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Defensive Patent Protection Strategies in the Pharmaceutical Industry – A Response to a Legal Problem?

Supervisor: HANNS ULLRICH

Thesis presented by

Nicoleta Tuominen

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Statutory Declaration

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Abstract

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.

Keywords

sector inquiry

‘evergreening’

defensive patenting

clusters/thickets

Art. 102 TFEU

Table of Contents

Statutory Declaration	ii
Abstract.....	iii
Keywords	iv
List of Abbreviations	vii
1 Introduction.....	1
1.1 Objectives	1
1.2 Structure.....	1
1.3 Scope and Limitations	2
2 The Unique Nature of the European Pharmaceutical Industry	3
2.1 The Market.....	3
2.2 Major Issue: Research and Development	5
2.3 Price Controls and Purchase Arrangements.....	6
2.4 Conflicting Interests in the Pharmaceutical Sector.....	8
2.4.1 The Industry’s Need for Intellectual Property Exclusivity.....	8
2.4.2 The Community Competition Rules	10
3 Legal Tools for Protecting IP for Pharmaceuticals	12
3.1 Patents.....	12
3.1.1 Patent Rights	12
3.1.2 Patent Application Process	14
3.2 Supplementary Protection Certificates	15
3.3 Regulatory Data Protection.....	16
4 Strategic Patenting of Pharmaceuticals in the European Union.....	18
4.1 Introduction to ‘Evergreening’	18
4.2 Innovator Product vs. Generic - Extended Patents	19
4.3 Competition between Originator Manufacturers	23
4.4 Scope for Applying Article 102 TFEU (ex Art. 82 EC) to Strategic Patenting	25
5 Patent Infringement Lawsuits – the Judiciary’s View on Strategic Patenting	30
5.1 Introduction.....	30
5.2 Strategic Patenting in Litigation	31

6	Is Strategic Patenting a Response to a Legal Problem?	36
6.1	Is Patent Legislation Too Permissive?.....	36
6.2	Is Patent Protection Sufficient?.....	40
7	Conclusion	43
	Bibliography	45

List of Abbreviations

Art.	Article
ECR	European Court Reports
EC	European Community
ECJ	European Court of Justice
ECLR	European Community Law Review
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIPR	European Intellectual Property Law Review
EPC	European Patent Convention
EPO	European Patent Office
F.S.R.	Flat Street Reports
GRUR Int.	Gewerblicher Rechtsschutz und Urheberrecht/International Teil
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
IIC	International Review of Industrial Property and Copyright Law
IP	Intellectual Property
IPR	Intellectual Property Rights
JPTOS	Journal of Patent and Trademark Office Society
NIR	Nordiskt Immateriellt Rättsskydd
OJ EPO	Official Journal of the EPO
R&D	Research and Development
R.P.C.	Report of Patent Cases
SPS	Supplementary Protection Certificates
TFEU	Treaty on the Functioning of the European Union

1 Introduction

1.1 Objectives

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.

1.2 Structure

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 investigation¹.

In addition to this introduction the study consists of six chapters. The second chapter briefly describes the background of the sector inquiry and the conflicting interests that shape the pharmaceuticals market. The third chapter provides an overview of the legal IP protection mechanisms presently available to the pharmaceutical industry. The fourth chapter considers, from a theoretical point of view, the findings of the sector inquiry as regards strategic patenting of pharmaceuticals in the European Union. The fifth chapter discusses and reflects on some of the relevant rulings of national courts regarding intra- and inter-brand competition in the pharmaceutical industry. Lastly, before making concluding remarks in the seventh chapter, the penultimate chapter of this paper considers the questions as to whether the pharmaceutical industry employs defensive patent strategies merely because patent legislation might fail to curb such practices or, whether they represent a response to a potential failure of the patent legislation to provide sufficient protection of intellectual property in this field.

¹ 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>, 18 April 2010.

1.3 Scope and Limitations

The present study has its focus on strategic patenting. Issues relating to the relationship between originator companies and parallel importers as well as to the role of trademarks in what is commonly termed as “total product strategies” have been left outside the scope of this paper.

2 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 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:

“These features are 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.”²

2.1 The Market

“Pharmaceuticals are big business. It is the world's most profitable industry: in 2002, (...) the combined profits of the top ten drugs companies in the Fortune 500 list were greater than the profits of the 490 other companies in the list combined, at US\$56 billion.”³

The process behind the discovery, production and ultimately the distribution of drugs differentiates the pharmaceutical sectors from any other industry⁴. As concluded in the Single Market Law Review on the pharmaceutical sector in the European Union⁵, 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

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

³ Carinne Bruneton, *[e-med] IndustriePharmaceutique: Protéger Ses Profits*. Available at: <http://www.essentialdrugs.org/emed/archive/200410/msg00053.php>, 22 April 2010.

⁴ Subseries I: Impact on Manufacturing, Vol. 2: Pharmaceutical Products, ‘The Pharmaceutical Sector in the EU’, (1997), *The Single Market Review*, p. 99.

⁵ *Ibid.*

comprises companies of various sizes⁶, of which the large ones are engaged in R&D and have extended their business operations to cover also markets outside the European Union.

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.⁷ 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.⁸ According 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"⁹, which makes it significantly more profitable than any other sector of the manufacturing industry.

Manufacturers of "generics"¹⁰ 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 States¹¹. Delays

⁶ *Ibid*, p. 103.

⁷ *The Pharmaceutical Industry in Figures*, Edition 2009, p. 14, EFPIA Publication. Available at: <http://www.efpia.eu/content/default.asp?PageID=559&DocID=4883>, 18 April 2010.

⁸ *Ibid*.

⁹ 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, 23 April 2010.

¹⁰ "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 7, p. 17.

¹¹ *Ibid*.

in generic entry have a significant economic impact as prices for generics are on average 25% lower than prices of originator medicines before patent expiry¹².

