Abusive Acquisition of
Intellectual Property Rights

The case of AstraZeneca

Katarzyna T. Klepaczka
ANR: 737759

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Thesis Supervisor:
Matteo P. Negrinotti LLM

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# Table of Contents

Abbreviations ................................................................................................................................................. 3

INTRODUCTION ................................................................................................................................................ 4
  Purpose ............................................................................................................................................................ 4
  Methods .......................................................................................................................................................... 6
  Delimitations .................................................................................................................................................. 7

Chapter 1: INTERPLAY BETWEEN COMPETITION LAW AND IPR LAW ..................................................... 8
  1.1. The existence/exercise dichotomy ........................................................................................................... 8
  1.2. When is the exercise of IPR abusive? ....................................................................................................... 10
  1.3. Shift in the policy ....................................................................................................................................... 15

Chapter 2: AstraZeneca AND FRAUDULENT ACQUISITION OF PATENT .................................................. 19
  2.1. AstraZeneca’s first abuse placed within the sector characteristics ....................................................... 19
  2.2. Acquisition of patent can be abusive ...................................................................................................... 22

Chapter 3: IMPACT OF AstraZeneca ON THE ACQUISITION AND POSSESSION OF PATENTS IN COMPETITION LAW REGIME ..................................................................................... 26
  3.1. Role of intent in addressing abuses under 102 TFEU .............................................................................. 27
    3.1.1. Intent as a legal standard in antitrust law ......................................................................................... 27
    3.1.2. US antitrust ....................................................................................................................................... 28
    3.1.3. EU competition law ....................................................................................................................... 30
    3.1.4. Intent in the area of IPR .................................................................................................................. 32
    3.1.5. Possible implications of the use of the intent legal standard ......................................................... 34
  3.2. No need for exercising IPRs .................................................................................................................... 36
    3.2.1. US practice ....................................................................................................................................... 36
    3.2.2. Mere possession of patents ............................................................................................................ 37
    3.2.3. ITT Promedia inapplicable to acquisition of rights? ......................................................................... 38
  3.3. More economic approach in the field of IPRs ....................................................................................... 39
    3.3.1. Need for more economic approach .................................................................................................. 39
    3.3.2. Guidance Paper on the exclusionary abuses .................................................................................... 43
    3.3.3. Anticompetitive effects of AstraZeneca’s conduct .......................................................................... 44
  3.4. Conclusions ............................................................................................................................................... 47
Chapter 4: PATENTS IN PHARMACEUTICALS POST-ASTRAZENECA

4.1. Sector Inquiry

4.1.1. Patenting strategies

4.2. New investigations

4.2.1. Commission’s investigation

4.2.2. National Competition Authorities

4.3. Addressing the “toolbox” with AstraZeneca

CONCLUDING REMARKS

Bibliography

Books and Articles

Legislation

EU Case Law

US Case Law

European Commission’s decisions

Official Documents

Other documents
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>DOJ</td>
<td>Department of Justice</td>
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<tr>
<td>ECJ</td>
<td>European Court of Justice</td>
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<tr>
<td>EPC</td>
<td>European Patent Convention</td>
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<td>ECLR</td>
<td>European Competition Law Review</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>EIPR</td>
<td>European Intellectual Property Review</td>
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<tr>
<td>FTC</td>
<td>Federal Trade Commission</td>
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<td>NCS</td>
<td>National Competition Authority</td>
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<td>PTO</td>
<td>Patent and Trademark Office</td>
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<tr>
<td>RRC</td>
<td>Raising Rival Costs</td>
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<td>SPC</td>
<td>Supplementary Patent Certificate</td>
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<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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INTRODUCTION

Recent judgment of the General Court T-321/05 AstraZeneca v Commission\(^1\) has shown the move the Commission has done in pursuing against the abuses of dominant position in the pharmaceutical sector. Even though the sector is highly regulated, little case law can be found regarding regulatory abuses. The specific character of this industry was already suggested by the Advocate General Jacobs\(^2\) and has been also considered by the European Courts in cases concerning parallel trade.\(^3\) Also in patent law there is a distinction made between pharmaceuticals and other industries by granting extra protection to pharmaceutical innovations on the basis of the Supplementary Patent Certificate.\(^4\) The AstraZeneca case and the following Sector Inquiry\(^5\) into pharmaceutical sector show actually that the Commission undertook new impetus into scrutinizing this regulated sector when it comes to the use of patent law. The Commission has noted that some of the practices regarding the patent strategies might be worrying when the compliance with competition rules is at stake. AstraZeneca judgement has potential, if confirmed by the Court of Justice, to become a starting point in scrutinizing the use of patents in business decisions of pharmaceutical companies.

Purpose

The aim of this master thesis is to assess impact of AstraZeneca judgment on the process of acquisition of patents in pharmaceutical sector and further developments in addressing emerging patent strategies in obtaining patent protection. The traditional clear division between the existence and exercise of the intellectual property rights seems to play less important role in the relations between competition law and IPR law then it used to.

\(^{1}\) Case T-321/05 AstraZeneca AB and AstraZeneca plc v European Commission [2010] ECR II-02805
\(^{3}\) Joined cases C-468/06 to C-478/06 Sot. Lélos kai Sia and Others v GlaxoSmithKline [2008] ECR I-07139
Throughout the years this distinction has been set aside by creating new sets of exceptional circumstances in which competition law could apply.

The first chapter of the thesis constitutes the overview of the development in creating the special regime in coexistence of competition law and patent law. *AstraZeneca* has in this matter significant position as it provides new category of abuse of dominant position related to the use of patent. For better understanding of the peculiarities of the case, short explanation of the characteristics of the sector and the facts of the case will be presented in the second chapter. The third chapter constitutes analysis of the potential impact of *AstraZeneca* in the antitrust assessment. Focusing on the first abuse detected by the Commission, namely the misuse of patent system while acquiring SPC protection, the question on the role of intent in the assessment of the use of the patent system will be addressed. Although the notion of intent is not new to the Commission, the given case might become a boosting factor in its further application. I will furthermore address the issue of exercising patent rights as not being essential in finding an abuse. This is in contradiction to hitherto practice and is directly linked to the intention of defendant and to the proof of harm, which is the subject of consecutive analysis. What is to be shown is that the case constitutes a further development in the Commission policy in addressing issues of the patent protection in the pharmaceutical sector. Although the *AstraZeneca* case didn’t revolutionize the relationship between competition law and IPR regime, it did indicate the current direction of the Commission’s priorities. This case brought attention to the fact, that the intention of the defendant can constitute important element of the allegedly anticompetitive behaviour. Also essential for the patent system is finding that the possessed exclusionary rights do not have to be exercised to become the instrument of abuse. The fact that the dominant undertaking acquires an exclusive right is sufficient to consider such behaviour indicative of an abuse, if the exceptional circumstances are present. The current changes in the Commission’s practice and the more-economic approach might be found useful in the assessment of the
alleged patent misuse, especially when the formalistic approach to distinguishing between the application of patent laws and competition law is fading away.

The last chapter presents the application of the findings from *AstraZeneca* in practice. The Sector Inquiry, initiated after the Commission decision in the *AstraZeneca case*, demonstrates the direction in which Commission turns its efforts. The recent investigation by the Commission and Italian competition authority are also shown as examples of implementation of the Commission’s policy with regard to treating patent strategies in pharmaceutical sector.

**Methods**

In developing the analysis the traditional legal method will be used in order to establish the current state of European law. Primary sources for this analysis will be legislation and case law. For the proper placing of the case in the current competition law regime, I will refer to the economic theories which stood behind the Commission’s decision, namely the cheap exclusion and raising rival costs. In the analysis of the possible outcome of the case I will refer to the US antitrust law. The reason for that is that the US law and practice have already faced the problems identified in *AstraZeneca*. This comparison has as its aim indicating problems and challenges which the European courts might find in addressing issues arising between patent law and competition law the way it happened in *AstraZeneca*.

As the analysis contains elements of comparison between the European competition law and US antitrust law, the case law of the US courts will be addressed. Because of the fact that the US jurisprudence in the area of concern is very extensive, I will address only the most important judgments confining my analysis to the extraction of the main principles governing US antitrust and IPR laws.
**Delimitations**

The main goal of this paper is to address the issue of the acquisition and possession of the patent in the regulated pharmaceutical sector as a potentially abusive. Therefore, I will focus on the part of the judgment which concerns directly the misuse of the patent system by AstraZeneca. The second abuse related to the regulatory strategies is not relevant for this particular topic.
Chapter 1: INTERPLAY BETWEEN COMPETITION LAW AND IPR LAW

1.1. The existence/exercise dichotomy

The relationship between competition law and intellectual property law has been under the investigation of scholars for many years now. Under the Treaty provisions the systems of property ownership are national in principle.\(^6\) Such a situation creates a practical problem: while IP regime grants exclusive rights to its proprietor, they can be subsequently used to circumvent the general interest of the European Union which is based on the free movement and undistorted competition principles. This creates the tension between the two law regimes and the question when the EU competition can encroach on the rights which are protected by national IP law. IP lawyers challenge competition law for undermining incentives to innovate, whereas competition law practitioners see IPRs as overly-broad protection undermining short-run price competition and long-run dynamic competition.\(^7\) The European Court of Justice in order to clarify its standing on that issue and provide legal certainty created, which later appeared to be the rather unsatisfactory, formalistic distinction between existence and exercise of the intellectual property rights. Following the practice of the early days of competition law based on legal formalism, the ECJ created the existence/exercise dichotomy as a “device for determining regulatory competence”\(^8\) by which the Court directly avoided adjudication on any issue concerning the granting of IPR. The national autonomy was left untouched even in situations which could raise the problems as

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\(^6\) Consolidated Version of the Treaty on the Functioning of the European Union [2010] C83/47 (TFEU), Article 345: “The Treaties shall in no way prejudice the rules in Member States governing the system of property ownership.”


to the validity of the protected right.\textsuperscript{9} This dichotomy served the purpose of allocating the competences both when the free movement and competition rules were at stake.

The assumption behind the distinction was the already mentioned principle of the autonomy of the national systems of property ownership. The ECJ made this argument for the first time in \textit{Consten and Grundig} case\textsuperscript{10}, one of the foundation cases for the whole system of European competition law. Grundig, a German manufacturer, used its trade mark to reinforce a sole distribution agreement with French distributor. It was the agreement which frustrated competition law principles and not IPR itself. The decision by the Commission regarding the setting obstacles to parallel import was confirmed that it “does not affect the grant of those [IP] rights but only limits their exercise to the extent necessary to give effect to the prohibition under [ex] Article 85(1).\textsuperscript{11} The Court didn’t address the issue in terms which we use it now as the existence/exercise distinction but referred instead to the fact that “the Treaty shall in no way prejudice the rules in Members States governing the system of property ownership.”\textsuperscript{12}

The assertion that the existence of IP rights granted under national law is not affected by the Treaty rules has been confirmed on numerous occasions. In \textit{Parke, Davis} the Court for the first time used the term existence of the right stating that “the existence of patent rights is (...) a matter solely of national law”.\textsuperscript{13} The case concerned a situation whether the patent could be used to prevent the importation of the antibiotics to the Netherlands from Italy.

\textsuperscript{9} As the examples, few cases can be given: Case 35/87 \textit{Thetford v Fiamma} [1988] ECR 3585; Joined cases C-241/91 P and C-242/91 P \textit{RTE and others v Commission} [1995] ECR I-743 (\textit{Magill}) or Case C-418/01 \textit{IMS Health} [2004] ECR I-5039. The validity as to the given protection could be questioned in cases of portable toilets (\textit{Thetford}) which lacked of novelty and inventive step under British 50-year rule, or in the cases of broadcasting listings (\textit{Magill}) and databases (\textit{IMS}) protected by copyright where actually there was no ‘creative work of mind’. However, in the lack of any harmonisation at the European level, the ECJ confined itself to adjudicating on the issues of compatibility of the exercising of the right with the internal market and free competition.

