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**Current Patent Strategies in Pharmaceutical Industry and Their Impact on EU
Competition Law Policies**

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Prohlašuji, že jsem předkládanou diplomovou práci vypracovala samostatně, všechny použité prameny a literatura byly řádně citovány a práce nebyla využita k získání jiného nebo stejného titulu.

V Praze dne.....

Podpis

We are at the very beginning of time for the human race. It is not unreasonable that we grapple with problems. But there are tens of thousands of years in the future. Our responsibility is to do what we can, learn what we can, improve the solutions, and pass them on.

Richard P. Feynman

Knowledge is controlled in every society through mechanisms of power. Anywhere you find knowledge; there also you will find power. They are linked. They are conditions for the possibility of one another.

Michel Foucault

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Abstract

The thesis reviews current patent strategies of original pharmaceutical companies and their tangled role in the fabric of European pharmaceutical innovation and competition. It addresses several components of the European pharmaceutical industry such as regulatory framework, patent filing and dispute strategies and competition law. It argues that patent law is embedded in a broader competition law framework however plays on a separate field where it governs primarily the entry to its exclusive space by market actors. However it asserts that competition law should serve as a time referee for the patent law playfield and check if the abusive prolongation of exclusive patent position does not occur. The thesis deliberates that in view of ever rising number of patent applications, abuse of the patent system may become symptomatic to the system. The Commission data presented in the Final Report on the pharmaceutical sector inquiry are again inspected. Although data should be used with caution, it revealed a good quantitative base for assessment of a system which seemingly becomes more entropic, complex and susceptible to abuse. Therefore the underlying principles in both patent and competition law should be upheld more strongly than ever. It is the principle of fairness that should have normative force and enable the Commission to address abusive patent filing and litigation strategies and finally point the warning finger not accepting abuses of patent prosecution in competition framework. The thesis offers support for better competition policy justification and defends return to fairness as a baseline norm in the EC's competition law policies in its interaction with patent law.

Abstrakt

Práce vychází z kritického hodnocení současných patentových strategií farmaceutických společností v rámci širšího evropského soutěžního a inovačního rámce. Nabízí přehled hlavních oblastí, které ovlivňují evropský farmaceutický průmysl: regulační oblasti léčiv, patentového řízení a patentových sporů a soutěžního práva. Práce vychází z koncepce patentového práva jako součásti širšího rámce soutěžněprávní politiky, ale zároveň vymezuje patentové právo jako zvláštní “hrací pole”, na kterém reguluje především vstup tržních hráčů. Soutěžní právo pak přebírá úlohu časového rozhodce a ověřuje, zda se hráči nedopustili nepoctivého jednání, které prodlužuje jejich setrvání v hracím poli. Práce se zamýšlí nad vzrůstajícím počtem patentových přihlášek a jeho průvodním jevem, čímž je možné zneužití patentování. Výsledky sektorového šetření Evropské komise prezentované v rámci Finální zprávy jsou opětovně zkoumány. I když by měly být prezentované údaje a informace brány s určitou opatrností, odkryly dobrý kvantitativní základ pro posouzení fungování systému, který se zdá být čím dál komplikovanější, entropický a náchylný ke zneužití. Z toho důvodu by měly být základní principy patentového a soutěžního práva prosazovány silněji než jindy. Princip poctivosti a spravedlnosti má v obou oblastech normativní sílu a umožňuje tak Evropské komisi postavit se vůči zneužívajícím patentovým strategiím a zvednout varovný prst neakceptující zneužití patentového řízení v rámci soutěžněprávních pravidel. Práce nabízí lepší odvodnění soutěžněprávní politiky a obhájí návrat k poctivosti jako základní normy evropského soutěžního práva v interakci s patentovým právem.

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List of Abbreviations

AZ – AstraZeneca

CFI – Court of First Instance

CHMP - Committee for Medicinal Products for Human Use

CJEU – Court of Justice of the European Union

EC – European Commission

EEA – European Economic Area

EGA – European Generic Medicines Association

EPC – European Patent Convention

EPO – European Patent Organization

EU – European Union

FTC – Federal Trade Commission

INN – International Non-proprietary Name

J&J – Johnson & Johnson

MS – Member State/Member States

SPC – Supplementary Protection Certificate

TFEU – Treaty on the Functioning of the European Union

TRIPS - The Agreement on Trade-Related Aspects of Intellectual Property Rights

UK – United Kingdom

US – United States of America

USPTO – United States Patent and Trademark Office

WIPO – World Intellectual Property Organization

I. Introduction

Pharmaceutical industry stands on the rim of three systems and from each part is played by numerous societal and economic interests. In this thesis I will discuss this interplay. The debate does not look to have lost the steam over the past few years - quite the contrary. Media widely report that key medicinal products are reaching patent cliff every year, innovation processes are slowing down and that life-saving tactics of blockbusters and rent-seeking rather than innovativeness dominate the current market of pharmaceuticals.

Again this year several of the most-selling drugs of Big Pharma are losing regional patent protection.¹ As for the global market trend, it is estimated that approximately 150 billion dollar worth of drugs will be off-patented during the period 2010 to 2017, which equally corresponds to the opportunities for pharmaceutical companies to develop generic drugs.² At the same time the EU is facing some pressing demographic realities, rising number of elderly population which pushes on national healthcare budgets and on prices of pharmaceuticals to be squeezed down.

This thesis examines commercial and legal practices of pharmaceutical companies and on this background reflects the underlying principles of patent and competition law. It tries to find the common thread sewing up these branches of law with regard to current patent-related practices of pharmaceutical companies in the overall public policy framework. The Community institutions emphasized that they regard access to generic medicines as one of the primary objectives of Community pharmaceutical legislation and policy.³ This thesis reveals where the institutions stand now with regard to the supervision of these practices and the safeguard of these objectives and where the stance should shift to. Some attempts have already been made by the Commission to rectify the distortions in competition caused by patent settlements between pharmaceutical companies. However no case has been closed with regard to abusive filing strategies

¹ <http://www.wallstreetdaily.com/2014/11/03/patent-expiration/> (accessed on 10 December 2014).

² <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3555014/> (accessed on 15 December 2014).

³ http://europa.eu/rapid/press-release_MEMO-12-148_en.htm?locale=en (accessed on 15 December 2014).

ever since the Final Report⁴ following a thorough and lengthy sector inquiry was published in 2009 and revealed some disturbing data.

The number of patent applications related to the pharmaceutical industry rises year by year. Quality of granted patents has become more questioned ever since. More complex and entropic such system becomes more it may oppose its own underlying principles that have led to its creation. Misuse of patent rights and abuse of law can become symptomatic to the ever-increasing volume of patent applications. Intentional or unintentional this practice is, the European institutional framework must be prepared to identify the abuse and encroach in order to safeguard the underlying principles, if these principles are not going to be reconsidered or reviewed in the light of changing "standard operating procedures" in innovation competition.

One must also bear in mind two other facts that shape the reality of today's EU pharmaceutical industry: one of continuing unification and harmonization efforts (continuous cooperation efforts on the side of WIPO, creation of the Unified Patent Court and the European enhanced patent cooperation) and in the other corner of the regulatory triad, continuous fragmentation and lack of common action within the field of pharmaceutical regulations, mostly in terms of drug reimbursements and pricing that result in substantial single market distortions.

Nicoleta Tuominen at the end of her research paper "*Patenting Strategies of EU Pharmaceutical Industry. Crossroad between Patent Law and Competition Policy*"⁵ leaves one question open to debate. She asks if "*patent law is an element within the framework of competition rules or is rather itself the framework of innovation competition*". Here, I would like to answer the question and argue that patent law indeed works within and is abided by the framework of competition rules. The aspect of time and fairness are the two decisive elements of competition oversight in patenting practice. Therefore whenever time abuse and abuse that consists in providing misleading and false information occurs, competition law must encroach. To this, *AstraZeneca* case was the seminal one that articulated the Commission's role to

⁴ European Commission, Competition DG, Pharmaceutical Sector Inquiry Final Report, adopted on 8 July 2009.

⁵ Tuominen, N., *Patenting Strategies of the EU Pharmaceutical Industry -Crossroad between Patent Law and Competition Policy*. Research Papers in Law, 1/2011 College of Europe.

safeguard competition face to face with the extensive patenting attempts. The same applies to patent litigation strategies with the same justification and the same goal. Competition law intervenes whenever dominant position granted by patent rights is misused in payment settlements. These settlements bear formal signs that mark their problematic character. Under closer scrutiny they seem to cover patent weakness and unmerited patent grant which on its turn goes back again to fairness as the ultimate goal of EC's competition policies of patent strategies. As we will see, the Commission has recently closed several such cases and fined the companies involved heavily. The thesis gives an account of these problems and systematically reviews the realities of today's competition law policies in limelight of the current pharmaceutical patenting practices.

1.1. Outline of the Thesis

The thesis is structured in a way that guides the reader through all realms that govern and shape the European pharmaceutical industry of today.

First part of the thesis deals with regulatory setting of the European pharmaceutical industry. At the moment, various mechanisms creating exclusionary positions for pharmaceutical companies exist under European and national law. It is important to bear in mind that as a matter of policy making, the legislator provides for several distinguished but somewhat intertwined forms of exclusivity and protection. From this, the underlying rationale and policy objective will be drawn. The regulatory setting can also easily clear up the key market realities of the pharmaceutical industry. The drug product development and marketing authorization requirements will be explained. As it will be demonstrated, clinical trials regulation and complex safety and efficacy assessments have significant ramifications on the pharmaceutical patenting strategies.

In the second part of the thesis, patent law specifically applied in pharmaceutical industry is dealt with in more depth. It will be relevant to see what the patentable subject-matter is and how the patent claims are drafted in the pharmaceutical area. Two theories of patent grant, reward and contract theory will be mentioned and contract theory further debated as the intersection with competition law objective is sought.

Further, criticism related the current state of patent system is discussed as many abusive practices are occurring with the system growing ever bigger and bigger. The downsides of the extensive patent filing practice will be addressed in more detail, such as creation of patent thickets and divisional patent applications. This part heavily relies on the Final Report of the Commission published after an in-depth pharmaceutical sector inquiry in 2009. A quick comparative look at the patent prosecution requirements related to disclosure and inequitable conduct before the USPTO will be provided.

In the following part, practice of the EU institutions in dealing with patent right abuse in pharmaceutical industry is considered. The recent Commission's competition case law in the pharmaceutical sector will be reviewed and the CJEU confirming decision in *AstraZeneca* will be given a quick glimpse. From this, the Commission's objectives in competition law policies will be deduced. This part of the thesis turns the attention mainly to the practice of settling patent disputes between originator and generic companies and draws mainly from the EC's Final and 5th report on pharmaceutical sector. Again a short comparative analysis with the US practice will be made as the American counterpart faces similar issues.

In the final part of the thesis, European competition law and its objectives under the European legislation are discussed. The attention finally turns to fairness as the unifying principle of patent and competition law. Definition of fairness in competition scrutiny is sought and special consideration is dedicated to abuse of dominance and contractual fairness. Suggestions will be made as to strengthening the Commission's position in abusive patent filing strategies prosecution. I conclude that two objectives should be now pursued by the Commission when keeping an eye on the patent system: watching the time limits and abuse of procedural rights and make a strong and cautionary case involving provision of false and misleading information in patent applications.

1.2. Definitions

- A) Original pharmaceutical medicine is a drug that contains a new chemical entity (such that was never used in any medicine before) and has a desirable therapeutic effect. New chemical entity must always be described in terms of its structural formula, including stereochemistry, molecular formula and molecular mass. New chemical entity is given its own specific international non-proprietary name that is usually applied for early in the clinical development. It can take two distinct forms: a free neutral form and a derivative form (e.g. salt).⁶
- B) Generic product is a medicinal product that is simply characterized as a copy of original pharmaceutical medicine.
- C) Medicinal product is defined according to directive 2001/83/EC as any substance or combination of substances presented as having properties for treating or preventing diseases in human beings. The definition is very broad and covers vast variety of chemical substances used in humans such as antibiotics, hormones, blood products, vaccines, proteins etc. Substance may be of human, animal, vegetable nature or a chemical substance, i.e. substance occurring naturally or obtained by chemical change or synthesis.
- D) Polymorphs are one type of solid form of the same chemical composition. Sometimes the chemical and physical properties of a drug can vary substantially and can have a dramatic effect on manufacturing process, stability, dosage and pharmacokinetic properties. Great variety of properties of a molecule can be altered by a change in polymorphism such as solubility, crystal shape, stability, melting points, etc. In a pharmaceutical ingredient (active substance), these variations in properties can lead to differences in dissolution rate, oral absorption, bioavailability, levels of gastric irritation, toxicology results, and eventually results of clinical trials.⁷
- E) Salts are ionic compounds that can result from a neutralization reaction of an acid and a base. Salts are composed of cations and anions and form an electrically neutral product. An estimated 50% of all drug molecules used in medicinal therapy are administered as salts. This fact indicates that the

⁶ Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, Case COMP/A.37.507/F3 – AstraZeneca, para 15.

⁷ <http://www.ssci-inc.com/Information/RecentPublications/ApplicationNotes/WhatEveryoneNeedstoKnowAboutPolymorphs/tabid/141/Default.aspx> (accessed on 10 January 2015).

salification, or salt formation, of a drug substance is a critical step in drug development. A drug substance often has certain suboptimal physicochemical or biopharmaceutical properties that can be overcome by pairing a basic or acidic drug molecule with a counterion to create a salt version of the drug. The process is a simple way to modify the properties of a drug with ionizable functional groups to overcome undesirable features of the parent drug.⁸

- F) Intermediate is a substance formed in the course of chemical reaction that proceeds to participate in further reactions.
- G) Pharmaceutical formulation is the processes in which different active chemical substances will be combined together to produce a medical compound i.e., medical drug.⁹ One can typically distinguish between oral formulations, inhalation, topical treatments or injections.¹⁰
- H) Impurities are other undesirable substances present in the drug. Drugs can also differ in amount of impurities that can originate from starting material and synthetic route (process impurities) or from storage (degradation impurities). Elimination of impurities renders the product improved and of higher quality.¹¹ Drug development processes can then lead to significant changes of the drug properties.
- I) Excipients are various types of additives that are formulated alongside the active substance in a drug. They serve various purposes (bulking-up the drug, preservation, etc.) and include among others sorbents, flavors, sweeteners, coatings and anti-adherents.

⁸ <http://www.pharmtech.com/node/230746?rel=canonical> (accessed 8 January 2015)

⁹ <http://omicsonline.org/overview-on-pharmaceutical-formulation-and-drug-design-2153-2435.1000e140.pdf> (accessed 8 January 2015).

¹⁰ <http://www.linnaeus.uu.se/online/pharm/lakemedelform.html> (accessed 8 January 2015).

¹¹ Ed. by Smith R. and Webb M. L., Analysis of Drug Product Impurities, Blackwell Publishing, 2007, p. 4.

II. Pharmaceutical Regulatory Framework

With regard to the above definitions, the major market segments of the pharmaceutical industry are original chemical drugs with new active substances, generic drugs, over the counter drugs (drugs that do not require prescription), biologicals and biosimilars.¹²

Below, two most important segments (originator and generic) are given a brief description of its specific characteristics and functioning.

2.1.Original Pharmaceutical Companies

As a matter of commercial purpose, originators innovate, lead pharmaceutical research, develop new active substances for various human diseases, conduct related activities promote and sell medicinal products.

Often cited criterion of originator's research pointing to its demanding character is the number of new chemical entities that need to be synthesized in order to establish the right molecule for a new original drug. In the first half of the 1990s, such a number was estimated to be 10.000 new chemical entities. Rationalization of methods of research and development and understanding of pathological processes of diseases at the molecular level however improved significantly over the last decade.¹³ In the early 2000s the number was estimated to be 4000 new molecules and is still decreasing.¹⁴ Methods of combinatorial chemistry and automatic processing of biological activity at the receptor's level (so-called high throughput screening) is pushing the number still down. At the current stage of research and development, it is not difficult to prepare several thousand derivatives simultaneously on one matrix and together with fast biological assessment overcome difficulties of 'try and fail' that scientists encountered in the past.¹⁵

¹² <http://www.ita.doc.gov/td/health/PharmaceuticalIndustryProfile2010.pdf> (accessed 10 January 2015)

¹³ Kuchař M., Výzkum a vývoj léčiv, Vysoká škola chemicko-technologická v Praze 2008, at 11.

¹⁴ Ibid.

¹⁵ Ibid.

For original pharmaceutical companies very strict pre- and post-marketing regulations apply. Their role is to safeguard human health. Whenever a pharmaceutical company wants to introduce a new product on any of the EU 28 markets, it must go through an approval procedure and apply for the so-called marketing authorization, a thorough drug assessment that can take up to one year.¹⁶

The aim behind stringent legislation that requires drug's testing, controlling, verifying and monitoring prior to its assessment is public health and environment protection. There is also an economic goal which is to ensure that the public health care budget spending provides for the most efficient and the safest treatments. Pre-clinical stage (takes up to 3 and half years¹⁷) as well as clinical stages (take up to 8 years¹⁸) in drug development are very drawn-out if results of the highest reliability, comprehensiveness, accurateness and verifiability should be achieved and presented with the application. Therefore no medicinal product may be placed on the market of any MS unless a marketing authorization has been issued by the competent authority of that MS or the EC after a due scientific opinion is delivered.¹⁹ Marketing authorization requirements are dealt with in more detail below.

2.2. Generic pharmaceutical companies

According to the basic definition, generic pharmaceutical company manufactures, promotes and sells generic drugs. Its entry into the market follows years after the first marketization of the original branded product, therefore it seizes all the benefits of its previous marketization, clinical experience and verification.

Prior to entry generic company must also make important marketing decisions. This includes choosing the appropriate therapeutic class that suits its strategic interests (e.g. dermatology or cytostatics), acquiring knowledge of data exclusivity and patent expiry dates and predicting market position and market share of the future generic drug. It

¹⁶ http://www.ema.europa.eu/docs/en_GB/document_library/Brochure/2011/03/WC500104233.pdf (accessed on 12 January 2015).

¹⁷ <http://ca-biomed.org/pdf/media-kit/fact-sheets/cbradrugdevelop.pdf> (accessed on 15 December 2014).

¹⁸ Ibid.

¹⁹ Supra 16.

requires thorough market and scientific analyses in terms of indication areas of the generic drug, future market and therapeutic trends and drug's pricing.²⁰

After a concrete molecule was chosen, generic company usually simply buys a ready-to-use dossier which describes the drug in terms of manufacturing processes and other data relevant for production and product commercialization. Company can decide either to buy the active substance from an external supplier or to produce the substance on its own. Generic company may also find its own original adjustments and optimization to synthetic production processes that can be protected by original patents.²¹ In the manufacturing process, generic company develops or imitates the drug form of the original drug.²²

Recently, apart from the traditional production and marketing of generic drugs, one can take a note of certain new business trends of generic companies which include:

- 1) research and development of their own original products with new active substances.
- 2) research and development of so-called supergenerics, with the same active substance of branded drugs but with other properties modified by the transformation of original product into a salt, a functional derivate, or a polymorph.
- 3) reformulations, research and development aiming at a change of drug form in order to modify its pharmacokinetic properties or development of other transport forms in order to target the right site of action. This also includes novel controlled releases, delivery routes, modified dosage strengths, etc.
- 4) research and development of improved manufacturing process.
- 5) research and development of biosimilars.²³

It is apparent that any marketization of medicine (generic or original) gives rise to new or additional safety issues. However, as for generic drugs, the requirements for market entry are significantly reduced. It is sufficient that the generic company proves by

²⁰ Supra 13, at 150.

²¹ Supra 13, at 151.

²² Ibid.

²³ Supra 13, at 149.

comparative studies of bioavailability or bioequivalence (therapeutic identity), that the generic compound and the compound of reference (branded drug) are the same or equivalent and that the reference medicinal product is or has been authorized for not less than 8 years in a MS or the Community.

2.3. Marketing Authorizations: A Closer Look

Understanding European procedures for marketing authorization is relevant in four aspects for the subject matter of this thesis.

First, the significant disproportion between the regulatory requirements for branded drug and generic drug marketization elucidates, why becoming the first marketer is a demanding performance in terms of time and money. Recent studies indicated that the clinical trials in Europe declined by 25 percent over the past few years, costs have doubled and delays in market entry have also increased.²⁴ From this, the prevailing rationale behind data exclusivity and market protection must be understood. Based on a successful marketing authorization, the legislator provides for the entire intellectual property package that protects the product, its developer and manufacturer and incentivizes further research.

Secondly, outlining regulatory requirements will also shed more light on different stages of research and development of new medicines as all standards and protocols of performed tests and trials that take account of these stages and are compiled in complex dossiers should enhance the effective control of new medicines marketed in the EU.

Thirdly, it is also important to understand what the marketing authorization for generic products entails because it is often after the initiation of the procedure that original pharmaceutical companies get alert, send warning letters and may trigger various legal disputes against generic companies. Originator companies also often start legal actions

²⁴ Watson R., European Commission Proposes New Laws to Halt Decline in Number of Clinical Trials, BMJ 2012, published 18 July 2012.

against decisions reached in marketing authorization procedures in which they claim patent infringement or qualitative shortcomings of a generic product (safety issues).²⁵

Fourthly, the EC also recognized that patent linkage may be the aspect of the authorization procedures in some MS and patent 'clearing' may be required before the marketing authorization is granted.²⁶ However, the practice is neither supported by the Commission, nor justified *de lege lata* as the Article 81 of Regulation (EC) 726/2004 and Article 126 of Directive (EC) 2001/83 provides that an authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the regulation and the directive and the patent status is not included in the grounds.

