



FACULTY OF LAW  
Lund University

Tim Sjöström

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Henrik Norinder

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# Summary

The innovative efforts of the pharmaceutical sector have provided society with numerous new remedies and medicines. Innovation is considered to be of key importance to the sector. The aim of the thesis is to analyse how the relevant legal frameworks should be developed to account for the innovative need of the sector. In order to develop these frameworks it is important to understand the underlying economic theory. Traditionally, economic theory is focused on static competition. This kind of economic theory is not able to account for innovation, which is why an innovation based economic theory is necessary. Joseph Schumpeter developed the theory of dynamic competition. Dynamic competition focuses on innovation as the most important aspect of economic theory, which makes it an appropriate theory for the pharmaceutical sector. However, due to the nature of the pharmaceutical industry, dynamic competition has to be viewed from a product market/ research area perspective.

The analysis of the pharmaceutical sector and the innovation process shows us the importance of an efficient patent framework as well as provides a structure for the antitrust analysis to focus on.

Due to the inefficiencies of the current patent framework changes for a new centralized European framework has been proposed. The inefficiencies in the current patent give companies the opportunity to abuse the system. The proposed changes would make it easier to deal with these kinds of abuses. However, instead of replacing the current inefficient system a third system is introduced. Even though there might be some justification for doing so, it is argued in the thesis that these issues could as well have been dealt with under one system. The proposed changes also give rise to discussion regarding the interplay between the antitrust and the patent frameworks.

The antitrust framework has traditionally been based on static competition. When assessing anticompetitive behaviour in the pharmaceutical sector the antitrust analysis will have to account for the innovative nature of the sector, which means that an antitrust analysis that is based on dynamic competition is needed. The theories on dynamic competition has been developed further, and focus have been shifted from only being on innovation to also include detailed analysis of the dynamic capabilities of a company. The success of a company will depend as much on these capabilities as on the actual innovation. For this reason it is important that antitrust analysis considers dynamic capabilities and does not only focus on innovation. The thesis divides the pharmaceutical sector and the innovation process in different segments that needs to be considered by the antitrust analysis.

Finally, further developments of the relevant legal frameworks are suggested.

# Abbreviations

AG	Advocate General
ECJ	European Court of Justice
EMA	European Medicines Agency
EPO	European Patent Office
EU	European Union
IPR	Intellectual Property Right
MRP	Mutual Recognition Procedure
R&D	Research and Development
SME	Small and Medium-sized Enterprise
SPC	Supplementary Protection Certificate
TFEU	The Treaty on the Functioning of the European Union

# Introduction

*"Innovation in human medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago."<sup>1</sup>*

The European Commission has recently conducted a sector inquiry in the pharmaceutical sector that, among other things, states that innovation is of key importance for the sector. However, as will be shown below, traditional economic theory (known as static competition) is not able to account for innovation. Joseph Schumpeter argued for an innovation based approach to economic theory (called dynamic competition) where the introduction of new products or new ways to produce already existing products is central. The theories proposed by Schumpeter did not have immediate success. Since these theories were not adhered to, the traditional approach became the most influential economic theory. As a result, other areas have been influenced by static competition, one such area is antitrust law. Antitrust law is very dependent on economic analysis when assessing the behaviour of companies. The result of the antitrust investigation will depend on the economic model used to assess the companies and markets in question.

However, in recent years scholars have started to acknowledge that innovation has a more prominent role than earlier believed. In other words, the theories of Schumpeter have become relevant.

All markets are in some way affected by innovation. Research intensive sectors, like the pharmaceutical industry, are more affected than other industries. If we consider that markets are more affected by innovation than by traditional price competition then the legal framework governing those markets should reflect this. Since the antitrust framework is dependent on economic analysis, that framework has to be built on an economic model that reflects the modus operandi of the market. It is also important for an innovative sector to have access to an efficient patent system. Recently, changes to the patent framework have been proposed in order to make it more efficient.

## 1.1 Purpose

The purpose of this thesis is to analyse the dynamic structure of the pharmaceutical sector and how the relevant legal frameworks should be developed in order to be better able to account for the dynamic aspects of that sector. The relevant legal frameworks considered are the patent framework as well as the antitrust framework. However, since the theories on dynamic competition as well as the proposed changes to the patent framework are still on a developing stage, it is not possible to present a

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<sup>1</sup> Pharmaceutical Sector Inquiry, Final Report, page 11

complete solution, the aim is then to present the theories as they stand today. Focus will be on the suggested changes to the patent framework as well as what the antitrust analysis should focus on if the theories on dynamic competition were to be implemented.

Accordingly, I will have to provide a comprehensive overview of the underlying economic theory as well as the pharmaceutical sector in order to understand the dynamic aspects.

## **1.2 Method**

The economic theory on dynamic competition will, in a strong sense, provide the foundation for this thesis, which is why this will serve as the starting point for the thesis. Since the focal point will be on the pharmaceutical sector, a detailed analysis of this sector is necessary to understand the dynamic structure of that sector. Innovation lies at the core of dynamic competition therefore it is important to understand this process, which is why this will be dealt with in a separate section. Finally, the relevant legal frameworks adjustment and development towards a more dynamic nature will be analysed.

Consequently, the thesis will address both legal as well as economic issues making a law and economics method appropriate. Analysis of these areas will make it possible for me to assess the impact of the changes to the patent framework on the pharmaceutical sector as well as how the antitrust framework should be structured and what it should take into consideration when analysing anticompetitive behaviour in that sector.

## **1.3 Delimitations**

The first issue to be addressed is who will read the thesis. This will be a determinant of what level of explication is needed in the different sections. I have identified the reader at a level where one has good understanding of the basic functioning of economic theory, the patent and antitrust frameworks. Accordingly, I will not present a detailed overview of these areas, except where necessary.

Since the focus is on how the legal frameworks need to be developed or what they should focus on, it is the future implications that are interesting. Meaning that, when discussing these frameworks I am not as interested in the present framework as in the changes being/ or should be made. Consequently, excluding short introductions in the areas of the current frameworks, focus will be on the relevant issues and developments.

When discussing the legal frameworks I will mainly have a European perspective. Even though antitrust policy is usually referred to as

competition policy in Europe I have decided to use the American equivalent, antitrust, to make it easier to distinguish between when I am discussing antitrust policy and the theories of dynamic competition. When reference is made to legislative material the language of the Lisbon treaty will be used consequently throughout the thesis.

I do not consider the different pricing and reimbursement strategies applied by Member States and its potential influence on innovation. I consider this to be outside of the scope of this thesis since the pricing and reimbursement strategies do not depend on either economic theory or the behaviour of companies. In addition, I do not, in general, consider different pharmaceutical product segments, however, where reference is made, pharmaceutical products should be understood as prescription drugs.

I do not analyse how the antitrust framework defines innovation. This is so since the purpose is not to make a case law analyses of how innovation has been defined but rather to see how antitrust should deal with innovation. I satisfy myself with equating technological progress with innovation.<sup>2</sup>

## 1.4 Literature

Much of the discussion in this thesis has been centred around a few seminal works. The work of David J. Teece has influenced much of the discussion on complementary assets as well as the incorporation of a more dynamic approach to antitrust analysis. The importance of the 1986 work, *“Profiting from Technological Innovation”* can be seen by the extensive reference to this work as well as the comment made by Sidney G. Winter in *“The Logic of Appropriability: From Schumpeter to Arrow to Teece”*<sup>3</sup> stating:

*“...that the Teece analysis is second to none in placing the analysis of appropriability on a sound logical footing...”*<sup>4</sup>

For the discussion on the pharmaceutical sector in Europe, information has mainly been gathered from the Pharmaceutical sector enquiry put together by the European Commission<sup>5</sup>. The reason for this is that the sector inquiry composes a comprehensive study of the European pharmaceutical sector of a scale and depth that would be difficult for a private company or researcher to imitate. Since the sector inquiry is based on observations from many different stakeholders, mainly originator and generic companies but also other stakeholders such as industry associations, pharmacists and hospitals as well as the European patent Office (EPO) to name a few<sup>6</sup>, we can assume

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<sup>2</sup> See section 5.2

<sup>3</sup> Winter, Sidney G., *“The Logic of Appropriability: From Schumpeter to Arrow to Teece”*, page 18

<sup>4</sup> Ibid. page 18

<sup>5</sup> The Sector inquiry and supporting documents can be found at:

<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

<sup>6</sup> Pharmaceutical Sector Inquiry, Final Report, page 17



a certain level of objectivity from the work. Some concern should be expressed over the sector inquiry as articulated by the criticism made by Robert M. Schwartz.<sup>7</sup> However, his criticism seems to be directed towards how the Commission has used the information.<sup>8</sup> Meaning that the results presented by the sector inquiry should be viewed with some scepticism. Despite this, the information gathered by the sector inquiry should provide us with a solid basis for understanding the structure of the sector and the interplay between different market actors.

The dissertation by Marcus Glader should also be mentioned. This work served as a reference work through which I was given a thorough understanding of antitrust analysis in innovative markets. Allowing me to understand dynamic competition better, and thus giving me the initial tools for analysing dynamic competition and the pharmaceutical sector.

There is one area for which I have not been able to find any detailed information. The discussion on competition in the pharmaceutical sector seems to be focused on competition between originator companies and between originator and generic companies. Consequently, it has been difficult to find detailed information regarding the competitive structure between generic companies. The information provided for this area is thus based on observations.

## 1.5 Disposition

Section two will provide the reader with an understanding of the underlying economic theory of dynamic competition and how it differs from the traditional static approach to economic theory. Section three is analysing the structure of the pharmaceutical sector and provides a structure for the competition and innovation aspects of the sector. Section four strives to provide an in depth analysis of the innovation process, highlighting different segments that antitrust framework will need to take into account. Section five analyses the development of the relevant legal frameworks and how they should be structured in order to better meet the demands of a dynamic market. In sections six and seven, all the above sections are analysed and two main concerns are highlighted for which I suggest further developments.

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<sup>7</sup> Schwartz, Robert M., *A Critical Analysis of DG Competition's Preliminary Pharmaceutical Sector Report*

<sup>8</sup> Ibid. page 95

## 2 Economic Theory

This section will deal with the economic theories behind dynamic competition. In order to be able to fully understand the concept of dynamic competition I will first have to give a short background on static competition, also known as neoclassical competition. Since traditional antitrust policy have been built on static competition theories<sup>9</sup> it is important to understand these theories in order to understand how the introduction of dynamic competition will have to change the way antitrust policy is shaped.

### 2.1 Static Competition

Static competition is the pursuit of perfect competition in a perfect world. Perfect competition occurs when the demand and supply curves of a product intersect. In a simplified example, where there does not exist any transaction costs or other external costs, i.e. where production costs are the only costs, perfect competition will take place where the price of the product equals the production cost. Equilibrium takes place when price is set at the level where marginal cost (MC) and average total costs (ATC) intersect,  $P = MC = ATC$ .<sup>10</sup> Market forces will strive to keep this balance on the market. This is so since if price is set at a level that is above the point where MC and ATC intersect this will create an excess that will attract other firms to enter the market with prices closer to the equilibrium level. The opposite is also true, where a firm has set price below the point where MC and ATC intersect this will, in the long run, force that company from the market and the price will in that way move towards the equilibrium.<sup>11</sup>

One of the objectives of antitrust law is to manage the equilibrium.<sup>12</sup> For example, predatory pricing is not allowed according to antitrust rules and this is in order to stop a strong company from lowering prices below ATC and thus forcing a competitor out of the market.<sup>13</sup> The stronger company can afford to sell the products at a loss for some time and then raise prices over the equilibrium when the competitors have exited the market.

However, static competition is a theoretical framework and as such, it is based on assumptions that do not reflect the actual state of the world.<sup>14</sup> The assumptions are that there are a multiple number of both sellers and buyers that have perfect knowledge regarding products and prices and that takes decisions in a rational way, meaning that they always maximise. There can

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<sup>9</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 32

<sup>10</sup> Ippolito, Richard A., *Economics for lawyers*, fig. 3-4, page 94

<sup>11</sup> Ibid. Fig. 3-5, page 96

<sup>12</sup> Craig, Paul and de Búrca, Gráinne, *EU LAW*, pages 950-951

<sup>13</sup> Ibid. Pages 1034-1036

<sup>14</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 602

neither be any externalities or costs regarding transactions on the market. Finally, the actors on the market, both sellers and buyers, have to be of similar size so that no one can influence the price or the output on the market on their own.<sup>15</sup> One can summarize static competition as competition that is based on price and output within different markets.<sup>16</sup>

There is another issue to be considered when discussing static competition and that is that the theory fails to account for innovation. In a market characterized by no innovation there will be no new products, all firms will have the same technology and use the same business models. Consequently, prices will be drawn down towards the equilibrium point and stay there. Customers will never be forced to pay too much for the products, on the other hand, they will also not be offered any new products.<sup>17</sup>

Since antitrust policy tends to follow static competition it shares the same faults and as a result, scholars have made a call for antitrust policy to follow a more dynamic approach. Dynamic competition has been much debated in recent years and will be discussed further below.

