Specialeafhandling

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Titel: The legal status of patent settlements with a reverse payment in the pharmaceutical sector and how to approach them

Emnebeskrivelse: The aim of this thesis is to examine the legal status of patent settlements with a reverse payment concluded in the pharmaceutical sector in the European Union. Based on the interface of the areas of competition law and patent law it is analysed if such patent settlements can be considered to restrict competition. An approach to patent settlements is discussed based on Art. 101 of TFEU and US case law. Finally a suggestion is made for a legal status of such patent settlements and how to approach such agreements.

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Abstract

The aim of this thesis is to examine the legal status of patent settlements with reverse payments in the pharmaceutical sector in relation to competition law in the EU. This thesis examines patent settlements that are concluded between the pharmaceutical companies that develop new medicines, also called originator companies, and pharmaceutical companies that produce generic versions of medicines, also called generic companies.

A short introduction of the relevant legislation within competition law and patent is made. The interface between the area of competition law and patent law and the goal of the two legislative areas is discussed.

Hereafter the most common terms of patent settlements are described. This thesis focusses on patent settlements that include a reverse payment. The incentives for entering a patent settlement with a reverse payment are analysed and it is concluded that a reverse payment in itself cannot be considered to be anti-competitive.

The European Commission’s Pharmaceutical Sector Inquiry Report of 8 July 2009 and the following Reports on the Monitoring of Patent Settlements are analysed. It is concluded that the data is slightly misrepresented in parts of the Sector Report, which gives the impression that there is an underlying assumption of patent settlements with reverse payments being anti-competitive. It is therefore concluded that the Commission’s reports do not only present factual data but also draw conclusions based on the data.

The approach of patent settlements with a reverse payment according to article 101 of TFEU is analysed. It is concluded that such agreements cannot in general be considered to have as their object to restrict competition but that only in exceptional circumstances will such an approach be reasonable. Consequently the advantages and disadvantages of assessing the competitive effect of a patent settlement are discussed.
It is concluded that, although comprehensive, an assessment of the factual, legal and economic context of such agreements is necessary.

A further consideration is if the US and its experience with patent settlements can be used in the EU. It is concluded that the US can be used as guidance but that a more direct application will not be advisable because of the differences in the history of the two legal systems. The existence of and a future implementation of a "rule of reason" in the EU is discussed but this thesis concludes that the current structure of Article 101 of TFEU will not accommodate the application of a "rule of reason".

Finally it is concluded that the legal status of patent settlements with a reverse payment is uncertain due to the lack of guidance from the Commission and the lack of case law.
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1. Introduction to the subject and definition of problem

Based on a decrease in the number of new and innovative drugs entering the market and a delay in the entry of generic products to the market European Commission launched an inquiry into the pharmaceutical sector in order to find out if and in what way, the behaviour of the companies played a role in this development.

The result of the inquiry was the Pharmaceutical Sector Inquiry Report (hereafter Sector Report) that was published in the summer of 2009. The report leads to a lot of attention to the patent settlements that were entered between the companies that develop pharmaceutical products (hereafter originators) and the companies that produce the generic substitute to these products (hereafter generics). The Sector Report focussed in particular on the patent settlements including a value transfer from the companies that develop pharmaceutical products to the generic producers.

The attention has created a lot of uncertainty regarding the legal status, in relation to competition rules, of the patent settlements including reverse payments. Despite the report being quite extensive and being followed up by four reports on monitoring these patent settlements so far, it has provided very little guidance in this area. There is no doubt that the European Commission will not tolerate any delay in the entrance of generic products, but because there is hardly any case law in this area the approach to these patent settlements is still unsure.

The discussion about patent settlements including reverse payments revolves around the relationship between the area of competition law and patent law. On the one hand the necessity of maintaining a pharmaceutical sector where companies will continue to invest in research and development of new innovative drugs is recognised. On the other hand there is a need and a desire to be able to eliminate patent settlements that restrict competition in order to limit expenses for consumers and the national healthcare systems. The balance between the two areas is difficult and is complicated further by patent law within the pharmaceutical sector being highly complex and factually complicated.
Definition of problem

The aim of this thesis is to examine the legal status of patent settlements with a reverse payment concluded in the pharmaceutical sector in the European Union.

The structure of patent settlements is described in this thesis. Based on the interface of the areas of competition law and patent law it is analysed if patent settlements including a reverse payment can be considered to restrict competition. The Pharmaceutical Sector Inquiry Report is analysed. An approach to patent settlements with a reverse payment is discussed based on the Article 101 of TFEU and US case law. Finally a suggestion is made for the legal status for patent settlements with a reverse payment and how to approach such agreements in the EU.
2. EU competition law

This chapter contains a short introduction to competition law in the European Union in order to explain the relevant regulation when discussing patent settlements with reverse payments. The consideration of market integration and consumer welfare will be described and the prohibition against anti-competitive agreements in Article 101 of the Treaty on the Functioning of the European Union (hereafter “TFEU”). In addition the application of Article 101(1) in relation to Article 101(3) will be explained.