2.2 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 in 2007 estimated the average cost of researching and developing a new chemical or biological entity at €1,059 million.”¹³

Almost all R&D costs are financed from the industry’s own resources. As the Commission observed¹⁴, 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 market¹⁵ 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 10,000¹⁶. 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”.¹⁷

¹² Commission Communication, *supra* note 9, p. 9.

¹³ <http://www.efpia.org/content/Default.asp?PageID=361>, 18 April 2010.

¹⁴ 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.

¹⁵ Alfonso Gamardella, Luigi Orsenigo, Fabio Pammolli, *Global Competitiveness in Pharmaceuticals: A European Perspective*, November, 2000, p. 16. Available at: www.pharmacos.eudra.org, 18 April 2010.

¹⁶ <http://www.efpia.org/content/Default.asp?PageID=361>, 18 April 2010.

¹⁷ Valentine Korah, “Merck v. Primecrown – The Exhaustion of Patents by Sale in a Member State where

Thus not every attempt to develop a new medicine turns out to be a commercial success such as Prozac. Sometimes there are tragedies like Thalidomide¹⁸ and numerous drugs which turn out to be of no therapeutic value after having exhausted important R&D resources.¹⁹

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 expiry²⁰ and intense generic competition.

However the business activities of pharmaceutical companies remain extremely profitable 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.²¹

2.3 *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 fully competitive market in pharmaceuticals are therefore a common feature and a frequently used instrument in this field.²²

The Treaty on the Functioning of the European Union provides that:

a Monopoly Profit Could not be Earned”, (1997) 4 *ECLR* 273.

¹⁸ <http://fr.wikipedia.org/wiki/Thalidomide>, 18 April 2010.

¹⁹ Stephen Kon, Fiona Schaeffer, “Parallel Imports of Pharmaceutical Products: A New Realism, or Back to Basics”, (1997) 3 *ECLR* 124.

²⁰ <http://www.efpia.org/content/Default.asp?PageID=361>, 18 April 2010.

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

²² Hunter, *supra* note 2, p. 10.

“ A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”²³

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.²⁴

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”.²⁵ However, this argument is untenable, since the value of a patent consists of that what the market is willing to pay for it²⁶. 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.²⁷

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 policies²⁸. 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 discrimination²⁹.

²³ Article 168 (1) TFEU (ex 152 EC).

²⁴ *Policy Principles for a Competitive Healthcare Environment*, p. 1. Available at: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=3826>, 18 April 2010.

²⁵ *Ibid*, p. 4.

²⁶ Hans Ullrich, “Lizenzkartellrecht auf dem Weg zur Mitte”, (1996), *GRUR Int.*, p. 564.

²⁷ *Policy Principles*, *supra* note 24, p. 5.

²⁸ 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.

²⁹ *Ibid*.

Pharmaceutical price policies should also be assessed with due consideration to the effectiveness of the patent system in general³⁰. 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.

2.4 *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.

2.4.1 The Industry's Need for Intellectual Property Exclusivity

Intellectual property rights undoubtedly play an important role in fostering medical and scientific progress. According to the originator companies³¹, IPR only enable them to recoup their R&D investment and compensate for the risks they have assumed. In this regard, the industry argues that “the patent system balances the interests of the inventor with the broader interests of society at large,”³² since they are a means for the inventor to eliminate “free riders” and for the society to increase its knowledge base³³.

“Patents are pivotal to the research-based pharmaceutical industry, given the enormous investment and risk required to develop innovative medicines. It can cost €1 billion or more to develop a new medicine in the period between discovery and marketing, normally a duration of 12

³⁰ 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.

³¹ <http://www.efpia.org/Content/Default.asp?PageID=538>, 19 April 2010.

³² *Ibid.*

³³ *Ibid.*

to 13 years. Only around 20% of new products ever recover the cost of development.³⁴

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,³⁵ since normally patent applications are filled early in the research phase. Although most profits from a branded pharmaceutical are derived during the first five- to eight-years of market exclusivity³⁶ 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 products³⁷.

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”.³⁸

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

³⁴ 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>, 19 April 2010.

³⁵ <http://www.efpia.org/Content/Default.asp?PageID=538>, 19 April 2010.

³⁶ 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>, 22 April 2010.

³⁷ EFPIA FACTSHEET, *supra* note 31.

³⁸ EFPIA: *Intellectual Property and Pharmaceuticals*, p. 15. Available at: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4901>, 19 April 2010.

approval is not difficult to obtain since the product will be entering an already existing market³⁹.

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.”⁴⁰

2.4.2 The Community Competition Rules

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 producers⁴¹. The relevant question in this context is “what type of competition”⁴² 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-Praxis Biologicals* decision⁴³ refused to apply the general rule on compulsory licensing as established in *Magill*⁴⁴ 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

³⁹ *Ibid.*

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

⁴¹ Hunter, *supra* note 2, p. 13.

⁴² *Ibid.*, p. 14.

⁴³ 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.

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

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.”⁴⁵

However, the Commission is not always consistent in this view, as evidenced by the *Bayer-Adalat* decision⁴⁶, 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 strategies⁴⁷.

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.⁴⁸ As Russell G. Hunter concluded:

“It is therefore in light of these factors that the present Community regime must be analysed. This 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.”⁴⁹

⁴⁵ Cited in *See Hunter, supra* note 2, p. 15.

⁴⁶ 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.

⁴⁷ Hunter, *supra* note 2, p. 15.

⁴⁸ *Ibid.*

⁴⁹ *Ibid.*, p. 16.

