

Strategic Patenting in the Pharmaceutical Sector – A Competition Law Perspective

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1. Introduction

The aim of this thesis is to show to what extent competition law can be enforced in the field of strategic patenting by dominant undertakings in the pharmaceutical sector. Strategic patenting is sought to refer to practices involving the fragmentation of patent rights or the extension of the basic patent protection that aims at constraining the freedom of action of other undertakings on the relevant market. The inevitable result is the unjustified enhancement of the breadth and length of the exclusionary right which is deemed abusive under Article 102 TFEU. The objective of an undertaking in using strategic patenting is to protect or enhance its market power by imposing barriers to entry, thus raising rival's costs to entry. This conduct runs counter to "competition on the merits".

In light of this, the first part of this discussion sets out the main objectives of both competition law and intellectual property law in order to see whether they pull in the same direction and, if not, whether they can be conciliated.

The pharmaceutical industry is targeted given the recent issuance of the Final Report of the Pharmaceutical Sector Inquiry¹ which seeks to underline the anti-competitive use of an array of patent strategies by dominant undertakings that are aimed at distorting competition on the pharmaceutical market. This includes both price competition and competition by innovation. The focus of this paper is placed on price competition. Hence, references are made to the barriers to entry encountered by generic manufacturers as a result of practices undertaken by originator producers such as patent clustering, divisional patents and regulatory abuses in patent filings. For this purpose, a discussion on the findings of the Commission in its Sector Inquiry² is carried out in the second part of this paper. Emphasis is placed on the finding that intellectual property law is too permissive as a legal framework, fostering the creation of a "giungla brevettuale"³.

The third part of this paper incorporates an analysis on how strategic patenting can be dealt with under competition law in the light of the decision delivered by the Commission⁴ which was later upheld by the General Court in *AstraZeneca*⁵. This paper focuses solely on the first line of abuse of dominant position

1 Pharmaceutical Sector Inquiry Final Report, European Commission, Competition DG, 8 July 2009, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, accessed on 1 June 2012.

2 Id.

3 Term meaning "patent jungle" adopted by the Italian Competition Authority in Case A431 *Ratiopharm v Pfizer*, Autorità Garante della Concorrenza e del Mercato, Decision no. 23194, Italy, 11 January 2012 at ¶129.

4 Commission Decision (Case COMP/A. 37.507/F3), delivered on June 15, 2005, O.J. [2006] L 332/24.

5 Case T-321/05, *AstraZeneca AB and AstraZeneca plc v Commission*, [2010] 5 C.M.L.R. 28.

by AstraZeneca because it tackles the precise concern regarding the interface between competition law and the procurement of intellectual property rights. The first line of abuse is characterised as the the artificial maintenance of market dominance by way of extending the term of the patent protection through fraudulently obtaining a supplementary protection certificate for Losec, a proton pump inhibitor. This practice had the effect of delaying the entry on the market of generic medicines which are deemed to be cheaper and more accessible, deterring consumer welfare as a result. In addressing the issue of regulatory abuse in patent filings, this discussion aims at proving whether the pending judgement of the European Court of Justice, if upholding the judgement delivered by the General Court⁶, could serve as a precedent in addressing the procurement of patents in a compliant manner by a dominant undertakings, where the sole purpose is to exclude competition on the market.

For this purpose, in the fourth part of this paper, an analysis of the Italian Competition Authority's finding of abuse in *Ratiopharm v Pfizer*⁷ concerning Pfizer's use of the patent system to delay entry of generics on the market is conducted, contrasting it to the legal reasoning adopted by the General Court in *AstraZeneca*⁸.

The finding of abuse in *Pfizer*⁹ is controversial because, as the facts of the case stand, Pfizer simply used the legal instruments available to obtain divisional patents for Xalatan, a medicine used to treat glaucoma, in order to be entitled to a supplementary protection certificate for the medicine, which, otherwise would not have been possible because the pharmaceutical company missed the original deadline for the the extension of the basic patent protection. The finding of abuse by the national competition authority was done in the light of the effects on the market of such strategic behaviour. This decision could be regarded as confirming the Commission's conclusion in its Sector Inquiry¹⁰ where it has been stated that the possible causes of the delay in generic entry and the decline in innovation can be attributed to these kinds of strategic behaviours. However, it shall be shown that the legal reasoning of the National Competition Authority in *Pfizer*¹¹ has departed from intent of the Commission displayed in both *AstraZeneca*¹² and in the Sector Inquiry¹³ to the extent that the authority shifted the balance too far in favour of the generic manufacturers. This is because the authority placed too much focus on the anti-competitive effects of the conduct. In so doing, it disregarded the principle of "competition on the merits" as prescribed by the General Court in defining the notion of abuse in *AstraZeneca*¹⁴.

In light of the above, is to be concluded that to proceed by correcting systemic failures of intellectual

6 Id.

7 Case A431 *Ratiopharm v Pfizer*, Autorità Garante della Concorrenza e del Mercato, Decision no. 23194, Italy, 11 January 2012.

8 *AstraZeneca*, *supra* note 5.

9 *Pfizer*, *supra* note 7.

10 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

11 *Pfizer*, *supra* note 7.

12 Commission Decision in *AstraZeneca*, *supra* note 4.

13 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

14 *AstraZeneca*, *supra* note 5.

property law by competition may not be the appropriate way. This is more so because there is a lack of clear guidance in the legal reasoning which may lead to false positive effects, chilling innovation.

2. The Interface between Intellectual Property and European Competition Law

“It is a long standing topic of debate in economic and legal circles: how to marry the innovation bride and the competition groom”¹⁵.

As Mario Monti affirmed, there has been a long standing debate on whether the objectives pursued by intellectual property and competition law run in parallel or whether they in fact complement each other. The conflict between effective competition and the right to property is apparent when looking at an undertaking’s right to choose how to dispose of its own property. The European Court of Justice¹⁶ emphasised the potential clash between ensuring the attainment of competition law objectives and the exercise of intellectual property rights as early as 1966 in the case of *Établissements Consten S.à.R.L and Grundig-Verkaufs v Commission*. The case concerns a contractual attempt to secure absolute territorial protection by agreement to register a trademark with the ultimate effect of deterring parallel imports. It was held that the agreement restricted trade within the meaning of Article 101(1) TFEU. The ECJ stressed that the finding does not affect the existence of the intellectual property right granted by the national authority in question but the exercise of it¹⁷. Thus, it could be inferred that competition and intellectual property law are separated as far as their particular uses are concerned. This is because intellectual property law is limited to the assignment and defending of intellectual property rights, whereas, competition law is confined to regulating the use of such rights.

In spite of this, there has been a departure from this approach. The Commission, in both reaching the decision in *AstraZeneca*¹⁸ and in its Sector Inquiry Report¹⁹, stresses that it will not hesitate in taking actions, through the use of competition law powers, against undertakings which use the national patent filing mechanisms in order to create barriers to entry on the market to generic manufacturers. Therefore, it is submitted that the aforementioned distinction between the exercise and existence of an intellectual property right has been blurred. This distinction shall be further addressed in acknowledging the different objectives of both competition and intellectual property law.

2.1. The objectives of intellectual property law

Intellectual property represents a creation of the mind to which property rights have been affixed by the national governments. Pierre Régibeau and Katherine Rockett emphasised the public good that may derive from the issuance of intellectual property rights: “intellectual property has strong public

15 M. MONTI, “The New EU Policy on Technology Transfer Agreements”, Speech/04/19, Ecole des Mines, Paris, 16 January 2004.

16 Henceforth ECJ.

17 Id., at p. 345.

18 Commission Decision in *AstraZeneca*, *supra* note 4.

19 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

characteristics and tends to generate significant amounts of socially useful information, making diffusion of information an important concern”²⁰. Thus, it could be said that such rights have been created to stimulate social welfare.

In the light of the above, the assignment of exclusive rights under the form of a patent is said not to be aimed by the national legislators at granting monopoly power to undertakings, but rather at enabling and incentivising them to make the findings of their research public so that others can build upon what has been discovered upon patent expiry. This objective runs complementary to that of competition law as patents in such case would lead to dynamic competition between undertakings on a given market as they would strive to compete in being the first to bring a better and improved product on the market. In turn, consumers would benefit from having a wide range of products at arguably lower prices.

Another view is that intellectual property rights are granted in order to reward the inventor for the costs and effort undertaken to develop his creation. The reward is characterised by a temporary exclusionary right. This intent can be seen in the ECJ’s definition of the specific subject-matter of a patent:

“the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by grant of licences to third parties, as well as to oppose infringements”²¹.

It is to be acknowledged that the rate of scientific and technological advancements could be so rapid that the right to exclude others from the patented matter represents the only form of exploitation that could enable an undertaking to recover its R&D costs. J. Schumpeter’s doctrine of creative destruction whereby monopoly power or quasi-monopoly power “incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one”²², supports this view. Based on this theory, the exclusionary right shall not constitute a concern in as much as there is dynamic competition or in other words competition by innovation namely: “competition from the new commodity, the new technology, the new source of supply, the new type of organization”²³. Notwithstanding, the criticism that can be brought to this theory is that it dismisses the importance of price competition which yields consumer welfare. Moreover, it is not to say that intellectual property rights confer monopoly power to each undertaking holding them. This view can be inferred from the approach adopted by the ECJ²⁴ in dismissing the argument that the mere procurement of an intellectual property right by an undertaking can confer to it a dominant position.

In juxtaposition to the reward theory, it may be argued that intellectual property rights do not provide such an important incentive for R&D activity. This is true for the activity of large corporations in competitive

20 P. RÉGIBEAU and K. ROCKETT, “The Relationship Between Intellectual Property Law and Competition Law: An Economic Approach” *Economics Discussion Papers 581*, University of Essex, Department of Economics (2004).

21 Case C- 15/73, *Centrafarm v Sterling Drug*, [1973] ECR 1147, at ¶ 9.

22 J. SCHUMPETER, *Capitalism, Socialism and Democracy* London: George Allen & Unwin LTD, 1942, at p.83

23 Id.

24 Case C-78/70, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG.*, [1971] ECR 487, at ¶ 16.

markets where the short term advantage appropriated through the developing of a new product and by being the first to put the product on the market may be a sufficient incentive in itself. Strong criticisms have been brought to the acquisition of patents as being inhibitors of innovation. Namely, as J. Robinson argues “a patent prevents the diffusion of new methods before the original investor has recovered profit adequate to induce the requisite investment”²⁵. Thus, the stagnancy of dynamic efficiency for a prescribed period of time overweighs the need for the protection of patents. Nevertheless, one ought to observe that this is not necessarily true as intellectual property law seeks to strike a balance between the diffusion of new methods and innovation. In addition, it has been argued that these potential anti-competitive effects are mitigated through the prescribed validity period of a patent²⁶.

Alternative mechanisms have been suggested in lieu of intellectual property rights such as fees, awards, acknowledgement, status and public financial support. S. Shavel and T. Van Ypersele have suggested a reward system by which the governments would remunerate innovation at their own discretion.²⁷ Nonetheless, public funding is not sufficient to support the ambit of technological developments. In addition, the burden that would be placed on taxpayers would be unsustainable. Consequently, intellectual property rights remain the only incentives for innovation.

2.2. The objectives of competition law

In the Commission’s First Report on Competition Policy in 1972²⁸, it was affirmed that a competition policy makes it easier to adjust the demand and supply structures of the market in order to suit ongoing technological developments. Efficient markets are thought to be the best instruments that deliver benefits in a modern economy. Hence, competition law seeks to cater for the sustainability of such markets. Furthermore, Mario Monti expressed that “the ultimate goal of the competition rules is simple: to assure that consumers benefit from new and improved products and lower prices”²⁹. It follows that competition authorities should intervene only where the conduct of an undertaking is likely to deter consumer welfare³⁰. Thus, competition law is a mechanism that deters firms from acting in a way that worsens the given market’s performance to the detriment of consumers. Furthermore, it seeks to prevent outcomes that are not stemming from the natural interaction between demand and supply³¹. In light of this, it is submitted that competition law enforcement occurs when an undertaking’s business strategy goes beyond what is considered “competition

25 J. ROBINSON, *The Accumulation of Capital*, 3rd ed., London: Macmillan, 1969.

26 Article 63(1) European Patent Convention of 29th November 2000 and Article 33 TRIPS Agreement 1994 prescribe a time limitation on validity which is 20 years from the date of filing of the patent application.

27 S. SCHAVEL and T. Van YPERSELE, “Rewards versus Intellectual Property Rights” (2011) 44 *Journal of Law and Economics* 525.

28 Commission’s First Report on Competition Policy, 1972, available at http://aei.pitt.edu/31201/1/Comp_1971-1st.pdf accessed on 30 January 2012, at p.11.

29 M. MONTI, “Competition and Information Technologies”, Speech/00/315, Barriers to Cyberspace Conference, Kangaroo Group, Brussels 18 September 2000.

30 Communication from the Commission —Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009]O.J. C 45/7, at ¶ 5.

31 M. MAGGIOLINA, *Intellectual Property and Antitrust: A comparative Economic Analysis of US and EU law*, Cheltenham: Edward Elgar Publishing Limited, 2011, at p. xv.

on the merits”³².

To this effect, it can be inferred from the judgement in *AstraZeneca*³³ that competition law trumps intellectual property rights when they are procured in a fraudulent manner, merely to operate as barriers to entry. The Italian Competition Authority in *Pfizer*³⁴, on the other hand, went even further in stating that intellectual property rights cannot be obtained, even when in a compliant manner, merely for the purpose of shielding dominant undertaking against competition from generic manufacturers.

2.3. Should competition authorities intervene when intellectual property rights are involved?

An essential aim of intellectual property law is to reward innovation through the exclusive right. This might be in conflict with competition policy. On the other hand, because of the dynamism of these innovation markets, the exclusivity might not even offend competition because there is always a strive for rivals to bring a better product or service to the market. It is believed that rivalry leads to an efficient allocation of resources by steering the incentive to innovate. In support of this, Baumol expressed in his writing that “competitive pressures, not present in other types of economy, that force firms in the relevant sectors of the economy to unrelenting investment in innovation and that, contrary to the widespread belief, provide incentives for the rapid dissemination and exchange of improved technology throughout the economy”³⁵. Thus, intellectual property rights can enhance dynamic competition by inducing investments into alternative products.

In the light of the above, it could be said that the optimum level of interference of competition authorities in matters concerning the acquisition or exercise of intellectual property rights should be based on the balancing of the social benefits derived from providing incentives for innovation and the costs of otherwise limiting the diffusion of knowledge³⁶.

It is to note that it is not from the benevolence of “the butcher, the brewer, or the baker that we expect our dinner, but from their regard to their own interest”³⁷. If one was to transpose this theory to the pharmaceutical sector, one would observe that a rational undertaking behaving in its own interest would seek to adopt legal available means to achieve the highest degree of exclusivity, thereby excluding competition on the market by raising the cost of entry. These exclusive rights might go beyond the entitlement envisaged by the patent legislators, be it in the light of the reward theory or the public good. Strategic patenting could therefore be curtailed by competition authorities, when the undertaking in an already dominant position,

32 Case T-228/97, *Irish Sugar Plc v E.C. Commission*, [1999] 5 C.M.L.R. 1300 at ¶ 111. Article 102 TFEU is said by the General Court to “prohibit a dominant undertaking from eliminating a competitor and thereby reinforcing its position by having recourse to means other than those within the scope of competition on the merits”.