2.1. Goals of EU competition law: Consumer welfare & market integration

In the preamble of the TFEU one of the overall goals of the European Union (hereafter "EU") is to ensure economic and social progress for the Member States by eliminating the barriers dividing Europe. One of the means to reach this is creating a free inner market to ensure fair competition. In order to establish the necessary competition rules for the functioning of the market, the Commission is given exclusionary competence to do so.¹

The core rules that regulate competition in the EU, or rather the core prohibitions are found in Articles 101 and 102 of the TFEU. A specific aim of the competition rules in the EU has not been explicitly included in the TFEU. However, the underlying considerations of the enforcement of the competition rules can be seen through e.g. case law and communications from the Commission.

Previously the considerations for economic freedom, economic efficiency and market integration dominated the area of competition law as means to reach the object of consumer welfare. In the later years there has been an increased focus on the object of economic efficiency and consumer welfare.² The aim of consumer welfare is also

¹ Article 3(1)(b) of TFEU
expressed in the Commissions Guidelines on the application of the then Article 81 (now Article 101 of the TFEU)\(^4\).

In relation to the pharmaceutical sector, the Commission has clearly expressed its views on competition law’s vital role in improving consumer welfare and also limiting excessive expenses for the Member States in their healthcare systems.\(^5\) At the same time the Commission considers the competition rules to be necessary for stimulating innovation, which in the long term will also benefit consumers.

2.2. Article 101 of TFEU and the prohibition against anti-competitive agreements

The general provision in Article 101(1) prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market. If any such agreement exists it is automatically void according to Article 101(2).

The prohibition in Article 101(1) is applicable to both vertical and horizontal agreements. This thesis will be examining the relationship between companies that develop pharmaceutical products and companies that later compete with those products. The agreements that are discussed in this thesis are agreements that are entered into between competitors, which are known as horizontal agreements in the EU.\(^6\)

There are two ways an agreement can fall within the scope of Article 101(1). An agreement can restrict competition either by object or by effect. An agreement will restrict competition if the agreement has as its object to restrict competition. The

\(^3\) The Treaty on the Functioning of the European Union (hereafter TFEU)

\(^4\) Communication from the Commission, Guidelines on the Application of Article 81(3) of the Treaty (now Article 101(3) of TFEU), C 101/97 of 27 April 2004, para. 13

\(^5\) European Commission press release IP/13/563 of 19 June 2013

\(^6\) Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, C 11/1 of 14 January 2011, para. 1
Court of Justice (hereafter “CoJ”) has ruled that if an agreement has as its object to restrict competition, it is not necessary to take account of the actual effect of such an agreement. In order for an agreement to be anticompetitive and thereby void, it is sufficient to establish that the agreement has as its object to restrict competition. Second, in the cases where it cannot be established whether the object of an agreement is to restrict competition, it is necessary to assess whether the effect of the agreement restricts competition.\footnote{Bael, Ivo van & Bellis, Jean-Francois: "Competition Law of the European Community", 4th edition, Kluwer International Law (2005), p. 69}

2.2.1. The role of the Commission

The Commission has the competence to ensure that the competition law within the EU is carried out efficiently. The Commission also plays a legislative role in issuing regulations that implement the regulations of the Council. In addition the Commission issues guidelines which, although they are not binding, give e.g. companies an idea of how the Commission interprets certain areas.

With Regulation nr. 1/2003 the Commission can request and obtain information from undertakings. As an example of the Commission’s authority through Regulation nr. 1/2003 there is the Pharmaceutical Sector Inquiry Report of 2009, which has led to the Commission imposing a fine of 93.8 million Euros on the Danish pharmaceutical company Lundbeck.

2.2.2. The relationship between Article 101(1) and 101(3)

If an agreement falls within the scope of Article 101(1) by restricting competition either by object or by effect, Article 101(3) provides an exemption to such an agreement being void. Article 101(3) exempts agreements that restrict competition if the agreement has pro-competitive effects that basically outweigh or override the anti-competitive effects. However, Article 101(3) is narrow and it only applies if four conditions are fulfilled.
The conditions that must be fulfilled are: 1) The agreement must contribute to the production or distribution of goods or to promoting technical or economic progress, 2) consumers must be benefit with a fair share in this result, 3) the agreement must not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives and 4) finally the agreement must not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

The structure of Article 101 is therefore that first it is examined whether an agreement falls within the scope of Article 101(1) by restricting competition. Once an agreement is covered by Article 101(1), the only way out is if all four conditions in Article 101(3) are fulfilled. The approach consists of two steps, which must be applied in the right order. An assessment according to Article 101(1) cannot take into account potential benefits according to Article 101(3).\footnote{Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, C 11/1 of 14 January 2011, para. 29}
3. EU patent law and the pharmaceutical sector

The basic terms of patent law in relation to the pharmaceutical sector will be described in this chapter. In addition the structure of the pharmaceutical sector will be described including the process of a pharmaceutical product from the development stage to entering the market.