3 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 exclusivity for orphan drugs (drugs used for the treatment of rare conditions)⁵⁰. As regards the latter the European legislator has explicitly recognised the need to encourage the research also in drugs of little demand:

“Some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product ... [I]t is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry.”⁵¹

3.1 Patents

3.1.1 Patent Rights

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 similar⁵². This is because of the harmonising effect of the TRIPS Agreement, Member States are parties to the European Patent Convention 2000⁵³ 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 patentable⁵⁴, i.e. the invention is novel⁵⁵, inventive⁵⁶ and susceptible of industrial application⁵⁷. Patent claims can be

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

⁵¹ *Ibid*, paras. 1-2.

⁵² EFPIA: *Intellectual Property and Pharmaceuticals*, *supra* note **Error! Bookmark not defined.**, p. 16.

⁵³ 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.

⁵⁴ 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.”

filled 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”.⁵⁸ The period of protection is 20 years from the date of the filing⁵⁹.

According to Art. 28 of the TRIPs Agreement⁶⁰, 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, 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 valid⁶¹.

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

⁵⁵ 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.”

⁵⁶ 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.”

⁵⁷ 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.”

⁵⁸ See Art. 64 of the EPC.

⁵⁹ See Art. 63 of the EPC.

⁶⁰ 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.”

⁶¹ EFPIA: *Intellectual Property and Pharmaceuticals*, supra note 38, p. 17.

3.1.2 Patent Application Process

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 offices⁶².

Filing a claim in accordance with PCT offers also additional benefits, such as:

“The applicant can postpone the decision on which of the designated countries it wants to enter until approximately 30 months from the priority date. By this time, the invention which is the subject of the patent application will have been searched for relevant prior art, and an international preliminary examination report will have been established regarding the patentability of the invention. Negative search and examination reports enable the patent applicant to make the decision to discontinue before incurring the majority of costs associated with the patent filing when entering the European patent system. It also alerts the applicant to potential problems which will be encountered in substantive examination before the EPO. Many applicants choose to have a search and international report established by the EPO even when the receiving office is in a different country.”⁶³

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.⁶⁴ Applicants can put forward arguments in support of the patentability of their inventions, which can consist of technical data and expert reports.⁶⁵ Third parties can, also anonymously, file observations against patent application⁶⁶, to which the applicant has the opportunity to respond.⁶⁷ If an application is rejected, the applicant can lodge an appeal, which is then decided the Appeal Board⁶⁸.

⁶² *Ibid.*

⁶³ *Ibid.*, pp. 17-18.

⁶⁴ *Ibid.*, p. 18.

⁶⁵ *Ibid.*

⁶⁶ 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>, 20 April 2010.

⁶⁷ EFPIA : *Intellectual Property and Pharmaceuticals*, *supra* note 38, p. 19.

⁶⁸ *Ibid.*

3.2 *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 1768/92⁶⁹ 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 patent⁷⁰ as it extends the initial patent protection by up to 5 years⁷¹. However, the patent holder cannot enjoy more than 15 years of combined patent and SPS exclusivity from the first authorisation in the Community⁷². The certificate can be given in respect of products already enjoying the protection of a valid patent⁷³ and if different parties hold patents relating to the same product, each of them is entitled to a separate SPC⁷⁴.

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.*⁷⁵ 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

⁶⁹ 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.

⁷⁰ See Art. 5 of the Council Regulation 1768/92.

⁷¹ See Art. 13 of the Council Regulation 1768/92.

⁷² See Recital 8 of the Council Regulation 1768/92.

⁷³ See Art. 4 of the Council Regulation 1768/92.

⁷⁴ 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.

⁷⁵ Cases C-207/03 *Novartis v. Comptroller General* and C-252/03 *Ministre de l'Economie v Millenium Pharmaceuticals*, [2005] RPC 33.

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.”⁷⁶

Additional IP protection for exclusive rights against imitation is granted through Regulation EC 1901/2006⁷⁷. This Regulation requires for the release of a marketing authorisation relating to the use of a product in children (unless a waiver or deferral is granted) that a paediatric investigation plan is established and data is submitted to the European Medicines Agency⁷⁸. 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 period⁷⁹.

3.3 *Regulatory Data Protection*

“Regulatory data protection (“RDP”) is a form of exclusive right enforced through the marketing authorisation procedure.”⁸⁰

An originator company when releasing a new medicine on the market must provide vast amount of information on its product⁸¹ in order to obtain the necessary market authorisation⁸². 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

⁷⁶ *Ibid.*, para. 26.

⁷⁷ 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.

⁷⁸ See Art. 15 of Regulation 1901/2006.

⁷⁹ EFPIA : *Intellectual Property and Pharmaceuticals*, *supra* note 38, p. 20.

⁸⁰ *Ibid.*

⁸¹ *Ibid.*

⁸² 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.

certain period until it would be permitted to rely on the data provided by the innovator⁸³. 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 time⁸⁴: 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 reasons⁸⁵. 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.

⁸³ See Art. 10 of Directive 2001/83/EC.

⁸⁴ *Ibid.*

⁸⁵ EFPIA: *Intellectual Property and Pharmaceuticals*, *supra* note **Error! Bookmark not defined.**, p. 21.

4 Strategic Patenting of Pharmaceuticals in the European Union

4.1 Introduction to 'Evergreening'

In the final report of the European Commission's sector inquiry⁸⁶, the Commission identifies a series of originator patent strategies, which it describes as aiming "to extend the breadth and duration of their patent protection"⁸⁷ and "to delay or block the market entry of generic medicines"⁸⁸. 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"⁸⁹, which is why competition rules should not be applied in the same manner as they would in other technology areas⁹⁰.

As discussed in chapter 3, 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

⁸⁶ Available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, 22 April 2010.

⁸⁷ Commission Communication, of 8 July 2008, p. 11. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf, 22 April 2010.

⁸⁸ *Ibid.*

⁸⁹ Commission Pharmaceutical Sector Inquiry Preliminary Report (DG Competition Staff Working Paper), of 28 November 2008, p. 5. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf, 22 April 2010.