\textsuperscript{10} Joined cases 56 and 58-64 \textit{Consten and Grundig v Commission} [1966] ECR 299

\textsuperscript{11} ibid para 345

\textsuperscript{12} ibid

\textsuperscript{13} Case C-24/67 \textit{Parke, Davis & Co. v Probel and others} [1968] ECR 55 (\textit{Parke, Davis}) para 72
where it was produced without the consent of the Dutch patentee. The Court went on to explain “that the existence of the rights granted by a Member State to the holder of a patent is not affected by the prohibitions contained in [ex] Articles 85(1) and 86 of the Treaty” and “that exercise of such rights cannot of itself fall either under [ex] Article 85(1), in the absence of any agreement, decision or concerted practice prohibited by that provision, or under [ex] Article 86, in the absence of any abuse of a dominant position.”¹⁴ It was clear that the EU law would not touch upon the creation of the IP rights. However, the exercise was decided to be subjected to the scrutiny of the Treaty rules. In later cases this distinction was transferred also into the free movement field.¹⁵ In Phil Collins, the Court summed it up and stated that the industrial and commercial property rights “are by their nature such as to affect trade in goods and services and also competitive relationships within the Community. For that reason, and as the Court has consistently held, those rights, although governed by national legislation, are subject to the requirements of the Treaty and therefore fall within its scope of application.”¹⁶ The reluctance of the ECJ in tackling the existence of IPRs under competition rules thus appears to safeguard the nationally granted exclusive rights.

1.2. When is the exercise of IPR abusive?

Given the fact that through IPRs the State grants a limited monopoly over the use of the invention to the proprietor, the question which needs to be asked is when competition law should be allowed to censure its exploitation. The first and more general check involving the balancing between the need for reward and the need to encourage competition is done by State authorities while granting IPR. However, IPRs are granted on the basis of general criteria, no account being taken of the particular circumstances of each case.¹⁷ That is why

¹⁴ ibid  
¹⁶ Case C-92/92 Collins and Patricia v Imrat and EMI Electrola [1993] ECR I-5145, para 22 (Phil Collins)  
IPRs do not address all the concerns of competition law. Here appears the room for a legitimate role for Article 102. The Court has generally taken a cautious approach in determining what the rule should be.

The Court has repeatedly stated that the ‘normal exercise’ of IPRs was not caught by Article 102 of the Treaty. For the prohibition under Article 102 to apply all the elements have to be present in the given case: the existence of the dominant position, the abuse of this position and the possibility that interstate trade may be affected. The protection given by the patent does not imply the presence of all of these conditions. It could only do so if the use of the patent were to degenerate into an abuse of the abovementioned protection.\(^{18}\) Similarly, the Court has held that this is true in the field of trademarks\(^{19}\) and design rights\(^{20}\). The question was therefore what the ‘normal exercise’ of the right is. The answer was given in *Hoffman La Roche*\(^{21}\) where the Court created a test of permitted exercise of IPR. In paragraph 16 of the judgment it is said: “to the extent to which the exercise of a trademark right is lawful in accordance with the provisions of [ex] Article 36 of the Treaty, such exercise is not contrary to [ex] Article 86 of the Treaty on the sole ground that it is the act of an undertaking occupying a dominant position on the market if the trademark right has not been used as an instrument for the abuse of such a position.”\(^{22}\) Therefore, the exercise to be unlawful must be linked in some way to commercial practice which is itself unlawful under Article 102 and IPR must constitute an instrument of such an abuse.\(^{23}\) It is thus only in exceptional circumstances that IPR granted by the national law should be limited by competition law.

In order to decide what those exceptional circumstances are, the Court created the notion of the subject-matter of the right. It would thus allow delineating the difference between legitimate and abusive use of IPR. The Court has been deciding case by case what the

\(^{18}\) ibid  
\(^{19}\) Case 86/75 *EMI Records Limited v CBS Grammofon A/S* [1976] ECR 871, para 26  
\(^{20}\) Case C-144/81 *Keurkoop BV v Nancy Kean Gifts BV* [1982] ECR 2853, para 27  
\(^{21}\) Case 102/77 *Hoffman-La Roche v Centrafarm* [1978] ECR 1139  
\(^{22}\) Case 102/77 *Hoffman-La Roche v Centrafarm* [1978] ECR 1139, para 7  
specific subject matter of each IPR is, e.g. the specific subject matter of patent “is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.” The expression specific subject matter is not consistently held in all cases. The Court uses also terms such as ‘substance of the right’ or ‘essential function’. Despite those differences, the aim of putting the issue in such a way is not to deprive the proprietor of his exclusive right.

The Court has been deciding again case by case what the exceptional circumstances are. In the early cases the Court was not willing to recognize exploitation of IPR such as setting higher prices of the patented products or preventing the importation of products bearing identical mark as being abusive. Only later, specifically in Volvo v Veng and Magill the Court actually analyzed the circumstances in which the exercise of IPR can amount to abuse of dominant position: the arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation or preventing the appearance of the new product. The mere acquisition and possession of IPR should not give rise to competition scrutiny but “if accompanied by additional conduct designed to foreclose the market, the cumulative effect may be anticompetitive. The concern is with conduct that lies outside the natural scope of exclusivity offered by the [IPR].” In all those cases the Court has been focusing on the exercise of IPR already acquired under

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24 Sterling Drug, para 9
25 Case 19/84 Pharmon BV v Hoechst AG [1985] ECR 2281, para 26
26 Hoffman-La Roche v Centrafarm, para 7
27 Parke, Davis
28 EMI v CBS
29 Case C-238/87 Volvo v Veng Ltd. [1988] ECR 6211
30 ibid para 9
31 Magill, para 54
national laws. However, as competition law has been evolving, the clear distinction between the acquisition of IPRs and their exploitation seemed to be set aside as not being essential in assessing the anticompetitive behaviour of undertakings.

After presenting the criticism of the dichotomy amongst scholars, the focus will be given to the recent developments in the positions of the Commission and the Court to the idea of distorting competition by virtue of acquiring IPRs.

**Criticism**

The distinction between the existence and exercise of IPR has been widely criticised by many authors as being “vague, artificial, unhelpful and unworkable” and that it created “an artificial and incoherent demarcation of the scope of property rights.” It is believed to have no “clear meaning in relation to something as intangible as an intellectual property right.”

It has also been regarded as incoherent and unnecessary “hasty response” to Consten and Grunding. “On an academic level, the distinction between the inviolability of the existence of intellectual property rights and the vulnerability of their exercise under the Treaty of Rome is illogical. A prohibition on the exercise of rights means that an essential part of the relevant law is unenforceable and, as such, the prohibition constitutes an attack on the very existence of such laws.”

Also, building the dichotomy on the principle of sovereignty of the national system of property ownership seems to be debatable. Article 345 TFEU as being derived from Article 83 of the European Coal and Steel Community Treaty, which was intended only to ensure that Member States would be free to determine whether enterprises subject to the ECSC Treaty were publicly or privately owned, does not seem to provide proper legal basis

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33 Keeling (n 17) 54
35 ibid
37 Guy Tritton, ‘Articles 30 and 36 and intellectual property: is the jurisprudence of the ECJ now of an ideal standard?’ (1994) EIPR 16(10), 422, 423
38 Keeling (n 17) 54
for such a principle for some scholars.\textsuperscript{39} Some of them have already concluded that the distinction has been abandoned by the Court. By not making reference to the dichotomy, the ECJ is believed to “silently pronouncing its death”.\textsuperscript{40} However, one might think that the dichotomy has become so fundamental that it does not need further recitation. This doesn’t seem to be the convincing argument, as Rothnie has noticed in the case comment on \textit{HAG II}. He suggested that the Court after mentioning the dichotomy went straight to consider the compatibility of national laws with Community law. This makes it hard to believe that the existence of IPRs remains inviolable against the free movement of goods.\textsuperscript{41} Advocate General Fennelly took the same position in his opinion in \textit{Merck v Primecrown}: “The distinction between the `existence’ and the `exercise’ of rights can, at times, be quite unreal; it has not been referred to in recent case-law, such as HAG II, and may now, at least in so far as the interpretation of Articles 30 to 36 of the Treaty is concerned, be discarded.”\textsuperscript{42} What some sees as the only useful element in the existence/exercise dichotomy is that “whatever limitations Community law imposes on the exercise of an intellectual property right, it must not destroy the substance of the right. The nucleus of the exclusive right recognized by national law must remain intact. The judicial and legislative organs of the Community must not curtail the exercise of the right to such an extent as to produce a confiscatory effect.”\textsuperscript{43}

Nevertheless, not everyone agrees with that criticism. Marenco and Banks, although confirming that there was a shift in the policy of the ECJ regarding the existence/exercise dichotomy, they do not find this distinction obsolete.\textsuperscript{44} That is true that the distinction being

\begin{footnotesize}
\begin{enumerate}
\item Tritton (n 37) 423; For the review of Article 345 TFEU see Bram Akkermans and Eveline Ramaekers, ‘Article 345 TFEU (ex Article 295 EC), Its Meanings and Interpretations’ (2012) European Law Journal Vol.16 No. 3, 292
\item Haracoglou (n 34) 106
\item Warwick A. Rothnie, ‘Hag II: putting the common origin doctrine to sleep’ (1991) EIPR 13(1), 24, 29
\item Joined cases C-267/95 and C-268/95 \textit{Merck v Primecrown} [1996] ECR I-6285, Opinion of AG Fenelly, para 93
\item Keeling (n 17) 56; \textit{Consten and Grunding} was one of the cases where the existence of the right was upheld but in practice it was emptied of its substance. (Govaere I, \textit{The Use and Abuse of Intellectual Property Rights in EC Law} (Sweet&Maxwell 1996) 36). Also the Court has gone very close to destroying the essence of IPR recognized by national law in cases 192/73 \textit{Van Zuylen v Hag} [1974] ECR 0731 (\textit{HAG I}) and \textit{Magill}.
\item Marenco and Banks (n 15) 230
\end{enumerate}
\end{footnotesize}
transferred from the field of competition law to the free movement policy has created problems with its application. The reason for this is that those two fields regulate behaviour of different subjects. Competition rules apply to the behaviour of undertakings and the free movement rules address the measures created by the Member States. That is why the distinction even though it might not be that evident any more when it comes to assessing national measures, it seems still to have some value in the field of restrictive agreements or abusive exercise of a dominant position by undertakings.

To sum it up, it has been suggested that there is a strong case in abandoning the dichotomy on the grounds that it is vague and arbitrary. While the existence/exercise distinction was regarded as a guiding principle in the early cases, in more recent judgments the ECJ seems to deviate from this principle and use the ‘circumstance-based’ approach. To determine if particular behaviour can constitute an abuse each case is to be judged according to its circumstances. It was hoped that the Court will give an interpretation what constitutes the exceptional circumstances.