3.1. Purpose of patent law: Innovation incentive for research and development

Patent protection creates incentive for companies that develop pharmaceutical products to invest in research and development of new and innovative products.

Through patent protection the patentee obtains an exclusive right for a limited amount of time to produce and market products within the scope of the patent. The idea of creating a limited monopoly is to create favourable conditions that allow the company to regain what has been invested in the product. Creating an incentive to invest in development pharmaceutical products is beneficial to the consumers in the long run because new medicines continue to be developed and improvements of the current treatments. The pharmaceutical sector in the EU has one of the highest investments in research and development and relies significantly on the exclusivity of rights that is granted through patent law and other mechanisms.\(^9\)

3.2. Patent protection, Supplementary Protection Certificate and Market Authorisations

Prior to a pharmaceutical product entering the market, the product has undergone a long journey in its development. For the pharmaceutical companies that develop new products or enhancements of existing products it is a big expense when investing in the research and development of a new product. The average cost of developing a new

\(^9\) The Sector Report para. 9
drug including entering it on the market has been estimated to cost more than $1.3 billion.\textsuperscript{10} According to the Pharmaceutical Sector Inquiry Report\textsuperscript{11} (hereafter the Sector Report) originators spent an average of 17% of their global turnover from prescription medicines on research and development in the period 2000-2007.\textsuperscript{12}

The term of a European patent is 20 years\textsuperscript{13} but an originator company does not profit from their product for the full term of the patent. It will often be 10-12 years after a compound has been patented before it reaches the market\textsuperscript{14} which puts even more pressure on the product to become a commercial success once it enters the market in order for the originator company to regain what has been invested in the product.

As a solution to the limited protection granted by the patent and to ensure continued investments in research and development the Supplementary Protection Certificate (hereafter "SPC") was introduced.\textsuperscript{15} The SPC gives the patentee a longer period of exclusivity with a maximum of 5 years in addition to the 20 years granted by the patent.\textsuperscript{16} Another instrument to increase the term of protection is through the market authorization by which an originator company enjoys regulatory data exclusivity for 10 years.\textsuperscript{17}

Once a pharmaceutical product has entered the market another important factor is often whether a product is granted reimbursement status in the national healthcare systems. Being granted reimbursement status can be crucial to becoming a financial success.\textsuperscript{18} Naturally, the Member States are meticulous in assessing the cost/benefit balance before granting a new pharmaceutical product reimbursement status.

\textsuperscript{11} European Commission, Pharmaceutical Sector Inquiry Report of 8 July 2009
\textsuperscript{12} The Sector Report para. 72
\textsuperscript{13} Article 63(1) of the European Patent Convention (15th edition)
\textsuperscript{15} The SPC was introduced with Council Regulation No. 1768/92 which has since then been replaced by Council Regulation No. 469/2009
\textsuperscript{16} Article 13(2) Council Regulation No. 469/2009
\textsuperscript{17} Council Regulation No. 726/2004
\textsuperscript{18} Priddis, Simon & Constantine, Simon: "The Pharmaceutical Sector, Intellectual
The success rate of new pharmaceutical products reaching the market and regaining what has been invested in the research and development phase is low. It is therefore a long and potentially winding road for a new pharmaceutical product to become a commercial success. Consequently the originator companies rely a great deal on the exclusivity granted through patent protection.
4. Relationship between patent law and competition law

This chapter considers seemingly conflicting interests of competition law and patent law. The boundaries of the two areas of law facing each other and the role of state intervention in the pharmaceutical sector are described. Finally it is discussed how to find a balance between competition law and patent law.

4.1. Conflicting interests?

Patent law and competition law is often presented in a rather simple way by having the interest of the public on one side wishing for a competitive market with corresponding low prices and a wide range of selection in products. On the other side the interest of the originator company is to be able to secure exclusivity for a certain period of time in order for the company to regain what has been invested in the product. In some cases there can also be a need or wish for a commercially successful pharmaceutical product to regain not only its own investment, but also investments in failed products that never even entered the market.

However, the desire to have both a competitive and innovative single market within the EU does not necessarily have to be viewed as conflicting goals. It is a question of balance between the two areas.

In the short term patent protection is a reward to the inventor, but in the long term a system of patent protection benefits the public because it ensures that innovative products will continue to be developed. Another aspect is the relationship between inventors and not only between a "single inventor" and the public. If a patent system grants too much protection or for too long, it can make it difficult to ensure that progress does not stagnate. When looking at it from a competition perspective, the public benefits from a competitive market in the short term because the prices are
kept down, but in the long term the low prices can make it difficult to reach commercial success when investing in new products.²⁰

4.2. The boundaries of patent law and competition facing each other

Claiming that the solution to conflicts between patent law and competition law is a matter of balance is a lot simpler to claim in theory than to actually produce a balanced solution in real life. There are cases where the common area of patent protection and fair competition are seemingly weighed against each, and where the opinions on the balanced solution are many.