## 2.2 Dynamic Competition

Joseph Schumpeter devised the theories regarding dynamic competition during the first half of the 20<sup>th</sup> century. Schumpeter argued for an evolutionary view on how companies behave and develop which means that it is the introduction of new products and new processes that drives competition.<sup>18</sup> When new products are introduced on the market demand for older or less effective products will regress in favour of the new and improved products. Since innovation, and through innovation the introduction of new products, shifts the demand curves from one demand curve to a new one, this means that the equilibrium will be changed as well. If we then consider innovation as a continuous process, we can see that equilibrium will never be achieved. The equilibrium sought after in the static model is thus not compatible with innovation.<sup>19</sup>

With regard to innovations disruptive influence on static competition Schumpeter stated that:

*“...perfect competition is and always has been temporarily suspended whenever anything new is being introduced – automatically or by measures devised for the purpose – even in otherwise perfectly competitive conditions.”*<sup>20</sup>

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<sup>15</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, pages 32-33

<sup>16</sup> Vaaler, Paul M., McNamara, Gerry., *Are Technology-Intensive Industries More Dynamically Competitive? No and Yes*, page 272

<sup>17</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 603

<sup>18</sup> Schumpeter, Joseph A., *Capitalism, Socialism and Democracy*, pages 82, 84

<sup>19</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 33

<sup>20</sup> Schumpeter, Joseph A., *Capitalism, Socialism and Democracy*, page 105

Where the static model focuses on limiting the deadweight loss in order to maximise consumer welfare, dynamic competition has a forward looking perspective and realizes that certain business practises can create new markets and thereby satisfy the demand for new products.<sup>21</sup> In addition, dynamic competition recognizes the need for a longer perspective, the benefits from dynamic competition does not arrive immediately, therefore some short term inefficiencies have to be tolerated in order to support innovation.<sup>22</sup>

Innovation is the key feature when discussing dynamic competition, however, it is important to understand that it is not only innovation in new products that is important. It is equally important for a company to develop existing products, improve production processes as well as internal business processes enabling the company to better respond to external change and thereby keep a competitive edge.<sup>23</sup> The impact of dynamic competition will be discussed further in section 2.3.

Schumpeter argued that in order for a company to be dynamically competitive it had to have a monopolistic position on the market in order to have the funds necessary to engage in costly and risky innovative activities. This might have been the reality for Schumpeter at the time when he wrote it, however in today's society with the possibility to obtain funds from, for example, venture capital the importance of the size of the company has become less important.<sup>24</sup>

Another thing that has been discussed by economists for a very long time is the market structures impact on innovation. Teece argue that there is no evidence supporting the idea that market structure creates innovation, instead they argue that it is innovation that creates the market structure.<sup>25</sup>

McNamara and Vaaler distinguishes between static and dynamic competition by stating that static competition is price and output based competition within markets whereas dynamic competition is innovation based competition for markets.<sup>26</sup> The key word here being for, what it means is that businesses are competing for existing markets as well as future markets. This creates problems for antitrust policy when defining the parameters for an antitrust violation. From the perspective of dynamic competition it is not enough to consider actual markets and competitors, future, foreseeable and potential, markets and competitors have to be taken into consideration.<sup>27</sup>

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<sup>21</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 600

<sup>22</sup> Ibid. page 610

<sup>23</sup> Ibid. page 603

<sup>24</sup> Ibid. page 598-599

<sup>25</sup> Ibid.

<sup>26</sup> Vaaler, Paul M., McNamara, Gerry., *Are Technology-Intensive Industries More Dynamically Competitive? No and Yes*, page 272

<sup>27</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 614

For dynamic competition to work it is necessary that competition on the merits is allowed.<sup>28</sup> Generally, competition on the merits is understood as the way in which a company lawfully can behave, even if that behaviour leads rival companies to be forced out of the market.<sup>29</sup> Meaning that a company should not be punished for simply being innovative and more efficient than their competitors are, since this would be detrimental to competition and consumer welfare in the long run.<sup>30</sup>

## 2.3 Dynamic Competition in Practice

By looking back on our economic history and the developments of markets, one finds many examples on how a company's ability of being dynamic and innovative has reshaped an entire industry. As seen above dynamic competition takes into account the development of new product as well as the development of present products and processes. By looking at past experiences we might understand how dynamic competition can influence industries in the future.

### 2.3.1 New Products

Boeing developed the first civilian aircraft using jet engines after the Second World War, namely the Boeing 707. The 707 was a civilian version of the KC-130 jet tanker that the company had built for the U.S. Air Force. By transforming it into a civilian carrier, they were able to take the lead globally. Boeing managed to keep this lead until the development of the Airbus.<sup>31</sup> Consequently, the development of the jet engine and the 707 destroyed many of the traditional aircraft manufacturers that were still using the traditional internal combustion engine.<sup>32</sup>

Another good example of how a new product can have a big impact on the market is the free newspaper METRO. The founders of METRO took two existing products (free newspaper and morning newspaper) and combined them to make a new product, a free morning newspaper. After only two years METRO made a SEK 38 million profit and in 2006, only ten years later they were the fourth largest paper in the world.<sup>33</sup>

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<sup>28</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 63

<sup>29</sup> OECD, *What is Competition on the Merits?* page 1

<sup>30</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 317

<sup>31</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, pages 596-597

<sup>32</sup> Ibid. page 603

<sup>33</sup> Härén, Fredrik, *Idébok*, page 178

## 2.3.2 New Processes

As have been stated above dynamic competition does not only concern the development of new products, development of processes are equally important. In order to be able to show dynamic competition in processes I have decided to use two examples from the American car industry. The first example is from the beginning of the 20<sup>th</sup> century, the second is from the end of the same century. The purpose of having two examples from the same industry is to show the effect of dynamic competition not only on the market but also over time.

On October 1 1908, the first Model T Ford was delivered. The model made by Henry Ford soon became so popular that the demand overwhelmed the capacity for the production facility. Henry Ford realized that it was not enough to only build a new production facility, a new way of producing was also needed.<sup>34</sup> Ford did not invent the assembly line, what he did was to develop it to work faster. By introducing the motorized conveyor belt, he was able to cut production time. The result was that production time dropped from 728 minutes to 93 minutes and eventually his improvements of the assembly line meant that his factory produced a Model T every 24 seconds.<sup>35</sup> In 1914 13 000 workers at Ford produced 260 720 cars, the rest of the industry needed 66 350 workers to produce an equivalent number of cars. By successfully streamlining the production process Ford managed to go from a 9.4 percentage market share in 1908 to a 48 percent market share in 1914.<sup>36</sup>

By being innovative Henry Ford managed to make his company the market leader on the leading global market. One might then assume that the American car industry would follow in the footsteps of the Ford Company and thus secure an even stronger position on the global market. However, as will be demonstrated by the next example it is not enough to be innovative in one specific field or to stop development after the first breakthrough innovation. As the theory on dynamic competition states, Companies need to be continuously innovative to survive in the long run.

American car manufacturers dominated the global car market for a long time. Eventually, other car manufacturers entered the American market. In the 1980s Japanese car manufactures started, and continued to capture market shares from the American manufacturers. The American car industry offered many rationales as to why this was happening. It took the industry nearly two decades to discover that the Japanese success came from improved labour management and improvement in management itself.<sup>37</sup> By being innovative in management issues the Japanese car manufacturers became more competitive than their American counterparts did. Japanese

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<sup>34</sup> <http://www.wiley.com/legacy/products/subject/business/forbes/ford.html>

<sup>35</sup> <http://inventors.about.com/od/fstartinventors/a/HenryFord.htm>

<sup>36</sup> <http://www.wiley.com/legacy/products/subject/business/forbes/ford.html>

<sup>37</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 606

car manufacturers captured more and more of the global market and in 2008 Toyota became the largest car company in the world.<sup>38</sup>

## 2.4 Concluding Comments

From this, it is possible to see that dynamic competition, or competition from innovation, is important for the development of a market. However, dynamic competition should not be understood as replacing the static framework, rather the two complement each other, albeit with dynamic competition taking the leading role. Thus, the minimization of deadweight loss triangles, which is the goal of static competition, is a secondary concern.<sup>39</sup> This also means that companies might have to tolerate some static inefficiencies in order to support innovation

The development of the American car industry gives us an understandable perspective of how dynamic competition works over time. Even though Henry Ford was the undisputed innovative force of his time and the rest of the American car industry followed his example, it was not enough in the long run. The Japanese car manufacturers developed other aspects of the industry and were therefore better suited to meet the demands of the market. The implications are that, as have also been stated above, that it is not enough to be innovative just once. If a company becomes stagnated, a competitor that either performs better or introduces better products on the market will outmanoeuvre them.

There also seems to be a difference between dynamic competition in processes and in new products. Dynamic competition that concerns new products has a more direct effect on the market than dynamic competition in processes has. It takes time to develop and implement new processes whereas a new product can change the market completely as soon as it reaches the market. Imagine, for instance, that a pharmaceutical company developed a complete cure for HIV/AIDS tomorrow. The pharmaceutical product is a small tablet that instantaneously cures the patient from the illness. As soon as that product becomes available on the market, it will destroy the market for any other pharmaceutical intended to treat HIV/AIDS. As a comparison, consider the example of Henry Ford. Even though the processes developed by Ford were revolutionary it was still a continuous process over a number of years, making the impact on the market gradual. These two examples show the difference between new products and new processes when introduced on the market, they might in the end have the same impact on the market but the timeframe is different.

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<sup>38</sup> <http://www.washingtonpost.com/wp-dyn/content/article/2009/01/21/AR2009012101216.html>

<sup>39</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 601

## 3 The Pharmaceutical Sector

*“...the conclusion which I have reached here [is] highly specific to the pharmaceutical [sector] in its current condition...”<sup>40</sup>*

This statement made by Advocate General (AG) Jacobs regarding his opinion in the Syfait case<sup>41</sup> underlines the disparities to be found on the European pharmaceutical market as compared to a normal market. The pharmaceutical market is shaped by large innovation costs, a company has to commit enormous resources in order to put a finished product on the market. As a result, patent usage is extensive, in fact, the pharmaceutical sector is one of the main users of the patent system.<sup>42</sup> Another issue is the lack of harmonization in the market. The pharmaceutical sector is heavily regulated on the national level especially concerning pricing and reimbursement rules for medicines.<sup>43</sup> The price setting and the demand side on the market is also different from a normal market. It is normally not the end consumer that ends up paying for the medicine, instead it is usually a national healthcare system that pays for the main cost. In addition, the pharmaceutical companies are not free to set prices on their products, this is done through negotiations with national agencies.<sup>44</sup>

Due to the specific nature of the pharmaceutical market, it is important to have a comprehensive understanding of the market in order to be able to discuss dynamic competition from this perspective. This section aims to analyse the market actors, the product lifecycle and the innovative and competitive structure of the pharmaceutical market in detail.

### 3.1 The Market Actors and Their Relationship

It is possible to discern four main actors on the market. Originator and Generic companies as well as end consumers and States (governments). Originator companies are companies that are involved in Research and Development (R&D) for new products. Originator companies make it possible for patients to benefit from new treatments and medicines.<sup>45</sup> Generic companies are companies that enter the product market after the exclusivity rights have expired. Generic companies produce products that are more or less copies of the original product, or at least have equivalent

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<sup>40</sup> AG opinion in Case C-53/03, para 101

<sup>41</sup> Ibid.

<sup>42</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 9

<sup>43</sup> [http://ec.europa.eu/competition/sectors/pharmaceuticals/overview\\_en.html](http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html)

<sup>44</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 8

<sup>45</sup> Fact Sheet 3, "Originator-Originator competition", page 1



properties. Generic entry on the market has the effect of lowering prices.<sup>46</sup> The State, through its healthcare system, is the large buyer of pharmaceuticals, and the consumer is the one who ultimately will be benefited by the pharmaceuticals. When discussing the market actors it is prudent to divide them in two groups. On the one side, we have the supply side consisting of the originator companies and the generic companies, on the other side we find the demand side consisting of end consumers and national states.

