the refusal<sup>134</sup>. *"The conditions for applying Article 82 to refusals to licence can be condensed into the following: A footprint test: Does control of an upstream IP confer dominance on a downstream market? A consumer welfare balancing test: Does the refusal prevent competitors from producing value added products? Is an obligation to deal likely to chill investments and innovation by dominant firms?"*<sup>135</sup>

The limits of the footprint test have been expanded in *IMS Health*<sup>136</sup>, in which the ECJ held that the duty to supply arises only if there are separate markets, one upstream and one downstream<sup>137</sup> and "it is sufficient that a potential market or even a hypothetical market can be identified"<sup>138</sup>.

From an *ex ante* perspective, patents are a necessary incentive for the manufacturer to commit to R&D investments<sup>139</sup>. However, "[o]nce it is shown that the refusal prevents the marketing of a new improved/differentiated product, arguments based on *ex ante* incentives will by definition be more abstract and difficult to substantiate [and] [t]he dominant firm has the burden of providing evidence that the refusal is justified"<sup>140</sup>. The *ex post* test, whereby

<sup>130</sup> Alison Jones, Brenda Sufrin, *EC Competition Law*, Oxford, Oxford University Press, 2007, p. 554.

<sup>131</sup> Whish, *supra* note 116, pp. 758 - 759.

<sup>132</sup> Commission, Preliminary Report, *supra* note 8, p. 5.

<sup>133</sup> Case 238/87, *AB Volvo v. Erik Veng*, [1988] ECR 6211, [1989] 4 CMLR 122.

<sup>134</sup> Jones, Sufrin, *supra* note 130, p. 560.

<sup>135</sup> Lars Kjolbey, *The pharmaceutical sector inquiry and strategic patenting. What is the Commission's scope for action under Article 82 EC?*, LES Topic Meeting, Rotterdam, 18 March 2009, p. 8. Available at: <http://les-benelux.org/level2a/documents/L.Kjolbey.pdf>, accessed on 18 March 2011.

<sup>136</sup> Case C-418/01, *IMS Health GmbH & Co v. NDC Health GmbH & Co*, [2004] ECR I-5039, [2004] 4 CMLR 1543.

<sup>137</sup> *Ibid*, para. 42.

<sup>138</sup> *Ibid*, para. 44.

<sup>139</sup> Valentine Korah, *An Introductory Guide to EC Competition Law and Practice*, Oxford, Hart Publishing, 2007, p. 364.

<sup>140</sup> Kjolbey, *supra* note 135, p. 10.

investment in innovation has been successful if it has generated valuable patents<sup>141</sup> was developed in the *Volvo*<sup>142</sup> case, where the ECJ stated in paragraph 8 that: “[T]he right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right . It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right, and that a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position.”

This seems to support the idea that free competition should only prevail over the economic freedom of an IP owner, if the “refusal to grant a licence prevents the development of the secondary market to the detriment of consumers”<sup>143</sup>. However, Geradin<sup>144</sup> expressed the concern that the impact of mandatory access on incentives to invest can be very serious, the real problem being the effect this will have on incentives to invest in facilities which are likely to be subject to compulsory sharing. Geradin believes that the use of balancing tests as regards *ex post* and *ex ante* efficiencies is rather problematic and their role should be limited.

While ownership of IP rights and patenting does not automatically signify the existence of a dominant position and of abuse<sup>145</sup>, Art. 102 TFEU can be applied in “exceptional circumstances” in the interest of consumer welfare<sup>146</sup>. The question thus arising is whether there is actually a convincing consumer welfare case for intervening against strategic patenting under Art. 102 TFEU<sup>147</sup>.

In the case of patent thickets, in the absence of a clear legal ground for determining when multiple patenting becomes illegal<sup>148</sup>, such an analysis has to be conducted on a case-by-case basis, which can lead to controversy<sup>149</sup>. While “[i]t cannot be abusive to use the patent system to obtain optimal protection of an innovation”<sup>150</sup>, Art. 102 TFEU will be contravened if besides the normal patent use, an additional element would be present<sup>151</sup>. Such an additional element could for instance consist in vexatious conduct: “[V]exatious conduct that delays initial generic entry only for a few months may be profitable for the brand company and acutely harmful to consumers. (...) Rules in the European Community that allow brand pharmaceutical companies to initiate litigation in multiple Member States also foster an

<sup>141</sup> Korah, *An Introductory...supra* note 139, p. 364.