1.3. Shift in the policy

First case where a change in the Commission’s and the Court understanding of the dichotomy in the field of competition can be noticed is the Tetra Pak I case. In this case the issue at stake was the acquisition of the exclusive licence through takeover of the company Liquipak by Tetra Pak. As the Commission concluded in its decision “Tetra abused its dominant position by the acquisition of exclusive licence which had the effect of strengthening its already dominant position, further weakening existing competition and rendering even more difficult the entry of any new competition.” The case didn’t involve the acquisition of IPR according to national law regimes as a first user but only a commercial

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45 Haracoglou (n 34) 106
46 ibid
47 Case T-51/89 Tetra Pak v Commission [1990] ECR II-309 (Tetra Pak I)
transaction between two parties for assignment of IP rights. This constitutes the clear case of exercise of IP rights. However, as some noticed, the Commission chose to attack the acquisition of the licence rather than the merger itself which it could have done.\textsuperscript{49} Advocate General Kirschner also pointed out that the normal exploitation of originated rights should be distinguished from acquisition through purchase. The principles which Court has developed in regard to the original acquisition of industrial property rights cannot be transposed directly upon the derived acquisition of the exclusive license.\textsuperscript{50} The Advocate General made it clear that in this case not only the acquisition of the exclusive right was not protected by the existence of IPR but it was disproportionate conduct infringing Article 86 of the EC Treaty. However, the Court of First Instance didn’t address the difference in the original and derived acquisition of IPR either. It confined itself to the statement that the mere fact that an undertaking in a dominant position acquires an exclusive licence does not per se constitute abuse within the meaning of [ex]Article 86.\textsuperscript{51} What mattered were the circumstances surrounding the acquisition and its effect on the structure of competition. The Court has confirmed that the Commission didn’t question the exclusivity of the acquired right but the anticompetitive effect of its being acquired by Tetra Pak. It has “strengthened Tetra Pak’s very considerable dominance but also [it] had the effect of preventing, or at the very least considerably delaying, the entry of a new competitor into a market where very little if any competition was found.”\textsuperscript{52}

Where does this change in the perception of only holding a property right as abusive comes from in the agenda of the Commission? As Anderman notices, previously the legal monopoly conferred by a patent in the form of excluding everyone from exploiting the patented invention was presumed to coincide with market power. This was further replaced by a more appropriate judicial and administrative understanding that the actual market power

\textsuperscript{49} Steven D. Anderman, \textit{EC Competition Law and Intellectual Property Rights. The Regulation of Innovation} (OUP 1998) 85
\textsuperscript{50} Case T-51/89 Tetra Pak (I) v Commission [1990] ECR II-309, Opinion of AG Kirschner, para 364
\textsuperscript{51} Tetra Pak I, para 23
\textsuperscript{52} Tetra Pak I Commission Decision, para 45
associated with an IPR must be assessed empirically in each case.\textsuperscript{53} Moreover, the new more-economic approach has been introduced to the Commission’s assessments. These developments mean that competition law can be treated now as a ‘second tier’ of the regulation of the exercise of IPRs, which applies to anticompetitive conduct not prevented by the ‘internal’ system of regulation offered by IP legislation.\textsuperscript{54} The Commission is seen as revisiting the dichotomy approach in its enforcement agenda, especially in its sector inquiry.\textsuperscript{55}

There has also been noticed the rise in an actual number of confrontations between the owners of IP and competition authorities. On the one hand IP owners have developed new and more aggressive commercial strategies while exploiting their IPRs. On the other hand, the regulatory authorities have adapted their techniques for measuring market power and defining abuse in response to that.\textsuperscript{56} The Microsoft\textsuperscript{57} case investigates the vertical integration strategies such as tying and bundling aimed at leveraging the market power to ‘aftermarkets’ by dominant firm and gives the revised position on the anticompetitive effect of refusal to supply in the information technology sector. The Intel\textsuperscript{58} case focuses on the limits put on anticompetitive discounting in which dominant firms are engaged in order to create exclusivity in primary markets. Finally, AstraZeneca, the main focus of this thesis, fits into this trend and offers interesting case of misuse of the patent system as an abuse of dominance in the pharmaceutical sector.

AstraZeneca was fined for two abuses of the dominant position, firstly, for the misrepresentations before the national patent authorities while applying for a supplementary patent certificate and secondly, for the use of patent lifecycle strategies in order to maintain

\textsuperscript{54} Ibid 4
\textsuperscript{55} Priddis and Constatine (n 7) 255
\textsuperscript{56} Ibid 5
\textsuperscript{57} Case T-201/04 \textit{Microsoft Corp v Commission} [2007] ECR II-3601
the market power. This case adds a new perspective to the Commission’s assessment of the use of IPR. It also opened the discussion on the patent strategies in this sector placing the companies under constant scrutiny of the Commission. For some it raises the question of whether the Commission’s actions, taken in the name of competition, are stifling the legitimate commercial practices of a free market economy. The focus will be paid to the first abuse identified by the Commission which deals with the obtaining of SPC, as this addresses the main issue of this paper.

In the next chapter I will present the facts of the case and the characteristics of the pharmaceutical sector within Commission’s enforcement strategy.

Chapter 2: AstraZeneca and Fraudulent Acquisition of Patent

The interaction of patent law and competition law in the pharmaceutical industry is even more complex then introduced in the first chapter because of the characteristic of the sector. Patents are vital to this sector because of “the necessity to address current and emerging health problems and the long life cycle of products”. The innovation in human medicines allows for continuous efforts in order to find new medicines. The exclusivity period granted through patent law and other mechanisms provide incentives for originators to continue innovating. The importance of patents has been also emphasised by the EFPIA:

“The extent to which IPR protection is an essential part of a particular industry’s business model will largely depend on the cost, risk and time involved in bringing an innovative product to market, and on the cost and risk of imitation. […] Given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation.”

The business model and current business strategies will be presented with the view to place AstraZeneca’s behaviour and Commission’s decision in the market place.

2.1. AstraZeneca’s first abuse placed within the sector characteristics

Traditionally, the pharmaceutical industry has been divided between research-based and generic companies. The former are typically involved in R&D activities and in manufacturing their own invented products. Generic companies base their business on exploring inventions of original companies once the period of patent protection has expired. What characterises the industry is the high level of cost and risk for the originators and the relative low price of

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imitation of the pharmaceutical innovation and its intensification within last decade. Therefore, the period of exclusivity is crucial. Otherwise, no company would take the burden of financing big investments without having a chance to gain competitive advantages which could consequently lead to market failure.

Only one in 5000-10000 discovered compounds reach the market, most of the products fail at the development stage. The drugs which are finally put on the market are those which have to generate the companies’ revenue. The top selling products, called block-busters, are the backbone of the companies’ strategies allowing them for recouping the R&D investments for most of the products, also those which failed throughout the process of bringing them to live. Blockbusters offer profit margins of up to 80%. Hence, most of the originator companies focus on the business strategies which would allow them to recoup most of their costs from the sale of the top-selling products. They engage in patent strategies involving life-cycle management before or after patent expiry, in order to keep the acquired market shares for as long as possible. That is why pharmaceutical industry heavily relies on the protection offered by IP law. It is noted that IP protection has shifted from the traditional invention-based protection (patents) towards other sui generis IPRs that are based on product protection.

Another feature of the pharmaceutical sector is the time needed for the development of the drug. It is commonly estimated that from the time the compound is granted a patent protection to the moment the drug receives the authorisation to be marketed, it takes

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65 Sector Inquiry (n 5) para 28
66 Von Braun and Pugac (n 62) 609-610
between 10-12 years. This leaves the companies with less than half of the 20-years period of protection guaranteed by the patent for recovering the costs of R&D and gaining profit. This development time led the EU to the adoption of the Supplementary Protection Certificate (SPC). SPC offers supplementary compensation for the R&D investments by providing additional exclusivity period taking effect at the end of the lawful end of the primary patent. The extra maximum of 5 years of protection can be granted to the owner of the patent not exceeding however 15 years of the overall protection on the given product. The conditions which need to be fulfilled in order to obtain the SPC are: basic patent has to be in force, the product has to possess valid authorisation to be placed on the market and that authorisation has to be the first authorisation in the market. The crucial date for the determination of the length of the extra protection is therefore the date of the first authorisation of the product on the market in the Community. As the Court clarified in the case Hässle, the concept of first authorisation granted in any of the Member States did not refer to the authorisations required under legislation on pricing or reimbursement for medicinal products (effective authorisation). It is the technical authorisation in the form of the administrative decision issued by the competent authority which should be taken into account while applying for the SPC.

AstraZeneca is a pharmaceutical group active on a worldwide market for inventing, developing and marketing innovative medicines. Its business is based on the top selling products as described above. For AstraZeneca the major product bringing most of the profit to the company was Losec, a brand name used in most of the European markets for omeprazole, a drug treating gastrointestinal conditions. Losec was protected at the time of the case by substance and formulation patents. Facing the loss of exclusivity and the unavoidable entrance of generic companies on the market for omeprazole, AstraZeneca

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67 PhRMA (n 64)
68 See Article 63 of the Convention on the grant of European patents (European Patent Convention) 1973
69 Case C-127/00 Hässle AB v Ratiopharm [2003] ECR I-14781
70 ibid, para 79
prepared the strategy for expanding the protection of Losec up to the maximum applying for a protection offered by SPC. As at the time of the case the notion of first authorisation was not clarified, AstraZeneca tried to obtain or preserve SPCs for omeprazole by interpreting the authorisation date as the effective authorisation date (date on which a price or reimbursement level was agreed) rather than technical authorisation date (the first grant of a marketing authorisation). This behaviour was scrutinised by the Commission as abusive according to Article 102 TFEU. The abuse, as defined by the Commission, consisted of the submissions of deliberately misleading representations to patent agents, national patent authorities and national courts in order to acquire or prolong the SPC protection to which AstraZeneca was not entitled or was entitled for a shorter duration.  

According to AstraZeneca, the infringement took place because of the lack of clarity in the wording of the regulation. However, as the Commission stated, abusive was the fact that AstraZeneca didn’t proactively explain its basis upon which it thought it was entitled to an SPC for Losec and not the wrong interpretation presented by the company. This behaviour was also considered to be part of the overall strategy intended to exclude competitors by raising their costs and suffer the delays associated with legal proceedings.

2.2. Acquisition of patent can be abusive

In *Hoffmann La-Roche* the Court explained that “the concept of abuse is an objective concept relating to the behaviour 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 that


72 Ibid, para 736-740
competition.” By that the Court created an objective notion of abuse which does not imply the fault and it does not depend on the intention of the undertaking to exclude competitors or weaken the competition. The Court distinguished also between the competition on merits and recourse to methods different from normal competition. Moreover, the abuse is not limited to the behaviour on the market but also covers the use of public procedures and regulations if such behaviour can create entry barriers capable of preserving market power over extended period of time.

With this regard, AstraZeneca behaviour of providing the inaccurate information to the Member State authorities has abused its dominant position on the omeprazole market. It managed to extend the patent protection and its position on the market beyond the period guaranteed by the law undermined legislators’ objective of rewarding genuine innovation. AstraZeneca application was therefore recognized as anticompetitive, not meeting the requirements of competition on merits. These misrepresentations before the national patent authorities have been recognized as the aforementioned misuse of public procedures and regulations. Important part of the Commission’s assessment of the case played proof of anticompetitive intent of the company in question. The Commission, answering the arguments of the applicant that the abuse as objective concept implies no intention to cause harm, has argued that the intention is a relevant factor in deciding whether behaviour is objectively capable of restricting competition. The Court confirmed the Commission’s statement that in this situation the intent can be taken into account in assessing the abusive character of the AstraZeneca’s behaviour. This approach has been supported also by the Advocate General Mazák in its opinion in AstraZeneca: “I consider that the General Court correctly stated that proof of intention to resort to practices falling outside the scope of

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73 Case 85/79 Hoffmann La-Roche v. Commission [1979] ECR 461, para 91
75 Mateo Negrinotti, ‘Abuse of regulatory procedures in the intellectual property context: the AstraZeneca case’ (2008) ECLR 29(8), 446, 452
76 AstraZeneca, para 334
77 Ibid, para 359
competition on the merits may (...) be relevant where it supports the conclusion based on objective factors that an undertaking abused its dominant position.”

Despite this assertion, the core of the case must be based on the actual actions aimed at executing this intent, not leading though to the conclusion that these actions had led to the actual aim being achieved. This means that the intent and goal which the company undertakes does not need to result in its enforcement, which is specifically significant for assessing the misrepresentations before the United Kingdom patent office which didn’t grant the SPC to Astra Zeneca and withdrawal of the application from Denmark patent offices to avoid explaining the used date of first marketing authorization.