The pharmaceutical market differs from normal markets in that the final consumer has very little to do with the actual decision making. The decision on which drugs a patient should use is taken by the prescribing doctor or in certain cases the pharmacist. Neither the prescriber nor the receiver of the drug is sensitive with regard to price since prescription drugs are reimbursed in most Member States.<sup>47</sup> From this, we can conclude that the prescriber and the ultimate user does not have any significant impact on the market, they will therefore not be discussed further.

The national governments (the State) play an important role on the market as a regulatory power. The State creates the framework within which the companies may operate. The State also forms the national healthcare system through which the patients are reimbursed. Different states have different forms of healthcare systems, which also mean that the level of reimbursement will be different in different healthcare systems. Even though patients do not pay the price of the medicine received, they may have to make a direct contribution to the price, known as a co-payment. The co-payment can consist either of a percentage of the full price or through a flat fee contribution. Some Member States have a co-payment as high as 50 % of the full price, however this is more the exception than the general rule. The healthcare system can be organised either as a state agency or through autonomous social insurers. Another feature of the national healthcare systems is that they are highly involved in negotiating prices for medicines.<sup>48</sup>

Originator companies are companies that are highly involved in R&D. The purpose of originator companies is research into and the development of new as well as already existing chemical entities. Many pharmaceutical companies are also active in the biopharmaceutical industry. The focus of these companies are in other words to provide the market with new medicines and cures.<sup>49</sup> In 2006, the pharmaceutical and biotechnology sector accounted for 19.4% of the global top 1250 companies based on the amount spent on R&D. It is also the one sector that has the highest rate of re-investment of their sales revenue back into R&D.<sup>50</sup>

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<sup>46</sup> Fact Sheet 2, "Originator-Generic competition", page 1

<sup>47</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 8

<sup>48</sup> Pharmaceutical Sector Inquiry, Final Report, pages 46-47

<sup>49</sup> Ibid. page 23

<sup>50</sup> OECD Health Policy Studies, *Pharmaceutical Pricing Policies in a Global Market*, page 52

According to the sector inquiry there are three kinds of originator companies. Aside from the big pharmaceutical companies, there are small and medium-sized enterprises (SMEs)<sup>51</sup> that are highly specialised and focus on innovation in specific pharmaceutical fields. These companies usually do not have the capabilities to market the product themselves. SMEs usually either sell or license their innovations to large originator companies.<sup>52</sup>

The third kind of originator company is biopharmaceutical companies. The biopharmaceutical sector emerged in the 1970s<sup>53</sup> and subsequently the industry is characterised by young SMEs that are in the process of developing their first product and is therefore very dependent on investors. Even so, the biopharmaceutical sector is the most research intensive sector in the world.<sup>54</sup> The innovative nature of originator companies has a great value to society since the R&D efforts makes it possible to treat more as well as new diseases. The value of SMEs is visible when considering substances awaiting market authorisation. In 2007, 35% of originator companies' substances awaiting market authorisation were either in-licensed or acquired from third parties.<sup>55</sup>

There are very high costs associated with the pharmaceutical sector and the development of medicine. During the period 2000-2007, originator companies spent on average 17% of their total turnover on R&D of which 1.5% were spent on research for potential new medicines. Marketing and promotion costs for the period were 23% of total turnover. In 2007, the production costs were 21% of total turnover.<sup>56</sup>

This should be compared to the costs structure of generic companies that on average spent, in 2007, 51% of annual turnover on production, 13% on marketing and promotion and only 7% on R&D.<sup>57</sup> This shows the different structure between originator companies and generic companies. Generic companies tend to be SMEs that are mostly producing medicine for their local market, although there are larger companies as well. As a comparison, in 2007 the amount spent on marketing and promotion activities by the largest originator companies accumulated to more than twice the combined global turnover of the ten largest generic companies.<sup>58</sup>

The business plan for generic companies is to produce medicine that is identical or equivalent to a successful originator medicine as soon as that

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<sup>51</sup> For a definition on SMEs in Europe, go to:  
[http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index\\_en.htm](http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm)

<sup>52</sup> Pharmaceutical Sector Inquiry, Final Report, page 24

<sup>53</sup> Ibid. footnote 41

<sup>54</sup> Ibid. page 24

<sup>55</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 8

<sup>56</sup> Ibid. pages 7-8

<sup>57</sup> Pharmaceutical Sector Inquiry, Final Report, table 7

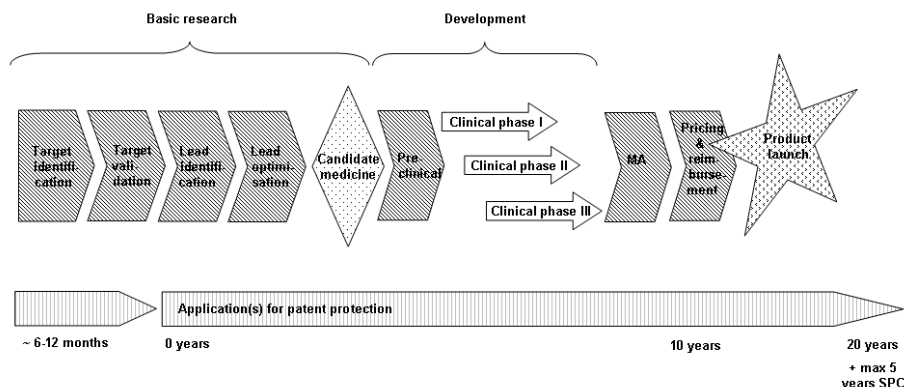
<sup>58</sup> Ibid. page 40

medicine loses its exclusivity. Large generic companies have the capability to manufacture almost any medicine but typically choose to focus on the most successful ones. Since generic companies are able to provide cheaper medicines, they play an important part in managing costs for national healthcare systems.<sup>59</sup>

## 3.2 The Product Lifecycle

The process of developing a new product and finally being able to put it on the market takes a lot of resources as well as time. The whole process can be divided into three main areas, basic research, development and marketing efforts as shown in the figure below.

Figure 1: Product Life Cycle<sup>60</sup>



During the basic research, focus will be on identifying molecular targets associated with a disease and to understand how they function. The researchers then tries to find new molecules that interact with the targets and shows promise as a potential treatment to the disease. The final step of the basic research is to find the molecules that have the largest potential to be developed into a medicine that is safe and effective. When this is done the pharmaceutical company will have a “candidate medicine” that will progress to the development phase. Sometime during the second half of the basic research phase, the company will start to consider filing for a patent for the active substance.<sup>61</sup> These kinds of patents that are concerned with the initial innovative substance/product are referred to as “primary patents”. During the following development, as well as after the launch of the product, pharmaceutical companies will file for subsequent patents that are based on the primary patent, these are referred to as “secondary patents”.<sup>62</sup>

<sup>59</sup> Pharmaceutical Sector Inquiry, Final Report, pages 35-36

<sup>60</sup> Ibid. figure 8

<sup>61</sup> Ibid. pages 50-51

<sup>62</sup> Ibid. page 51

When a candidate medicine has been identified, the development phase begins. The new molecule (medicine) is first tested in a laboratory and on animals before moving on to the three clinical phases. The medicine is then tested on a very small number of healthy human subjects. If the medicine passes this stage the company will proceed to testing on patients that are suffering from the disease in question. In the final stage of clinical trials, testing will be performed for a longer period of time as well as on larger patient groups. During stage two and three of the clinical trials companies may have to experiment with different formulations and dosages of the medicine, this makes it possible for companies to file for secondary patents.<sup>63</sup>

When all three steps of the clinical trials have been passed the company has a product that they are able to put on the market. However, in the European Union no product may be marketed prior to the approval of a market authorisation.<sup>64</sup> A company can apply for a marketing authorisation in two ways, either through a centralised procedure at the European Medicines Agency (EMA) or through a decentralised procedure where application is made nationally, also known as the Mutual Recognition Procedure.<sup>65</sup>

Regulation (EC) No 726/2004 governs the centralised procedure. With regard to the market authorisation the regulation contains two parts, one obligatory and one voluntary. For medicinal products produced through certain biotechnological processes or aimed at certain diseases companies have to apply for a market authorisation through the centralised procedure.<sup>66</sup> If the medicinal product in question does not fall under the first criterion companies can elect to use the centralised procedure if the product contains a new active substance, or if it can be shown that the product represents a significant therapeutic, scientific or technical innovation, or that the granting of a market authorisation is in the best interest of the European Union.<sup>67</sup>

The other option for companies is to apply for national authorisations. If a product has already been authorised in a member state the authorisation holder can apply for a Mutual Recognition Procedure (MRP) in order to receive authorisation in other Member States as well.<sup>68</sup> However, if the product has not received a market authorisation in any member state, a company can apply for a market authorisation in more than one member state at the same time, known as the decentralised procedure.<sup>69</sup>

When market authorisation has been given the product in question is ready for the market. However, many Member States only allow a product to be marketed if a decision on pricing and reimbursement has been taken. Price

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<sup>63</sup> Pharmaceutical Sector Inquiry, Final Report, pages 51-52

<sup>64</sup> Ibid. page 54

<sup>65</sup> Ibid. page 115

<sup>66</sup> Regulation (EC) No 726/2004, art. 3.1

<sup>67</sup> Ibid. art. 3.2

<sup>68</sup> Pharmaceutical Sector Inquiry, Final Report, page 115

<sup>69</sup> Ibid.

and reimbursement decision are used to make sure that necessary medicine is available for patients as well as keeping the budget for the health system under control. Not all Member States uses fixed prices, however prices is still fixed indirectly through the reimbursement policy. If a product, that is facing competition, does not qualify for reimbursement patients will likely refrain from using that product. The policies of the Member States can therefore have a large innovative impact.<sup>70</sup>

Once the pricing and reimbursement decision has been taken companies can launch their products. Companies will then have the exclusive right to exploit their product on the market for as long as they enjoy exclusivity. The period of exclusivity granted by a patent in Europe is normally 20 years from the date of the filing for the patent.<sup>71</sup> However, the actual period of patent exclusivity might be a lot shorter depending on how long it takes from filing for the patent to the actual marketing of the product. It is for this reason possible to extend the exclusivity period in certain circumstances through a supplementary protection certificate (SPC). The SPC can be granted for a maximum period of five years and the combined exclusivity period of patent protection and SPC can not be longer than 15 years.<sup>72</sup>

After the loss of exclusivity generic companies are free to enter the market. Generic companies are also subjected to heavy regulation especially regarding market authorisation as well as price and reimbursement decisions. Generic companies are subjected to the same rules when it comes to market authorization as originators, however they do not have to do clinical trials if they can show that their product is equivalent to an originator product for which such trials have already been made.<sup>73</sup>

When generic entry has occurred one can see it as the end of that products life cycle, from the perspective of the originator companies. The impact of generic entry will be discussed further in the next section.

### **3.3 The Competition and Innovation Structure of the Sector**

The structure of the pharmaceutical market gives rise to three areas of competition. There is competition between different originator companies, between originator and generic companies as well as between different generic companies. As have been describe above innovation is the main driver of competition meaning that the innovative structure of one these areas has an impact on the competition in the other areas as well.

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<sup>70</sup> Pharmaceutical Sector Inquiry, Final Report, page 54

<sup>71</sup> Ibid. page 95

<sup>72</sup> Ibid. page 112

<sup>73</sup> Ibid. page 36

### 3.3.1 Originator vs. Originator

There seems to be two main areas of competition between originator companies. Firstly, there is direct competition between patented products that are aimed at the same therapeutic area. The main competitive aspects are efficacy and absence of side effects of the products. Marketing and promotional activities also play an important competitive role as does competition on prices in those cases where it is possible with regard to the national pricing and reimbursement systems.<sup>74</sup>

The second area is competition through innovation in order to bring new products, for which there are no substitutes, to the market. These kinds of products are essential to originator companies since these products will generate high profits making it possible to recoup losses as well as finance future R&D. Companies are then competing against each other, by being innovative, to be the first to discover and patent molecules that can be developed into medicine.<sup>75</sup>

We can then see that there is fierce competition between competitors for new products as well as for already existing products. Following the definition of McNamara and Vaaler we can see that both static (competition within markets) and dynamic competition (competition for markets) is present.

