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Patent misuse and '*sham*'

-Development of new principles
under EU competition law

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Summary

This thesis takes its stance in the *AstraZeneca* judgment from the General Court and the latest developments in EU competition law and compares these with the equivalent standards of US antitrust law. Focus is on similarities and divergences between the EU application of competition law and the more developed doctrines of *Walker Process* and *Noerr-Pennington* in the US. The analysis is made in respect to the pharmaceutical sector, but the principles derived are presumed to be generally applicable. The thesis also features an economic approach to the current situation in the pharmaceutical sector and provides some reasoning as to the effects of the current enforcement of EU competition law.

The thesis concludes that the General Court in *AstraZeneca* diverge from both the Commission's decision and the US *Walker Process doctrine*, even though the General Court also finds *AstraZeneca's* conduct abusive. A smaller part of the thesis is devoted to the *Noerr-Pennington* doctrine and the EU case of *ITT Promedia* and concludes that the case law between EU and US in this regard seems similar, at least more similar than the *Walker Process* concept.

It is also concluded that competition between generic and originator firms, and the success of the generic products on the market, is more linked to the national legal frameworks, and in what way the member states create incentives' for generic substitution. These obstacles are estimated to be far larger than the effect dominant firms can have on the prolonging exclusivity or hindering competition in other ways.

Lastly, it is concluded that competition law is not well suited to deal with issues of regulatory frameworks such as the patent law framework. It is therefore of great importance that the EU receives a unified patent system with an EU patent court to deal with issues as the ones in *AstraZeneca*.

Preface

To me, the intersection between competition law and IP has always been an interesting area to do research. As I saw it, I had two possible subjects that incorporated the problems of both IP and competition law and that were 'hot'. One was the abuse of the standard setting procedure in different Standard Setting Organizations (SSOs), and the other was abuse of regulatory frameworks such as the patent system. The later won the day since it incorporated, what we expected already in March, but did not receive until the 1st of July, the *AstraZeneca* judgment. Especially interesting from my point of view was the fact that the Commission actually referred in its decision to US doctrine, and that the analysis was indeed very US oriented as such. This I thought of as irregular, but positive, since, in my view, the US approach to antitrust law and unlawful monopolization is more consistent if the aim is to achieve economic growth and efficiency.

During the time I wrote the thesis there was times when there was need for me to discuss certain points of principles how the law should be applied, and would like to thank my fellow students at the masters program for some most interesting conversations and good input.

Finally, I would like to thank my supervisor professor Hans Henrik Lidgard for good advice on how to structure and formulate the problem of the thesis, even though I might have deviated a bit from what we originally agreed on.

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Abbreviations

ATC	Average Total Cost
AVC	Average Variable Cost
AZ	AstraZeneca
EC	European Community
ECHR	European Convention on Human Rights
EEA	European Economic Area
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
PCT	Patent Cooperation Treaty
R&D	Research and Development
RO	Receiving Office
SPC	Supplementary Protection Certificate
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
US	United States

1 Introduction

“Competition as an ideology, as a dogma, what has it done for Europe?” The words were spoken by France president Nicolas Sarkozy during the negotiations for the Reform Treaty, indicating the French president’s skeptic view of the current competition enforcement policy pursued by previous competition Commissionaire Neelie Kroes. Indeed, competition is one of the branches of the Internal market that has evolved the most during the previous years. Moving both articles 81 and 82 EC (now articles 101 and 102 TFEU) toward a more economic approach, allowing for efficiency defenses and other objective justifications, has benefited the system and hopefully consolidated the Internal market even more. However, the use of more economic methods of assessment has also spurred the Commission to pursue new abuses under the competition rules. The assessment of abuse of dominance has indeed developed as the Commission increasingly has made use of rather complex economic methods applied to markets characterized with a high degree of innovation such as the markets within the pharmaceutical sector. While the pharmaceutical sector contains a high degree of innovation the markets also contain rather strict regulatory attributes making an economic analysis more difficult than in a market of free market competition.

The Commission’s search for new abuses to fit under the competition rules has started a rather large debate on what actually can be considered an abuse of dominance. Of course, it is no surprise that the wording of article 102 TFEU is non-exhaustive. Nevertheless, when firms occupied in highly regulated markets, playing by the regulatory rules, suddenly find themselves in a situation where the Commission considers that the use of these regulatory frameworks are excluding competition and therefore also violate article 102 TFEU, many scholars and practitioners started to question the long run effects of such a policy. Not only the pharmaceutical sector is concerned by such competition policy, and the EU courts have confirmed that using regulatory frameworks within telecommunications can be abusive if the framework allows the dominant undertaking to pursue a less exclusionary corporate strategy.¹

In the pharmaceutical sector, little case law can be found on regulatory abuses even though the sector is highly regulated. Previous cases in the pharmaceutical industry regarding parallel trade have distinguished the sector as *highly specific* and allowed for certain restrictions in relation to article 102 TFEU abuses.² *Restrictions*, however, means that competition

¹ Case T-271/03 Deutsche Telecom AG v. Commission. [2008] where the General Court upholds the Commission’s reasoning in relation to that the competition rules indeed are a higher set of norms than regulatory regimes and, therefore, dominant firms must make sure that they tread easily while competing with their smaller rivals, even in regulated sectors.

² Opinion by AG Jacobs in case C-53/03 Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. Glaxosmithkline AEEVE [2004]

law, as a main rule, still is applicable and the exceptions are very specific and narrow. This view was confirmed just recently by the high profile judgment in case *AstraZeneca v Commission*.³

The US view seem to differ, the question is how, and why? Over there, in the US, case law suggest that antitrust law is generally not applicable to regulated industries, given that the behaviour of competitors is monitored, and remedied, by regulatory frameworks such as sector specific regulations.⁴ While the ‘new’ abuses under European competition law follow similar reasoning as the US case law and doctrine, there seems to be a big discrepancy between when behaviour is considered illegal in the light of antitrust in the two jurisdictions.

1.1 Purpose

The purpose of this master thesis is to analyze, the application of competition law in Europe to the specific concept of patent misuse and sham, and compare the specifics of such misuse to the more developed American case law. The thesis aims to describe and analyze the current state of EU competition law enforcement in this area and to evaluate the results of such enforcement with regard to economic theory.

1.2 Method

When working with the legal framework in the EU and the US a traditional legal method will be used to establish ‘what is the current state of the law’. In this analysis the primary sources will be legislation and case law. Especially in the US, being a common law tradition and the fact that there is a much wider range of cases both as to subject matters and to numbers, the case law analysis will be more extensive in this jurisdiction. The EU analysis, lacking in case law, will therefore have to emphasize on legislative materials and doctrine to a higher degree than the US analysis, even though case law analysis will be used to a large degree to understand the how the European courts conceptualize legal problems and solve issues with regard to the Internal market.

³ Case T-321/05 *AstraZeneca plc v Commission* [2010]

⁴ See, for the general view of the interaction between section 2 liability and sector specific regulation the opinion in *VerizonCommunications v. Law Offices of Curtis V. Trinko* [2004] and the interaction between patent law, constitutional protection of the right to judicial review and antitrust law in the Federal Circuit opinion in *NobelPharma Inc. V. Implant Innovations Inc.* [1998].

After establishing the ‘current state of the law’ in EU and US, a comparative legal method is used to highlight similarities and divergences between the two jurisdictions. The effects of these differences will then be analysed using a law and economics method applying concepts of economic theory within the field of industrial organization and microeconomics. In this part of the thesis a rather large part will be devoted to analyzing relevant doctrine, especially doctrine which emphasizes rational economic thoughts. It will not go deep in the underlying mathematics and proofs of economic theories but rather give the reader the intuition of different enforcement policies. For instance, if policy makes market entry and exit easy more firms will probably be interested in competing in the marketplace resulting in higher social welfare, i.e. lower prices, better product differentiation, better quality products etc.

In general materials used will be legislation, case law, official documents, opinions and doctrine. These materials will be used to build up a nexus of contact points between one another and create an environment which then can help to explain situations and problems yet not addressed by legislative or other judicial institutions such as the Union courts.

1.3 Delimitations

To make a full assessment of this topic one would perhaps like to assess every aspect of national patent law in the EU and the application of EU competition law, however, I do neither think that such an analysis is necessary, nor for me possible. The issue is to analyze EU competition law, relevant legislation and doctrine to the US antitrust law. The US doctrine of patent misuse is a rather large concept and in this thesis it will be limited to the *Walker Process* doctrine which highlights the interaction between patent law and antitrust law, and the *Noerr-Pennington* doctrine defining the exceptions of antitrust immunity in relation to vexatious litigation (‘sham’).

The economic analysis must be rather constrained, this being a paper in law, and the subject of pharmaceutical economics being a more difficult and complex subject than most other branches of economic theory. The thesis will focus on the general perceptions of health economics and the interaction with the patent systems as such and not so much go into detail with regard to different types of pharmaceuticals (as over the counter drugs and prescription drugs etc.), different insurance structures and state regulatory schemes. It is noted, however, that many things can be said as regards these economic features of the pharmaceutical industry and how they interact with prices, demand and innovation. The general effort will therefore aim to describe the fundamentals.

The concept of ‘sham’ litigation will be limited to litigation issues in relation to patents while it is noted that litigation could be used in many

ways by firms to deter and hamper competitors' possibilities to compete on the merits in the marketplace. While the same underlying thought should also apply for those situations, this thesis is limited to the situations where pharmaceutical firms, generic or originator, misuse their right to petition or enforce non-existing rights and/or use fraudulent behaviour in relation to obtaining patent protection from patent offices. A further limitation is that the majority or reasoning is limited to the pharmaceutical sector, but the principles should be similar in other markets. This choice of limitation is logical since a wider scope would need a wider market analysis, which would perhaps give too much attention to economic appraisals of complex facts and theories, in relation to the legal question to be assessed and analyzed. A second argument for limiting the scope to the pharmaceutical sector is that this is a very hot topic at this time, and given the latest developments (AZ litigation and the pharmaceutical sector inquiry) in the EU, the pharmaceutical sector is the most interesting area to do this type of research.

1.3.1 Article 102 TFEU

Since this paper is aimed at the specific abuses incorporated under patent misuse and sham, a full review of article 102 TFEU is superfluous. For more fully developed view of abuse of dominance, I would encourage people with limited knowledge in this area to study *The Law and Economics of Article 82 EC* by O'Donoghue and Padilla.⁵

1.3.2 The Concept of Patent Misuse

When discussing the concept of *patent misuse* it is appropriate to take stance in the most legally developed area concerning this concept. This is the US courts' development of the concept into a defined doctrine, i.e. the patent misuse doctrine. Today the patent misuse doctrine incorporates various improprieties committed by a patentee, making it a broader concept in terms of applicability in relation to what is necessary to prove antitrust liability.⁶ When patent misuse also incurs antitrust liability, that very specific and narrowly defined exception is referred to as the *Walker Process doctrine* and incorporates the affirmative defence of *Walker process fraud*. For example, to be able to find antitrust liability mere failure to disclose materials to the patent office is not enough, the more severe concept of fraud⁷ must be proven to make an antitrust counterclaim effective.

⁵ O'Donoghue, A., Padilla, J. 2006. *The Law and Economics of Article 82 EC*. Hart Publishing, Portland.

⁶ Areeda, P., Hovenkamp, H., 2004. *Antitrust Law – An analysis of antitrust principles and their application*. at 1781a.

⁷ In this regard 'fraud' refers to the notion of 'common law fraud' which has been known as *Walker Process fraud* since the Supreme Court's landmark decision in *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corporation*. 382 U.S. 172, 86 S.Ct. See also Areeda, P., Hovenkamp, H., 2004. *Antitrust Law – An analysis of antitrust principles and their application*. at 1781a, footnote 2.

Therefore, an honest mistake to disclose facts might violate the patent misuse doctrine, but not the antitrust laws, with the consequence that the patent will be unenforceable but not possible to attack with an antitrust damages claim.⁸

In this thesis, however, patent misuse will refer to only such use of patents, by a patentee, which misuses a patent in such a way as to also incur antitrust liability, i.e. *Walker Process fraud*. In addition to this situation, the situation where the patent or non-patent owner uses sham litigation to the detriment of a competitor, for instance, seeking declaratory judgment on the invalidity of a patent that the plaintiff know is a valid patent will be analyzed in connection to patent misuse, as well as the reverse situation where the patentee knows the patent is unenforceable but still tries to enforce it against its competitors.

This last notion of exclusionary and predatory abuse is not usually referred to under the patent misuse doctrine, but rather under the *Noerr-Pennington* doctrine where only lawsuits which are considered objectively baseless are liable to antitrust scrutiny.⁹ However, when looking at Europe and the Commission and Courts reasoning in decisions and case law it will be apparent that both the *Walker Process* and the *Noerr-Pennington* doctrines will come into play when analyzing possibly abusive behaviour by dominant firms in relation to patents. We therefore conclude that patent misuse, as an antitrust law violation, incorporates both the *Walker Process doctrine* and the *Noerr-Pennington doctrine*, while other types of misuses also might violate the patent misuse doctrine but not incur antitrust liability as such.¹⁰

⁸ *NobelPharma Inc. V. Implant Innovations Inc.* 141 F.3d 1059

⁹ See for instance Fed. Cir. Discussion in, *NobelPharma Inc. V. Implant Innovations Inc.* 141 F.3d 1059. at 1068, stating the situations which can remove the ‘shield’ of patent law and/or first amendment protection and exposes the patentee or litigant to the ‘sword’ of antitrust law.

¹⁰ This would typically be inequitable conduct and contributory infringements which is governed by patent law exclusively.