The EU competition rules shall take the patent rules as they are. The patent rules are defined by the legislators within the EU and not by the scope of the competition rules. If the patent rules are in some way distorted or protecting special interests too much as opposed to the public interest, the scope of patent protection should not be altered through the application of competition rules.

However, there are situations within the patent law area that potentially affect the competition law area, and in those cases the question arises what competence the Commission has to assess the scope of a patent.

According to case law and e.g. the Commission’s Guidelines on Technology Transfer²¹ the Commission may assess the scope of intellectual property rights when applying competition law. Once the Commission has made such an assessment a review by European Courts shall only be concerned with whether the assessment was reasonable in light of the applicable law.²²

²¹Guidelines on the application of Article 81 of the EC Treaty (now article 101 of TFEU) to technology transfer agreements, § 32
Here it is important to be aware that the pharmaceutical sector is special in more than one way. Looking at the sector from a patent law perspective the amount spent on research and development in the pharmaceutical industry exceeds that of any other sector, which means that the companies that invest great sums rely heavily on patent protection. The pharmaceutical companies themselves find it very difficult to assess the exact scope and thereby level of protection when assessing a patent dispute.

For patent law it is a highly complex sector with a lot at stake for all the stakeholders. It could therefore be uncertain if the Commission having a general access to assessing patents and their scope in this sector is the best solution for all parties.

4.3. The role of state intervention in the pharmaceutical sector

The pharmaceutical sector is subject to a lot of regulation from the earliest stages of developing new products to when the products enter the market and everything in between and after that.

The obvious reason for the need for regulation is the consideration for public safety. Because the pharmaceutical sector produces products that are expensive and where a lot of the products are always in demand, each Member State plays a big role when setting out the rules for price setting and reimbursement.

This makes the pharmaceutical sector special when it comes to the competition with both the supply and demand side being influenced by the Member States’ governments. When a Member State decides whether or not to grant a product reimbursement status the Member State is strongly influencing what products enter the market. Another example of influence on the supply is the incentive to develop orphan medicines which are medicines that treat diseases that do not occur in more

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24 The Sector Report, para. 727
than 5 in 10,000 persons or it must be unlikely that the medicine would generate sufficient returns to justify the investment.\textsuperscript{25}

On the demand side, the Member States play a big role because there are often rules or limitations when price setting and they are at the same time often the largest buyer of pharmaceutical products. When trying to limit expenses in each Member State it automatically impacts the commercial and economic success of the pharmaceutical companies.\textsuperscript{26}

\textbf{4.4. Finding the balance between competition law and patent law}

The pharmaceutical sector plays a very important role because of the products that are produced in the pharmaceutical industry and it plays a big role because of the great amount of money that is spent on these products – both at the developing stage but also when they enter the market. It is therefore also very important that both the patent system and the competition rules are both effective and enforceable. The balance between the two systems or areas of regulation is paramount to the functioning of the pharmaceutical sector and direction in which it develops.

Finding the balance is complicated because it is a balance of benefits that will show at different stages. If all the emphasis is put on ensuring efficient competition at the expense of patent protection, the consumers and Member States will at first benefit from the low prices. If a patent cannot effectively ensure that the patentee has a protected right that he/she can enforce, the long term damage to the consumers and Member States will be that fewer products will be developed and the level of innovation will decrease.

It is only possible to find a balance between the two policies by keeping in mind that they ultimately share the same goals. Finding the balance in the pharmaceutical sector might have special challenges of its own. The cases of patent challenges are highly

\textsuperscript{25} Council Regulation No. 141/2000
complex and the competition between products is heavily impacted by national rules of price setting and reimbursement. In addition the stakes are particularly high in the pharmaceutical sector because the issues concern the medical treatment of human beings and so much money is spent on developing these products.
5. What are patent settlement

The most common terms of patent settlements will be described. The meaning of patent settlements including so-called "reverse payments" and a "pay for delay" will be explained, while making a distinction between the two terms. The incentives for entering patent settlements including reverse payments will be discussed. Finally the pros and cons of patent settlements are discussed.

5.1. Patent settlements and common terms

When an originator's patent expires, and thereby the protection that comes with the patent ends, a generic is allowed to enter the market freely and compete with the originator's product. However, this is a very simple description and it is uncommon that the process of generic entry is so easy. The generic's right to enter the market and the validity and scope of the originator's patent are often challenged, which results in disputes between originators and generics.

The dispute will often revolve around whether or not the generic's product is covered by the originator's patent and thereby infringes the rights of the originator. The generic will often claim that the product is not covered by the originator's patent or if it is, that the specific patent is invalid.

Disputes like this can be concluded through litigation but as an alternative to this, entering a settlement agreement is often used as a solution. Even when litigation has been initiated a patent settlement can be concluded right up until a judgment is made by the court.