However, companies are not exclusively competing within or for the product market. Fierce competition is also to be found with regard to marketing and promotion activities as well as patent strategies. During the period 2000-2007 companies spent more on marketing and promotion than they did on actual R&D.<sup>76</sup>

Companies are constantly developing the best patent strategy in order to be able to protect their assets. However, companies may apply patent strategies that may interfere with competing companies ability to develop a medicine. These kinds of patent strategies are known as defensive patent strategies. One of the responding companies to the sector inquiry gave the following statement concerning defensive patent strategies:

*"We identify options to obtain or acquire patents for the sole purpose of limiting the freedom of operation of our competitors."*<sup>77</sup>

Companies file for patents on inventions or molecules that they have no interest in developing or bring to the market for the only reason to be able to stop competing companies from developing those inventions.<sup>78</sup> As a result patent disputes and litigation costs are high.

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<sup>74</sup> Pharmaceutical Sector Inquiry, Final Report, page 25

<sup>75</sup> Ibid. page 25

<sup>76</sup> Fact Sheet 3, "Originator-Originator competition", page 1

<sup>77</sup> Ibid.

<sup>78</sup> Pharmaceutical Sector Inquiry, Final Report, page 387

As well as these general competition strategies we also have to consider the nature of the specific company. As was stated above, there are considered to be three kinds of originator companies, large pharmaceutical companies, SMEs and biopharmaceutical companies. Not only are all originator companies competing against each other, but they are also competing in segments. In 2007, 35% of originator companies molecules where market authorisation had been applied for were acquired or in-licensed.<sup>79</sup> Originator companies can therefore be divided into a demand and supply structure for these in-licensed or acquired molecules. Meaning that there is a competitive market within the originator segment.

The focus of the R&D efforts of originator companies will be determined by the profitability of the relevant research area. Originator companies produce detailed reports in order to be able to focus on the most profitable area.<sup>80</sup>

### **3.3.2 Originator vs. Generic**

When the exclusivity period ends, generic companies can enter the market. Generic entry means lower prices and increases access to affordable treatments. Generic entry also functions as an incentive to innovate for originator companies. Competition from generic companies limits the time span during which originator companies are able to recoup the costs they have had with regard to R&D. Therefore, originator companies will have to develop a new product for which they can receive exclusivity and in that way earn profit.<sup>81</sup> The focus of generic companies will, at least initially, be on the most profitable products.<sup>82</sup>

In order to counter the competition presented by generic entry originator companies employ a number of different strategies aimed at either prolonging their exclusivity period by hindering generic entry or by actively competing with the generic companies.<sup>83</sup>

Originator companies use different patent strategies to delay or block generic entry on the market. By filing for additional patents for the same medicine, originator companies create patent clusters. These clusters surround the original patent and can block or delay the generic companies from developing a generic version of the medicines.<sup>84</sup> As the patent cluster grows larger the more difficult it will be for a generic company to market its generic version of the medicine. Even though the originator medicine has

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<sup>79</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 8

<sup>80</sup> Pharmaceutical Sector Inquiry, Final Report, page 57

<sup>81</sup> Ibid. page 36

<sup>82</sup> Ibid.

<sup>83</sup> Fact Sheet 2, "Originator-Generic competition", page 1

<sup>84</sup> Ibid.

lost exclusivity the generic company still risks infringing one of the multiple patents surrounding the original patent.<sup>85</sup>

As a result of the heavy patent usage, patent litigation is also high. It is legitimate for companies to protect their intellectual properties, however it can also be a way for originator companies to create obstacles for generic companies, especially smaller companies. The average time for the litigation procedures looked at in the sector inquiry was 2.8 years.<sup>86</sup> This means that the originator companies managed to extend their exclusivity period by that much.

Patent disputes are also solved by patent settlements, during the period of investigation over 200 settlement agreements were concluded. In more or less half of these settlements the generic companies ability to market the generic medicine was restricted. In addition to this restriction a large proportion of the settlement agreements contained a value transfer from the generic company to the originator company.<sup>87</sup> Originator companies also intervened in front of national authorities when generic companies were applying for market authorisation, arguing that the generic medicine were of inferior quality and thus not safe or effective. In cases where originator companies intervened it took on average four months longer to grant a market authorisation.<sup>88</sup>

Finally, at then end of the exclusivity period originator companies will try to switch patients from the original medicine to a second generation medicine. If originator companies manage to do this before the generic entry it is unlikely that the generic company will be able to gain a significant share of the market.<sup>89</sup>

In addition to applying strategies aimed at blocking or delaying generic entry, originator companies have started to compete directly with generic companies. The direct competition between originator and generic companies comes from originator companies lowering prices or introducing their own generic version on the market.<sup>90</sup>

Due to the strategies applied by originator companies the time between loss of exclusivity and entry of generic medicine was on average more than seven months. Since generic entry is an important cost saver for national health systems it is important that entry occurs as soon as possible. If generic entry had taken place immediately after loss of exclusivity the savings due to generic entry would have been 20% higher.<sup>91</sup>

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<sup>85</sup> Pharmaceutical Sector Inquiry, Final Report, page 196

<sup>86</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 11

<sup>87</sup> Ibid. pages 12-13

<sup>88</sup> Ibid. pages 13-14

<sup>89</sup> Fact Sheet 2, "Originator-Generic competition", pages 4-5

<sup>90</sup> Pharmaceutical Sector Inquiry, Final Report, page 553

<sup>91</sup> Ibid. page 94



### 3.3.3 Generic vs. Generic

Generic companies will not exclusively compete against originator companies. Generic companies will also face competition from other generic companies for the generic market. From an innovation perspective this kind of competition will not be of much importance. As was already explained above, generic companies primarily focus their attention on the most successful medicines. However, if there are already a large generic presence on a market this market would not be as attractive and one can surmise that generic companies would choose another, more attractive market, meaning a market with limited generic activity. The competition between generic companies is thereby selective. This means that there will not be a high level of innovation in a specific product market. However, generic companies will most likely be competing for being the first to enter a new market, innovation will thereby be on processes in order to be better able to react to new markets.

We can see that the segment of generic vs. generic functions like a static market, even though generic companies launch products that are new for that company they are not new to the market, they are only copies. The focus of innovation will be on improving production efficiencies. Even though innovation will not have a great effect on this segment, the improvement of generic companies production efficiencies will make the generic company better at competing with the originator companies.

The static nature of this competition area is collaborated by findings by the US Congressional Budget Office.<sup>92</sup> The study comes to the conclusion that the price of generic drugs is directly linked to the number of competing generic drugs present on the product market.<sup>93</sup> The sector inquiry have been criticised for not accounting for this aspect of the pharmaceutical sector. If generic entry is as important to consumer welfare as have been articulated by the inquiry then it should be recognised that competition between generic companies are as important as the competition between originator and generic companies after loss of exclusivity.<sup>94</sup>

## 3.4 Concluding Comments

The analysis has shown that there are three main market actors in the pharmaceutical industry. It is the originator companies, the generic companies and the national Member States in the form of regulators and national healthcare systems. The importance of the State on the pharmaceutical market is significant. By being responsible for the nature of

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<sup>92</sup> See, Congressional Budget Office Study, *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry.*

<sup>93</sup> Ibid. page 32

<sup>94</sup> Schwartz, Robert M., *A Critical Analysis of DG Competition's Preliminary Pharmaceutical Sector Report*, page 93

the healthcare system the different Member States are, indirectly, the main buyers on the market as well as, to a large extent, the price setters on the market. One could argue that the State is the most important actor on the market and that might be true in the sense that they have the powers to regulate the legal framework as well as influence price levels on the market. However if we consider the market from a progress and innovation perspective it becomes clear that the most important actor is the Originator companies.

Originator companies are the source of, nearly, all progress made in the pharmaceutical industry. New treatments and medicines that reach the market come from the R&D efforts of originator companies. Due to the importance of national health and reimbursement systems, national authorities are highly involved in determining the price for medicines on the market. Since companies cannot compete on the basis of price, they instead compete with more efficient products or completely new products. We can then conclude that the main source of competition is in innovation.

However, originator companies are competing in two other areas that does not directly correspond to innovation. Firstly, companies are highly involved in marketing and promotional activities. Originator companies devote more resources to this area than they do to actual R&D. We can here see that companies will be competing against each other, trying to win over customers to their product. Secondly, originators compete in the way that they are applying patent strategies to block competitors, originator companies as well as generic companies. It seems like the originator companies are being more innovative in marketing strategies and patent defending than in research for new medicines and treatments.

When assessing the innovative structure of the originator market it is important to account for the different segments. We can divide originator companies in two groups. Companies that are in-licensing or acquiring, these companies are typically larger pharmaceutical companies, and the companies that are licensing or selling their innovative products, these are typically smaller specialised companies. This means that there exists a competitive market within the originator market. Since 35% of the molecules that market authorisation had been applied for in 2007 came from this market, it is important to ensure the continued competitive structure of this market. It is important to make sure that the small specialised companies that are the driving innovative force of that market are able to remain autonomous.

Generic entry on the market has two main purposes, first it increases access to medicine by introducing cheaper medicines and thereby also helps to manage the costs of national health systems. The second purpose is that generic entry forces originator companies to be continuously innovative. For these reasons it is important that originator companies can not influence generic companies in a way that will result in delayed generic entry.

As have been seen, originator companies as well as generic companies focus their R&D attention on the most profitable areas. Meaning that innovation in less profitable areas are not pursued, which is not beneficial to society.<sup>95</sup> For this reason special efforts have been made in order to give incentives to companies to enter these areas.<sup>96</sup>

Finally, patent litigation within the European Union is very high, in the period 2000-2007 the cost of patent litigation was estimated to exceed €420 million. The sector inquiry stated that the cost would have been a lot lower with the presence of a European Union patent as well as a specialised patent litigation system.<sup>97</sup> The patent system in Europe will be discussed in chapter five.

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<sup>95</sup> Pharmaceutical Sector Inquiry, Final Report, pages 57-58

<sup>96</sup> Ibid. see footnote 112

<sup>97</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 12

## 4 The Innovation Process

Companies can be innovative in many different ways. There is not one company structure that will be more suitable for innovation than others. The innovative success of a company depends on how its internal structure functions together as a whole and thus the way in which a company develop ideas will differ greatly.<sup>98</sup> However, innovations, regardless of how they are developed, will share some basic characteristics.

Since dynamic competition focuses on the introduction of new products and new processes it seems prudent to look deeper at what a successful innovation consist of. I have identified three main elements of a successful innovation. First, a company has to have an idea. Second, when the company has realised that they have a potentially profitable idea the company has to have incentives to develop the idea. Finally, the company has to have access to complementary assets in order to be able to capitalize from the innovation.

### 4.1 Idea = $p(k+i)$

Any innovation starts with an idea. In order to be able to assess whether an action is encouraging or hindering the first vital step of the innovation process we need to understand how new ideas occurs. In order to develop this I have decided to use the simple equation “Idea =  $p(k+i)$ ”, constructed by Fredrik Härén.<sup>99</sup>

Fredrik Härén shows through his equation that an idea is the result of a person (p) taking his knowledge (k) and combining it with his information (i) in a new way. This definition shows that it is impossible to create something new from nothing. This means that a person has to have access to both knowledge and information to be able to create something new. The number of new ideas created is then dependent on how many persons that have access to knowledge and information.<sup>100</sup>

In order to understand how companies obtain new ideas we can simply replace the (p) in the equation with (c) that stands for company. Following this reasoning it becomes apparent that the most important aspect of the development of a new idea is the access to knowledge and information.

Since dynamic competition focuses on innovation it is important that companies can not block other companies from knowledge and information. It is also important that the company has access to the most recent

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<sup>98</sup> <http://members.forbes.com/forbes/2007/1112/137.html>

<sup>99</sup> Härén, Fredrik, *Bli en Vinnare i Den Globala Världen*, page 30

<sup>100</sup> Ibid

information and knowledge since a new idea based on outdated information and knowledge will not be as competitive as a new idea based on the most up to date information and knowledge. If a company managed to prevent other companies from using or having access to the most relevant information and knowledge it might be able to keep its market position even though its competitors might be more innovative.