The main point of interest in this paper is the Commission’s statement that the acquisition of IPR can constitute an abuse for the purpose of Article 102. The Commission stated that the arguments of AstraZeneca as to the special treatment of acquisition of SPC must be rejected. In its decision, it has stated that the dichotomy between existence and exercise of IPR “has gradually been abandoned (...) and been replaced by the concept of the subject-matter of the right in question.” Even though in the given case the misleading representations cannot be treated as part of the specific subject-matter of the patent, the Commission produced a statement that both the acquisition of a right and its enforcement may in themselves constitute an abuse and that there is no reason “why the conduct in the procedure relating to the acquisition of the right cannot be considered an abuse.” Some see it particularly striking that the Commission officials have declared that the acquisition of a right may constitute an abuse which seems to depart from the initial views expressed by Commissioner Monti in the press release issued by the Commission shortly after the investigation was launched. Commissioner Monti stated in the press release dated 31 July

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78 Case T-321/05 AstraZeneca AB and AstraZeneca plc v European Commission [2010] ECR II-02805, opinion of AG Mazák, fn 32
79 AstraZeneca, para 336
80 AstraZeneca Commission’s Decision, para 741
81 AstraZeneca Commission’s Decision, para 742
82 Manely (n 59) 270
2003: “This is not about the use or enforcement of patent rights which are necessary and even indispensable to foster a competitive European research-based pharmaceutical industry. It is about suspected misuses of governmental systems and procedures which have the effect of blocking or delaying entry to the market of cheaper medicines which involves savings for both health systems and patients.” The abuse in AstraZeneca according to the Commission involved the acquisition of patent, based on the judgement Tetra Pak I. The General Court however didn’t address this issue directly from the point of view of acquisition of the exclusive right. It did only a remark that the situations in Tetra Pak I and AstraZeneca involved different situations. The General Court nevertheless agreed that the “the mere possession by an undertaking of an exclusive right normally results in keeping competitors away” and it does not have to be enforced to produce such an effect. The existence of an SPC, as the existence of any exclusive right, has deterrent effect on the generic competition. Existing rights are presumed to be valid and this creates specific expectations and places constrains on the subsequent behaviour of the generic companies on the market. SPC in question delayed the preparations by potential generic competitors with a view to launching omeprazole-based products. AstraZeneca by obtaining extra protection was able to threat and sue competitors. Potential new entrants on the market had to initiate legal proceedings against AstraZeneca. All those considerations result in deterring effect on the generic competition. The Commission and the Court has concluded that AstraZeneca’s behaviour was exclusionary and capable of harming rivals and short-term consumer welfare. Such behaviour was therefore capable of producing anticompetitive foreclosure on the market dominated by the patent.

84 AstraZeneca Commission’s Decision, para 742
85 AstraZeneca, para 365
86 ibid, para 362; Confirmed later in the Opinion of AG Mazák in AstraZeneca, para 70
Chapter 3: IMPACT OF ASTRAZENECA ON THE ACQUISITION AND POSSESSION OF PATENTS IN COMPETITION LAW REGIME

Core of this paper consist of the analysis of the impact of the AstraZeneca judgement on the practice of the Commission in addressing issues of compatibility of the acquisition and possession of IPRs with competition law. Firstly, the issue of intent and its importance in the antitrust assessment will be highlighted. The disagreement as to the role of intent as a legal standard is noticeable in the academic world. Although neither the Commission nor the General Court in AstraZeneca claimed that the intent can constitute main evidence in finding the abuse of dominant position, it observed that the intention can still be taken into account to support such a conclusion. This can have an impact on the process of acquiring patent protection, especially taking into account the fact that one of the reasons for applying for patent protection is to exclude others from exploiting the invention. Secondly, the focus will be paid to the fact of exercising the obtained IPRs. In traditional approach the rights have to be exercised for competition law to be applied and exceptional circumstances have to be proven to exist. AstraZeneca brings a new field of application for Article 102 TFEU and it states that the exercise of IPRs is actually not necessary for finding an abuse. This suggests that the role of competition law will be importantly enlarged. Also the no-exercise notion confirms the changes in the formalistic approach to IPRs. In the third part I will address the issue of the effects which the acquisition of IPR can have on the competition and competitors. The importance of the proof of harm in the antitrust assessment will be highlighted as a part of more economic approach. This element seems to be particularly important in the area of IPR and competition law where balancing between the aims of these two law regimes is essential.

87 AstraZeneca, para 334, 359
3.1. Role of intent in addressing abuses under 102 TFEU

3.1.1. Intent as a legal standard in antitrust law

Legal standards set the facts or conditions which must be proved or implied by the evidence to win the case. They can be divided in two categories: conduct standards and intent standards.\(^{88}\) Conduct standards describes the kind of conduct which the plaintiff must demonstrate for the case to prevail. The two best known conducts standards are the rule of reason and per se rule. While in rule of reason test the reasonableness is taken into account and it needs the balancing act of the costs and benefits to be undertaken, the per se rule does not involve such weighting.

The second category of legal standard, the intent standard, “determines liability in part by the evidence concerning the defendant’s state of mind.”\(^{89}\) Here also two types are identified: general intent standard which covers merely intent to carry out the alleged anticompetitive conduct without the need to show the purpose of the conduct and specific intent standard which requires proof that the defendant intended to harm competition. Specific intent standard is moreover seen as different that subjective intent which would require direct evidence revealing the defendant’s state of mind.\(^ {90}\) The subjective intent inquiries looking for subjective statements made by the company officers, such as documents or testimonies, drew significant criticism as to their relevance, unreliability or for being prone to misinterpretation.\(^ {91}\) Specific intent therefore is based on the objective evidence where the state of mind can be inferred in the light of the presented conduct. For instance, in case of predatory pricing a rational business would not sacrifice its profits unless it is believed that


\(^{89}\) ibid 6

\(^{90}\) ibid 4

the practice would allow for further recoupment of losses. Such objective indication of motivation and intent is seen as no less reliable than any other kind of evidence.\textsuperscript{92}

It is argued that legal standards in competition assessment should be seen as the combination of conduct and intent assessment.\textsuperscript{93} While the general intent, understood as awareness of own conduct, can constitute part of the per se rule and rule of reason assessment, the specific intent standard requiring objective proof of intention to harm competition is suitable in particular for the reasonable conduct test.\textsuperscript{94} Pure economic effects analysis often do not allow for the balancing activity. As an example can serve the RRC theory which provides the possible explanation of the conduct but it does not take into account possible efficiency gains. Intent evidence can help determine which dominant firm conduct is exclusionary and which is efficient as it can provide clues about ambiguous strategies and their effects on competition.\textsuperscript{95}

3.1.2. US antitrust

In the US jurisprudence the intent evidence has a long standing tradition. It is recognized that the Court favours the ‘specific intent test” rather than ‘subjective intent’\textsuperscript{96}, as the subjective intent would move beyond making inferences about intent from evidence of the actions taken by firms\textsuperscript{97} and would cause problems with obtaining reliable evidence for a firm’s business practice. Although the Sherman Act is silent on intent, the intent of the actors while determining antitrust liability under the Sherman Act is continuously considered as a part of the analysis. The intent test was developed by the Supreme Court’s unanimous

\textsuperscript{92} ibid 200
\textsuperscript{93} Cass and Hylton (n 88) 7
\textsuperscript{94} ibid 9
\textsuperscript{95} Lao (n 91) 198
\textsuperscript{96} Lao (n 91), Cass and Hylton (n 88). Some of the authors use nevertheless the notion of subjective intent without distinction with specific intent (W. Michael Schuster, ‘SUBJECTIVIE INTENT IN THE DETERMINATION OF ANTITRUS VIOLATION BY PATENT HOLDERS” (2007) 49 S. Tex. L. Rev. 507-534)
\textsuperscript{97} Cass and Hylton (n 88) 22
decision in Aspen Skiing Co v. Aspen Highlands Skiing Corp. with regard to refusal to deal.\textsuperscript{98} Against the strict economic approach of the Chicago School, Aspen held that monopolist’s refusal to deal may violate Sherman Act Section 2 if the monopolist lacks legitimate competitive reasons for refusal.\textsuperscript{99} The distinction exists as to the recognition of intent for per se rule and rule of reason. In per se illegal activities there is no need to prove the specific intent or the “perpetrator’s knowledge of the anticipated consequences”\textsuperscript{100} Nevertheless, when the rule of reason standards apply to the given case, the government must show that defendant either intended a clearly illegal result or acted with knowledge that illegal results were probable.\textsuperscript{101} In Kodak the Ninth Circuit’s stated that it is for a plaintiff to rebut the presumption that the defendant undertook its actions (in this case withheld sales of patented goods) for a valid business purpose.\textsuperscript{102} Specific intent test is actionable only if the defendant cannot produce a valid justification of the conduct based on legitimate business justifications. Without that excluding others from markets would constitute an abuse of possessed market power. In Chicago Board of Trade the court indicated the importance of the intention evidence. It was stated that “knowledge of intent may help the court to interpret facts and to predict consequences.”\textsuperscript{103}

Following this case, the defendant’s intent is being evaluated in finding the offence of monopolisation or attempted monopolisation.\textsuperscript{104} The intent evidence has in cases where the court must predict the likely competitive effects probative value and is defined narrowly: “evidence of the intent behind the conduct of a monopolist is relevant only to the extent it helps understand the likely effect of the monopolist’s conduct.”\textsuperscript{105} Also, the narrow reading of

\textsuperscript{98} 472 U.S. 585 (1983)  
\textsuperscript{99} Aspen, 472 U.S. para 604-05  
\textsuperscript{100} United States v. U.S. Gypsum Co., 438 U.S. (1978) para 446  
\textsuperscript{101} ibid 444-46  
\textsuperscript{102} Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997) para 1218  
\textsuperscript{103} Chicago Board of Trade 246 U.S. 231 (1918) para 238  
\textsuperscript{105} United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001)
the intent has been proven in *Trinko*\textsuperscript{106}. In this case new indicative element of intent and exclusionary conduct was added as a requirement, specifically sacrifice of profits.\textsuperscript{107} One may think that this development decreased the significance of the role of intent. Despite that, the intent is considered important because “business strategies and competitive effects in complex antitrust cases can be ambiguous, and the line between predation and aggressive competition difficult to discern.”\textsuperscript{108} Consequently, the Court in its assessment of the rule of reason finds the specific intent relevant for antitrust cases.

Despite this clear indication, there is also a criticism of such an approach. According to the Chicago School intent plays no useful role in the attempted monopolization claim. “If the courts use the vigorous, nasty pursuit of sales as evidence of a forbidden “intent”, they run the risk of penalizing the motive forces of competition. […] Intent does not help to separate competition from attempted monopolization and invites juries to penalize hard competition.”\textsuperscript{109} Also, the intent concept is not useful in drawing the distinction between pro- and anticompetitive conduct, because all sorts of pro-competitive behaviour may be motivated by eliminatory intent.\textsuperscript{110} It is argued that determining the legality or illegality of certain actions should be assessed in objective terms without considering the defendant’s intent.