<sup>142</sup> *Volvo v. Veng*, *supra* note 133.

<sup>143</sup> *IMS Health Case*, *supra* note 136, para. 48.

<sup>144</sup> Damien Geradin, “Limiting the Scope of Article 82EC: What Can the EU Learn from the Supreme Court’s Judgment in *Trinko* in the Wake of *Microsoft*, *IMS* and *Deutsche Telekom*?”, [2005] CMLR, Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=617263](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=617263), accessed on 18 March 2011.

<sup>145</sup> Jones, Sufrin, *supra* note 130, p. 554.

<sup>146</sup> Whish, *supra* note 116, p. 789.

<sup>147</sup> Kjolbey, *supra* note 135, p. 11.

<sup>148</sup> *Ibid*, p. 12.

<sup>149</sup> Inge Govaere, *The Use and Abuse of Intellectual Property Rights in E.C. Law*, Sweet & Maxwell, London, 1996, p. 113.

<sup>150</sup> Kjolbey, *supra* note 135, p. 12.

<sup>151</sup> Govaere, *supra* note 149, p. 155.

*environment conducive to vexatious conduct. The effect of those rules is to allow brand pharmaceutical companies to re-litigate issues in a second Member State that they have already lost against the same generic entrant in a prior litigation in a different Member State.*<sup>152</sup>

Secondary Patents raise similar difficulties in terms of how to argue a possible Art. 102 TFEU case. The problem that the Commission faces is lack of competence in determining the value of patents in order for it to be able to override weak patents and free the way for generic entry<sup>153</sup>. Although the purpose of compulsory licensing is to foster innovation, it should remain a matter of patent law and not competition law<sup>154</sup>.

In line with the above considerations, defensive patenting would merely appear to form part of normal conduct between competing companies, each trying to be the first to patent and thereafter to defend their positions<sup>155</sup>. Furthermore, according to Art. 52 of the EPC 2000<sup>156</sup>, intent of working the patent does not constitute a condition for patentability, nor does lack of such intent give rise to an exception of patentability according to Art. 53 EPC<sup>157</sup>. However, in its *Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses*<sup>158</sup>, the Commission Services (DG Competition) suggest that: “[T]he refusal by a dominant company to license access to the IPR could be considered abusive when (...) the refusal to grant a licence prevents the development of the market for which the licence is an indispensable input, to the detriment of consumers. This may only be the case if the undertaking which requests the licence does not intend to limit itself essentially to duplicating the goods or services already offered on this market by the owner of the IPR, but intends to produce new goods or services not offered by the owner of the right and for which there is a potential consumer demand.”<sup>159</sup>

In conclusion, it appears evident that competition law cannot provide an adequate mechanism for remedying the imperfections of the patent system.<sup>160</sup>

<sup>152</sup> Teva, *Overview of Alendronate Litigation in the EC*, p. 12. Available at: [http://ec.europa.eu/competition/consultations/2009\\_pharma/teva\\_annexes.pdf](http://ec.europa.eu/competition/consultations/2009_pharma/teva_annexes.pdf), accessed on 18 March 2011.

<sup>153</sup> Kjolbey, *supra* note 135, p. 13.

<sup>154</sup> Whish, *supra* note 116, p. 787.

<sup>155</sup> Kjolbey, *supra* note 135, p. 14.

<sup>156</sup> Article 52 EPC 2000: “Patentable inventions - (1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.”

<sup>157</sup> Article 53 EPC 2000: “Exceptions to patentability - European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to “ordre public” or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.”

<sup>158</sup> Available at: <http://ec.europa.eu/competition/antitrust/art82/discpaper2005.pdf>, accessed on 18 March 2011.

<sup>159</sup> *Ibid*, para. 239.

<sup>160</sup> Kjolbey, *supra* note 135, p. 15.