2.4.Human Drug Regulatory: Originator Companies

As explained above, every new medicine entering the EU market requires systematic review and scientific assessment in the so-called marketing authorization procedure. Pharmaceutical company can effectively choose between centralized procedure, mutual recognition procedure, decentralized procedure and national procedure. All procedures are more or less unified in terms of specific requirements for the data submitted by the company. The decision which procedure to use depends on whether the applicant wishes to market the medicinal product in one or more MS or throughout the whole EU and whether the medicinal product itself has certain properties or is used to treat specific disorders.²⁷

Centralized procedure is generally used mostly by larger pharmaceutical companies that desire to market products on a Community basis. National procedure may still be preferred by small to medium sized enterprises who only wish to market in their domestic MS. Pharmaceutical companies search for particular markets for their

²⁵ Pharmaceutical Sector Inquiry Final Report, adopted 8 July 2009, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf, para 882.

²⁶ Ibid.

²⁷ Shorthose S., Guide to EU Pharmaceutical Regulatory Law, Wolters Kluwer Law and Business, 2014.

products. State-specific reimbursement policies, price controls and particular launch strategy can stand behind this decision as well.²⁸

In the EU, marketing authorization for medicinal products for human use is governed by the Regulation (EC) No. 726/2004.²⁹ The Regulation provides for centralized procedure at the EU level for any marketing authorization for medicinal products. Harmonization of the internal market brought the necessity of simplified and centralized procedure mostly for certain high-technology medicines, orphan drugs and other medicines of high societal importance (for which the therapeutic indication is the treatment of AIDS, cancer, diabetes and neurodegenerative disorders, auto-immune and viral diseases). Those medicines must be assessed under centralized procedure. Under centralized procedure, the medicine is evaluated on the basis of objective scientific criteria of safety, quality and efficacy.³⁰ The application for marketing authorization must be accompanied with a dossier that includes following documentation:

- Pharmaceutical (physico-chemical, biological, microbiological) tests;
- Preclinical (toxicological, pharmacological) tests;
- Clinical trials.³¹

After a target molecule is identified and verified in pharmaceutical testing, pre-clinical tests are undertaken, where usually in-vitro tests and animal models are used. Their role is to determine drug's pharmacology (how the drug acts in human body). The molecule is synthesized and purified. Safety pharmacology, local tolerance and toxicity are determined and single and multiple dose toxicity is studied.³² It is an obligatory stage before any testing on human subjects can be carried out.

Before clinical trials commence, an approval from the competent authority (the Ethics Committee) must be obtained. The Ethics Committee issues an ethical decision whether

²⁸ Ibid.

²⁹ Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136/1, 30 April 2004.

³⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF> (accessed on 16 January 2015).

³¹ http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2013-06_en.pdf (accessed on 16 January 2015).

³² http://www.vivoscience.de/download/PARA_Dossier2.pdf (accessed on 25 January 2015).

the trial is permissible.³³ The company must already at this point give satisfactory information demonstrating the quality of the drug and its non-clinical safety. A study plan must be submitted delineating processes according to which the trial will be carried out and the drug effects systematically investigated. Numerous aspects of the testing are considered: i.e. how the trial is designed, what facilities are contracted in which the trial will be conducted, verification of the profiles of the investigator and all supporting staff, enrollment of clinical trial's subjects, confirming indemnity and insurance of the pharmaceutical company and other financial provisions such as payment to subjects, the investigator or the testing facility.³⁴ Trial must then comply with strict ethical guidelines and guidelines of good clinical practice.

The European Clinical Trials Directive³⁵ brought standardization in clinical trials' practice in the EU and overall led to better clinical trial procedures. It laid down provisions concerning protection of clinical trials' participants and operative monitoring of adverse reactions whereas ensuring better standards of handling personal information, protecting rights and dignity of human beings and increasing transparency of clinical results.³⁶ Reliability of all collected data, use of qualified individuals (i.e. biostatisticians, clinical pharmacologists and physicians) must be ensured.³⁷ Other post-trial activities, high-quality analysis of the trial data and relevant reporting is required. The trial master file must be maintained and submitted to the relevant authority and include all the essential documents related to the stage prior the commencement of the clinical trials, during the clinical conduct and after its completion. All clinical trials taking place in the EU must be registered within the EU register of trial data.

Clinical trials of a new drug are conducted on human subjects and are intended to determine clinical pharmacological, pharmacokinetic and pharmacodynamic effects of the drug. Clinical trials are also used for comparing two existing treatments or to test second indications of existing medicine. Adverse reactions are identified and

³³ Supra 16.

³⁴ Supra 27.

³⁵ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L 121/34, 1 May 2001.

³⁶ Supra 27.

³⁷ Ibid.

recorded.³⁸ Pharmaceutical company is under obligation to take responsibility of initiation, management, supervision, realization and financing of clinical trials and pharmacovigilance which all accounts for substantial economic costs. There are four stages of clinical trials. In Phase I small group of healthy individuals are used for testing of drug's primary parameters – safety and toxicity. In Phase II the drug is given to a larger group of people in order to further assess its safety and evaluate its efficacy. In Phase III, efficacy is further monitored and confirmed in even larger group of patients and side effects are determined with a low incidence rate.³⁹ Phase IV covers studies after the drug has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use⁴⁰.

In the EEA, approximately 4,000 clinical trials are authorized each year.⁴¹ Each trial involves two MS on average. Up to 61% of clinical trials are sponsored by the pharmaceutical industry and 39% by non-commercial and academic sponsors.⁴² Estimated cost for all stages of the drug development was at 800 million dollars in 2001, some more recent estimates operate with numbers of 1.2 billion dollars or even up to 1.4 billion dollars.⁴³ Usually drug development takes 13 years to be completed.⁴⁴ Just glancing at this data and the requirements provides evidence to the demanding nature of original drug development process.

2.5.Data and market exclusivity

All the required data serves for accurate assessments by the Committee for Medicinal Products for Human Use (CHMP). The CHMP rules whether or not the medicines

³⁸ Ibid.

³⁹ Drexl, Josef / N. Lee (Hrsg.): Pharmaceutical Innovation, Competition and Patent Law – A Trilateral Perspective. Cheltenham, UK / Northampton, MA, Edward Elgar, 2013, at 145.

⁴⁰ <http://www.nlm.nih.gov/services/ctphases.html> (accessed on 7 January 2015).

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000489.jsp&mid=WC0b01ac058060676f (accessed on 8 January 2015).

⁴² Ibid.

⁴³ http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (accessed on 7 January 2015).

⁴⁴ <http://www.cmidd.northwestern.edu/drug-discovery-development> (accessed on 10 January 2015).

concerned meet the necessary quality, safety and efficacy requirements and whether it has a positive risk-benefit balance in favor of patients once it reaches the marketplace.⁴⁵

After the application is approved and the marketing authorization granted, the originator is given time of exclusivity for producing accurate, complete and verifiable trial data. Data protection is accessory to the issuance of marketing authorization.⁴⁶ It equals to specific market position with regard to potential generic applicants. Data exclusivity is as a special form of exclusive intellectual property rights related to medicinal products' testing. Data exclusivity prevents generic companies from applying for a marketing authorization for a period of 8 years and make reference to the data submitted by originators in the application.⁴⁷ But at any time neither EMEA nor a national regulatory body will give the test data to the disposal of a generic applicant. Reference means only a reference to the evidence of safety and efficacy as presented by the original application.⁴⁸

The rationale behind data exclusivity is to compensate and reward pharmaceutical companies for massive investments in drug development and testing and thus to provide for exploitation of its unique market position.⁴⁹ The goal is to strike market balance between original and generic drugs in certain time framework that bears the tension of public and private commercial interests. Data exclusivity can be perceived as additional type of investment protection and can run concurrently with patent term. The obligation to provide for data exclusivity protection also emerges under the TRIPS Agreement.⁵⁰ Article 39(3) states the following: *“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition,*

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000095.jsp&mid=WC0b01ac0580028c7a (accessed on 13 January 2015).

⁴⁶ Supra 39, at 156.

⁴⁷ Supra 29, Article 10(1).

⁴⁸ Supra 39, at 158.

⁴⁹ http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf (accessed on 7 January 2015).

⁵⁰ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.”

Under the Regulation (EC) No. 726/2004, additional protection arises which stands for the period of 2 years of market exclusivity during which a generic company may not enter the market with a generic product although the abridged application may have been filed and assessed (together with the Article 10(1)(2) of Directive (EC) No. 2001/83⁵¹).

2.6.Human Drug Regulatory: Generic Companies

According to the Regulation (EC) No. 726/2004, if a generic company wants to place a generic medicinal product of a reference medicinal product onto a market of a MS, it must also file the application for authorization and prove that the summary of the product characteristics is in all relevant aspects consistent with that of the medicinal product authorized by the Community except for those parts of the summary referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed.⁵²

Legislation requires proving that the generic product is equivalent of the reference medicinal product in following characteristics: the identical active substance (the same new chemical entity), drug formulation, the same bioavailability and the same therapeutic effect. The identity of active substance is described both qualitatively (structural analysis) and quantitatively (analytical assessment of content and impurities). Drug formulation is the same in terms of composition, strength (amount of active substance), impurities profiles, dissolution and route of administration.⁵³ Bioavailability is proven by the same plasmatic levels (amount available in the blood stream) of active substances in generic and reference product. When these three requirements are met,

⁵¹ 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, OJ L 311, 28.11.2001.

⁵² Regulation (EC) No 726/2004 of the European Parliament and of the Council of the European Union, OJ L 136, 30.4.2004, Article 3.

⁵³ Supra 13, at 9.

one can expect the same therapeutic effect. A question of chemical and pharmaceutical equivalency follows a basic assumption that “*two products are considered equivalent when the rate and extent of absorption of the generic drug does not show a significant difference from the rate and extent of absorption of the brand drug, when administered at the same dose under similar experimental conditions.*”⁵⁴ Equivalency is then achieved in terms of efficacy and safety.

Bioequivalent studies are the only clinical studies performed on volunteers necessary for registration of generic drug. Well-known molecule indeed does not require such an in-depth assessment as a product of unusual and novel pharmacology. The costs and time associated with bioequivalence studies are only a tiny part of what an originator must spend in order to be the first marketer.⁵⁵

2.7.Legislative Intent in Pharmaceutical Regulatory

To summarize, it is important to keep in mind the underlying rationale behind exclusive rights *sui generis* granted to originator pharmaceutical companies. First, it is to compensate and to reward for bearing risk (time and cost) associated with drug development and safety, quality and efficacy verification and bringing new solutions to patients. Secondly and consecutively, it is to incentivize.

Notionally, and as a matter of broader policy perspective, a distinction between compensation and reward must be upheld. The former should be understood as a set of advantages that a policy maker exchanges for suffered disadvantages, losses or damages. Compensation is also an act of reparation for missed opportunities. On the other hand, reward should be regarded as consideration for voluntarily performed task, a socially desired goal and exerting effort in pursuit of this goal. Reward is an expression of societal appraisal of a certain activity and it functions as a guarantee that the company is given the opportunity to recoup its investments for what the TRIPS Agreement calls in the Article 39.3 “*considerable effort*”. As we will see, the notion of

⁵⁴ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> (accessed on 10 January 2015).

⁵⁵ *Supra* 39, at 154.

consideration and value exchange is also pivotal for contract theory that is one of the theories justifying patent grants, however in patent law the contract theory is associated with the negotiable extent of protection, expectation of invention disclosure and contribution to the general public knowledge whereas in data exclusivity no such expectation is expressed. Therefore I do not rely on this theory as justification for the existence of data and market exclusivity rights.

Data exclusivity and patents are two distinct intellectual property rights which follow analogous rationale. However there are linked to different economic realities and different societal expectations. They are becoming increasingly more intertwined as patents are filed for in later stages of drug development and respond to the initial loss of data exclusivity which heralds a soon generic entry. Pharmaceutical companies vividly use these advantages and seek to establish an optimal strategy which extracts the most from marketing authorizations and patent right terms.

2.8. Supplementary Protection Certificates

With regard to European patent and the EC's competition case law that is discussed below, it is also relevant to mention Council Regulation (EEC) No. 1768/92⁵⁶ supplementary protection certificate which offers another exclusivity protection for medicinal products on Community market.

The regulation pledges that by supplementary protective mechanism, the development of medicinal products in the EU is further encouraged and the additional protection mitigates the disparities and shortcomings in national patenting and regulatory systems in connection with the pharmaceutical drug development and commercialization. Within the limits of the protection, the certificate effectively extends the patent protection only to the product covered by the marketing authorization. The application for a certificate shall be lodged within six months of the date on which the authorization to place the product on the market was granted. The application for a certificate shall be lodged with the competent industrial property office of the MS which granted the basic

⁵⁶ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182, 2 July 1992.

patent.⁵⁷ The certificate is effective at the end of the term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years. However the duration of the certificate cannot exceed the period of 5 year and the duration of protection afforded by a patent and by the certificate together cannot exceed 15 years overall for the holder's first marketing authorization.⁵⁸

III. Pharmaceutical Patent Landscape

This Chapter aims at explaining basic rules of European patent procedure and patent granting, its fundamental conceptions and modes of function with the emphasis on the pharmaceutical industry.

Existence of weak patents is debated in light of several propositions on how to improve the filter that decides whether an invention is justifiable player in exclusive patent law playfield. It is of inherent importance in assessing competition law interests in patent law playfield.

3.1.In Search for a Strategy

First, I turn to explaining some principal facets of company's strategic behavior in competitive market place and what patents serve for at the company level.

Strategy can be defined as tactics, employing certain a direction of plans with the use of corporate internal resources. It is a careful plan, a search for the most extensive and effective competitive advantage in terms of time, strength of the exclusionary position (enforceability of rights) and market share (extent of such a position). In patenting practice and especially in patent filing strategies, this means that a company tries to

⁵⁷ Ibid.

⁵⁸ http://europa.eu/legislation_summaries/other/121156_en.htm (accessed on 1 January 2015).

overcome the risk of filing too early or too late and find the right extent of the protection by appropriate claiming in the application. For that reason, company seeks to be the first to file among the competitors but must be aware of former disclosures and other competitive products under the development.

Developing the most suitable strategy requires constant communication between IP specialists, regulatory professionals and marketing managers.⁵⁹ The drug under development must be continuously monitored because at every stage new potentially patentable features may come up. Any opportunity for the so-called second generation patents is under close watch because it brings the company one step ahead of other competitors. Company must also anticipate possibilities of inventing around its primary and secondary patents and draft patent claims accordingly. Scope of the patent is carefully established when the patent claims are reviewed with the inventor and with regard to the prior art and any loop hole that is found is of advantage for the company.⁶⁰ Optimizing product life cycle through strategic patenting is natural and logical result of rent-seeking behavior of all private undertakings. With patent strategies, pharmaceutical company seeks to achieve *inter alia* following goals separately or in combination:

- Profit maximization;
- Maintenance of its monopolistic position, securing the market share and expanding other market;
- Pursuing further research;
- Preventing imitation;
- Stockpiling technologies.⁶¹

The goals are either of a purely business (financial) nature or follow research purposes. All in all in market economy these goals are both inextricably intertwined and they are not surprising for a profit-oriented pharmaceutical company, which seeks to maintain its proprietary advantage for the current and promising innovations.

⁵⁹ Ibid.

⁶⁰ Ibid.

⁶¹ Committee on Development and Intellectual Property, Thirteenth Session, Geneva, May 19 to 23, 2014, Summary of the study on patent's role in business strategies: research on Chinese companies' patenting motives, patent implementation and patent industrialization, CDIP/13/INF/8.

In terms of innovation competition, the legislative intent of patent protection follows the premise that patent protection drives competitiveness because it incentivizes companies to innovate to the extent that they pass through the filter with the cutting edge inventions. However, it does not tell the first part of the story, which begins with managerial decisions of each individual company. The vision of patent grant makes companies compete so they will be able to exclude each other in the future. If a dominant position can be secured by a patent application then the task is to draft the application at right time and in right manner and broadness of patent claims.. The primary aim of any patent filing at the level of pharmaceutical companies' decision-making is not to compete all over again but to exclude each other. Initial competition follows the purpose of exclusion that is guaranteed and enforceable. The individual intention and interest of every company is therefore *a priori* anticompetitive and is as such approved by the state. The goal of a patent strategy is then to get through the filter and enjoy exclusivity rights with assumption that dictates that if the patent is valid and infringed, it can be enforced and a company is protected. Individual company does not consider pro-competitive effects of the pre-grant race from a global perspective. It seeks to stay in the field and do not let the defense to advance its ten yards with the use of the so-called defensive patent strategy or actively tackle down the competitors without the intention to commercialize the invention with offensive patent strategies. This can be done by a single patent or by a thicket of multiple patents. A patent strategy in the most generic terms is a process of constant decision making about the company's current and future stand towards its competitors with the use of patent rights and their enforcement. However the company's commercial intention is not part of the patent law rhetoric and is never examined in patent grant procedures.

Thinking about patents cannot get by without stressing the underlying policy reasoning of patent protection which figures as an irrefutable feature of every patent grant. To take an example of the legislative intent, the words of the US Constitution put it eloquently that granting patent rights aims at "*promoting the progress of useful arts by securing for limited times to authors and inventors the exclusive right to their perspective writings and discoveries*". According to the classic patent theory the prospect of monopoly

profits increases the incentive to innovate.⁶² It is a socially desirable type of monopoly which according to theory should lead to increased welfare and competitiveness. A company would have difficulty in recouping sunk cost for research and development activities if results of its research are quickly imitated by its rivals. Secondly, there is a significant public interest behind law on patents that consists in earliest conveyance of the latest scientific information so that the public can immediately benefit from disclosure of the invention. However, innovation is costly and resource intensive. Patents try to reflect the recognized hurdles of innovation and turn the new realizable ideas into property rights. Patents in their basic intentions "*create incentives that maximize the difference between the value of the intellectual property that is created and used and the social cost of their creation.*"⁶³

It is apparent that there is a significant disaccord between what is sought by an individual inventor/company and what economic consequences the legislator predicts if all companies act in the same rent-seeking behavior in the pre-grant race. When we project patent law theory and practice on competition law screen, we observe many overlapping patches. But bleak shades of divergence are also visible under closer look where the company's basic intention misses the competition law object of protection and renders the patent practice difficult to scrutinize. Some commentators see the competition law as background norm and granting intellectual property rights as a departure from the public domain background that must be justified.⁶⁴ Then, if properly justified, patent grants should escape the competition scrutiny and exist independently in a separate 'immune' domain. Therefore *au premier plan* it seems rather difficult to find the proper policy justification for any intrusion of competition law into patent strategies and especially patent filing itself with or without consideration of the patentee's intent. As we will see, this difficulty was mirrored in one of the tests to patent settlements' assessments that considered any exercise of rights conferred under a patent grant as lawful and only looked into adherence to patent exclusionary scope.

⁶² Tabarrok A., „Patent Theory versus Patent Law“, Contributions to Economic Analysis & Policy, Vol. 1, Issue 1, Article 9, 2002, at 1.

⁶³ Stanley M. Besen and Leo J. Raskind, An Introduction to the Law and Economics of Intellectual Property, Journal of Economic Perspectives, Winter 1991, at 5.

⁶⁴ Lemley, M., Property, Intellectual Property and Free Riding, Stanford Law School John M. Olin Program in Law and Economics Working Paper No. 291 August 2004, available at <https://dlc.dlib.indiana.edu/dlc/bitstream/handle/10535/6438/property%20intellectual%20property%20and%20free%20riding.pdf?sequence=1>.

However as we will follow several problematic aspects of patent filing and prosecution, other doors for competition law scrutiny open up.

3.2.EPC Convention, Patent Examination and Patentability Requirements

There are four basic requirements for patentability of an invention under the EPC. The invention must fall within one of the technology fields, must be susceptible of industrial application, must be new and must involve an inventive step. Two other requirements are implicitly contained in the EPC: a person skilled in the art must be able to carry out the invention on the basis of description contained in the application and the invention must be of technical character.⁶⁵ The latter requirement presupposes that the invention is related to a technical field and solves a technical problem and has technical features that are sought to be protected by patent claims.⁶⁶ That means that subject-matter of the claim must be of technical nature.⁶⁷ This however does not mean that the EPC requires the invention to bring some technical progress or useful effects in order to be patentable.⁶⁸ Reduction to practice is not required under the EPC's conditions.

Before the EPO and in practice the same person usually acts as search examiner and substantive examiner.⁶⁹ The search report is handed to the applicant and is accompanied by an initial opinion on the patentability requirements.⁷⁰ Upon the initial report, the applicant can amend the application in order to proceed only with viable claims or abandon the application entirely, if its entire scope is anticipated in the prior art.⁷¹ A distinction must be made between prior art that discloses the same or similar utility of

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[http://documents.epo.org/projects/babylon/eponet.nsf/0/56911A5DDF284B55C1257D81005FA359/\\$FILE/guidelines_for_examination_2014_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/56911A5DDF284B55C1257D81005FA359/$FILE/guidelines_for_examination_2014_part_g_en.pdf) (accessed on 11 January 2015).

⁶⁶ Ibid.

⁶⁷ <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf> (accessed on 8 January 2015).

⁶⁸ From the EPC's Guidelines for Examination, http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_i_3.htm (accessed on 8 January 2015).

⁶⁹ Grubb P. W, Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy, 4th edn, Oxford University Press, Oxford, 2004, at 386.

⁷⁰ Ibid, at 390.

⁷¹ Ibid.

the invention and prior art that discloses different utility or no utility at all. The latter case is regarded only as "*accidental anticipation*".⁷²

Novelty is the first and the clearest requirement of patentability and is usually the least difficult to establish and prove. Under the EPC, the concept of 'absolute novelty' is applied which presumes that an invention is new if it is not part of the 'state of the art'.⁷³ State of the art in its turn encompasses everything "*everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application*".⁷⁴ Also a European patent application that has not been yet published is prior art against a new application.