2 The Pharmaceutical Sector Analyzed

2.1 The Economics and other Characteristics

There are important differences when considering the pharmaceutical sector in Europe, as to other regulated sectors within the Internal market. This is mainly because the inherent problem of the social economy; policy makers need to create incentives for R&D for new medicines at the same time as society wants, and needs, *low-priced* high quality pharmaceuticals to treat its citizens from disease. The task for the policy maker is thus to optimize both innovative efforts to bring new products to the market while keeping costs for the society down. Innovation is typically promoted through the patent system by giving innovators limited monopoly power for their inventions and costs are kept down by price regulation.¹¹ Conceptually this is rather straight forward. By giving a legal monopoly, prices are likely to be high for the protected product, which induces innovation. However, this could severely affect the healthcare budget of the Member states if not properly (price) regulated, therefore price regulation is seen as essential to regulate costs and plan for future healthcare expenditures.¹²

The pharmaceutical industry consolidated considerably during the 1990's by mergers and acquisitions which led to the result that top selling drugs were concentrated to fewer and fewer firms.¹³ Recent trends also indicate that fewer and fewer blockbuster drugs are brought to the market indicating that the industry might see structural problems ahead.¹⁴ Even though this illustrates a rather dark picture of the pharmaceutical sector there seems to be a rather high degree of inter firm competition if looking to entry and exit statistics of innovative smaller firms.¹⁵

¹¹ It is noted that other types of protection than patents are available for pharmaceuticals such as data exclusivity protection.

¹² Price regulation usually consists of one of the following mechanisms, either, price cap regulation, where a maximum price is set; or, reference pricing, where price depends on competing prices. For a more extensive explanation see Danzon, Patricia – "Reference Pricing: Theory and Evidence", Wharton University.

¹³ Desogus, C. 2010. "*Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade*" p. 16.

¹⁴ Bernson, 2005. "Big Drug Makers See Sales Decline with Their Image", New York Times, November 14. See also Pharma sector inquiry para. 79 for the effect that originator firms do have issues filling the pipeline with new block busters.

¹⁵ Schweitzer, 1997. "Pharmaceutical Economics and Policy", p. 24.

2.1.1 Features of the Supply Side

There are three main phases where competition takes place within the pharmaceutical industry. First, there is competition in the upstream market of innovation, typically known as the innovation market. This type of competition is usually referred to as *dynamic competition*¹⁶ and is very complex. When finally a substance is cleared for market authorization that substance will lead to either a pure monopoly outcome or the substance will in some instances compete against another substance achieving similar therapeutic results. However, if two different substances are eligible to treat the same condition, they usually have different side effects and/or show different therapeutic efficiencies, making it possible to establish separate markets for two similar products.¹⁷ In any event, competition will be between originator firms and price will likely be substantially above the competitive equilibrium. This is not surprising since investments in R&D are sunk and there is a need to recoup all invested capital. On top of this, only one out of 10 000 substances synthesized will eventually enter the market making many R&D projects nothing but a loss to the firm.¹⁸ The last phase of competition is the post patent period, characterized by a higher degree of price competition stemming from generic firms entering the marketplace.

When patent protection expires the market opens up for generic competition. Since generic firms do not have the high costs involved with R&D the price for a generic product is substantially lower and price is in theory presumed to drop in the market place. In an economic model price would drop to the level where price equals marginal cost of production (competitive equilibrium price) since this would be the most efficient outcome. However, this is not what is empirically happening.¹⁹ Even though generic firms enter the market at a substantially lower price than the branded

¹⁶ Dynamic competition, as opposed to static competition, refers to firms' efforts in the competitive process of achieving new technologies or products. The model for classical antitrust analysis is based on static efficiencies, i.e. competition in the marketplace should lead to a pareto-optimal solution. When assessing innovation such an analysis is not feasible due to several reasons and therefore no formalistic model for achieving dynamic efficiency exists. To understand the problem of dynamic efficiency and Competition Law see Glader, M., 2004. "*Innovation Markets and Competition Analysis – EU competition Law and US Antitrust Law*".

¹⁷ In this regard the Commission's Notice on the definition of relevant market sets out the objective "[t]o identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behavior and of preventing them from behaving independently of effective competitive pressure" and "demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a particular product, in particular in relation to their pricing decisions".

¹⁸ Desogus, C. 2010. "*Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade*" p. 22.

¹⁹ Danzon, P.M., Chao, L.W. 2000, "Does Regulation drive out Competition in Pharmaceutical markets? p. 311 et seq.

product, originator firms still maintain positive market shares.²⁰ This is mainly thought of as the effect that price competition in pharmaceuticals is weak.²¹ However, it has also been argued that price regulation in the post-patent period in itself is hampering the competitive forces in the market.²² This evidence comes from empirical studies where, for instance, the US system of free pricing has been compared to highly regulated markets as found in some EU Member states such as France and Italy.²³ The results have shown that price drops more in unregulated markets.²⁴

Interesting in this regard is also that branded products not necessarily will decrease in price as generic firms enter the market as theory would predict. Instead empirical evidence show that originator products sometimes will increase in price as generic substitutes enter the market,²⁵ other research confirms the original theory by finding that price indeed does drop for originator products as generics enter.²⁶ The differences between these opposing outcomes are usually explained by analyzing business strategy among originator firms. When faced with generic competition the originator firm can adopt two main strategies. Either, the originator firm chooses to forgo the price sensitive market segments and instead put efforts to keep the 'brand loyalists' while increasing price or, the originator firm chooses to fight for the entire market by meeting generic price competition.²⁷ In any event total profits for originator firms decrease as generic firms enter the market even though originator firms in both situations have supra competitive prices in relation to the generic equivalents.²⁸ This last effect means that generic competition provides for a transfer of welfare from the originator firms to the generic competitors while society gains a fair share in that trade.

What sort of strategy the originator firm adopts will therefore depend on the future profits and the generic competitors will always fight for the entire

²⁰ Scherer, F.M. "The Pharmaceutical Industry"

²¹ Brekke, K.R., Holmås, T.H., Straume, O.R. 2007 "Regulation, generic competition and pharmaceutical prices: Theory and evidence from a natural experiment. p. 2.

²² Danzon, P.M., Chao, L.W. 2000, "Does Regulation drive out Competition in Pharmaceutical markets?"

²³ Ibid. p. 312.

²⁴ It should perhaps here also be noted that price in unregulated markets such as the US usually have a higher price to begin perhaps giving room for a substantially larger drop in prices.

²⁵ See, Grabowski, Henry G. and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act"; and, Frank, Richard G. and David S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals".

²⁶ Caves, Richard E., Michael D. Whinston, and Mark A. Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry"; and, Wiggins, Steven N. and Robert Maness, "Price Competition in Pharmaceutical Markets"., these findings relate to US pharmaceutical industry and the EU Commission's Pharmaceutical Sector inquiry suggest a relatively clear relation between price decrease and generic competition among originator products, see for instance chapter 1.3.2.1. Effects on Prices.

²⁷ Marco, A. 2005. "Patent protection, creative destruction, and generic entry in pharmaceuticals: Evidence from patent and pricing data". p. 2.

²⁸ Id. These findings are also in line with the findings of the Pharmaceutical sector inquiry, see for instance para. 166.

market by price competition. If then, the originator firm estimates that profits by engaging in price competition with the generic firms would give a lower return than adopting a strategy built on some sort of price discrimination, the later strategy would end up in a Nash equilibrium where price could be higher in the post-patent period. This reasoning indicates that public policy needs to create disincentives for such strategies since they are likely to adversely affect both healthcare expenditures and (follow on) innovation.

The type of price regulatory regime in the post-patent period is therefore of essential importance to minimize incentives for price discrimination strategies by originator firms as such. Here, the EU Member states have chosen to adopt different policies to enhance the penetration of generic substitutes in the post-patent period. In the UK, pharmaceuticals are prescribed by the non-proprietary name making the prescription indifferent to whether the patient gets an originator product or a generic equivalent substitute.²⁹ In Denmark and France pharmacists are allowed to dispense equivalent generic substitutes if the prescription does not expressly forbid substitution. Together with a budget kick-back system for pharmacies to create incentives to dispense cheaper products this has shown to increase generic market shares in especially Denmark.³⁰ In France generic market shares are relatively small possibly due to the fact that physicians are reluctant to allow for generic prescriptions and the lacking of an incentives mechanism for pharmacists to dispense cheaper generic equivalents which also reduces overall generic penetration.³¹

In essence, all Member states that have a coherent generic strategy also have substantially higher percentage of generic products traded in the market place.³² This indicates that generic penetration in the post-patent period of pharmaceuticals is much related to the Member states' policy programs and strategies to create incentives for generic market penetration after patent expiration. This gives the intuition that generic market penetration not necessarily is as strongly connected to patent expiry as to the price regulatory frameworks in the post patent period. However, for generic market participation to be possible, the exclusivity must have ended making expiry a prerequisite for competition but not necessarily meaning that inter firm competition will end up in a competitive equilibrium where consumers receives a fair share of that competition.

²⁹ Simons, S. 2010. "Creating sustainable European health-care systems through the increased use of generic medicines: A policy analysis", p. 132-133.

³⁰ Id., p. 136.

³¹ Ibid.

³² Simons, S. 2010. "Creating sustainable European health-care systems through the increased use of generic medicines: A policy analysis", p. 135. Indicating generic market shares in Denmark 68.8 %; UK 57.5 % as high, while most southern Member states and those not having a coherent generic strategy having low generic market shares, between France 16.0 % and Italy 7.2 %. Here Poland is the exception probably due to physicians relatively positive view of generic substitutes and a history of use of generics (the Soviet Union period). Data is provided from year 2006.

2.1.2 Features of the Demand side

In general, the problem with the pharmaceutical sector, as described above, can be linked to the presumption that price competition is weak between drugs. The reason for this is most probably that the demand is not driven in the same way as 'normal' demand, i.e. the consumer can evaluate the good and pay for it according to their optimal consumption level. Instead, demand depends on the interaction between consumers' demand for medical care, the choice of physician who prescribes the product and the pharmacist who sells it.³³ The consumer wants good care, but does not usually know what type of pharmaceutical is needed to be cured. The choice of physician therefore plays an important role in choosing the optimal drug, but the physician does not pay. This is why demand might not be optimal in relation to the patients constrained budget, i.e. the interests of the physician and the patient are not perfectly aligned since the physician might prefer to prescribe a more expensive drug. The Physician is therefore an imperfect agent for the patient since he makes the choice of product but does not pay the actual cost for it. Patients thus are put in a position where they have to trust the physician prescribing the drug. Not very surprising, pharmaceutical companies make major efforts to make their products the preferred choice for treating specific symptoms.

Health care is also to be considered a credence good³⁴, meaning that the patient cannot evaluate the healthcare it receives. The effect of co-payments and insurance schemes also offsets the optimal market outcome by subsidizing certain drugs. This could then be linked to inefficiencies as overconsumption and other negative effects for both patients and the society as whole.

Most regulatory systems does not demand that the patient pays for the product by him or herself, instead this is done via an insurance scheme that can be provided by the state or by private entities. Most systems, however, provides for some sort of co-payment scheme where the patient have to pay a certain part of the cost by own funds. Co-payments therefore serve to make demand more elastic, but since they usually are not very large in

³³ Danzon, P.M., Chao, L.W. 2000, "*Does Regulation drive out Competition in Pharmaceutical markets?*". p. 314.

³⁴ A credence good is characterized as a good which is difficult or impossible for the consumer to evaluate. Therefore the consumer cannot determine the utility level it received from consuming it making optimal consumption virtually impossible for the consumer to determine. Credence goods is also a probable explanation to why originator firms are able to raise prices and keep market shares after patent expiry since there is a direct connection between demand and price as to the usual inverse relationship between price and demand (when prices rise, demand drops).

comparison to the total cost, they only affect the demand only on the margin.³⁵

When it comes to off-patent drugs some countries allow the pharmacists to substitute a prescribed product if the prescription is generically written.³⁶ This has been proven to be an effective way to reduce costs if the regulatory scheme provides incentives for the pharmacist to actually sell the cheaper generic product. As described in previous sub heading, penetration of generics in for instance Denmark is relatively high while in France generics have only marginal market shares. Both countries allow the pharmacist to dispense cheaper generic products if the prescription does not explicitly forbid changing the specified product. However, in Denmark the pharmacists are given economic incentives to dispense the cheaper product while in France they are not.

It is therefore clear that generic substitution depends to a large extent on how each member state has chosen to set up their health care schemes.

2.2 The Legal Framework

To understand the pharmaceutical sector, it is appropriate to also consider the legislative efforts undergone by the EU institutions briefly. The very first initiative was taken as a consequence of the ‘Thalidomide disaster’, one of the biggest medical tragedies in modern time.³⁷ The underlying thought was to establish and maintain a high level of protection for public health within the Community by harmonizing the requirements to put medicinal products on the market.³⁸ The effort resulted in Directive 65/65/EEC which is still the backbone of pharmaceutical regulation in the EU. During the 70’s and 80’s a number of directives and regulations were issued with the aim to consolidate the Internal market within the pharmaceutical industry.³⁹

Originator firms rely on patents largely to protect and make possible the recoupment of the R&D investment. Usually patent protection is given for a period of 20 years from the filing date. Here the pharmaceutical sector differs from many other industries since the product cannot be placed on the

³⁵ For a more thorough analysis of co-payments and demand elasticity see, for instance, Winkelmann, R. 2003. *“Co-payments for prescription drugs and the demand for doctor visits – Evidence from a natural experiment”*.

³⁶ *Generically written* is here used as the chemical name of the active substance in the product, i.e. instead of writing “Losec” the physician writes the prescription for “Omeprazole” indicating that any product with the chemically equivalent ingredient can be sold by the pharmacist, increasing the probability of generic equivalent products to be sold.

³⁷ For more information regarding the adverse effects of this compound see http://news.bbc.co.uk/2/hi/uk_news/2031459.stm (accessed on the 10th of May 2010)

³⁸ Ingress to Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.