33 *AstraZeneca*, *supra* note 5.

34 *Pfizer*, *supra* note 7.

35 W.J. BAUMOL, *The Free Market Innovation Machine: Analysing the growth miracle of capitalism*, New Jersey: Princeton University Press, 2002, at p.3

36 M. LEMLEY, “A New Balance between IP and Antitrust” (2007) 13 *Southwestern Journal of Law and Trade in the Americas* 1, 10

37 A. SMITH, *An Inquiry into the Nature and Causes of the Wealth of Nations*, 5th ed. London: Methuen & Co., Ltd. 1904, ¶ I.2.2.

adopts the practice merely to impose barriers to entry to competitors and secure monopoly profits. However, in order to avoid over-enforcement, as A.G Jacobs explains in *Oscar Bronner*³⁸, competition law should balance the “interest in free competition with that of providing an incentive for research and development”³⁹.

Nonetheless, there seems to have been a hesitation on the part of the Commission to intervene. Prior to its decision in *AstraZeneca*⁴⁰, the Commission has not outlined the conditions under which competition law interference is justified. The Commission has previously been sitting timidly behind the distinction of exercise and existence of intellectual property rights. A more interventionist approach can be seen in *Magill*⁴¹ where a compulsory licence was seen as the corrective measure against invoking an “aberrant national right in a manner which foreclosed competition”⁴². A balancing exercise is displayed in *Magill*⁴³ where it was stated:

“to resolve the conflict...between copyright on the one hand and the rules on, *inter alia*, freedom of competition on the other, the proper approach is, as has consistently been held, to identify in each particular case the 'specific subject-matter' of the intellectual property right, which alone merits special protection within the Community legal order and thereby justifies certain encroachments on the Community rules”.

The criticism that can be brought, is how are the competition authorities to balance the public and private interests at stake. It could be said that this would not be a sufficiently predictable exercise for undertakings in planning their business strategies, thus lacking legal certainty. In spite of this, competition law does not operate in a vacuum. Moreover, the increasing interest of competition law in this sector has, perhaps, been influenced by the increasingly more noticeable intellectual property rights strategies adopted by dominant undertakings. As Anderman argues,

“competition law gives explicit recognition to the pro-competitive nature of IPRs and maintains that the exercise of an IPR is compatible with competition rules but it reserves the right to step in when an IPR is used as a means or instrument of commercial strategy that involves conduct incompatible with either Art. 101 and 102 or the Merger Regulation”⁴⁴.

Consequently, competition authorities should intervene in order to address practices where dominant undertakings procure intellectual property rights with the aim of foreclosing or unnecessarily delaying entry of potential or actual competitors on the market.

The essential question is whether the Commission has too readily found conflicts between the two bodies of law. It is true that whilst having the same objectives as intellectual property law in some respects,

38 Case C-7/97, *Oscar Bronner GmbH &Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH &Co. KG and others*, [1998] ECR I-7791

39 Id., at ¶ 62.

40 Commission Decision in *AstraZeneca*, *supra* note 4.

41 Case T- 185/00 *Metropole télévision SA and Reti Televisive Italiane SpA and Gestevisión Telecinco SA and Antena 3 de Televisión v Commission of the European Communities*, [2002] E.C.R. II-3805.

42 I. FORRESTER, “Regulating Intellectual Property via Competition? Or Regulating Competition via Intellectual Property? Competition and Intellectual Property: Ten Years On, the Debate Still Flourishes” available at <http://www.eui.eu/RSCAS/Research/Competition/2005/200510-CompForrester.pdf> accessed on 4 March 2012.

43 Case T-69/89, *Radio Telefís Eireann v E.C. Commission*, [1991] 4 C.M.L.R. 586, at ¶ 45.

44 S. ANDERMAN and A. EZRACHI, *Intellectual Property and Competition Law New Frontiers*, New York: OUP, 2011, at p. vi.

the primary objective of competition law remains to maintain a competitive market structure. In doing so, it seeks to curb the excesses inherent in the exclusive rights granted by national authorities in the form of intellectual property rights. It has been argued that responsible antitrust enforcement creates the conditions that allow business initiatives to flourish by assuring that innovators, having crossed the threshold of discovery, are not stopped in their progress by impediments generated by uncompetitive markets⁴⁵. What constitutes reasonable enforcement is open to discussion.

There is an array of reasons why the Commission is regarding with suspicion the firms holding a dominant position. This is in light of the influence of neoclassical economics and the aim of achieving allocative and productive efficiency as well as maximum consumer welfare. The challenge faced by the competition authorities is to design a regime which establishes constraints on the intellectual property right holders which are not discouraging.

As it has been explained, the ECJ took a formalistic approach in differentiating between the existence and exercise of intellectual property⁴⁶. This distinction could be said as being empty of substance. Consequently, the Commission and the ECJ later articulated the need to address questions related specifically to the process of obtaining the protection for the intellectual property right. More light has been shed on this matter by the ECJ in *Tetra Pak International SA v Commission of the European Communities*⁴⁷ where it was held that the acquisition of an exclusive licence strengthened the dominance of the undertaking concerned and had the effect of preventing or delaying the entry of a new competitor on the market. Whilst, not stating that the acquisition of an exclusive right is in itself a *per se* breach of Art. 102 TFEU, it has been suggested that it shall be taken into account when defining the requirement of a dominant position and particular attention shall be granted to its effects on the structure of competition on the relevant market⁴⁸.

In cases concerning intellectual property rights, an effect based approach would be more favourable because an analysis of consumer harm would be undergone. This analysis would focus on the maintenance of open competitive markets by treating with suspicion any exclusionary conduct of actual or potential competitors on the market. This suspicion is justified on the basis that free competition is deemed to result in efficiencies such as lower prices, better, improved and products and processes. Aside from benefiting consumers, an effect based approach which focuses on identifying consumer harm could be better suited because it may provide a higher degree of predictability to undertakings planning their business strategy. In the light of the above, consumer welfare should represent the standard against which such conduct shall be assessed as to whether it is detrimental to competition.

This effects based analysis coincides with the Lisbon Agenda which suggests as one of the targets the

45 R. GILBERT, "Intellectual Property and Antitrust Laws : Protecting innovators and innovations" Speech Before the Annual Winter Meeting of the Licensing Executives Society, Phoenix, AZ, 17 February 1995, available at <http://www.justice.gov/atr/public/speeches/0130.htm> accessed on 4 March 2012.

46 *Consten and Grundig*, *supra* note 17.

47 Case C-333/94 P, *Tetra Pak International SA v Commission of the European Communities*, [1996] E.C.R. I-5951.

48 *Id.* at ¶ 23.

opening up of the markets by way of economic modernisation. This is said to be key to the maintenance of Europe's unique social model in the face of increasingly global markets and technological change⁴⁹. Notwithstanding, the weaknesses of such approach shall be discussed when drawing a comparison between the approach adopted by the General Court in *AstraZeneca*⁵⁰ based on the concept of "competition on the merits" and that adopted by the Italian Competition Authority in *Pfizer*⁵¹ which is based on the notion of "effects on the market".

49 Communication from the Commission, "Strategic report on the renewed Lisbon strategy for growth and jobs: launching the new cycle (2008-2010) Keeping up the pace of change" COM (2007) 803 final part I.

50 *AstraZeneca*, *supra* note 5.

51 *Pfizer*, *supra* note 7.

3. The Specificity of the Pharmaceutical Sector – the interaction of antitrust and intellectual property rights

The pharmaceutical industry is one of the most attractive industries for R&D investment given the high rate of profitability⁵² upon commercialisation notwithstanding the high degree of risk undertaken at the R&D stage⁵³. In the Final Report⁵⁴ of the Pharmaceutical Sector Inquiry conducted by DG COMP it has been estimated that the pharmaceutical market accounts for 2% of annual EU GDP⁵⁵.

Patricia Danzon characterises R&D investments in the pharmaceutical sector as “investments with a multi-year payment over the market life of a drug”⁵⁶. The costs of R&D activity and the rate of the technological changes are high. Therefore, as mentioned in the first part of this paper, successful innovation requires a temporary shelter from competition. Schumpeter explains that investments made in sectors, characterised by rapidly changing conditions having an impact on the innovative product, are “like shooting at a target that is only indistinct by moving and moving jerkily at that”⁵⁷. Therefore, as he argues “it becomes necessary to resort to such protecting devices as patents”⁵⁸. For this reason, it is said that patent protection plays a vital role in this industry not only in allowing the harvesting of benefits deriving from one’s work by granting him exclusivity for a limited period of time but also for the society in general as valuable innovation may not be developed if it can be anticipated that the product when entering the stage of commercialisation may easily be replicated or substituted. Consequently, patents serve to foster consumer welfare through innovation. Moreover, patents stimulate diffusion of information. The diffusion of information reduces the risk of wasteful duplication of innovative products⁵⁹, undertakings redirecting their intended investments in other areas not covered by patents, stimulating innovation even further.

3.1. Why is there an interest in the pharmaceutical sector?

From a competition law perspective, the issue of market power acquired as a result of the exclusivity

52 See Annex 1.

53 The risk is due to the fact that most projects fail in the trial II phase of the clinical tests. This is evidenced by the fact that in the period 2010-2011 due to staged financing, 46% of the R&D investments has been injected in the later stage from phase III to submission. - Deloitte and Thomson Reuters, “Measuring the return from innovation. Is R&D earning its investment?”, 2011, available at http://www.deloitte.com/view/en_GB/uk/industries/life-sciences/da3c9279595c3310VgnVCM1000001a56f00aRCRD.htm accessed on 1 May 2012.

54 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

55 *Id.*, at ¶ 2.

56 P. DANZON, “The pharmaceutical Industry” in Bouckaert, Boudewijn and De Geest, Gerrit, “The History and Methodology of Law and Economics” *Encyclopedia of Law and Economics* I, Cheltenham: Edward Elgar, 2000, at p. 1078.

57 SCHUMPETER, *supra* note 23, at p.88.

58 *Id.*

59 RÉGIBEAU and ROCKETT, *supra* note 21, at p. 19.

inherent a given patent may raise concerns in some circumstances. Thus, whilst a patent cannot in itself raise any anticompetitive concerns, the Commission committed itself to detecting the strategic uses of such patents by pharmaceutical companies such as creating additional barriers to entry to generic entrants upon initial patent expiry. It is acknowledged that, by making use of strategic patenting, an undertaking aims at prolonging the product's life-cycle rather than competing by way of innovation with other originator companies or through price competition with generic manufacturers⁶⁰. There is, therefore, a loss in efficiency as prices rise above marginal costs, enabling firms under the realm of a given patent to adopt a profit maximising behaviour to the detriment of the consumer. In addition, there is a decline of dynamic efficiency in as much as other originator undertakings are discouraged from innovating further when there is, for example in the case of patent clustering, uncertainty as to which subject matter is patented.

As a result, the Commission initiated an inquiry into the pharmaceutical sector by conducting down-raids of several pharmaceutical companies and by sending out questionnaires to various undertakings aiming at identifying behaviours which might be anticompetitive. Delaying market entry of generic medicines as well as the decline in innovation in bringing new medicines onto the market has been the main concern expressed in the Final Report⁶¹.

In terms of patent strategies adopted by the pharmaceutical originator companies for the purpose of delaying market entry to generic undertakings, the Final Report⁶² addresses the creation of patent clusters, the strategic use of litigation, the interventions in national regulatory processes for authorising generic medicines, ever-greening and pay for delay settlements.

It is submitted that through the market power acquired as a result of the procurement of a patent protection, the originator is placed in a position that offers it not only the necessary compensation for the recuperation of its sunk investments in R&D but also given the situation where generic entry is absent, "there is usually nothing to stop the incumbent firm from maintaining non-competitive prices long after it has profitably recouped its investment"⁶³. This argument is supported by the finding that an undertaking in the pharmaceutical market does not respond to the normal forces of supply and demand.

Thus, as aforementioned, originator companies tend to become profit maximising and adopt strategies to serve this end. This is exemplified in both *AstraZeneca*⁶⁴ and *Pfizer*⁶⁵. In both cases, the

60 N. DE SOUZA, "Competition in Pharmaceuticals: the challenges ahead post AstraZeneca", Competition Policy Newsletter, no. 1, Spring 2007, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/2007_1_39.pdf, accessed on 10 June 2012, at p.42.

61 Pharmaceutical Sector Inquiry Final Report, *supra* note 1. The Commission carried out the sector inquiry pursuant to Art. 17 of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (2003)OJ L 1.

62 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

63 OECD: Directorate for financial and enterprise affairs competition committee, "Roundtable on Generic Pharmaceuticals" DAF/COMP (2009)39 available at <http://www.oecd.org/dataoecd/24/48/46138891.pdf> accessed on 5 May 2012, at p.18.

64 *AstraZeneca*, *supra* note 5.

65 *Pfizer*, *supra* note 7.

pharmaceutical originators resorted to strategic patenting in order to extend the breadth and duration of the protection of their respective products, thereby delaying competition from generic manufacturers.

Moreover, in the Preliminary Report⁶⁶, the Commission estimated that generic entry brings a 25% reduction in prices for consumers upon the expiration of the originator's patent and 40% after two years following such expiration⁶⁷. The generic manufacturers' market share is also seen as increasing from 30% in the first year to 45% after two years⁶⁸. This means that competitive pressures are placed on the originators to lower their prices on their products upon expiry of the validity of the patent.

Commissioner Neelie Kroes stated: "if innovative products are not being produced and cheaper generic alternatives to existing products are being delayed then we need to find out why and if necessary take action"⁶⁹. Thus, one can observe that the Commission developed an interest in the pharmaceutical sector as a result of the practices adopted by the originator companies in fencing off the markets and as such denying entry to generic manufacturers which ultimately results in the hindrance of consumer welfare by way of high costs and diminution of innovation. The focus of the Commission has shifted from intra-brand competition to inter-brand competition as it has acknowledged that there has been under-enforcement in the past due to the focus having been placed on parallel imports⁷⁰.

3.2. Characteristics of the pharmaceutical industry

The pharmaceutical industry is characterised by a two tier structure. Originator firms are driven by patentability of their products, assuming high initial investments covering their R&D progress, whereas the generic manufacturers do not incur such expenses as they focus on the manufacturing of off patent products.

The R&D costs for a new medicine can account to approximately €1 billion⁷¹. These high initial investments are justified in relation to R&D activities on the basis of a prospective high rate of return. Notwithstanding, it has been estimated the time frame within which a new medicine is brought on the market varies between 10-12 years. There is a high degree of risk incurred as many fail to pass the clinical trials

66 Pharmaceutical Sector Inquiry Preliminary Report, European Commission, Competition DG, 28 November 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf accessed on 2 May 2012.

67 See Annex 2.

68 European Commission, Competition DG, "Fact Sheet -Prices, time to generic entry and consumer savings" available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> accessed on 2 May 2011.

69 Commission Press Release IP/08/49 of 16 January 2008, "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections" available at <http://ec.europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&guiLanguage=en> accessed on 2 May 2012.

70 Pharmaceutical Sector Inquiry Preliminary Report, European Commission, Competition DG, 28 November 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf accessed on 2 May 2012, at ¶ 15.