#### IV. Is Strategic Patenting a Response to a Legal Problem?

##### 1. Is Patent Legislation Too Permissive?

In legal literature ‘evergreening’ has frequently been labelled as an unfair and abusive practice which should be restrained with stricter patent legislation.<sup>161</sup>

In this respect the issue of ‘evergreening’ thus boils down to the question as to whether the existing patent legislation is capable of maintaining an adequate control over such practices or whether improvements are necessary? It is doubtful whether adopting new legislation is worth the risk<sup>162</sup> of freezing innovation. As discussed in previous sections a strong patent protection encourages ex ante innovation and as long as an invention is patentable (it is new, it involves an inventive step and it is susceptible to industrial application) competition law ought not to intervene.<sup>163</sup>

Against this background, it is nevertheless true that the practice of ‘evergreening’ reflects a specific flaw of the system: “inventions must not solve an unsolved problem to be patentable and must not be efficient per se to be granted patent protection”<sup>164</sup>. It cannot be disputed that in some cases patents are granted for inventions that may contribute to scientific progress but do not bring about any solutions for problems that would not have already been resolved before<sup>165</sup>: *“In principle this scheme allows for instance the patenting of different processes leading to the same result. Although not solving an unsolved problem a priori, these processes and methods nonetheless bring about progress. Indeed, novelty has no threshold to effectiveness or to progress (it just needs to be new) and industrial applicability does not require a ‘new’ or ‘more efficient’ use (there must simply be ‘a’ use).”*<sup>166</sup>

The criterion of inventiveness needs to be assessed on the basis of the entire invention and not only by focusing on the individual characteristics of it<sup>167</sup>. Most patent systems employ this test to ensure that trivial changes to prior art are precluded from patentability<sup>168</sup>. In this sense, the inventiveness test was designed with the purpose of eliminating the possibility that patents granted for minor alterations of existing inventions would result in unjustifiable trade distortions<sup>169</sup>.

<sup>161</sup> Bansal, *supra* note 90, p. 8.

<sup>162</sup> Michelangelo Temmerman, *The TRIPS Agreement, the Evergreening of Patents and Access to Medicines: Novartis v. India*, NCCR Trade Regulation, Swiss National Centre of Competence in Research, Working Paper No. 2008/16, p. 38. Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1185282](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1185282), accessed on 18 March 2011.

<sup>163</sup> Mavroghenis, *supra* note 91, p. 11.

<sup>164</sup> Temmerman, *supra* note 162, p. 35.

<sup>165</sup> *Ibid.*

<sup>166</sup> Temmerman, *supra* note 162, p. 35.

<sup>167</sup> William R. Cornish, *Intellectual Property: Patents, Copyrights, Trade Marks, and Allied Rights*, London, Sweet and Maxwell, 1999, p.198.

<sup>168</sup> Article 27 § 1 TRIPS Agreement: “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”; Article 52 § 1 European Patent Convention: “European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.”

<sup>169</sup> Lionel Bently and Brad Sherman, *Intellectual Property Law*, Second Edition, Oxford University Press, 2004, p. 470.

In this context, one suggestion made by the sector inquiry was to “raise the bar”, in the sense that patent offices should perform better and grant higher quality patents at a faster rate<sup>170</sup>. However laudable such a proposal might be, it still remains to be seen how it can be put into practice. Patent offices are increasingly over-flooded by applications, of which pharmaceutical patents represent only a small part, while their resources remain unchanged<sup>171</sup>. Moreover, examination of pharmaceutical patent applications must remain non-discriminatory and EPO should not apply standards different from those used when dealing with applications relating to innovations in other fields<sup>172</sup>. The grant of a patent by a patent office cannot be considered as certificate of validity, because “[i]n truth a Patent Office is a kind of coarse filter – rejecting clearly bad cases but having to allow those which may be good”<sup>173</sup>.