## 4.2 Incentives to Innovate

When a company has realised an idea that they consider to be potentially profitable they have to have the incentives to continue developing it into a finished product that can be put on the market. The problem with innovation is that innovation is basically information and information is a public good. That information is a public good means that once the information has been made public it is available for everyone at no cost.<sup>101</sup> The following example further illustrates the problem:

*“An invention such as a wireless palmtop is a combination of tangible embodiments and an intangible idea, as well as information about how to manufacture it. Typically, both the information and the tangible embodiments are costly to the inventor, but only the tangible components are costly to a rival.”<sup>102</sup>*

In order to be able to market an innovation a company will have to be able to protect their innovation. The need for protection will be higher in cases where it is easy for competitors to imitate the innovation. This is the case in the pharmaceutical industry. The chemical compounds of a pharmaceutical product does not cost a lot to manufacture, the real cost is the development costs for the product. When the product is made available on the market it would be easy for competitors to make their own product using the same chemical compound. Without protection the inventor will be at a disadvantage compared to other competitors that have not had to invest in developing the product. Without a means to protect their innovation a company would be dissuaded from investing.<sup>103</sup>

Patents have long been used to protect an inventor’s innovation. The underlying goals of the patent system is to promote R&D and encourage inventors to disclose their inventions so others can take part of it as well as allow others to use the research results for further development.<sup>104</sup> A company that is given a patent is essentially granted a monopoly for a limited duration, which normally is 20 years, for the patented invention. The protection provided by patents cover most commercial uses of the patented innovation. The trade of for receiving this monopoly is that the inventor has

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<sup>101</sup> Ippolito, Richard A., *Economics for lawyers*, page 199

<sup>102</sup> Gallini, Nancy T., and Scotchmer, Suzanne, *Intellectual Property: When Is It the Best Incentive System?*, page 53

<sup>103</sup> Ibid.

<sup>104</sup> Gallini, Nancy T. , *Patent policy and costly imitation*, page 52

to disclose the technical information of the invention.<sup>105</sup> In this way patents benefit both society, in the way that new innovations are introduced, as well as the inventor, in that he can profit from his inventions. Patents create incentives to innovate by promising future profits (a prize) from an invention.

The price of a patent will depend on how much protection it grants to the patentee. The protection will be determined by the scope of the patent. The scope of the patent can be divided into two dimensions, length as well as breadth. The length of a patent is simply the duration of the exclusivity granted by a patent. Different authors have defined the breadth of a patent in different ways, however in general patent breadth relates to what is protected by the patent. Patent breadth can encompass such things as how different must a competing product be from the patented product in order to be marketed and sold without infringing the patent as well as how many applications of an innovation is reserved for the patentee.<sup>106</sup> The breadth and length of the patent can then be used to determine the level of protection granted.

From these two dimensions we can deduce that there are four possible ways to combine length with breadth. However, there are only two ways that are feasible, either a narrow patent breadth with a longer duration or a broad patent with shorter duration. The two other possibilities are not desirable since a narrow patent with short duration would not offer enough protection to the patentee and therefore lower his incentives to innovate. On the other hand a patent with a very broad breadth and a long time span would create excessive monopoly power, which is not desirable from society's point of view.

The effectiveness of the patent system depends on competitors' ability to imitate or invent around the patent.<sup>107</sup> If the patent system is constructed in such a way that it is easy for competitors to circumvent the patent, the patent will not be as valuable to the patentee and the incentive to innovate will decrease. Gallini finds in her article that a long patent life will give competitors incentives to imitate and invent around the patent since they will have to wait a long time to be able to use the invention therefore patent length should in general be short.<sup>108</sup> She concludes that patent length should in general be short to discourage imitations. Where both patent breadth as well as length can be chosen, it is optimal to grant a broad patent, which does not allow for imitation, and then adjust the length of the patent to generate the desired return from research.<sup>109</sup> Denicolò takes a different approach to determining the optimal breadth of a patent. He starts with a patent with maximum breadth and then states that a narrowing of the

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<sup>105</sup> Bently, Lionel and Sherman, Brad, *Intellectual Property Law*, page 335

<sup>106</sup> Denicolò, Vincenzo, *Patent Races and Optimal Patent Breadth and Length*, pages 251-252

<sup>107</sup> Gallini, Nancy T., *Patent policy and costly imitation*, page 52

<sup>108</sup> *Ibid.* pages 52-53

<sup>109</sup> *Ibid.* Page 62

breadth can only be socially optimal where it increases social welfare more than it reduces the incentive to innovate.<sup>110</sup>

We can then see that the prize of a patent is very much dependent on how the scope of the patent is created. Through this we can conclude that the incentive to innovate is equal to the prize the patent holder will receive, i.e. the post innovation profits.<sup>111</sup>

### 4.3 Dynamic Capabilities

In his article Profiting from technological Innovation Teece identifies the factors that determine who will be the main winner from an innovation, the innovating firm or firms that enter the market later. He states that it is common that competitors/imitators profit more from an innovation than the innovator.<sup>112</sup> This implies that it is not enough for a company to be able to innovate, the company also need some other capabilities in order to be successful. For example:

*“RC Cola, a small beverage company that was the first to introduce cola in a can, and the first to introduce diet cola. Both Coca Cola and Pepsi followed immediately and deprived RC of any significant advantage from its innovation.”<sup>113</sup>*

A firms possibility to profit from an innovation depends on the appropriability of the product as well as the complementary assets. Appropriability means the innovators ability to profit from the innovation, disregarding the structure of the market as well as the firm. The most important aspects of appropriability is the nature of the technology and the effectiveness of the legal framework. The key aspects of the legal framework is the patent and copyright systems as well as the possibility to use trade secretes. The technology aspect relates to the nature of the innovation, is it a process or a product and whether the information surrounding the product is tacit or codified. Codified knowledge is easy to transfer which means that it is easy to imitate, whereas tacit knowledge is difficult to explain. In order to transfer tacit knowledge it has to be demonstrated in order to be transferred, making it difficult to imitate.<sup>114</sup> To clarify, the dynamic capabilities of a company are made up by the appropriability of the product as well as the complementary assets of the company. Since I have already discussed the nature of pharmaceutical products as well as patents, which is the main legal protection for pharmaceutical products, I will not discuss these issues further but instead focus on complementary assets.

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<sup>110</sup> Denicolò, Vincenzo, *Patent Races and Optimal Patent Breadth and Length*, page 263

<sup>111</sup> Ibid. page 253

<sup>112</sup> Teece, David J., *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, page 285

<sup>113</sup> Ibid.

<sup>114</sup> Ibid. page 285

### 4.3.1 Complementary Assets

In order for an innovation to generate profit it must in one way or another be sold or in some way be used on the market. In almost all cases a successful commercialisation of an innovation demands that the innovation is used in combination with some other assets. Marketing, manufacturing and after sales support are services that are almost always needed but that does not directly relate to the innovation. These types of services come from complementary assets.<sup>115</sup> However, complementary assets are not limited to any specific assets, they can entail any number of assets used in combination with the innovation.<sup>116</sup>

Complementary assets can be divided into three groups, specialized, co-specialized and generic assets. Specialized assets are assets that are completely dependent on the innovation, or where the asset is dependent on the innovation. Co-specialised assets refer to situations where the innovation and asset are mutually dependent on each other. The example given by Teece is that of the introduction of the rotary engine by Mazda. The rotary engine is quite different, technologically, from a normal combustion engine.<sup>117</sup> Since the engine was different the technical know-how was not available on the market. This meant that Mazda had to set up specialized repair shops in order to be able to introduce the rotary engine on the market. Finally, generic assets are assets that serve a general purpose but that does not have to be tailored to the innovation.<sup>118</sup>

The importance of the complementary assets will depend on how strong the appropriability of the innovation is. The weaker the appropriability position of the innovation the more important it will be for the innovator to have fast and easy access to complementary assets.<sup>119</sup>

There are three ways for an innovator to access complementary assets. Either the innovator applies a contractual solution with another company that has the assets that the innovator needs or the company applies an integration solution where the innovator acquires the complementary assets himself. The third way is to use a mixed model where the innovator acquires some of the assets and contracts for others.<sup>120</sup> Each model has its pros and cons and the determinant of which one will be used will be the nature of the complementary asset needed for a specific innovation.

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<sup>115</sup> Teece, David J., *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, page 288

<sup>116</sup> Ibid. page 289

<sup>117</sup> For an overview of the rotary engine see:

<http://library.thinkquest.org/C006011/english/sites/wankel.php3?v=2>

<sup>118</sup> Teece, David J., *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, page 289

<sup>119</sup> Teece, David J., *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, Page 290

<sup>120</sup> Ibid. pages 293-295, 298



In subsequent papers Teece have developed his thesis and there are two findings that need to be commented upon. In the 1986 paper, complementary technologies were treated on the same terms as other complementary assets. Technology advances has progressed quite a bit since 1986. The availability of complementary technologies have become increasing important and we therefore need to give special consideration to this aspect. Today, successful commercialisation requires combining complementary technologies as well as patents. For example, the digital camera could not be fully commercialised until the flash memory became available at low cost.<sup>121</sup>

The other issue is that of supporting infrastructure, which suggests that it is not only owners of complementary assets that are relevant but also e.g. regulators standard setting bodies and the courts themselves. It is suggested that for especially innovative innovations complementary assets as well as supporting infrastructure might be needed before an innovation can be put on the market.<sup>122</sup>

The theory put forth by Teece stresses that it is not the ex-ante market share of an innovator that determines success but rather the complementary assets structure of the company.<sup>123</sup> Also, even though the performance of an enterprise over time is in some measure determined by external factors, it is how a company development and exercise its internal dynamic capabilities that determines if the company will succeed or not.<sup>124</sup>

## 4.4 Concluding Comments

We can then conclude that there are three main areas of interest when we are analysing innovations. It is necessary for a company to have access to all three areas in order to successfully develop an idea to a final marketable product. It is therefore important that companies are not able to exclude competitors, actual as well as potential, from any of these areas.

These areas can be seen as three different segments of the innovation process, where, within each of them, innovation can be hindered. As well as being segments of innovation they also represent different timeframes. The development of an idea lies at the very beginning of an innovation, as does the incentive to develop it further that comes from the patentability of an innovation. Within this timeframe, it is still quite far until the actual marketing of the product, this is especially true for the pharmaceutical market where substance matter is patented long before the product itself has been fully developed. This means that the potential competitive market of

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<sup>121</sup> Teece, David J., *Reflections on "Profiting from Innovation"*, pages 1138-1139

<sup>122</sup> Ibid. pages 1139-1140

<sup>123</sup> Ibid. page 1132

<sup>124</sup> Teece, David J., *Explicating Dynamic Capabilities: The Nature and Microfoundations of (Sustainable) Enterprise Performance*, page 1320

the product can be difficult to identify. When we move into the segment of dynamic assets we come closer in time to the marketing of the product. It then becomes easier to predict the competitive market as well as the competitive impact of the product on the market.

The discussion on complementary assets has also shown that there is a certain type of innovation that needs to be given some extra discretion. Certain exceptional innovations may need access to supporting infrastructure, or that supporting infrastructure be developed, in order to be able to reach the market. Since these kinds of innovation are more difficult to develop, it might be prudent to grant extra protection to companies involved in this kind of exceptional innovation.

# 5 Dynamic Aspects of the Legal Framework.

Since both the dynamic competition theory as well as the pharmaceutical sector has its main focus on innovation the following discussion on the legal framework will be focused on that. The discussion on the patent framework will cover the problems with the present framework, as articulated by the commission sector inquiry, and the changes proposed by both the Draft Agreement on the European and Community Patents Court<sup>125</sup>, which is currently under judicial review by the European Court of Justice (ECJ), as well as the Proposal for a Council Regulation on the Community patent.<sup>126</sup>

The discussion on the antitrust framework will be focused on exclusionary behaviour from an innovation perspective, meaning situations where a company through different means restricts the possibility of a competitor to innovate and thereby compete with that company.

## 5.1 Patent Framework

The patent framework in Europe started with the European Patent Convention (EPC) of 1973. The EPC is an intergovernmental agreement that has largely harmonized the criteria for patentability within Europe.<sup>127</sup> Even though it has been amended and that a new and revised convention entered into force in 2007<sup>128</sup> it is as of yet not possible for companies to apply for and be granted a patent that is valid and enforceable throughout the European Union. Presently, companies can obtain a patent in two different ways. Either they file for a patent application on a national level in the Member States where they wish to have protection, or they file for a so called European Patent at EPO.<sup>129</sup> Even though the “European Patent” is granted through a centralised procedure, meaning that the examination procedure for the application is only made once, subsequent applications for validation of the “European Patent” will have to be made for all Member States where the patent holder wants to have the possibility to enforce his patent. The “European Patent” is therefore not a European Patent but merely a bundle of national patents granted through a centralised procedure.<sup>130</sup>

When the patent has been validated on the national level it becomes legally enforceable in those Member States where validation has taken place. However, the enforcement procedure available to the patent holder will

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<sup>125</sup> Council Working Document 7928/09 of 23 March 2009

<sup>126</sup> Council Working Document 16113/09 of 27 November 2009

<sup>127</sup> Pharmaceutical Sector Inquiry, Final Report, page 99

<sup>128</sup> Ibid.