71 ECORYS, "Competitiveness of the EU Market and Industry for Pharmaceuticals" Final Report, December 2009, available at http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_1_welfare_implications_of_regulation_en.pdf accessed on 2 May 2012.

phase⁷². Thus, this factor can be seen as a stimulus for the originators in seeking to impose barriers to entry for generics under the form of brand loyalty, market segmentation and control over key inputs in order to retain high profits that would compensate for previous failures as well as ensuring a high rate of return. This leads to tensions between the interest in profit and the improvement of public health. To this effect, Commissioner Kroes stated that the Commission will “not circumspect about rigorously applying the antimonopoly provisions in the pharmaceutical sector, for generic competition is an area which has suffered from under-enforcement in the past”⁷³.

a) Features of the supply side

Radical innovation is particularly likely to be incentivised by the supply side rather than the demand side. This is because a new drug would not be developed if it can be anticipated that once commercialised it can be easily substitutable by another product. Evermore, the development of a new drug may not be carried out if there were no legal means to prevent the development of substitutes⁷⁴. Consequently, it can be implied that unless an undertaking can be assured that it would hold an exclusive right upon the development of a new drug, being shielded from competitive pressures, it would not innovate. It can be seen that a development, whilst covered by a patent, will not be exposed to competitive pressures from existing supplies of actual competitors, or from a threat of future expansion by actual or potential competitors. Furthermore, as it may be seen in relation to the features of the demand side and regulatory framework, the bargaining strength of the buyers is often weak. As a result, as long as covered by a patent, an undertaking may charge excessive prices to the detriment of the consumers. On the other hand, a balance has to be drawn in the light of the fact that a patent is seen as indispensable and proportionate to the goal to be achieved, namely, securing investments for the development of new medicines.

In a competitive market, it is expected that upon patent expiration, the price would drop from the monopoly level to that equal to the marginal cost of production, leading to the entrance of generic manufacturers on the market. Nonetheless, this is not what happens when for instance an originator patents around the basic patent to extend the breadth and longevity of that patent, creating uncertainty which in turn delays market entry of generics.

b) Features of the demand side

On the demand side, the final users⁷⁵ do not seem to have much role in the competitive process. This

72 Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 162.

73 Commissioner Neelie Kroes' reply to the Oral Question put by the honourable Member of the European Parliament Mr Von Boguslaw Sonik on 13th June 2006 (H-0459/06) reported at p. 41 by N. DE SOUZA “Competition in Pharmaceuticals: the challenges ahead post AstraZeneca”, Competition Policy Newsletter, no. 1, Spring 2007, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/2007_1_39.pdf, accessed on 10 June 2012.

74 OECD Directorate for Financial Fiscal and Enterprise Affairs Committee on Competition Law and Policy, “Competition and Regulation Issues in the Pharmaceutical Industry” DAFFE/CLP (2000) 29 available at <http://www.oecd.org/dataoecd/35/35/1920540.pdf> accessed on 5 May 2012, at p.35.

75 Here, the final users are the patients.

is because the pharmaceutical market is a monopsonist one, whereby, the National Health Authorities hold the buyer power. The National Health Authorities, however, often lack price sensitiveness and bargaining power. This argument is supported, in *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proionton*, where the ECJ stated: “the level at which the selling price or the amount of reimbursement of a given medicinal product is fixed reflects the relevant strength of both the public authorities of the relevant Member States and the pharmaceutical companies at the time of the price negotiations of that product”⁷⁶. It can be thus implied that even when there is a monopsonist on the market, if the drug has important functions, the bargaining power of the buyer will be weakened. In addition, one ought to have regard to the potential for the existence of an asymmetry of information between the monopsonist buyer and the pharmaceutical company that ultimately impedes the setting on equal footing of the two in the negotiation process.

The prescribing practice also has an effect on demand. Depending on a country’s price reimbursement scheme, doctors and pharmacists may not be price sensitive in prescribing medicines, causing the consumer or the health insurer, as the case may be, to bear a greater cost as originator medicines may be prescribed in cases where a cheaper generic version is readily available on the market. Moreover, this prescribing practice is inefficient because it encourages the shift of resources of an undertaking from R&D activities to promotion efforts. To this effect, it can be seen that pharmaceutical companies undertake great efforts to make their products the preferred choice. They enter into negotiation regarding discounts for doctors and pharmacists in exchange for their product to be prescribed to the patients. In the Final Report, the Commission estimated the marketing costs for prescription medicines in 2007 at 21% of the annual turnover, whilst the R&D expenditure represented only 18% of the annual turnover⁷⁷. In addition, the number of employees in the marketing departments was equivalent to twice of the number of workers involved in R&D. It could be thus appreciated that the consumers do not hold any countervailing power, consequently, the dominant undertaking in the pharmaceutical sector is able to act independently of its consumers. A solution would be to shift more cost onto the final consumer which will incentivise him to be more “demanding, hungrier for information and more sensitive to value”⁷⁸.

In the light of the above arguments, it is submitted that the “pharmaceutical sector is to a significant extent shielded from the free play of supply and demand”⁷⁹. This statement is even more strengthened when looking at the effects of the regulatory framework which varies from one Member State to another.

⁷⁶ Joined Cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proionton*, [2008] 5 C.M.L.R. 20 at ¶ 63.

⁷⁷ Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 77.

⁷⁸ GlaxoSmithKline Briefings “Key Aspects of a Sustainable Health Care System”, September 2006, available at <http://www.gsk.com/policies/GSK-and-key-aspects-of-a-sustainable-healthcare-system.pdf> accessed on 6 May 2012

⁷⁹ T-168/01, *GlaxoSmithKline Services Unlimited v Commission of the European Communities*, [2006] 5 C.M.L.R. 29, at ¶ 133.

c) The regulatory framework

The life-cycle of a drug is highly regulated from patent application, marketing authorisation, commercial exploitation and patent expiry. The regulatory measures are generally adopted at the national level, although, competence is shared with the EU institutions in as far as cooperation between Member States and third countries is concerned as well as the setting of standards for quality and safety for medicinal products⁸⁰. Notwithstanding, Member States and health stakeholders must respect the Treaty provisions concerning free competition as well as the free movement of goods and services within the internal market.

The decentralised system causes discrepancies from one Member State to another. To exemplify this, in the United Kingdom, generic entry on the market is facilitated by the reimbursement price system whereby general practitioners are incentivised to prescribe generics and pharmacists to dispense them. The reimbursement by the National Health Service to the pharmacists is calculated taking into account the returns to the Department of Health by all generic manufacturers in light of the volume sold and the net revenues gained. The general practitioners write their prescriptions using an international non-proprietary name, unless, there is a clinical justification for not doing so⁸¹. As a result, in 2002, 53% of the prescribed medicines dispensed in England were unbranded. This is a significant factor generating cost savings for consumers as the average price difference in England between the generic and originator drugs is 80%⁸².

On the other hand, in Spain, there is a reference pricing system whereby the National Health Authority decides the reference price for the reimbursement of the drug. In this case, it is said that the reimbursement scheme acts as a disincentive for generic manufacturers to commercialise their products because they fulfil the role of being the reference and as such originator manufacturers bring their prices down to those of the generic versions. A study⁸³ analysing policy implications on generic entry proved that in such case, the entry of generics on the market does not add more to the competition already existing within the respective market. This can be contrasted with the policies implemented in the U.K whereby the reimbursement system has the effect of encouraging generic entry which brings significant price reductions for the consumers.

In the light of the above it can be seen, as Patricia Danzon argues, that “the extent of generic penetration and speed of generic erosion of the originator market share differs significantly across countries and over time depending on the policies adopted by the regulators”⁸⁴.

80 See Article 168 TFEU.

81 BGMA, “About Generics” available at <http://www.britishgenerics.co.uk/about-generics/the-generics-industry> accessed on 1 May 2012.

82 House of Commons Health Committee, “*The influence of Pharmaceutical Industry*” 4th Report of Session 2004-2005, Vol.1 available at <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>, at p. 13, accessed on 1 May 2012.

83 I. Moreno-Torres, J. Puig-Junoy, J.R. Borrell-Arqué, “Generic entry into a regulated Spanish pharmaceutical market” (2009) 34 *Rev. Ind. Organ.* 373.

84 Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 1067.

d) Generic entry

As one may have observed, the competitive impact of generic entry depends on the nature of the demand which ultimately depends on the national legal mechanisms that regulate the demand for pharmaceuticals⁸⁵. Moreover, this depends on the brand loyalty and the price sensitivity of the buyers. Notwithstanding, the Commission in the sector inquiry finds that even though the delays to generic entry may be in some respects attributable to the regulatory framework, the behaviour of originators is to be placed under antitrust scrutiny as patent strategies cause a detriment of €3 billion worth of potential savings.

The strategies which were characterised in the Final Report⁸⁶ as raising competition issues were divisional patenting, patent clusters and patent settlements. The first two will be addressed. A divisional patent is one acquired by submitting a patent application which contains matters from the previously filed parent application. Although, retaining the same filing date as the parent patent application, it has a separate life. This means that divisional patents may be approved whilst the application for the parent patent is pending approval. Patent clustering, on the other hand, is a process whereby upon approaching the end of the parent patent life, the originator seeks to patent around the initial subject matter. This is for example for non-formulation products such as salts, polymorphic forms, particles and solvates. Both have the effect of generating legal uncertainty as to what is protected. This leads to the delay of generic entry as the risk for the generic undertaking infringing other secondary patents upon the expiration of the primary patent is high. To this effect, when looking at the timing of such filings, one may observe that these forms of patenting are used as a strategy to delay market entry. Both strategies seem to be adopted towards the end of the validity period of the parent patent⁸⁷.

In the Final Report it is stipulated that increased antitrust scrutiny shall be expected from the EU authorities as regards to the pharmaceutical companies' patent strategies which may cause delay to the entry of generic manufacturers⁸⁸. Nevertheless, this is to be pursued by taking into account the need to maintain the incentives of the originator companies for the development of new drugs and continued investment in R&D.

3.3. Mechanisms for IP protection in the pharmaceutical industry

"The pharmaceutical industry is a textbook example of a science based sector characterised by high R&D costs, uncertainty and spill overs, for which patent protection assures appropriable, thus providing incentives for innovation"⁸⁹. Without intellectual property rights granting exclusive control over intellectual assets developed by pharmaceutical companies, innovation which would increase consumer welfare is deemed not to happen. For this purpose, a discussion will be conducted for the purpose of describing the

85 OECD, *supra* note 75, at p. 3.

86 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

87 See Annex 3.

88 Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 1608.

89 Magazinni, Pammolli and Riccaboni, "Patent Disclosure and R&D Competition in Pharmaceuticals" (2009) 18 *Economics of Innovation and New Technology*, 467, 467.

mechanisms adopted by the Member States to secure intellectual property protection. This shall be followed by an analysis of whether intellectual property law is too permissive, allowing for strategic patenting which delays market entry to generic manufacturers.

a) Patents

Patents are granted according to the legal requirements of the Member State where the application has been filed. Although, one may expect discrepancies from one Member State to another, they are fairly similar. This is as a result of the effect of the TRIPS Agreement and European Patent Convention 2000⁹⁰ which has been transcribed in the legal systems of most Member States. Consequently, Article 52(1) European Patent Convention states: “European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application”. Within the pharmaceutical sector, as it has been seen in the case of patent clusters, the inventive step is not always seen in terms of added therapeutic value relative to existing alternatives.

One may note, that even though the duration of a patent protection is 20 years from the filing of the application, this may not be sufficient. This is because applications are filed very early in the R&D stage. However, the process which leads to the final commercialisation of the product takes on average 10-12 years. The long period that it takes for the drug to arrive on the market is due to the increased number of clinical trial tests which a new drug has to undergo before being granted a marketing authorisation. To compensate this, the European Council passed Regulation 1768/92⁹¹ which allows for an extension of the patent validity to a maximum period of 5 years.

b) Supplementary Protection Certificate

Regulation 1768/92⁹² is seen as a balancing exercise between the need of the pharmaceutical industry to ensure financial stability and public health policy. Thus, the supplementary protection certificate serves to compensate for the period of time between the date of patent filing and the time when the product can be effectively commercialised. For the grant of such certificate, the medicine shall be protected by a basic patent which shall still be valid at the time of the application. In addition, the medicine shall hold a marketing authorisation which shall be the first authorisation used to place the medicine on the market. The disadvantage of this protection certificate is that it relies on the first marketing authorisation granted for a given product which means that incremental innovation that might have taken place at a later stage is not taken into account.

⁹⁰ Although, discussions for a truly European patent are undergoing, the patent conferred under the European Patent Convention represents a bundle of national rights.

⁹¹ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products. (1992) OJ L 182.

⁹² Id.

3.4. Strategic patenting – is IP law too permissive?

Intellectual property law governing the conditions under which patents are granted can be seen as being too permissive because there is no requirement to show added therapeutic value. In this context, it can be observed that divisional patents and patent clusters are easily obtainable by undertakings in their quest to delay or foreclose generic entry. Thus, a patent jungle or “giungla brevettuale”⁹³ can be created using the legal instruments available.

A solution to this problem could be served by revising the requirements for patentability in such a way as to only allow for patentability of bigger inventive steps. In this way, the generic undertakings may proceed with the manufacturing process without regard to the risk of infringing such secondary patents. A study which used the game theory contradicts this proposition⁹⁴. The study confirms that by doing so, innovation would be more infrequent. This is because “patentability criteria affect profits because they determine the likelihood that a firm’s invention will lead to a competitive advantage and the speed at which that advantage will be eroded”⁹⁵. Hence, by only granting patents for bigger inventive steps, there will ultimately be an increase in uncertainty regarding future returns as well as increasing complexity and costs for the originator company. Consequently, increased requirements would reduce anticipated profits, thereby undermining ongoing pharmaceutical innovation⁹⁶. To this extent, it is submitted that a system evaluating pharmaceutical companies’ contributions to health care and improved outcomes may be better suited at stimulating a more competitive market.

Notwithstanding, intellectual property law and competition law intervene at different stages of a product’s life-cycle. As such, it could be said that a proper balance may be established through competition law enforcement. Competition law intervenes only in regulating the use of intellectual property law when the acquisition of patents gives rise to foreclosure effects which are not justified. Under this framework, secondary patenting with the scope to extend market power and eliminate competition might be better addressed. As argued by Régibeau and Rockett, competition authorities are better informed about the economic importance of an innovation and the structure of the market as there is a “difference in timing ... the information available when property rights are granted is not the same as the information available when competition law cases arise”⁹⁷. To analyse the effect of competition law enforcement, the findings in *AstraZeneca*⁹⁸ and *Pfizer*⁹⁹ will be individually analysed.

93 *Pfizer*, *supra* note 7, at ¶ 129.

94 R. M. HUNT, “Patentability, Industry Structure and Innovation” (2004) 52 *The Journal of Industrial Economics* 401.

95 *Id.*, at p. 402.

96 F. PAMMOLLI, and M. RICCABONI, “Market Structure and Drug Innovation” (2004) 23 (1) *Health Affairs* 48.

97 RÉGIBEAU and ROCKETT, *supra* note 21, at p. 26

98 *AstraZeneca*, *supra* note 5.

99 *Pfizer*, *supra* note 7.

4. AstraZeneca – a redefined notion of abuse

Prior to the Pharmaceutical Sector Inquiry, the Commission first addressed the anti-competitive nature of strategic patenting in the case of *AstraZeneca*¹⁰⁰. The Commission found that misrepresentations made to the patent offices in Germany, Belgium, Denmark, Norway, Netherlands and United Kingdom to extend the patent protection for Losec, through a supplementary protection certificate to which AstraZeneca was not entitled, represented an abuse of dominant position as prescribed by Article 102 TFEU. This is said to be a redefinition of the notion of abuse in as much as it can be inferred from the judgment of the General Court¹⁰¹ that the acquisition of an intellectual property right or extension of the exclusionary right by a dominant undertaking may constitute an anti-competitive infringement.