Further obviousness or inventive step requirement is examined. If an obviousness objection is raised by the patent examiner, it is advisable to limit the scope of the claims by additional features that are not part of prior art and to highlight the differences between the prior art and claimed invention.⁷⁵ Patent claims can be constructed in a restrictive manner so that the applicant will be able to obtain patents only on some features of the entire product.⁷⁶ Of course, this does not apply if the invention is disclosed in the prior art as whole. The notion of 'unexpectedness' is crucial in the assessment.⁷⁷ The invention is not very obvious if it can be reconstructed only with the benefit of hindsight, by selecting bits and pieces from three or more different publications.⁷⁸ Therefore the examiner's point is not a strong one if he refers to several priority documents as this would not occur obvious to anyone reading the references altogether.⁷⁹ The EPO adopts the problem-solution approach to obviousness: the invention is seen as the solution to the problem of getting from the closest prior art to the advantageous new result.⁸⁰ Grubb comments that the problem is often fictitious

⁷² Ibid at 393.

⁷³ Ibid at 62.

⁷⁴ http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iv_1.htm (accessed on 4 January 2015).

⁷⁵ Supra 69, at 394

⁷⁶ Pharmaceutical Product Patenting Strategies, Leman consulting S.A., available at http://www.lemanconsulting.ch/doc/GB_PATENT_Product_patenting_strategies.pdf (accessed on 1 January 2015).

⁷⁷ Supra 69, at 395.

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Ibid, at 398.

derived from the analysis of prior art with the benefit of hindsight.⁸¹ The EPO gives following instructions to the non-obviousness assessment:

- Identify closest prior art;
- Identify technical problem based on the differences between the closest prior art and the invention;
- Consider whether there is any teaching in the prior art as whole that would prompt the skilled person, faced with the technical problem, to modify the closest prior art, taking account of such teaching, so as to arrive at what is claimed.⁸²

Any defense to the obviousness objections is aimed at one of these three points.

As for the requirement of industrial application, an invention is capable of industrial application if it can be used or made in any kind of industry.⁸³ Utility or industrial applicability presupposes that there is a utility for the entire patent scope although sometimes the utility does not have to be disclosed specifically if it is obvious for a skilled reader⁸⁴ or it is not obvious from the nature of the invention. The teaching of the patent must indeed solve the problem that it intends to solve. The EPO Board of Appeals stated that patent system does not require absolute proof that the compound is approved as drug before it may be claimed however the patent application must provide at least some information e.g. experimental data, to the extent that the claimed compound, administered as stated in the claims, has a direct effect on metabolic mechanism specifically involved in the treated disease.⁸⁵ For a new pharmaceutical use, it is advised to insert comparing data with the previous available pharmaceutical compound because the EPO pays more attention to the pharmacological data.⁸⁶

⁸¹ Ibid

⁸¹ Supra 69, at 395.

⁸² http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5.htm (accessed on 13 January 2015).

⁸³ Supra 69, at 393.

⁸⁴ Ibid at 365

⁸⁵ Decision of EPO Board of Appeals Decision, T 491/08 of October 2010.

⁸⁶ Experimental data - the standard to be met to support patentability of a potential biological pharmaceutical by Directorate General EPO, available at: https://www.aippi.org/download/hyderabad2011/presentations/PWS_2_BGellie_Experimental_data.ppt (accessed 28 January 2015).

If the above requirements are met, patent is granted. Patent examination procedure is however not conclusive. The EPC provides for a possibility to revoke patent in 9 month period from grant and must be based on one of these grounds:

- The European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art
- The subject-matter of the European patent is not patentable
- The subject-matter of the European patent extends beyond the content of the application as filed.⁸⁷

3.3. Patent Claiming in Pharmaceutical Applications

Different types of protection may be obtained around a pharmaceutical product. These are product patents (chemical composition), process patents (methods of production), product by process patents (if chemical composition is unknown), method of administration patents and new indication patents (claiming use of the product which determines its utility).

A new chemical entity which is the primary patented technology is either expressed as a new compound (combination of two or more chemical elements), a new polymer (a larger synthetic compound that has a broad usage in pharmaceutical development, e.g. material, excipient or molecule⁸⁸), a new salt or other physical form of a substance (e.g. hydrates). Products can be defined in terms of its material composition, structure or in combination with certain properties. Claimed processes can be understood as production, mechanical, chemical, physical or operational processes. In pharmaceuticals, process claims claim inventions in synthesis, isolation, purification, extraction of chemical substances and they also encompass the first and the second medical use claims.⁸⁹

⁸⁷ Sherman B., Bently L., Intellectual property law, 3rd Edition, Oxford University Press 2009, at. 385.

⁸⁸ <http://www.ncbi.nlm.nih.gov/pubmed/11578099> (accessed on 13 January 2015).

⁸⁹ Supra 69, at 373.

Patent claims describe the subject of patent protection in technical terms. Patent claims delineate the extent of patent protection and exclusivity rights which they give rise to. They should be expressed coherently in one sentence and should be clear and brief.⁹⁰ Yet there is usually more than one patent claim included in the patent application. The practice of multiple patent claims in patent application with respect to new chemical substances arose in the UK in 1919 when courts allowed enforcing valid claims in a patent that was partly invalid.⁹¹ Also claims may be written as independent or dependent meaning that they can either exist alone or refer back to previous claims.

Interestingly, chemical compounds may still be patentable even if the inventor does not know the structure of the compound or he is not able to determine it in sufficient manner. What an applicant may do is to claim manufacturing process, i.e. how the compound is made, or can claim the invention in terms of its properties. This means that patentee gives certain particular characteristics of the compound such as solubility, melting point, infrared spectrum, nuclear magnetic resonance spectrum, crystal form, optical rotation etc. These are typical physico-chemical properties usually defined in the patent application. The other method involves so-called product-by-process claiming. In the EPO, the only type of product-by-process claim allowed would be type "the compound (structure unspecified) obtained by process X, only if the product is patentable *per se* and can only be described in terms of its manufacturing processes."⁹²

First medical use is the target medical use or first known and identified therapeutic application of a substance. First medical use as a patent claim is usually formulated as "substance X for use as a medicament".⁹³ Second and other medical use, if novel and inventive, is a patentable property of a substance or a composition which is already known for other uses in medical or non-medical spheres.⁹⁴ The so-called Swiss type claims are used to claim new and inventive therapeutic application of a known product: "use of compound X for the preparation of an agent for the treatment of disease Y".⁹⁵ It is an exception from a general rule, that process patent claims only protect absolutely

⁹⁰ European Patent Convention, Article 84.

⁹¹ Supra 69, at 374.

⁹² Decision of EPO Board of Appeal, T 150/82 of 7 February 1984, IFF/Claim categories.

⁹³ http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1.htm (accessed on 25 December 2014).

⁹⁴ Ibid.

⁹⁵ Supra 69, at 264.

novel products. The EGA argues that in the practice before the EPO these claims have been stretched and now cover dosage regimes or new patient populations.⁹⁶ Such patents could result from routine and basic research techniques in the process of drug development⁹⁷ and it is many times the case that all the indications are based on long-known pharmacodynamic properties of drug.⁹⁸

These are the basic types of claiming for any new pharmaceutical product. The key to commercially successful behavior is to prolong and maintain the exclusivity in every possible aspect. It is in the companies' economic interests to use broad claims and back up their position around one patent. To understand how sensitively patent claiming and appropriate protection is sought and is indeed a delicate art let us consider a basic example. The wording of "a composition consisting of A, B and C means that only A, B and C and no other components may be present, since infringement would be avoided by adding substance D."⁹⁹ If the patent drafter changes the wording so the patent claims "a composition comprising A, B and C" this is normally understood that also other substances may be present in the composition. Another permissible wording is "a composition consisting essentially of A, B and C". Sometimes even the use of word "or" may cause troubles. Is a composition comprising A and B infringing?¹⁰⁰

Patent attorney is under obligation to help his clients to obtain the best possible protection for their invention. This entails to claim inventions as broadly as possible, taking into account the limitations imposed by the prior art known at the time of drafting and by the technical feasibility.¹⁰¹ Yet there is a resonating conflict, in which it is on the other hand advisable to draft narrow independent claims and to enforce patents as quick as possible.¹⁰² The scope of the claims must be just, as the unnecessarily broad claims are difficult to prosecute before patent offices and even if the patent succeeds, it

⁹⁶ http://www.egagenerics.com/images/Website/IP_Barriers_web_Patent-related_Barriers.pdf (accessed on 25 December 2014).

⁹⁷ Ibid.

⁹⁸ EGA gives following example: the alendronate 70mg dosage regime patent or finasteride 5mg for the treatment of benign prostate hyperplasia and 1mg for the treatment of male pattern baldness. The patent for the latter indication (EP 724 444) extends the patent protection on the commercial product by more than seven years.

(http://www.egagenerics.com/images/Website/IP_Barriers_web_Patent-related_Barriers.pdf)

⁹⁹ Supra 69, at 376.

¹⁰⁰ Ibid, at 377.

¹⁰¹ Ibid, at 381.

¹⁰² Ibid, at 375.

is more likely to be litigated. Sometimes the broadness of the claims stretches too far to the prior art.¹⁰³ One of such examples could be a claim drafted as "a physiologically acceptable substance stabilized in an acid medium" which sounds like a great new invention except that it literally covers a jar of pickled onions.¹⁰⁴

Patenting is a continuous process of negotiations and searching for the right path to establish the right quality of patent or product that it covers and to reach applicant's strategic interests. It is a usual practice in all industrial sectors that the applicant sometimes attempts to manipulate the information in patent application in a way which suits his own interest.¹⁰⁵ Patent filing is a part of a broader corporate patent strategy and pursues the same common corporate goals. The aspect of searching, determining and negotiating is very important to stress in relation to further deliberated contract theory as this resembles contract term negotiations, compromising and reaching the final draft of a contract. Under the EPC, there is no duty to disclose any information relevant for patentability examination that a patentee knows at the time of filing. It is neither the requirement to undertake searches to verify patentee's position. Therefore a patentee's subjective position is usually only defined as a certain level of confidence as to how the application is drafted and how the invention is s drafted and how the invention is 'good' for a patent grant. Yet it will be revealed that although pharmaceutical companies have no such duty, many times that know and possess right information about their position which can easily turn to be advantageous in patent prosecution.

3.4. Pharmaceutical Sector Inquiry 2009 – Final Report

Getting back to the pharmaceutical sector inquiry in a more detailed manner, it is important to say that 7-year sector inquiry was triggered primarily by insufficient level of innovation¹⁰⁶ and cooling down of shift between original products and generics. In its continuous narrative about progress, the Commission was concerned about the ramifications of commercial and legal practices that proliferated in the industry over the

¹⁰³ Ibid, at 384.

¹⁰⁴ Ibid.

¹⁰⁵ Supra 87, at 360.

¹⁰⁶ Supra 39, at 241.

years. Yet the Commission from the very beginning acknowledged that patent protection has a huge bearing on the commercial success of a company¹⁰⁷ and that pharmaceutical companies are one of the most frequent filers of patent applications to support their businesses and further research development. This means that the EC is aware that patents are strategically used business instruments tailored for specific commercial goals and acknowledges their legitimacy and purpose.

Hereby, I try to briefly reconstruct the mosaic of main practices concerning pharmaceutical patents as presented by the Commissions's Final Report with the pieces of information that I consider most relevant. Using the reported data from the monitoring period I clarify some discomfoting patent filing strategies that the Final Report paid most attention to.

The Final Report worked with the sample of 219 active substances (some of them the best-selling drugs in Europe) covered by nearly 40,000 patents filed mostly with the EPO.¹⁰⁸ Importantly 87 percent of those patents involved secondary patents. Majority of the secondary patents claimed products (around 81 percent). Other patents involved at least one claim related to processes (38 percent) and first and second uses of pharmaceutical product (24 and 6 percent respectively).¹⁰⁹ A further breakdown of the product claims shows that the majority of them claimed formulation products (57 percent). Different physical forms (salts, hydrates, polymorphic forms) accounted for a further 13 percent of product claims.¹¹⁰

The Report also observed that the majority of the patent applications were filed during research phases¹¹¹ but also that patenting is a process continuing throughout the entire lifecycle of the product. It means that patent strategy is usually successive and many product features are protected at different times. In 50% of the filed patent applications, no decision had yet been reached by 2007, 17% of applications were granted a patent, 31% of applications were withdrawn and 2% were refused.¹¹² It is important to bear in mind these numbers; first the low of number of refusals and relatively low number of

¹⁰⁷ Supra 69, at 413.

¹⁰⁸ Supra 4, para 425.

¹⁰⁹ Ibid, para 429.

¹¹⁰ Ibid, para 430.

¹¹¹ Ibid, para 423.

¹¹² Ibid, para 436.

actual patents granted. On average 15 states (out of 38 signatories of the EPC and back then 27 EU MS) are designated for each patent application at the EPO, with France, UK and Germany being designated almost in all applications.¹¹³

The EC took under microscope *inter alia* following strategies:

- creating a so-called pre-launch patent portfolio when secondary patent applications were filed before the first launch of the product.¹¹⁴ Usually the first launch of the product followed the first application (covering new active substance) after 6 to 10 years.¹¹⁵
- extending exclusivity period after the patent term of the primary patent expires. This patent strategy aims at surging patent applications in the years immediately preceding the loss of exclusivity. The Commission could not find an explanation why this improvement is then suddenly discontinued immediately after the exclusivity is lost.¹¹⁶ Respondents to the survey suggested that the surge of application is result of continuous improvement and innovation of originator's products. However the general tendency was to file patent applications after the product is launched and in particular before and after the primary patent in the portfolio expired.¹¹⁷ The Commission acknowledged that this may be result of specificities of each product and company's launching strategy. It is therefore hard to deduce a universal justification for all patent portfolios in this regard as patent life-cycles differ from one to another.
- so-called trapping strategy which puts the generic companies into an inescapable position of infringement of one of multiple patents of the originator.¹¹⁸ Patent claims covering key intermediates for several routes or process claims turned up to be very suitable tool for this aim.
- filing for divisional patent applications. Divisionals have the same protection period and extent as the parent application but can prolong the examination period before the EPO. They can be either mandatory or voluntary. Voluntary

¹¹³ Ibid. para 418.

¹¹⁴ Ibid. para 446.

¹¹⁵ Ibid. para 448.

¹¹⁶ Ibid. para 453.

¹¹⁷ Ibid. para 451.

¹¹⁸ Ibid. paras 493 & 494.

applications are 3 times more frequent than those required by the EPO¹¹⁹ although only about 25 percent of originators reported to have filed for divisional applications. The number of divisionals derived from one parent application varied from 1 to 30 applications.¹²⁰ One of the reasons behind the practice is to differentiate between more commercially viable claims and other less commercially interesting claims. It is also the question of enforceability - narrower claims might be easier to defend in court. Nonetheless divisionals could lead to prolonged legal uncertainties and unpredictability of investments. It is often the case that examination of divisionals continues even after the parent application is withdrawn or revoked.¹²¹ Divisionals then serve merely as patent fencing, a defense patent tool. Sometimes they are taken out of a toolbox of market position enhancement tools and also used in offensive manner in assertive patent litigation or motions preliminary injunction. The patent position of a generic company regarding one molecule may then stay unclear for many years and the generic product kept effectively out of the market until final decision on patent validity is reached.

3.5. Weak and Strong Patents

Patents concerning new active substances are also referred to by the industry as 'primary patents' because they relate to the first patents for their medicinal products. They are usually constructed as the product patent or as process patents.

Second generation patents usually aim at protecting other features of the medicinal product than the active substance and they always follow the primary patent. The active substance alone is insufficient for proper functioning in human body and in the course of drug development, these other drug features are consequently discovered, determined, refined and tested. Most of the secondary patents encompass new

¹¹⁹ Ibid. para 433.

¹²⁰ Ibid. para 511.

¹²¹ Kjølbye L., Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?, 32 World Competition, Issue 2, 2009, at 167.

formulations, combinations and devices.¹²² Fewer involved polymorphs, salts, intermediates, second medical uses, product by process claims, hydrates, particles or solvates.¹²³ We talk about the incremental innovative steps. The EC in the Final Report acknowledges that secondary patents may rightfully indicate continuous incremental innovation which can be of significant importance for patients and consumer welfare.¹²⁴ At the same time it draws attention to their far side which is that numerous secondary patents (in granted or pending applications) gives rise to a crust, a defense tool, often denominated 'patent cluster'¹²⁵ that could have the opposite effect on consumer welfare. Patent clusters aim at two principal business targets: to keep generic companies far from reaching the market and to secure the position of the originator in long-term perspective overstretching the exclusivity period of the primary patent. It must be maintained that both generic and originator companies file for secondary patents.¹²⁶

Strong patents are synonym for enforceable patents. Strong patents have a strong stand before the court and the probability of winning in case of litigation or opposition is high when compared to weak patents. A company can secure a stronger position usually by conducting its own private search for prior publications for similar inventions before filing the application and verify its position.¹²⁷ Of course certain features of the invention might have been already disclosed. But any improvements that add significantly to the prior art could sustain any challenge by a potential competitor.¹²⁸

In its Final Report the Commission also uses the terms “*weak*” and “*strong*” patents but avows that term weak can be perceived as inaccurate when describing certain properties of patents because any patent can be challenged and invalidated. The 'weak' then stands for such a patent that is of higher probability to be invalidated on the basis that is highly probable to prove that novelty or inventive step requirements were not met. Sir Robin Jacob, a former judge of the High Court and the Court of Appeal of England and Wales, in his response to the EC's report argued that the patent grant was never intended to

¹²² Supra 4, table 21.

¹²³ Ibid, para 430.

¹²⁴ Ibid. para 485.

¹²⁵ Ibid. para 476.

¹²⁶ http://ec.europa.eu/competition/consultations/2009_pharma/european_patent_office.pdf (accessed on 16 January 2015).

¹²⁷ Knight H. J., Patent Strategy for Researchers and Research Managers, John Wiley & Sons, Ltd, 2013 at 96.

¹²⁸ Ibid, at 157.

stand as a confirmation of validity of the patent in question. Instead, the system is designed as a “*coarse filter that can reject clearly bad cases but has to allow those which may be good*”.¹²⁹ Some commentators go so far as asserting that patents are not even presumptively valid, if there is the immediate threat of its invalidation or revocation and law provides and foresees these mechanisms.¹³⁰

Also it cannot be concluded automatically, that the value of these additional patents is low however their value is definitely lower than of the primary patent. Generally low patent value means that all these additional features to a product (new active ingredient) that are covered by secondary patents, might be deemed unnecessary for the market place. However it is important to understand and upheld the value of incremental innovation as this can bring significant benefits to patients.

Nevertheless there is a growing number of voices criticizing the rising number of applications covering weak inventions. For example just between 2000 and 2007, the number of patent applications in organic chemistry rose by 61 percent for pharmaceutical sector.¹³¹ Some arguments address low examination standards by the EPO that are even more deteriorated by the influx of applications. The EPO does not verify the submissions provided by the applicant by any experiments and the search for prior art can be sometimes very difficult to perform.¹³² However one cannot forget that the EPO applies the same patentability requirements to all applications, irrespective if an application for primary or secondary patent is submitted. If the basic patent is published, the patentability of the subject-matter of a secondary patent will depend on the non-obviousness of the subject-matter with respect to the basic patent.¹³³ Non-obviousness is then determined by the predictability of result, unexpected benefits, problems that needed to be overcome and unexpected new findings of a secondary pharmaceutical invention.¹³⁴ Inventive step requirement must meet the usual standards

¹²⁹ Speech by the Rt. Hon. Sir Robin Jacob, Court of Appeal of England and Wales presented during public presentation of preliminary findings on 28 November 2008, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf>.

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¹³¹ Supra 4, para 420.

¹³² http://www.egagenerics.com/images/Website/IP_Barriers_web_Patent-related_Barriers.pdf (accessed on 16 January 2015).

¹³³ <http://webmail.egagenerics.com/gen-evergrn.htm> (accessed on 6 January 2015).

¹³⁴ http://www.icdd.com/ppxrd/10/presentations/PPXRD-10_Ann_Newman.pdf (accessed on 7 January 2015).

as well. Absent duty of disclosure examination after all only depends on how successful the examiner is viability of each patent application.

The EGA, a fierce critic of the current patenting strategies of original pharmaceutical companies, states on its website that in the 1980s the list of a drug's properties eligible for patenting was relatively limited. They included primary uses, processes and intermediates, bulk forms, simple formulations and composition of matter.¹³⁵ However 1990s added to the possibility of extensive patent claiming. Now, additional aspects of a single drug molecule can be covered by patents such as new medical uses, methods of treatment, mechanisms of action, packaging, delivery profiles, dosing regimens, dosing routes and ranges, combinations, screening methods, chemistry methods, biological targets and fields of use.¹³⁶ Others include crystalline forms, metabolites, new salts, esters etc. According the EGA many of these patented inventions are merely properties inherent to the drug, lack any novelty and fail to meet the substantive patentability requirements but can be turned into follow-on patents. The characteristics purportedly invented are inherent characteristics of the drug in question and are result of very standard experimental techniques. More precise and quantitative analysis is required in order to fully understand reasons and consequences of extensiveness of patent claiming nonetheless it is compelling to suggest that it can lead to deteriorating patent quality and mislead the examiner. In any case the EC's Final Report also suggests that the pharmaceutical companies are aware of the weakness of their patents and the fact that they did not have viable claims.¹³⁷ Grubb concurs however limits his criticism of patent evergreening.¹³⁸ According to Grubb there is no reason why a genuine invention such as a new crystal form that increases the stability or a new formulation that improves bioavailability of a drug should not be protected by patents.¹³⁹ But when companies e.g. file for later patents on metabolites this is something what cannot be justified on any reasonable interpretation of patent law. "*A much better approach is to apply inventive*

¹³⁵ Supra 133.

¹³⁶ Ibid.

¹³⁷ Supra 4, para 503.

¹³⁸ Supra 69, at 428.

¹³⁹ Ibid.

*step requirements strictly during examination. If a novel LCM invention has unexpected advantages it should be patentable, if not patent should be denied.”*¹⁴⁰

One of the propositions that have been made on how to improve the *status quo* of the current patent system in the EC’s report was to rise bar of patent examination.¹⁴¹ Sir Jacob however acutely notices that with regard to the current numbers of patent applications it is hardly imaginable, also in the view of the ever-rising importance of Chinese prior art. Pharmaceuticals still account for a relatively small portion of the total number of applications (as of 2013, 5396 applications were filed in this field out of almost 150.000) and patent office cannot apply different examination standards in this field, simply because the existence of weak patents is not exclusive to pharmaceuticals but appear throughout other industry sectors as well.¹⁴² Raising the bar of substantive examination would then mean an enormous increase in costs and time.