⁹⁰ 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, 22 April 2010.

tend to protect delivery profiles, packaging, derivatives, and isomeric forms, mechanism of action, dosing regimen, and dosing route, and dosing route, different methods of treatment, combinations, screening methods, biological targets and field of use for the same old molecule.”⁹¹

‘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 inventions⁹². At the same time, multiple patents on the same product can prolong the exclusivity that the patentee enjoys⁹³ 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 blocked⁹⁴. 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”⁹⁵.

4.2 *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 specimen⁹⁶. The manufacturer of the original product seems less

⁹¹ Inderjit Singh Bansal, Deeptymaya Sahu, Gautam Bakshi, Sukhjeet Singh, “Evergreening – A Controversial Issue in the Pharma Mileu”, (2009) Vol. 14 *Journal of International Property Rights*, p. 299.

⁹² GlaxoSmithKline Briefings, *Evergreening*. Available at: <http://www.gsk.com/policies/GSK-and-evergreening.pdf>, 22 April.

⁹³ 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.

⁹⁴ Bansal, *supra* note 91, p. 2.

⁹⁵ John R. Thomas, *Patent “Evergreening”: Issues in Innovation and Competition*, p. 4. Available at: http://ipmall.info/hosted_resources/crs/R40917_091113.pdf, 22 April 2010.

⁹⁶ Hanns Ullrich, “Wahrung von Wettbewerbsfreiräumen innerhalb der Schutzrechtsverwertung“, *Die Sektoruntersuchung Pharma - kartellrechtliche Disziplinierung des Patentsystems? Symposium 17 Juli*

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 cycles⁹⁷.

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"⁹⁸. To protect their interests, originator companies engage in 'evergreening' which involves i.a.: forming patent clusters, secondary patent applications, divisional patent applications or conclusion of agreements with generic manufacturers in order to postpone generic market entry. While such defensive strategies are frequently used in the pharmaceutical sector, comparable practices of patent applications are not unprecedented in other industries either.

Patent 'thickets' or patent 'clusters' are formed when "originators file numerous broad and 'weak' patents around the original molecule patent."⁹⁹ Divisional patent applications split parent patent application into one or several narrower patent applications¹⁰⁰.

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 market¹⁰¹, 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 litigation¹⁰². 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

2009 *Munchen - Vorträge und Materialien*, (to be available as of July 2010) Bücher Carl Heymanns Verlag.

⁹⁷ *Ibid.*

⁹⁸ Bansal, *supra* note 91, p. 4.

⁹⁹ Mavroghenis, *supra* note 90, p. 5.

¹⁰⁰ *Idem*, p. 6.

¹⁰¹ Mavroghenis, *supra* note 90, p. 7.

¹⁰² European Generic Association, *Evergreening of Pharmaceutical Market Protection*. Available at: <http://www.egagenerics.com/gen-evergrn.htm>, 22 April 2010.

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”¹⁰³. The European Commission in its turn seems to take the view that legitimate business practices cannot become illegitimate simply by their cumulative application¹⁰⁴, 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 them¹⁰⁵.

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.”¹⁰⁶

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”¹⁰⁷, since it can delay competition between products based on same original invention¹⁰⁸. However, “patenting throughout life of a product is not novel and not restricted to the pharmaceutical sector”¹⁰⁹. Moreover, if it can be confirmed that:

¹⁰³ Mavroghenis, *supra* note 90, p. 10.

¹⁰⁴ Commission, Final Report, *supra* note 9, p. 16.

¹⁰⁵ Commission, Final Report, *supra* note 9, p. 15.

¹⁰⁶ *Ibid*, p. 11.

¹⁰⁷ 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>.

¹⁰⁸ Commission, Final Report, *supra* note 9.

¹⁰⁹ Mavroghenis, *supra* note 90, p. 7

“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”¹¹⁰

it is a fair question to ask 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 manufacturers¹¹¹ raise doubts whether the expected quality and legal safeguards of the patenting process are always fully observed.

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 companies¹¹² or enter into settlement agreements¹¹³. 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 doubt¹¹⁴.

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”¹¹⁵. 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

¹¹⁰ 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, 22 April.

¹¹¹ Commission, Final Report, *supra* note 9, p. 13.

¹¹² 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, 22 April 2010.

¹¹³ Commission, Final Report, *supra* note 9, p. 12.

¹¹⁴ Hanns Ullrich, “VI Abschnitt. Kartellverhaltensverordnung” in Ulrich Immenga, Ernst-Joachim Mestmäcker, *Wettbewerbsrecht Kommentar zum Europäischen Kartellrecht*, 4. Auflage, München, Verlag C. H. Beck, 2007.

¹¹⁵ 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, 23 April 2010.

conclusion¹¹⁶. 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 Guidelines¹¹⁷.

Combe¹¹⁸ 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 companies¹¹⁹. 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.

4.3 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 innovation¹²⁰. 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 conflicts¹²¹. In this

¹¹⁶ *Ibid.*

¹¹⁷ 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."

¹¹⁸ 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.

¹¹⁹ 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

¹²⁰ Commission, Final Report, *supra* note 9, p. 17.

¹²¹ *Ibid.*

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 competition¹²².

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 them¹²³ 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”¹²⁴.

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 (...)”¹²⁵

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 application¹²⁶.

¹²² 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, 23 April 2010.

¹²³ Mavroghenis, *supra* note 90, slide 8.

¹²⁴ 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.

¹²⁵ Commission, Final Report, *supra* note 9, p. 16.

¹²⁶ Ullrich, Wahrung von Wettbewerbsfreiräumen... *supra* note 96.

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 presence¹²⁷. 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 all¹²⁸.