### 3.1.3. EU competition law

Evidence of intent traditionally plays a limited role in Article 102 TFEU analysis. The definition of abuse is a well established objective concept relying on the objective evidence of the anticompetitive conduct without reference to the intent which always covers the

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\textsuperscript{107} This judgment has been criticized as excluding entire categories of potentially predatory conduct by transforming the sacrifice into a required element of exclusionary conduct. (Lao (n 91) 173)

\textsuperscript{108} Lao (n 91) 177

\textsuperscript{109} *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1401-03 (7th Cir. 1989) cited in Stucke (n 104) 21

subjective element. This view was strongly supported by the Advocate General Mazák in his opinion on the AstraZeneca case.\textsuperscript{111} Nevertheless, it can be argued that there is a place for the intent as a legal standard of assessment. The attempt to introduce intent to the antitrust assessment was already undertaken in \textit{Magill}.\textsuperscript{112} The Court considered there that “pursue [of] an aim manifestly contrary to the objectives of [ex]Article 86” was outside the essential function of the protected copyright.\textsuperscript{113} Although the intent was not directly mentioned by the Court and it was characterized as an element in the analysis of essential function\textsuperscript{114}, the case can be regarded as pointing out the possibility to rely on the intent in assessing the anticompetitive character of the undertakings’ behaviour.

Evidence of intent was then recognized for Article 102 TFEU analysis in situations where it is unclear whether the conduct can be classified as competition on merits or whether there is likelihood competitive harm.\textsuperscript{115} The example of this approach has been presented in \textit{AKZO}\textsuperscript{116} where the test for predatory pricing was considered. In this case three areas in pricing have been identified which determine whether the price can be abusive or not. Prices that do not recover the average variable costs of the products are presumed to be abusive. Prices that cover costs on a fully allocated cost basis constitute competition on merits and cannot be abusive. Problematic is the grey area that covers variable costs but not a total cost. In such a case conduct is deemed to be abusive only where it is a part of an anticompetitive scheme or plan to exclude competitors. This approach has been confirmed by the Court’s statement in \textit{Wanadoo} case: “In the case of non-recovery of variable costs, the second element, that is, predatory intent, is presumed, whereas, in relation to prices below average full costs, the existence of a plan to eliminate competition must be proven.”\textsuperscript{117}

\textsuperscript{111} AstraZeneca, Opinion of AG Mazák, paras 47-52
\textsuperscript{112} Kallaugher (n 8) 129
\textsuperscript{113} Magill para 28
\textsuperscript{114} Kallaugher (n 8) 129
\textsuperscript{115} ibid 130
\textsuperscript{116} Case C-62/86 AKZO Chemie BV v Commission [1991] ECR I-3359
\textsuperscript{117} Case T-340/03 France Télécom SA v Commission [2007] ECR II-0170, para 197
These cases suggest that eliminatory intent, which is independent of anticompetitive effects, may constitute a basis for finding of abuse, despite that fact that abuse is defined as an objective concept. The relevance of the intention is confirmed but the General Court in *AstraZeneca*. In paragraph 359 the Court says: “The fact, relied upon by the applicants, 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 intention to resort to practices falling outside the scope of competition on 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 the objective finding that the abusive conduct actually took place.” The Commission has therefore power to examine anticompetitive conduct of firms relying in part on their intent.

The Court in the given cases did not rule on the kind of intent, which can be taken into account. I would argue that the only plausible understanding of the intent, if it is to be taken into account, is the specific objective intent, based on the objective evidence from which the state of mind can be inferred. Such an approach would be consistent with the US practice, where the intent evidence has considerable tradition, and it would allow avoiding problems with gathering evidence of specific subjective intent clearly stating the state of mind of the firm.

**3.1.4. Intent in the area of IPR**

The presented construction of intent in the area of patents needs a slightly different approach. As it is true that invoking patent involves the intention of excluding rivals, evidence of such intent would have little value in distinguishing between legitimate acquisition of patent and abuse. Concerns that in the area of IPR intent cannot be other than exclusionary is explicitly expressed by the European Patent Office. In its comments to the Sector Inquiry the European Patent Office showed “discomfort in classifying behaviours on the basis of the
applicant’s intent in applying for patent rights.” The EPO suggests that the subjective intent in acquiring patent right as well as in exercising those rights “in a particular manner, as long as such behaviour remains in line with prevailing rules of competition law” should remain irrelevant as the EPO requirements are strictly objective, predictable and thus enhancing legal certainty. Therefore this statement confirms the general view shared in the area of competition law that, unless the patent rights are exercised within the limits of competition law, the intent should not matter. It could nevertheless play a role in addressing issues which are in the context of exceptional circumstances. Legitimate claims for the patent protection have as their main aim receiving reward for the innovation and the exclusionary effect is a result of intent to receive such a reward. It is however only allowed under the conditions set out by the legislator, e.g. within the time of the protection. The balance for such temporary exclusion of competitors constitutes the full disclosure principle. Therefore, once the firm uses the protection offered by IPR regime to circumvent the goals of this regime by keeping the competition away from the market for longer time then it is prescribed, such intention is no longer legitimate.

AstraZeneca’s conduct, as presented by the Commission, concerned prolonging the monopoly given by the patent right. The extra protection, to which the company was not eligible, was obtained as a result of misrepresentations to the patent offices. Such conduct could not be described as a legitimate use of patent system. The intention of the AstraZeneca was interpreted on the basis of the strategy aimed at excluding competitors. Providing misleading information to patent offices in different countries, relying on different dates of the marketing authorisation of Losec was defined not as a mere faulty interpretation.

119 ibid 6
120 Priddis and Constantine (n 7), Kallaugher (n 8)
121 AstraZeneca, paras 329, 330
122 ibid, para 337
of ambiguous legal provisions. The main point in the Commission’s assessment was the fact that there was no consistency in the interpretation of the notion of marketing authorisation.\(^{123}\)

The question can be asked what would happen in the situation of genuine error in providing information, where the only aim of the company was obtaining the protection with no intention to illegitimate exclusion of competitors. The objective notion of abuse would cover such patent applications, as they bring the anticompetitive exclusionary effects. Lack of illegitimate intention would not change the qualification of such conduct as abusive. As the Court has stated in *AstraZeneca*, the intention can constitute only a support in antitrust claims. Advocate General Mazák considered also that the General Court " in assessing whether a particular course of behaviour is misleading, (...) was not obliged (...) to assess AstraZeneca’s alleged subjective beliefs on an interpretation of law, bona fides or otherwise, but rather to examine their actual conduct."\(^{124}\) Therefore, I would argue that only the specific intention to act anticompetitively can play important role as an additional factor for finding abuse. Lack of anticompetitive intent would not render the behaviour immune from the antitrust responsibility.\(^{125}\)

### 3.1.5. Possible implications of the use of the intent legal standard

The Commission stated that “the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes.”\(^{126}\) The Commission therefore shares the US courts view on the probative value of the intent. It is believed, that if the Commission’s view that the intention can also be taken into account in competition law assessment is confirmed by the Court of Justice, as the General Court has done already, it will expand the reach of competition law review to a large extent.\(^{127}\)

\(^{123}\) ibid, para 338

\(^{124}\) *AstraZeneca*, opinion of AG Mazák, para 50

\(^{125}\) Unless the company can provide the proof that the conducts brings certain efficiencies. In case of IPRs the possible efficiencies are dynamic in nature.

\(^{126}\) Sector Inquiry (n 5) fn 375

\(^{127}\) Priddis and Constatine (n 7) 257
might have significant implications for the primary patent applications, where it is difficult to
decide whether such applications have the aim of excluding potential competition rather than
to protect the exploitation of the invention prior to grant, as well as on the secondary patent
applications which might be understood as a means of extending exclusivity period of the
product to the detriment of consumers. Therefore, important questions to be asked are: “in
what sort of exceptional circumstances the very fact of obtaining patent was abusive
conduct? is intent to exclude competition enough to identify a set of exceptional
circumstances?” The Commission proposed that the conduct in the procedure relating to
the acquisition of the right, such as in this example misleading representations, can
constitute abuse. Also, it was repeated that the use of public procedures and regulations
may be found abusive. One may wonder if any other conduct apart from deceptive or
fraudulent behaviour could lead to the same conclusion. The AstraZeneca judgment, apart
from providing another example to the Court’s case law, does not give clear answer to that
question. When it comes to the intention and question whether it can itself constitute
exceptional circumstance, this problem is not solved either. Some believe that the
Commission has implied so in its Sector Inquiry. However, it may be inferred from the
presented jurisprudence that, even in cases where the intent may be found relevant, the
further conduct needs to be shown. While the proof of intent indicates the possibility of
anticompetitive effects on the market, further investigation as to the conduct of the alleged
infringer would have to be presented.

The implications seen by the business world of that the judgment caused the situation that
companies with strong market position need to be aware that the evidence of a strategy

128 Sector Inquiry (n 5) paras 493-5, 503-5, 1122-6
129 Priddis and Constatine (n 7) 259
130 AstraZeneca Commission decision, para 742
131 ibid para 743
132 Priddis and Constatine (n 7) 259
intended to hinder competitors might “lower the bar for an infringement finding”\textsuperscript{133}. This suggests that it is crucial to “document carefully any pro-competitive reasons for commercial strategies and decisions and to avoid creating documents wrongly suggesting a strategy of ‘spoiling tactics’.”\textsuperscript{134}

\textbf{3.2. No need for exercising IPRs}

The exceptional circumstances in which exercising IPRs can constitute means of abuse is not a new concept as it was shown in the first chapter. After \textit{AstraZeneca} those exceptional circumstances will apply also for the processes of acquisition of IPRs. Traditionally, the exceptional circumstances test applied to the situations in which IPRs where exercised. The process of acquisition of the exclusive rights was left alone to the national law scrutiny and the exceptional circumstance test was not applied. However, it was already acknowledged by the Court that patent rights if they are used as an instrument of abuse or as a mean of restricting competition, competition law applies.\textsuperscript{135} This might suggest that the exercise of the exclusive rights granted by the patent is not the only situation around which the exceptional circumstances can appear. Also the acts of applying for patent rights and the mere possession of them have an impact on the competition and they might constitute an abuse.

\textbf{3.2.1. US practice}

In the US the mere procurement of fraudulent patents is exempted from violating antitrust law. The basis for this exemption has been established in case \textit{Walker Process}\textsuperscript{136}. In the given case the patent owner knowingly and wilfully misrepresented facts to the patent authority in order to gain the patent protection. The Supreme Court ruled that antitrust law encompassed fraudulent procurement of the patent, however such misconduct was not made a per se violation of Section 2 of the Sherman Act. The fraud in obtaining patent


\textsuperscript{134} ibid

\textsuperscript{135} \textit{Hoffman La Roche and Coditel}

\textsuperscript{136} \textit{Walker Process Equip., Inc. v Food Machinery Chemical Corp.} [1965] 382 US 172, 179
protection was only one element, next to enforcement of the patent and monopolisation or attempted monopolisation, of the new cause of action. This leads to the conclusion that FTC lacks jurisdiction if the patent holder has done nothing apart from obtaining the exclusive rights. In situation where the patent has not been enforced the improper attempt of patenting something that rightfully belongs to the public becomes a Patent Act violation “with probable result that the patent is not enforceable”.\(^\text{137}\) Enforcement within the meaning of a *Walker Process* occurs certainly in case of filling and pursuing infringement actions against alleged infringer. It can also happen when there is “an explicit threat to other actions by the patentee that created a reasonable apprehension on the part of the putative infringer that it will face an infringement suit.”\(^\text{138}\) This line of reasoning has been confirmed in *Dippin’ Dots* decision.\(^\text{139}\) The court held that in case in which patent applicant lied in a sworn statement to the Patent and Trademark Office (which would have invalidated its patent application) it could not show that a subsequent patent infringement suit violated the antitrust laws because the only bad conduct that the court could uncover was the misrepresentation to the PTO itself.\(^\text{140}\) The Federal Circuit could not held antitrust violation without additional evidence of anticompetitive conduct. The patents which are fraudulently obtained have to be enforced at least at minimum level.