The EGA asserts that the problem also lies in the fact that it is difficult for the examiner to raise novelty objections and that the examiner many times lacks confidence to reject patent applications. For the examiner, it is unlikely to find information and prior art as no one will be looking at the drug in the light of the basic patent.¹⁴³ The EGA further states that examiners are not well equipped for the assessment of inventive step because often they are not aware of common general knowledge and do not possess practical experience.¹⁴⁴ For this reason third party observations should be given more credit and not be merely ignored. Current practice is that following publication of the European patent application under Article. 93 EPC, any person may present observations concerning the patentability of the invention. Third party observations are expected to point out and effectively catch errors in many patent applications. Lack of novelty and inventive step are the most common objections raised by third parties. How efficient the practice is, needs yet to be answered. The EPO maintains that third party observations are already taken fully into account however it does not notify third parties about the

¹⁴⁰ Ibid.

¹⁴¹ Supra 129.

¹⁴² Ibid.

¹⁴³ Supra 133.

¹⁴⁴ Ibid.

result of their observations.¹⁴⁵ One of the solutions seems to be to introduce pre-grant opposition although this can again represent major drawbacks for the applicant, increase the costs incurred and in total slow down patent granting.¹⁴⁶

The EGA is aware that the rising number of patent applications already exerts enormous pressure on time and productivity of patent examiners. The EGA sees again behind these number originator companies' attempts to 'invent' new problems and to get around the problem-solution test with artificial non-existing problems.¹⁴⁷ The EGA criticizes that no comprehensive data about prior art or common general knowledge are required and that data with no statistical basis are accepted. The EGA suggests that "*patentees should be required to disclose full details about the experimental conditions and results which are very important for enabling assessment.*"¹⁴⁸ Judge Jacob on the contrary argues that it is hardly to foresee this requirement at reasonable cost and what this requirement would in practice entail (cross-examination of patent attorney, disclosure of legal advice, etc.).¹⁴⁹ Nevertheless from a comparative perspective the suggestion does not look so farfetched as it is a fundamental requirement of patent filing before the USPTO in the US and as such will be discussed below.

Moreover, the EGA is concerned with lengthy opposition procedures before the EPO. According to the EGA, it can take 18 months to obtain grant from filing application, however up to 4 years to obtain revocation before the first instance and if the case go under appeal, it takes another 3 years before the final decision is reached.¹⁵⁰ The legal uncertainty around one patent can last up to 9 years. Time taken in the opposition procedures has a great importance not only for generic companies which seek to establish legal certainty and clear up the path to the market entry but from broad perspective mainly for patients whose life is dependent on availability of affordable medicines. This is a widely acknowledged problem of the EPO and requires further investigation by public authorities. True is that dilatory practices exists on both sides –

¹⁴⁵ http://ec.europa.eu/competition/consultations/2009_pharma/european_patent_office.pdf (accessed on 15 January 2015).

¹⁴⁶ Supra 129.

¹⁴⁷ Supra 133

¹⁴⁸ Ibid.

¹⁴⁹ Supra 129.

¹⁵⁰ Supra 133.

generic and originator companies.¹⁵¹ According to the Final Report opposition procedures before the EPO concerned 73 distinct INN^s.¹⁵² 170 opposition procedures were identified in 7 years. Average duration of an opposition procedure is 3.6 years. In majority of the cases it took more than two years to render the decision and the EC's findings concur that can take up to 9 years in total (in 3 percent of cases).¹⁵³ With regard to the duration some generic companies rely on national courts to render the decision more quickly.¹⁵⁴ More INN^s were concerned by litigation than by opposition procedures. The Report observes that generic companies oppose predominantly secondary patents (97 percent) and opposition procedures in pharmaceutical industry are more frequent than in all other sectors taken together.¹⁵⁵ The patents were revoked in almost two thirds of the cases where final decision was reached which tells a lot about the legitimacy of claims in majority of the cases at least on statistical basis. The number could indicate that doubts about patent merits are many times justified.

Albeit A much better approach is to apply inventive step requirements strictly during examination. If a novel life cycle management invention has unexpected advantages it should be patentable, if not patent should be denied invalidation or revocation of patent should stay the primary remedies to fixing patent system, helping to prevent overprotection and clearing the field for a just market entry, sometimes it cannot be done in a reasonable time frame and one cannot wonder that the slowness of the system discourages companies to engage. Moreover current patent system does not provide any remedies to fraudulent or deceptive conduct of a patentee who can abuse patent system with numerous unmeritorious applications and artificially prolong patent protection around a single product.

¹⁵¹ Supra 145.

¹⁵² Supra 4, para 673.

¹⁵³ Ibid, para 683.

¹⁵⁴ Ibid para 685.

¹⁵⁵ Ibid para 693.

3.6. Antitrust Case Law and Patent Filing Strategies

Two cases have been so far investigated by the EC with regard to companies conduct in patent and SCP filing. One ended under appeal at the CJEU.

A. *AstraZeneca* case.¹⁵⁶ The Case concerned the AZ's drug called Losec. AZ committed various abuses in relation to two distinct regulatory systems: patent system and SPC protection and national marketing authorizations. Hereby, only the first abuse is being considered.

Losec was protected by a number of patent applications. Secondary formulation patents were filed as well. AZ obtained marketing authorization for around 17 indications for various versions of Losec. Approaching the patents' expiry, AZ feared that Losec sales would suffer from entry of generic substitutes for H2 blockers. In 1993 and 1994, AZ submitted applications to a number of national patent offices within the EEA in order to obtain SPCs.¹⁵⁷

AZ's abuse of dominance consisted in the provision of misleading information to national patent offices in order to obtain SPCs for longer periods than it would have obtained in the absence of this information and to obtain SPCs which the patent offices would not even have granted in the absence of the information.¹⁵⁸ AZ's patent department used the data in a very deceptive and selective manner in its final instructions to patent attorneys.¹⁵⁹ AZ's final instructions for the omezaprazole applications were drafted in highly misleading form and made reference to incorrect marketing authorization dates. According to the EC this strategy was highly successful, did not constitute normal business behavior and led to considerably longer duration of SPCs protection. AZ's defense was based on proclamations that it based its SPC applications on a *bona fide* and reasonable interpretation of the regulation.¹⁶⁰ It denied any deliberate misrepresentations and

¹⁵⁶ Commission Decision of 15 June 2005, COMP/A.37.507 - AstraZeneca.

¹⁵⁷ Ibid, para 143.

¹⁵⁸ Ibid, para 629.

¹⁵⁹ Ibid, para 628.

¹⁶⁰ Ibid, para 605.

concealment in relation to patent agents and patent offices.¹⁶¹ Technical authorization numbers were an unintended leftover of a previous draft of the application.¹⁶² AZ denied that it deliberately misled patent offices also because certain general uncertainties existed at the time of second round applications given the complexities of the amendments to the SCP Regulation.¹⁶³ The Commission considered AZ's practices unlawful regardless their effects on the market. The Commission did not find the defense persuasive and fined AZ with fine of EUR 60 million.

- B. *AstraZeneca* case under appeal. The CFI and subsequently the CJEU upheld the EC's decision.

The CFI held that “*the fact relied upon by the applicant that the concept of abuse of dominant position is an objective concept and implies no intention to cause harm does not lead to the conclusion that the invention to resort to practices falling outside the scope of the competition on the merits is in all events irrelevant, since that intention can still be taken into account to support the conclusion that the undertaking concerned abused a dominant position, even if that conclusion should primarily be based on an objective finding that the abusive conduct actually took place.*”¹⁶⁴

The CJEU tailored and supported the rhetoric in the current antitrust paradigms in more delicate way. First, the Court asserted that given the complexity of pharmaceutical regulatory environment (pricing and reimbursement mechanisms), it tends to make the market definitions narrower.¹⁶⁵ In the appeal the definition of relevant product market was challenged. In defining the relevant market the Court considered following: greater drug efficacy, differentiated therapeutic use (more severe conditions v mild or less serious forms), trend of asymmetrical substitution, price indicators and a body of relevant data that was sufficient to substantiate the

¹⁶¹ Ibid, para 606.

¹⁶² Ibid, para 609.

¹⁶³ Ibid, para 614.

¹⁶⁴ *AstraZeneca AB v Commission* Case T-321/05 (2010) ECR II-2805 para 359.

¹⁶⁵ Judgment of the Court (First Chamber) of 6 December 2012, *AstraZeneca AB and AstraZeneca plc v European Commission*. Case C-457/10 P.

conclusions that other medicines did not constitute a significant competitive constraint on the product in question during a certain period.

The Court asserted that a strong IP portfolio is a decisive factor in establishing dominant position.¹⁶⁶ It perceived the abuse of dominant position in provision of highly misleading information coupled with the aim of leading public authorities to error. The Court considered the overall strategy as well as the company's intention as decisive for establishing abusive practice.¹⁶⁷

C. *Boehringer/Almirall* case.¹⁶⁸ In the case, no formal decision had been reached and the Commission closed the investigation with seeking for remedies. Case started when Almirall submitted a complaint to the Commission. Almirall accused Boehringer of filing 'unmeritorious patents' as those identified in the Commission's Final Report. Although no official document has been released by the Commission, many of the facts of the case come out from English High Court's decision in a dispute concerning Almirall's challenge of Boehringer's patents.¹⁶⁹ Boehringer filed three patent applications in relation to various combinations of Aclidinium, an anticholinergic used in treatment of chronic pulmonary obstructive disease. Betamimetics are another class of drugs commonly used to treat the disease. In severe cases, both drugs are used in combination.

At a conference in Seattle in 2003, Almirall presented posters displaying its clinical experience with Aclidinium and one of the Boehringer's scientists leaked several photographs of those posters to his management.¹⁷⁰ Three months later, Boehringer filed the patent applications in relation to various combinations of Aclidinium. The applications stated that there was an "unexpectedly beneficial therapeutic effect" observed.¹⁷¹ The applications did not provide any information about the beneficial therapeutic effect.

¹⁶⁶ Podszun R., Can competition law repair patent law and administrative procedures? *AstraZeneca*. *Common Market Law Review* 51, 2014, at 285.

¹⁶⁷ *Ibid.*

¹⁶⁸ http://ec.europa.eu/competition/antitrust/cases/dec_docs/39246/39246_1582_3.pdf (accessed on 28 January 2015).

¹⁶⁹ <http://www.crowell.com/files/European-commission-enforcement-in-the-pharmaceutical-sector-CPI-antitrust-chronicle.pdf> (accessed on 18 January 2015).

¹⁷⁰ *Ibid.*

¹⁷¹ *Ibid.*

Nonetheless patents were granted despite the fact that the use of combination therapies was at the time not only part of general knowledge but it was already well-known and recommended therapeutic practice. Without adding the words “unexpectedly beneficial therapeutic effect” the patents would not have been granted. The English judge found that the statement was false and the company did not observe anything relevant or close the claimed unexpectedly beneficial. The UK patent was revoked.¹⁷²

As a result of the Commission’s investigation of this case, the Commission mediated patent settlement between the companies with the antitrust rules. The blocking positions were removed, pending litigation stopped and licenses granted for two countries outside of the EU.¹⁷³ According to the press release “*settlement between the parties is the most efficient and speedy way to ensure that consumers will be able to benefit from Almirall's product*”.

AstraZeneca brought some lessons in respect to obligations which a dominant company should bear. A dominant company might arguably be obliged to disclose the interpretation of legal provisions upon which it relies when applying for IP rights, to detail the “counterfactual” in the event that its interpretation of the law is incorrect.¹⁷⁴ Further, a dominant company should notify patent offices if it finds out that its submissions were made on inaccurate and misleading basis. The Court states in this regard: “*in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility not to impair, by methods falling outside the scope of competition on the merits, genuine undistorted competition ... requires it, at the very least, to inform the public authorities of this so as [to] enable them to rectify those irregularities*”. The Court then specifies these obligations with a qualitative sign of a “*manifest lack of transparency*”. It is not required that the conduct will actually harm competition. A potentially anticompetitive effect propagated by the conduct is sufficient

¹⁷² Ibid.

¹⁷³ http://europa.eu/rapid/press-release_IP-11-842_en.htm?locale=en (accessed on 15 January 2015).

¹⁷⁴

<http://www.mondaq.com/x/222774/Antitrust+Competition/Lessons+In+Losec+The+Astrazeneca+Dominance+Decision> (accessed on 6 January 2015).

to prove the violation.¹⁷⁵ Podszun observes that “*competition law shows its traditional power as the field of law that serves as a 'repair service' for other fields of economic law.*”¹⁷⁶ The case is even strong if one realizes that the internal remedial mechanisms are either not functioning properly, are ignored by private parties or are not present in a particular field. Dominant companies should be able to successfully defend themselves against challenges of abuse by demonstrating that there is an objective justification for their behavior.¹⁷⁷

In the recent *Almirall/Boehringer*, the Commission stepped down and considered efficiencies of the settlement and again upheld consumer welfare rationale. The case could have been the first warning case and first practical result of the EC’s investigation and its Final Report expressing concerns about patent filing strategies at number of instances. Still, as in *AstraZeneca* any future case would require a strong policy justification laying out principles in which the competition law is grounded. Nevertheless, for now the EC sent a clear signal that is prepared not to tolerate the unprecedented legal opportunism in patent system.

3.7.Contract Theory and Fairness in Patent Law

Patent scholarship usually draws on two theories to justify and reason patent grants - contract and reward theory. Reward theory is close to the reward justification of data and market exclusivity as seen before. My attention here turns to the contract theory which through the notion of contractual fairness creates the zip between patent and competition law.

Patents are understood as hypothetical contract between the inventor and the government or society resulting in *quid pro quo* of innovation for exclusivity.¹⁷⁸ In contract theory, two things come to the fore: existence of consideration on both sides of

¹⁷⁵ Supra 39, at 299.

¹⁷⁶ Supra 166, at 167.

¹⁷⁷ http://ec.europa.eu/competition/international/multilateral/2005_june_merits.pdf (accessed on 6 January 2015).

¹⁷⁸ Ghosh S., Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred, Berkeley Technology Law Journal, Vol 19:1315, 2004, at 1316.

the contract (the inventor and the state) and the equal position of the parties. The consideration is faced rather squarely: disclosure of the invention is traded for limited exclusive market protection. Typical features of a contract can be identified: a general logic of a contract dictates that two considerations of certain amount and certain quality, of the same or similar value and of different utility for the contractors are exchanged as this provides for the strong incentive to engage in such a contract. The duration of exclusive rights must be at least as long as the duration of secret if no contract has been concluded.¹⁷⁹ The contract does not require disclosure *per se*; it requires disclosure in specific mode that ensures so-called enablement of the invention. Enablement is the patent teaching, it is the description of how to make and how to use the invention disclosed in the application by a person skilled in particular art. Such consideration involves a promise that the invention must be able to be performed and have the promised benefits as stipulated in the patent application. The term consideration also resonates in an alternative way as the toil the inventor must exert in order to create an invention.¹⁸⁰ If no effort has been exerted simply because the inventor took something what existed in the world before, no award is given. Each party enters the contract with certain expectations and certain level of confidence with regard to the value, quantity and quality of considerations that is assessed by each party. The same applies for an individual inventor and his patent attorney: the contract (patent grant) is negotiated or as we say the patent application is prosecuted before the patent office. This encompasses the interaction between the patent applicant, his representatives and the patent examiner, drafting the first application, tailoring its claims (terms), negotiating the terms facing prior art search and substantive examination and finally the patent grant (contract closure). Here for example Lord Hoffman in *Kirin-Amgen* case decided by House of Lords noticed that “*the claims must be construed in a way which attempts so far as it is possible in an imperfect world, not to disappoint the reasonable expectations of either side.*”¹⁸¹ The state has a reasonable expectation to conclude a contract that will raise general public knowledge and teach the society about a useful and novel invention. These expectations are incorporated in the patentability requirements. The inventor’s

¹⁷⁹ Denicolo V., Franzoni L. A., The Contract Theory of Patents, *International Review of Law and Economics* 23, 2006, at 367.

¹⁸⁰ *Supra* 178, at 1320.

¹⁸¹ *Kirin-Amgen Inc v. Hoechst Marion Roussel Ltd*, House of Lords HL, [2004] UKHL 46, para 47.

reasonable expectation is to be paid off with exclusive proprietary rights that can be enforced. It is however interesting to notice, that the government does not guarantee the enforceability of the consideration before court. The one who contributes to the greater enforceability of the contract is foremost the inventor and patent attorney.

Some commentators argue that the contract theory does not serve as an adequate description of the patent grants because the terms of such contract are renegotiated absent consent of the parties and changes circumstances. Specifically patent law allows the grant to be renegotiated and reinterpreted in opposition procedures or infringement cases.¹⁸² Seeing the contract theory more broadly as a social contract, one must reject this argument and support the view that invalidation and revocation challenges brought by third parties should be the first remedies at place for an invalid contract between society and the inventor. Social contract theory also leaves space open for secondary competition oversight and looks for additional guarantees for contracting parties in case the contract is abused because the notion of 'social' enables to encompass contractors and consumers in one turn.

To proceed further, one cannot forget that the contract for European patents is negotiated and concluded at the EPO, an international organization, but also that after the patent grant, patents pursue their own life as national patents and as of 2015 no such instrument as unitary patent exists. It is therefore difficult to substantiate unifying contract theory and contractual principles that would appeal to European patent in general. In any case there are fundamental contractual principles with wide-European support and as one of such universally applicable principles, principle of contractual fairness should be upheld.

In this regard some guidance is provided by the Research Group on the Existing EC Private Law on the EC Private law in its effort to formulate principles of EC contract law recognized the duty to act in accordance with good faith applies especially in pre-contractual dealings. From a contract law perspective one may argue that the commercial fairness rules could also be understood as a concretization of the duty to act in accordance with good faith in pre-contractual dealings. So the interdependence between contract law rules and the provisions regarding commercial fairness is

¹⁸² Supra 178, at 1340.

especially obvious in the field of information requirements since both fields of law oblige a business, under certain circumstances to provide information.¹⁸³ The Research Group formulated *inter alia* the following principles with the purpose to enforce the standards of fairness and reasonableness in pre-contractual dealings:

Article 2:101 Good faith: In pre-contractual dealings, parties must act in accordance with good faith. The requirement of good faith in Community law is however not limited to pre-contractual dealings. An alternative could have been to include a general rule on good faith.¹⁸⁴

Article 2:201: Duty to inform about goods or services: Before the conclusion of a contract, a party has a duty to give to the other party such information concerning the goods or services to be provided as the other party can reasonably expect, taking into account the standards of quality and performance which would be normal under the circumstances. Supplier of goods and services is in possession of information about the quality and performance of those goods or services, disclosure of which can be reasonably expected by the other party. It requires disclosure of information which is relevant in assessing the quality and performance that can be expected should be given.

Commentators generally distinguish two types of fairness in contracts: substantive fairness dictates the distribution of obligations and rights under the contract, and procedural fairness that refers to the process of obtaining the result and outcome of the contract.¹⁸⁵ Duress, fraud and abuse of circumstances are generally accepted grounds for avoiding contract and granting relief.¹⁸⁶ Other commentators refer to fairness in contracts as to the adequacy in exchange, i.e. equal split of the surplus under the contract.¹⁸⁷ Under the common law doctrine of 'inequality of bargaining power', the unfairness of the contract figures as result of this inequality between contracting

¹⁸³ Research Group on the Existing EC Private Law, Contract I. Pre-contractual Obligations, Conclusion of Contract, Unfair Terms, Sellier European Law Publishers, 2007, at 62.

¹⁸⁴ Both the ECJ and the CFI have recognized the principle of good faith and concretized in many cases its content particularly the prohibition of abusive exercise of a right (C-367/96 – Kefalas, para 20 and C-373/97 – Diamantis para 22).

¹⁸⁵ Smith S. A., Future Freedom and Freedom of Contract, Modern Law Review, Vol. 59 Issue 2, 1996.

¹⁸⁶ Akman P., The Concept of Abuse in EU Competition Law: Law and Economic Approaches, Hart Publishing, 2012 at 166.

¹⁸⁷ Ibid, at 160.

parties.¹⁸⁸ Power (dominance) is usually described as the ability to influence the bargain of the contract and achieve the preferred outcome. Notionally, we can say that the second party 'exploits' the first party under such bargaining terms or abuses the contract. Melzer and Tégel understand the fairness as obligation to take into account legitimate interests of parties involved in contract.¹⁸⁹ Concept of fairness however does not entail that the performances exchanged are of equal value.¹⁹⁰ On the other side, the state, as the second contractual party must look its own interest when entering the contract. The state usually secures this aspect by thorough patent examination.

Specifically in patent theory, the contractual obligation of fairness should be deployed in the process of communication and instructions to the patent attorney, communication with the patent office and finally information provided in the patent application. In terms of obliged subjects, fairness in patenting should be of course understood broadly, encompassing not only dominant undertakings but all applicants filing for a patent. It is though true as Judge Jacob argued such duties have been never formally part of the European patent law. Level of confidence about a patent application varies significantly, intent of the applicant is irrelevant for the examination and on the top of that misleading and fraudulent conduct has never been prosecuted. At some occasions patent law tries to prevent unmeritorious applications when requiring submission of certain data, though the data are never verified. However, we if we try to understand patent grants on the basis of the contract theory, fairness as a basic principle comes up implicitly from the fact that patent grant equals bargain. Patent law operates through legal doctrine, not administrative means.¹⁹¹ Taken together with competition law, it is the prohibition of misuse of dominant position that draws the boundaries and delineates fair behavior in patent law.¹⁹² To put this in concise terms here I suggest to take for inspiration the US patent law. For the purposes of contract theory of patent grant fairness specifically entails:

- the duty of disclosure

¹⁸⁸ *Ibid.*, at 162.