³⁹ See for instance, Directives 75/318/EEC and 75/319/EEC introducing mutual recognition by Member states with regard to their respective market authorization procedures.

market before it also has been fully tested for use on humans and given specific regulatory approvals.⁴⁰ If a new formula (molecule) is showing signs of having a desired therapeutic effect on some illness or other medicinal problem it therefore have to undergo substantial testing which is also often associated with high costs. This testing procedure can sometimes be very lengthy and, therefore, patent protection sometimes can be near the end when the product is finally cleared for the market. In the EU this situation is addressed by the SPC Regulation which gives the possibility to prolong patent protection for a maximum of five years.⁴¹

Management of national healthcare is so far the competence of the member states and not an issue to be regulated by the EU institutions. But, as the EU becomes more of a social union more competences will likely be within the scope of EU law. As will be shown in this thesis, this might be the greater concern than actual inter firm competition if the overall objective is a social welfare increase.

⁴⁰ See, for instance, Directive 2001/83/EC, as amended by Directive 2004/27/EC of the Parliament and the Council (the so called 'Human Use Directive')

⁴¹ Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.

3 EU Patent Law

3.1 Economic rational for patents

The pharmaceutical sector relies heavily on patent protection since the products are costly in both time and capital to bring to the market while imitation costs are very low. The pharmaceutical industry therefore is at the core of what patent protection is supposed to protect.⁴² Patent protection also gives other benefits to society than the incentive to innovate, it also demand that the patentee makes all necessary information regarding the patent available in the public domain increasing the knowledge available to society as a whole.⁴³

Patents are therefore the means by which policy makers guarantees that the market provide the society with new and better products. The difficult question for policy to solve is; what is optimal the scope⁴⁴ for protection? Economists have tried to find an optimal solution, but the underlying problems of different subject matters and different industry needs have made it rather impossible to identify a universal theory for the scope of patents.⁴⁵ On top of this, patent protection is subject to national law, possibly giving different interpretations in different jurisdictions. These peculiarities of the patent systems in Europe is one of the issues why a unified European patent system is necessary to ease the process of gaining

⁴² Pharama-report 251 et seq, see also EFPIA: Intellectual property and Pharmaceuticals, June 2008, pages 12 and 15.

⁴³ Pharma report para 255.

⁴⁴ 'Patent Scope' usually refers to patent length and patent breadth, where length is how long time the patent is valid for, and breadth is usually referred to as how much can be protected. Breadth creates practical difficulties due to that the standard to measure breadth is not universal. Time is the same everywhere and is therefore easier to solve a workable solution for. See Nordhaus. W., 1969. "Invention, Growth and Welfare", for the most known standard for optimal patent length.

⁴⁵ Many different papers have suggested different approaches to patent scope. Nordhaus is usually referred to in regard to the time dimension, but many have elaborated on breadth with very different conclusions. In this regard see, Klemperer, Paul. 1990 "How broad should the scope of a patent be?" for the view that patents should be broad if demand is inelastic and narrow if demand is elastic; Gilbert, R. Shapiro, C. 1990 "Optimal patent length and breadth" argued that patents should be narrow and of unlimited length if patent breadth is increasingly costly due to the dead weight loss; Gallini, N. 1992. "Patent policy and costly imitation" pointing out that narrow lengthy patents encourage competitors to invent around the patented subject matter, and that this is an inefficiency because those resources could be better spent inventing new technology, therefore patents should be short but rather broad so that the paten would protect the interest of society; Denicolò, V. 1996 "Patent races and optimal patent breadth and length" argues that the degree of competition in the market is the key and the less efficient the competition is the more likely it is that patent of maximum breadth are optimal.

patent protection and simplifying the different processes in regard to patent litigation.

The market where the pharmaceutical firms operate, like most other markets, is driven by scarcity, making products with high demand more expensive than less wanted products. A new drug could equal one core technology patent, or basic patent, which then perhaps is the only known cure for a certain disease. If the disease affects many people in the rich world, the patent is going to be enormously valuable, due to the high demand and high willingness to pay by individuals and welfare states. A firm that receives such a patent therefore has big incentives to prolong the exclusivity period as long as possible. The concern from the Commission is thus that this is done illegally, and therefore is a violation of the competition rules.

3.2 Regulatory framework for patents

There is no EU patent that can be obtained to cover the entire EU. When patenting a new subject matter within the EU there are three possibilities; (i) file one application for every member state, or; (ii) file one application with the EPO (European Patent Office), known as a European patent, or; use the Patent Cooperation Treaty where the applicant designates one patent office as receiving office (RO) which then transmits the application to the other designated states (the EPO can be the RO). However, in the latter two cases the patent still have to be validated by every national patent office. The above procedures result in a cluster of national patents that are issued by the patent offices in every specific Member state. Since there is no EU patent, all national patents must be enforced through proceedings in national courts, making patent litigation both complex and costly.

The EPC (European Patent Convention) contains the substantive elements on when a patent will issue in the EU. Article 52(1) set out the conditions that a new invention have to fulfil to be patentable. A patent will be granted if the invention is (i) novel⁴⁶; (ii) contains an inventive step⁴⁷; (iii) is susceptible for industrial application⁴⁸. To fulfil the novelty requirement an invention must differentiate from 'prior art', that is, if the invention has been made available to the public previously it is not novel and can thus not be patented. The concept of prior art is therefore enormous since it incorporates more or less everything that is known. It is therefore not extremely rare that prior art can be found after a patent have been issued and that a court therefore determines that the patent is invalid, or unenforceable, due to previous art. When deciding on whether the patent application

⁴⁶ EPC Article 54

⁴⁷ EPC Article 56

⁴⁸ EPC Article 57. See also, to this effect, Article 27 of the TRIPS Agreement.

contains an inventive step the examiner must first decide on what the closest prior art is. Then, the objective technical problem to be solved by the claimed invention is compared to the prior art, and the examiner establishes if the claimed invention is non-obvious for a person skilled in the art to figure out in light of the prior art and the objective technical problem.⁴⁹

3.3 EU instruments

As previously stated, there is no common European patent that can be enforced through the European judiciary. This does, however, not mean that it will always be as it is now. Both the Commission and the Council have made efforts to promote a European patent system with a common European patent court and a common enforceable substantive European patent right.⁵⁰ The current regulatory framework more or less consist of the Brussels I Regulation⁵¹ and the IP Enforcement Directive⁵² which lacks the tools of cross-border injunctions and induces delay strategies and *Italian torpedo* processes. The substantive problems creates additional, and unnecessary, costs of enforcement by duplicating litigation in multiple jurisdictions, creating divergent outcomes without the possibility for consolidation, and creating disincentives to consolidate differences through settlements by making litigation strategies and forum shopping a profitable exercise.⁵³

If an inventor files a patent with the EPO, designating the entire EU for protection, and that patent is approved by the EPO examiner on all the substantive parts, that patent will issue as 27 different national patents (given that no national patent office has any objections). If then, after the patent have issued, litigation is necessary to enforce it against an alleged infringer there is a rather big chance that some jurisdictions might find in

⁴⁹ Pharma report para 263. In this regard it is often a conceptualized difficulty to understand what claims contain an inventive step. Sometimes the solution to a specific problem is so simple that after seeing the invention and reading the claims any person should be able to understand that the invention was obvious. However, if no one recognized the problem and found a solution to it, it is not possible to argue that it was obvious. Simple inventions are sometimes the best patents!

⁵⁰ Proposal for a Council Regulation on the Community patent, COM(2000) 0412 final (OJ C 337, 28.11.2000); Proposal for a Council Decision establishing the Community Patent Court and concerning appeals before the Court of First Instance, COM(2003) 0828 final; Proposal for a Council Decision conferring jurisdiction on the Court of Justice in disputes relating to the Community patent, COM(2003) 0827 final; Proposal for a Council Regulation on the Community Patent (Working document of 30 October 2009 (15149/09) of the Council of the European Union) with references; Draft Agreement on the European and Community (EU) Patents Court and Draft Statute, Working Document (7928/09) of 23 March 2009 from the Council of the European Union.

⁵¹ Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I Regulation), (2001) OJ L 12/1.

⁵² Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (Enforcement Directive), (2004) OJ L 157/16.

⁵³ See Promoting innovation through patents - Green Paper on the Community patent and the patent system in Europe, COM (1997) 314 final.

favour of an infringement, some might find that the infringed claim is unenforceable due some particularity, and some might not even find an infringement at all. This is due to Article 22(4) of the Brussels I Regulation gives exclusive jurisdiction to the courts of the member state where the patent is registered.⁵⁴ Even a situation where a firm is initiating proceedings against alleged infringers of the same corporate group making the same infringement in different jurisdictions the national court of the first proceedings must decline to rule on whether the other national patents have been infringed.⁵⁵ The Court has even held that a situation where two German companies litigate over an alleged infringement of one of the companies' French patents in a German court, that German court must decline jurisdiction as soon as one party invokes an argument of patent invalidity during the proceedings.⁵⁶ This ruling by the Court has been heavily criticised by scholars and even been suggested to rule against previous case law.⁵⁷

⁵⁴ Article 22(4) reads; "in proceedings concerned with the registration or validity of patents, trade marks, designs, or other similar rights required to be deposited or registered, the courts of the Member State in which the deposit or registration has been applied for, has taken place or is under the terms of a Community instrument or an international convention deemed to have taken place. Without prejudice to the jurisdiction of the European Patent Office under the Convention on the Grant of European Patents, signed at Munich on 5 October 1973, the courts of each Member State shall have exclusive jurisdiction, regardless of domicile, in proceedings concerned with the registration or validity of any European patent granted for that State."

⁵⁵ See case C-539/03 *Roche v. Primus* ECR I-6535 [2006].

⁵⁶ Case C-4/03 *Gesellschaft für Antriebstechnik mbH & Co. KG v. Lamellen und Kupplungsbau Beteiligungs KG*. ECR I-06509 [2006]

⁵⁷ Briggs, A., 2006. "Jurisdiction over defences and connected claims" *Lloyd's Maritime & Commercial Law Quarterly* (L.M.C.L.Q. 2006, 4(Nov), 447-452)

4 The Commission's efforts to enhance competition

4.1 Commission's enforcement priorities in general

With the launch of the Pharmaceutical Sector Inquiry in early 2008 the Commission openly suggested that competition within the sector was not functioning optimal.⁵⁸ Special attention was devoted to the alleged obstacles of market entry for generic medicines by analyzing market behaviour of both generic and originator firms.⁵⁹ The Sector Inquiry highlights that the industry is in the process of consolidating itself, i.e. either firms are merging or they grow by acquisitions, resulting in a more dense market structure where competition could be hampered to the detriment of innovation and output if not the Commission monitors and assesses the market continuously.⁶⁰ The report also highlights, even if it is not at the core of the inquiry, that there are flaws in the regulatory system that must be addressed. However, the Commission still makes it perfectly clear that certain practices by originator companies within the regulatory procedures can constitute competition law violations according to articles 101 and 102 TFEU.⁶¹ In practice this view is expressed through the *AstraZeneca* decision's both alleged abuses that both relate to some regulatory mechanism which AZ by its own will used to deter or postpone generic entry in the market for Omeprazole.

4.2 The AstraZeneca decision

In 1999, the Commission received a complaint from two generic companies alleging that AZ was abusing its dominant position in several national markets within the EEA by preventing generic firms to bring their equivalent generic products based on omeprazole to the market. AZ was said to be involved with two types of abuses, both relating to AZ's business strategy within two separate regulatory frameworks.⁶² The first, which is relevant for this thesis, consisted of AZ's alleged deceptive conduct and fraud on several national patent offices to gain SPCs for its patents relating to the product Losec, i.e. abusing the patent law framework to delay generic

⁵⁸ European Commission IP/08/49. 2008.

⁵⁹ European Commission - Pharmaceutical Sector Inquiry: Final Report. 2009. para. 3.

⁶⁰ European Commission - Executive Summary Pharmaceutical Inquiry. 2009. p. 17 et. seq.

⁶¹ Ibid. p. 19

⁶² Commission Decision COMP/A. 37.507/F3 - AstraZeneca, relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, 2005 para. 1-4.

entry. The second abuse, not relevant here, allege misuse of the regulatory procedures under EU law and national law in relation to the market authorization procedure to place generic products on the market, i.e. switching customers from one product to another and then withdrawing market authorization for the former making generic authorization more costly and difficult.⁶³

4.2.1 The SPC Abuse

In 1992, the Council issued Regulation 1768/92⁶⁴ ('SPC Regulation') making it possible for patent holders to extend the length of patent protection for certain medicinal patents to up to five years. In 1993 and 1994, AZ applied to several national patent offices for SPCs for the active substance patents for omeprazole⁶⁵, the active ingredient in Losec. The Commission contends that AZ made misleading representations of facts to the patent offices to receive SPCs for a longer period than they were entitled to.⁶⁶ Since omeprazole was already a patented formula when the SPC Regulation entered into force the transitional rules found in Article 19 of that regulation applied instead of the main rule found in Article 7 which demanded that the application for a SPC had to be made with the national patent offices within six month from the date of market authorization. To balance the needs of the pharmaceutical industry on the one hand, and that of public health policy on the other, each member state therefore struck a balance between the need to protect innovation and the need to ensure financial stability within the national health systems.⁶⁷ This resulted in different dates for obtaining SPC protection in different member states according to article 19 of the SPC Regulation. The general rule became that if market authorization was first approved within the Community after 1 January 1985 the patent was eligible for SPC protection. Two derogations to this rule established that (i) in Germany and Denmark 1 January 1985 was to be replaced by 1 January 1988; (ii) in Belgium, Italy and Austria 1 January 1985 was to be replaced by 1 January 1982.⁶⁸ This had the effect that if a product originated from a basic patent that got market authorisation before 1 January 1988, SPC protection would not be possible in Germany and Denmark.

⁶³ Ibid. para. 5-7.

⁶⁴ Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.

⁶⁵ It is here noted that the Commission also considers AZ's patent strategy in relation to two other substance patents (omeprazole-sodium and felodipine) as abusive and exclusionary, however, it will suffice to show the strategy in relation to omeprazole since the strategy for the other two substances will follow by analogy to the abuse considered under AZ's strategy for omeprazole. See for instance para. 633-635 of the AZ Decision.

⁶⁶ Commission Decision COMP/A. 37.507/F3 - AstraZeneca, relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, 2005 para. 144.