### 3.2.2. Mere possession of patents

In this case, AstraZeneca in its observations during the appeal procedure before the General Court has stated that “evidence of conduct preparatory to an abuse (...) is not, in itself,

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\(^\text{139}\) *Dippin’ Dots, Inc. v. Mosey* 476 F.3d 1337 (Fed. Circ. 2007)

\(^\text{140}\) *Dippin’ Dots, Inc. v. Mosey*, paras 1347–48
capable of restricting competition.”\(^\text{141}\) “Conduct that has not been implemented or is not capable of having the effect of a restriction on competition does not constitute an abuse.”\(^\text{142}\) The Court rejected this claim of AstraZeneca. Without going into details, it stated that when granted patent is assumed to be valid the mere possession by an undertaking of an exclusive right normally results in keeping competitors away.\(^\text{143}\) Therefore, the Court has confirmed that in the special circumstances, the fact of possession of patent, without it being executed, is able to be the instrument of an abuse. The specific circumstances of the case must be assessed \textit{in concreto}. In \textit{AstraZeneca} the specific circumstances were connected with the fact that the public authorities have limited discretion or no obligation to verify the accuracy or veracity of the submitted information in the SPC applications. Waiting for an execution of the patent rights would make application of Article 102 conditional upon infringement proceedings claimed against competitors. Instead, the Commission and the Court focused on the effects which the possession of patent can have on competitors and consumer welfare. While there is no need in the EU to show actual effects on the competition or consumers, such a construction of the abuse was possible. The introduction of the second element of the \textit{Walker Process} doctrine - the fact of enforcement - would render the potential effects inapplicable in cases where patent rights are at stake.

\textbf{3.2.3. \textit{ITT Promedia} inapplicable to acquisition of rights?}

AstraZeneca also claimed that an abuse of dominant position can only exist where the fraudulently obtained patent is enforced. That enforcement would have also met the conditions set out in Case T-111/96 \textit{ITT Promedia v Commission}\(^\text{144}\). The conduct, according to the applicant, would have to have the only purpose of harassing the opposite parties without any attempt to establish the legitimate rights and it would have to constitute the part of a plan to eliminate competition.\(^\text{145}\) If the conduct by which the company claims the rights is

\(^{141}\) \textit{AstraZeneca}, para 309
\(^{142}\) ibid
\(^{143}\) \textit{AstraZeneca}, para 362
\(^{144}\) Case T-111/96 \textit{ITT Promedia v Commission} [1998] ECR II-2937
\(^{145}\) \textit{AstraZeneca}, para 311
based on reasonable facts, there would be no abuse. This argument has been rejected by the Court as the facts of the case did not address the litigation proceedings brought by AstraZeneca. There was no relevance between the facts of both cases.

One may claim though, that if we look at the conduct connected with vexatious litigation and misuse of regulatory procedures as presented in both cases, they have the same reasoning behind it and they produce similar effects. Both the litigation and patent applications seek to establish legitimate rights which could be invoked against competitors. The rights in question are granted by law. It is therefore suggested that the conditions elaborated for the vexatious litigation should apply to cases involving abuse of regulatory and government procedures.\(^\text{146}\) Such a solution could bring a level of legal certainty to the process of acquisition of rights and it could serve as an indication of what are the circumstances in which claiming rights constitutes an abuse: if one can reasonably consider its rights, the strategy or intention to eliminate competition would not generate the result of finding the conduct abusive.\(^\text{147}\)

**3.3. More economic approach in the field of IPRs**

**3.3.1. Need for more economic approach**

The basic proof for finding an abuse of dominant position is the proof of anticompetitive effects on the competition and consumers. Therefore, in order to properly assess any competition concern the right focus should be given to articulate the theory of harm. In the Commission’s practice in recent years we can notice increasing attention in this matter. As it is said “the requirement to present a theory of harm imposes a logically consistent approach to the assessment of anticompetitive behaviour. If the theory of harm is made explicit by competition authorities, then this makes it much harder for internally inconsistent or

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\(^{146}\) Negrinotti (n 75) 457

\(^{147}\) In the case of *AstraZeneca*, both of the conditions, if applied, were fulfilled, so the qualification of the conduct would not change.
speculative competition concerns to survive the process of assessment.\textsuperscript{148} The theory of harm in \textit{AstraZeneca} consists of the extension of a market-dominant position through delaying the market entry of generic producers. The reason for accepting the possibility of filling patent applications as potential abuse without any evidence that the rights have been enforced is its exclusionary effect the obtained rights will have on the market. The patent rights granted by patent authorities create a legal situation which requires competitors to respect these rights and abstain from action which would violate them. \textit{AstraZeneca} is therefore seen as creating a rule according to which “the filling of an intellectual property right has an immediate effect on competition in the relevant market and therefore constitutes potential abuse in the sense of Article 102 TFEU.”\textsuperscript{149}

The negative effects on competition in this case are mainly visible in terms of static price competition. The dynamic competition was not of a great interest for the Commission which might be found regrettable. Balancing the static and dynamic efficiencies is believed to be proper way of assessment between legal and illegal use of IPRs.\textsuperscript{150} The violation of competition law should be recognized only if negative effects on allocative efficiency outweigh the dynamic efficiencies. While IPRs focus greatly on the dynamic efficiencies and further technological advances brought by innovators by granting them exclusive rights and promise of reward, competition law keeps the market open. It forces undertakings to innovate ensuring at the same time that static competition is protected. While traditionally competition law has been focusing greatly on the static efficiencies and the model of perfect competition, the concept of dynamic competition needs to be further developed as it is

regarded as prerequisite for the use of economic theory as an analytical tool for analysis under Article 102 TFEU.\textsuperscript{151} The so called ‘more economic approach’ has been already introduced by the Commission to the assessment of anticompetitive agreements and mergers.\textsuperscript{152} This reform allowed to move from legalistic based approach to an interpretation based on sound economic principles. The same idea accompanied the reforms of Article 102 TFEU. Applying economic theories to the abusive conduct will allow balancing between static and dynamic efficiencies. There are two particularly important theories of harm which could be helpful in such an assessment: raising rivals’ costs and cheap exclusion. Both of those theories are especially suited for treatment the abusive use of IPRs.

\textit{Raising rivals’ costs}

Scrutinizing anticompetitive exclusion through manipulation of governmental and legal processes has been the topic of concern since 1980s when in US the theory of raising rival’s costs (RRC) appeared.\textsuperscript{153} It was argued that “the sound policy basis for concern with non-price predation by a dominant firm has increased over time. Certainly, manipulating the government and the patent system are fruitful areas of concern with potentially anticompetitive conduct.”\textsuperscript{154} While usually actions which raise rivals’ costs will increase the dominant firm’s own costs, non-price manipulation forms rather cheap version of exclusion, making it effective way of enlarging its own market position. Focusing on this form of exclusion brings our attention to the patent misuse involving patent inappropriately obtained. Obtaining patent protection raises expectations as to its validity. The only possibility for competitors to claim the opposite is to bring actions to the court which usually engages costly and timely litigation. In US the FTC/DOJ hearings on intellectual property highlighted concerns with the patent quality and the possible anticompetitive outcome in case of lack of

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\textsuperscript{151} Ibid 10
\end{flushright}
proper assessment of their validity. Typically, it is argued, that it should be patent authorities dealing with solving the problem of inappropriately granted patents. However, “in limited circumstances, [e.g. when behaviour has clearly exclusionary character] the antitrust (...) laws can (and should) attack anticompetitive use of patents.” RRC theory focuses therefore on the impact of anticompetitive behaviour on the static competition. In US however “credible anticompetitive effects must be required for any viable RRC-theory case”, which might be difficult as in RRC there are many false positives (erroneous findings of liability). This is because competition on merits also often causes injury to rivals and potential rivals, not necessarily making the behaviour anticompetitive. Thus, the effect on the consumer welfare has to be provided for the case to be substantial.

**Cheap exclusion**

For the greater focus on the efficiencies allows the cheap exclusion doctrine. The cheap exclusion as defined by Susan Creighton has two dimensions. Firstly, it means “conduct that costs or risks little to the firm engaging in it, both in absolute terms and when compared to the gains (or potential for gains) it brings, and that is, therefore, attractive for an aspiring monopolist.” Because firms prefer low cost strategies, it can be expected that cheap exclusion can become a common practise. Therefore, such behaviour deserves closer scrutiny. Secondly, the cheap exclusion means “a particular kind of low-cost exclusionary strategy, namely, one that does not raise any cognizable efficiency claims; that is, ‘cheap’ in that it has little positive value.” What is also striking about the cheap exclusion is that most of the time the only defence (apart from factual issues) lays outside the efficiencies for the consumer welfare, such as immunities, jurisdiction, or statutes of limitations. Thus, cheap

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156 Scheffinan, Higgins (n 154) 382

157 ibid

158 ibid


160 ibid 977

161 ibid

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exclusion focuses on practices such as opportunistic rent seeking, or deceptive or fraudulent conduct. Lack of efficiencies or precompetitive effects lead to little concern on false positives while assessing the cheap exclusion cases. As no trade-off can be seen, there should be no over deterrence. Application of the doctrine of cheap exclusion is of particular interest to intellectual property practitioners, as most of the high profile cases concerned the anticompetitive efforts to extend the duration of IPR.

Gaming a specific governmental process that involve IPRs, extending royalty payments beyond a patent’s expiration date, tying the purchase of patented product to the purchase of an unpatented product, these are the examples of the involvement of IPR in cheap exclusion.

Both of those theories show the need for indicating the efficiencies which the behaviour should bring. Especially important it becomes while applying the RRC theory, because its application may erroneously find competition on merits as anticompetitive.

3.3.2. Guidance Paper on the exclusionary abuses

The Commission in its Discussion Paper on the reform of Article 102 stated that in the applying of this article it ‘will adopt an approach which is based on the likely effects on the market’ with the focus on ‘those types of conduct that are most harmful to consumers’. The essential objective of Article 102 is “the protection of competition on the market as a means of enhancing consumer welfare and ensuring an efficient allocation of resources.”

The Guidance Paper represents a substantial shift in policy from the old case law by moving

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165 Commission “Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings issued in December 2008” (Guidance Paper) [2009] OJ C45/7, para 5
166 Discussion Paper (n 164) para 4
towards solid theories of harm. Grounding assessment of alleged patent misuse and anticompetitive patent strategies in proper theories of harm seem to viable way of dealing with these problems. Proper assessment of the effects on competition and customer welfare would make the case more reasonable. Focusing on theory of harm benefits the quality of competition law assessment. It ensures that harm to competitors, where there is no harm to consumers, do not survive, it emphasises the fact that anticompetitive effects are only likely when firms have the incentive and ability to act anticompetitively and it focuses on the empirical evidence that is required to underpin the potential competition concern\(^\text{167}\). The fact that in the EU no actual harm needs to be shown makes it even easier to scrutinize the alleged anticompetitive behaviour with competition law. The Guidance Paper explains that two conditions must be met in order to find the foreclosure anticompetitive: the conduct is capable of excluding rivals and by that sheltering own market power and harming consumer welfare by increasing market prices, reducing market output, worsening product quality and variety and/or harming innovation.\(^\text{168}\) Neither Commission nor Court has followed this approach expressly. Nevertheless, it is seen that AstraZeneca’s behaviour was capable of producing the abovementioned effects\(^\text{169}\): SPC sheltered the market power and harmed short-run consumer welfare as delayed entry of generic drugs on the market prevents the fall of market prices\(^\text{170}\).

### 3.3.3. Anticompetitive effects of AstraZeneca’s conduct

The behaviour of AstraZeneca was not a competition on merits. The applications for SPC brought no cognizable efficiency and caused more consumer harm. In the US in such a case the harm to consumers would have to be shown before finding behaviour anticompetitive. In Europe however the actual anticompetitive effects do not have to be proven. In *Michelin v Commission* the Court of First Instance ruled that the effects required to prove an abuse of

\(^{167}\) Zenger and Walker (n 148) 29  
\(^{168}\) Guidance Paper (n 164) para 19  
\(^{170}\) AstraZeneca Commission Decision, para 116 and 772
Article 102 TFEU “does not necessarily relate to the actual effect of the abuse conduct complained of. (...) it is sufficient to show that the abusive conduct of the undertaking tends to restrict competition or, in other words, that the conduct is capable of having that effect.”