¹⁸⁹ Tégel P., Melzer F., *Občanský zákoník Velký komentář § 1-117 -- Svazek I. § 1-117 Obecná ustanovení*, Leges 2013.

¹⁹⁰ *Supra* 186, at 160.

¹⁹¹ *Infra* 236, at 2

¹⁹² *Ibid.*

- the duty of candor and good faith.

Again if we understand competition law as a 'guardian of time' for the entire competition framework and patent law as meritorious and time limited exemption to this framework, then the logical outcome within this policy is competition law that responds to “deviations” but mostly non-compliance with the requirements of merited and time-limited exemption. This would of course only apply to dominant undertakings that are susceptible to distort competition on common market and are under special obligation to act under this principle. In the next section we will particularly discuss how fairness as principle is dealt with in the US patent legislation.

3.8. The US Perspective

The theory in the transatlantic comparative perspective of patent systems mirrors itself as duty of disclosure, candor and good faith in US patent law.

In the US each person who is substantially associated with the preparation and prosecution of the application has a duty to disclose to the USPTO all information known to that individual to be material to patentability as defined.¹⁹³ The persons that are obliged under this duty include the inventors, the practitioner, and any other person substantively involved in the patent application. The duty exists with respect to every pending patent claim. However breaching the duty affects all the claims, not just the particular claims in which the inequitable conduct is directly connected.¹⁹⁴ Breach of the duty to disclose is one of several bases for the finding of inequitable conduct resulting in the unenforceability of a patent.¹⁹⁵

Information is material to patentability if it a) establishes a *prima facie* case of unpatentability or 2) refutes or is inconsistent with the applicant's position in prosecution.¹⁹⁶ The material is not limited to prior art; it embraces all possible public

¹⁹³ Bucknell D., *Pharmaceutical, Biotechnology and Chemical Inventions*. World Protection and Exploration, Vol. I Oxford University Press 2011, at 405.

¹⁹⁴ <http://www.uspto.gov/web/offices/pac/mpep/s2016.html> (accessed on 17 January 2015).

¹⁹⁵ *Ibid.*

¹⁹⁶ <http://www.uspto.gov/web/offices/pac/mpep/s2001.html#d0e195810> (accessed on 17 January 2015),

uses of the invention, prior sales, or offers to sell the claimed invention, public knowledge, inventorship conflicts and similar issues.¹⁹⁷

There is a continuing obligation to inform the USPTO of relevant information as it becomes known. The PTO's Manual of Patent Examining Procedure describes that information that should be disclosed entails:

- Material information learned from co-workers, trade shows, communications from or with competitors, potential infringers, or third parties;
- Material information relating to or from co-pending US applications;
- Material information from litigation related to the subject matter of the patent application, including evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of fraud, inequitable conduct, and violation of duty of disclosure, or any assertion that is made during litigation which is contradictory to assertions made to the examiner; and
- Where the claims are copied or substantially copied from a patent, the identity of patents and the number of the patent claims.

Inequitable conduct occurs when there has been a breach of duty. Conduct is considered inequitable if misrepresentation or omission by an applicant of a material fact with the intent to deceive the USPTO is present.¹⁹⁸ Inequitable conduct is broader than common law fraud.¹⁹⁹ Two elements must be present to support a finding of inequitable conduct: the undisclosed, misrepresented or omitted fact must be material and the act alleged to constitute inequitable conduct must be done with intent to deceive.²⁰⁰ Hence the innocent mistake, albeit material will preclude a finding of inequitable conduct. The party alleging inequitable conduct bears the burden to prove each and every element by clear and convincing evidence.

In Europe however there is no legal requirement in the EPC to provide information to the EPO. As a consequence there is no sanction for inequitable conduct or fraud before

¹⁹⁷ Supra 193.

¹⁹⁸ Ibid, at 802.

¹⁹⁹ Ibid, at 807.

²⁰⁰ Supra 198.

the EPO²⁰¹ and when the systematic remedies fail, under patent law there is no tool left to prosecute anticompetitive abuse that lead to grave competition endangerments. In the next chapter, how principle of fairness and contract theory can provide a better justification of competition law scrutiny of patent law related practices.

IV. Patent Filings and Patent Settlements under Competition Scrutiny: Comparative Perspective

4.1. Patent Infringement

Generic companies usually start their preparation for market entry with careful marketing and legal analysis. They scan the patent landscape (including SPCs) and verify their position with regard to data and market exclusivity for the purposes of marketing authorization. After identifying the right commercially viable molecule (product) that can be marketed, generic companies buy a 'ready-to-use' dossier, usually from other company than the originator (subcontractor, producer, etc.) with full description of the product. This serves as a basis for drug development, bioequivalence studies and finally for marketing authorization.

After the data exclusivity is lost, when the patent protection and the additional market exclusivity are still ongoing, generic companies file their applications for marketing authorization. If a legal uncertainty concerning patent position around a medicinal product persists, generic companies can try to challenge a patent and clear the patent landscape before making their entry. In case of patent revocation or invalidation actions, generic companies search for prior art that could anticipate or render the patented invention obvious or not novel. With these actions they can proceed before the EPO or a national court. In the drug development stage, substantive defenses to infringement are crucial for generic companies to prepare for market entry. Namely prior secret use, experimental use and use in clinical trials, the so-called Bolar exemption, and

²⁰¹ Ibid, at 407.

exhaustion of rights apply as defenses to patent infringement.²⁰² Nevertheless generic companies can only hardly be ever sure if the field is completely and effectively cleared prior their entry. Pharmaceutical infringement cases aim to establish whether generic version of a drug copied its essential characteristics such as active pharmaceutical ingredients, salts, processes of making drug or drug formulations. In pharmaceutical sector it is usually easier to establish that patent was infringed²⁰³ than in other sectors. Common procedural defenses to such claims are either declaration of non-infringement or invalidity action.

Patent gives its holder right to exclude others from making, selling, using and importing the invention protected by patents. Some commentators argue that because the right needs to be enforced in court, it is more accurate to talk about “*right to try to exclude others*”.²⁰⁴ Alleged infringer usually finds himself charged with infringement if the infringing acts fall within the extent of patent claims i.e. within the technical scope of the invention. Infringement occurs when each and every limitation of the asserted claim is present in the accused product, either literally or equivalently.²⁰⁵ Infringing acts however vary across the MS to some extent. Some countries remedy only literal infringement of the invention, in which structure and functions of the claimed invention are identically copied, some provide remedies also to other types of infringement including so-called servile reproduction (where the claimed product or process is reproduced identically in terms of form and structure), minor variants of execution (where essential means of the patent are reproduced) or partial infringement (not all the elements of a claim must be practiced by an infringer).²⁰⁶

Any protection given to an individual inventor must constitute a solid and effective shield for his rights otherwise it would fall behind its target. For the reason of effectiveness and ultimately speed of protection, interim injunctions can be granted. They oblige generic companies to stay provisionally out of the market, withdraw the

²⁰² Bucknell D., *Pharmaceutical, Biotechnology and Chemical Inventions*. World Protection and Exploration, Vol. II, Oxford University Press 2011, at 3.

²⁰³ *Supra* 69, at 423.

²⁰⁴ Lemley M., Shapiro C., *Probabilistic Patents*, John M. Olin Program in Law and Economics Working Paper No. 288, August 2004, Draft 14 July 2004, at 2.

²⁰⁵ Steifl A., *Doctrine of Equivalence and the European Patent Convention*, CASRIP Publication Series: Rethinking Int'l Intellectual Property No. 6, 2000, at 116.

²⁰⁶ *Supra* 202, at 1018 & 1019.

products already marketed or stop any production or distribution of a product. Sometimes courts assess patentees' rights only *prima facie* and grant interim injunctions almost automatically. Delays of market entry of several years may occur. Directive 2004/48/EC on the enforcement of intellectual property rights²⁰⁷ was introduced with the aim to harmonize enforcement standards at the EU level and ensure a highly equivalent and homogeneous level of protection of intellectual property rights. The Final Report found that interim injunctions were granted on average for a period of 18 months²⁰⁸ and companies reported 255 requests for interim relief out of which 112 (42 percent) were granted.²⁰⁹ The Commission was particularly concerned about preliminary relief taken together with other tools of strategic patenting that have potential to substantially impede generic competition.

The Final Report identified that the number of disputes and contacts between pharmaceutical companies reported in the period 2000-2007 was 1337 and concerned 80 INN's out of 217 INN's investigated (roughly 37 percent). 10 most disputed INN's (5 percent of total) accounted for approximately 59 percent of all contacts and disputes between originator and generic companies. 457 disputes were examined in the Final Report. 91 percent of them were brought up by originator companies. In 74 percent of disputes, the originator companies claimed patent infringement. In the remaining 9 percent of disputes initiated by generic companies, generic companies brought 15 invalidity claims and 3 claims of combined invalidity with non-infringement.²¹⁰ Primary patents were the object of disputes between originator and generic companies in over half (53%) of all disputes reported whilst the remaining 47% of all disputes involved secondary patents.²¹¹ The data reveal that original pharmaceutical companies assert almost equally primary and secondary patents and are much more likely to initiate a dispute than generic companies. Generic companies launch at risk of infringement rather than attempt to clear the field. The EC's sector inquiry indicated that "*in nearly half of disputes, the generic company decided not to launch its product prior to the*

²⁰⁷ Directive 2004/48/EC on the enforcement of intellectual property rights of the European Parliament and of the Council of 29 April 2004 (OJ L 195/16 of 2 June 2004).

²⁰⁸ *Supra* 4, para 645.

²⁰⁹ *Ibid*, para 641.

²¹⁰ *Ibid*, para 564.

²¹¹ *Ibid*, para 570.

expiry of the originator company's patent".²¹² Originator companies however do not assert all claims that they hold against generic companies in a dispute.

The 'internal' remedial actions that the patent system primarily operates with are private party actions which follow private parties' interests (economic, financial, research, etc.). Specifically, weak patents can be revoked before a patent office, invalidated before a court, a declaration of non-infringement can be sought or *vice versa* an infringement action can be brought. In the previous chapter we critically assessed time frameworks and resulting costs of opposition procedure. Further analysis is required to understand if the rectifying mechanisms to the patent system as envisaged by the legislator fulfill their purpose or fall behind their target to safeguard merited innovation in the ever growing and complex system in which length of litigation varies significantly across the EU and the shattered procedural system provides for growing uncertainties. With regard to competition law, it is important to emphasize that the General Court did not consider the existence of these remedies as a sufficient argument for non-establishing abuse under Article 102.²¹³ The consideration is of more importance once we realize how difficult and time-consuming it can be to clear the field absent a unified patent judiciary and with regard to the number of applications surrounding one pharmaceutical product.

In the previous chapter we have discussed that shaping a patent application and maneuvering in patent prosecution is a usual practice in all industries. We have also acknowledged that swinging level of confidence about one's patent application is an inherent characteristic of patent filing. Problem arises when the patentee does not genuinely rely on its substantive patent rights but rather looks for procedural entitlements and privileges linked to the effective enforcement of its exclusionary position. With regard to the length and time of patent dispute resolutions in Europe, where usually faster litigation means more costly litigation, and where multiple patents in a patent thicket must be litigated in number of MS in order to clear the way, it may be practically more advantageous for generic companies to drop any court challenge and to settle on more favorable terms. In *Lundbeck* the EC maintained that patent litigation is an expression of competition.²¹⁴ If these mechanisms do not effectively rectify the

²¹² Ibid, para 571.

²¹³ Supra 166, para 366.

²¹⁴ Infra 258, para 625.

system, the system is then more prompt to abuse and if the premise that patent law works within the framework of competition law rules is upheld, then competition law is the only tool how to preserve common grounding principles.

4.2. Monitoring of Patent Settlements

Since its Final Report from 2009, the Commission concentrated its effort exclusively on monitoring of patent settlements. Five reports have been published since then. Here, I provide an overview of the most recent findings by the EC.

The Commission considers patent settlements to be a legitimate method of settling down various disputes, litigation or opposition proceedings concerning original or generic products. In terms of cost and time or probabilities of winning and losing, it may be more advantageous for parties to settle at specific terms and bring the disagreement to an end. Generic companies maintained they are unable to afford litigation costs which they always balance against their day-to-day business operations. For generic companies the most important consideration is given to the expected costs versus avoided costs of litigation and impact made on personnel costs together with inherent uncertainty involved in the patent litigation.²¹⁵ On the other hand when an originator decides about the settlement, it looks at the strength of its standing in the case, market size and revenue for the product, expected and avoided costs, uncertainty involved in patent litigation and the expected duration of litigation (listed in order of importance).²¹⁶ For originator companies, it is also the number of potential generic companies coming to the market that is important for the decision to settle or not.

Having in mind consumer welfare perspective, such instances when generic companies despite being aware of patent weakness simply do not have interest in challenging the patent are very troublesome. They maintain weak patents valid and do not clear the field to market entry for cheaper generic products. Although in *Boehringer/Almirall*, the EC considered the settlement to be a more favorable outcome than private litigation, one must articulate that in the case all disputed patents were withdrawn on the basis of the

²¹⁵ Supra 4, para 738.

²¹⁶ Ibid, para 735.

settlement. Yet not all patent settlements concluded between pharmaceutical companies are directly endangering competition. We will see that several plausible tests apply to assessment of patent settlements anticompetitive nature.

The EC categorizes patent dispute settlements as following:

- a) Settlements without limitation of generic market entry;
- b) Settlements limiting generic entry but without value transfer from originator to generic company;
- c) Settlements limiting generic market entry showing a certain value from originator to generic company.²¹⁷

Limitation of generic entry can be executed e.g. by explicit clause stating that a generic company recognizes the validity of originator's patents and refrains from entering the market until the patents have expired.²¹⁸ As for the value transfer requirement, value transfer can take different forms. It can be concluded as a direct monetary transfer (payment), as an early entry clause or a license.²¹⁹ Distribution agreements or side-deals are also considered to be value transfer. A license provided to a generic company also does not preclude limitation of generic entry in particular if the licensor provides an inducement for the licensee (financially or otherwise) to accept more restrictive settlement terms than would otherwise have been put at place based on the quality of licensed technology.²²⁰

According to the Final Report, one third of initiated litigation cases resulted in patent settlements. 38 percent of closed cases ended up with settlements that involved a value transfer from originator to the generic company and/or enabled early entry.²²¹ However also opposite cases occurred with value transfer from a generic to an originator. They accounted for 10 percent of all cases. 53 percent of investigated originator companies

²¹⁷ 5th Report on the Monitoring of Patent Settlements, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report5_en.pdf (accessed on 26 January 2015).

²¹⁸ Supra 4, para

²¹⁹ Supra 217, para 46.

²²⁰ 4th Report on the Monitoring of Patent Settlements, para 4, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf (accessed on 26 January 2015).

²²¹ Supra 4, para 653.

and 44 percent of generic companies concluded patent settlements. Settlements concluded by 5 originator companies accounted for nearly two thirds of all patent settlements. The data reveal that patent settlements are a usual practice in pharmaceutical industry. Few companies are more prone to settle which could indicate fogging of other practices behind settling. The newest 5th report uncovered that the number of concluded patent settlements is steadily rising since the beginning of the monitoring.²²² The Commission underlines that around 92 percent of patent settlements fall into category of *prima facie* no need of competition law scrutiny. The number of investigated settlements that involved a value transfer from an original company dropped to 8 percent from the previous monitoring.²²³ 45 percent of the investigated patent settlements did not limit the market entry at all.²²⁴

It will be interesting to further investigate what lies behind this drop: a sheer discipline of pharmaceutical companies after they have been warned at several occasions that patent settlements in category 3) will not be disregarded by the EC, improving quality of patent applications which puts originators at stronger position or if this is not the case, a corresponding increase in patent litigation and opposition procedures that do not end in settlements?

4.3.Examples of originator – generic correspondence and a typical non-problematic patent settlement

Patent settlements which involved a value transfer and delayed generic market entry were labeled problematic and critical from the competition law standpoint. Usually such patent settlements were concluded as a result of certain actions taken by generic companies in the course of its preparation for market entry (legal, administrative, commercial). According to the Final Report the originator companies are getting regularly into the contact with marketing authorization bodies and notify the potential infringement of their patent rights. However Community rules on the marketing authorization of generics are not by any means related to the patent position of the

²²² Supra 217, para 23.

²²³ Ibid, para 45.

²²⁴ Ibid, para 30.

generic.²²⁵ Yet filing for marketing authorization by a generic company can be a first point of contact of the tectonic plates that triggers the earthquake of disputes or worse patent litigations. Original pharmaceutical companies usually get alert and caution generic companies that their patent standing is firm and that they do not hesitate to proceed further with legal or other action to assert their rights under patent grants. This can be part of so-called 'threat letter' tactics and could have a strong dissuasive effect on generic company's preparations for market entry.

Following are the excerpts from anonymized common warning letters received by generic companies after they undertook an action in preparation for market entry:

- It recently comes to the Company A's attention that Company B obtained a marketing authorization in one of the EU countries. Company A considers any launch by Company B of such a product in the EU country as potentially infringing the intellectual property rights.
- Company A notes that a marketing authorization has been granted in a number of EU countries for a generic product *XY*. For Company A it falls from this that from a regulatory standpoint Company B is in a position to market product *XY* in the relevant European territories. Company A is concerned that Company B intends to market and sell, or otherwise exploit its products containing compound *XY*. In the view of the above Company A informs Company B that their patents and corresponding SPCs are enforceable and will serve to prevent any form of marketing of generic *XY* in the corresponding European territories. Company A therefore requests that within 14 days of the date of this letter Company B provides an unambiguous binding written assurance that it will not commercialize a generic *XY* where patents and SPCs granted on these patents remain in force or authorize, aid, abet, counsel or procure other persons to engage in any of the acts described. If Company B fails to provide the undertaking by the date specified or if, having given the undertakings, Company B fails to comply with them, Company A and its subsidiaries reserve their rights to take whatever action they consider necessary to protect their rights through the courts.

²²⁵ Supra 4, para 863.

Another scenario involves a letter of this kind:

- Company B must be aware of the fact that *XY* as a chemical compound *per se* and its non-toxic salts are protected in EU countries by the SPC and the patent which already expired in 2014. Company A's attention was directed upon to the fact that as of certain date, the product *XY* received a marketing authorization and the Company B is the holder of this authorization. Company B is requested to inform Company A simultaneously with the expectable request for reimbursement, to be filed with the national authority, on the date of its planned market entry. Alternatively, if this request for reimbursement was filed, the Company B should send Company A letter of agreement that Company A is entitled to request file inspection at the authority in respect of this date.

Usually, a settlement without any consideration takes the following form:

- The Defendant agrees not to seek damages or compensation against the Plaintiff in relation to any of the court proceedings, in particular in relation to the ordered preliminary injunction.
- The Plaintiff agrees not to seek damages, reinstatement of the previous state of affairs, recovery of unjustified enrichment and/or compensation for any harm based on its right to the patent.
- The parties agree to bear their own costs and expenses incurred in connection with this dispute.

From another patent settlement that responded to a filed arbitration procedure due to a marketing authorization in possession of the defendant for the generic medicine, an agreement can be reached in succinct manner:

- The Defendant warrants and undertakes not to market, manufacture, keep in store, import, hold, use, promote or place on the market a medicinal drug in which *XY* is the active substance while European Patent and corresponding SCP remain in force.

- The Defendant may transfer or assign the marketing authorizations to any company or companies having a mutual or reciprocal shareholding, control or dominant group relationship with the Defendant.
- The Defendant also warrants and undertakes not to transfer or assign to any third party or parties the marketing authorizations.
- The Plaintiff also undertakes to immediately withdraw the arbitration action that has been filed against the Defendant.

To complete the review, these are excerpts from another settlement this time falling into the category of problematic ones currently investigated by the EC:

- Company B undertakes during the term of this agreement not to make, dispose of, offer to dispose of, use or, import or keep for disposal or otherwise the product XY which Company A alleges to infringe its rights and, to enable Company A to ascertain if there may be an infringement, during the term to provide Company A with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in the infringement litigation.
- During the term of this agreement, Company B shall maintain all licenses and marketing authorization and may not dispose of such licenses or marketing authorizations neither as sale, license or in any other way.
- Company A shall grant Company B a compensation for the consent injunction of USD XX million.
- On payment of compensation Company A shall obtain delivery of Company B's current stock of XY consisting of approximately 1 million tablets which shall comply with the marketing authorization granted by the public authorities, at cost price being USD XX.
- In consideration of Company B not seeking a cross undertaking in damages in respect of the period, Company A shall provide Company B with a total of USD XX million.
- In the event that the final unappealable, enforceable court decision in the infringement litigation rules that Company B does not or has not infringed

Company A's rights the compensation granted by Company A shall constitute full and final compensation from Company A.

To conclude, a general patent and launch strategy followed by generic companies vis-à-vis the pressure exercised by originators could be to:

- Launch at risk of litigation.
- Try to invalidate patent or seek a declaration of non-infringement in legal proceedings prior to launch.
- Oppose the patent before national patent bodies or the EPO, revoke the patent or request narrower scope.
- Try to reach an agreement and accept to be blocked in some countries until some patents are still valid. No consideration is involved in the agreement.
- Try to reach an agreement and accept not to launch while the basic patent and the secondary patents are in force and e.g. keep door open to discuss non-infringement of e.g. process patents at a later stage. Consideration may be involved.

In negotiating patent settlements, two possible outcomes for market entry arise:

- Patent settlements stipulating that a generic product cannot enter the market before a specific date but not later than the patent term expires;
- Patent settlements stipulating that a generic product is allowed to enter the market after the patent term expires or on a later date.

To test the anticompetitive nature of an agreement on the basis of the scope of the patent in question is however only one of the possible options for competition scrutiny. In reality, competition law scrutiny can take into account other arrangements in patent settlements as demonstrated and finally deliberations about patent validity can play a cardinal role in such assessments.