⁶⁷ C-127/00 *Hässle AB v Ratiopharm GmbH* para. 35 et seq

⁶⁸ Commission Decision COMP/A. 37.507/F3 - AstraZeneca, relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, 2005 para. 157 et seq.

As evidence for AZ's deceptive conduct the Commission relied on several internal memorandums within the AZ organization. In essence these memorandums show that AZ's patent department, responsible for obtaining the SPCs, were pushing the product companies⁶⁹ to sign documents which would indicate that market authorization was first approved later than 1 January 1988 in the EU, giving omeprazole SPC protection in Denmark and Germany as well, even though the first memorandums clearly stated 'France April 1987' as first market authorization in the EC.⁷⁰ The Commission contends that AZ was first working on the assumption that '*first authorization to place on the market*', as Article 19 in the SPC Regulation states, referred to the technical market authorization, i.e. obtaining the approval with regard to product safety to place the product on the market according to Directive 65/65/EEC. However, since this made it impossible for AZ to obtain protection in Germany and Denmark AZ instead adopted a new interpretation of the wording in Article 19 of the SPC Regulation, where AZ understood '*first authorization to place on the market*' as the date where it actually could be sold, i.e. the date where the Member state also approved the price, which is the second regulatory prerequisite to be able to start placing the product on the market *de facto*.⁷¹ This interpretation of AZ's behaviour, the Commission contends, is the evidence needed to establish that AZ knew it did not have the right to obtain SPCs in Denmark and Germany. It therefore had to resort to fraud on the national patent offices to obtain SPC protection for the entire EU.

The Commission works under the assumption that every decision a dominant firm takes that affects competition in a presumably negative manner is illegal according to article 102 TFEU, given that the firm has the intention to restrict competition. This has effects on the general application of competition law as will be seen in chapters 5 and 7.

4.3 Vexatious Litigation

There has only been one case involving vexatious, or sham, litigation in the EU courts. This case, *ITT Promedia*, is interesting since it gives guidance on what the Commission considers to be factors relating to finding an abuse of dominant position within the meaning of article 102 TFEU.

⁶⁹ In this regard it must be noted that the patents at issue were not registered to AZ as such but to several wholly owned subsidiaries to AZ, where Hässle AB is one of these entities. Therefore the AZ patent department had to get sign documents from these entities stating the information needed to complete a SPC application, especially the date of first market authorization.

⁷⁰ Commission Decision COMP/A. 37.507/F3 - AstraZeneca, relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, 2005 para. 163-174

⁷¹ The Commission also identifies that AZ uses a third date which relates to the publishing date of the national approval in a public official journal or gazette. See recitals 646 and 246 et seq of the Commission Decision.

4.3.1 The ITT Promedia case

ITT Promedia concerns the annulment of a Commission decision rejecting complaints alleging the existence of behaviour of a dominant firm contrary to the rules on competition. The applicant, Promedia, alleged that the incumbent firm, Belgacom, had initiated vexatious litigation to hamper competitors' abilities to compete with it.

Access to justice is a fundamental right common to most member states and enshrined in articles 6 and 13 of the ECHR, which is also part of the general principles of EU law.⁷² It is therefore an obvious problem to characterize legal proceedings as abusive using traditional EU competition law criteria since it can only be in very limited circumstances that litigation amounts to an abuse.

When the Commission initiated the inquiry, it formulated a two-part test to find abuse in connection to the initiation of legal proceedings. First, it is necessary that the action; (i) cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and can therefore only serve to harass the opposite party and; (ii) it is conceived in the framework of a plan whose goal is to eliminate competition.⁷³ The applicants challenged the Commission's application of these criteria but failed to challenge the compatibility of such criteria with the competition rules. The result was that the General Court refrained from addressing the issue of compatibility directly, instead it confirmed the Commission's application of the criteria, giving an indirect approval of the proposed test. In any event, a test that potentially infers liability on the initiation of legal proceedings must be construed strictly so that the general principle of access to courts is not threatened.⁷⁴ The General Court therefore found that none of the pleas in support of annulment of the Commission decision could fulfil the first criterion of the test.

4.4 The Pharmaceutical Sector Inquiry

The Sector inquiry was launched in 2008 as the Commission received indications that competition was not working optimal in the industry. A major concern from the Commission's view was that originator firms deliberately created artificial barriers to entry for generic products by misusing patent rights and resorting to vexatious litigation strategies. The *AstraZeneca* decision is an example on misuse of the patent system and *ITT*

⁷² See also article 47 Charter of Fundamental Rights. See also cases Case C-432/05 *Unibet* [2007] ECR I-2271, paragraph 37, and Joined Cases C-402/05 P and C-415/05 P *Kadi and Al Barakaat International Foundation v Council and Commission* [2008] ECR I-0000, paragraph 335

⁷³ Case T-111/96 *ITT Promedia NV v Commission*. [1998] para. 55.

⁷⁴ *Id.*, para 61.

Promedia reveals the Commission's and Court's views of abusing a legal proceeding to hinder effective competition.

In its final report, the Commission observes that court proceedings are an effective barrier to entry where originator firms might block or deter entry by generic firms at the end of the patent protection.⁷⁵ However, bringing a legal action before a court is a fundamental right and a general principle of law as protected by both the European Convention of Human Rights and the Charter. The Sector Inquiry concludes that a majority of cases brought by originator firms to court either is won by generic firms, or is settled in what the Commission observes as favourable outcomes to the generic firms. Therefore, the Commission indicates that originator firms might not be using litigation to protect legitimate interests, but rather using litigation to delay and deter generic firms that wish to enter the market.

⁷⁵ Pharma report chapter 3.2.2

5 EU Competition Law

This section will be devoted to give a brief general explanation of the EU competition law as interpreted by the EU judiciary, and a more extensive analysis of the limited material concerned with the fraud and sham inquiries in competition law cases.

5.1 Article 102 TFEU liability

To incur Article 102 liability an undertaking has to have a dominant position in the relevant market. This has been defined as “a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained in the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of consumers”.⁷⁶ In this regard the most central inquiry is the finding of facts to establish the relevant geographical market, the relevant product market and the particularities of the market structure as such, i.e. the concerns about the functioning of competition in the market. After dominance has been established the analysis shifts towards the inquiry into the alleged abusive behavior of the undertaking. The Court has held that the concept of an ‘abuse’, for the purpose of Article 102 TFEU, is an objective concept referring to the behavior of an undertaking in a dominant position which is such as to influence the structure of a market on which, as a result of the very presence of the undertaking in question, the degree of competition is already weakened and which, through recourse to methods different from those conditioning 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.⁷⁷ This was then extended in the *Michelin I* judgment to actually limit the exercise of competitive strategies for dominant firms. The Court held, “[i]t follows from the nature of the obligations imposed by Article [102 of the TFEU] that, in specific circumstances, undertakings in a dominant position may be deprived of the right to adopt a course of conduct or take measures which are not in themselves abuses and which would even be unobjectionable if adopted or taken by non-dominant undertakings”.⁷⁸ Abuse is in EU competition law referred to as an objective concept meaning that a subjective criterion as intent is mainly irrelevant to establish an abuse, even though it can be of importance in some situations.⁷⁹

⁷⁶ Case 27-76 R. *United Brands Company and United Brands Continentaal BV v Commission*. para. 65.

⁷⁷ Case 85/76. *Hoffmann-La Roche & Co. AG v Commission*. para. 91.

⁷⁸ Case 322/81. *NV Nederlandsche Banden Industrie Michelin v Commission*. para. 57.

⁷⁹ See, Case 85/76. *Hoffmann-La Roche & Co. AG v Commission*. para. 91. Case T-228/97 *Irish Sugar plc v Commission*. [1999] para 111. (upheld under appeal in case Case C-

The behavior of dominant firms is thus limited after that the undertaking has been found to have market power. Interesting is that this can also be extended to behavior which lies outside the relevant market under scrutiny.⁸⁰

5.1.1 Objective concept of an abuse

A key point made by the EU Courts is that an abuse is an objective concept. This implies that subjective criteria are irrelevant in most cases and that dominant firms must tread easily when competing, and not act in such a way that competition might be hampered. Dominant undertakings are therefore stripped from engaging in certain business practices otherwise allowed in the market place. Even though the dominant undertaking has no intention to exclude or weaken competition its actions can still be abusive if they are likely to hamper the competitive environment.⁸¹ To claim that an abuse is *always* an objective concept in EU competition law is however not the entire truth. In predatory pricing cases the Court has held that pricing between ATC and AVC is only abusive if it is part of a plan to hamper competition or eliminate competitors.⁸² At the core of this inquiry the Commission must establish that the reason for a pricing strategy below ATC is the subjective intention of eliminating competition. Similarly in refusal to deal cases the Court and Commission has held that refusal to supply a competitor or customer as a strategy to exclude or discipline that undertaking is illegal in contrast to the situation where the dominant undertaking has a legitimate business interest in terminating a supply contract or declining to enter into such business relations.⁸³ Consequently, the concept of an abuse, although an objective concept, may need an inquiry into the subjective motives of the alleged abusive conduct to actually find that conduct *de facto* abusive.

5.1.2 Special responsibility not to impair competition

From the ‘objective concept of an abuse’ the Court have derived the notion of a special responsibility on behalf of the dominant undertaking not to impair, by measures falling outside the scope of competition on the

497/99) [2001]. In, for instance, *AKZO* the Commission and Court held that if pricing was between ATC and AVC the intent of such pricing strategy was relevant to establish if the pricing scheme amounted to an abuse (predatory pricing).

Case C-62/86 *AKZO Chemie v. Commission* [1991] para 69.

⁸⁰Joined Cases C-395/96 P and C-396/96 P, *Compagnie Maritime belge and others v. Commission*. para. 82-88.

⁸¹ Jones, A., Sufrin B. 2004. *EC Competition Law* (Second ed.). p. 280.

⁸² Case C-62/86 *AKZO Chemie v. Commission* [1991] para 63 et seq.

⁸³ See Case 27-76 R. *United Brands Company and United Brands Continentaal BV v Commission*; Commission Decision of 29 July 1987 relating to a proceeding under Article 86 of the EEC Treaty (IV/32.279 - BBI/Boosey & Hawkes) para 19 et seq.

merits, genuine undistorted competition on the internal market.⁸⁴ This implies that as long as the dominant undertaking operates within the boundaries of competition on the merits its behavior might not be abusive. However, it can very well be abusive if the result is that the dominant undertaking strengthens its dominant position on the market, then competition as a whole is diminished and the actions taken by the dominant undertaking illegal.⁸⁵ This is drawn from previous articles 2 and 3(1)(g) EC⁸⁶ which set out that the functioning of competition was an overarching goal.⁸⁷ Dominant undertakings is thus deprived the ability to compete fiercely to gain more market shares. However, they are allowed to protect their legitimate business interests.⁸⁸ Under normal circumstances this has the effect that the undertaking can compete modestly so that their dominance is not strengthened but neither diminished.

5.1.3 Objective justifications

To give firms a possibility to exempt some behavior under article 102 TFEU the Commission and Court has allowed for ‘objective justifications’ as an affirmative defense by a dominant firm.⁸⁹ This opens up for some flexibility in the application of the otherwise very strict rules applicable to dominant undertakings. It is however argued that this flexibility is rather weak in comparison to the potential discussed in contemporary academia.⁹⁰ Conceptually it is tempting to use objective justifications to balance between commercial interests and/or interest for society, but the Court has been reluctant to understand the concept in such a way. Instead the Court understands it as either (i) considerations built on purely objective factors beyond the control of the dominant firm that make competition for competitors more difficult, or (ii) public policy considerations as, for example, those connected to article 106 TFEU and Services of General Economic Interests.⁹¹ An undertaking with an efficiency defense is thus not likely to win a case on the merits in an EU court if not the concept of an abuse as such will change. The objective tests emphasized by the Court

⁸⁴ Case 322/81. *NV Nederlandsche Banden Industrie Michelin v Commission*. para 57.

Case T-83/91 *Tetra Pak International SA v Commission* [1994] para 114.

⁸⁵ *Ibid.*

⁸⁶ “...a system ensuring that competition in the internal market is not distorted.”

⁸⁷ While article 3(1)(g) EC is removed from the new Treaties, the wording is preserved in protocol 27 annexed to the treaties and has the same status as the treaties themselves.

⁸⁸ Case T-65/89 *BPB Industries and British Gypsum v Commission* [1993] para 69; Case 27-76 R. *United Brands Company and United Brands Continentaal BV v Commission*.

⁸⁹ See judgments Case 27-76 R. *United Brands Company and United Brands Continentaal BV v Commission*; Case T-30/89 *Hilti AG v. Commission* [1991]; Case 311/84 *Centre Belge d’Etudes du Marché-Télémarketing (CBEM) v CLT SA* [1985]. For the Commission’s more recent analysis 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.

⁹⁰ See, for instance, Rousseva, E. 2006. “*The Concept of ‘Objective Justification’ of an Abuse of a Dominant Position: Can it help to Modernise the Analysis under Article 82 EC?*”.

⁹¹ *Ibid.*

under current EU competition law are ill equipped to incorporate tests for efficiency, meeting of competition and ‘necessity’.

However, the Commission seems to be more prone to effect-based inquiries and is currently promoting certain efficiency defenses and necessity defenses in its latest guidance notice on the application of previous article 82 EC.⁹² For instance, the Commission will analyze claims put forward by a dominant undertaking that its conduct is justified due to that the conduct is necessary or that it produces efficiencies that outweigh any anticompetitive effects on consumers. This is however an inquiry that the Court is reluctant to review because it is a factual inquiry into complex economic facts, and the Court will therefore limit its review to whether the Commission in its investigation has committed any ‘manifest errors of assessment’.⁹³ The Commission therefore has a wide discretion of assessment, but, is still constrained by the previous case law of the Court. The Commission is therefore bound to only base its efficiency and necessity arguments on objective considerations which are outside the control of the dominant firm.⁹⁴

5.1.4 Exclusionary and exploitative abuses

Article 102 TFEU prohibits both exclusionary and exploitative practices. Exclusionary practices are those that, for instance, are referred to in *Hoffmann La-Roche* where the dominant firm seeks to use its market power to influence the structure of the market by excluding competitors and thereby weakening competition as such. This can be done in numerous ways, for instance, it can be that the dominant firm raises the costs for its competitors, refuses to deal with them or denying them access to essential facilities.⁹⁵ Exploitative abuses are typically aimed directly at the customer or consumer by inferring unreasonable terms and conditions or excessive prices for the products or services. It follows that an exclusionary strategy, if successful, not unlikely will be followed by an exploitative one to reap the benefits of the weakening of the competitive market structure.