4.4 *Scope for Applying Article 102 TFEU (ex Art. 82 EC) to Strategic Patenting*

Paragraph seven of the Technology Transfer Guidelines¹²⁹ says:

“Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive economy”.¹³⁰

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 abusive¹³¹ 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 welfare¹³².

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

¹²⁷ 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.”

¹²⁸ Ullrich, *Wahrung von Wettbewerbsfreiräumen...* *supra* note 96.

¹²⁹ See *supra* note 117.

¹³⁰ European Commission’s Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements, [2004] C101/2.

¹³¹ Alison Jones, Brenda Sufrin, *EC Competition Law*, Oxford, Oxford University Press, 2007, p. 554.

¹³² Whish, *supra* note 117, pp. 758 - 759.

a “tool box” of practices which in its view hamper market entry by generics and other innovators¹³³. However, does the Commission have a case under Art. 102 TFEU?

Conditions for applying Article 102 TFEU (ex Art. 82 EC) to refusals to licence have been established in the *AB Volvo v. Erik Veng* case¹³⁴, 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 refusal¹³⁵.

“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?”¹³⁶

The limits of the footprint test have been expanded in *IMS Health*¹³⁷, in which the ECJ held that the duty to supply arises only if there are separate markets, one upstream and one downstream¹³⁸ and “it is sufficient that a potential market or even a hypothetical market can be identified”¹³⁹.

From an *ex ante* perspective, patents are a necessary incentive for the manufacturer to commit to R&D investments¹⁴⁰. However, “[o]nce it is shown that the refusal prevents the marketing of a new improved/differentiated product, arguments

¹³³ Commission, Preliminary Report, *supra* note 9, p. 5.

¹³⁴ Case 238/87, *AB Volvo v. Erik Veng*, [1988] ECR 6211, [1989] 4 CMLR 122.

¹³⁵ Jones, Sufrin, *supra* note 131, p. 560.

¹³⁶ 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>, 23 April 2010.

¹³⁷ Case C-418/01, *IMS Health GmbH & Co v. NDC Health GmbH & Co*, [2004] ECR I-5039, [2004] 4 CMLR 1543.

¹³⁸ *Ibid*, para. 42.

¹³⁹ *Ibid*, para. 44.

¹⁴⁰ Valentine Korah, *An Introductory Guide to EC Competition Law and Practice*, Oxford, Hart Publishing, 2007, p. 364.

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”¹⁴¹. The *ex post* test, whereby investment in innovation has been successful if it has generated valuable patents¹⁴² was developed in the *Volvo*¹⁴³ 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”¹⁴⁴. However, Gerardin¹⁴⁵ 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. Gerardin 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 abuse¹⁴⁶, Art. 102 TFEU (ex Art. 82 EC) can be applied in “exceptional circumstances” in the interest of consumer welfare¹⁴⁷. The

¹⁴¹ Kjolbey, *supra* note 136, p. 10.

¹⁴² Korah, *An Introductory...supra* note 140, p. 364.

¹⁴³ *Volvo v. Veng*, *supra* note 134.

¹⁴⁴ *IMS Health Case*, *supra* note 137, para. 48.

¹⁴⁵ Damien Gerardin, “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, 23 April 2010.

¹⁴⁶ Jones, Sufrin, *supra* note 131, p. 554.

¹⁴⁷ Whish, *supra* note 117, p. 789.

question thus arising is whether there is actually a convincing consumer welfare case for intervening against strategic patenting under Art. 102 TFEU (ex Art. 82 EC)¹⁴⁸.

In the case of patent thickets, in the absence of a clear legal ground for determining when multiple patenting becomes illegal¹⁴⁹, such an analysis has to be conducted on a case-by-case basis, which can lead to controversy¹⁵⁰. While “[i]t cannot be abusive to use the patent system to obtain optimal protection of an innovation”¹⁵¹, Art. 102 TFEU (ex Art. 82 EC) will be contravened if besides the normal patent use, an additional element would be present¹⁵². 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 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.”¹⁵³

Secondary Patents raise similar difficulties in terms of how to argue a possible Art. 102 TFEU (ex Art. 82 EC) 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 entry¹⁵⁴. Although the purpose of compulsory licensing is to foster innovation, it should remain a matter of patent law and not competition law¹⁵⁵.

¹⁴⁸ Kjolbey, *supra* note 136, p. 11.

¹⁴⁹ *Ibid*, p. 12.

¹⁵⁰ Inge Govaere, *The Use and Abuse of Intellectual Property Rights in E.C. Law*, Sweet & Maxwell, London, 1996, p. 113.

¹⁵¹ Kjolbey, *supra* note 136, p. 12.

¹⁵² Govaere, *supra* note 150, p. 155.

¹⁵³ Teva, *Overview of Alendronate Litigation in the EC*, p. 12. Available at: http://ec.europa.eu/competition/consultations/2009_pharma/teva_annexes.pdf, 23 April 2010.

¹⁵⁴ Kjolbey, *supra* note 136, p. 13.

¹⁵⁵ Whish, *supra* note 117, p. 787.

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 positions¹⁵⁶. Furthermore, according to Art. 52 of the EPC 2000¹⁵⁷, 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 EPC¹⁵⁸. However, in its *Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses*¹⁵⁹, 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.”¹⁶⁰

In conclusion, it appears evident that competition law cannot provide an adequate mechanism for remedying the imperfections of the patent system.¹⁶¹

¹⁵⁶ Kjolbey, *supra* note 136, p. 14.

¹⁵⁷ 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.”

¹⁵⁸ 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.”

¹⁵⁹ Available at: <http://ec.europa.eu/competition/antitrust/art82/discpaper2005.pdf>, 23 April 2010.

¹⁶⁰ *Ibid*, para. 239.

¹⁶¹ Kjolbey, *supra* note 136, p. 15.