4.4. The European Competition Law – Anticompetitive Practices and Abuse of Dominance

The prohibition of abuse of dominant position is based on Article 102 TFEU that provides that any abuse by one or more undertakings of a dominant position within the internal market shall be prohibited as incompatible with the internal market in so far as it may affect trade between MS. The demonstrative list of such practices includes:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

It must be stressed that the list of abusive practices is not exhaustive. Such conduct which results in lessening or deteriorating competitive environment is prohibited and deemed illicit and the company is subjected to financial penalty or any directions that may bring the infringement to the end. A company of dominant position is regarded as company having significant market power, a major market player that is able to squeeze market competition (in terms of number of players) and edge it away (eliminate or halt their operation). The test in competitive analysis whether a company is dominant is just a one part of the puzzle. Equally important is to determine whether it is abusing its dominant position and how it is doing so. In *British Airways* the CFI held that *“for the purposes of establishing an infringement of Art.82 EC, it is not necessary to demonstrate that the abuse in question had a concrete effect on the markets concerned. It is sufficient in that respect to demonstrate that the abusive conduct . . . tends to restrict competition, or in other words, that the conduct is capable of having, or likely*

to have, such an effect’’.²²⁶ The relevant product market within a certain geographical area must be judged in its complexity and totality as a market comprising all interchangeable and substitutable products or services in terms of their characteristics, price and their intended use.²²⁷

Article 102 applies both to exclusionary and exploitative practices.²²⁸ Exclusionary and exploitative practices are not mutually exclusive types of abuse; they can appear simultaneously in one conduct.²²⁹ Such dominant undertaking’s behavior directly prejudices the interests of consumers.²³⁰ Dominant undertaking is under a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market.²³¹ In *Hoffman La Roche* the Court also held that: “*The concept of abuse is an objective concept relating to the behavior of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of competition still existing in the market or the growth of that competition*”.²³² Abuse of dominance is an objective concept – it does not imply any fault and does not depend on the undertaking’s subjective intent to exclude competitors or weaken competition.²³³

In assessment of anticompetitive patent settlements concluded between pharmaceutical companies the Commission relied heavily on Article 101. Agreements breaching this provision are automatically considered void. The article provides that all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between MS and which have as their object or effect

²²⁶ Judgment of the Court of First Instance (First Chamber) of 17 December 2003, *British Airways plc v Commission of the European Communities*, T-219/99, para 293.

²²⁷ Judgment of the Court of First Instance (Fifth Chamber) of 9 September 2009, *Clearstream Banking AG and Clearstream International SA v. Commission of the European Communities*, T-301/04, para 3.

²²⁸ Alison J., Sufrin B., *EC Competition Law*, 4th Edition, Oxford University Press, 2010, at 363.

²²⁹ *Ibid*, at 364.

²³⁰ *Ibid*, at 363.

²³¹ Akman P., *Exploitative Abuse in Article 82EC: Back to Basics?*, CCP Working Paper 09-1, at 4.

²³² Judgment of the Court of 13 February 1979, *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, C-85/76, para 91.

²³³ *Supra* 228, at 386.

the prevention, restriction or distortion of competition within the common market are prohibited as incompatible with the common market, and in particular those which:

- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
- (b) limit or control production, markets, technical development, or investment;
- (c) share markets or sources of supply;
- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

In competition law analysis such agreements are scrutinized in order to determine, whether they have for their object or effect restriction on competition. Article 101 may not be applicable in case the agreement in question provides substantial benefits, allows consumer a fair share of the benefit, does not contain any indispensable restrictions and does not limit competition on substantial part of the market. If the object of the agreement restricts competition violation of Article 101 is proved, the actual anticompetitive effects are not considered. An assessment must be made not only in the content of the provisions of the agreement, but the goals it seeks to achieve and in a broader context of economic and legal realities. As for the intent, *“the parties’ intention is not a necessary factor in determining whether an agreement is restrictive, there is nothing prohibiting the competition authorities, the national courts or the Courts of the European Union from taking that factor into account...”*²³⁴

The Commission is granted the investigative powers to enforce European legislation in this regard. It has ample powers of investigation, namely is allowed to conduct sector inquiries, if evidence suggests that competition may be being restricted or distorted within the common market, to request from undertakings and associations of undertakings to provide any information it needs to carry out its duties assigned, to take

²³⁴ Judgment of the Court (First Chamber) of 14 March 2013. Allianz Hungária Biztosító Zrt. and Others v Gazdasági Versenyhivatal, C-32/11, paras 35 to 38.

statements and to conduct inspections (more specifically to enter the premises, land and means of transport of undertakings and associations of undertakings, to examine the books and other records related to the business and to seal them, to take copies of or extracts from such books or records).²³⁵ So far the EC investigated 12 undertakings as a result of the abuse of their dominance position and abuses of dominant position are much less investigated than concerted practices.

As it was stressed before, patents represent an exception from free competition, an exception that must be justified and merited and this filter is controlled by patent law. Current views in antitrust consider intellectual property charitably, recognizing that although intellectual property rights to exclude might lead to antitrust violations, they are generally no more likely to do so than any other property right and must be evaluated on a case-by-case basis.²³⁶ The monopoly created by patent rights possesses inherently following traits:

- 1) The monopoly is effectively granted for the period of 20 years;
- 2) The monopoly entails significant barriers to entry;
- 3) The monopoly can be lawfully exercised within the scope of patent claims;
- 4) The monopoly is limited geographically;
- 5) The purpose of the monopoly is to exclude competition in order to reap monopolistic gains;
- 6) The monopoly entails exploitation of exclusionary position in particular market segment in order to eliminate competition to secure presupposition 4).

One must think of these enhanced monopolies as already restricted in several ways: restricted in duration, restricted in scope and restricted geographically. Competition law controls if these restrictions are observed by companies. It should also observe a company's behavior at the entry and at the exit of patent system and control the time a company spends within the patent law playfield. However competition law only applies if the conditions laid down in Articles 101 and 102 are met. This produces an interesting conflict of two objective systems that are not effect-based. If one wants to resolve the

²³⁵ http://europa.eu/legislation_summaries/competition/firms/126092_en.htm (accessed on 16 January 2015).

²³⁶ Dam K. W., The Economic Underpinning of Patent Law, Coase-Sandor Institute for Law & Economics Working Paper No.19; 1993.

tension and make sure that one system is not relativize under the second system, a common thread must be found. As we will see competition law attempted to get around this conflict by scrutinizing patent settlements as 'classic' agreements between undertakings. Patent law can be softened by contract theory and by implicit obligations which operate with intent and good faith but at the second turn it is harden again by restriction by object concept in competition law scrutiny. In the next part, it will be discussed how this approach is successful in solving conflict of objective – objective system and if fairness as common thread does not offer more reconciling approach.

4.5. Turning Back to Fairness

Several social, economic and political objectives have been pursued under Articles 101 and 102 TFEU. In the Commission's competition policy it is above all consumer welfare.²³⁷ Other objectives include fairness, single market enhancement, promotion of efficient use of resources and freedom of economic activity.²³⁸ Padilla distinguishes three categories of competition policy goals:

- Fairness goals – include fairness, protection of economic freedom, the standard protection of rivalry and the competitive process and protection of small and medium-sized firms;
- Welfare and efficiency goals;
- Market integration goals.²³⁹

In terms of welfare and efficiency goals competition policy seeks to enhance production of better goods for cheaper prices that would satisfy consumer demands and needs in more satisfactory way. The Commission reiterated several times that the aim of its competition policies is not to defend competitors but to safeguard competition and here two types of competition can be targeted: substitution competition of products of better

²³⁷ <http://www.oecd.org/daf/competition/2486329.pdf> (accessed on 28 January 2015).

²³⁸ Ibid.

²³⁹ Padilla A. J., From Fairness to Welfare: Implications of the Assessment of the Unilateral Conduct under EC Competition Law, available at <http://www.eui.eu/Documents/RSCAS/Research/Competition/2007ws/200709-COMPed-Padilla-Ahlborn.pdf> (accessed on 28 January 2015).

properties, higher cost-effectivity ratio and increased efficiency on one hand, and price competition of decreased production costs, increased availability and again higher cost-effectivity ratio on the other hand.

The intrusion of the competition law in patent law is relatively new and needs a steady and comprehensive justification in the EC's policy making. Putting the objective of consumer welfare alone is insufficient in this regard giving the specificities of patent law principles as presented in previous chapters. Kjølbye writes that "*there is no convincing consumer welfare case for intervening against secondary patents to facilitate generic entry.*"²⁴⁰ The justification for abusive patent strategies prosecution must find the right approach to balance interests protected by competition law without demolishing basic patent law principles.

I assert that the most important goal pursued by the Commission in its competition policy with regard to patent law abuse should be protection and enhancement of procedural fairness. Specifically in patent filing related cases, procedural fairness should be understood in line with contract theory and contractual fairness as presented above. Also complying with requirement of fairness in patent filing must suffice as a baseline justifying competition on the merits. Gerla understands that "*competition on the merits means that firms must compete through the intrinsic qualities of their products rather than through extraneous conditions such as tying an inferior product to a more desirable product, or bribing dealers to promote one product at the expense of competitors' products. Innovation and improvement of product quality are virtually the only methods for competing on the merits.*"²⁴¹ Further the transition from fairness to consumer welfare could be instinctive in problematic patent-related cases and as a consequence both principles are coupled and mutually enhancing. "*In some situations it may be necessary to protect competitors in order to protect competition as a way of enhancing welfare.*"²⁴² Although Akman observes that the concept of fairness in European competition law has developed rather haphazardly and is not entirely clarified

²⁴⁰ Supra 121, at 184

²⁴¹ Gerla H. S., Competition Policy – A Sound Industrial Policy for Antitrust Law, 36 U. Fla. L. Rev. 553 (1984).

²⁴² Supra 228, at 17.

neither by the Commission's case law nor by the CJEU judgments under appeal²⁴³ one can simply say it is a policy which seeks to protect competitors and market structure and puts fair competition before free competition.²⁴⁴ Fairness in competition law establishes what makes conduct fair and what does not. In patent law related dealings the principle is wide enough to subsume patentee-patent office dealings (inventor-state contracts) as fairness diverges towards several actors - competitors, partners or both horizontally and vertically.²⁴⁵

To substantiate the content of fairness under the Commission's and the CFI's jurisdiction following examples may provide good guidance. As for now, the European institutions only applied fairness in 'standard' contractual dealings and the concept of fairness was strongly avoided in *AstraZeneca* by the EC. For example in *SABAM*, the Court maintained that fairness is about balancing the rights and obligations of trading parties.²⁴⁶ *Tetra Pak II* involved contract clauses going beyond the recognized right of a dominant undertaking to protect its commercial interests which was deemed unfair.²⁴⁷ In *Michelin II*, the Court implies that fairness requires transparency, objectivity, certainty and limited discretion and abuse may consist of exclusionary conduct that lacks objective economic justification.²⁴⁸ In *AKZO Nobel Chemicals*, the Commission emphasizes that a dominant firm is entitled to compete on merits.²⁴⁹ Finally in *ITT Promedia*²⁵⁰ the CFI held that an abuse may have the form of bringing legal action. Moreover the conception of fairness is planted directly in the Article 102 TFEU which bans conduct that consists in “*directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions*”. These examples show that contracts and

²⁴³ Akman P., *The Concept of Abuse in EU Competition Law: Law and Economic Approaches*, Hart publishing, 2012, at 146.

²⁴⁴ *Supra* 242.

²⁴⁵ *Supra* 228, at 149.

²⁴⁶ *Ibid* at 154.

²⁴⁷ *Ibid* at 155.

²⁴⁸ Padilla, J. A., *From Fairness to Welfare: Implications for the Assessment of Unilateral Conduct under the EC Competition Law*, at 17 available at <http://www.eui.eu/Documents/RSCAS/Research/Competition/2007ws/200709-COMPed-Padilla-Ahlborn.pdf> (accessed 28 January 2015).

²⁴⁹ Judgment of the Court (Fifth Chamber) of 3 July 1991. - *AKZO Chemie BV v Commission of the European Communities*, Case C-62/86., para 81.

²⁵⁰ Judgment of the Court of First Instance (Fourth Chamber, extended composition) of 17 July 1998. *ITT Promedia NV v Commission of the European Communities* T-111/96.

contractual dealings were scrutinized many times by the European institutions and found justification for punishment within the concept of competition on the merits.

Principle of fairness and concept of merited exclusionary position comes particularly strong and practical in patent strategies scrutiny. If we however operate with different view that competition law has no saying in practices on patent playfield, we must also admit that patent law does not dispose of any means to rectify abuses within the patent system that can have significant impact on competition and lead to its distortion and those which it has at its disposal can many times fail because of the system itself. In the US antitrust practice, acquiring and maintenance of monopoly through anticompetitive conduct of misleading patent filing lead to company's antitrust liability.²⁵¹ The US practice asserted that the undertaking's "*willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident*" must be proved.²⁵²

4.6. Antitrust Case Law and Patent Settlements

Four cases involving a patent settlement between pharmaceutical companies have been so far investigated by the EC. Hereby, I provide an overview of the cases and deduce the indicative aims and considerations of the Commission's policy with regard to problematic patent settlements.

- A. *Lundbeck* case.²⁵³ Lundbeck held several patents on the product citalopram, an antidepressant drug, and its manufacturing process. In 2002, the patent term for the citalopram came to the end. Citalopram was Lundbeck's blockbuster drug and at the time accounted for 80 percent of Lundbeck's²⁵⁴. Several generic companies were preparing for market entry although the process patents were still in force. Lundbeck initiated patent litigation and alleged the generic

²⁵¹ Leslie C. R., Antitrust, Inequitable Conduct, and the Intent to Deceive Patent Office, UC Irvine Law Review, Vol 1:2, 2011, available at <http://www.law.uci.edu/lawreview/Vol1No2Articles/Leslie.pdf> (accessed on 29 January 2015).

²⁵² Ibid, at 331.

²⁵³ Infra 258.

²⁵⁴ <http://www.independent.co.uk/life-style/health-and-families/health-news/nhs-pays-millions-of-pounds-more-than-it-needs-to-for-drugs-2365615.html> (accessed on 15 January 2015).

companies of infringing its process patents. As a result four settlement agreements were concluded between 2002 and 2003. Lundbeck paid lump sum payments to generic companies and agreed to purchase the stocks of the drug them. Moreover Lundbeck offered these companies guaranteed profits in a distribution agreement²⁵⁵.

The EC started the investigation on the basis of potential violation of Articles 101 and 102²⁵⁶ however the later decision relied on infringement of 101(1). It is interesting to remark that the EC abandoned the charges under Article 102 and focused exclusively on the prohibition of anticompetitive agreements.

The EC ruled that such agreements were presumptively illegal (anticompetitive by object) and imposed a fine on Lundbeck and generic companies involved in the agreements. In *Lundbeck*, the Commission treated the payment from the originator as a *prima facie* indication of the patent weakness (unenforceability).²⁵⁷ The process patents were still valid at the time and one cannot rule out that they could not have been enforced in court. Yet, the Commission seemed to presume that because of the originator's reluctance to engage in confrontational litigation, it is not confident about its position and tries to quench the potential loss of market share. In absence of the single European patent jurisdiction such an *en bloc* rule may be indeed viewed somewhat too resolute. Today, every patent in the bundle of European patents must be litigated separately and each court may find the infringement and validity differently. It is interesting to ask what would be the Commission's position after subsequent court's finding of non-infringement or confirmed patent validity.

Lundbeck appealed the Commission's decision in September 2013 and the case is now being decided by the General Court. Following main points have been raised in the action:

- The EC wrongly concluded that Lundbeck and under parties to the agreement were actual competitors;
- Wrongful application of the principles on restriction by object;

²⁵⁵ http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en (accessed on 15 January 2015).

²⁵⁶ http://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_319_8.pdf (accessed on 15 January 2015).

²⁵⁷ *Infra* 263, at 2.

- The EC erroneously concluded that their intended scope went beyond the scope of Lundbeck's patent rights;
- The EC failed to carry out a proper examination of the efficiencies arising from the agreements, and
- The EC errs and lacks reasoning in dismissing the 'scope-of-the-patent test' as the relevant standard for the competition law assessment of patent settlement agreements under article 101(1) TFEU.²⁵⁸

B. Johnson & Johnson Case.²⁵⁹ It involved another recent breach of Article 101 TFEU. Johnson & Johnson's (J&J) patent protection for fentanyl (painkiller) expired in 2005 in the Netherlands. Sandoz (subsidiary generic company of Novartis) was preparing to enter the market with a generic substitute (according to the Commission's findings Sandoz was already preparing packaging for the product). This came into J&J's attention and as a result a settlement was concluded that took a form of a co-promotion agreement. However, the EC found that the agreement was not designed as a co-promotion agreement rather it was designed to impede entry of generics to the market. Interestingly, the case differs from the concept of reverse payment settlement because the relevant patent was already expired and no infringement was faced.²⁶⁰ The EC reached this decision on following basis:

- a) No other co-promotion partners were considered;
- b) Sandoz did not take part in any promotional activity;
- c) Sandoz received payments for these services and they exceeded those which Sandoz might have been expecting to receive after the generic's launch in Netherlands.

²⁵⁸ Commission Decision of 19 June 2013, Case T-472/13, Lundbeck v Commission, 2013 O.J. (C 235) 76,

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=144427&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=362634>.

²⁵⁹ Commission Decision of 10 December 2013. Case COMP/AT.39685 – Fentanyl.

²⁶⁰ Di Tomaso E., Reverse Payment Settlements under Competition Law, LLM International Business Law 2013/2014, Tilburg University, at 22.

The EC concluded that interests of patients and effective distribution of the public money for the reimbursement of medicals were affected by the settlement.²⁶¹ The agreement was concluded in detriment to patients and taxpayers (consumer welfare objective).²⁶² The EC reached this conclusion also after investigation of internal documents of both companies where wording such as dividing up the "cake" and keeping "the current price high" were used.²⁶³ The Commission made again clear that paying a competitor to stay out of the market would be not tolerated.

- C. *Servier* case.²⁶⁴ In *Servier* the Commission has recently imposed fine of almost EUR 500 million on Servier as the originator and five other producers of generic drugs. Although the decision is not yet publically available (as of December 2014), nevertheless the EC's press release provides some key issues that have been dealt with.

Servier's patent for the perindopril molecule expired in 2003. Generic competitors continued to face a number of secondary patents relating to processes and form but these provided a more limited protection. Generic companies tried to find their way around with patent free technology however Servier made an acquisition of the most advanced technology and edged the competitors out of the market. Servier however avowed that it was never intended to be put to use and served only as defense mechanisms. After that generic companies tried to challenge Servier's patents, Servier settled with all of them.

Absence of competition was traded for participation on Servier's profits. This included direct cash payments from Servier to generics which amounted to tens of millions of euro. In one case, a license for 7 national markets was offered; in return, the generic company agreed to "sacrifice" all other EU markets and "stop

²⁶¹

[http://qr.jur.lu.se/Quickplace/jaen41/Main.nsf/0/DF5FBF23913CCE96C1257C98004D91F0/\\$file/Patryk%20Wymyslowski.pdf](http://qr.jur.lu.se/Quickplace/jaen41/Main.nsf/0/DF5FBF23913CCE96C1257C98004D91F0/$file/Patryk%20Wymyslowski.pdf) (accessed on 11 January 2015).

²⁶² europa.eu/rapid/press-release_IP-13-1233_en.htm (accessed on 11 January 2015).

²⁶³ Zafar O., Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 'Pay-For-Delay' Decisions. *Journal of European Competition Law & Practice*, Vol. 5, Issue 4, 2014, p. 207-208.

²⁶⁴ Commission Decision of 9 July 2014. Case COMP/AT.39612 – Perindipril (Servier).

efforts to launch its perindopril there".²⁶⁵ The EC concluded that technology of promising competition was thus shut down. According to the Commission Servier's behavior violated EU antitrust rules and amounted to the abuse of a dominant market position (Article 102 TFEU). Each of the settlements was also an anti-competitive agreement prohibited by Article 101 TFEU.

Contrary to Lundbeck, in Servier the EC found violations of both Articles 101 and 102 TFEU. In the press release the Commission explained that Servier was fined for violation of Article 102 TFEU because it pursued 'abusive strategies'. Although it recognizes that to enforce patents, transfer technologies and to settle litigation are all legitimate tools in competition, Servier's conduct was close to so-called patent non-assertive entities.

- D. *Cephalon/Teva* case.²⁶⁶ Another pharmaceutical case involved settlement between two pharmaceutical companies Cephalon and Teva in 2005. It is under investigation. Details are still unknown and there is no legal deadline to complete inquiries into anticompetitive conduct.²⁶⁷ Their duration depends on a number of factors, including the complexity of each case, the extent to which the undertakings concerned co-operate with the Commission and the exercise of the rights of defense.²⁶⁸ Cephalon has subsequently been acquired by Teva, and the merger cleared by the Commission under the EU Merger Regulation.

From a competition standpoint, public interest plays on both hands: first, there is a public interest in immediate market entry of a competitor once a product is off the patent and the prices should fall (price competition). Secondly, there is a public interest to remove invalid patent as an unjustifiable barrier to entry and innovation (product competition). The Commission follows a straightforward reasoning: patent settlements are a legitimate way to settle a dispute and to find a mutually acceptable compromise to a *bona fide* disagreement.²⁶⁹ The notion of *bona fide* is critical in final assessment of the EC's policies. We saw that violations of Articles 101 and 102 are construed as objective conducts. Although in *AstraZeneca* the company's intent was taken into consideration,

²⁶⁵ http://europa.eu/rapid/press-release_IP-14-799_en.htm (accessed on 17 January 2015).

²⁶⁶ COMP/AT 39686 – Cephalon. Case was opened on 19 April 2011.

²⁶⁷ http://europa.eu/rapid/press-release_IP-11-511_en.htm (accessed on 17 January 2015).

²⁶⁸ Ibid.