When a patent dispute is concluded in court there is likely to be a winner and a loser. If the generic wins the case the originator's patent will either be found invalid or not covering the generic's product. If the generic has been prevented from marketing its product through an interim injunction, the originator will have to pay damages to the
generic for the loss of profit in addition to the costs of litigation. If the originator wins the case the patent will be found valid and covering the generic’s product. The generic will have to pay damages to the originator if the generic product had already entered the market in addition to the costs of litigation. With costs of litigation the loser of the case risks not only having to pay their own costs but also the opponent’s costs.

In a patent settlement, however, there is not always a clear winner and loser. A settlement is the result of negotiation between the parties contrary to one judge (or more) who is required to judge according to the truth of what has been presented before the court. When negotiating the parties are free to give a little and take little where they chose to. A patent settlement will therefore be a compromise between the parties but the agreement will also contain a benefit of some form for both parties. If a patent settlement does not contain both a benefit and a compromise for both parties, it is unlikely they will agree to it.

The potential terms of a patent settlement are numerous but there are some terms or components that more often occur than others. A patent settlement will often include a non-challenge clause where the generic acknowledges the validity of the originator’s patent and agrees to refrain from challenging the validity in the future. If the generic’s product has already entered the market the parties could agree on the generic withdrawing their product or that the generic product is allowed on the market, but where the generic cannot market the product freely. A limitation on marketing could be a geographical limit. Another example of actual cooperation between the parties could be a license or a distribution agreement, where the generic ends up producing and/or distributing the originator’s product instead of its own generic product. The parties can also decide to split the costs of litigation.27

Patent settlements that are concluded in the pharmaceutical sector in the EU have received a lot of attention because of a registered delayed in the entry of generic medicines and a decrease in the number of novel medicines entering the market.28

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28 European Commission press release IP/09/1098 of 8 July 2009
addition the public budgets are under significant restraints and competition between generic companies is essential to keep public budgets under control.\textsuperscript{29}

As long as the originator company’s patent is valid and has not yet expired, a patent settlement including conditions that either forbid or limit marketing of the generic product should not, as a rule clash with competition rules.\textsuperscript{30} As described earlier a patent grants an exclusive right to the patentee, in this case the originator company, which effectively means that the normal competition rules are put on standby regarding the specific product for the period of the patent. In such a case a limitation of the generic company’s possibility to market its own product is not a restriction of competition because the generic has no right in the first place to compete as long the patent exists.

\textbf{5.2. Patent settlements including a value transfer}

Some patent settlements include a vale transfer from one party to another. If a value transfer flows from the generic to the originator, this is considered normal because a generic might be paying for being able to distribute or produce the originator’s product. The generic would be paying for a share in the patentee’s right. If a value transfer flows from the originator to the generic in a patent settlement it is referred to as a "reverse payment" because it flows in the opposite direction than expected.\textsuperscript{31}

When such a reverse payment has taken place it is sometimes referred to as a "pay-for-delay" agreement.\textsuperscript{32} It is, however, important to make a distinction between "reverse payment" and "pay for delay".

\textsuperscript{29} The Sector Report, para. 11
\textsuperscript{30} This presupposes that the generic product is covered by the originator’s valid and existing patent.
\textsuperscript{32} Ellery, Tony & Hansen, Neal: "Pharmaceutical Lifecycle Management, Making the Most of Each and Every Brand", John Wiley & Sons, Inc. (2012), p. 108
5.2.1. Distinction between "reverse payment" and "pay for delay"

A "pay for delay" is a patent settlement that goes beyond the scope of the originator's patent. In a "pay for delay" the originator pays the generic to stay off the market although the originator's patent is invalid or the generic product is not covered by the scope of the originator's patent. The originator is effectively buying rights that it does have.

A "pay for delay" will include a reverse payment because it is the originator that pays the generic to stay off the market. However, if a "reverse payment" has taken place in a patent settlement, this does not automatically mean that the patent settlement goes beyond the scope of the patent or that the patent is invalid. Establishing that a "reverse payment" is therefore not the same as establishing that the generic has been wrongfully limited in its access to the market.

A "pay for delay" can be described as a subcategory to patent settlements that include a "reverse payment".

If a patent settlement prohibits the generic product from entering the market or in any way limits the marketing of it after the patent has expired, the rights of the originator are expanded beyond the rights conferred by the patent. After the patent has expired the originator has no legal right to keep the generic from entering the market. These are the types of patent settlements that collide with the competition rules.

Patent settlements that go beyond the scope and period of the patent are obviously favourable to the originator. In order for the originator to obtain such favourable conditions a value transfer from the originator to the generic will most likely take place where the originator basically pays off the generic in order for the originator to maintain exclusivity for its product.

The payment for the delay in generic entry can be a mere transfer of money. An example could be that the originator and the generic split the originator's profit of
from continued "high" prices due to market exclusivity. It does not have to be a simple cash payment, but any value transfer can be considered as payment. If the originator knows that its patent is weak or even invalid, an agreement where the generic only distributes the originator’s product instead of its own generic product will also represent a value transfer because the originator thereby continues to control price setting at a higher level, which the generic then benefits from.