5 Patent Infringement Lawsuits – the Judiciary’s View on Strategic Patenting

5.1 Introduction

One of the objectives of the sector inquiry was to determine the reasons for the observed delays in market entry that generic medicines experience and the decline in innovation measured by a drop in the number of new medicines being released¹⁶². In addition to this observation, the Commission also notes that several brand-name drugs have lost patent protection or will do so in near future which in the absence of new market releases forces the originator companies to rely on existing “blockbusters”¹⁶³, for which they aim at maintaining exclusivity as long as possible¹⁶⁴ by using for instance life cycle management strategies. One such strategy involves the filing of secondary patents, through which generic market entry could be delayed.

Secondary patents can be defined as patented discoveries which appeared during the course of the research process¹⁶⁵. Such patents can only be filed later than the principal patent, which becomes prior art in relation to the secondary patent¹⁶⁶.

The following sub-chapter summarises a series of decisions of the UK Patents Court regarding the validity and enforcement of secondary patents with a view to consider on the one hand, how the judiciary defines the tolerable limits for strategic patenting and, on the other hand the potential benefits and risks involved in litigation¹⁶⁷.

¹⁶² Commission, Final Report, *supra* note 9, p. 3.

¹⁶³ “[M]edicines whose annual global turnover exceeds US\$ 1 billion”, Commission, Final Report, *supra* note 9 p. 3.

¹⁶⁴ Commission, Final Report, *supra* note 9, p. 3.

¹⁶⁵ Michael Burdon, Kristie Sloper, “The Art of Using Secondary Patents to Improve Protection”, [2003] Vol. 3, No. 3, *International Journal of Medical Marketing, Special Issue*, p. 3. Available at: http://www.olswang.com/pdfs/secondary_patents_jun03.pdf, 24 April 2010.

¹⁶⁶ *Ibid.*

¹⁶⁷ The body of case law in the UK in this field is reasonably sizeable. The position of the UK Patents Court may therefore be presumed to be matured and consistent enough to prove useful in this context. Moreover, the content of patent legislation in the EU is unlikely to differ significantly from one jurisdiction to another and it is a fair assumption that the views of courts in other Member States tally with those taken by the UK judiciary.

5.2 Strategic Patenting in Litigation

Case law has shown that secondary patents can be efficient in extending patent exclusivity in spite of the difficulty of maintaining the validity of such patents.¹⁶⁸ An example of such an outcome is *SmithKline Beecham v Generics (UK) Ltd (23 October 2001)*¹⁶⁹, which concerns GSK's antidepressant product Paroxetine, a “blockbuster” traded in the UK as Seroxat®. Patent protection on the basic compound paroxetine hydrochloride had expired in the UK in January 1999. However, GSK managed to obtain secondary patents referring to the same product. SmithKline Beecham applied for an interim injunction restraining infringement of one of these secondary patents, injunction which was granted. This was the first interim injunction granted in patent proceedings in the UK for a number of years which made it a very important victory for the patentee. What played a crucial role in this case was the fact that the generic manufacturer was aware of the patent for a long time and could have cleared its position before launching its product. This is a landmark decision which without a doubt will have an influence on the decisions of generic companies to put their products on the market in situations where they are or ought to be aware of the existence of secondary patents¹⁷⁰.

Following the decision in *SmithKline Beecham v Generics (UK) Ltd*, in *SmithKline Beecham v Apotex & others*¹⁷¹, SmithKline Beecham applied for a another interim injunction against the infringement of the same patent by Apotex and others, patent which had been held partially invalid in *BASF AG v SmithKline Beecham*¹⁷².

The defendants in this case argued that since the patent was not used by the plaintiff, they had not suffered any losses and should not be entitled to damages. Moreover, an interim injunction would be disproportionate, since damages would be sufficient in the event the Court would find a patent infringement. Again, the court remained unconvinced by the arguments put forward by the defendants and stood by its previous ruling, stating that:

¹⁶⁸ *Ibid*, p. 16.

¹⁶⁹ *SmithKline Beecham v Generics UK Ltd*, [2002] IPD January 25005.

¹⁷⁰ Burdon, Sloper, *supra* note 165, p. 4.

¹⁷¹, Case *SmithKline Beecham PLC & another v Apotex Europe Ltd & others*, [2003] 26 IPD 26005.

¹⁷² Case *BASF AG v SmithKline Beecham PLC*, [2002] EWHC 1373.

"Where litigation is bound to ensue if the defendant introduces his product he can avoid all the problems of an interlocutory injunction if he clears the way first. That is what the procedures for revocation and declaration of non-infringement are for".

Courts may be reluctant to acknowledge the validity of formulations patents, as *Cairnstores Ltd & Generics (UK) Ltd v Aktiebolaget Hassle* (6 March 2002; 22 October 2002) (*OMEPRAZOLE*)¹⁷³ illustrates. In this case, the main patent was granted for an oral preparation of Omeprazole, a drug "which inhibits the secretion of acid in the stomach and is used in the treatment of gastric ulcers"¹⁷⁴. After patent expiry, the plaintiff had obtained a Supplementary Protection Certificate for the drug. The invention consisted of manufacturing procedure, which would render the orally administered drug resistant to stomach acid but also bioavailable in the intestines.¹⁷⁵ However, agreeing with the claimants in the sense that the patent was based on prior art, the Court revoked the patent stating that:

"(1) the possibility of chemical interaction between a new drug and each of the excipients contemplated for use in the dosage form, including the coating material, would have been recognised by the skilled formulator. Compatibility tests would have been carried out as a matter of course, which would have shown incompatibility between the omeprazole and the coating material;

(2) a soluble intermediate layer or coat would have been expected to work by the notional skilled man, or to be sufficiently likely to work to warrant trial. There was nothing which would have deterred him from trying such a separating layer. Therefore Claim 1 and all the remaining claims failed for obviousness, and the prior art (various technical leaflets/books) relied on by the claimants also rendered the claim invalid for obviousness."¹⁷⁶

Nevertheless, should the validity of formulation patents be confirmed, they can prove very useful from the viewpoint of consumers.