Obviously, some companies have tried to ensure their exclusivity by taking out “weak” patents as part of an ‘evergreening’ strategy. It should however be borne in mind that these practices are by no means confined to the pharmaceutical sector.<sup>174</sup>

A figure of “up to 1,300” patents for one patent cluster as brought up as an example by the Commission<sup>175</sup> might appear suspicious and hence, warrant watchful and critical assessment. However, regarding this particular case it should be recalled that the figure covers all the 27 Member States. Further, the Report does not imply that those patents are “weak”, and therefore the figure merely shows evidence for the grant of 1,300 patents for presumably perfectly good inventions.<sup>176</sup>

Another suggestion made to reduce the risk of strategic patenting was to introduce an obligation to disclose all information known to be material to patentability by the patentee. However, this would entail extremely high cost for the applicant and raises questions regarding the actual ambit of such a proposal, such as whether the applicant would really need to make public internal documents and legal advice he had received prior to the patent claim<sup>177</sup>. Such disclosure could potentially compromise its position in relation to its competitors or in possible later legal litigation.

Another point made in the sector inquiry concerned the involvement of third parties already at the patent pre-grant stage. Third parties are free to submit prior art to the office and make observations at the pre-grant stage but the only truly efficient measure would be a pre-grant opposition, which was rightly rejected as the grant of patent rights would be held up for years<sup>178</sup>. Furthermore, generic companies would be unlikely to make use of such an

<sup>170</sup> European Commission, Final Report, *supra* note 8, p. 21.

<sup>171</sup> Rt. Hon. Sir Robin Jacob, *Patents and Pharmaceuticals* – a Paper given on 29th November at the Presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-Sector Inquiry, p. 6. Available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf>, 18 March 2011.

<sup>172</sup> *Ibid.*

<sup>173</sup> *Ibid.*

<sup>174</sup> *Ibid.*, p. 7.

<sup>175</sup> Commission, Final Report, *supra* note 8, p. 10.

<sup>176</sup> Jacob, *supra* note 171, p. 7.

<sup>177</sup> *Ibid.*

<sup>178</sup> *Ibid.*, p. 8.

opportunity, since generally they do not oppose to the granting of a patent unless the product covered by it was already on the market<sup>179</sup>. In this context it is nevertheless a valuable recommendation that opposition proceedings should be dealt with faster, although the existing shortcomings in this respect remain more general, i.e. not specific to the pharmaceutical sector<sup>180</sup>.

The Commission does indeed acknowledge the need for a strong and fast Central Patents Court for Europe<sup>181</sup>, which would contribute to “reducing the costs associated with multiple filings, by eliminating essentially parallel court cases between the same parties in different Member States and by enhancing legal certainty through the avoidance of conflicting rulings.”<sup>182</sup>

Moreover, Judge Jacob is of the opinion that ‘evergreening’ through “weak” patents can and should be dealt with by courts. In terms of practical measures for implementing such recommendation he has suggested the following steps: “(a) *forgetting about all changes to the law of grant, (b) a serious look at current opposition procedures within the EPO and (c) above all the creation of a respected, fast, and reliable European Patent Court.*”<sup>183</sup>

Intellectual property legislation should of course not confer on patent holders dominant positions or inflate their market power<sup>184</sup>. Where however that should be the case competition law should help to identify such situations<sup>185</sup>. While the exercise of IPR is not in itself abusive patents can be used as an instrument to gain and to abuse a dominant position<sup>186</sup>. However, in such situations it would seem that the abuse of patents amounts to a violation of competition rather than patent law.

Although the pharmaceutical sector is one that is prone to stir up emotional responses, it is important to see beyond bad patents and realise that patents fulfil a crucial role to the benefit of mankind.<sup>187</sup> Changes to the system should be designed and implemented with prudence, as any too dramatic changes could work against a significant part of the industry<sup>188</sup>. The Commission recognises the importance of patents for encouraging innovation and from a broader perspective, the relevance of patents to the pharmaceutical

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<sup>179</sup> *Ibid.*

<sup>180</sup> *Ibid.*, p. 9.

<sup>181</sup> However, for the moment this suggestion is put on hold by the Court’s Opinion 1/2009, which states that the draft agreement on the European and EU Patents Court is incompatible with the Treaties, due to the fact that it would confer on the future patent court, which is outside the institutional and judicial framework of the EU, the exclusive jurisdiction to hear a significant number of actions brought by individuals in the field of the EU patent and to interpret and apply EU law in that field. OJ C 23, 28.1.2008.