Before generic entry the originator is able to decide the price of its product\textsuperscript{33}, but once generic entry has occurred the products compete and the prices go down. On average prices drop by almost 20% and the price may continue to fall after that. In some cases, although rare, prices have dropped by 80-90%. The price setting of pharmaceutical products is not harmonized and the drop in prices after generic entry therefore depends on national legislation in each Member State.\textsuperscript{34} Although the originator enjoys exclusivity for what may seem a long time, it is towards the end of this period that the originator regains what it has invested in developing and commercializing its product and begins to make a profit.\textsuperscript{35} An originator can therefore have a lot to gain financially if it can obtain even an extra six months of exclusivity through a patent settlement.

5.2.2. The Relevance of a Reverse Payment

The fact that a patent settlement includes a value transfer does not indicate what is being given in return for the value transfer. It cannot be determined whether a patent settlement including a value transfer is a "pay for delay" agreement by reviewing the value transfer alone. A value transfer is only part of an agreement and in order to determine whether there is any delay in generic entry as a result of the value transfer, the whole agreement must be assessed.

A reverse payment merely states that a value transfer from an originator to a generic

\textsuperscript{33} The influence of national rules of price setting and reimbursement is not discussed here.
\textsuperscript{34} The Sector Report, para. 212
has taken place, whereas a "pay for delay" states what the value transfer is payment for. A "pay for delay" indicates that generic entry has been delayed beyond the period that would be objectively justified through a valid patent.\textsuperscript{36} The fact that a reverse payment has taken place does not in itself suggest that an agreement is anti-competitive.

5.3. Incentives for Entering Patent Settlements with Reverse Payments

When it comes to patent settlements that include a reverse payment there are many different opinions on the originators incentive to enter such an agreement. In some cases it is argued that the existence and size of a reverse payment is of no relevance when assessing whether an agreement is anti-competitive.\textsuperscript{37} In other cases it seems that a distinction between a reverse payment and a "pay for delay" agreement is not even made when considering the motives for entering the agreements.\textsuperscript{38}

For both parties (the originator and the generic) the immediate advantage of entering a patent settlement is avoiding high costs of litigation and gaining commercial certainty regarding their products. The logic of an originator claiming its patent to be valid and strong while at the same time agreeing to or offering a reverse payment, however, seems to be a little less obvious.

It is argued that the whole basis of such a patent settlement is to maintain high prices by paying for an extension of the exclusivity granted by the patent,

"Clearly, the branded drug industry would prefer to lose less [...] Realizing these goals is the whole basis for so-called pay-for-delay settlements. The underlying concept is very simple – keeping the unit price of the NME as high as possible [...] for as long as possible and redistributing post patent the same


\textsuperscript{38} Ellery, Tony & Hansen, Neal: "Pharmaceutical Lifecycle Management, Making the Most of Each and Every Brand", John Wiley & Sons, Inc. (2012), p. 109
level of profits that were made by the branded drug company alone pre-patent expiry, ensuring that as little as possible of the benefit goes to the payer [...].”

As patent settlements with reverse payments are presented in the quote above there is an anti-competitive intent when transferring a reverse payment.

Whether generic entry is delayed or not depends on the patent. If the patent is valid and the generic product is covered by the scope of the patent, the point of delay will be any time later than patent expiry. If the patent is invalid or the generic product is not covered by the scope of the patent, any agreement prohibiting or limiting generic entry constitutes a delay in generic entry. However, no such distinction is made when assuming the anti-competitive intent of a reverse payment. If the intent of a reverse payment is assumed to be anti-competitive in agreements where generic entry is not allowed until the originator’s patent has expired, the underlying patent must necessarily be believed to be either weak or invalid.

This leads to the assumption that the weaker the patent, the stronger the incentive is to get the generic to stop challenging the patent by entering a settlement agreement. The reasoning behind this assumption is that whatever it may cost to pay off the generic to stay off the market, it will still be a smaller loss for the originator compared to losing the rights conferred by the patent. If instead the patent is held to be strong it is implicitly understood that the originator does not need to pay off the generic, because the patent will most likely be found valid in court. If a dispute revolving a strong patent is concluded with a patent settlement, it is unlikely that it will include a

40 Assuming a generic product is ready to enter as soon as the patent expires.
reverse payment. If the originator knows its patent is strong, there can be no motive to pay off the generic.\textsuperscript{44}

Indeed, the scenario described above is likely to occur. Based on the questionnaires that were sent out in connection with the Sector Report the probability of winning or losing a case in court was the most important consideration for entering a patent settlement agreement for 95% of the originators.\textsuperscript{45} 67% of the generics considered the probability of winning or losing as one of the most important concerns when considering entering a patent settlement.\textsuperscript{46}

It would, however, be remarkable if this consideration was not at the top of the list entering a patent settlement agreement. Of course the assessment of the strength of the patent will play an important role in the course of solving a dispute with a generic, but it does not unambiguously explain the reasons for entering a patent settlement from the originators point of view.