<sup>129</sup> Ibid. page 441

<sup>130</sup> Ibid. pages 102-103

differ between Member States, due to incomplete harmonization in that area.<sup>131</sup> Without a unified system on patent litigation it is for the national courts to enforce patents on their own territory. This means that a party, either as challenger or enforcer of a patent, will have to pursue the legal action in the national court of each of the Member States concerned. These kinds of multiple legal actions can become very costly.<sup>132</sup>

The bundle of national patents created by the “European Patent” creates a big problem for generic companies that have to challenge these patents in the different national courts. Seeing as a pharmaceutical product usually consists of more than one patent it can be very costly and time consuming for generic companies to be able to enter a market.<sup>133</sup> As articulated by the European Generic Medicines Association:

*“A generics company may have to work through literally hundreds of patents and patent applications from the originator and other companies who are developing forms of that product, steering a precarious course through all of the potential issues.”<sup>134</sup>*

As was stated in section 3.4 the cost of patent litigation is very high in the European Union, for the period 2000-2007 the total cost of patent litigation was estimated to more than € 420 million. The commission inquiry concluded, on this note, that a significant proportion of that cost could have been saved if cross border duplication of cases could have been avoided through a European patent and a unified patent litigation system.<sup>135</sup> All stakeholders expressed the need for the introduction of a proper European Patent and a unified patent litigation system.<sup>136</sup>

### 5.1.1 European Patent

The council proposal for a Council Regulation on the Community Patent starts off in a general way, stating that one of the activities of the European Union is the establishment of an internal market. The development of a European Union Patent (EU Patent) that will have uniform effect as well as protection throughout the European Union will help to achieve this goal.<sup>137</sup>

The EU Patent will be a patent that is designated to the whole of the European Union. It shall have a unitary character, meaning that it will be given equal effect in the whole territory, the same is true for any changes made to the patent.<sup>138</sup> It is articulated that the creation of a EU Patent should

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<sup>131</sup> Pharmaceutical Sector Inquiry, Final Report, page 108

<sup>132</sup> Ibid. page 109

<sup>133</sup> Ibid. page 443

<sup>134</sup> European Generic Medicines Association: *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, page 18

<sup>135</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, page 12

<sup>136</sup> Ibid. page 20

<sup>137</sup> Council Working Document 16113/09 of 27 November 2009, preamble 1

<sup>138</sup> Ibid. article 2

make the patent system less costly as well as less risky, which would lead to a more easily accessible patent system. This would in particular be of importance to SMEs.<sup>139</sup> EPO would be given a central role as the sole responsible body of the administration of the EU Patent. Applications for an EU Patent should be filed directly with EPO or through the national patent office of a Member State. EPO would be solely responsible for examination and granting of EU Patents.<sup>140</sup>

As was explained above, the current system provides innovators with two different ways to obtain a patent. The proposal for a new EU patent system does not replace the current systems, instead it adds a third way of obtaining patents. If the proposal is incorporated in its present form, applicants will be able to apply for a national patent, a bundle of national patents (the “old” European Patent) as well as a EU Patent.<sup>141</sup>

Any negative effects resulting from the granting of an EU Patent shall be dealt with through a system of compulsory licensing.<sup>142</sup> A compulsory license shall be grantable upon application thereof, if the patent in question has not been exploited properly four years after the filing of the patent application or three years after the granting of the patent.<sup>143</sup> A compulsory license may also be granted for a patent in the situation where a holder of a second patent are unable to exploit that patent without infringing the first patent.<sup>144</sup> A compulsory license may only be granted where the applicant have tried, on reasonable terms have made efforts to obtain permission from the patent holder, but have been unable to secure permission within a reasonable period of time.<sup>145</sup>

### **5.1.2 Unified Litigation System**

The draft agreement initially states that the cooperation between Member States in the field of patents is of great importance for the integration process in Europe and especially for the development of the internal market. However, the fragmented market for patents as well as large variations between national court systems makes it more difficult for companies to enforce and defend their patents, which may be detrimental for innovation. This would especially be a problem for SMEs, since these companies might not have the necessary resources to enforce their patent rights. In order to deal with this problem the draft agreement aims to set up a European and Community Patents Court for litigation related to infringement and validity

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<sup>139</sup> Council Working Document 16113/09 of 27 November 2009, preamble 1a

<sup>140</sup> Ibid. preambles 2a,2b

<sup>141</sup> Ibid. preamble 4b

<sup>142</sup> Ibid. preamble 6

<sup>143</sup> Ibid. article 21.1

<sup>144</sup> Ibid. article 21.2

<sup>145</sup> Ibid. article 21.6

of patents. This would improve the enforcement of patents as well as enhance legal certainty.<sup>146</sup>

## 5.2 Antitrust Framework

Companies can, in general, restrict competition in two ways, either through contractual means or through using their market position to restrict access to essential inputs from competitors. The EU antitrust rules governing these behaviours can be found in article 101 and article 102 in The Treaty on the Functioning of the European Union (TFEU)<sup>147</sup>.

Article 101 states that any agreement, decision by associations of undertakings or concerted practices that has the effect of preventing, distorting or restricting competition shall be prohibited. There are some general types of agreements that are considered to be of particular anticompetitive nature, among which we find agreements that aim to limit or control technical development.<sup>148</sup> These types of agreements are automatically void,<sup>149</sup> unless the agreement can be exempted under the rules in article 101.3.

Article 102 states that any abuse made by a company in a dominant position, or multiple companies with a combined dominance shall be incompatible with the internal market and thus prohibited. One of the issues that are specifically mentioned as an abuse is the limitation of technical development.<sup>150</sup> There are any number of issues that can constitute an abuse, consequently, the list of abuses in the article is not exhaustive.<sup>151</sup>

Thus, the limitation of technological development, i.e. innovation, is seen as abusive from both a contractual as well as a dominance perspective. However, in order to be able to see if a behaviour is prohibited there are some issues that need to be addressed. In order to determine whether an agreement falls under article 101 we first have to make sure that it is not exempted under the derogation rules in article 101.3. As well as having to fulfil the obligations imposed by article 101.3 the companies can also not have a too large market share, either jointly or alone. The size of the market share allowed will depend on the agreement at hand as well as the competitive structure between the companies. For example, agreements that concern technology transfer can be exempted as long as the combined market share does not exceed 20% for companies that are competing on the relevant technology or product market and 30% for non competing companies.<sup>152</sup> When assessing whether an abusive behaviour falls under

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<sup>146</sup> Council Working Document 7928/09 of 23 March 2009, preamble

<sup>147</sup> Official Journal C 83 of 30.3.2010

<sup>148</sup> TFEU, article 101.1

<sup>149</sup> Ibid. article 101.2

<sup>150</sup> Ibid. article 102.b

<sup>151</sup> Craig, Paul and de Búrca, Gráinne, *EU LAW*, page 1019

<sup>152</sup> Commission Regulation (EC) No 772/2004, article 3

article 102 a first important step is to determine what level of market power the company holds and whether that market power constitutes a dominant position.<sup>153</sup>

Regardless of the nature of the abuse, and whether it is through contractual means or through an abuse by a dominant company market power has a central role in the antitrust analysis. The market share of a company will depend on how the relevant market is defined. There are two dimensions to the relevant market, it can be divided into the relevant geographic market as well as the relevant product market.<sup>154</sup>

The static nature of the European antitrust framework can then be seen in the strong focus on market shares. In an innovative market, such as the one advocated by Schumpeter where new products will replace the old, market shares might not be as important as for example entry barriers.<sup>155</sup>

The Commission will, as demonstrated by the Commissions “Guidance on enforcement prioritise when applying article [102] to abusive exclusionary conduct”, not only account for market shares but also focus on other issues, such as how existing and potential competitors affect the company in question.<sup>156</sup> However, the guidance states that market shares is useful as a first indication on the structure of the market.<sup>157</sup> The guidance states that the Commission will consider a low market share to be a good proxy for the absence of market power.<sup>158</sup> This means, that even though the antitrust analyses will focus on more dynamic considerations the starting point will still be in the static framework, thereby it might fail to account for dynamic inefficiencies already from the start of the analysis.

## 5.2.1 Dynamic Antitrust Framework

As the importance of innovation has become greater so has the need for a corresponding antitrust policy become greater. This section will focus on the main findings in Glader’s dissertation followed by the more recent developments by Teece.

Glader starts of by explaining the general aim of a policy regarding analysis of innovation. The main goal of such a policy would be to maintain a structure for the development of new products as well as technologies. It is also important that the structure is reasonably open to competition. In such a case where the innovation process is exposed (at least potentially) to

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<sup>153</sup> Communication from the Commission, (2009/C 45/02), para 9

<sup>154</sup> Craig, Paul and de Búrca, Gráinne, *EU LAW*, page 1006

<sup>155</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 56

<sup>156</sup> *Implementing an effects-based approach to Article 82*, page 17

<sup>157</sup> Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, para 13

<sup>158</sup> *Ibid.* para 14

competition the traditional focus on market structure will be of limited use. Focus should instead be on whether the market practise has a detrimental effect on incentives to innovate, if it artificially determines the “winners” or if it is of an exclusionary nature.<sup>159</sup> Consequently, behaviour that makes technological progress possible is beneficial to competition. To combine resources in this way is a means of competing on the merits and should thus be allowed.<sup>160</sup>

The analysis is then divided into different segments depending on where in time the behaviour takes place, current markets or potential future markets. Potential future markets are then divided into imminent future markets and distant future markets.<sup>161</sup> Where the analysis is concerned with current markets and innovation is an important aspect of competition, the analysis will need to conduct detailed investigations in the innovation process.<sup>162</sup> Such an investigation will make it possible for us to:

*“...fully appreciate the level and nature of current and potential competition and thus the likely effect of the [behaviour].”<sup>163</sup>*

The benefit of an analysis with focus on R&D developments, as opposed to only focus on product market, is that it allows for changes that are outside the product market to be taken into account.<sup>164</sup> Where the parties involved would not have been able to achieve the relevant R&D objectives independently in an effective way it is assumed that anticompetitive concerns would not arise.<sup>165</sup>

An analysis on the level of potential future markets is appropriate when the behaviour will affect the innovation process for new products or technologies. One of the main issues would then be whether the behaviour will have anticompetitive effects on R&D.<sup>166</sup> In imminent future markets it is possible to reasonably predict the characteristics, market boundaries as well as the attractiveness to consumers of the future product.<sup>167</sup> At this level of analysis focus would first be on lessened product variation, whether unified control over two new competing products would lead to one of them being cancelled or delayed.<sup>168</sup> The second concern would be on pure price competition in the future product market. In order to find anticompetitive effects the analysis will have to identify other R&D projects as well as their timing and competitiveness. The effects on the future product market will

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<sup>159</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 321

<sup>160</sup> Ibid.

<sup>161</sup> Ibid. pages 322, 325 and 328

<sup>162</sup> Ibid. page 322

<sup>163</sup> Ibid.

<sup>164</sup> Ibid. page 323

<sup>165</sup> Ibid. page 325

<sup>166</sup> Ibid.

<sup>167</sup> Ibid. page 328

<sup>168</sup> Ibid



depend on the status of the current product market as well as the significance and number of products under development.<sup>169</sup>

Analysis in distant future markets, where R&D efforts are combined at a stage where the outcome is unsure, should be focused on innovation in a broader sense. It should focus on long term incentives to innovate as well as foreclosure of third parties.<sup>170</sup> For such an analysis it is less important to identify boundaries of a future product market that the R&D is directed towards.<sup>171</sup> The pharmaceutical sector is used as an example, stating that it might be hard to predetermine the characteristics and effects of a future drug, which implies that even if R&D programmes are directed towards the same disease the application of the future drugs could vary.<sup>172</sup> It is argued that through an analysis of distant future markets ““*true*” *competition in innovation*” can be assessed. However, the discussion on distant future markets is limited to R&D sources directed at potentially substitutable future products, which leads him to one more distinction.<sup>173</sup>

Technology bases is at the very top of the innovation ladder. This level of analysis is appropriate where the competitive restraints do not correspond to any particular R&D project or possible future products. Therefore, focus must instead be on diminished competition between companies within a certain technological area. Focus should especially be on the creation of anticompetitive foreclosure in that area.<sup>174</sup> The problem on this level is that certain behaviour that combines technology and know-how may create bottlenecks that can restrict innovation for a variety of potential product markets.<sup>175</sup> The limits of the bottleneck will, at some level, be determined by the availability of alternative technologies. However, rather than focusing on availability of alternative technologies the analysis should be an assessment of critical technologies, in, where appropriate, combination with other factors, needed for continued R&D in a broader research area. Research tools protected by IPR in the biotechnology sector are used as an example. Certain behaviour in combination with such a bottleneck could have a negative effect on future technology and product markets.<sup>176</sup>

Finally, Glader considers innovation analysis in abuse cases. For abuse to exist a company must have a very strong market position. Such a position can come from e.g. certain key patents. The abusive behaviour can only have an appreciable effect on the market if the dominant company controls the relevant innovation market or in some other way significantly impedes possibilities for competition in innovation.<sup>177</sup>

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<sup>169</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 329

<sup>170</sup> Ibid. page 326

<sup>171</sup> Ibid.