Subsequent medical uses can be patentable if the new application is novel compared to the known one.

Article 53 c) of the European Patent Convention states that:

¹⁷³ Case *Cairnstores Ltd v Aktiebolaget Hassle*, [2002] FSR 35

¹⁷⁴ Burdon, Sloper, *supra* note 165, p. 8.

¹⁷⁵ *Ibid*, p. 9.

¹⁷⁶ *Ibid*.

“[M]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

Article 54 of the same Convention in its turn establishes that:

“(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.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art. (Emphasis added)

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art. (Emphasis added)

In *Lilly ICOS v Pfizer (23 January 2002) (VIAGRA)*¹⁷⁷ the object of the case was Pfizer's patent for a second medical use of Viagra (sildenafil citrate). In 1991 and 1992 Pfizer patented a series of compounds useful in the treatment of angina and hypertension. In 1992 and 1993 several research articles also suggested that one of these compounds could also be used in treating impotence and male erectile dysfunction (MED). In June 1994 Pfizer applied for a patent for that new medical use, which covered basically the same compounds.

The plaintiff argued that the patent was invalid because of obviousness given the fact that its substance had been revealed through the published research between 1992 and 1993. According to the court, the only difference between the prior art and the patent claim was that the drug could be administered orally¹⁷⁸, which did not amount to an invention. The court upheld the plaintiff's view and invalidated the patent.

¹⁷⁷ Case *Lilly ICOS Ltd. v Pfizer Ltd.*, [2002] EWCA Civ 1.

¹⁷⁸ Burdon, Sloper, *supra* note 165, p. 12.

Upon appeal, the Court of Appeal confirmed the previous ruling, stating that prior art would have led any skilled observer to the conclusion that the inhibitors would also be effective in the treatment of impotence and MED and that testing the compounds out for that purpose did not constitute an inventive step¹⁷⁹. Regarding its oral administration, the Court said that since there was nothing in the specification suggesting a difficulty in adapting the drug for oral use, the latter would seem as an obvious administration method¹⁸⁰.

However, new treatment regimes claims could also easily backfire since they are very likely to be considered as claims regarding a method of treatment and consequently non-patentable according to the provisions of the EPC¹⁸¹.

As observed above, Article 53 c) of the European Patent Convention sets as exception from patentability “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body”¹⁸². Therefore, it might prove difficult to seek patents for new treatment regimes in Europe, as *Bristol Myers Squibb v Baker Norton (23 May 2000) (TAXOL)*¹⁸³ shows.

The case concerned the substance Taxol, one of Bristol Myers Squibb's products. Taxol is used in the treatment of cancers, but as is often the case with such preparations has severe side effects such as neutropenia, a reduction in the white blood cell count¹⁸⁴. Paclitaxel/Taxol is a natural substance which can be obtained from the bark of the Pacific Yew tree. The substance had been known for its anti-cancer properties. In 1993, Bristol Myers Squibb filed for a patent in UK for a particular regime covering the dosage and the infusion duration of Taxol.

During the appeal, the decision of the High Court was upheld. It was confirmed the patent claim had been made for a "method of treatment" and was therefore non-patentable. Since the patent claim was not made for the treatment of a different illness,

¹⁷⁹ *Ibid.*

¹⁸⁰ *Ibid.*

¹⁸¹ Burdon, Sloper, *supra* note 165, p. 16.

¹⁸² Art. 53 c) EPC.

¹⁸³ Case *Bristol Myers Squibb Co. v Baker Norton Pharmaceuticals Inc.*, [1999] RPC 253.

¹⁸⁴ Burdon, Sloper, *supra* note 165, p. 14.

nor was it made for the treatment of the same disease but in a different way, the court held that the patent was covering the same therapeutic use¹⁸⁵.

Litigation can prove an efficient means for pharmaceutical companies to protect their interests but it may be costly and might involve risks. By way of an example, even if a secondary patent is held to be invalid generics' market entry will anyway be delayed, while litigation costs might have the effect of inhibiting further competition from other generic manufacturers¹⁸⁶. Moreover, in some situations, depending on the success of the product, the sales determined by the additional, albeit only temporary, exclusivity might bring a greater benefit than the costs of patent litigation¹⁸⁷. Obviously, patent litigation can negatively influence consumers' wellbeing, by delaying generic market entry, and may also distort research efforts.¹⁸⁸

What the courts have been trying to accomplish is to encourage claims for broad initial patents, but still leave enough space for valuable secondary patents. One possible reason for this approach is the belief that initial broad patents could have a chilling effect on further research¹⁸⁹. For this reason, the scope of some patents would need to be limited.¹⁹⁰ By allowing courts a certain level of discretion in the interpretation of claims, they might also be able to foster additional incentives for valuable future secondary patents¹⁹¹.

¹⁸⁵ Audrey Horton, *Taxol Appeal*, Available at:

http://www.twobirds.com/English/News/Articles/Pages/taxol_appeal.aspx, 24 April 2010.

¹⁸⁶ Burdon, Sloper, *supra* note 165, p. 16.

¹⁸⁷ *Ibid.*

¹⁸⁸ Sandy Campart, Etienne Pfister, "Les conflits juridiques liés à la propriété industrielle : le cas de l'industrie pharmaceutique et biotechnologique", (2002) Vol. 99, *Revue d'économie industrielle*, pp. 87-106.

¹⁸⁹ Bengt Domeij, "Patent Claim Scope: Initial and Follow-on Pharmaceutical Inventions in Europe", in Ove Granstand, *Economics, Law and Intellectual Property*, Dordrecht, Kluwer Academic Publisher, 2003, p.197.