<sup>182</sup> Commission, Final Report, *supra* note 8, p. 21.

<sup>183</sup> Jacob, *supra* note 202, p. 10.

<sup>184</sup> Josef Drexler, “The Relationship between the Legal Exclusivity and Economic Market Power. Links and Limits”, in Inge Govaere, Hanns Ullrich, *Intellectual Property, Market Power and the Public Interest*, “College of Europe Studies No 8, P.I.E. Peter Lang, Brussels, 2008, p. 33.

<sup>185</sup> *Ibid.*

<sup>186</sup> Mario Siragusa, Is There an Independent/Additional (European, International) Open–Market Criterion for Determining Abuse? Syfait, GSK, Microleader: May Dominant Firms Sub-Divide their Supra-National Territory of Economic Exploitation into (Legally Separate?) National Markets?, in Inge Govaere, Hanns Ullrich, *Intellectual Property, Market Power and the Public Interest*, “College of Europe Studies No 8, P.I.E. Peter Lang, Brussels, 2008, p. 116.

<sup>187</sup> Jacob, *supra* note 202, p. 10.

<sup>188</sup> *Ibid.*

industry<sup>189</sup>. In fact, the truth is that if the revenue sources of research companies are put in peril, so is future research which would be to the detriment of European citizens<sup>190</sup>.

However, the fact that applications for secondary patents can be filed by the originator manufacturers purposefully just before the expiry of the primary patent (or other exclusivity periods), is indicative of some level of distortion in the patent system as it seems to enable pharmaceutical companies to obtain extended patent protection whenever they might perceive it useful<sup>191</sup>.

## 2. Is Patent Protection Sufficient?

As discussed and emphasised in previous sections, the risks involved in R&D investment and the fact that finding a patentable compound is extremely difficult, with most research leading nowhere and the few successful drugs having to recover all expenses<sup>192</sup>. It is therefore in principle not unreasonable to require stronger guarantees and greater rewards with increasing risk.<sup>193</sup>

As previously stated, a patent offers a limited monopoly. Of an average of 20 years from the date of application, together with the supplementary protection system, patent holders enjoy around 10 or 11 years of exclusivity<sup>194</sup>. Such a relatively short period of time might not be sufficient to compensate for the expenses and risks involved in creating new drugs which therefore may in certain circumstances provide a feasible justification for 'evergreening' practices. However, regardless of how long patent protection lasts, it is unlikely ever to be long enough from originator businesses' point of view and short enough for the generics companies.

In this regard it is also important to recall that the prices of medicines in Europe are state regulated which is why irrespective of the length of the patent exclusivity innovative manufacturers can never obtain the real value of their medical products, i.e. what the market would be willing to pay for them, but a mediated one – that is, what governments are prepared to pay, or what they regard as a correct price, for them. Their generic competitors should also be taken into account. Their situation is considerably more advantageous: little or no research costs, no risks assumed, not even marketing costs<sup>195</sup>, since the road has already been cleared by their predecessors – the originators.

Traditionally, and to some extent misleadingly, generic companies have always emphasised that due to their presence on the market customers can have access to medicines at more affordable prices, without mentioning how profitable it actually is for them<sup>196</sup>. It is not realistic to assume that generic companies favour low prices, or that their

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<sup>189</sup> Commission, Final Report, *supra* note 8, p. 2.

<sup>190</sup> Jacob, *supra* note 202, p. 11.

<sup>191</sup> Ullrich, *Wahrung...supra* note 128, p. 24.

<sup>192</sup> Jacob, *supra* note 202, p. 4.

<sup>193</sup> *Ibid.*

<sup>194</sup> *Ibid.*

<sup>195</sup> Jacob, *supra* note 202, p. 5.

<sup>196</sup> *Ibid.*

values would be those of a charity. Just like their originator competitors, they are businesses and as such, in pursuit of profit<sup>197</sup>.