It is here US Section 2 liability and abuse of dominance in EU competition law clearly differs. While Section 2 does not generally prohibit exploitation it does prohibit exclusionary strategies which are not based on meritorious competition.

⁹² 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.

⁹³ See, for instance, Case T-111/96 *ITT Promedia NV v Commission*. [1998]

⁹⁴ See, Communication from the Commission on the application of article 82 EC. para. 28 et. seq.

⁹⁵ Goyder, D.G. 2003. *EC Competition Law* (fourth ed.). p. 283.

5.2 The specific conducts

When it comes to abuse of dominance in the specific situations considered in this thesis, sham litigation and fraud on governmental institutions, little case law can generally be found. I will in this subsection give a summary of the present state of EU law in the relevant areas.

5.2.1 Vexatious litigation and sham the *ITT Promedia* case

When considering vexatious litigation there is the case of *ITT Promedia*⁹⁶ in which the Commission invented a two part test which has to be fulfilled for an undertaking to incur antitrust liability in relation to sham litigation. The test considers that for abuse of dominance to be found it is necessary that the action; (i) cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and can therefore only serve to harass the opposite party and; (ii) it is conceived in the framework of a plan whose goal is to eliminate competition.⁹⁷ The action must therefore be objectively and manifestly unfounded at the time when the action was brought. It is thus immaterial whether the rights which the undertaking concerned was asserting at the time when the action was brought actually existed.⁹⁸ It is rather an inquiry into what that undertaking reasonably could consider to be its rights at the time when it initiated the proceeding.⁹⁹

The test is rightly very strict since access to court is a general principle of law, protected by both the constitutions of the Member states, articles 6 and 13 of the European Convention of Human Rights, and also article 47 of the Charter of Fundamental Rights, now an integral part of EU primary law.

In *Compagnie Maritime Belge* the Court failed to directly answer the question whether mere incitement or inducement of government action could be regarded as an abuse of dominance.¹⁰⁰ In that case the issue to be solved by the Court was whether the enforcement of an exclusive right under an agreement with a government (government of Zaire) could constitute an abuse if that right had the effect of excluding the only potential competition. Since there is a distinct difference between inducing government action and demanding compliance with provisions under an agreement the Court merely held “[i]t is therefore unnecessary to consider whether, and in what circumstances, mere incitement of a government to take action may constitute abuse within the meaning of Article [102 TFEU]”, perhaps indicating that there could be situations where inducement

⁹⁶ Case T-111/96 *ITT Promedia NV v Commission*. [1998]

⁹⁷ *Id.*, para. 55

⁹⁸ *Id.*, para. 72-73

⁹⁹ *Ibid.*

¹⁰⁰ Joined Cases C-395/96 P and C-396/96 P, *Compagnie Maritime belge and others v. Commission*. para. 83.

could be found to give rise to antitrust liability.¹⁰¹ This is, however, indeed speculative.

The situation where inducement of government action could add up to a potential abuse of dominance is thus at this stage even more hypothetical than the situation where a court action is brought in bad faith. However, there are similarities between the situations, and the right to petition for government action¹⁰² is protected under EU primary law, indicating that a similar strict test should be applied in a situation of government inducement as in a situation of access to a court.

5.2.2 Fraud on governmental institutions the *AstraZeneca* case

The *AstraZeneca* judgment from the General Court is at this time the latest development in EU competition law. The General Court essentially upholds the Commission's decision only pointing out that the start of the abuse, as described by the Commission, was incorrect for some member states. The Commission contended that the abuse started when AZ instructed its patent attorneys to file the SPC applications with the different national patent offices. However, the General Court points out that the start of the abuse cannot be before the actual misrepresentation took place, i.e. when the patent attorneys actually filed the applications with the patent offices.¹⁰³ This is logical since not even a potential negative effect could be appreciated on competition if the market would not know about AZ intentions, which only became clear after the actual misrepresentations.

This minor deficiency in the Commission's analysis did only amount to a slight reduction in fines. More interesting is what the General Court deemed necessary for the Commission to show to make a case. The General Court confirmed the Commission's decision, but it did not follow the Commission's reasoning as to the finding of an abuse of dominance. The General Court consequently rejected all of AZ's arguments and theories on how competition law should be applied in situations where a dominant firm is found to have made misrepresentations of facts to national patent offices.

¹⁰¹ Ibid., See for more discussion, Czapracka, K. 2009. Intellectual Property and the Limits of Antitrust: A Comparative Study of US and EU approaches.

¹⁰² In the EU the right to petition the European Parliament could be considered to be equal to the right to petition a government of a Member state. All member states do not protect this right in their constitutions but EU law enshrines this right in article 44 of the Charter of Fundamental Rights, now an integral part of EU primary law.

¹⁰³ Case T-321/05 *AstraZeneca v Commission* [2010] para. 369-373

5.2.2.1 AstraZeneca's arguments

As a general defense AZ is promoting its own interpretation of the factual situation and using strong parallels in law to similar case law from the US federal court and Supreme Court.

First AZ argues that the mere intention to fraudulently obtain a patent or an SPC, nor an application for the same, which cannot be immediately enforced, is to be considered as an abuse of dominant position. Since abuse is an objective concept, AZ's intention is irrelevant since it must be established that there is an actual or potential effect on competition. 'Subjective intention' to commit an abuse and evidence of conduct preparatory to an abuse, conduct which is not in itself capable of restricting competition, are not sufficient to find an abuse of dominant position.¹⁰⁴ As a second argument AZ maintain that abuse of dominance can only be found if the dominant undertaking has acquired a patent or SPC with willful fraud and then actively enforces that right.¹⁰⁵ As a alternative theory, AZ argues that the acquisition of a patent or SPC must be capable of influencing the behavior of competitors and that clear and convincing evidence of intentional fraud on the patent offices must be proven; mere negligence or inconsistency on the part of the applicant is not sufficient.¹⁰⁶

In any event, AZ argues that any misrepresentations or fraud on the patent offices should be remedied by patent law and not competition law, and only where patent law does not give any remedy for a specific conduct a competition law claim could reasonably succeed.

5.2.2.2 Arguments by the Commission

The Commission's main reasoning consists of arguments that relate to AZ's intention to hinder effective competition. It maintains that when intent to harm competition is proved, that proof of intention to limit competition is also capable to produce such anticompetitive effects, i.e. establishing the intent and the effect is one and the same.¹⁰⁷ Since AZ argues that the mere intention is not enough to prove a breach of article 102 TFEU, the Commission also holds that it has proven that the specific behavior of AZ (the misrepresentations to the national patent offices) is liable to exclude competitors.¹⁰⁸ It is immaterial to the case if the conduct has been implemented or is likely to actually restrict competition since the core of the Commission's decision is the linear conduct by AZ from the start when it instructed its patent agents, to the unlawfully obtained SPCs in several member states.¹⁰⁹ It also infers, referring to case *Tetra Pak I* and *ITT Promedia*, that the acquisition of an exclusive right in some circumstances can be abusive for an undertaking in a dominant position. It should neither

¹⁰⁴ Id., at 309.

¹⁰⁵ Id., at 312.

¹⁰⁶ Id., at 314.

¹⁰⁷ Case T-321/05 *AstraZeneca v Commission* para 334,

¹⁰⁸ Ibid., see to that effect *Michelin I* and the objective concept of an abuse.

¹⁰⁹ Id., para 336.

be a prerequisite that an exclusive right obtained by misrepresentations or fraud has to be enforced to constitute an abuse of dominance as AZ claims.¹¹⁰

Interesting enough is that the Commission meets AZ's arguments relating to US law and tries to rectify its decision in the light of principles of both the *Noerr-Pennington* doctrine and *Walker Process*.¹¹¹ It argues, contrary to AZ's view, that the SPC Regulation did not provide any remedies which were effective against the type of behavior used by AZ. Therefore, the framework would not be shielded against antitrust immunity in either the US or EU. A patent procured by misrepresentations can also constitute an abuse in the US, however, what exact case the Commission refers to is not mentioned in the judgment.¹¹²

5.2.2.3 Reasoning by the General Court

The General Court first establishes, in line with the *Hoffmann La-Roche* and *Michelin I* reasoning, that dominant undertakings have a special responsibility as to their behaviour in the market place and are therefore deprived of resorting to certain conduct that would otherwise be impossible to object if the undertaking would not be dominant.¹¹³ Since 'abuse' is an objective concept, the General Court concludes that intent and proof of the deliberate nature of the conduct and of the bad faith of the undertaking in a dominant position is thus not required for the purposes of identifying an abuse of a dominant position.¹¹⁴

Consequently, the General Court rejects all of AZ's arguments and theories on how competition law should be applied in situations where a dominant undertaking is found to have made misrepresentations of facts to national patent offices, but also in a way rejects the Commission's reasoning on 'subjective intention' as unnecessary. However, the General Court recognizes that subjective motives can be an element of assessment to conclude the bigger picture even though the abuse as such is based on objective factors.¹¹⁵

Misleading representations has to be assessed *in concreto* and that assessment is to be subject to a rule of reason assessment which, in particular, must examine whether the alleged illegal practice was such as to lead public authorities to create regulatory obstacles to competition.¹¹⁶ The assessment should consider whether the public authorities was limited in their discretion to act or if the public authority lacked any obligation to

¹¹⁰ Id., para 350.

¹¹¹ Id., para 339 et. seq.

¹¹² Id., para 340.

¹¹³ Id., para. 355.

¹¹⁴ Id., para. 356.

¹¹⁵ Id., para 359.

¹¹⁶ Id., para 357.

verify the accuracy of the information provided by the dominant undertaking.¹¹⁷

AZ's argument that the exclusive right has to be enforced to be able to constitute an abuse of dominance is rejected since the General Court finds that it would be unwanted to make article 102 TFEU dependent on the contravention of competitors, which are perhaps not fully informed about which rights might have been granted through abusive methods.¹¹⁸

¹¹⁷ Ibid.

¹¹⁸ Id., para 362-363.

6 US Antitrust Law

6.1 Preliminary remarks

The United States of America has inherited the common law tradition from the previous British rulers. Under patent law, the patentee's conduct can amount to either *inequitable conduct*¹¹⁹ or the more severe finding of *common law fraud*¹²⁰, the difference being that if fraud is found antitrust remedies will become available to the defendant. However, if only inequitable conduct can be proven, only remedies under patent law will be available to the court.

6.2 US antitrust law and the *Walker Process doctrine*

By statute patents are presumed to be valid.¹²¹ Usually, even if a court finds a patent to be invalid, an antitrust counter claim under section 2 of the Sherman Act cannot survive. The rationale is that patent law is used to promote innovation by creating limited monopolies while antitrust law is used as a measure of last resort to punish behaviour that has the object of illegally maintaining or gaining a monopoly.¹²² However, there are exceptions. It was first recognized in the landmark judgment of *Walker Process*¹²³ where the Supreme court acknowledged that a patentee who brings an infringement suit may be subject to antitrust liability if the alleged infringer (the antitrust plaintiff) can prove that the disputed patent was

¹¹⁹ *Inequitable conduct* is a less severe finding than common law fraud (see below). It can be found if the patentee breaches its duty to disclose relevant information to the patent office and can include a failure to submit material prior art; failure to explain references in foreign languages; misstatements of facts; and misdescriptions of inventorship.

¹²⁰ *Common law fraud* incorporates nine elements which all have to be pled with clear and convincing evidence; a representation of an existing fact; its materiality; its falsity; the speaker's knowledge of its falsity; the speaker's intent that it shall be acted upon by the plaintiff; plaintiff's ignorance of its falsity; plaintiff's reliance on the truth of the representation; plaintiff's right to rely on it; and consequent damages suffered by the plaintiff. See US case *Schnellmann v. Roettger*, 373 S.C. 379, 382, 645 S.E.2ed 239, 241 (2007) and *King v. Oxford*, 282 S.C. 276, 281, 204, S.E.2ed 50, 52 (1974)

¹²¹ 35 U.S.C. § 282

¹²² See case *Verizon v. Trinko*, where a unanimous Supreme Court recognizes that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue. Where [...] there exists a regulatory structure designed to deter and remedy anticompetitive harm, the additional benefit to competition provided by antitrust enforcement will tend to be small and it will be less plausible that the antitrust laws contemplate such additional scrutiny." In this particular circumstance the patent law framework is serving a specific purpose (innovation) and only if this regulatory framework cannot remand improper behavior, antitrust remedies are necessary. see also *Credit Suisse Securities v. Billing*.

¹²³ *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corporation*. 382 U.S. 172, 86 S.Ct.

obtained by defraud on the patent office.¹²⁴ In a concurring opinion in *Walker Process* Justice Harlan distinguished the situation where a section 2 claim could survive and where it would have to fail. First, a distinction must be maintained between patents procured by “deliberate fraud” and those that were rendered invalid or declared unenforceable due to other reasons.¹²⁵ That is, if “deliberate fraud”¹²⁶ can be proven, then, a section 2 claim can prevail, but if not, the patent will just remain unenforceable. The second point made by Justice Harlan is that if this separation of the two seemingly similar situations (inequitable conduct and common law fraud) cannot be upheld, there is a great risk that innovation might be chilled due to the fact that section 2 monopolists would perhaps be subjected to vexatious or punitive consequences from firms claiming treble damages under the Clayton Act.¹²⁷

Inequitable conduct is therefore a less severe offence than “deliberate fraud” as used in *Walker Process* because conduct before the patent office that may render a patent invalid or unenforceable is broader than common law fraud, where inequitable conduct includes other types of conduct that is not as serious as “knowing and wilful fraud”.¹²⁸ The more important question is thus whether the patentee has used the patent in an exclusionary manner which is outside the scope of patent law.¹²⁹

The Federal circuit made the distinction even more clear in *NobelPharma* where it stated that “[i]nequitable conduct is thus an equitable defence in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword”.¹³⁰ The allegory is very clear and catches the spirit of Justice Harlan’s opinion in *Walker Process* as well as the unanimous Supreme Court opinion in *Verizon v. Trinko* - antitrust should only be used as a last resort.