<sup>172</sup> ibid. footnote 931

<sup>173</sup> Ibid. page 330

<sup>174</sup> Ibid.

<sup>175</sup> Ibid.

<sup>176</sup> Ibid. page 331

<sup>177</sup> Ibid. page 333

Where a company have acquired its position through product development or other pro-competitive means it should only be obliged to share its R&D assets with competitors in very exceptional circumstances. However, where the structure of a company does not come from its internal efficiencies but rather from its conduct in relation to its competitors the possibility for intervention is greater. Glader finishes the analysis with a note on competition on the merits and states that it is vital for antitrust law not to limit the possibility for large companies to compete themselves, and that:

*“Superior efficiency must not be held against any company.”*<sup>178</sup>

Teece, like Glader, argues that market shares will be irrelevant in situations where change is rapid, due to the fact that competition for markets will be as significant as competition within it.<sup>179</sup> Teece then states that even though efforts have been made to shift focus towards the innovation market from the product market, these efforts have been too narrowly focused on R&D as the determinant of competition in innovation. R&D, even if it is defined broadly, is only one of the factors that are necessary for innovation.<sup>180</sup> He states that:

*“The resources that firms must commit and the skills that firms must employ to succeed at innovation usually exceed those needed for merely conducting R&D”*<sup>181</sup>

Teece argues that companies show more stability in its capabilities than in their products, from this perspective it is easier to analyse a companies capabilities than their products. Since capabilities are proxies for the competitive significance of a company, these capabilities are a better determinant of a company’s competitive position than its downstream market share.<sup>182</sup> This is a point also argued by Glader.<sup>183</sup>

The question, from an antitrust perspective, should thus not be whether competition will be harmed in the product market, since this is too much of an immediate concern.<sup>184</sup> The question should be whether capabilities will end up under a unitary control and thereby possibly hinder future innovations. An antitrust framework that favours dynamic competition over static competition should thus put less value on market share and instead focus on assessing innovation and capabilities.<sup>185</sup>

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<sup>178</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 333

<sup>179</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 615

<sup>180</sup> *Ibid.* page 617

<sup>181</sup> *Ibid.*

<sup>182</sup> *Ibid.* page 616

<sup>183</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 44

<sup>184</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 619

<sup>185</sup> *Ibid.*

## 5.2.2 Sector Specific Regulation?

One question that occurs when discussing IPRs and antitrust law is where the border between the two goes. One of the main purposes of intellectual property law is to promote the disclosure of an innovation. This is done through the granting of an exclusive ownership of the patent. Then, antitrust steps in and demands that the patent holder relinquishes the exclusive right on the basis that the patent is essential for further development. However, if the patent framework does not in itself deal with certain problems it should not be surprising that antitrust law tries to solve them instead.<sup>186</sup>

On the other hand, if the relevant framework does regulate the relevant market, should antitrust law still be applicable to that area? This question is developed under US case law, and will be exemplified here through the decisions in *Verizon Communications Inc. vs. Curtis V. Trinko*<sup>187</sup> (Trinko) and *Credit Suisse vs. Billing*<sup>188</sup> (Credit Suisse).

The Trinko case concerns the question whether sector specific regulation should preclude the use of antitrust rules. The US Telecommunications Act of 1996 imposes certain conditions on incumbent firms in the telephone sector for the purpose of making it easier for competitors to enter the market. The question is whether a breach of the duties imposed by the Telecommunications Act would justify a claim under antitrust rules.<sup>189</sup> The court states that one important factor to consider is whether there is, for the relevant sector, a regulatory structure that is designed to discourage and remedy anticompetitive harm. If such a structure exists, it is argued that the benefit of antitrust law will be limited.<sup>190</sup>

The Credit Suisse case develops this concept further and elaborates on four criteria that have to be fulfilled for antitrust law not to be applicable. (1) there has to be a regulatory authority governed by the relevant regulatory structure that supervises the activities in question, (2) it has to be proven that the authority actually exercises its powers, (3) there has to be a risk that if both antitrust rules and the relevant regulatory framework are applicable would lead to conflicting “*guidance, requirements, duties, privileges, or standards of conduct*”, (4) that the practices potentially affected by the conflict falls within the area that the relevant regulatory framework aims to regulate.<sup>191</sup>

It is then clear that antitrust law will not be applicable in the US when these criteria are fulfilled.

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<sup>186</sup> Glader, Marcus, *Innovation Markets and Competition Analysis*, page 318-319

<sup>187</sup> *Verizon Communications Inc. vs. Curtis V. Trinko*, No. 02-682 (January 13, 2004)

<sup>188</sup> *Credit Suisse vs. Billing*, No. 05-1157 (June 18, 2007)

<sup>189</sup> *Verizon Communications Inc. vs. Curtis V. Trinko*, No. 02-682 (January 13, 2004), page 1

<sup>190</sup> *Ibid.*, page 12

<sup>191</sup> *Credit Suisse vs. Billing*, No. 05-1157 (June 18, 2007), page 10

## 5.3 Case Law

This section aims to give example on how pharmaceutical companies are allowed to behave. The two cases presented will give an idea of what the ECJ will allow and what is outside the scope of acceptable behaviour. The Syfait II<sup>192</sup> case concerns refusal to supply and parallel trade. The AstraZeneca case<sup>193</sup>, currently under appeal before the court of first instance<sup>194</sup>, concerns fraudulent behaviour with the aim to extend the exclusivity period for its patents.

The Syfait II case is between Glaxosmithkline PLC, a UK based pharmaceutical research and manufacturing company, and its Greek subsidiary Glaxowellcome A EVE (both companies will be referred to as GSK) against a number of Greek wholesalers.<sup>195</sup>

The Greek wholesalers had for a number of years bought all medicines offered by GSK, for the purpose of distribute them on the Greek market as well as in other Member States.<sup>196</sup> At the end of 2000 GSK changed its distribution system to the effect that GSK stopped meeting the orders made by the wholesalers.<sup>197</sup> It was commonly understood between the parties that the aim of restriction supply was to limit the parallel export of the wholesalers to other markets in other Member States where pharmaceutical prices, for the relevant products, were higher.<sup>198</sup>

The wholesalers considered this to be abusive behaviour and took up the matter before the competent Greek authority who referenced it to the ECJ for a preliminary ruling.<sup>199</sup>

The ECJ then states that there can be no escape form the prohibition in article 102 TFEU for a company in a dominant position that aims to limit parallel trade, which might be detrimental for effective competition.<sup>200</sup> However, in cases such as the one at hand, it has to be taken into account that the opportunities for parallel trade comes from State intervention.<sup>201</sup> In addition, the treaty provisions cannot be interpreted in such a way that the only option open to a company to protect its commercial interest is to not put their product on the market in the first place.<sup>202</sup> The ECJ then concluded that even though a company in a dominant position has a responsibility to supply, they still have to be in a position to, in a reasonable and proportional

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<sup>192</sup> Joined Cases C-468/06 to C-478/06

<sup>193</sup> Case COMP/37.507

<sup>194</sup> T-321/05

<sup>195</sup> Joined Cases C-468/06 to C-478/06, paras 2, 9

<sup>196</sup> Ibid. para 10

<sup>197</sup> Ibid. para 11

<sup>198</sup> Ibid. para 36

<sup>199</sup> Ibid. para 18

<sup>200</sup> Ibid. para 66

<sup>201</sup> Ibid. para 67

<sup>202</sup> Ibid. para 68

manner, protect their commercial interests.<sup>203</sup> In order to ascertain whether the refusal to supply by a company in a dominant position with the aim of limiting parallel trade constitutes an abuse, it has to be determined whether the orders of the wholesalers are out of the ordinary.<sup>204</sup>

In the AstraZeneca case the Commission found that AstraZeneca had misused public procedures and regulations for the purpose of excluding generic companies and parallel traders from competing with the anti-ulcer product Losec made by AstraZeneca.<sup>205</sup> AstraZeneca abused its dominant position in two ways. The first abuse consisted of AstraZeneca, while applying for a SPC protection, gave misleading information to patent offices in a number of different Member States. Due to the fact that AstraZeneca gave misleading information extra protection was approved and thus the exclusivity period were extended, which meant that the entry of generic versions of Losec was delayed. This entailed higher costs for the national health care systems as well as for consumers, compared to if generic entry had occurred earlier.<sup>206</sup> The second abuse consisted in AstraZeneca requesting that the market authorisation was withdrawn for Losec capsules at the same time as AstraZeneca introduced Losec in a new form, namely in the form of tablets. Generic companies and parallel traders were dependent on the market authorisation for Losec capsules in order to be able to enter and/or remain on the market. The Commission concluded that through its conduct AstraZeneca managed to secure protection for Losec much longer than it should have had according to the applicable rules.<sup>207</sup>

## 5.4 Concluding Comments

As have been articulated above, the current patent framework does not work properly. Efforts have been made in order to make the system more effective. The proposed changes are twofold, first the introduction of a proper EU patent that will be, upon granting, directly applicable throughout the EU. Second, the introduction of a unified litigation system, aimed at making it easier and less costly to solve patent disputes. Introducing a system that is on its own able to regulate and impose remedies, e.g. the issuing of compulsory licenses, makes it appropriate to ask the question whether the EU is moving towards a sector specific regulation regime as the one used in the US. Even though the proposals explicitly states that they do not preclude the use of EU antitrust rules, the question where the border between the proposed patent system and the antitrust rules is will still be relevant.

With regard to the antitrust framework, especially in situations where innovation is high, it should shift from strongly focusing on market shares

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<sup>203</sup> Joined Cases C-468/06 to C-478/06, para 69

<sup>204</sup> Ibid. para 70

<sup>205</sup> <http://ec.europa.eu/competition/sectors/pharmaceuticals/astrazeneca.pdf>

<sup>206</sup> Ibid.

<sup>207</sup> Ibid.

too instead focus on future markets and potential competitors. In situations where there is no discernable future market, focus should be on the prevention of bottlenecks. Teece takes the discussion one step further and states that focus should not only be on R&D. Antitrust analysis will also have to take into account the capabilities of a company. Since capabilities are as important as innovation itself, if not more, the antitrust analysis should have focus on both innovation and the capabilities available to a company.

The case law provides us with a basic understanding on competition on the merits in the pharmaceutical sector. Companies are allowed to protect their commercial interests, they are however not allowed to artificially extend the exclusivity period as demonstrated by the AstraZeneca case.

## 6 Analysis

Dynamic competition focuses on innovation as the determinant of market structure. Innovative companies develop superior products or processes that force less efficient companies out of the market, or create new markets making the old market obsolete. The strong focus on innovation also demands that companies, especially large companies, are allowed to compete on the merits. Due to the heavy regulations on the pharmaceutical sector, companies are not able to determine prices themselves, thus the main form of competition in the pharmaceutical sector is innovation. Is it then possible to conciliate dynamic competition with the pharmaceutical sector?