Putting aside emotion and irrational prejudice<sup>198</sup> against big pharmaceutical manufacturers one can conclude that an average of 10-11 years of exclusivity seems at first sight barely enough to make up for R&D costs and risks. However, it is equally important not to lose sight of the fact that big pharma is big business. The pharmaceutical industry is one of the most lucrative industries in Europe which is in line with the widely embraced economic theory suggesting that the higher the risk the greater the potential return on investment should be. However, putting it rather bluntly, if the originators' situation was so precarious as they at times imply it is, why would they continue to be interested in staying in business?

## Conclusion

The Commission began its sector inquiry by investigating the economic and geographic dimensions of the pharmaceutical industry. It is unclear though whether it has actually taken due account of the fact that drug companies are after all businesses, of which the primary purpose is to make profits<sup>199</sup>. Surely the social welfare function of medicines acts as a catalyst for very passionate reactions towards the business practices of the pharmaceutical industry. The civil society feels particularly vulnerable on the topic of treatments for illnesses and while other business sectors also make use of the same patent strategies, consumers tend to feel more personally affected when those strategies are employed by the pharmaceutical sector.

The first place where to look for the right approach towards 'evergreening' and defensive patenting would be patent law. However, what the EPC says is only that, provided the conditions set out in Art. 52 *et seq.* are met, an invention is rightly patentable.

Turning for assistance towards competition law, we find that the case-law on refusal to licence reveals the fact that competition law is not apt to deal with the imperfections of the patent system. From a competition law perspective, Article 102 TFEU can be applied to patents only in the interest of consumer welfare and only in very rare situations. Otherwise it would inhibit innovation and hinder competition. Therefore, it should be interesting to see the findings of the surprise investigations in the pharmaceutical sector launched by the Commission on 9 December 2009<sup>200</sup> and the eventual results of the legal proceeding against the pharmaceutical company Lundbeck<sup>201</sup>. It will be very difficult to demonstrate that patent

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<sup>197</sup> *Ibid.*

<sup>198</sup> *Ibid.*, p. 6.

<sup>199</sup> Hunter, *supra* note 2, p. 11.

<sup>200</sup> Commission MEMO/09/546, of 9th December 2009, *Antitrust: Commission confirms surprise inspections in the pharmaceutical sector*. Available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/546&format=HTML&aged=0&language=EN&guiLanguage=en>, accessed on 18 March 2011.

<sup>201</sup> Commission Press Release IP/10/8, of 7th January 2010, *Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck*. Available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/8&format=HTML&aged=0&language=EN&guiLanguage=en>, accessed on 18 March 2011;

strategies are abusive<sup>202</sup>, especially since the application of competition rules could interfere “with the patent regime itself and its very rationale”<sup>203</sup>.

Strategic patenting will obviously remain an issue which will be subject to legal disputes and consideration as to at which point it becomes an abusive practice. It may however be regarded as an area where there are no obvious legislative (*de lege ferenda*) solutions to it apart from perhaps improvements to procedures and in view of ensuring consistent interpretation of law, the creation of a European Patent Court as suggested by judge Jacob<sup>204</sup>. It will also remain an issue of social dialogue between the stakeholders (originators, generics and consumer/customers). In this respect a general demonization of the pharmaceutical industry, of which the Commission may be regarded to be guilty at least in parts of its conclusions is not constructive. It diminishes the confidence of the pharmaceutical industry in the neutrality of the Commission and may damage the image of the industry. There is a need to strike a balance between the interests of all parties involved.

In the area of ‘evergreening’ patents should be analysed on a case-by-case basis. When interpreting the requirement of inventiveness it is crucial to consider the invention as a whole and not to overlook “the linkages between the inventiveness requirement and the novelty assessment”<sup>205</sup>.

Both patents and competition law are vital for the wellbeing of consumers and the society at large. Patents encourage innovation and so does competition law by eliminating the risk of lazy patentees who want to endlessly exploit the same patents and by disallowing patents which could block development of further improvements to them in their respective domains. One question still remains open to debate: is patent law an element within the framework of competition rules or is rather itself the framework of innovation competition?

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<sup>202</sup> See also *supra* note 124.

<sup>203</sup> Mavroghenis, *supra* note 89, p. 18.

<sup>204</sup> See *supra* note 200.

<sup>205</sup> Temmerman, *supra* note 193, p. 38.



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