²⁶⁹ http://ec.europa.eu/competition/consultations/2013_technology_transfer/ipla_lsew_en.pdf (accessed on 31 January 2015).

officially it served merely as a supportive argument. It would be interesting to see how the EC's justification would have evolved absent its deliberations about company's intent but this is rather improbable to see in any future Commission's decision related to patent filing or other dealing with administrative bodies.

Curiously, the Commission's position is that when considerations are contained in the settlement, the disputed patent is presumptively of lower strength and thus likely unenforceable. Anticompetitiveness of such agreements seems to be evaluated only in terms of presumable patent strength as its key determinant²⁷⁰, and lacks the analysis if the settlement terms fall within the scope of patent term. This is also one of the main points of Lundbeck's appeal. One may argue that knowing about the patent weakness is not in compliance with principles of fairness, good faith and candor and so far it goes against competition on the merits based on true innovativeness and substantiated by patentability requirements. To assess a company's intent is indeed one of the most difficult exercises in competition law scrutiny. In my opinion it is therefore why the Commission relies on external indicators and intervenes only when rectifying mechanisms of patent system clearly fail. *Almirall/Boehringer* could have been the first case in which the Commission has stroked instantly after inequitable patent filing occurred. It is also for this reason why the EC never clearly upheld the fairness standard and why it has a hard time to link in with patent filing strategies.

Several possibilities are being offered in how to add to accuracy patent strength evaluation for the competition law purposes. For example the EC could use the power to investigate the internal documents of the company. In *AstraZeneca* we saw that also the handwritten instructions to the patent attorney were of relevance for establishing antitrust violations. From external factors multiple challenges of a patent and multiple points of contact can also be an indication of its potential weakness. Preliminary ruling and refusal to grant an interim injunction in one of the MS can be also indication of relative patent unenforceability. Various analytical reports may help to assess the likelihood of generic entry to a certain date. It is also worth to notice, originator

²⁷⁰ <http://www.bristows.com/assets/documents/JECLP%20-%20Lundbeck%20and%20Johnson%20%20Johnson%20and%20Novartis.pdf> (accessed on 16 January 2015).

companies may have strong incentives to settle despite strong patent rights on the side of the originator.²⁷¹

In the light of the above-mentioned it is also interesting to consider if the conduct of a pharmaceutical company resulting in patent settlements should not be scrutinized after all as abuse of dominance position rather than as a prohibited agreement under the Article 101. The argument goes in line with the Commission's reasoning in *AstraZeneca* case. The Commission held that "*pattern of misleading representations began well before the acquisition of SPCs. Therefore AZ's conduct can be hardly described as belonging to the subject-matter of the rights, in the question.*"²⁷² Making false statements and misrepresentations cannot be viewed as part of the bundle of rights granted by the patent office. It is indeed right to enter into a patent settlement that makes belongs to patentee's rights. If however such agreement is tackled as an agreement anticompetitive by object, then the anticompetitiveness began long before the settlement in question was concluded. By conclusion the very acquisition of a right may amount to an abuse if the agreements are assessed on the basis of patent strength. Under this conclusion legal standard for assessment of patent settlements must take account of lack of uniformity of European patent enforcement and absence of unified patent court.

4.7. The US Perspective

As we could observe, strategic use of patent rights can also take form of strategic patent settlements resulting from a patent dispute. So-called reverse payment settlements challenge the usual arrangements in patent settlements that presuppose the infringer pays damages the patentee and sometimes agrees on licensing terms. Important is also to consider on what basis these unusual arrangements are made and if there was no a previous conduct wrapped inside the agreement.

Problematic reverse payment settlements were recently handled under close watch in the United States. The practice of the US settlement cases is also studied and cited

²⁷¹ Clancy M. J., Geradin D., Lazerow A., *Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law*, 2013, at 9.

²⁷² *Supra* 156, para 742.

directly in the EC's report and is of interest for the EC's antitrust policies. The US courts offered three tests under which patent settlement could be reviewed:

- Illegal *per se* or invalid under Sherman Act; in the EU violation by object;
- 'Scope of patent test' requires that antitrust analysis is performed with regard to the scope of the exclusionary capacity of a patent, the extent to which the agreement has exceeded that scope and the resulting anticompetitive effects.²⁷³ Under the test, the courts frequently concluded that if the settlement did not reach out the patent terms (i.e. its exclusionary scope determined by territory, period of protection and extent of claims), it did not violate antitrust laws.²⁷⁴ Any conduct within this scope is considered to be a lawful exercise of patentee's rights.
- 'Rule of reason' test.²⁷⁵ In *Actavis Inc. v Federal Trade Commission* the US Supreme Court²⁷⁶ held that reverse payment settlements should be analyzed on case by case basis and refused the argumentation that they are presumptively illegal. Quick look approach is insufficient for patent settlements scrutiny under competition law.²⁷⁷ Therefore reverse payment settlement should be assessed by the rule of reason test which leaves significant space to lower courts to consider which settlements should be held illegal and which are permissible. Addanki and Butler notice that the burden in the antitrust inquiry may be much lower than many commentators have suggested when the judge has acquired considerable knowledge of the merits of the underlying patent.²⁷⁸ *“A judge in that position has more than enough information about the underlying patent suit to have an informed judgment of the strength of the patent, certainly enough to be able to judge [...] whether a given settlement of that suit is likely to benefit*

²⁷³ Di Tomaso E., Reverse Payment Settlements under Competition Law, LL? International Business Law 2013/2014, Tilburg University, at 7.

²⁷⁴ Carrier A. M., Why the scope of the patent test cannot solve the drug patent settlement problem, 6 Stan. Tech. L. Rev. 1 (2012), at 1.

²⁷⁵ Supra 271, p. 6.

²⁷⁶ Supra 281.

²⁷⁷ Supra 271, p. 12.

²⁷⁸ Addanki S., Butler H. N., Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements, George Mason Law & Economics Research Paper No. 13-49, 2013, at 11.

consumers.”²⁷⁹ Marth and McFarlane²⁸⁰ summarize potentially dangerous features or red flags in patent settlements as following:

1) Large consideration paid from the originator to the generic company. For the purposes of antitrust enforcement, any form of consideration, a direct monetary or indirect non-monetary (license, distribution or supply agreement) could be regarded as consideration. According to the US Supreme Court “*an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival*”²⁸¹. The Court however did not specify how large the consideration should be in order to label or indicate the settlement as anticompetitive.

2) Significant delay to generic entry is a specifically negotiated restraint with significant potential to harm competition.²⁸²

3) External indication of patent weakness raises an interesting point in the reasoning of the Supreme Court (e.g. analysts reports, market reactions). The Court shifted from the long-asserted position that patent holder has the right to exclude others to the position that the patent holder has only the right to try to exclude others. Interestingly “*the Court reasoned that a settlement could be anti-competitive even if the generic entered before a patent expired, especially if the patent was viewed as “weak”*”.²⁸³

Per se approach and rule of reason test tend to rely on patent strength as central stone of the assessment. The first approach rules absolutely that a patent in question is weak, the second asks preliminarily what the strength of a patent is with help of several possible indices. On the other hand, scope of patent test first assumes validity of a patent, then examines if an agreement did not exceed rights conferred to a patentee under a patent grant. Unlike the US approach, the EC’s position of applying presumptively illegal

²⁷⁹ Ibid.

²⁸⁰

<http://www.rkmc.com/~media/PDFs/5%20Red%20Flags%20In%20Pharmaceutical%20Settlements.pdf> (accessed on 25 January 2015).

²⁸¹ Federal Trade Comm’n v. Actavis, Inc., 570 U.S. ___, 133 S. Ct. 2223 (2013) at 18.

²⁸² Ibid, at 17.

²⁸³ <http://www.law360.com/articles/534822/5-red-flags-in-pharmaceutical-settlements> (accessed 16 January 2015).

(restriction by object) standard still waits to be tested in courts²⁸⁴ as the EC is heavily criticized by this approach.

4.8. Patent Filing and Patent Settlements Case Law – What Lessons To Learn?

AstraZeneca confirms that filing a patent application can in principle constitute an abuse in the sense of Article 102²⁸⁵ although Article 102 cannot provide a remedy against all forms of misuse of patent procedure²⁸⁶. The EC likewise understands that abuse of market dominance may be not applied to all patent filing strategies.²⁸⁷ It applies only to dominant undertakings and their conduct assessed within the relevant product market. Also competition law liability should be established positively, meaning that a certain anti-competitive harm must be showed.²⁸⁸ Some commentators argue that the Commission did not succeed to prove clearly anti-competitive effects of conduct by pharmaceutical companies and set a low bar.²⁸⁹

The underlying principles of patent grants follow precise economic milestones placed on a roadmap by legislator to promote innovation and competitiveness. And here both patent law and competition law provide incentive to innovate and operate with this broader political goal. On the first teleological layer there is no principal schism in underlying conceptions of patent and competition law as a matter of policy making.

Where we hit hard is on the second teleological layer of corporate strategy, the layer on the basis of which company's behavior is assessed and potentially penalized. The Commission lacks a clear statement of its objective if company's behavior in patent filing shall be punished; a clear statement that would reasonably cope with the fact that patent filing and prosecution strategies intrinsically bear the anticompetitive effect in their own existence. Particularly in pharmaceutical sector market realities strongly justify patent strategies and it would be denying the very reason of patent protection not

²⁸⁴ Supra 271, p. 16.

²⁸⁵ Supra 39, at 312.

²⁸⁶ Ibid, at 294.

²⁸⁷ Supra 4, at 315.

²⁸⁸ Supra 39, at 320.

²⁸⁹ Batchelor B., Healy M., Restricting a Broad Precedent, Competition Law Insight, 2013, January 22 2013, pp. 9, 10.

to take into account its primary anticompetitive intent and character. This is even more highlighted by the fact that the entire regulatory body and other 'incentivizing' exclusionary rights which are different from patents are set around pharmaceutical products and are effectively designed to exclude competition and safeguard the innovator. That is the undeniable intent of the legislator.

In the Final Report the Commission also noted that secondary patent strategies as presented above are “*in line with the underlying objectives of patent system*” but “*may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation*”.²⁹⁰ Some authors argue that competition law liability could also arise under patent-compliant behavior.²⁹¹ I incline to argue with the other group of commentators that competition law should apply to patent filing only if the factor of inequitable or fraudulent behavior is present in such filing.²⁹² From the perspective of corporate strategy such filing aims to prolong time during which company plays on exclusive patent law playfield and to reap unmerited protection of procedural rights.

Following patent filing strategies should be taken with great caution under competition scrutiny as they all present elements of abuse of patent system and violate principle of fairness:

- Abuse of patent prosecution and providing misrepresentations, false and inaccurate information - pharmaceutical companies could deliberately involve in malicious patenting and provide false and misleading information or experimental data. For the purposes of competition law scrutiny this can also encompass knowing about former disclosure and existing prior art. *AstraZeneca* brought some lessons in respect to obligations that a dominant company should bear when dealing with public authorities. A dominant company might arguably be obliged to disclose the interpretation of legal provisions upon which it relies when applying for IP rights.²⁹³ Further, a dominant company should notify

²⁹⁰ Supra 4, para 523.

²⁹¹ Maggiolino M, Montagnani M. L., *AstraZeneca's Abuse of IPR-Related Procedures -A Hypothesis of Antitrust Offence, Abuse of Rights, and IPR Misuse*, 34 *World Competition*, Iss 2, 2011, at 258.

²⁹² Supra 121, at 180.

²⁹³ Supra 175.

patent offices if it finds out that its submissions were made on inaccurate and misleading basis. Several questions of course need to be solved in practice by competition law: How far the competition authority needs to go in order to establish abuse? Can we foresee all obligations to disclose? Do they entail legal advice, patent attorney – client communication?

- Abuse of time as abuse of procedural rights is present if a company is aware that a patent is likely not to be upheld and was filed for the sole purpose to stay in exclusive market position and if necessary engage in lengthy dispute, opposition procedure or litigation (many times with the help of *prima facie* assessment of patent rights in interim injunctions). The company is aware of the time-consuming nature of these actions and of possibility to effectively keep the competition off the market. The company files for patent, but the strategy is not to rely on the substantive content of the granted right, rather on temporary maintained higher 'ground' in procedural matters;
- Abuse of time can as abuse of number of applications when a company relies heavily on patent cluster in its strategy. Let say that the company has bigger confidence in its substantial rights in patents covering one product but the confidence is randomly distributed in the patent cluster – we do not know which patents are weak and which are strong. The costs associated with litigation of multiple patents and related legal uncertainties can discourage the generic companies to such extent that they would never try to subtract the weak ones in a patent cluster and try to revoke patent granted due to inequitable or fraudulent conduct.

To summarize a company abuses its dominance if it abuses the time given under patent law (prolongs it) when provides false or misleading information or intentionally violates its duty to disclose that is implicit to European patent grant in order to take advantage of the procedural position and to prolong its exclusivity around a single product. Competition law should stand as a time referee that holds the clock in its hand, as an official who is responsible for maintaining the order of the game and enforcing its rules at the entry and the exit of patent system. It is time for the Commission to turn to the sound construction of applicability of fairness as maxim of its competition law policies vis-à-vis patent filing strategies. Fairness should become a standard *modus operandi* in

'contractual dealings' with the state – patent prosecution - and develop into a special interface concept in competition/patent relationship.

However a patent applicant cannot abuse law or its position when seeking protection from a patent grant just because his or her confidence in patent application is relative and varies significantly. But if the ultimate purpose or motive of the patent applicant is to abuse the procedural advantages of the grant, its position at the court, right to file for a motion of infringement and engage in lengthy litigation or enjoy substantive right without merits providing false information, and the company is dominant, competition law must be ready to punish such behavior. Dominant position of company that emerged out of the grant of primary patent rights may lead to its misuse with filing for secondary patent applications. These applications reset the clocks after the expiry of the first patent, when the investment has been already recouped. In the thesis many rectifying mechanisms that are put in place were recognized, such as third party observations before grant, opposition procedures, invalidity and non-infringement actions. However if all these mechanism did not stop the clock ticking, the competition as the time referee should address these issues. The interaction must be guided by reformulation or rather accentuation of fairness as competition law objective.

Many questions are open to discussion and need to be resolved by the Commission's practice and the public awaits the Commission's first case to be closed vis-à-vis patent filing abuse.

V. Conclusion

In this thesis it was established that competition and patent law are two branches of law that in principle do not contradict each other but could work together hand by hand. Founding the justification for competition law scrutiny of patent strategies on contract theory of patent law and implicit duty of fairness is the right approach for both the current patent settlement cases and the yet to be prosecuted patent filing cases. *AstraZeneca* as the Commission's seminal case established the rule according to which providing misleading and false information and deceiving public authority in order to unjustly extend exclusionary position does not escape the competition law scrutiny. If we consider competition law as a supervisory tool for competition and related privileges based on the merits, it is foremost the abuse of time that is cautionary in extensive undeserved patenting practice. It is though truth that is subjective intent of a patentee in acquiring patent right should be deemed irrelevant and anticompetitiveness is inherent to all patent strategies at a company level, nonetheless the intent is of relevance when we consider 'veracity' of information contained in a patent application and patentee's awareness of any information that renders his application unmerited. The unclosed *Boehringer/Almirall* case could have set a strong warning signal in this regard however the Commission chose rather efficiencies and immediate consumer's benefit than company prosecution. It remains to be seen and assessed what effects has the current Commission's scrutiny of patent settlements and if the Commission ever finds itself positioned in patenting practice *via* the principle of fairness.

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Resumé v slovenskom jazyku

Úvod

Farmaceutický priemysel sa úzko spojuje a dotýka troch oblastí práva a regulácie: patentového práva, farmaceutického práva a súťažného práva. Médiá v súčasnosti často reportujú o tom, ako veľké množstvo najpredávanejších liekov stráca patentovú ochranu a ako sa farmaceutické spoločnosti orientujú čoraz viac na zisk než na skutočnú inovatívnu činnosť. Súčasná výskumná a tržná realita by sa v súčasnosti dala stručne popísať ako situácia s neustále narastajúcim tlakom zo strany generických spoločností a malou úspešnosťou nahradzovať najpredávanejšie lieky, ktoré stratili patentovú ochranu novými.

Táto práca skúma obchodné a právne praktiky farmaceutických spoločností a na tomto pozadí reflektuje základné princípy patentového a súťažného práva. Snaží sa nájsť spoločnú niti, ktorá pretkáva tieto právne oblasti hlavne s odkazom na patentové stratégie farmaceutických spoločností v súčasnom tržnom prostredí a s prihliadnutím k realite spomaľovania inovačných procesov a pomalému nahradzovaniu najpredávanejších liekov novými. Farmaceutický priemysel rozlišuje niekoľko tržných segmentov: originálne lieky, generiká, voľnopredajné lieky, biologické liečivá a biosimiláry. Práca pracuje so základnými definíciami farmácie odvodenými z daných tržných segmentov a preklenuje ich do hmotného patentového práva pre účely pochopenia podmienok patentovateľnosti, prieskumu patentovým úradom a práce patentového zástupcu pri naplňovaní cieľov patentovej stratégie.

Práca rovnako reflektuje veľmi striktné požiadavky na farmaceutický vývoj a výskum, ktoré sa uplatňujú v súčasnom legislatívnom rámci Európskej únie a majú podstatný dopad na pochopenie úlohy patentov vo farmaceutickom priemysle. Rovnako odrážajú legislatívny zámer ďalších foriem ochrany investícií a produktov vo farmaceutickom priemysle, ako je exkluzivita dát a exkluzivita trhu. Jedná sa predovšetkým o povolenia k uvedeniu liečiva na trh. Rozlišuje sa národná cesta, cesta vzájomného uznávania, centralizované a decentralizované konanie pre udelenie povolenia. Rozhodnutie akou

cestou sa vydať sa odvíja primárne od toho, v ktorých štátoch spoločnosť zamýšľa uviesť prípravok na trh a od toho, či prípravok nespadá do jednej z kategórií, pre ktorú je určité konanie povinné. Žiadosť o udelenie povolenia k uvedeniu na trh je zložitým administratívnym krokom, ktorý ale výrazne osvetľuje finančnú a inú náročnosť a komplikovanosť výskumu a vývoja, ktoré predchádzali tejto žiadosti. Zahrnuje niekoľko rozhodovacích inšancií a súčinnosť veľkého počtu subjektov. Spis, ktorý sa prikladá k žiadosti musí obsahovať výsledky farmaceutických testov, predklinických štúdií ako a klinických štúdií. Práca poskytuje podrobnejší prehľad všetkých vyššie uvedených aspektov.

Proces výskumu a vývoja by sa v skratke dal zhrnúť do nasledujúcich etáp: identifikácia cieľovej molekuly, testovanie v rámci predklinických testov na in vitro a zvieračích modeloch a následné klinické testovanie v štyroch fázach. Molekula je následne syntetizovaná a purifikovaná. Spresnia sa bezpečné farmakologické parametre, lokálna tolerancia a toxicita, ako aj jednotlivá a násobná toxicita. Spoločnosť musí tiež pred testovaním obdržať vyjadrenie etickej komisie. Klinické testovania prebiehajú na ľudských subjektoch a určujú farmakologické (farmakokinetické a farmakodynamické) účinky liečiva. Skúmajú sa nežiaduce účinky, liekové interakcie a ďalšie vlastnosti liečiva. V EHP je ročne povolených okolo 4000 klinických štúdií. Približný odhad nákladov spojených s výskumom a vývojom liečiv sa pohybuje až do výšky 1,4 miliardy amerických dolárov.

Farmaceutické patentové stratégie

Stratégia je podrobne vypracovaný plán, hľadanie najefektívnejších a najširších súťažných výhod oproti konkurencii, ktoré sa merajú v čase, v sile výlučnej tržnej pozície a tržnom podiele. U patentových stratégií sa jedná prevažne o prihlasovanie patentov v správnom časovom momente a so správnou šírkou patentových nárokov. Farmaceutické spoločnosti sa logicky snažia, aby podali patentovú prihlášku ako prvé, ale musia si byť vedomé predchádzajúcich zverejnení a pre účely správneho načasovania i ostatných konkurenčných produktov vo vývoji.

Patentové stratégie obecné cielia na nasledujúce méty: maximalizácia zisku, udržanie monopolistického postavia, zaistenie podielu na trhu, rozšírenie tržného podielu, pokračovanie vo výskume, zabránenie imitácie a zhromažďovanie technológií. V tržnej ekonomike sú výskumné a obchodné ciele úzko prepojené, preto uvedené ciele nie sú výlučné.

V protiklade k vyššie uvedeným cieľom patentových stratégií je dôležité zdôrazniť a uvedomiť si hlavný legislatívny zámer, ktorý sa skrýva za patentovým právom a udeľovaním patentov obecné. Podľa obecné prijímaného poňatia patentová ochrana stimuluje súťažné prostredie, pretože primárne firmy inovovať v takom rozsahu, aby ich inovácie prešli prednastaveným filtrom, podmienkami patentovateľnosti. Napríklad ústava Spojených štátov amerických, ktorá môže slúžiť ako jasne formulovaný príklad, hovorí, že cieľom práv duševného vlastníctva je podpora a vývoj užitočného umenia a vedy tým, že sa autorom a vynálezcom garantujú exkluzívne práva k perspektívnej literárnej tvorbe a vynálezom. Na vynález môže byť v takom prípade nazerané ako na spoločensky žiaduci typ monopolu. Ďalší záujem verejnosti spočíva v čo najskoršom prevedení poznatkov od pôvodcu do verejnej sféry. Zároveň je však potrebné zdôrazniť, že inovácie sú náročné na zdroje a investície. Patenty sa snažia reflektovať tieto prekážky a pretvoriť nové realizovateľné nápady do vlastníckych práv. Vo svojich základných intenciách vytvárajú podnety, ktoré maximalizujú rozdiel medzi hodnotou duševného vlastníctva a spoločenskými nákladmi na ich vytvorenie.