Contrary to what AstraZeneca claimed, the ability of the practice in question to restrict competition may be indirect. At the time of the case, the Commission in applying Article 82 was focusing mostly on the effects of the conduct on the structure of the competition. The actual harm for the consumer would only be assumed as indirectly coming from the restricted competition caused by the anticompetitive conduct.

Applications made to the UK and Danish patent authorities

The likely effects on the several European markets where SPC was granted has been shown by the Commission. However, situations on UK and Denmark markets, one might think, should be treated differently. In UK patent office rejected AstraZeneca’s application because the condition based on the time of the market authorisation was not fulfilled, while in Denmark the SPC application has been withdrawn. The Court has noted that Denmark application seem to provide certain proof of the possible effects on the market because the misleading information “would have made it possible to obtain SPC in Denmark” if the application was not withdraw. The decision of UK authorities however, seemed to prevent any effects from occurring on its national market. With regard to these facts the Commission asserted that in both countries there was a risk that the AstraZeneca’s strategy of elimination of competition would have succeeded, what was confirmed later by the Court.

171 Case T-203/01 Michelin v Commission [2003] ECR II-4071 para 239
172 According to the Guidance Paper it seems that the Commission would have to pay more focus to the consumer harm, as the application of the ‘more-economic approach’ which would bring more consistency in European and American practice. There is however concern that the Commission cannot solely focus on the efficiency and consumer welfare consideration without first reshaping the existing case law of the European courts (Wolfgang Wurmnest, “The Reform of Article 82 EC in the Light of the Economic Approach” in Mark-Oliver Mackenrodt, Beatriz Conde Gallego and Stefan Enchelmaier (eds), Abuse of Dominant Position: New Interpretation, New Enforcement Mechanisms? (Springer 2008) 15)
173 AstraZeneca, para 555
174 AstraZeneca Commission decision, para 736
I nevertheless argue that in the situation where the UK patent office didn’t grant any patent rights to the applicant, no harm to the competition or to the consumer would have been possible. The Commission by addressing the practice in question applied the formalistic approach focusing on the anticompetitive behaviour rather than on its effects. Joseph Drexl has noted that the Court added an important reservation that the ‘patent fraud’ by itself does not constitute a restraint of competition. The justification for such treatment of the applications to UK and Danish patent authorities which have been given by the Court concerned the special responsibility of the dominant undertaking not to impair competition and to the fact that the patent authorities in the case of SPC have limited or no discretion in granting SPC. The mere possibility of creating regulatory obstacles has been sufficient for the Court to find the given practice abusive. This situation shows that in the Court’s jurisprudence the traditional approach prevails. Harm to competitive process is sufficient to find conduct abusive and the effects-based approach “will not be necessarily approved”. This seems to be regrettable especially in cases where the Commission is required to pursue ex ante evaluation of the likely effects of alleged anticompetitive behaviour in the future. Departing from facts-based approach and reliance on economic theories seem to be rational choice.

In the UK situation, the important question can be asked as to the coexistence of the law systems and the remedies they offer. “Competition law is specifically designed to control anticompetitive private conduct entailing restrictions of competition, in particular by excluding competitors. (...) The fact that other laws and remedies prohibit misleading representation or provides remedies against them is irrelevant where the objective of competition enforcement

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175 Drexl, “ASTRAZENECA AND THE EU SECTOR INQUIRY: WHEN DO PATENT FILINGS VIOLATE COMPETITION LAW?” (n 149) 7
176 AstraZeneca, para 355, 357
is not to penalise such misconduct *per se*, but rather to prevent the anticompetitive effects of such misconduct in the market place.”¹⁷⁹ This quotations explains the preventive and deterring nature of competition law. Even in situations where the remedies of patent law were applied to the misleading applications or invalid patents, there would be no sanctions for failed attempts not resulting in an SPC.¹⁸⁰ What is contended here is the attempt to abuse. By such an approach the Commission is sending a message that the preparatory conduct, even if constrained by factors, has a potential to break the rules of competition law and be challenged by it. This produces important implications for patent applicants: application without being objectively justified can be found to fall foul of competition law. The Commission focuses here again on the traditional for the EU concept of competition law, which is not based on the economic theories of harm. This, in my view, can lead to many false positives where the company’s conduct is challenged without presenting proof of the impact on the competition.

### 3.4. Conclusions

To sum it up, *AstraZeneca* can provide some guidance on how the emerging strategies on the pharmaceutical market (and not only) can be addressed by competition law in cases where patent regime is not suited to do so. Competition law supplements the IP and market regulation regimes in a positive way and prevents their manipulation. The acquisition of patents which is regulated by the national law traditionally has been left alone by the Commission and treated in a very formalistic way. With the emergence of more economic approach and use of theories of harm, it seems reasonable to address the problems which the not always legitimate patent protection can cause to the competition and consumers. Still, there is a lack of agreement between the Court and the Commission as to the use of more economic method in the assessment under Article 102 TFEU, which in case of patents seems to be problematic. *AstraZeneca* can be still regarded as an example of traditional...

¹⁷⁹ *AstraZeneca* Commission decision, para 744
¹⁸⁰ *ibid*, para 748
approach to the Article 102 TFEU cases. This is especially seen in the case of rejected applications to the UK authorities, which proves the importance of the deterring function of competition law. The facts that intent has been confirmed as relevant in certain circumstances to the antitrust assessment and that patent rights do not have to be exercised to produce anticompetitive effects give also a broader field of action for the Commission. The formalistic approach to the relationship with IPR regime has been proved to be abandoned. These changes make the EU law more prone to challenge acquisition of patents than it is a case in the US. The *Walker Process* requirements are found not well suited for the application of EU competition law. The reason for that might be that in the EU there is no European patent court, which would assume the resolution of cases involving patent rights. For the sake of consistency, the Commission seems to undertake the responsibility for keeping the use of patents and other IPRs in consistency with the EU legal order. Such an evolution might be also a response to the already recognized importance of patents for the business world and new ways in which they can be utilized by the companies. The creativity of the private sector must be properly addressed by the law enforcement.

The last chapter will address the Commission’s practice in the pharmaceutical sector in dealing with patent misuse post-*AstraZeneca*. 
Chapter 4: PATENTS IN PHARMACEUTICALS POST-ASTRAZENECA

_AstraZeneca_ case brought the Commission to the conclusion that the pharmaceutical sector might not be functioning well.\(^{181}\) The _Boehringer_ case\(^ {182}\) was the second case by the Commission where the issue of strategic patenting has become the forefront of the debate about the interface of IP and competition law.\(^ {183}\) The proceedings where based on the allegations that Boehringer had infringed Article 102 TFEU by filling and then relying on unmeritous patents with the view to exclude potential competition from the market for lung disease drugs.\(^ {184}\) The case has been recently closed after Boehringer agreed to remove the blocking positions which allowed for the settlement with complainant Almirall. The Commission took this as a success.\(^ {185}\) Nevertheless, the legal question as to the filing applications for patents and their possible anticompetitive character is considered to remain unanswered.\(^ {186}\) Both _AstraZeneca_ and _Boehringer_ cases as well as the delays in the entry of generic companies and the apparent decline in innovation of new medicines coming onto the market brought the Commission to instituting the Sector Inquiry. Findings of _AstraZeneca_ regarding obtaining patent protection can be relevant for the strategies identified by the Commission. Although the judgement of the General Courts has not been yet confirmed by the Court of Justice, the Commission and national competition authorities seem to pursue the goals set in the Sector Inquiry based on that case. Implications inferred from _AstraZeneca_ appear to play important role in challenging business practices in pharmaceutical sector. _AstraZeneca_ is the only precedent at the moment dealing with

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\(^{181}\) _Sector Inquiry_ (n 5) para 42


\(^{183}\) Drexl, ‘ASTRAZENECA AND THE EU SECTOR INQUIRY: WHEN DO PATENT FILINGS VIOLATE COMPETITION LAW?’ (n 149) 3


\(^{186}\) Drexl, ‘ASTRAZENECA AND THE EU SECTOR INQUIRY: WHEN DO PATENT FILINGS VIOLATE COMPETITION LAW?’ (n 149) 4
misuse of patent systems as *ITT Promedia* has been rejected as being relevant for the acquisition of rights. After pointing out the relevant strategies and explaining findings of the Inquiry, I will conclude with the consequences so far drawn from it. Two already existing examples of the formal proceedings will be presented.

4.1. Sector Inquiry

The Commission has started the investigation in the pharmaceutical industry as it believed that the trends in this sector regarding the use of the patent systems are worrying and highly questionable under Article 102 TFEU. Using the powers granted by Article 17 of the Regulation 1/2003, in situations “[w]here the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market, the Commission may conduct its inquiry into a particular sector of the economy or into a particular type of agreements across various sectors.”

Although the aim of the Sector Inquiry was limited to collecting information of a general nature as to the working of the sector, these findings produced results of initiating proceedings against individual firms. The Commission focused on the competition between originator and generic producers of medicines. Nonetheless, the relationship between originators took also some attention in the inquiry.

4.1.1. Patenting strategies

The Commission recognized that the primary functions of patents are exclusion/protection of information and next to it stand freedom to operate, bargaining, standardisation and company imagine. However, in some cases originator companies might also have incentives to use patents to block or delay generic products. Companies use the so called ‘tool box’ of different patent strategies which not only impact the early entrance of generic products.\(^{188}\)

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187 Council Regulation (EC) 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] OJ L1/1
188 Sector Inquiry (n 5) para 468
189 ibid
companies, which would allow for price decrease on the market, but they also use the patent applications for blocking original companies from competition in substitution. In the Sector Inquiry the Commission addresses a number of such potentially anticompetitive patent strategies. The Commission identified potential abuses as to their effect on both static price competition as well as dynamic competition. The Commission by that argues that acquisition of the patent protection has to be put under competition law examination because of the alleged anticompetitive intent of such applications. The relevant for this analysis are patent filling strategies, specifically patent clusters, divisional applications and defensive patents.