Nonetheless, it is questionable whether the judgment in this case, if confirmed by the ECJ¹⁰², could serve as precedent for addressing cases whereby patent compliant behaviour is adopted by an undertaking in a dominant position for the purpose of restraining price competition¹⁰³ and dynamic competition¹⁰⁴ on the relevant market. This is because the legal reasoning in this case is fact specific. Moreover, it could be said, as it shall be discussed later on, that the judgment in *AstraZeneca*¹⁰⁵ could only address defensive patenting where there is an additional factor such as fraudulent behaviour¹⁰⁶.

The Commission, followed by the General Court, in the case of *AstraZeneca*¹⁰⁷ placed focus on the importance of maintaining inter-brand competition in a market driven by intellectual property rights. Consequently, the objective can be seen as increasing price competition stemming from generic entry after patent expiry. The importance of such approach is emphasised by Commissioner Neelie Kroes who argued before the European Parliament that the aim of challenging intellectual property rights in the pharmaceutical sectors as lifecycle management strategies is “to encourage inter-brand competition from generic substitutes

100 Commission Decision in *AstraZeneca*, *supra* note 4.

The case further concerned the deregistration of the marketing authorisations for the capsule form of the drug from Denmark, Sweden and Norway which was meant to artificially protect AstraZeneca from competition stemming from generic entry and parallel imports.

101 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

102 The case is currently under appeal before the European Court of Justice. Advocate General, Mazák, delivered his opinion, largely reflecting the view adopted by the Commission and the General Court - Opinion of A.G. Mazák, delivered on May 15, 2012, in Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [not yet published]

103 Price competition refers to competition between originator and generic manufacturers upon the expiry of the basic patent.

104 Dynamic competition is used here to refer to competition by innovation, namely competition amongst originators.

105 *AstraZeneca*, *supra* note 5.

106 Opinion of A.G. Mazák delivered on May 15, 2012, in Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [not yet published].

107 *AstraZeneca*, *supra* note 5.

after patent expiry”¹⁰⁸.

4.1. Can intellectual property rights confer a dominant position?

Dominance serves as the threshold for the application of Article 102 TFEU. This element has been defined in *United Brands and United Brands Continentaal v Commission*¹⁰⁹ as “a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers”. Therefore, dominance gives rise to a loss in efficiency. This is because the ultimate result, more often than not, would be prices rising above marginal costs to the detriment of the consumer as the undertaking’s behavior is not constrained by any countervailing power.

It has been settled through case law that the mere possession of intellectual property rights cannot be considered as conferring dominance to an undertaking¹¹⁰. Notwithstanding, their possession may lead to a dominant position where it enables the undertaking to prevent effective competition on the market¹¹¹. The Commission held in its decision that “a factor of considerable importance in determining dominance in this case relates to AZs technology in the form of intellectual property”¹¹². Therefore, the extension of the patent protection enabled AstraZeneca to exert pressure on competitors, having a foreclosure effect. This has been considered by the General Court as indicative of dominance¹¹³ because the undertaking is found to be acting independently of its competitors.

In spite of this, Frances Murphy argues that the success of a pharmaceutical product is short lived because it is vulnerable to other innovative products and to entry of generic manufacturers¹¹⁴. Whilst, true in consideration of the fact that patent protection grants exclusivity to the holder only for a limited period, this is not to say, as the General Court found, that the patent protection held by AstraZeneca in relation to its product, did not enable it to exert significant pressure on its competitors.¹¹⁵ As the ability to behave independently of the competitors is one of the criteria which sits at the heart of the notion of dominance, it is to be acknowledge that the exclusivity right inherent in the patent protection may render such position of dominance. This finding is however influenced by the strength of the patent protection as indicated by the Court: “Losec enjoyed particularly strong patent protection, on the basis of which AZ brought a series of

108 Commissioner Neelie Kroes’ reply to Oral Question put by the honourable Member of the European Parliament Mr von Boguslaw Sonik, H-0459/06.

109 Case C-27/76, *United Brands and United Brands Continentaal v Commission*, [1978] ECR 207, at ¶ 65.

110 Case C-78/70, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG.*, [1971] ECR 00487, at ¶ 16.

111 *AstraZeneca*, *supra* note 5, at ¶ 270.

112 Commission Decision in *AstraZeneca*, *supra* note 4, at ¶ 517.

113 *AstraZeneca*, *supra* note 5, at ¶ 272. In finding dominance, the Commission and the General Court looked at market shares, (70%-80% being indicative of dominance as established by Court of First Instance in Case T-30/89, *Hilti AG v Commission of the European Communities*, [1991] ECR II-1439, at ¶ 85), level of prices, first mover status, existence and use of intellectual property rights and financial strength.

114 F. MURPHY, “Abuse of regulatory procedures - the AstraZeneca case” (2009) 30 *ECLR* 223, 229.

115 *AstraZeneca*, *supra* note 5, at ¶ 272.

legal actions which enabled it to impose significant constraints on its competitors Takeda, Byk Gulden and Eisai and to dictate to a large extent market-entry terms to them”¹¹⁶.

4.2. The finding of abuse

The legal basis for the finding of anti-competitive practice is Article 102 TFEU. An infringement under this provision is represented as “any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it ... so far as it may affect trade between Member States”. The Treaty provision does not, however, define the notion of abuse but hints at some practices which may be contrary to the internal market. Thus, it has been established that for a finding of an exclusionary abuse there ought to be a conduct “limiting production, markets or technical developments, actual or potential effect on competition”¹¹⁷, prejudice to consumers¹¹⁸ and absence of objective, proportionate justification¹¹⁹. This can be said to cater for short term goals such as increasing competition, choice and lower prices, to the prejudice of longer term perspectives such as incentives for firms to innovate.

The lack of a definition encompassing the essence of what is abusive under Article 102 TFEU gives rise to unpredictability and legal uncertainty as there is an open list of abuses. On the other hand, a single definition encompassing exclusionary conduct that can constitute an abuse could lead to false negative or false positive effects¹²⁰. Notwithstanding, the ECJ defines the notion of abuse in a manner which addresses situations whereby competition on the market is reduced without generating any efficiencies¹²¹:

“an objective concept relating to the behaviour of an undertaking in a dominant position which is as such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition”¹²².

The use of a business strategy concerning the life-cycle management of a drug is not in itself an abuse falling under Article 102 TFEU. The General Court¹²³ in its decision stressed the fact that the finding of an abuse is interlinked with the notion of competition on the merits¹²⁴:

“the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. Such

116 *Id.*, at ¶ 271.

117 Article 102(b) TFEU.

118 *Id.*

119 Commission’s guidelines on exclusionary abuses, *supra* note 31, at ¶ 28.

120 R. O’ DONOGHUE and A. JORGE PADILLA, *The Law and Economics of Article 82 EC*” Portland:Hart Publishing, 2006, at p. 176.

121 Evidence of efficiencies can be depicted when looking at output, prices, quality and innovation.

122 Case C- 85/76, *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, [1979] ECR 461, at ¶ 6.

123 *AstraZeneca*, *supra* note 5.

124 The notion is used in order to ensure that effective competitive processes are maintained rather than using

conduct is not in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market”¹²⁵.

Therefore, the misrepresentations made by AstraZeneca regarding the first marketing authorisation date took the undertaking’s conduct outside the realm of competition on merits. This is because the patent system was used in a manner contrary to the regulatory intent. The SPC is granted, as aforementioned, for the purpose of compensating the owner for the period of the patent protection that lapsed between the date of filing and the approval of the marketing authorisation, period in which the exclusive right could not have been exercised. The goal has been to enable AstraZeneca, by excluding competition on the market to “rely on continued rents beyond the period envisaged by the legislator”¹²⁶. Through the adoption of the SPC strategy, the pharmaceutical undertaking imposed barriers to entry to generic manufacturers, thereby impeding effective competition on the relevant market. The fraudulently procured SPC had the effect of prolonging AstraZeneca’s dominant position without producing any efficiencies, impairing competitors’ opportunity to enter the relevant product market without improving market performance.¹²⁷ To that end, this practice hindered consumer welfare.

The finding of abuse by the Commission in this case is heavily reliant on the notion of intent¹²⁸. Moreover, before the General Court, the Commission restated the fact that an abuse of dominant position can be found where an undertaking adopts a strategy aimed at, or, in the knowledge that it will exclude competition. Notwithstanding, this finding has in part been dismissed by the General Court. The Court stated that there is no need to show that the undertaking has acted intentionally or in bad faith, but could not have been “reasonably unaware”¹²⁹ of the effects of its conduct. In spite of this, it is held that intent could serve as a relevant factor¹³⁰. However, one may depict that intent, in the General Court’s view, serves merely an ancillary role because emphasis is placed on the objective nature of abuse. This can be inferred from the Court’s holding that “intention can still be taken into account to support the conclusion that the undertaking concerned abused a dominant position, even if that conclusion should be primarily based on an objective finding that the abusive conduct actually took place”¹³¹. O’Donoghue and Jorge Padilla’s view regarding the

competition law to protect competitors. To this effect, in the Communication from the Commission —Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009]O.J. C 45/7, it is stated at ¶ 6: “The emphasis of the Commission’s enforcement activity in relation to exclusionary conduct is on safeguarding the competitive process in the internal market and ensuring that undertakings which hold a dominant position do not exclude their competitors by other means than competing on the merits of the products or services they provide. In doing so the Commission is mindful that what really matters is protecting an effective competitive process and not simply protecting competitors. This may well mean that competitors who deliver less to consumers in terms of price, choice, quality and innovation will leave the market”.

125 *AstraZeneca*, *supra* note 5, at ¶ 355.

126 *Id.*, at ¶ 338.

127 M. MAGGIOLINA, *Intellectual Property and Antitrust: A comparative Economic Analysis of US and EU law*, Cheltenham: Edward Elgar Publishing Limited, 2011, 105.

128 Commission Decision in *AstraZeneca*, *supra* note 4, at ¶ 626.

129 *AstraZeneca*, *supra* note 5, at ¶ 493.

130 *Id.*, at ¶ 359.

131 *Id.*

role of intent further support the submission that intent plays an ancillary role. They state that evidence of intent is useful in cross checking conduct that looks as if falling outside the ambit of competition on the merits¹³². Moreover, this argumentation is in line with previous case law in as much as in *Michelin I*¹³³ it has been stated that it is sufficient to show that the conduct is capable of having exclusionary effects. Thus, there being no requirement to investigate whether the effects of the abusive conduct actually occur, it can be inferred that the finding of intent can support the finding that the conduct is capable of having anti-competitive effects. This is because through intent, there is disclosure of what the conduct was aimed at, making it possible to appreciate the ability of the anti-competitive effects to materialise. Moreover, once it has been established that there is an anti-competitive effect, it becomes unnecessary to prove that there was an actual anti-competitive effect¹³⁴.

AstraZeneca argued before the General Court that the misrepresentations made before the patent offices and before some national courts in the affected geographical markets, did not constitute an abuse unless such misrepresentations were made in bad faith¹³⁵ and only when the SPC was enforced¹³⁶. Moreover, the undertaking claimed that the judgment in *ITT Promedia*¹³⁷ should be followed¹³⁸. As a result, a finding of abuse would be dependent on evidence that the patent was acquired and enforced in the knowledge that it was invalid so to harass opposite parties. In addition, this should have been conceived as part of a plan whose goal was to eliminate competition. This line of argument, although rejected by the Court, mirrors the line of reasoning adopted in the US.

The Court readily dismissed the relevance of the aforementioned judgment by suggesting that the factual background differs¹³⁹. This is because the case refers to the acquisition of intellectual property right by the dominant undertaking from another. Advocate General Kirschner in *Tetra Pak*¹⁴⁰ also pointed to this distinction stating that in the case of licensing a patent right, the license unlike an intellectual property itself, is not necessarily exclusive. From this, it can be inferred that there is no need for additional elements to prove that the conduct is capable of having exclusionary effects. Thus, the Court stated, as aforementioned, that proof of bad faith is not required in the objective assessment of the abuse¹⁴¹. Moreover, it was held that it is irrelevant whether the misrepresentations produced any effects because to hold otherwise would “tend to make the application of Article 82 EC conditional on the contravention by competitors of the public

132 R. O' DONOGHUE and A. JORGE PADILLA, *supra* note 121, at p.226.

133 Case C-322/81, NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities, [1983] ECR 346, at ¶ 104.

134 Case T-203/01, *Manufacture française des pneumatiques Michelin v Commission*, [2003] ECR II-4071, at ¶ 241.

135 AstraZeneca, *supra* note 5, at ¶ 316.

136 Id., at ¶ 314.

137 Case T-111/96, *ITT Promedia NV v Commission of the European Communities*, [1998] ECR II-2937.

138 AstraZeneca, *supra* note 5, at ¶ 311 and ¶ 312.

139 Id., at ¶ 336.

140 Opinion of Advocate General Kirschner, delivered on 21 February 1990, in Case T-5I/89, *Tetra Pak Rausing SA v Commission of the European Communities*, [1990] ECR II-309, at p.335.

141 AstraZeneca, *supra* note 5, at ¶ 356.

regulations by their infringing the exclusive right of an undertaking”¹⁴². This would be ineffective, leading to unnecessary time delays.

Notwithstanding, the Commission asserted that the advertisement placed by AstraZeneca in a pharmaceutical journal displaying the intention to “ensur[e] that these intellectual property rights are respected and … take legal action against infringers thereof”¹⁴³ represented sufficient proof of enforcement. Therefore, it is debatable, even if the criteria in *ITT Promedia*¹⁴⁴ was construed as relevant, whether the result of the case would differ. Notwithstanding, although, the reasoning for which the Court has dismissed the relevance of the mentioned judgment¹⁴⁵ is unclear, it seems that an objective assessment of abuse which is not dependent on the actual effects avoids under-enforcement.

Even more, in order to avoid the possibility of exclusionary effects, whereby barriers to entry are erected, the dominant undertaking is said to hold a special responsibility “not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market”¹⁴⁶. Hence, following the special responsibility criterion, the Court established that AstraZeneca was under a duty to disclose the legal interpretation of Article 19(1) of Regulation 1768/92¹⁴⁷ concerning the first marketing authorisation date¹⁴⁸ as well as a duty to notify the patent offices once it came to acknowledge its mistaken interpretation¹⁴⁹. Therefore, it can be seen that an undertaking which makes use of legal instruments, such as the SPC Regulation 1768/92¹⁵⁰, is not shielded from the competition law scrutiny.

4.3. Contrast with the U.S Supreme Court’s approach in Walker Process

In both the EU and U.S, the mere procurement of patent rights seem to be shielded away from competition law enforcement. This is reasoned in *Berkey Photo, Inc. v Eastman Kodak Co*¹⁵¹ where the Second Circuit held :“a monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits, any success that it may achieve through "the process of invention and innovation" is clearly tolerated by the antitrust laws”. The concept of “competition on the merits” is also adopted in the U.S legal reasoning.

142 Id., at ¶ 362.

143 Id., at ¶ 350.

144 *ITT Promedia*, *supra* note 138..

145 *AstraZeneca*, *supra* note 5, at ¶ 363.