Legislatívny zámer stimulácie súťaže, respektíve jeho teoretické vyjadrenie, ale nezahŕňa prvú časť „príbehu“, ktorá spočíva v samotnom rozhodovaní a konaní obchodných spoločností. To začína práve u jednotlivých manažérskych rozhodnutí a vyplýva predovšetkým z tržnej reality. Vízia patentovej ochrany núti spoločnosti inovovať práve preto, aby boli schopné vylúčiť svoju konkurenciu a eliminovať súťažné prostredie v budúcnosti. Pokiaľ je možné dosiahnuť dominantné postavenie cez patentovú prihlášku a udelenie patentu, potom je úloha definovaná tak, že sa má patentová prihláška napísať čo najoptimálnejším spôsobom pre prihlasovateľa a v patentových nárokoch, ktoré umožnia tú najširšiu možnosť ochrany. Primárnym cieľom teda nie je zvýšiť súťažné prostredie, ale práve naopak vylúčiť ostatných súťažiteľov na

relevantnom trhu. Zámerom patentovej prihlášky je teda získať exkluzívne práva, ktoré spoločnosť bude pre dané účely požívať.

Je zrejmé, že existuje značný nesúlad medzi tým, čo sa snaží dosiahnuť individuálny investor resp. spoločnosť a celkové ekonomické dôsledky, ktoré zákonodarca predpovedá, pokiaľ sa spoločnosti budú angažovať v "závode" o udelenie patentov. Na prvý pohľad je preto ťažké nájsť zdôvodnenie zásahov súťažného práva do práva patentového. Obzvlášť pokiaľ sa jedná o podrobné skúmanie a sankcionovanie patentových stratégií a stratégií podávania patentových prihlášok na úrovni spoločností z pohľadu súťažnoprávneho dohľadu.

Ako bude priblížené ďalej, zložitosť tohto vzťahu sa v súčasnosti odzrkadľuje v preskúvaní mimosúdnych dohôd v patentových sporoch, ktoré je najčastejším prípadom uplatňovania súťažnoprávnych pravidiel v patentových veciach na európskej úrovni.

Čo sa týka ďalšieho podstatného východiska patentového práva, na ktorom práca stavia, je ním zmluvní princíp udeľovania patentov. Práca popisuje jednotlivé aspekty udeľovania patentov a patentového prieskumu a pripodobňuje ho k základným aspektom zmluvného vzťahu. Dochádza k záveru, že zmluvný princíp poskytuje dobrý základ pre uchopenie patentových práv z hľadiska súťažnoprávneho prieskumu a zároveň zdôrazňuje princíp poctivosti a dobrej viery ako dominujúceho zmluvného princípu odzrkadľujúceho sa v patentovom konaní pred patentovým úradom. Z komparatívneho pohľadu je tento princíp silne zachytený v americkom patentovom práve, ktoré zahŕňa povinnosť zverejnenia informácií, poctivého a pravdivého konania a dobrej viery. Každý prihlasovateľ alebo iná osoba, ktorá je podstatne zapojená do prípravy a podávania patentovej prihlášky, ako aj správneho konania pred patentovým úradom, má povinnosť poskytnúť patentovému úradu všetky informácie, ktoré sú tejto osobe známe ako podstatné pre určenie patentovateľnosti vynálezu. Táto povinnosť sa viaže na každý predkladaný patentový nárok. Porušenie tejto povinnosti, ale ovplyvní všetky patentové nároky, ktoré sú dotknuté týmto konaním a vedie k nevymáhateľnosti patentových práv.

Práca ďalej poukazuje na to, že pri absencii podobného ustanovenia v európskom patentovom práve a neexistencie inej sankcie za podvodné a zavádzajúce podanie

patentovému úradu, neexistuje v súčasnosti systémový spôsob, ako sa vyrovnat' s protisúťažným zneužitím patentového konania, ktoré ohrozuje princíp poctivosti, ktorý sa subsumuje pod obecnú prijímanú zmluvnú teóriu udeľovania patentovej ochrany. V komparatívnej perspektíve práca zmieňuje aj prípady súťažnoprávnej zodpovednosti, ktorá vznikla práve porušením povinnosti poskytovať informácie a povinnosti poctivosti v konaní pred patentovým úradom.

Práca následne dala do jednej roviny a objasnila patentové nárokovanie na jednej strane a výsledky prešetrovania farmaceutického priemyslu Európskou komisiou na strane druhej, ktoré identifikovalo určité patentové stratégie ako vyžadujúce zvýšenú pozornosť dohľadu Komisie nad dodržiavaním súťažnoprávnych predpisov. Sú nimi predovšetkým vytváranie patentových zhlukov (klastrov), predlžovanie exkluzivity podávaním sekundárnych patentov, ďalej stratégie pasce, ktorá dostáva generické spoločnosti do pozície neodvratného porušenia patentových práv a podávanie divízných (drobných) patentových prihlášok.

Patentové stratégie farmaceutických spoločností často zahrnujú prvú a druhú generáciu patentov. Prvá generácia okolo farmaceutika je väčšinou konštruovaná ako patenty na produkt alebo procesné patenty. Druhá generácia (sekundárne patenty) chráni ďalšie vlastnosti liečiva rozdielne od účinnej látky a vždy nasledujú prvú generáciu patentov. Väčšina sekundárnych patentov sa týka formulácií, liekových kombinácií a zariadení. Ďalšie zahrnujú polymorfy, medzi produkty, ďalšie lekárske použitia, hydráty, solváty a ďalšie. Hovorí sa o prírastkovej alebo postupnej inovácií.

Je dôležité rozlíšiť ďalšie dva pojmy, a to tzv. slabé a silné patenty. Silné patenty majú vysokú pravdepodobnosť, že uspejú v konaní pred súdom a nedôjde k ich zrušeniu. Nemusí sa samozrejme jednať iba o súdne konanie, ale aj o návrh na zrušenie pred správnym úradom. Práca pojednáva o oboch možnostiach, ale kladie väčší dôraz na konanie pred súdom práve pre účely vyššie zmieňovaných dohôd o urovnaní sporov medzi farmaceutickými spoločnosťami zameranými na výskum a vývoj a generickými spoločnosťami. Slabý patent je teda naopak taký patent, u ktorého je vyššia pravdepodobnosť, že bude prehlásený za neplatný, pretože nepreukáže dostatočnú novosť alebo dostatok vynálezeckého kroku, pokiaľ by bol podaný návrh na jeho

zrušenie (v niektorých jurisdikciách), resp. by došlo ku konaniu o porušení patentových práv.

Z pohľadu súdnej praxe Európskeho súdneho dvoru, práca venuje v tejto časti pozornosť dvom prípadom a to prípadu AstraZeneca a Boehringer/Almirall. Pre väčšie podrobnosti odkazujem na samotný text práce v anglickom jazyku. V prípade Boehringer/Almirall, ktorý Komisia začala prešetrovať, ale nakoniec prípad uzatvorila dohodou medzi spoločnosťami, mohlo dôjsť k zásadnému posunu rozhodovacej praxe a potvrdeniu princípu poctivosti, ktorý stál v strede záujmu pri posudzovaní podozrenia zneužitia dominantného postavenia. Komisia namiesto toho uprednostnila spotrebiteľský prospech (blahobyť) ako vyšší cieľ pri uplatňovaní súťažnoprávných pravidiel.

Súťažné právo a patentové spory

Práca identifikovala niekoľko zásadných cieľov súťažnej politiky Európskej únie. Sú nimi poctivosť/rovnosť/spravodlivosť (fairness goals), blahobyť a prospech (welfare) a ekonomická integrácia. Podľa názoru niektorých komentátorov neexistujú presvedčivé argumenty, ktoré by sa opierali o ciele spotrebiteľského blahobytu (consumer welfare), ktoré by odôvodňovali zásah súťažného práva proti sekundárnym patentom ako jednej z uplatňovaných patentových stratégií. Odôvodnenie prešetrovania zneužívajúcich patentových stratégií musí balansovať záujmy chránené súťažným právom bez toho, aby došlo k poškodeniu základných princípov a cieľov patentového práva.

Na základe rozhodovacej praxe Európskej komisie a súčasnej literatúry práca odvodzuje, že najdôležitejším cieľom súťažnoprávnej politiky je princíp poctivosti s dôrazom na procesnú poctivosť/spravodlivosť. Tento cieľ by v danom prípade mal predchádzať prospechu spotrebiteľov (consumer welfare), respektíve ho dopĺňať pri úspešnom nasadzovaní politiky súťažnopráveho prieskumu v patentových záležitostiach.

Nasledujúce prípady poskytujú určité vodítko významu poctivosti/spravodlivosť/rovnosť v súťažnom práve. Napríklad v prípade SABAM Súdny dvor Európskej únie judikoval, že poctivosť je vyvažovaním práv a povinností zmluvných strán. Prípád Tetra Pak II zahrnoval zmluvné ustanovenia, ktoré presahovali rozpoznané právo dominantného podniku ochraňovať vlastné obchodné záujmy, čo súd považoval za odporujúce princípu poctivosti. V prípade Michelin II súd zastal názor, že poctivosť vyžaduje transparentnosť, objektivitu, určitosť a limitovanú voľnosť v uvážení a zneužitie môže predstavovať výlučné jednanie, ktoré nenesie objektívne ekonomické zdôvodnenie. V prípade AKZO Nobel Chemical Komisia zdôraznila, že dominantná spoločnosť je oprávnená súťažiť na základe hodnoty vlastných služieb a výrobkov (on the merits). A nakoniec v prípade ITT Promedia Všeobecný súd judikoval, že zneužitie môže mať podobu podania žaloby na súde. Zároveň je koncepcia poctivosti (resp. rovnosti) je priamo začlenená do článku 102 ZFEÚ.

V ďalšej časti sa práca zaoberá uplatňovaním súťažného práva v patentových sporoch, ktoré vyúsťujú do dohôd medzi farmaceutickými spoločnosťami. Zasadene do celkového regulačného rámca farmaceutického priemyslu práca rozoberá ako dochádza k porušovaniu patentových práv a následnej interakcii medzi porušovateľom a nositeľom patentových práv. Práca zároveň vychádza z najnovšej správy Erópskej komisie, ktorá priebežne monitoruje patentové spory vo farmaceutickom priemysle a uzatvorené dohody o ukončení sporov. Práca opätovne poskytuje prehľad všetkých súťažnoprávných prípadov Komisie, ktoré mali spojitosť s patentovými spormi vo farmaceutickom priemysle. Jedná sa o prípady Lundbeck, Johnson & Johnson, Servier a Cephalon/Teva.

V prípade patentových sporov je záujem verejnosti dvojaký: jednak je tu záujem na okamžitom vstupe na trh, keď už výrobok nie je chránený patentovou ochranou a ceny by mali klesnúť. Zároveň je tu záujem na odstránení neplatných patentov ako neodôvodnenej bariéry vstupu na trh a ďalším inováciám.

Závěrečné úvahy

Strategické používanie patentových práv môže nabráť formu dohôd a urovnaní patentových sporov. Takzvané dohody s obráteným plnením sú v určitom protiklade k obvyklým ustanoveniam v patentových dohodách, ktoré počítajú s tým, že porušovateľ patentových práv platí náhradu škody majiteľovi patentu a niekedy upravujú licenčné podmienky. Je preto dôležité uvažovať, na základe akých podmienok boli tieto neobvyklé podmienky uzatvorené a či nezakrývajú iné konanie, ktoré predchádzalo uzatvoreniu dohody.

Dohody, ktoré upravujú spätné plnenie sú obecné považované za problematické. Komparatívna analýza s prístupom súdov v Spojených štátov amerických ponúka nasledovné spôsoby súťažno-právnej analýzy a prešetreniu týchto dohôd:

1) Dohody sú buď považované za protiprávne per se;

2) Uplatní sa tzv. *scope of patent test*, ktorý analyzuje dohody na základe výlučných vlastností patentu (geografických, časových alebo určených patentovými nárokmi);

3) Tzv. *rule of reason test* určuje protisúťažný charakter týchto dohôd prípad od prípadu. Tento test bol nedávno potvrdený v prípade Actavis Inc. proti Federal Trade Commission Najvyšším súdom Spojených štátov. Niekoľko komentátorov sa snažilo spresniť daný test, ktorý bude musieť byť ešte uplatnený u nižších súdov v nasledujúcich bodoch, ktoré by mali indikovať protisúťažnú povahu týchto dohôd:

- Vysoké protiplnenie, ktoré poskytuje "originálna" farmaceutická spoločnosť generickej spoločnosti. Pre účely vymáhania súťažných pravidiel, akákoľvek forma protiplnenia, vrátane priamej peňažnej a nepeňažnej formy (licencia, distribučná zmluva, zmluva o dodávkach) je považovaná za plnenie.
- Značné oneskorenie vstupu generického prípravku na trh.
- Externé indície slabého patentu ako napríklad analytické správy, reakcie trhu, atď. Súd totiž dospel k záveru, že dohoda môže byť protisúťažná aj pokiaľ

generický prípravok vstúpil na trh pred tým, než vypršal patent, pokiaľ je patent považovaný za slabý.

Prístup *per se* a *rule of reason* sa primárne opierajú o silu patentu ako základu pre analýzu v súťažnoprávnom prešetrovaní. Prvý test predpokladá od začiatku, že patent, ktorý je predmetom sporu je slabý, druhý test hodnotí silu patentu na základe rozdielnych ukazovateľov.

Prípád AstraZeneca potvrdil, že podanie patentovej prihlášky môže v princípe predstavovať zneužitie dominantného postavenia, ale taktiež, že článok 102 nemôže poskytnúť nápravu všetkých konaní, ktoré zneužívajú udeľovanie patentovej ochrany. Európska komisia taktiež potvrdila, že zneužitie tržnej dominancie nemožno vzťahovať na všetky stratégie podávania patentových prihlášok. Týka sa iba dominantných podnikov a ich konania, ktoré musí byť preskúmané v rámci relevantného trhu. Zodpovednosť vyplývajúca zo súťažnoprávnych pravidiel musí byť postavená pozitívne, čo znamená, že určitá protisúťažná ujma musí byť preukázaná. Niektorí komentátori poukázali na to, že Komisia nedokázala v dostatočnej miere preukázať protisúťažné dopady konania farmaceutických spoločností a stanovila nízku latku.

Základné princípy udeľovania patentov sledujú presné ekonomické míľniky na mape zákonodarca, ktoré smerujú k podporeniu inovácií a súťažného prostredia. Na prvej teleologickej rovine neexistuje principiálna nezhoda medzi základnými koncepciami za patentovým a súťažným právom na úrovni vytvárania určitého politického smerovania.

Kde ale obe právne oblasti narazia, je druhá rovina korporátnej stratégie, na ktorej môže byť jednanie spoločnosti prešetrované a následne sankcionované. Komisii na tejto úrovni chýba jasná stratégia, ktorá by sa vyrovnala s tým, že patentové stratégie už svojou podstatou nesú a implikujú protisúťažné dôsledky. Obzvlášť vo farmaceutickom priemysle, kde tržná a výskumná realita silno odôvodňuje používanie najrôznejších patentových stratégií, bolo by popretím zmyslu udeľovania patentu, nevziať do úvahy protisúťažný zámer a povahu týchto stratégií. Táto úvaha je navyše podporená existenciou celého radu ďalších regulačných opatrení, ktoré podporujú výlučné práva okolo farmaceutík, rozdielne od patentu.

Vo svojej Finálnej správe týkajúcej sa vyšetrovania farmaceutických spoločností medzi rokmi 2000 až 2007 Komisia poznamenala, že sekundárne patentové stratégie ako sú prezentované v práci sú v súlade so základnými zámermi systému patentovej ochrany, ale môžu v určitých prípadoch byť zamerané na vylúčenie konkurencie a nie na ochránenie dôležitého obchodného záujmu. Niektorí autori tvrdia, že zodpovednosť vyplývajúca zo súťažnoprávnych pravidiel môže nastať aj v prípade konania, ktoré bude v súlade s patentovým právom (t.j. nebude odporovať ani princípu poctivosti). Práca argumentuje, že súťažné právo by sa malo vzťahovať na stratégie podávania patentových prihlášok, iba v prípade, že konanie bude odporovať poctivosti alebo je podvodné. Z pohľadu korporátnej stratégie takéto podávanie patentovej prihlášky mieri na predĺženie času, počas ktorého spoločnosť zostáva „hrať“ na exkluzívnom poli patentovej ochrany s vedomím, že tento čas poskytuje patent, ktorý sa nezakladá na opodstatnených základoch splňujúcich podmienky patentovateľnosti.

Nasledujúce patentové stratégie by mali vyvolať zvýšenú opatrnosť pri preskúvaní dodržiavania súťažnoprávnych pravidiel a porušujú princíp poctivosti:

- Zneužitie správneho konania udeľovania patentov tým, že sa poskytujú úmyselne nesprávne a nepresné informácie ako aj klamlivé a skreslené podanie vrátane experimentálnych dát. Pre účely súťažnoprávneho preverovania táto kategória môže zahŕňať vedomosť o predchádzajúcom odhalení princípu technológie alebo existujúceho stavu techniky. Prípady AstraZeneca poukázali na to, že spoločnosť v dominantnom postavení má určité povinnosti v konaní s úradmi verejnej správy. Podľa názoru niektorých komentátorov, spoločnosť v dominantnom postavení je povinná zverejniť, ako interpretuje právne predpisy, keď prihlasuje svoje práva duševného vlastníctva. Spoločnosť v dominantnom postavení má taktiež notifikovať patentové úrady, pokiaľ zistí, že určité podanie bolo nesprávne alebo zavádzajúce. Niekoľko otázok vyvstáva v tejto súvislosti, ktoré by mohli byť budúcnosti vyriešené súdnou praxou: ako ďaleko môže zájsť vo svojich kompetenciách úrad pre dohľad nad dodržovaním hospodárskej súťaže poprípade Európska komisia pri prešetrovaní zneužitia dominantného postavenia? Je možné predpokladať všetky povinnosti vzťahujúce sa k

zverejneniu informácii úradom verejnej správy? Zahrnujú tieto povinnosti i obdržané právne rady a komunikáciu s patentovým zástupcom?

- Zneužitie času ako zneužitie procesných práv je ďalším prípadom vyžadujúcim pozornosť súťažnoprávneho prešetrovania. Zahrnuje prípady, keď je patentová prihláška podaná iba so zámerom zotrvania na exkluzívne tržnej pozícii s vedomím, že toto zotrvanie je sprostredkované v dôsledku priťahov v súdnom konaní alebo obecné v dôsledku dlhého trvania sporu. Spoločnosť nepodala patentovú prihlášku preto, aby sa opierala o svoje hmotné patentové práva, ale iba aby využívala svoje dočasné silnejšie postavenie odvodené od procesných oprávnení.
- Zneužitie času ako zneužitie počtu patentových prihlášok je ďalšia zo stratégií identifikovaná Európskou komisiou ako nesúca hrozbu porušenia súťažného práva. Stratégia môže spočívať napríklad v tom, že spoločnosť má väčšiu dôveru vo svoje patentové práva ukryté v patentoch vzťahujúcich sa k jednému produktu. Táto dôvera v hmotné patentové práva je náhodne distribuovaná v zhluku patentov okolo jedného farmaceutického produktu. Nevie sa však, ktoré z patentov v patentovom zhluku sú slabé a ktoré silné a vyžaduje to nesmierne časové a iné zdroje, aby sa docielilo právnej istoty okolo jedného farmaceutika a slabé patenty boli zo zhluku odstránené.

Zhrnutím je možné povedať, že spoločnosť zneužíva svoje dominantné postavenie tým, že poskytuje nesprávne a zavádzajúce informácie a úmyselne porušuje princíp poctivosti a povinnosť poskytnúť informácie patentovému úradu s týmto princípom spojenou. Tým umelo predlžuje svoje exkluzívne postavenie na relevantnom trhu. Súťažné právo by sa malo vymedziť jednak ako časový rozhodca a jednak ako rozhodca, ktorý vymáha pravidlá na vstupe a na výstupe z exkluzívneho pola patentového práva. De lege ferenda by mohla poctivosť fungovať ako obecné prijímaný princíp, ktorý sa skrýva za zmluvným poňatím udeľovania patentov a pretvoríť rozhranie medzi patentovým a súťažným právom.

V tejto práci bolo ukázané, že patentové a súťažné právo nie sú právne odvetvia, ktoré si musia nutne protirečiť, ale naopak môžu fungovať na spoločnom princípe a s jednotným zámerom. Odôvodnenia zásahov súťažného práva, ktoré vychádza zo

zmluvného princípu poctivosti funguje jednak pre prieskum stratégií podávania patentových prihlášok a jednak pre stratégie týkajúce sa urovnání patentových sporov. AstraZeneca bol zárodočným prípadom, v ktorom Európsky súdny dvor a Európska komisia judikovali, že poskytovanie zavádzajúcich a nesprávnych informácií a zámerné zmätenie úradov verejnej správy s cieľom predĺženia respektíve rozšírenia výlučnej pozície neunikne súťažnoprávnemu prešetreniu. Pokiaľ sa súťažné právo považuje za nástroj dohľadu hospodárskej súťaže založenej na hodnote a kvalite, jedná sa predovšetkým o zneužitie času exkluzivity, ktorá je varovnou stratégiou pre súťažnoprávny prieskum. Je zároveň pravdou, že samotný úmysel prihlasovateľa je z hľadiska patentového konania nepodstatný a protisúťažný charakter je vlastný všetkým stratégiám na korporátnej úrovni, avšak úmysel je podstatný pokiaľ sa má súťažnoprávne prešetrovanie zakladať na pravdivosti informácií a vedomosti prihlasovateľa o informáciách relevantných pre patentovateľnosť (ako to aj bolo v prípade AstraZeneca). Neuzatvorený prípad Boehringer/Almirall mohol vyslať silný varovný signál v tomto ohľade, Komisia ale napokon uprednostnila okamžité prospech pre spotrebiteľa pred zdĺhavým prešetrovaním spoločnosti. Bude ďalej nutné počkať na oficiálne rozhodnutia Komisie v prípadoch prešetrovaných dohôd v patentových sporoch a potvrdiť, na akom základe Komisia postavila svoje zásahy do patentového práva.