¹⁹⁰ *Ibid.*

¹⁹¹ Domeij, *supra* note 189, p. 177.

6 Is Strategic Patenting a Response to a Legal Problem?

6.1 *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. By way of example:

“Patent evergreening promotes development of unfair means of competition and related abuse. Enhanced IP scrutiny may remove the curse of these practices which are widely followed by the innovator companies to create a roadblock for generic companies (...)”¹⁹²

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 risk¹⁹³. As discussed in previous chapters 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.¹⁹⁴

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”¹⁹⁵. 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 before¹⁹⁶:

¹⁹² Bansal, *supra* note 91, p. 8.

¹⁹³ 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, 25 April 2010.

¹⁹⁴ Mavroghenis, *supra* note 90, p. 11.

¹⁹⁵ Temmerman, *supra* note 193, p. 35.

¹⁹⁶ *Ibid.*

“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).”¹⁹⁷

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 it¹⁹⁸. Most patent systems employ this test to ensure that trivial changes to prior art are precluded from patentability¹⁹⁹. 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 distortions²⁰⁰.

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 rate²⁰¹. 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 unchanged²⁰². 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

¹⁹⁷ Temmerman, *supra* note 193, p. 35.

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

¹⁹⁹ 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.”

²⁰⁰ Lionel Bently and Brad Sherman, *Intellectual Property Law*, Second Edition, Oxford University Press, 2004, p. 470.

²⁰¹ Commission, Final Report, *supra* note 9, p. 21.

²⁰² 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>, 24 April.

fields²⁰³. 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”,²⁰⁴.

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.²⁰⁵

A figure of “up to 1,300” patents for one patent cluster as brought up as an example by the Commission²⁰⁶ 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.²⁰⁷

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 claim²⁰⁸. 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 years²⁰⁹. Furthermore, generic companies would be unlikely to make use of such an opportunity, since generally they do not oppose to the

²⁰³ *Ibid.*

²⁰⁴ *Ibid.*

²⁰⁵ *Ibid*, p. 7.

²⁰⁶ Commission, Final Report, *supra* note 9, p. 10.

²⁰⁷ Jacob, *supra* note 202, p. 7.

²⁰⁸ *Ibid.*

²⁰⁹ *Ibid*, p. 8.

granting of a patent unless the product covered by it was already on the market²¹⁰. 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 sector²¹¹.

The Commission does acknowledge the need for a strong and fast Central Patents Court for Europe, 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.”²¹²

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:

“(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.”²¹³

Intellectual property legislation should of course not confer on patent holders dominant positions or inflate their market power²¹⁴. Where however that should be the case competition law should help to identify such situations²¹⁵. While the exercise of IPR is not in itself abusive patents can be used as an instrument to gain and to abuse a dominant position²¹⁶. However, in such situations the abuse of patents amounts to a violation of competition rather than patent law.

²¹⁰ *Ibid.*

²¹¹ *Ibid.*, p. 9.

²¹² Commission, Final Report, *supra* note 9, p. 21.

²¹³ Jacob, *supra* note 202, p. 10.

²¹⁴ 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.

²¹⁵ *Ibid.*

²¹⁶ 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

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.²¹⁷ Changes to the system should be designed and implemented with prudence, as any too dramatic changes could work against a significant part of the industry²¹⁸. The Commission recognises the importance of patents for encouraging innovation and from a broader perspective, the relevance of patents to the pharmaceutical industry²¹⁹. 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 citizens²²⁰.

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 useful²²¹.

6.2 *Is Patent Protection Sufficient?*

As discussed and emphasised in previous chapters, 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 expenses²²². It is therefore in principle not unreasonable to require stronger guarantees and greater rewards with increasing risk.²²³

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,

Studies No 8, P.I.E. Peter Lang, Brussels, 2008, p. 116.

²¹⁷ Jacob, *supra* note 202, p. 10.

²¹⁸ *Ibid.*

²¹⁹ Commission, Final Report, *supra* note 9, p. 2.

²²⁰ Jacob, *supra* note 202, p. 11.

²²¹ Ullrich, *Wahrung...supra* note 128, p. 24.

²²² Jacob, *supra* note 202, p. 4.

²²³ *Ibid.*

patent holders enjoy around 10 or 11 years of exclusivity²²⁴. 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 costs²²⁵, 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 them²²⁶. It is not realistic to assume that generic companies favour low prices, or that their values would be those of a charity. Just like their originator competitors, they are businesses and as such, in pursuit of profit²²⁷.

“The lower the prices the less the profit. It is human nature for a generic company to want to be close to a high price. That is why, for instance, we often receive evidence from generic companies about how important it is that they should be first in the market. If it can be first it can and very likely will set its initial price at something like 10% below the patentee's. That will very likely take a substantial portion of the market and with a very large profit margin.”²²⁸

²²⁴ *Ibid.*

²²⁵ Jacob, *supra* note 202, p. 5.

²²⁶ *Ibid.*

²²⁷ *Ibid.*

²²⁸ *Ibid.*

Putting aside emotion and irrational prejudice²²⁹ 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?

²²⁹ *Ibid*, p. 6.

7 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 profits²³⁰. 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 (ex Art. 82 EC) 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 2009²³¹ and the eventual results of the legal proceeding against the pharmaceutical company Lundbeck²³². It will be very difficult to demonstrate that patent strategies are

²³⁰Hunter, *supra* note 2, p. 11.

²³¹ 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>, 25 April 2010.

²³² 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>, 25 April 2010;

abusive²³³, especially since the application of competition rules could interfere “with the patent regime itself and its very rationale”²³⁴.

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 Jacob²³⁵. 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”²³⁶.

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?

²³³ See also *supra* note 124.

²³⁴ Mavroghenis, *supra* note 90, p. 18.

²³⁵ See *supra* note 200.

²³⁶ Temmerman, *supra* note 193, p. 38.

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