146 Id., at ¶ 355.

147 SPC Regulation 1768/92, *supra* note 92.

148 The issuance of a SPC is dependant on the time lapse between the first marketing authorisation and the application.

Article 19(1) Regulation 1768/92 serves as a transitory measure and provides that “any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate. In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988. In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982”. AstraZeneca sought to overcome these time limits by construing the meaning of the first marketing authorisation as the effective marketing authorisation day.

149 *AstraZeneca*, *supra* note 5, at ¶ 496 and ¶ 498.

150 SPC Regulation 1768/92, *supra* note 92.

151 *Berkey Photo, Inc. v Eastman Kodak Co*, 603 F.2d 263 (2d Cir. 1979), at ¶ 82.

The *Walker Process*¹⁵² doctrine characterises the submission of misleading information during the patent filing as an abuse where the patent is acquired fraudulently¹⁵³ and where the patent has been enforced by an undertaking with an exclusionary intent. In addition to these conditions, there ought to be proof of all elements of an antitrust violation. The separate finding of the elements of the antitrust violation is due to the fact that there is immunity from antitrust proceedings of an undertaking seeking to acquire a patent protection. The high threshold is justified on the basis of the private enforcement incentives, i.e. treble damages, which could otherwise have an over-deterrent effect¹⁵⁴.

Although, the mere procurement of patent rights is shielded from antitrust scrutiny in the U.S, antitrust enforcement could take place in situations where the patent applied for is “weak” or does not meet the statutory requirements as it was the case in *In Re Bristol - Myers Squibb*¹⁵⁵. The test applied by the FTC in this case relies heavily on the discretion of the patent office to appreciate the implications of the application addressed to it. Hence, an undertaking cannot benefit from antitrust immunity granted under the scope of the “petitioning to the state” notion, enshrined in Noerr-Pennington doctrine,¹⁵⁶ in the situation where the patent office, as a governmental agency, acts merely in his ministerial role and has no discretion over its decision. Therefore, when a filing is made before a patent office which has no discretion as to its decision, an infringement of §2 Sherman Antitrust Act¹⁵⁷ can be established where the acquisition of a patent protection is deemed capable of creating or enlarging the monopoly power to the detriment of consumers.

In the EU, as discussed in first part of this paper, the existence-exercise dichotomy is applied in overcoming the jurisdictional barriers imposed by Article 345 TFEU. Therefore, it could be set that the mere existence and as such procurement of patents does not raise any anticompetitive concerns. It can be inferred from the judgement in *AstraZeneca*¹⁵⁸ that the mere use of the legal means available to maintain one’s market power and exclusionary right, which could be deemed as forming part of the best business judgement of an undertaking is not sufficient for the finding of an abuse. The Opinion of the A.G in *AstraZeneca* supports this view in as much as he stated that “a matter of fact that the SPC applications in question were ‘characterised by a manifest lack of transparency’ and were ‘highly misleading’”¹⁵⁹. This view has been previously advanced by the General Court in stating that it is the manifest of a lack of transparency, hence, the abuse of

152 *Walker Process Eqpt., Inc. v. Food Machinery Corp.*, 382 U.S. 172 (1965).

153 For a patent to be acquired fraudulently, misrepresentations made in the application process ought to be material. Moreover, there ought to be a deceptive intent and the patent should not have been issued but for the misrepresentation.

154 S. GALLASCH, “AstraZeneca v The Walker Process – A real EU-US Divergence or Just and Attempt to Compare Apples to Oranges?” (2011) 7(3) *European Competition Journal* 505.

155 FTC, “Administrative Complaint in the Matter of Bristol-Myers Squibb”, FTC file No 0110046

156 “petitioning activity, ostensibly directed toward influencing governmental action, is a mere sham to cover an attempt to interfere directly with the business relationships of a competitor” - *Railroad Presidents Conference v. Noerr Motor Freight, Inc.* .., 81 S.Ct. 529, at p. 144.

157 Sherman Antitrust Act 1890, 15 U.S.C. §§ 1-7.

158 *AstraZeneca*,*supra* note 5.

159 Opinion of A.G in *AstraZeneca*, *supra* note 107, at ¶ 65.

the regulatory procedures, that facilitates the finding of the abuse¹⁶⁰. This lack of transparency was found to be contrary to the special responsibility of AstraZeneca, undertaking occupying a dominant position, not to impair by its conduct genuine undistorted competition in the relevant market¹⁶¹. Notwithstanding, it can be appreciated that there has been a departure from the existence-exercise dichotomy in as much as the Court tackles the issue of whether the intellectual property right has been procured on the merits.

In response to the arguments put forward by the appellants in *AstraZeneca*,¹⁶² which mirrored the need for a U.S approach, the General Court held that, even if this was to be adopted, it would not shield the behaviour against competition law enforcement because Regulation 1768/92¹⁶³ does not provide for effective remedies against the abusive conduct adopted by AstraZeneca. In addition, the General Court stated:

“the existence of remedies specific to the patent system is not capable of altering the conditions of application of the prohibitions laid down in competition law and, in particular, of requiring, in cases of behaviour such as that at issue in the present case, proof of the anticompetitive effects produced by such behaviour”¹⁶⁴.

Therefore, the Court, in looking for the appropriate remedies, draws a balance between the public interest in access to health care and the incentives for investment of innovation¹⁶⁵. Evermore, the aim of undistorted competition and the public interest in access to affordable medicines is emphasised by the Commission in its observations: “only AZ was in a position at the relevant point in time to implement an exclusionary strategy aimed at excluding such generic competitors and artificially maintain prices for the whole range of PPIs”¹⁶⁶.

In light of this, it is submitted as argued by Xenox,¹⁶⁷ that competition law seeks to correct systemic failures in “light of the aim of undistorted competition and public interest in access to affordable and improved medicines”¹⁶⁸. Moreover, going back to the question addressed in first part of this paper on whether competition authorities should intervene when intellectual property rights are concerned, it is submitted that through the enforcement of Article 102 TFEU in these cases, ultimately it is established how broad the scope of intellectual property rights should be, balancing these rights against the consumer welfare factor.

4.4. The theory of harm

The redefinition of the notion of abuse is interlinked with the theory of harm applied in this case by the General Court. Consequently, the harm in relation to the filing of the SPC application is said to be the artificial maintenance of market dominance by way of extending the term of the patent protection. This harm

¹⁶⁰ *AstraZeneca*, *supra* note 5, at ¶ 493.

¹⁶¹ *Id.*

¹⁶² *Id.*, at ¶ 314.

¹⁶³ SPC Regulation 1768/92, *supra* note 92.

¹⁶⁴ *AstraZeneca*, *supra* note 5, at ¶ 366.

¹⁶⁵ *Id.*, at ¶ 367.

¹⁶⁶ Commission Decision in *AstraZeneca*, *supra* note 4, at ¶ 528.

¹⁶⁷ D. XENOX, “Limiting the IPRs of Pharmaceutical Companies Through EU Competition Law: The First Crack in the Wall”(2011) 8(1) *SCRIPTed* 92, 95.

¹⁶⁸ *Id.* at p.97.

is seen as deriving from the exclusionary effect of the extended patent protection on the market¹⁶⁹. It is noteworthy that there is no mention of the need to show that there has been a consumer harm. The analysis rested on appreciating structural changes on the market resulting from AstraZeneca's conduct.

It is said that anti-competitive exclusion should be analysed in light of whether the practice places the other competitors at a cost disadvantage which is sufficient to allow the dominant undertaking to raise its price through the exercise of its market power¹⁷⁰. This represents the raising rivals' cost theory. The definition of anti-competitive foreclosure provided by the Commission in its Guidance Paper on Exclusionary Abuses supports this two stage analysis:

"a situation where effective access of actual or potential competitors to supplies or markets is hampered or eliminated as a result of the conduct of the dominant undertaking whereby the dominant undertaking is in a position to profitably increase prices to the detriment of consumers"¹⁷¹.

Given this definition, it can be construed that a patent has the effect of raising rival's costs through the exercise of the exclusive right whereby an undertaking may constrain the supply of inputs¹⁷² available to rivals. In this way, the patent holder may then take advantage of its position in the market place and increase its prices. This is highly detrimental to consumers in as much as it affects both output and price.

To this effect, the complainants before the Commission argued that the fact that AstraZeneca would benefit from an extra period of protection over Losec, had a "chilling effect on those preparing to enter the market"¹⁷³. Moreover, the Commission further underlined the fact that generic manufacturers would have to incur significant expenses to have the SPC revoked¹⁷⁴. Thus, in applying the raising rival's cost theory, one could appreciate that the extra protection on granted on unmerited basis raised the cost of the generic manufacturers as they would have to incur expenses to first render the SPC invalid before proceeding with the manufacturing and commercialisation of their product which would be in direct competition to that of AstraZeneca.

Although, a patent cannot itself be considered an infringement of Article 102 TFEU, it is the strategic use of the patent system that results in inefficiencies and leads to effects detrimental to consumer welfare that needs to be addressed. The inefficiencies that may result could be the reduction of the competitor's incentive to innovate in the case of patent clustering, as this practice may give rise to fear of infringement allegations. Moreover, it could also result in the reduction of the undertaking concerned's incentive in innovating as it never commercialises the subject matter patented, this serving only as a shield from competition. In addition, in terms of price, as mentioned, they tend to rise above competitive levels as

¹⁶⁹ *AstraZeneca*, *supra* note 5, at ¶ 362.

¹⁷⁰ T. KRATTENMAKER and S. SALOP "Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price" (1986) 96(2) *The Yale Law Journal* 209, 214.

¹⁷¹ Commission's guidance on exclusionary abuses, *supra* note 31, at ¶ 19.

¹⁷² An input for this purpose would be the knowledge covered by the patent.

¹⁷³ *AstraZeneca*, *supra* note 5, at ¶ 349.

¹⁷⁴ *Id.*

there are no disciplinary forces¹⁷⁵ on the market which might deter such an effect. Consequently, it is submitted, as David Scheffman argues, that “it is appropriate to be aggressive about patent misuse, involving patents inappropriately obtained”¹⁷⁶.

In the light of the above analysis concerning the finding of the abuse, it could be said , that although the same situation as in *AstraZeneca*¹⁷⁷ would not re-occur, the judgment, if confirmed by the ECJ, would serve as precedent for strategic patent filing which have foreclosure effects. This depiction is strengthened by the express statement made by the Commission that the acquisition of intellectual property rights may be an abuse in itself “since other undertakings are expected to respect the exclusive right associated with it”¹⁷⁸. Although, this statement is erroneous to the extent that it does not take into consideration the objectives of intellectual property law and the pro-competitive effects derived from this process, it can serve as an indicator that the competition authorities are prepared to address directly the procurement of intellectual property rights. This is when these are procured either for purposes outside the scope of intellectual property law, for the mere purpose of foreclosing entry on the market of other undertakings. Consequently, the enforcement of competition law is an appropriate means to address situations where exclusionary conduct is not derived from competition on the merits and where such conduct does not produce any efficiencies but only serves the purpose of raising barriers to entry.

Competition law intervention in matters concerning the acquisition of intellectual property law is further supported by Drexel.¹⁷⁹ He states, in addition, that a patent officer would not be able to detect anti-competitive intent of exclusively using the patent for blocking purposes based on the filing of an application. Investigatory powers are needed in order to depict such an intent from the internal communication of the undertaking concerned. As mentioned earlier, evidence of intent “helps a court or competition authority to understand the likely effects of the dominant firm’s conduct and thus to interpret the facts and predict the consequences”¹⁸⁰. Thus, “patent law reform could not make patent law compliant with competition law principles”¹⁸¹ because the patent officers lack the appropriate investigatory power.

In addition, in the Pharmaceutical Sector Inquiry Final Report¹⁸² it has been emphasised that intention, when filing an application, would serve as a relevant criterion for identifying such patent strategies that may not be construed as competition on the merits: “the description of the underlying intentions is

175 Disciplinary forces which should be taken into consideration are degree of dominance, ability to compete of rivals, incentive to compete, barriers to entry and expansion, position of customers, extent of abusive conduct, evidence direct evidence of an exclusionary strategy.

176 D. SCHEFFEMAN, “20 Years of Raising Rivals’ Costs: History, Assessment, and Future” (2003) 12 *Geo. MASON L. Rev.* 371, 382.

177 *AstraZeneca*, *supra* note 5.

178 *Id.*, at ¶ 350.

179 J. DREXL, “AstraZeneca and the EU Sector Inquiry: When do Patent Filings Violate Competition Law?” Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 12-2, 31 January 2012, available at <http://ssrn.com/abstract=2009276> accessed on 7 June 2012.

180 O’DONOGHUE and JORGE PADILLA, *supra* note 121, at p. 227.

181 DREXL, *supra* note 180, at p.21.

182 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments”¹⁸³. Moreover, by relying on the intention of the dominant undertaking, patent strategies aimed at constraining dynamic innovation may also be caught. Nonetheless, one shall note that intention cannot serve as a conclusive factor for the finding of abuse. This has been explained by A.G Mazák¹⁸⁴ in his Opinion where he stated that in considering intent as a relevant criterion, would be an attempt to apply criminal evidence standards to administrative procedures. This would be contrary to Article 23(5) of Regulation 1/2003¹⁸⁵. For this purpose, intention is construed as playing a mere ancillary role of cross checking the type of conduct, against the yardstick of competition on the merits.

On the other hand, some question the applicability of such precedent to patent compliant behaviour and state that the judgment in *AstraZeneca*¹⁸⁶ could only address the procurement of a patent where there is an additional factor such as fraudulent behaviour¹⁸⁷. In support of this argument, it could be seen that the case concerns the issue of misleading representations to the patent offices which takes the conduct of the undertaking in a dominant position outside the scope of competition on merits: “an undertaking in a dominant position may not make objectively misleading representations to the public authorities to obtain a right irrespective of whether that undertaking believes it is entitled to that right”¹⁸⁸.

Accordingly, the Commission and the General Court seem to have left a wide margin of appreciation as to whether strategic patenting could be circumscribed through the application of Article 102 TFEU, where it leads to foreclosing effects to the detriment of consumer welfare. The implications of this argument, are evident in the legal reasoning of the Italian Competition Authority in *Pfizer*¹⁸⁹.

183 Id., at ¶ 523.

184 Opinion of A.G in *AstraZeneca*, *supra* note 107, at ¶ 50.

185 Council Regulation (EC) No. 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] O.J L 1.

186 *AstraZeneca*, *supra* note 5.

187 S. KJOLBYE, ”Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?” (2009) 32(2) *World Competition* 163, 180.

188 Opinion of A.G in *AstraZeneca*, *supra* note 107, at ¶ 51.

189 *Pfizer*, *supra* note 7.

5. The “Chilling” Effect of *AstraZeneca* on Innovation

Although, the judgment of the General Court in *AstraZeneca*¹⁹⁰ addresses the misrepresentations made in the procurement of an SPC, the judgment has been used as guidance in the *Pfizer*¹⁹¹ case. Notwithstanding, in doing so, the Italian Competition Authority too readily found an abuse, thereby, shifting the balance too far in favour of generic manufacturers. In following the line of reasoning put forward by the Competition Authority, the incentives to innovate provided by intellectual property law regime would be antagonized. This is because competitive pressure from generic manufacturers leads to originators “holding back on innovation until near patent expiry when incremental innovation is required to protect revenues”¹⁹². Therefore, this is an unfavourable decision which points out specifically to the need of clearer guidelines from the Commission, as otherwise, undertakings in dominant position can be held accountable merely because the competition law enforcers have the discretion to bend to different policy objectives¹⁹³ that the situation is deemed to require.