6.3 The Noerr-Pennington doctrine

Another line of case law is the cases following the *Noerr-Pennington* doctrine.¹³¹ This case law stems from the first amendment of the US constitution which emphasizes the prohibition of, for example, the petitioning for a governmental redress of grievances. The doctrine

¹²⁴ Ibid, at 350.

¹²⁵ Ibid, at 351-352

¹²⁶ Also known as *Walker Process Fraud*

¹²⁷ *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corporation*. 382 U.S. 172, 86 S.Ct. at 352.

¹²⁸ *NobelPharma Inc. V. Implant Innovations Inc.* 141 F.3d 1059. at 1069.

¹²⁹ Hovenkamp, H. 2008. “*The Walker Process Doctrine: Infringement lawsuits as antitrust violations*”, at 5.

¹³⁰ Ibid. at 1070

¹³¹ *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); and *United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965)

expressly bars the finding of antitrust liability in cases where a private party seeks governmental action by, for example, law that would restrain trade or extend the scope of a monopoly, or even create one.¹³² *Noerr*, however, withheld immunity from “sham” activities since the court found that the application of the Sherman Act in those circumstances could be justified since, “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” could be seen as abusive.¹³³ The standard of evidence for arguing that *Noerr* immunity does not exist in a patent case is however rather extensive since the inquiry starts off by presuming that a “patentee’s infringement suit is presumptively in good faith and that this presumption can be rebutted only by clear and convincing evidence”.¹³⁴ The party seeking to strip the other litigant from immunity therefore has a strict standard of proof to meet and circumstantial evidence will not suffice.

In *PRE*¹³⁵ the Supreme Court followed up the reasoning in previous cases and answered the important question, which both *Noerr* and *Pennington* did not address, whether litigation may be “sham” merely because a subjective expectation of success does not motivate the litigant. The Supreme Court answered this question in the negative and held that “an objectively reasonable effort to litigate cannot be sham regardless of subjective intent or purpose”.¹³⁶ By this standard an antitrust plaintiff must first establish that the lawsuit against it is objectively baseless, and only if this preliminary inquiry is answered in the affirmative the court will go on and analyze the subjective intent of the antitrust defendant.¹³⁷ Under the second part of the definition of “sham” it is thus the question if the lawsuit conceals “an attempt to interfere *directly* with the business relationship of a competitor”.¹³⁸ If “sham” is then proven, that does not automatically prove an antitrust violation, the substantive elements of a Sherman Act antitrust claim must still be proven by the antitrust plaintiff, i.e. antitrust injury.¹³⁹

In *NobelPharma* the main controversy was not a misrepresentation of facts, but rather a deliberate omission of an essential fact, which gave rise to the *Walker Process* claim. The court concluded that a fraudulent omission can be as reprehensible as fraudulent misrepresentation.¹⁴⁰ Since the court could

¹³² *Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, at 136, 81 S.Ct. 529.

¹³³ *Id.*, at 144, 81 S.Ct., at 533.

¹³⁴ *Handgards v. Ethicon (Handgards I)*, 601 F.2d 986 (9th Cir. 1979), cert. denied, 444 U.S. 1025 (1980)

¹³⁵ *Professional Real Estate Investors Inc., v. Columbia Pictures Industries Inc.* 508 U.S. 49, 123 L.Ed.2d 611 (1993)

¹³⁶ *Professional Real Estate Investors Inc., v. Columbia Pictures Industries Inc.*, at 56., referring to arguments in *California Motor Transports*, “sham” depends on the existence of anticompetitive intent, however, that does not transform the sham inquiry into a purely subjective investigation.

¹³⁷ *Professional Real Estate Investors Inc., v. Columbia Pictures Industries Inc.*, at 59.

¹³⁸ *Id.*, at 59, quoting *Noerr, supra*, 365 U.S., at 144

¹³⁹ *Id.*

¹⁴⁰ *NobelPharma Inc. V. Implant Innovations Inc.* 141 F.3d 1059. at 1070.

conclude that NobelPharma knew that the patent would not have been issued if the patent office had been aware of the omitted literature. The inventors had transmitted the reference literature to the patent agent who then had deleted the reference from the application.¹⁴¹ NobelPharma also knew that it was enforcing an invalid patent, and the Federal Circuit Court therefore also found that the action fulfilled the requirements of a “sham” suit within the meaning of *Noerr-Pennington*.¹⁴²

The fraud element thus requires; (i) a false representation or an omission of a fact material to patentability; (ii) made with intent to deceive the patent examiner; (iii) on which the examiner justifiably relied in granting the patent; (iv) but for which misrepresentation or deliberate omission the patent would not have been granted.¹⁴³ A plaintiff thus has to show that all of the above are clearly fulfilled. A strong finding in one inquiry cannot balance a weaker finding in another as in the case of inequitable conduct where the court is suppose to balance the findings and come with at general finding whether inequitable conduct has occurred.¹⁴⁴ The finding of *Walker Process* fraud cannot result from equitable balancing of different factors.¹⁴⁵ Because of this, it is possible that a case can reach the level of inequitable conduct, but not the level of *Walker Process* fraud, and that this difference of facts may be very small.¹⁴⁶

6.4 Summary

US antitrust law is not directly aimed at handling situations where an undertaking has made misrepresentations to the patent office or filed a lawsuit against a competitor. These situations are usually solved by applying the relevant legal framework such as the patent law framework in situations involving patents. The subjective intent of harming competition by resorting to fraud on governmental institutions or harassing an opponent in court knowing that there is no merits to the claims can however activate the antitrust laws. If a defendant in an infringement action can prove fraud it can invoke an antitrust counterclaim and thus sue the harassing undertaking for treble damages.

¹⁴¹ *Id.*, at 1072

¹⁴² *Id.*, at 1071.

¹⁴³ *C.R. Bard Inc. v. M3 Systems Inc.*, 157 F.3d 1340 (1998), at 1364. Referring to *Nobelpharma*

¹⁴⁴ *Dipping Dots Inc. v. Mosey et al.*, 476 F.3d 1337, at 1346.

¹⁴⁵ *Id.*, at 1347. Also, *NobelPharma* 141 F.3d at 1071.

¹⁴⁶ *Dipping Dots Inc. v. Mosey et al.*, 476 F.3d 1337, at 1348

7 Comparative analysis

Above, an introduction to EU competition law in relation to the components of sham and fraud as abuse of dominance have been outlined by the existing case law and the Commission enforcement in the AZ Decision and Pharmaceutical sector inquiry. An understanding of US antitrust law has also been given, and now it is time to compare the different legal systems. First, a comparison as to general liability will be made to see the difference between ‘abuse of dominance’ and ‘unlawful monopolization’ as provided by Article 102 TFEU and section 2 of the Sherman Act, respectively.

7.1 General Differences

The reason for outlining the main differences is because it is important to understand the different scopes of the two jurisdictions when analyzing the particular conducts of sham and fraud as abuses under EU competition law.

Under Article 102 TFEU any *abuse* of market power by a dominant undertaking is considered illegal, while in the US, section 2 of the Sherman act prohibits the *monopolization*, or the *attempt to monopolize*, a market. This linguistic difference indicates that EU competition law is occupied with the regulation of the behavior of dominant firms rather than the actual effect of that behavior, while US antitrust law is more occupied with the exclusionary effects of the actual behavior. If the behavior is not exclusionary, it is not violating the Sherman act in the US, while that same behavior very well can constitute an abuse of dominance in the EU since the EU courts do not demand proof of actual effect, the probability of harm to the competitive structure of the market is enough.¹⁴⁷ The US Supreme Court has held that the principles that governs the application of section 2 of the Sherman Act “[i]s not to protect businesses from the working of the market; it is to protect the public from the failure of the market. The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself. It does so not out of solicitude for private concerns but out of concern for the public interest”.¹⁴⁸

The free market is seen as the best motor to promote both static and dynamic efficiencies as Justice Scalia put it in *Trinko*; “it induces risk taking that produces innovation and economic growth”,¹⁴⁹ and when the successful competitor wins, he must not be turned upon.¹⁵⁰

¹⁴⁷ Case T-219/99 *British Airways plc v. Commission* [2003] para. 293. Case upheld by the Court in case C-95/04 P *British Airways plc v. Commission* [2007]

¹⁴⁸ *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)

¹⁴⁹ *Verizon v. Trinko* 124 S.Ct. 872, at 789.

¹⁵⁰ *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945)

The US section 2 enforcement is therefore rather focused on consumer harm. To prove section 2 liability one needs to prove that a specific behavior is producing anticompetitive exclusionary effects that prejudice consumers. In the EU, likely effect of diminished competition is enough and the analysis of whether consumers are worse or better off is never done, however, it is rather implied that diminished competition in the market is negatively affecting consumers.¹⁵¹ By this, it is not said that EU is indifferent to consumers or the actual effects on consumers. But it has become the Commission's almost exclusive competence to make such an analysis, and if the Commission finds that consumers could be worse off by certain behavior the EU courts only assesses if the Commission has misused its powers or if any manifest errors of assessment have been done by the Commission.¹⁵² This makes it very difficult for a dominant firm to win a case against the Commission based on substantive elements. The Commission therefore in a way serves as the prosecutor and the fact finder of the same court, to simplify a bit.

An important divergence of EU competition law and US antitrust law is exemplified by the US judgments in *Credit Suisse, Trinko* and *Linkline*¹⁵³ on the one hand and the EU judgment in *Deutsche Telekom AG v. Commission [2008]* on the other. All of these cases relate to highly regulated markets, *Credit Suisse* to the financial market and the other cases to the telecommunications sector. Both the EU and the US have instituted legal frameworks due to similar problems with competition. The telecommunications sector has historically been regulated in both the US and the EU, and to promote consumer choice and competition the governments issued legal frameworks, so called sector specific regulations, to open these markets to competition.¹⁵⁴ Both jurisdictions assigned

¹⁵¹ See for instance Case T-201/04 *Microsoft v. Commission* [2007] at para. 643 et seq. where the General Court refers to the *IMS Health* judgment by the Court, referring to AG Tizzano's opinion of that case where he suggests that 'consumer harm' should be a mandatory requirement in the analysis of when a refusal to deal situation can violate article 102 TFEU. However, this analysis is never done by the General court in *Microsoft* nor in the *IMS Health* judgment (or any other judgment for that matter).

¹⁵² When a decision is the result of complex technical appraisals, those appraisals are in principle subject to only limited review by the Court, which means that the Community Courts cannot substitute their own assessment of matters of fact for the Commission's, see, as regards a decision adopted following complex appraisals in the medico-pharmacological sphere, order of the President of the Court of Justice in Case C-459/00 P(R) *Commission v Trenker* [2001] ECR I-2823, paragraphs 82 and 83; see also, to that effect, Case C-120/97 *Upjohn* [1999] ECR I-223, paragraph 34 and the case-law cited; Case T-179/00 A. *Menarini v Commission* [2002] ECR II-2879, paragraphs 44 and 45; and Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, paragraph 323).

¹⁵³ *Supra* note 117 and *Pacific Bell Telephone Co. v. LinkLine Communications, Inc.* 128 S.Ct. 2957, 171 L.Ed.2d 883, 76

¹⁵⁴ In the US the Telecommunications Act of 1996 was designed to enhance competition in a previous non competitive environment. In the EU several directives and regulations on EU level have been issued, for instance, Directive 2002/19/EC on access to, and interconnection of, electronic communications networks and associated facilities. (Access Directive); Directive /21/EC on a common regulatory framework for electronic communications networks and services. (Framework Directive); Directive 2002/20/EC on

regulatory institutions to apply the legal frameworks and monitor the functioning of competition in the market.¹⁵⁵ Both the idea and the actual implementation of it seem very similar in the EU and the US. However, the consequences for antitrust remedies in the both jurisdictions are not similar at all. The US Supreme Court rectify its view, that antitrust remedies are only to use as a last resort when no other remedy is available, with the fact that the sector specific regulation and the monitoring authority was better equipped to solve issues relating to market access which often contained problems of access rates etc which on the other hand a court would be ill equipped to deal with.

In the EU the Commission and Court concluded almost the opposite. Competition law is primary law, and therefore it is superior to any secondary law framework law. It doesn't matter, according to the General Court in *Deutsche Telekom AG v. Commission [2008]*, if the national regulatory agency has approved a specific access price and that that price is within the spectrum provided for in the regulatory framework, if the consequence is that competitors are harmed, given that the dominant firm could resort to a pricing strategy less exclusionary. A reasonable explanation to this interpretation of EU law is that there is no "federal" agency that is assigned to monitor the entire EU to which firms can complain, only national regulatory agencies. If competition law would not be available to the Commission in such a situation, the EU institutions would lose much influence to apply effective remedies to firms it believes abused its market power. Since an EU objective is the integration of the Internal market, the Commission (and Court) is solicitous to stretch its influence over the market as far as possible, or at least not abide to national regulatory regimes that might produce different outcomes in similar situations. This is an understandable view, but not a very well functioning system as such, since legal certainty for dominant firms is practically non-existent since it cannot rely on a decision from a national regulatory agency.

7.2 Comparing

7.2.1 Walker Process

The US *Walker Process doctrine* and the EU case of *AstraZeneca* incorporate similar substantive elements of what could incur antitrust liability. The question to be analyzed in this section is whether the

the authorization of electronic communications networks and services. (Authorization Directive).

¹⁵⁵ In the US the Federal Communications Commission was instituted as a part of the 1996 Act, but every state also has its own regulatory body such as the Public Service Commission (PSC) in the state of New York. In the EU the Telecommunications package was assigned to national regulatory agencies (NRAs).