Dynamic competition does not work on the pharmaceutical sector as a whole due to the structure of the sector. However, it is possible to see dynamic competition on a micro level. The innovative nature of the sector means that a new product that is introduced will destroy competition on that special product market. In a normal market this might lead to what Schumpeter called creative destruction and the exit of all other competitors. However, in the pharmaceutical sector, companies can be innovative in so many different areas. Meaning that when a new blockbuster medicine is introduced, they only shift their attention to another area. Through strategic patent planning, extensive research is done by companies before starting R&D, which makes it possible to avoid research in an area that they will not be able to be granted a patent for later. The second and maybe most important reason why dynamic competition does not work is the entry of generic companies. When the exclusivity period is over, it does not matter how innovative they have been, since generic companies do not have large R&D costs; they can produce at a much lower cost, and thereby offer generic products at a much lower price than the originator products. Therefore, the creative destruction will only last as long as the period of exclusivity. In addition, the largest pharmaceutical companies are of such a size that even if they are not innovative, they can in-license innovation from smaller originator companies, making the innovation process less important. In these cases, it is not the innovative power of the company that determines the outcome, but rather the structure of the company, making the discussion on complementary assets very relevant. Without any innovative power, a company's success will depend on the complementary assets available to the company.

We can then, on this note, conclude that dynamic competition cannot be applied on the pharmaceutical market as such. However, if we assess the situation from a product perspective, we can see that innovation has a prominent role. Since the above analysis has shown that it is very difficult to specify product markets in an innovative sector, it might be more appropriate to discuss dynamic competition from the perspective of different research areas or different therapeutic areas. We can then see that it is

important that the legal framework reflects the Schumpeterian theories as developed by Teece when assessing the innovative markets.

Many of the inefficiencies in the pharmaceutical sector are the result of an inefficient patent system. The non-harmonization of the patent system gives companies many opportunities to abuse the system in a way that is detrimental to competition. The introduction of the unified litigation system and the EU patent will greatly reduce these inefficiencies. The unified patent litigation system will remove the problem of cross border duplication of patent cases, simplifying the procedure as well as making it less expensive to use. This will in the end be beneficial to consumers in the way of either more funds available for R&D or as lower prices for the products. The EU patent will also lower costs, since it will be directly applicable in the whole EU, companies will not have to spend time on trying to get it validated in each member state. It is also a benefit for companies to only have to deal with one agency when applying for a patent. The possibility to grant compulsory licences will lessen the negative impact of some of the patent strategies employed by originator companies.

However, the proposed EU patent is not replacing the current order but merely complementing it. This means that instead of having one unified system we will instead have three different systems. Which in my opinion may create more confusion than clarification. There are arguments for keeping the old systems, for instance there might be small national firms that only want protection in their own or in a limited number of Member States. However, I am of the opinion that these concerns would be better dealt with under a unified patent in combination with a proceeding where it is possible for the company applying for the patent to choose which Member States the patent should be designated to. The purpose of the EU patent and the unified litigation system is to reduce the inefficiencies of a fragmented patent system, it then seems odd that the inefficient system will remain in force.

The introduction of a patent framework that contains regulatory as well as remedial aspects leads us to the question whether the EU is moving towards a sector specific regulation regime as the one in the US. As have already been explained EU antitrust rules would preclude the rules in the patent framework. However, we should still explore the benefits of regulating anticompetitive behaviour on the sector specific level. There are three large benefits, first it would relieve some of the pressure on the EU courts, second, a specialised litigation system would be better prepared and qualified to deal with patent infringements. Third, in fast pace sectors it is important that decisions are made in as little time as possible. As we have seen in the pharmaceutical industry, the average time for patent litigation was 2.8 years<sup>208</sup>, a specialised litigation system would probably be able to deal with these issues in less time.

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<sup>208</sup> See section 3.3.2



Since dynamic competition focuses on innovation, the relevant antitrust framework should focus on anticompetitive behaviour with focus on innovation. However, the relevant framework is very much dependent on the analysis of market shares, despite the fact that the commission have started to account for other issues as well.<sup>209</sup> Antitrust analysis should therefore not, primarily, be concerned with market shares since this is a static concern, focus should instead be on dynamic concerns. The antitrust framework should thus focus equally on the innovation process as well as on capabilities.

Through the analysis of the pharmaceutical sector it has become apparent that there are different segments that have to be considered by antitrust analysis. These segments can be divided into two broad categories, anticompetitive behaviour between competitors and anticompetitive behaviour with regard to the innovation process.

Considering the competitors segment, antitrust analysis have to account for the competitive behaviour between originator companies, between originator and generic companies as well as between generic companies. When considering the competitive behaviour of originator companies it is important for antitrust analysis to also account for the competitive market within that segment.<sup>210</sup> Competition between originator companies is the segment that, most likely, will give rise to the most diversified possible anticompetitive behaviour whereas the anticompetitive behaviour between originator and generic companies will be focused on excluding or delaying generic entry. The competitive structure of generic companies will be of a more static nature, hence, anticompetitive behaviour will most likely follow traditional antitrust abuses. Competition between generic companies will thus not lead to any novel products, however they should still be innovative in processes. Fierce competition within this segment should lead to better and more efficient processes, consequently leading to lower prices which will be beneficial to consumers.

As have been seen above effective static competition is an important secondary goal<sup>211</sup> to dynamic competition. If we consider the whole of the pharmaceutical market, the primary concern of antitrust framework should be on dynamic competition between originator companies and between originator and generic companies. As a secondary, but just as important, goal the antitrust framework should focus on static competition between generic companies.

In the innovation process, there are three different segments, they can be divided into, (1) access to information and knowledge so that a company can develop an idea in the first place, (2) the incentive and patentability and (3) complementary assets, within all of these segments there is the potential for anticompetitive behaviour. From these segments we can delineate

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<sup>209</sup> See section 5.2

<sup>210</sup> See section 3.3.1

<sup>211</sup> See section 2.5

different timelines. The first two segments are quite distant, at least in the pharmaceutical sector but it could vary from sector to sector, from the actual marketing of the product. these two segment can then be connected to “technology base” and “distant product market” as argued by Glader. The segment of complementary assets will in general lie closer to the launch of the product since it is at this time it will be important to have assets that helps the company commercialize the product. However, it should be noted that complementary assets could play an important role over all timelines. For example access to a complementary technology before the R&D phase can even start.

To conclude, the changes proposed by Teece should be seen as an extension on the work done by Glader. We need to account for both innovation and its future implications as well as the capabilities of the company. However, since dynamic competition is a theory under development the tools for assessing capabilities have not been much developed yet. On this note, I would like to end the analysis with a quote from the article by Sidak and Teece:

*“Using the right concepts imperfectly is better than precisely applying the wrong ones.”<sup>212</sup>*

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<sup>212</sup> Sidak, J. Gregory, and Teece, David J., *Dynamic Competition in Antitrust Law*, page 617

# 7 Conclusion

During the course of writing this thesis there are two issues that I have perceived as especially troublesome. The first relates to the structure of patents. It has been shown that the current patent system gives patent holders many opportunities to use it in innovative ways in order to limit the competition from competitors. One gets the feeling that pharmaceutical companies are almost more innovative in patent strategies than in actual development of pharmaceuticals. The second issue relates to how we decide the market power of a company. If we conclude that market share is not a good proxy for determining market power, but rather that the competitive power of a company should be determined by its capabilities how is this to be done? Below I offer two suggestions on further development in these areas as well as one general comment regarding the pharmaceutical sector.

## 7.1 New Patent Structure

I am of the opinion that the introduction of an EU patent in combination with a unified litigation system will be very beneficial. However, as much of the inefficiencies stems from abusive usage of the patent as such, making the same system more efficient might not remove the opportunity to misuse the system altogether. I then suggest a change to the structure of the patent itself.

My suggestion for this issue is a development of the patent structure proposed by Gallini<sup>213</sup>. Gallini argued that, in situations where imitation is likely, which is the case in the pharmaceutical industry, a patent should have a broad application with an adjusted patent life to generate the desired return of innovation. As have been shown above the incentive to innovate is equal to the assumed profit of the innovation. My suggestion is then that we use the incentive to innovate i.e. the prize as the length of the patent.

The patent shall be broad in its application and then the patent life shall be determined, not by a predetermined number of years but by a predetermined level of generated income. For the purpose of this argument, let us assume that an adequate incentive to innovate amounts to x millions and that that amount equals 50% of the cost of developing and marketing the product. Then, loss of exclusivity should occur when the patent holder have reached the target of a profit that equals 50% of total costs.

In my opinion there are a number of benefits from applying such a patent structure. First, there would be no reason for patent holders to engage in patent strategies in order to delay entry of competitors since this would not allow them to profit more. Rather, it would be beneficial for companies to

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<sup>213</sup> See section 4.2

capitalize as fast as possible in order to make sure that they can profit from the product before another better product reaches the market. This would lead to faster generic entry. Another benefit is that this kind of structure would shift the innovation structure of companies from today being focused on developing a, e.g. blockbuster medicine to having to develop many innovations. It would force companies to be innovative in a wider sense. Finally, in the pharmaceutical sector companies mainly research the most profitable areas, a system such as the one suggested here would allow the competent authority to focus the innovative efforts on the market. It would be possible to increase the incentive to innovate simply by allowing companies to profit more from innovations in areas that are showing low levels of research.

From the corporate perspective I imagine that this will be looked at with some scepticism since the opportunity to make that big breakthrough might not be possible any more. However, I believe that even from the corporate perspective this system would have a positive impact. Since companies would be granted patents with broad application they would not have to put much effort into protecting the patent, in addition it would be easier to predict the profits from a patent.

## 7.2 Assessing Competitive Power

In order to be able to compare the competitive power of different companies we need a way to compare companies. My suggestion is that we use an income-costs structure to develop a ratio that we then can use to compare between companies. In order to develop this ratio we initially have to make two assumptions. First, that companies have access to the same appropriability regime, meaning that the patent framework and related issues, will not be a factor constituting differences found between companies. Second, a company that is efficient in innovation will have higher income than less efficient companies will, and that companies that have access to an efficient complementary assets structure will have lower costs for those assets than less efficient companies, leading to better commercialisation of their products, i.e. higher income. Then, by comparing income/ product sold with cost/ product sold we will get a ratio that will be indicative of how competitive a company is.

From the example below, we can see that company B is the most competitive company.

**Figure 3: Market power/ product sold**

	<b>Company A</b>	<b>Company B</b>
<b>Costs (C)</b>		
R&D	5000	6000
Promotion and marketing	10000	8000

Manufacturing	12000	11000
Other	3000	2000
<b>Total</b>	<b>30000</b>	<b>27000</b>
<b>Income (I)</b>	<b>45000</b>	<b>55000</b>
<b>Quantity Sold (Q)</b>	<b>20000</b>	<b>15000</b>
<b>Ratio: Competitive advantage per product sold = (I/Q)/(C/Q)</b>	<b>1,5</b>	<b>2,04</b>

It is not implied that the ratio should be understood as equalling dominance, however it might provide initial guidance on the competitive power of a company. It should at least prove a better starting point for antitrust analysis than the market shares of a company as proposed by the Commission Guidelines on application of article 102 TFEU.<sup>214</sup> Anticompetitive behaviour by a company with a high ratio would be more detrimental to competition than the same behaviour from a company with a low ratio would be.

One problem with this analysis lies in the practical execution of the analysis. It might prove difficult to secure access to all the information e.g. cost structure of a company, needed to perform the analysis.

### 7.3 Thoughts on the Innovative Nature of the Pharmaceutical Sector

The pharmaceutical sector is generally considered to be a very innovative sector. During the course of writing, I have considered this statement and started wondering if that is really true. I have come to understand the R&D aspects of the pharmaceutical industry as consisting of identifying key molecules and then cross referencing these key molecules with other known molecules in order to find molecules that interact. Finding molecules that interact with the key molecule is therefore a process of elimination. If a company tests enough molecules, eventually they will come across a match. Is this cross referencing really to be seen as innovative?

Schwartz argues that one possible reason why less originator medicines are reaching the market is because all the easy to reach molecules have already been discovered, and that due to the increase in the biotechnology sector this might be the big future research area.<sup>215</sup>

<sup>214</sup> See section 5.2

<sup>215</sup> Schwartz, Robert M., *A Critical Analysis of DG Competition's Preliminary Pharmaceutical Sector Report*, page 95

I do not contest the importance of new pharmaceutical products, merely the idea of considering them to be innovative. I would thus like to see a distinction be made between, what I would like to call, novel and innovative medicines. Where a novel medicine should be understood as a medicine that is produced using the normal method of the industry, which would probably correspond to the way we refer to innovative medicine today. An innovative medicine should be understood as a medicine that have been discovered through new means, an example would be early biotechnology medicines. However, as more companies enter the field of biotechnology, medicines will become more novel than innovative. This implies that in order for a medicine to be considered innovative it has to follow the most recent developments. The importance of making this distinction would be to favour companies that are “truly” innovative and thus spearheading the development within the sector. These kinds of companies should be given a certain amount of leeway in order to encourage the progress of the market.

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