5.1. Pfizer – the finding of abuse

The Italian Competition Authority, following the Sector Inquiry¹⁹⁴ and judgement in *AstraZeneca*¹⁹⁵, found that Pfizer abused its dominant position by artificially extending the duration for the patent protection for Xalatan, a drug used to treat glaucoma¹⁹⁶. The undertaking, relied on the divisional patent obtained for an active ingredient of Xalatan to secure an SPC to which otherwise would not have been entitled because the application was not submitted on time. Therefore, the reliance on patent instruments has been construed as an abuse of dominance which had the effect of making the entry on the market of generics more costly than the normal cost of market entry in terms of timing and efficiency as there was an entry delay of seven months¹⁹⁷. Moreover, it has been held that by artificially extending the duration for the patent protection, Pfizer maintained the exclusive commercialisation right over the given medicine even after the patent

190 *AstraZeneca*, *supra* note 5.

191 *Pfizer*, *supra* note 7.

192 Charles River Associates, “Innovation in the pharmaceutical sector” ENTR/03/28, available at http://ec.europa.eu/health/files/pharmacos/docs/doc2004/nov/eu_pharma_innovation_25-11-04_en.pdf, accessed on 25 June 2012, at p.88.

193 Amongst these different policy objectives, can be noted: market integration, efficiency, economic freedom, consumer welfare.

194 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

195 *AstraZeneca*, *supra* note 5.

196 *Pfizer*, *supra* note 7.

197 *Id.*, at ¶ 140.

expiration, causing a €14 million loss in savings for the Italian Health Authority¹⁹⁸.

The theory of harm, in this case, rested on the finding that the dominant undertaking engaged in a complex strategy conceived to protect its market share from competition from generics following the expiry of its patent protection, thereby causing consumer harm. By engaging in such a practice, the undertaking delayed market entry and allegedly created a situation of legal uncertainty for potential entrants¹⁹⁹. This practice which involves reliance on divisional patents, as previously mentioned, has been indicated by the Commission in the Final Report²⁰⁰ as potentially raising anti-competitive concerns.

The Italian Competition Authority, further pointed to the similarity between the reasoning in *AstraZeneca*²⁰¹, where emphasis was placed on the special responsibility of a dominant undertaking, in stating that there was a lack of transparency on behalf of Pfizer. This was because the pharmaceutical undertaking did not disclose to the patent authorities the fact that the request for an SPC was made on the basis of a divisional patent and not on that of the parent patent²⁰². Moreover, the Competition Authority alluded to the notion of competition on the merits. Consequently, the strategic use of legal instruments in this case was considered to fall outside the scope of competition on the merits leading to the artificial maintenance of market power by raising the cost of generic's entry on the market²⁰³.

The Competition Authority, like the General Court in *AstraZeneca*²⁰⁴, it relied on the intent derived from the internal communication of Pfizer to substantiate its finding of abuse. Thus, it found that the objective in procuring the divisional patent and the SPC was not to protect an extra added therapeutic use of the medicine but to exclude the entry of generic manufacturers²⁰⁵. Moreover, it was found that the undertaking had knowledge of the risk of competition that was imminent once the patent protection expired. In addition, the Italian Competition Authority took into consideration the timing of the request for the divisional patent and the SPC and the fact that the validation of the patent and the SPC was only requested for the Italian market and other countries where the original patent protection was due to expire sooner than in others²⁰⁶.

5.2. The Italian Competition Authority deviated from the intent of the Commission

The decision in *Pfizer*²⁰⁷ can be considered erroneous on several grounds. Whilst, relying on the Commission's findings in the Sector Inquiry²⁰⁸ regarding the anti-competitive use of divisional patenting, the

198 Id.

199 Id., at ¶ 88.

200 Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 518.

201 *AstraZeneca*, *supra* note 5.

202 *Pfizer*, *supra* note 7, at ¶ 179 and ¶ 191.

203 Id., at ¶ 175.

204 *AstraZeneca*, *supra* note 5.

205 *Pfizer*, *supra* note 7, at ¶ 193.

206 Id., at ¶ 203.

207 *Pfizer*, *supra* note 7.

208 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

Competition Authority fails to acknowledge that only in “exceptional circumstances” may reliance on divisional patents and on the legitimate use of legal procedures provided by intellectual property law, can be incompatible with competition law²⁰⁹. This is in line with the Charter of Fundamental Rights of the European Union²¹⁰ where Article 17(2) provides that “intellectual property law shall be protected”.

Unlike in *AstraZeneca*²¹¹, Pfizer merely made use of the legal available means provided by the patent system in order to obtain an SPC to which, if it met the deadline, it would have been entitled to in any case. The divisional patent does not extend the length or the breadth of the parent patent and as such it could not be said that the resulting SPC would grant an exclusivity right to Pfizer on an unmeritorious basis. To uphold this decision, would have a chilling effect on innovation. This is because, an undertaking even when occupying a dominant position, is entitled to and it has a legitimate expectation to its reward, namely the exclusivity granted through the patent protection. Should such a practice of acquiring an SPC based on a divisional patent be considered as falling outside the purpose of the patent system, then the “perceived failings of a patent system [would be best] addressed through legislative form rather than antitrust intervention”²¹² because this falls outside the limits of Article 102 TFEU application. Furthermore, in support of this argument, Thomas Graf suggests that: “if the decision were to stand this would therefore considerably increase legal uncertainty and potentially deter the use of legal instruments that EU law has introduced to stimulate innovation”²¹³.

Notwithstanding, whilst competition authorities should not too readily intervene in curtailing the exclusivity inherent in a patent, it is as stated when discussing the case of *AstraZeneca*²¹⁴, that patent filing or reliance on regulatory procedures may be addressed when they are used for purposes outside the intent of the legislators by dominant undertakings. This is, for example, when they are used to create legal uncertainty as to what subject matter is protected, making the rival’s entry more costly because they would have to inquire into this issue and delay their entry in the meantime. Patent clustering could also be better addressed under competition law where the aim is not to protect the subject matter concerned but to ensure that competitors cannot develop their own product, thus producing effects detrimental to consumers. In this situation, one could appreciate that there are no efficiencies created by the patent holder. Additionally, divisional patents can also be used for the same strategic purpose.

The decision in *Pfizer*²¹⁵ can be seen as reflecting the Commission’s Guidelines on exclusionary abuses. In both, an effect based approach is promoted, whereby, there ought to be proved that the alleged abusive conduct is capable, by its nature, to foreclose competition and that there is a likely market distorting

209 *Id.*, at ¶ 1568.

210 Charter of Fundamental Rights of the European Union, [2000] O.J. C 364

211 *AstraZeneca*, *supra* note 5.

212 G. DE STEFANO “Italy: abuse of Dominant Position-Pharmaceuticals” (2012) 36(6) *ECLR* 87,89.

213 T. GRAF, “The Italian Competition Authority fines company for abuse of dominance relating to visual glaucoma drugs challenging divisional patent filings (Pfizer)”, 11 January 2012, e-Competitions, No42180.

214 *AstraZeneca*, *supra* note 5.

215 *Pfizer*, *supra* note 7.

foreclosure effect²¹⁶. This practice is said by the Commission to only catch abuses which are most harmful to the consumer. Notwithstanding, the application of the effect based approach in this case, failed to take into consideration the long term benefits of the allegedly abusive conduct, in quest of protecting short term consumer benefits resulting from immediate price competition from generic manufacturers. The long term benefits that should have been taken into account can be depicted from the Schumpeter's creative destruction theory²¹⁷. Namely, in innovation markets, firms seeking to maintain or achieve a dominant position will always strive to compete by way of bringing new or improved products on the market. Thus, even if they benefit from a temporary protection from price competition, they are still disciplined by the rival originator companies' new advances in research and development. Moreover, price competition is often restricted by state intervention. This is because the price of medicines is largely controlled by the National Health Authorities.

The balance in *Pfizer*²¹⁸ has been shifted too far in favour of generic manufacturers. The effect based reasoning is too reliant on the assessment of reduction of output and raising of prices implications²¹⁹. This is detrimental to the assessment of intellectual property cases. This reliance leads to over-enforcement, effect not desirable because it deters the incentives of dominant undertakings to innovate. As aforementioned, one ought to be offered a temporary shelter from competition to be able to recoup the costs incurred through its R&D activity²²⁰. The special status of intellectual property rights has been acknowledged in *Magill* where it was stated that certain encroachments on the E.U rules are admissible and justified because the specific subject matter of an intellectual property right deserves special protection²²¹. Consequently, although the Commission clearly stated in the Sector Inquiry²²² that it will not hesitate to take action, by means of competition law, against undertakings in a dominant position which use the patent filing strategies to create barriers to entry to generic manufacturers, thus changing the structure of the market to the detriment of the consumer, a balance ought to be drawn between the legitimate interest of the patent owner and the maintenance of a competitive structure of the market. Moreover, the competition law enforcers should look at the long term effects of such conduct and not undermine innovation merely for the purpose of price competition.

In addition, should one proceed to apply the sacrifice test, namely whether the conduct adopted by Pfizer makes no business sense but for the anti-competitive effect, could lead to a misapprehended conclusion. This is because, the application of such test would place too much focus on the exclusionary

216 Commission's guidelines on exclusionary abuses, *supra* note 31, at ¶ 56.

217 SCHUMPETER, *supra* note 23.

218 *Pfizer*, *supra* note 7.

219 W. WURMNEST, "The Reform of Article 82 EC in the Light of the "Economic Approach"" in M. Mackenrodt, B. Gallego, & S. Enchelmaier, *Abuse of Dominant Position. New Interpretation, New Enforcement Mechanisms*, Munich: Springer, 2008, at p. 7.

220 SCHUMEPETER, *supra* note 23.

221 *Magill*, *supra* note 44.

222 Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 1570.

effects rather than appreciating them as a reward intended by the patent authorities for the launching of a new medicine on the market which benefits consumers. The extended patent protection, although, procured notwithstanding the fact that Pfizer was time-barred, was achieved by means which were legal. As mentioned, a divisional patent aims to correct procedural errors. Moreover, there is no legal requirement from a patent law perspective for an undertaking to disclose the fact that the application for the SPC is done on the basis of a divisional patent.

If one was to compare the approach in *AstraZeneca*,²²³ which was highly focused on competition on the merits, with the effect based approach in *Pfizer*²²⁴, one would come to appreciate the appropriateness of the former in this context. The Italian Competition Authority failed to conduct a thorough assessment of whether the conduct perceived as abusive did fall outside the scope of competition on the merits. The finding of abuse was limited to the intent of the dominant undertaking in raising the rival's costs which ultimately resulted in barriers to entry.

Stefano Grassani argues that "competition on the merits holds that a dominant company cannot be allowed to indirectly and subtly seek for such additional patent protection by resorting to tactics which, ultimately, have a purely foreclosing object; regardless of whether such tactics are formally lawful under IP law"²²⁵. Furthermore, he suggests that competition on the merits implies that the intellectual property rights are used in a rewarding activity such as the launching of a new drug or a new process so to enhance consumer welfare²²⁶. In this case, however, the divisional patent has not led to any new improvements or uses. Notwithstanding, Stefano Grassani fails to acknowledge that the purpose of a divisional patent is mainly a procedural one. This is for instance, when some matters in the parent patent application need to be clarified, in order not to lose the protection for the invention, a divisional patent might be filed. Consequently, the divisional patent encompasses the innovation covered by the basic patent. Thus, consumer welfare is already achieved through the innovation covered by the basic patent. To support the view put by Stefano Grassini in this circumstance, would entail to construe the purpose of Article 102 TFEU as merely ensuring easy access on the market to all competitors.

Through the application of the notion of competition on the merits, a dominant firm should have the opportunity to exercise competitive pressure on the market. This competitive pressure ought to be borne as a result of an undertaking's performance as opposed to practices that create guards or barriers to entry²²⁷. The competitive pressure in this case is exercised on the basis of Pfizer's performance in producing Xalatan.

223 *AstraZeneca*, *supra* note 5.

224 *Pfizer*, *supra* note 7.

225 S. GRASSANI, "Evolution or Revolution? The Italian Competition Authority and the Pfizer Decision: A Reply to Thomas Graf" Kluwer Competition Law Blog, 7 February 2012, available at <http://kluwercompetitionlawblog.com/2012/02/07/evolution-or-revolution-the-italian-competition-authority-and-the-pfizer-decision-a-reply-to-thomas-graf/> accessed on 18 June 2012.

226 Id.

227 R. WEZENBEEK and E. PAULIS "La Révision de la Politique Communautaire" in *Quelle Réforme pour l'article 82 CE? Tendances|Concurrences* No 4-2005, 10, at p. 14.

Accordingly, competition based on performance and hence merits existed. In light of this, it is to be acknowledged that competition on the merits does not mean competition for all competitors. To assume this, a chilling effect on innovation would occur. This is explained by Ramondino and Stothers who argued:

“the exclusive right provided by patents and SPC’s are intended to foster innovation by providing for innovation and thus to avoid market failure which would occur if pharmaceutical products are exposed to generic competition too soon. If such protection is arbitrarily reduced by competition intervention, incentives to develop new pharmaceuticals will be reduced”²²⁸.

5.3. Correcting systemic failures

The analysis of the decision in *Pfizer*²²⁹, ultimately leads to the question of whether competition authorities should step in to correct the systemic failures of the intellectual property law. Consequently, it raises the question whether competition law enforcers should intervene when procurement intellectual property rights does not lead to any efficiencies such as the development of new or improved products or processes but to exclusionary effects solely.

The scope of intellectual property law is too permissive in as much as it allows for the creation of a “giungla brevetuale”²³⁰. This can be seen in relation to patent clustering strategies whereby the patent holder, upon the expiry of the basic patent seeks to protect its product against competition by patenting around the basic patent. This would have the effect of impeding follow on innovation and also price competition from generic manufacturers because uncertainty as to the subject matter protected arises. Furthermore, to innovate further, a competing undertaking might require access to one of the patent included in the cluster, thus impeding further advances. Moreover, the original patent holder by maintaining its market power for a longer period, will price higher than competitive levels to gain profits that go far beyond its initial investment in R&D. Accordingly, the role of competition law, in this instance, would be to correct this market failure, as the dominant undertaking, holding the basic patent, would not be constrained by the natural demand and supply forces of the market.

Patent clustering is a straight forward example whereby no efficiencies are generated. Consequently, an effects based analysis would be appropriate in this case. Nonetheless, the judgment in *AstraZeneca*²³¹ and the analysis of the decision in *Pfizer*²³² lead to the conclusion that procurement of intellectual property rights can constitute an abuse under the scope of Article 102 TFEU, only in the circumstance where the objective for such procurement goes beyond the specific purpose of the intellectual property right, thereby unduly excluding competition on the relevant market to the detriment of the consumer.

²²⁸ M. RAMONDINO and C. STOTHERS, “Aftermath of AstraZeneca and the pharmaceutical Sector Inquiry: the big chill?” (2011) 32(12) *ECLR* 591, 594.

²²⁹ *Pfizer*, *supra* note 7.

²³⁰ *Id.*, at ¶ 129.

²³¹ *AstraZeneca*, *supra* note 5.

²³² *Pfizer*, *supra* note 7.