Another way of viewing the risk assessment of going to court or entering a patent settlement is that if the patent is strong, the potential loss if the patent is found invalid in court is even bigger. Put this way the incentive to enter a patent settlement is actually stronger if the patent is strong. In contrast if the generic has not entered the market at risk it will have everything to win and nothing more than litigation costs to lose. Although litigation costs can be high, a loss limited to litigation costs compared to potentially losing a patent is a small loss. This can also be described as the generic’s valuation of victory being smaller than the originator’s valuation of loss, which makes settlement highly likely.\textsuperscript{47}

\textsuperscript{44} McDonald, Kevin D.: "Patent Settlements and Payments That Flow The "Wrong" Way: The Early History of a Bad Idea" (2003-2004) http://www.drpaul.de/files/Publication/a28e8ba7-16f2-405c-a83a- c3ee2c49caee/Presentation/PublicationAttachment/e4223818-ac00-4ec0-a5de- 31aa5521d19b/patentsettlements.pdf latest access 29 January 2014
\textsuperscript{45} The Sector Report, Table 21 on p. 266
\textsuperscript{46} The Sector Report, Table 22 on p. 267
\textsuperscript{47} McDonald, Kevin D.: "Patent Settlements and Payments That Flow The "Wrong" Way: The Early History of a Bad Idea" (2003-2004) http://www.drpaul.de/files/Publication/a28e8ba7-16f2-405c-a83a- c3ee2c49caee/Presentation/PublicationAttachment/e4223818-ac00-4ec0-a5de- 31aa5521d19b/patentsettlements.pdf latest access 29 January 2014
There are also cases where the value of a victory in court cannot outweigh the practical benefits of entering a patent settlement. This can be the case where generic entry has already occurred and the originator has not been granted an interim injunction,

"Thus, there is no longer any significant commercial benefit in continuing litigation, in particular after the entry of other generic companies."\(^{48}\)

Another consideration that deserves to be mentioned is that no matter how strong an originator considers its patent to be, there is never a guarantee that the originator will win in court. There will always be a risk for both parties when going to court, which leads to commercial uncertainty,

"The alleged infringer will not know whether its plan to enter, or remain on, a particular market will still be viable after judgment. The right holder does not know if it may face new competition. [...] Rights owners will rarely be entirely confident that they will not lose such a validity challenge."\(^{49}\)

This view is also presented in the Sector Report by an originator, who also explains the multiplication of the risk when a patent has to be defended in more than one Member State,

"Even with the strongest case, there is always a risk in putting a case before a court. Extraneous factors (over and above the actual strength of the case) can affect the outcome: e.g. judicial error, poor court strategy, error on the part of the company or its advisors. [...] These concerns are magnified where similar issues may be raised in a number of jurisdictions, thus multiplying the uncertainty. This is currently the case in Europe, where the national nature of patent rights and of patent litigation enables a degree of "forum shopping" by a potential entrant who can (and will) choose jurisdictions which can give the

\(^{48}\) The Sector Report, quote from an originator on p. 263

The incentive for an originator, or the reasoning that lies behind the decision, to enter a patent settlement including a reverse payment cannot be boiled down to whether or not the originator considers its patent to be strong or not.

It is quite likely that there are patent settlements where an originator has paid off a generic knowing that its patent would not stand a chance in a courtroom. However, this cannot be determined based on a reverse payment alone. A patent settlement including a reverse payment does not automatically imply that the agreement is anti-competitive. It is not possible to establish either the intent or the effect of a patent settlement merely by establishing that it includes a reverse payment. Whether or not a patent settlement is anti-competitive because of the intent of the agreement or its effect, the total of the settlement’s terms and conditions must be assessed.

5.4. The pros and cons of patent settlements

Patent settlements have become a hot topic with most of the attention being given to the agreements that limit generic entry and/or include a reverse payment. Over the period of January 2000 to June 2008 a total of 207 patent settlements where entered between originators and generics within the pharmaceutical sector. Of the 207 patent settlements 108 of these agreements did not impose a limitation on generic entry or marketing. Of the remaining 99 patent settlements 45 of them included a value transfer from the originator to the generic.\textsuperscript{51} The number of patent settlements has increased since the Sector Report was written, which supports that patent settlements is a normal way of solving or concluding disputes in the pharmaceutical sector. When considering the pros and cons of patent settlements there are different aspects to consider. In regard to the parties to a patent settlement it has already been mentioned that both parties can benefit by limiting litigation costs. When a dispute is concluded through litigation it is also a further expense in the case of an appeal.