AstraZeneca decision with its specific facts could fall under the *Walker Process* exception to antitrust immunity, or if the behavior of AZ in any event should be found to violate Article 102 TFEU.

7.2.1.1 AstraZeneca and Walker Process

Let us consider the cumulative criteria for establishing a *Walker Process* claim. First, there need to be a false representation or omission of facts, second, there needs to be intent to deceive the patent office, third, the patent office must have relied on the false facts, fourth, the patent would not have issued without the misrepresentation or omission, and lastly, the patentee must have enforced or threatened to enforce the patent against the potential antitrust plaintiff. According to the General Court, the finding of an abuse of dominance only need to prove that the facts that has been represented to the patent office is materially false, and that the patent office therefore is likely to issue a patent or SPC that otherwise would not have issued if not for the misrepresentation, intent to deceive on behalf of the dominant undertaking being irrelevant. The perhaps most important prerequisite to successfully plead a *Walker Process* claim in the US, the prerequisite of intent, is therefore nonexistent in EU law even though the General Court admits that it can be of relevance when looking to the abuse as a whole. The General Court also observes that the enforcement, or the threat to enforce, a patent or SPC is not a prerequisite to finding an abuse of dominant position, the mere acquisition of such a right clearly has anticompetitive effects since patents and SPCs are presumed to be valid.¹⁵⁶

The Commission, in contrast to the General Court, seems to have argued for more of a *Walker Process* test in EU law in its decision. However, the Commission's analysis only requires that the exclusive right is issued, the need for actual enforcement is not a requirement to categorize it as an abuse. Most of the Commission's argumentation is trying to establish a picture where AZ deliberately and knowingly tried to fool the different national patent offices with their *effective marketing theory*. But, would such an interpretation of EU law be prohibited by previous case law such as *Hofmann La-Roche* and *Michelin I* describing the concept of an abuse as an objective concept? I believe not and will give an example. In *AKZO* the Court had to establish what could be considered a predatory pricing scheme. It found that if the firm priced over average total cost (ATC) the pricing scheme would be legal *per se*, and if the dominant undertaking would price below average variable cost (AVC) it would be *per se* illegal. The Court then had to establish what would be considered illegal if the dominant undertaking would price below ATC, but above AVC.¹⁵⁷ Since it would be

¹⁵⁶ Case T-321/05 *AstraZeneca v Commission*. Para. 362.

¹⁵⁷ A price below ATC indicates that the firm is not making a profit for any good sold. It is instead subsidizing its own output by using firm equity to pay for overhead costs and in the long run the firm would go bankrupt if it cannot either raise price or diminish its costs so that unit price would be above ATC. If we assume that all firms would have the same cost,

tantamount to all economic theory to prohibit a price below ATC the Court found that a pricing strategy between AVC and ATC had to be accompanied with a strategy to eliminate competition, clearly a subjective criteria.

It seems that the concept of an abuse as a main rule is an objective concept, but that it in some cases needs to be accompanied with facts establishing a subjective intention to cause harm to competitors. The consequence being that it should have been possible for the General Court to phrase paragraph 356 in a different manner, indicating that the concept of an abuse is by nature an objective concept, *but* that it in this circumstance would need to be accompanied by facts supporting the subjective intention to harm competition. This would not change the outcome of the case since the Commission in a consistent manner established the anticompetitive intent by AZ.

More problematic is the GC's reasoning about the special responsibility that dominant undertakings have to observe not to distort competition. To interpret the old case law from the *Michelin I* and *Tetra Pak I* in such a way that every action a dominant undertaking takes in the process of obtaining an exclusive right or other regulatory right might be considered abusive is very strict rules on the dominant firm. Since originator firms are usually dominant, this interpretation is a major burden for the innovative industry.

It also seems that there have been some differences of opinion within the General Court. As previously mentioned, only objective factors are required to establish the abuse, and a dominant undertaking have special responsibility to not distort the competitive process, but at paragraph 358 the General Court points out that *if* a dominant undertaking receives an exclusive right due to misrepresentations, that undertaking, when becoming aware of the falsehood of those misrepresentations, must at the very least inform the public authority of that to enable the authority to change its decision, i.e. revoke the patent or SPC. This wording indicates that the General Court might have been unanimous as to the fact that AZ was in breach of article 102 TFEU, but not as to what type of conduct the Commission would need to establish. If all that is needed to show an abuse of dominance is objective factors, the good or bad faith of the undertaking filing for a patent or SPC should not matter. But that is exactly what paragraph 358 indicates, i.e. if the dominant undertaking was in good faith when it filed the false information it could be without liability if it as soon as it became aware of the misrepresentations informed the authorities of its

the dominant firm would, objectively speaking, exclude its smaller competitors that would have less ability to withstand a price below ATC. A price below ATC would also bar any entry to the market, effectively hindering competition. However, if the market is price elastic and a firm enters at a price lower than ATC but above AVC, then, the dominant undertaking would have to act by cutting price to meet the new price of the entrant. This is optimal behavior since at a price above AVC the dominant undertaking would still get more money per good sold than it actually cost to produce, but it would not make up for the overhead costs. It is therefore optimal for the firm to produce to the point where price subside AVC. A strategy to price between AVC and ATC could be a response to the market and used while the firm reorganizes to diminish overhead and/or variable costs.

mistake. But, as the General Court points out, AZ did not do this, and therefore, it also failed the less strict test in paragraph 358.

We therefore find several different opinions on how a dominant undertaking can incur antitrust liability. The General Court favors foremost the test where the dominant firm only has to submit incorrect information which is essential to the issuance of the exclusive right. Second, the General Court puts forward the theory that the undertaking might be shielded from antitrust remedies if it was in good faith when filing the original information, but as soon as that dominant undertaking becomes aware of that false information it has to rectify itself by informing the authorities of its previous mistake. The Commission seems to be working under the assumptions made under *Walker Process*, but without the prerequisite of the enforcement, or threat to enforcement. AZ, on the other hand, is favoring a ‘copy-paste’ application of *Walker Process* in EU law, alternatively it could agree with the Commission’s test given that the exclusive right actually had come into force thereby producing a potentially illegal exclusionary effect. But, since the wrongfully obtained SCPs were revoked before they could enter into force, AZ maintains that there could be no effect on competition, actual or potential.

What can be the market outcome of these different proposed applications of EU competition law? If we consider the test that prevailed in the judgment, i.e. whether false information had been presented and whether that information was necessary for the authority to issue the exclusive right, it raises difficult questions for market participation for dominant undertakings.¹⁵⁸ If a dominant undertaking filing for a patent or a SPC gets something wrong, then, it would be in violation of article 102 TFEU no matter if it was in good faith when it made the misrepresentation. This is going even further than the test set out in *ITT Promedia* where the Commission argued that the key question to be answered was whether the undertaking initiating a legal action, objectively speaking, could reasonably believe that it was enforcing an existing right, no matter whether that right existed or not.¹⁵⁹ Clearly, a test as the one found in paragraphs 356-357 will have a negative effect on dominant undertakings’ incentives to file for borderline patent claims and other related exclusivity issues since it could very well be that it could be considered an abuse of dominance. The underlying thought of applying for patents is that the firm wishes to limit competition, the effect of that will then of course also be that competition will be restricted, and this is at the core of what patent law is all about.

The second test proposed by the General Court where the dominant undertaking could be in good faith, but later would have to rectify itself if it found information that might invalidate the exclusive right, is also not satisfactory. First it confuses the line between patent law and competition law. If a firm has received an exclusive right through the lengthy and

¹⁵⁸ See, for instance, Murphy, F., 2009. "ABUSE OF REGULATORY PROCEDURES: THE *ASTRAZENECA CASE*"

¹⁵⁹ Supra chapter 5.2.1

complex patent process under the patent law framework, that exclusive right has to be presumed to be valid. Firms cannot be liable to supply the patent offices with every single theory or fact that might have an impact on the validity of the exclusive right after issuance of the same. Firms might not be one hundred percent sure as to what bearing new information could have on a patent. That is why patent law and patent litigation exists, so it is possible to test borderline arguments and facts, and perhaps make the exclusive right unenforceable or invalid and/or demand injunctions. If no enforcement has taken place by the dominant firm, antitrust liability cannot be a solution to a wrongfully obtained patent since competition law is to regulate the undertaking's behavior outside the scope of the patent.

The more dynamic test that would allow for an inquiry into subjective intention as proposed by the Commission would be of greater good since it would punish the intent to harm competition. If the dominant firm obtained a patent by fraud, that patent would not unlikely have a negative effect on competition since firms would be aware of the patent, presuming that it is a valid patent. But the problem is the same as above; it is unsatisfactory to apply competition law to a situation inside the scope of the patent. However, the Commission's reasoning clearly rebuts AZ's theory based on the notion that the exclusive right has to actually enter into force. Clearly, the existence of an exclusive right will chill competitors' competitive efforts within the scope of that exclusive right.

The only satisfactory test is therefore the one adopted by the US courts, i.e. the *Walker Process* doctrine. This would leave the regulation of patent validity to patent law, as it should, and only when clear and convincing evidence that a competitor is using a fraudulently obtained patent to exclude competitors, antitrust remedies become available.

An alternative theory that the General Court declined to consider is the one proposed by the Commission in *ITT Promedia* and that considers what a reasonable firm could have thought was its rights or what facts it thought was the correct at the time when it filed for the patent or SPC at the patent office.¹⁶⁰ This test would be difficult to apply since the wording as such is very ambiguous and it is always a problem to assert what someone could reasonably believe at a specific time, even though such inquires are not uncommon to EU law.¹⁶¹ However, Neither the Commission, nor AZ, argued for such an application before the General Court.

The *AstraZeneca* decision incorporates many similarities with the *NobelPharma* judgment from the US Federal Circuit, but section 2 and article 102 TFEU are not applied in a consistent manner with each other. The standard of proof required in the US to activate Section 2 of the Sherman Act, common law fraud, is mainly an inquiry into the subjective

¹⁶⁰ *AZ v Commission* para. 363

¹⁶¹ See for instance the Court's reasoning in case Case C-280/00 *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH*, and *Oberbundesanwalt beim Bundesverwaltungsgericht (Altmark Trans)* [2003]

intent of the undertaking in question. In the EU the main question is whether the representations to the patent office were false and whether it made the authority to issue an exclusive right that would not have issued if not for the false information, intention and enforcement being irrelevant.

7.2.1.2 Conclusion

The EU approach to *Walker Process* is as interesting as it is potentially harmful to the EU markets. The Commission is very prone to maintain and preserve a competitive environment within the pharmaceutical sector that is mainly dominated by ‘big pharma’, and therefore might be more likely to feature abusive conduct by dominant undertakings. However, there is no compelling evidence that competition is lacking in this dynamic sector if we see to entry and exit statistics. To indicate that competition is hampered is presumably most likely to be a *false positive*. The main problem is what the underlying policy objective is. In EU the main policy objective is unclear since there is not a unanimous view what is to be used as a measurement stick. The Court holds on to its case law which preserves the policy objective of a market with a competitive market structure as such, that is the previous article 3(1)(g) EC now contained in a protocol annexed to the new Treaties. This is likely to promote the finding of false positives since competitive conduct is likely to change the market structure as the better firm or firms exclude the weaker ones, just as the US Supreme Court correctly points out in *Spectrum Sports*. In the US the measurement stick is rather consumer focused and this is also what the Commission is more and more promoting in the EU.

From an economic and social planner perspective it should be obvious that the inquiry into the abusiveness of a certain conduct should be focused at consumer harm. If consumer harm is unlikely, the finding of an abuse should also be unlikely since the change in the market structure is likely to be the will of the consumer that prefers certain goods over others. Therefore classic economic resource allocation theory predicts that resources must be relocated to enhance the productiveness of the market as a whole and the market structure must change accordingly. It is therefore a bad proxy for consumer benefits to suffice with the analysis of objectively exclusionary practices since this very well might be a part of the competitive process and not an abusive practice at all.

The conclusion of the *AstraZeneca* judgment is that the General Court’s application of article 102 TFEU is very unfortunate. There are indeed problems with the internal market and having 27 national patent offices’ acting under national law. However, applying competition law to behavior that usually is remedied by patent law is from the EU institutions point of view understandable. Since there is no EU patent court, it would be tantamount to the integration of the internal market to allow national patent offices and national courts to solve issues relating to abusive practices of dominant undertakings within the patent law framework. The difference can be understood if we realize that the US has a Federal patent framework and

a specialized federal patent court (the Court of Appeals for the Federal Circuit). If EU would have an EU patent court and true EU patents the story might have been different. The problem is that EU would lose a big part of its ability to regulate these issues if competition law would not be available. The only possibility for the Commission to keep the EU framework together would then be to sue the member state that it recognize has breached its duty to apply the EU framework for SPCs or any other exclusive right. That would not be a workable solution at all, and very unfortunate.

In the EU, abuse of the patent system is subject to the objective concept of an abuse while in the US the abuse is subject to the concept of fraud, and the enforcement of the fraudulently obtained right, to find a breach of the rules on competition. However, it should have been fully possible to the General Court to approve the Commission's reasoning in its decision against AZ as to the need to prove the intention to cause harm. In any event, when, or if, the EU receives a union patent framework and patent court, case law will have to evolve towards the US *Walker Process doctrine*. Anything else would be very unfortunate. The case law from *AstraZeneca*, if not appealed and changed, will therefore constitute a major concern at the time the unified patent system becomes a reality.

7.2.2 Noerr-Pennington and ITT Promedia

The *Noerr-Pennington doctrine* incorporates the elements of the *ITT Promedia* case and some of the issues emphasized in the Pharmaceutical Sector Inquiry, i.e. the issues relating to vexatious litigation. Under *Noerr-Pennington* and *ITT Promedia* the proposed tests are very similar. Under *Noerr-Pennington* the first question to be answered is whether, objectively speaking, the firm initiating the legal action reasonably could believe it had rights to protect, which is more or less the same as the test proposed by the Commission in *ITT Promedia*.¹⁶² Here, only objective factors are taken into consideration, and it is what the firm initiating the proceeding reasonably could believe at the time the lawsuit was initiated that is relevant, later events having no bearing on that finding. Second, both tests propose that if one can find that there was no merit to the case the court will have to decide whether the lawsuit was conceived in a plan whose goal was to eliminate competition, the last inquiry being an inquiry into the subjective intent of the dominant undertaking.