5.4. Recommendations

In light of the above, it can be seen that there is no clear guidance as to what may constitute an abuse in the field of intellectual property right procurement. This not only causes legal uncertainty for undertakings which might find themselves in a dominant position, but also results into unfavourable decisions by the national competition authorities, as seen in *Pfizer*²³³, that tend to sacrifice the long term incentives for innovation at the cost of price competition. Although not advocating for a pure Schumpeterian approach, whereby price competition is considered insignificant, it is submitted that long term goals that aim at consumer welfare such as stimulating R&D investments ought not to be disregarded.

Moreover, the Pharmaceutical Sector Inquiry, undergone by the Commission, has further policy implications other than just competition law enforcement. It points to the difference in the regulatory frameworks, effects that have been discussed in the second part of this paper. In an attempt to harmonise the pricing and reimbursement schemes, it is believed that a more price competitive structure of the market would be achievable as a whole. Thus, policy change rather than individual assessment of undertakings in dominant positions would more efficiently stimulate price competition, whilst still encouraging investments in R&D. The harmonisation of the pricing and reimbursement schemes for pharmaceuticals would deter the incentives of the dominant originators to impose barriers to entry to originators and instigate a re-direction of resources to further R&D activities. Furthermore, the adoption of a single European patent is also considered to be a step that would eliminate the uncertainties present in regards to strategic patenting as it would be a more transparent mechanism²³⁴. Notwithstanding, it is acknowledged that this would not be welcomed by some Member States that are unwilling to give up their sovereignty over property rights.

In the absence of policy change and the establishment of a single European patent, it is submitted that if competition law was to correct the systemic failures of the intellectual property legal systems through the application of Article 102 TFEU, it should do so by adopting a rule of reason approach, considering both the short and long term economic implications of the alleged abuses. Notwithstanding, clear guidance shall be provided at the European level as to what factors shall be taken into account when strategic patenting is used for the purpose of artificially maintaining market power.

233 Id.

234 Pharmaceutical Sector Inquiry Final Report, *supra* note 1, at ¶ 267.

6. Conclusion

Patents are considered to generate efficiencies by way of new products or processes from which consumers can benefit. Innovation, which in the pharmaceutical market can be understood as a progress which leads to an entirely new product, the reduction in cost or augmentation in the therapeutic value of an existing product, distorts competition on the market by itself. Furthermore, the incentive to innovate is rendered through a temporary shelter from competition which is granted as a reward in the form of a patent. This is said not to raise any anti-competitive concerns. This is more so in the light of the fact that to curtail an intellectual property right, would be to undermine the Charter of Fundamental Rights of the European Union²³⁵. Notwithstanding, an anti-competitive concern can be raised when the procurement of the intellectual property right falls outside competition on the merits.

As it has been seen the criteria applicable in finding of abuse in cases concerning the procurement of intellectual property rights is broad and fact dependent. This has been even more emphasised in the Sector Inquiry²³⁶ where the Commission asserted that such types of abuses will be addressed on a case by case basis. Unfortunately, as seen in the analysis of the *Pfizer* case²³⁷, this is not an appropriate solution because the broad construction of the notion of abuse leaves much discretion to the enforcing authorities. Even more, it is questionable whether the notion of abuse as defined by the General Court in *AstraZeneca*²³⁸ can be transposed to cases concerning the procurement of intellectual property rights with the objective of foreclosing market entry where no fraudulent behaviour is exhibited. This realm of legal uncertainty is prejudicial to dominant market players' incentives to innovate as they run the risk of being found to infringe competition law through the mere reliance on available legal means. This arguably depends on the different policy objectives that the situation requires.

Given that the Commission, through the Sector Inquiry²³⁹, identified anti-competitive practices across the whole pharmaceutical sector, and not just in individual cases, a better result may be achievable by setting the right balance between generic and originator manufacturer's interests through legislative changes to pricing and reimbursement schemes and also through the creation of a single European patent. Should this be possible, the focus of competition law enforcement would depart from price competition to dynamic competition through innovation as this is the precise factor which enhances consumer welfare to a greater

235 Charter of Fundamental Rights, *supra* note 211.

236 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

237 *Pfizer*, *supra* note 7.

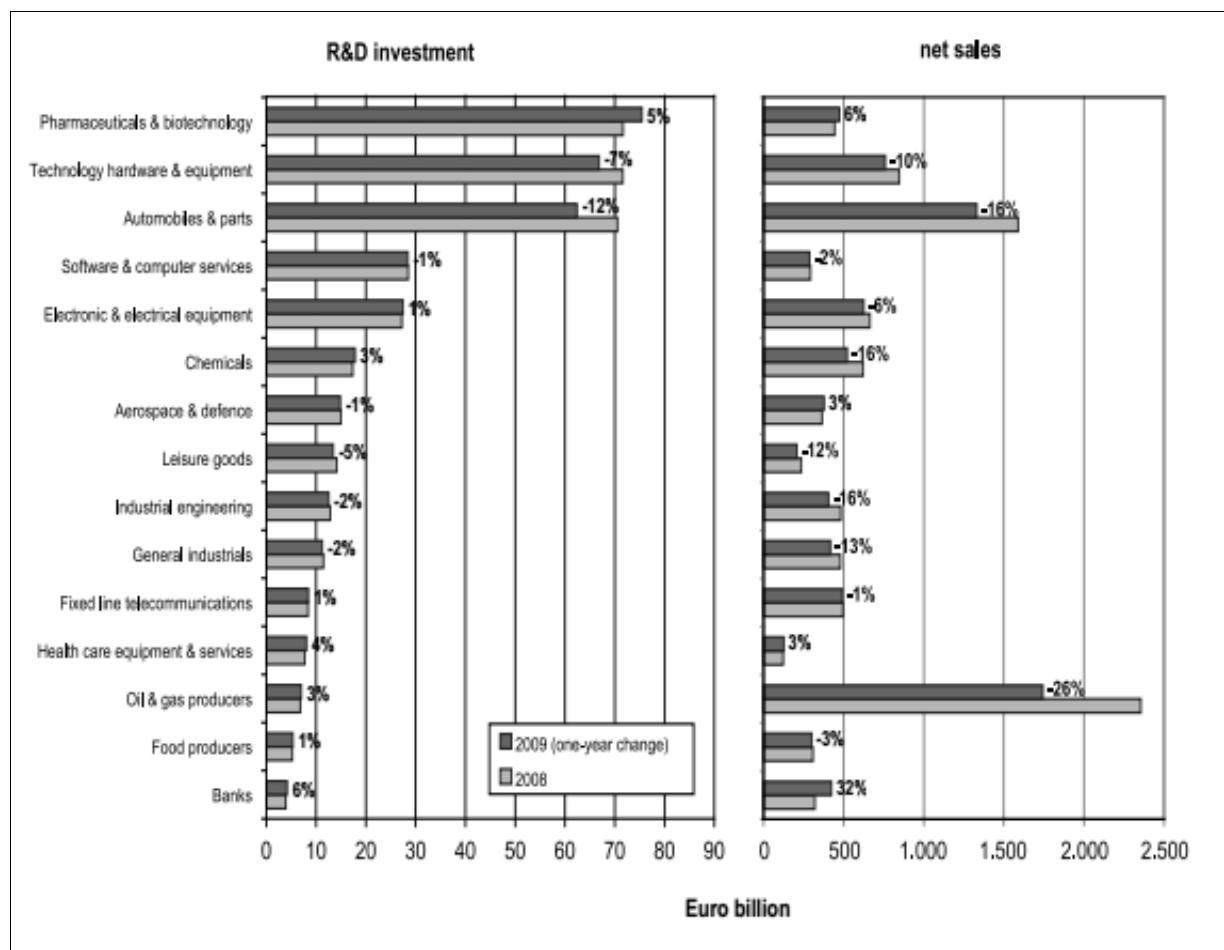
238 *AstraZeneca*, *supra* note 5.

239 Pharmaceutical Sector Inquiry Final Report, *supra* note 1.

extent in these particular economies.

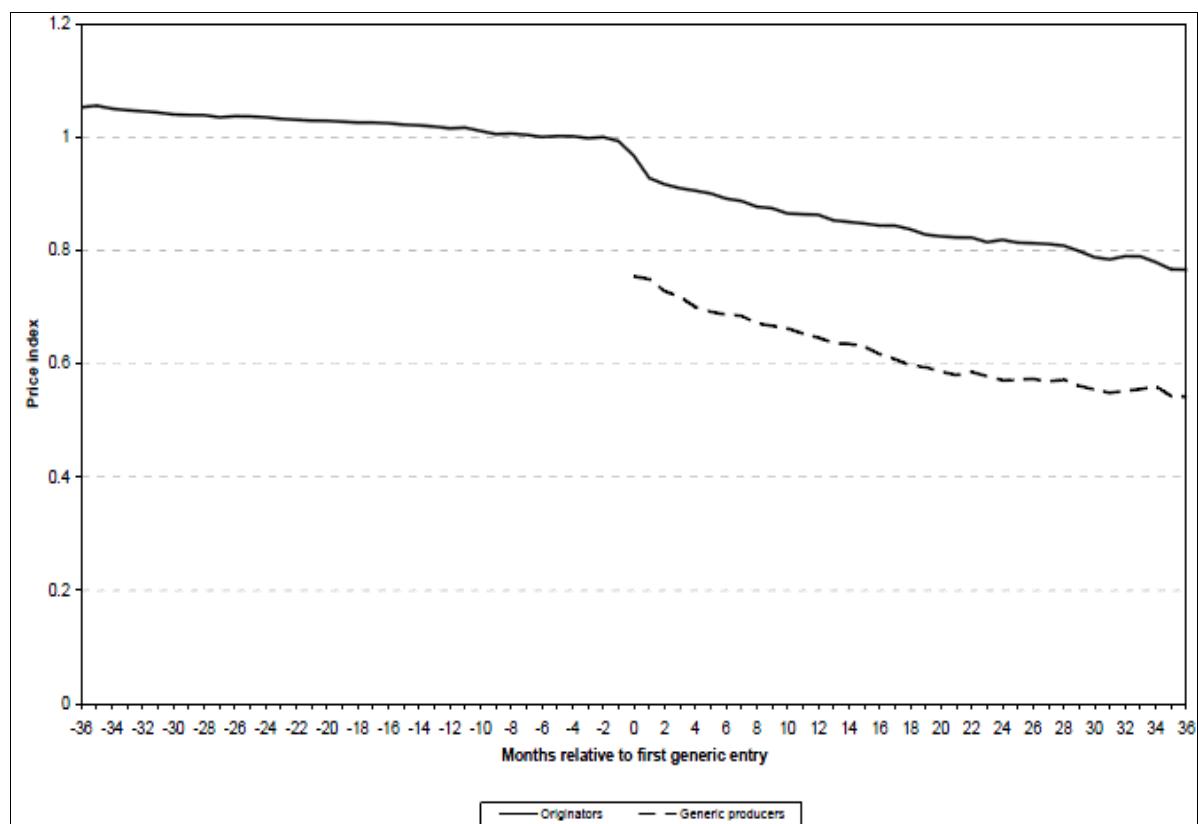
7. Appendices

Annex 1. Rate of R&D Investments and Net Sales across the top sectors in the period 2008-2009



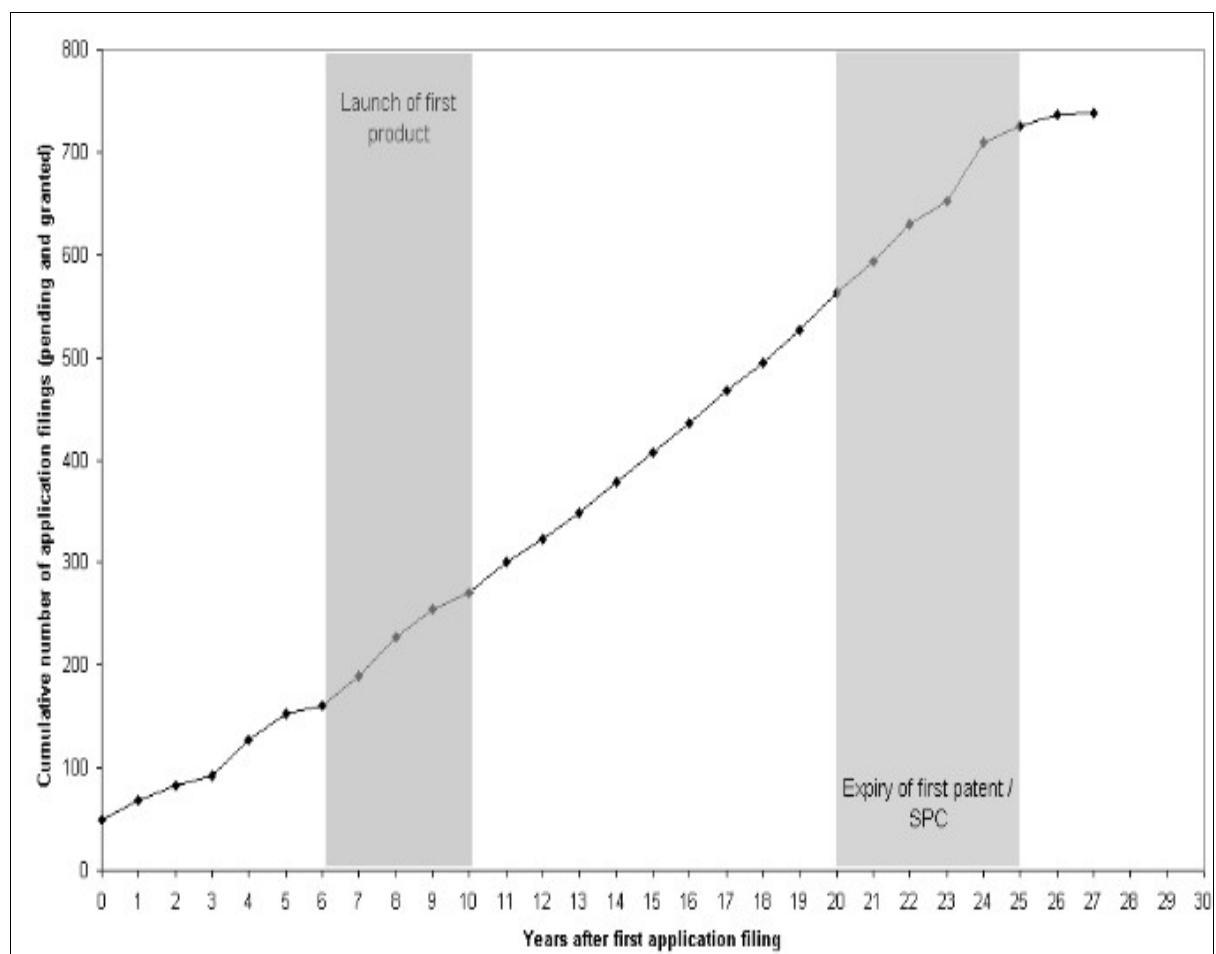
Source: The 2010 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD

Annex 2: Price index upon generic entry



Source: *Pharmaceutical Sector Inquiry, Final Report (2009)*

Annex 3: Number of patent application filings for top 21 INNs



Source: *Pharmaceutical Sector Inquiry, Final Report (2009)*

8. Bibliography

Books

Anderman, S. and Ezrachi, A., *Intellectual Property and Competition Law New Frontiers*, New York: OUP, 2011.

Baecker, P., *Real Options and Intellectual Property Capital Budgeting Under Imperfect Patent Protection*, New York: Springer Berlin Heidelberg, 2007.