**Patent clusters**

“A patent cluster may consist of granted patents as well as pending applications.”\(^{190}\) Companies to ensure exclusivity at least until the end of the patent protection apply (next to the primary basic patent) so-called secondary patents for processes or re-formulations or other forms of incremental innovation such as salt forms, metabolites, new medical uses. The Commission has concluded that the aim of this strategy called ‘evergreening’ is to extend the breadth and duration of patent protection and delay market entry of generic products.\(^{191}\) By filling even up to 1300 patents and pending patents in some cases involving blockbusters, the situation of legal uncertainty for generic firms is created as to the time when all the patent rights elapses. From patent law perspective these strategies constitute the legitimate use of the available procedures. As EPO noticed in patent law there is no secondary patent notion.\(^{192}\) Each and every application is evaluated as to its novelty and commercial use.\(^{193}\) The Commission’s concern lays with the types of patents, their strength, market effects and the conduct and outcome of litigation involving them. The Commission suspects that they are implemented with the clear intention of blocking generic companies by raising legal uncertainty. One of the Commission’s findings is that the originator

\(^{190}\) ibid para 481  
\(^{191}\) Sector Inquiry (n 5) Summary 201  
\(^{192}\) EPO (n 118) 3  
\(^{193}\) See EPC, Articles 52-57
companies apply also for ‘weak patents’, raising concerns as to their novelty and inventive step, whose only purpose is to create an extra obstacle for the generic companies.\textsuperscript{194}

\textit{Divisional patents}

“Divisional patent application is created where the applicant (…) divides out from a patent application one or several patent applications.”\textsuperscript{195} Fillings for divisional patents do not extend the scope of the patent or the time of protection but they, similarly to secondary patents, have a potential of reducing significantly the legal certainty for generic companies. Divisional patents extend the period where the applications are pending as each divisional application has to be assessed individually, even in situations where the parent application has been refused or withdrawn.\textsuperscript{196} The successful challenge of the parent application does not provide legal certainty unless neighbouring divisional applications are pending. Relying on such divisional applications was found a new popular trend within pharmaceutical sector.\textsuperscript{197}

\textit{Defensive patenting}

Defensive patents are described as being solely or in a big extent aimed at limiting other originator companies’ freedom of operation in the area of R&D.\textsuperscript{198} The main concern of the Commission is that the intention behind patenting might be reducing competition by substitution on the relevant market for treatment of a certain diseases and health conditions rather than for protecting an invention. Defensive patents protect against actual or potential competition especially when they are directed towards inventions which the company considers to have no prospect of being developed or commercialised.\textsuperscript{199} The problem which arises here is that most of the time companies which apply for patent protection have already invested significantly in developing the given invention. At the stage of application for

\textsuperscript{194} Sector Inquiry (n 5) paras 498-500. The use of term ‘weak patent’ has been criticized by originator companies and IP associations as the patent cannot be weak or strong, but only valid or invalid, if declared by the relevant office or court. (Sector Inquiry, fn 360)
\textsuperscript{195} ibid, para 509
\textsuperscript{196} ibid, para 517
\textsuperscript{197} ibid, para 510
\textsuperscript{198} ibid, para 1117
\textsuperscript{199} ibid, para 1118
patent the potential benefits of the invention are not known to the applicant. The subsequent commercialisation of the invention might render useless in the subsequent stages of developments. Competition law application to such decision would encroach significantly on the business decisions involving early stages of R&D processes.

Two main problems arises from the given strategies. Firstly, patent clusters and divisionals result in legal uncertainty as to the duration and breadth of the patent protection. The successful legal proceedings claiming the invalidity of patents which can be instituted by generic companies do not provide foregone conclusion that the companies have freedom to operate. Many other layers of protection may still exist, which can effectively constrain the business decisions of generic companies. Secondly, defensive patenting which covers most of the time the basic chemical entity, in cases where the patent holder does not aim in its further development, effectively limits the competition in substitution and emerging new drugs. EPO in its comments on the Preliminary Report regarding Sector Inquiry has expressed the view that the Commission has put the patent application in a negative light calling as a success the revocation or amendment of a patent and the upholding of a patent as a defeat\textsuperscript{200} suggesting the overall conclusion that the Commission sees the patents in pharmaceutical sector as a threat to the competition in the EU which should be effectively battled. Notwithstanding the fear of the patent lawyers that the Commission will interfere with the decisions of patent offices and by that it will undermine the purpose of patenting, none of the presented issues are straightforward under competition law. They cover areas where there is little or no EU precedent.\textsuperscript{201} Therefore, the question is how far reaching the implications of AstraZeneca will be.

\textsuperscript{200} EPO (n 118) 5
4.2. New investigations

4.2.1. Commission’s investigation

The knowledge acquired during the pharmaceutical sector inquiry, specifically on ways originator companies obstruct the entry of generic drugs onto the market, has allowed the Commission to draw conclusions on where Commission action could be appropriate and effective. First investigation which directly followed the Sector Inquiry focused on the international pharmaceutical undertaking, Lundbeck. The Commission decided to examine potential breaches of competition rules on restrictive business practices and on the abuse of a dominant market position under Articles 101 and 102 TFEU. The Commission in particular intended to investigate unilateral behaviour and agreements by Lundbeck which may hinder the entry of generic citalopram, an antidepressant drug, into the European markets. The investigation is ongoing.

4.2.2. National Competition Authorities

Anticompetitive practices of pharmaceutical companies after AstraZeneca have been also pursued by national competition authorities. The latest example is the Italian case where the competition authority fined anticompetitive practices of Pfizer aimed at delaying market entry for generic medicines. The abusive conduct concerned a complex strategy involving an illegitimate extension of patent duration through the request for a divisional patent and SPC, patent-related law suits, actions aimed at preventing the national regulatory body from granting generic companies marketing authorisations and the reimbursement price, providing misleading information in order to get a marketing authorisation for its own generic product and an application for the extension of the paediatric patent. The case was based

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204 Ibid
on the effects the Pfizer’s conduct had on the generic entry and the National Health System by impeding the decrease of the reimbursement price of the drug. This conduct had an abusive character as it lacked reasonable justification and was based on intent to exclude competitors. This case shows that the Commission’s practice is followed by national authorities and has practical application in addressing problematic issues of the pharmaceutical industry.

4.3. Addressing the “toolbox” with AstraZeneca

The presented strategies are recognized as a ‘toolbox’ of pharmaceutical companies. As summarised above, they have potential of having anticompetitive effects on both static and dynamic competition. However, the Commission did not seek to explain specifically in what circumstances these practices would constitute infringement of Article 102. Nevertheless, one implication can be inferred from the report: the Commission places great focus on the intention of the companies.\(^{205}\) The report claims that the Commission has found numerous documents that could be read as describing intent to delay generic entry or ensure market free from competition faced from other originator producers. The main question stemming from it is therefore whether the attempt to obtain patent protection is reasonable. The Commission seems to suggest that it will be pursuing an aim of ensuring that pharmaceutical companies are not in a position to be granted or to maintain patents for allegedly abusive purposes.\(^{206}\) The process of acquisition of patent protection has been clearly taken under investigation of the competition authorities.

AstraZeneca confirmed that intent although not necessary can become a helpful proof of finding infringement. This has been confirmed in Italian case against Pfizer. Proving intent of

\(^{205}\) Drexel, ASTRAZENECA AND THE EU SECTOR INQUIRY: WHEN DO PATENT FILINGS VIOLATE COMPETITION LAW? (n 149) 18

the company in the objective terms may be well suited to find the proper balance between the aims of IP laws and competition law. Patent strategies would have to be proven as aimed solely at preventing innovation or deterring generic entry in order to be regarded as anticompetitive. Nonetheless, the intention has to be accompanied by the conduct aiming at its execution, as only that can be scrutinized by the Commission. Important expansion of competition law appears to be suggested in AstraZeneca, that even preparatory acts not resulting in obtaining any exclusionary rights, can also be challenged by the competition authorities. This conclusion can be particularly important for voluntary divisional patents. These patents are dependent on the primary patent as to their duration. Nevertheless, if the applications were submitted and subsequently the primary patent application has been withdrawn or revoked, the divisional patents have their own lives and have to be subjected to separate proceedings. This means that none of the applications may succeed in being granted a patent but the duration of the procedure could have been significantly affected. Possibility to challenge such preparatory conduct seems to open new opportunities for the Commission.

Important implication which can be drawn from the AstraZeneca is that it increases field of operation of competition law by moving away from the existence/exercise dichotomy. Therefore, possessing ‘defensive’ patents or secondary patents are not immune from Article 102 TFEU. Mere possession of exclusionary rights, if in exceptional circumstances, create legal expectations as to their validity and barriers to entry for potential competitors. There is no need for them to be exercised. AstraZeneca gives only one example in which acquisition of patent constitutes abuse of dominant position, however by introducing this new area, it proves the flexibility of Article 102 TFEU. This case confirmed also, that till now more economic approach is not applied towards IPRs. The assessment under 102 TFEU is still understood by the Court as formalistic process, protecting structure of competition. This seems to be regrettable, especially in the field of IPRs, where the use of economic theories of harm can be beneficial. What can also be inferred from that is once the exceptional
circumstances are found around the process of acquisition of rights, the burden of proof is not difficult to be met. The IPRs in their nature impact the level of competition significantly.
CONCLUDING REMARKS

The presented analysis of the AstraZeneca case has been driven by the question on the impact of competition law on the process of acquisition and subsequent possession of IPRs, especially patents in the pharmaceutical industry. While it is presumed, that patents and regulatory procedures governing their use are explored in the ways, which not always are consistent with the goals and aims they should pursue, the new field seems to be created for antitrust. The traditional approach stating that the acquisition of rights is not a matter of interest for competition law does not suit the emerging business practices. Patents are often seen as pursuing the aim of impeding competition in the given market, rather than focusing on the reward for the introducing new products on the market and promoting innovation. Such a use of patents seems to fall foul with competition law purpose of keeping the markets open and competitive. The Commission has brought its attention to these facts and set new priorities with that regard. AstraZeneca is a good example of the flexibility of Article 102 TFEU to punish this novel types of abusive conduct.

The potential of competition law to address issues connected with patent applications and possession of exclusionary rights seems to be welcomed by competition law practitioners. It will allow scrutinizing the behaviour of the pharmaceutical companies which may misuse the regulatory procedures to prolong their market power by excluding potential generic and originator competitors from the market. While it is not new to the Court’s case law, that the use of public procedures and regulations may be found abusive, AstraZeneca does not provide an answer if any other situation surrounding the procedures of obtaining the patent, apart from the fraudulent conduct, will lead to the antitrust investigation. The subsequent investigations by the Commission and the Italian competition authority do not provide new examples either.
The findings of *AstraZeneca* might be however useful as the case raises the question of the intent in the antitrust assessment. Lack of objectively proper business justification and unreasonable applications to patent offices may constitute important proof of the anticompetitive behaviour. The Commission by focusing largely in its Sector Inquiry on the evidence of the anticompetitive intent seems to imply that such an intent may itself constitute exceptional circumstance in which the patent rights would be scrutinized by competition law. However, the Court’s case law indicates that, even in cases where the intent may be found relevant, the accompanying conduct needs to be shown. While the proof of intent indicates the possibility of anticompetitive effects on the market, further investigation as to the behaviour of the alleged infringer would have to be undertaken.

*AstraZeneca* can also provide some guidance on how the patent strategies in the pharmaceutical market can be addressed by competition law in cases where patent regime is not suited to do so. Competition law supplements the IP and market regulation regimes in a positive way and prevents their manipulation. Competition law, as the Court has confirmed, can apply to conduct which was found legitimate under another law regime. While the right is granted, it is presumed to be valid and unless the long procedures for invalidity are concluded, it prolong the time of uncertainty for the competitors. In such cases waiting for an execution of the patent rights would make application of Article 102 conditional upon infringement proceedings claimed against competitors. The preventive and deterring character of competition law seem not to allow for such solution. In case of IPRs the Commission has found it particularly important to prevent companies from availing of illegitimate patent protection.

Although *AstraZeneca* is an example of the traditional approach towards the application of Article 102 TFEU, the emergence of more economic approach and use of theories of harm seem reasonable to address the problems which the not always legitimate patent protection can cause to the competition and consumers. Economic theories would allow to avoid
problems with many false positives which in the area of IPR are often by introducing balancing between the static efficiencies protected by competition law and dynamic efficiencies inseparable from patent law. I find it therefore regrettable that there is a lack of agreement between the Court and the Commission as to the use of more economic method in the assessment under Article 102 TFEU.

The Commission has in its agenda maintaining the proper level of competition in the pharmaceutical sector which is dominated by international ‘big pharma’. AstraZeneca has been starting point for this new priority of the Commission. This case has finally confirmed that the dichotomy existence/exercise of IPRs is not suited for the new technology markets, where IPR regimes are used in not always competitive ways. The effects on the level of competition on the given market was proved to be affected even by patent applications and mere possession of exclusive rights. Once this development has been confirmed, it seems reasonable to introduce the economic theories into the antitrust assessment which would allow to balance the difficult and not always straightforward relationship between the exclusivity protected by IPRs and the maintaining proper level of competition.
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63
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