Section 2 and Article 102 TFEU liability should therefore be similar in this regard. However, the *ITT Promedia* case was delivered by the General Court and never reviewed by the Court of Justice. If we consider the *AstraZeneca* case and the General Courts emphasis on *only* objective factors when identifying the abuse, it is unclear what legal status *ITT Promedia* actually has. It is however likely that competition law very well could be applied to these situations. *Compagnie Maritime belge* also suggest that

¹⁶² See chapter 5.

actions taken by a dominant firm aimed at a government institution that has as purpose to hinder effective competition indeed could be within reach of the rules on competition. Here the Court will have to tread more careful since access to courts and the ability to petition for a governmental redress of grievances is to be considered fundamental rights which has to be respected by the Court. Clearly this situation is more likely to be similar between EU and US than the very divergent situation in the *Walker Process* scenario.

8 Concluding Remarks

If we see to the whole of this thesis it is apparent that competition law as a social welfare enhancer only has effect on the margin. If the main objective with the Pharmaceutical Sector Inquiry is to bring in more generic competitors and to enhance competition as such it is not the market actors that produces the main problems with market entry. It is rather the member states themselves that need to enhance their generic substitution programs. Since generic penetration differs widely between member States that is an indicator that it is not big pharma that creates the main barriers but national legislation. Denmark with a coherent generic strategy and an incentives driven penetration mechanism for generic substitutes where the government stimulates private entities to promote social welfare by giving, for example, the pharmacist a share of the gain is by far a better framework to bring in competition than limiting big pharma's abilities to act freely on the market.

The above is valid for the post patent period. For the actual patent period competition law is also problematic since this is traditionally regulated through patent law. Since the patent is suppose to hinder competition in itself, the use of competition law within the scope of the patent would be illogical. However, as soon as the undertaking holding the exclusive right acts outside that right competition law kicks in if we use EU competition law. That is, if the undertaking tries to extend the scope of the patent that it is not entitled to. That should presumably apply to both patent length (*AstraZeneca*) and patent breadth (for example, a situation where a patentee brings an infringement suit in relation to a fraudulently obtained patent). It is to me problematic that the General Court did not produce a coherent judgment in *AstraZeneca* and that the current wording not only is contradictory but also unfortunate if we ever get an EU patent court. Should competition law still be applicable in the same sense then? Preferably *AstraZeneca* will be appealed and the Court of Justice will clear up the inconsistencies in the case and maybe show some more guidance to the future.

Originator firms are under the implications from *AstraZeneca* in a very exposed position to competition law enforcement. The Commission, favoring generic competition in the post patent period, seems to have little faith in these firms' abilities to litigate against originator firms' borderline exclusive rights. This might not at all be true. The Sector inquiry clearly states that a majority of litigation is won by generic firms and in many settlements originator firms agree to pay substantial amounts to generic competitors. The *AstraZeneca* judgment itself has its roots in the case *Hässle AB v Ratiopharm GmbH* where Hässle is a fully owned subsidiary of AZ and Ratiopharm a german generic manufacturer.

Lastly, even though somewhat critical to current competition law enforcement, I believe that there is a great need for competition law

monitoring from the EU institutions perspective. Competition law is one of the motors of European integration and has served the Union well. President Sarkozy's rhetorical question on what competition law has done for Europe should therefore be answered: A lot. But a critical eye must always follow the evolution of the law, comment and question the application to the gain of all. That is the true objective of this thesis.

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Bibliography

Books

Areeda, P., Hovenkamp, H., 2004. Antitrust Law – An analysis of antitrust principles and their application. Aspen publishers, New York.

Glader, M., 2004. *“Innovation Markets and Competition Analysis – EU competition Law and US Antitrust Law”*, Lund University, Faculty of Law.

Goyder, D.G. 2003. EC Competition Law (fourth ed.). Oxford University Press. Oxford.

Jones, A., Sufrin B. 2004. EC Competition Law (Second ed.). Oxford University Press. Oxford

O’Donoghue, A., Padilla, J. 2006. The Law and Economics of Article 82 EC. Hart Publishing, Portland.

Articles

Batchelor, B. 2009. "PATENT ATTACK - THE EC SECTOR INQUIRY INTERIM FINDINGS" European Competition Law Review pp. 212-215

Bernson, 2005. "Big Drug Makers See Sales Decline with Their Image", New York Times, November 14.

Brekke, K.R., Holmås, T.H., Straume, O.R. 2007 “Regulation, generic competition and pharmaceutical prices: Theory and evidence from a natural experiment.

Briggs, A., 2006. *“Jurisdiction over defences and connected claims” Lloyd’s Maritime & Commercial Law Quarterly (L.M.C.L.Q. 2006, 4(Nov), 447-452)*

Caves, Richard E., Michael D. Whinston, and Mark A. Hurwitz, “Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry,” Brookings Papers on Economic Activity (Microeconomics), 1991, pp. 1—48.

Czapracka, K. 2009. Intellectual Property and the Limits of Antitrust: A Comparative Study of Us and Eu approaches. Edward Elgar Publishing Ltd

Danzon, P.M., Chao, L.W. 2000, “Does Regulation drive out Competition in Pharmaceutical markets? Journal of Law and Economics XLIII, pp 311-357.

Denicolò, V. 1996 “Patent races and optimal patent breadth and length”, *The Journal of Industrial economics*, Vol. 44, No. 3.

Desogus, C. 2010. “*Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade*”

Frank, Richard G. and David S. Salkever, “Generic Entry and the Pricing of Pharmaceuticals,” *Journal of Economics & Management Strategy*, Spring 1997, 6 (1), 75—90.

Gallini, N. 1992. ”Patent policy and costly imitation”, *RAND Journal of economics*, Vol. 23, No. 1.

Gilbert, R. Shapiro, C. 1990 ”Optimal patent length and breadth”, *RAND Journal of economics*, Vol. 25, No. 1.

Grabowski, Henry G. and John M. Vernon, “Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act,” *Journal of Law and Economics*, October 1992, 35 (2), 331—50.

Hovenkamp, H. 2008. “*The Walker Process Doctrine: Infringement lawsuits as antitrust violations*”.

Klemperer, Paul. 1990 ”How broad should the scope of a patent be?”, *RAND Journal of economics*, Vol. 25, No. 1.

Marco, A. 2005. “Patent protection, creative destruction, and generic entry in pharmaceuticals: Evidence from patent and pricing data”, Vassar College, New York

Murphy, F., 2009. "ABUSE OF REGULATORY PROCEDURES: THE *ASTRAZENECA CASE*", *European Competition Law Review*, pp. 223-229.

Murphy, F., 2009. "ABUSE OF REGULATORY PROCEDURES: THE *ASTRAZENECA CASE: PART 2*", *European Competition Law Review*, pp. 314-323.

Murphy, F., 2009. "ABUSE OF REGULATORY PROCEDURES: THE *ASTRAZENECA CASE: PART 3*", *European Competition Law Review*, pp. 289-300.

Negrinotti, M., 2008 "*ABUSE OF REGULATORY PROCEDURES IN THE INTELLECTUAL PROPERTY CONTEXT: THE ASTRAZENECA CASE*" *European Competition Law Review*. pp. 446-459

Nordhaus. W., 1969. “Invention, Growth and Welfare”, MIT Press.

Rousseva, E. 2006. "The Concept of 'Objective Justification' of an Abuse of a Dominant Position: Can it help to Modernise the Analysis under Article 82 EC?" *The Competition Law Review*. Volume 2 Issue 2.

Scherer, F.M., 2000. The pharmaceutical industry. In: Cuyler, A.J., Newhouse, J.P. (Eds.), *Handbook of Health Economics*. North Holland, Elsevier, Amsterdam, Chapter 25.

Schweitzer, 1997. "Pharmaceutical Economics and Policy", New York; Oxford: Oxford University Press.

Simons, S. 2010. "*Creating sustainable European health-care systems through the increased use of generic medicines: A policy analysis*", *Journal of Generic Medicines* Vol. 7, 2, 131–137.

Wiggins, Steven N. and Robert Maness, "Price Competition in Pharmaceutical Markets," 1994. Unpublished Manuscript, Department of Economics, Texas A&M University.

Winkelmann, R. 2003. "*Co-payments for prescription drugs and the demand for doctor visits – Evidence from a natural experiment*", Working Paper No. 0307. Socioeconomic Institute, University of Zürich.

Table of Cases

EU Cases

Court of Justice

Case 27-76 R. *United Brands Company and United Brands Continentaal BV v Commission*. ECR 00425 [1976]

Case 85/76. *Hoffmann-La Roche & Co. AG v Commission*. ECR 00461 [1979]

Case 322/81. *NV Nederlandsche Banden Industrie Michelin v Commission*. ECR 03461 [1983]

Case 311/84 *Centre Belge d'Etudes du Marché-Télémarketing (CBEM) v CLT SA* [1985] ECR 3261

Case C-62/86 *AKZO Chemie v. Commission* [1991] ECR I-3359

Joined Cases C-395/96 P and C-396/96 P, *Compagnie Maritime belge and others v. Commission*, [2000] ECR I-1365.

Case C-120/97 *Upjohn* [1999] ECR I-223

Case C-497/99 P. *Irish Sugar plc v Commission* [2001] ECR I-05333

C-127/00 *Hässle AB v Ratiopharm GmbH* [2003] ECR I-14781

Case C-280/00 *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht (Altmark Trans)* [2003] ECR I-7747

C-459/00 P(R) *Commission v Trenker* [2001] ECR I-2823

Case C-4/03 *Gesellschaft für Antriebstechnik mbH & Co. KG v. Lamellen und Kupplungsbau Beteiligungs KG*. ECR I-06509 [2006]

C-539/03 *Roche v. Primus* ECR I-6535 [2006]

C-95/04 P *British Airways plc v. Commission* [2007] ECR I-02331

General Court

Case T-30/89 *Hilti AG v. Commission* [1991] ECR II-1439

Case T-65/89 *BPB Industries and British Gypsum v Commission* [1993] ECR II-389

Case T-83/91 *Tetra Pak International SA v Commission* [1994] ECR-00755

Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-02937

Case T-228/97 *Irish Sugar plc v Commission*. [1999] ECR II-02969

Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305

Case T-219/99 *British Airways plc v. Commission* [2003] ECR II-5917

Case T-179/00 *A. Menarini v Commission* [2002] ECR II-2879

Case T-271/03 *Deutsche Telecom AG v. Commission*. [2008]

Case T-201/04 *Microsoft v. Commission* [2007] ECR I-3601

US Cases

United States v. Aluminum Co. of Am., 148 F.2d 416, 430 (2d Cir. 1945)

Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961)

United Mine Workers v. Pennington, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965)

Walker Process Equipment, Inc. v. Food Machinery and Chemical Corporation. 382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965)

California Motor Transport Co. V. Trucking Unlimited, 404 U.S. 508, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972)

King v. Oxford, 282 S.C. 276, 281, 204, S.E.2ed 50, 52 (1974)

Handgards v. Ethicon (Handgards I), 601 F.2d 986 (9th Cir. 1979), cert. denied, 444 U.S. 1025 (1980)

Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993)

Professional Real Estate Investors Inc., v. Columbia Pictures Industries Inc. 508 U.S. 49, 123 L.Ed.2d 611 (1993)

C.R. Bard Inc. v. M3 Systems Inc., 157 F.3d 1340, 1998-2 Trade Cases P 72,289, 48 U.S.P.Q.2d 1225 (1998)

NobelPharma Inc. V. Implant Innovations Inc. 141 F.3d 1059, 1998-1 Trade Cases P 72,100, 46 U.S.P.Q.2d 1097 (1998)

VerizonCommunications v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 n. 5, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004)

Credit Suisse Securities (USA) LLC, fka Credit Suisse First Boston LLC v. Glen Billing, et al, 551 U.S. 264, 127 S.Ct. 2383, 168 L.Ed.2d 145 (2007)

Dipping Dots Inc. v. Mosey et al., 476 F.3d 1337 (2007)

Schnellmann v. Roettger, 373 S.C. 379, 382, 645 S.E.2ed 239, 241 (2007)

Pacific Bell Telephone Co. v. LinkLine Communications, Inc. 128 S.Ct. 2957, 171 L.Ed.2d 883, 76 (2008)

Official Documents

Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products. (SPC Regulation)

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, OJ 2009/C 45/02

Proposal for a Council Regulation on the Community patent, COM(2000) 0412 final (OJ C 337, 28.11.2000; Proposal for a Council Decision establishing the Community Patent Court and concerning appeals before the Court of First Instance, COM(2003) 0828 final.

Proposal for a Council Decision conferring jurisdiction on the Court of Justice in disputes relating to the Community patent, COM(2003) 0827 final.

Proposal for a Council Regulation on the Community Patent (Working document of 30 October 2009 (15149/09) of the Council of the European Union) with references.

Draft Agreement on the European and Community (EU) Patents Court and Draft Statute, Working Document (7928/09) of 23 March 2009 from the Council of the European Union.

Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (Enforcement Directive), (2004) OJ L 157/16.

Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I Regulation), (2001) OJ L 12/1.

Promoting innovation through patents - Green Paper on the Community patent and the patent system in Europe, COM (1997) 314 final.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal L – 311, 28/11/2004, p. 67 – 128

Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal L – 136, 30/04/2004, p. 34 – 57.

Commission Decision COMP/A. 37.507/F3 - AstraZeneca, relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, 2005

European Commission IP/08/49. 2008.

European Commission - Pharmaceutical Sector Inquiry: Final Report. 2009.

European Commission - Executive Summary Pharmaceutical Inquiry. 2009.