Baumol, W.J., *The Free Market Innovation Machine: Analysing the growth miracle of capitalism*, New Jersey: Princeton University Press, 2002.

Boldrin, M. and Levine, D.K., *Against Intellectual Monopoly*, Cambridge: CUP, 2008.

Bouckaert, Boudewijn and De Geest, “The History and Methodology of Law and Economics” *Encyclopedia of Law and Economics* I, Cheltenham: Edward Elgar, 2000.

Cellini, R. and Cozzi, G., *Intellectual Property, Competition and Growth. Central Issues in Contemporary Economic Theory and Policy*, Basingstoke: Palgrave Macmillan, 2007.

Drexel, J., *Research Handbook on Intellectual Property and Competition Law*, Cheltenham: Edward Elgar Publishing, 2008.

Govaere, I., *The Use and Abuse of Intellectual Property Rights in E.C Law*, London: Sweet and Maxwell, 1996.

Mackenrodt, M., Gallego, B. and Enchelmaier, S., *Abuse of Dominant Position. New Interpretation, New Enforcement Mechanisms*, Munich: Berlin/Heidelberg: Springer, 2008.

Maggiolina, M., *Intellectual Property and Antitrust: A comparative Economic Analysis of US and EU law*, Cheltenham: Edward Elgar Publishing Limited, 2011.

O’ Donoghue, R. and Jorge Padilla, A., *The Law and Economics of Article 82 EC*, Portland: Hart Publishing, 2006.

Robinson, J., *The Accumulation of Capital*, 3rd ed., London: Macmillan, 1969.

Schumpeter, J.A., *Capitalism, Socialism and Democracy*, London: George Allen & Unwin LTD,

1943.

Smith, A., *An Inquiry into the Nature and Causes of the Wealth of Nations*, 5th ed. London: Methuen & Co., Ltd., 1904.

Articles

Batchelor, B. "EC tones down in its final report into the Pharma Sector, but ramps up enforcement activity" (2010) 31(1) *ECLR* 16.

Battaglia, L., Larouche, P., Negrinotti, M. "Does Europe Have an Innovation Policy? The case of EU economic law" Grasp Working Paper 11, January 2011, available at http://grasp.cepr.org/files/working_papers/D6%20WP5%20Does%20Europe%20Hav%20an%20Innovation%20Policy.pdf accessed on 5 May 2012.

BGMA, "About Generics" available at <http://www.britishgenerics.co.uk/about-generics/the-generics-industry> accessed on 1 May 2012.

Deloitte and Thomson Reuters, "Measuring the return from innovation. Is R&D earning its investment?", 2011, available at http://www.deloitte.com/view/en_GB/uk/industries/life-sciences/da3c9279595c3310VgnVCM1000001a56f00aRCRD.htm accessed on 1 May 2012.

Drexel, J. "AstraZeneca and the EU Sector Inquiry: When do Patent Filings Violate Competition Law?" Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 12-2, 31 January 2012, available at <http://ssrn.com/abstract=2009276> accessed on 7 June 2012.

EGA "The Future of Pharmaceuticals: Generic Medicines Enhancing Pharmaceutical Competition and Ensuring Healthcare Sustainability", October 2007, available at http://www.egagenerics.com/doc/ega_FuturePharmaceuticals.pdf accessed on 30 January 2012.

Forrester, I. "Regulating Intellectual Property Via Competition? Or Regulating Competition Via Intellectual Property? Competition and Intellectual Property: Ten Years On, the Debate Still Flourishes", 2005, available at <http://www.eui.eu/RSCAS/Research/Competition/2005/200510-CompForrester.pdf> accessed on 4 March 2012.

Gallash, S. "AstraZeneca v The Walker Process – A real EU-US Divergence or Just and Attempt to Compare Apples to Oranges?" (2011) 7(3) *European Competition Journal* 505.

GlaxoSmithKline "Global Public Policy issues: Evergreening", August 2011, available at

<http://www.gsk.com/policies/GSK-and-evergreening.pdf> accessed on 30 January 2012.

GlaxoSmithKline Briefings “Key Aspects of a Sustainable Health Care System”, September 2006, available at <http://www.gsk.com/policies/GSK-and-key-aspects-of-a-sustainable-healthcare-system.pdf> accessed on 6 May 2012.

Graf, T. “The Italian Competition Authority fines company for abuse of dominance relating to visual glaucoma drugs challenging divisional patent filings (Pfizer)”, 11 January 2012, e-Competitions, No 42180.

Grassani, S. “Evolution or Revolution? The Italian Competition Authority and the Pfizer Decision: A Reply to Thomas Graf” *Kluwer Competition Law Blog*, 7 February 2012, available at <http://kluwercompetitionlawblog.com/2012/02/07/evolution-or-revolution-the-italian-competition-authority-and-the-pfizer-decision-a-reply-to-thomas-graf/> accessed on 18 June 2012.

Hall, M. “EU Competition Law in the Pharmaceutical Sector: What Has Happened Since 2009?” (2011) 1 *International Antitrust Bulletin*, American Bar Association 4.

Hareid, J., “In Search of an Elixir: What Ails the Pharmaceutical Industry in Europe and How to Use the Competition Law to Cure It?” (2008) 10 *Minn. J.L. Sci&Tech* 727.

Hermann, A.M. “Choosing and Successfully Sustaining Competitive Strategies in the European Pharmaceutical Industry” *MPIfG Discussion Paper 08/9*, September 2008, available at http://www.mpifg.de/pu/mpifg_dp/dp08-9.pdf accessed on 30 January 2012.

Hunt, R. M. “Patentability, Industry Structure and Innovation” (2004) 52 *The Journal of Industrial Economics* 401.

Kjolby, S., “Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?” (2009) 32(2) *World Competition* 163.

Krattenmaker, T. and Salop, S., “Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price” (1986) 96(2) *The Yale Law Journal* 209.

Lemley, M. “A New Balance between IP and Antitrust” (2007) 13 *Southwestern Journal of Law and Trade in the Americas* 1.

Magazinni, Pammolli and Riccaboni “Patent Disclosure and R&D Competition in Pharmaceuticals” (2009) 18 *Economics of Innovation and New Technology* 467.

Moreno-Torres, I., Puig-Junoy, J., Borrell-Arqué, J.R., “Generic entry into a regulated Spanish pharmaceutical market” (2009) 34 *Rev. Ind. Organ.* 373.

Murphy, F. “Abuse of regulatory procedures - the AstraZeneca case: Part 2” (2009) 30(6) *E.C.L.R.* 289.

Pammolli, F. and Riccaboni, M. "Market Structure and Drug Innovation" (2004) 23 (1) *Health Affair* 48.

Poore, A. "The European Union patent system: off course or on the rocks?" (2011) 33 (7) *E.I.P.R.* 409.

Ramondino, M. and Stothers, C., "Aftermath of AstraZeneca and the pharmaceutical Sector Inquiry: the big chill?" (2011) 32(12) *ECLR* 591.

Régibeau, P. and Rockett, K. "The Relationship Between Intellectual Property Law and Competition Law: An Economic Approach" *Economics Discussion Papers 581*, University of Essex, Department of Economics (2004).

Scheffeman, D., "20 Years of Raising Rivals' Costs: History, Assessment, and Future" (2003) 12 *Geo. MASON L. Rev.* 371.

Shavel, S. and Van Ypersele, T. "Rewards versus Intellectual Property Rights" (2011) 44 *Journal of Law and Economics* 525.

Wezenbeek, R. and Paulis, E., "La Révision de la Politique Communautaire" in *Quelle Réforme pour l'article 82 CE? Tendances|Concurrences* No 4-2005, 10.

Xenox, D. "Limiting the IPRs of Pharmaceutical Companies Through EU Competition Law: The First Crack in the Wall" (2011) 8(1) *SCRIPTed* 92.

Policy Papers

Charles River Associates, "Innovation in the pharmaceutical sector" ENTR/03/28, available at http://ec.europa.eu/health/files/pharmacos/docs/doc2004/nov/eu_pharma_innovation_25-11-04_en.pdf, accessed on 25 June 2012.

Commission Press Release IP/08/49 of 16 January 2008, "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections" available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&guiLanguage=en> accessed 2 May 2012.

Commission's First Report on Competition Policy available at http://aei.pitt.edu/31201/1/Comp_1971-1st.pdf accessed on 30 January 2012.

Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions "Europe 2020 Flagship Initiative: Innovation Union" COM (2010) 546 final 06.10.2010.

Communication from the Commission, "A Single Market for Intellectual Property Rights, Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and

services in Europe" COM (2011) 287 final 24.05.2011.

Communication from the Commission, "Strategic report on the renewed Lisbon strategy for growth and jobs: launching the new cycle (2008-2010) Keeping up the pace of change" COM (2007) 803 final part I.

DAFFE, "Competition and Regulation Issues in the Pharmaceutical Industry" DFFE/CLP (2000) 29.

De Souza, N. "Competition in Pharmaceuticals: the challenges ahead post AstraZeneca", Competition Policy Newsletter, no. 1, Spring 2007, available at

http://ec.europa.eu/competition/sectors/pharmaceuticals/2007_1_39.pdf , accessed on 10 June 2012.

EAGCP, "An economic approach to Article 82", July 2005, available at

http://ec.europa.eu/dgs/competition/economist/eagcp_july_21_05.pdf accessed on 15 March 2012.

ECORYS, "Competitiveness of the EU Market and Industry for Pharmaceuticals" Final Report, December 2009, available at http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_1_welfare_implications_of_regulation_en.pdf accessed on 2 May 2012.

European Commission, Competition DG, "Fact Sheet -Prices, time to generic entry and consumer savings" available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> accessed on 2 May 2012.

House of Commons Health Committee, "The influence of Pharmaceutical Industry" 4th Report of Session 2004-2005, Vol.1, 5 April 2005, available at
<http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf> accessed on 1 May 2012.

OECD Directorate for Financial Fiscal and Enterprise Affairs Committee on Competition Law and Policy, "Competition and Regulation Issues in the Pharmaceutical Industry" DFFE/CLP (2000) 29 available at <http://www.oecd.org/dataoecd/35/35/1920540.pdf> accessed on 5 May 2012.

OECD: Directorate for financial and enterprise affairs competition committee, "Roundtable on Generic Pharmaceuticals" DAF/COMP (2009)39 available at
<http://www.oecd.org/dataoecd/24/48/46138891.pdf> accessed on 5 May 2012.

Pharmaceutical Sector Inquiry Final Report, European Commission, Competition DG, 8 July 2009, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, accessed on 1 June 2012.

Pharmaceutical Sector Inquiry Preliminary Report, European Commission, Competition DG, 28 November 2008, available at

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf
accessed on 2 May 2012.

Speeches

Gilbert, R., "Intellectual Property and Antitrust Laws : Protecting innovators and innovations" Speech Before the Annual Winter Meeting of the Licensing Executives Society, Phoenix, AZ, 17 February 1995, available at <http://www.justice.gov/atr/public/speeches/0130.htm> accessed on 4 March 2012.

Higgins, A. Speech on the occasion of the Presentation of the Preliminary Report of the Pharma Sector Inquiry, Brussels 28 November 2008.

Monti, M. "Competition and Information Technologies", Speech/00/315, Barriers to Cyberspace Conference, Kangaroo Group, Brussels 18 September 2000.

Monti, M. "The New EU Policy on Technology Transfer Agreements", Speech/04/19, Ecole des Mines, Paris, 16 January 2004.

Commissioner Neelie Kroes' reply to Oral Question put by the honourable Member of the European Parliament Mr. von Boguslaw Sonik, H-0459/06.

Cases

EU

Case T-321/05, *AstraZeneca AB and AstraZeneca plc v Commission*, [2010] 5 C.M.L.R. 28.

Case T-24/93 to T-28/93, *Compagnie Maritime Belge Transports SA v Commission of the European Communities*, [1996] E.C.R. II-1201.

Case C-15/73, *Centrafarm v Sterling Drug*, [1973] ECR 1147.

Case C-78/70, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG.*, [1971] ECR 00487.

Joined Cases C-56 and 58/64, *Établissements Consten S.à.R.L and Grundig-Verkaufs v Comission*, [1966] E.C.R 322.

Case T-168/01, *GlaxoSmithKline Services Unlimited v Commission of the European Communities*, [2006] E.C.R. II-2969.

Case T-30/89, *Hilti AG v Commission of the European Communities*, [1991] ECR II-1439.

Case C-85/76, *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, [1979] ECR 461.

Case T-228/97, *Irish Sugar Plc v E.C. Commission*, [1999] 5 C.M.L.R. 1300.

Case T-111/96, *ITT Promedia NV v Commission of the European Communities*, [1998] ECR II-2937.

Case T-203/01, *Manufacture française des pneumatiques Michelin v Commission*, [2003] ECR II-4071.

Case T-185/00, *Metropole télévision SA and Reti Televisive Italiane SpA and Gestevisión Telecinco SA and Antena 3 de Televisión v Commission of the European Communities*, [2002] E.C.R. II-3805.

Case T-201/04, *Microsoft Corp v Commission of the European Communities*, [2007] E.C.R. II-3601.

Case C-322/81, *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 346.

Case C-7/97, *Oscar Bronner GmbH & Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG and others*, [1998] ECR I-7791.

Opinion of A.G. Mazák, delivered on May 15, 2012, in Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [not yet published].

Case T-69/89, *Radio Telefís Eireann v E.C. Commission*, [1991] 4 C.M.L.R. 586.

Commission Decision (Case COMP/A. 37.507/F3), delivered on June 15, 2005, O.J. [2006] L 332/24.

Joined Cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proionton*, [2008] 5 C.M.L.R. 20..

Case C-333/94 P, *Tetra Pak International SA v Commission of the European Communities*, [1996] E.C.R. I-5951.

Case C-27/76, *United Brands and United Brands Continentaal v Commission*, [1978] ECR 207.

Italian Competition Authority

Case A431 *Ratiopharm v Pfizer*, Autorità Garante della Concorrenza e del Mercato, Decision no. 23194, Italy, 11 January 2012.

U.S

Berkey Photo, Inc. v Eastman Kodak Co, 603 F.2d 263 (2d Cir. 1979).

Brief for the United States and Federal Trade Commission as Amici Curiae Supporting Petitioner, *Verzion Communications, Inc v Law Office of Curtis V. Trinko LLF*, No. 06-682 (docketed US Supreme Court, 13 December 2002)

FTC, “Administrative Complaint in the Matter of Bristol-Myers Squibb”, FTC file No 0110046.

Railroad Presidents Conference v. Noerr Motor Freight, Inc. .., 81 S.Ct. 529.

Walker Process Eqpt., Inc. v. Food Machinery Corp., 382 U.S. 172 (1965).

Legislation

EU

Treaty for the Functioning of the European Union.

Art. 101 TFEU.

Art. 102 TFEU.

Art. 168 TFEU.

Charter of Fundamental Rights of the European Union, [2000] O.J. C 364.

Art. 35 Charter of Fundamental Rights of the European Union, [2000] O.J. C 364.

Art. 17(2) Charter of Fundamental Rights of the European Union, [2000] O.J. C 364.

Regulations

Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal product, [1992] O.J. L 182.

Council Regulation (EC) No. 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] O.J. L 1.

Soft Law

Communication from the Commission —Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009]O.J. C 45/7.

International Agreements

Convention on the Grant of European Patents (1973) 13 ILM 268 (European Patent Convention, as amended).

TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh

Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

U.S

Sherman Antitrust Act 1890, 15 U.S.C. §§ 1-7.