\textsuperscript{50} The Sector Report, quote from an originator on p. 264
\textsuperscript{51} The Sector Report, para. 743
Once both parties enter a patent settlement and thereby have some sort of common ground or have agreed on the level of compromise for both parties, patent settlements are in general considered an efficient and desirable way of ending litigation and according to generics,

"Companies should therefore be given flexibility in concluding such agreements."\(^{52}\)

5.4.1. Consumers and national health care systems

The general concern that is presented in relation to patent settlements is the fear of generic entry being delayed, which would result in a delay of prices decreasing after generic entry. According to the European Commission,

"When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices."\(^{53}\)

Provided that the generic delay goes beyond the scope of the originator’s patent, the longer the period before generic entry occurs, the longer the consumer is forced to buy the medicine at the originator’s "high" price. Although the rules of price setting are not harmonized within the EU, the area is highly regulated by national regulation. It is in some case argued that a decrease after generic entry does not always lead to a significant drop in prices because the prices are regulated beforehand.\(^{54}\) The fact that regulation plays a role in price setting in the pharmaceutical sector is also acknowledged by the European Court of Justice,

"[...] unlike the prices of other consumer goods [medicines] are to a significant extent shielded from the free play of supply and demand."\(^{55}\)

\(^{52}\) The Sector Report, para 1347
\(^{53}\) European Commission press release IP/09/1098 of 8 July 2009
\(^{55}\) Case T-168/01 GlaxoSmithKline Services Unlimited v. Commission of the European Communities, para. 133
In Denmark the prices of medicines are not fixed but the pharmacies are obliged to sell the prescriptive medicines at the price set by the manufacturer. The manufacturer must notify the Danish Health and Medicines Authority of the prices of its product but the prices do not have to be approved of. However, once generic products have entered the market and are sold at a lower price, the pharmacies are obliged to offer the cheaper alternative to the consumers. In addition the reimbursement of prescription medicines is based on the medicine with lowest price. This way the consumer is both made aware of a cheaper alternative, when it exists, and can benefit from generic entry.\textsuperscript{56}

In the cases of patent settlements leading to an earlier generic entry this can lead to an actual benefit for the consumers, because the prices will decrease earlier than the patent’s expiry date. According to the Sector Report patent settlements are generally believed to be beneficial to consumers by generics.\textsuperscript{57}

The national healthcare systems will also benefit the lower the prices are, both because of expenses in reimbursement but also in the bigger picture when consumers can afford to buy the medicine they need.

It is important to bear in mind that in relation to competition rules it is only a requirement that an agreement does restrict competition either by object or by effect.\textsuperscript{58} A patent settlement that does not result in generic entry before patent expiry is valid as long as it is within the boundaries of a valid patent.

\textsuperscript{56} The Danish Health Act nr. 506 of 20 April 2013 and chapter 10 in the Danish Medicines Act nr. 913 of 13 July 2010
\textsuperscript{57} The Sector Report, para. 1347
\textsuperscript{58} Article 101(1) of TFEU
6. The Pharmaceutical Sector Inquiry Report

The background and legal outset of the Pharmaceutical Sector Inquiry Report will be described. The presentation of data concerning interim injunctions and patent settlements concluded between originator and generic companies will be analysed. In addition the Commission’s reports on the monitoring of patent settlements are described. Finally the result of the Commission’s reports will be discussed.

6.1. Introduction to the Pharmaceutical Sector Inquiry Report

On January 16th 2008 the European Commission’s Directorate General for Competition (hereafter DG for Competition) announced that an inquiry had been initiated into the pharmaceutical sector. The reason for the Commission’s interest in the pharmaceutical sector was that there had been indications that the entry of generic medicines seemed to be delayed and that less new pharmaceuticals were entering the market.\(^{59}\)

The legal basis and frame for the Commission to conduct such an inquiry is set in article 17 of regulation nr. 1 of 2003 (hereafter regulation nr. 1/2003), according to which the Commission may conduct an inquiry when it suspects there could be a restriction or distortion of the competition. The purpose of the investigation is to ensure the effect of articles then 81 and 82 of the Treaty (now articles 101 and 102 of the TFEU).

According to Article 17 of Regulation nr. 1/2003, articles 14, 18, 19, 20, 22, 23 and 24 apply to the investigation \textit{mutatis mutandis}, which among other things gives the Commission the right to require undertakings and associations to supply the necessary information for the investigation. If an undertaking or association does not meet a

\(^{59}\) European Commission press release from the Commission IP/08/49 of 16 January 2008
requirement from the Commission, a fine can be imposed by decision of the Commission.60

The Pharmaceutical Sector Inquiry Report of 2009 (hereafter "the Sector Report") will be reviewed in this chapter of the thesis. The three subsequent reports on monitoring patent settlements from July 2010, 2011 and 2012 respectively will be included in the review.61

6.2. The outset and frame of the pharmaceutical sector inquiry report

The pharmaceutical sector has one of the highest investments in research and development in Europe62, which means that the protection of intellectual property rights is of vital importance to the pharmaceutical companies in order for them to continue to invest in researching and developing new medicines.

The scope of the inquiry is outlined with the focus being on company behaviour between originator companies and amongst originator companies. The Commission selected 43 originator companies and 27 generic companies that represent 80 % of the relevant turnover in the EU.63 The thesis will focus on and discuss the patent settlement agreements that are entered into between originator and generic companies, leaving the behaviour between originator companies outside the scope of the thesis.

The first goal of the Sector Report that is mentioned is the aim of a safe, effective and affordable healthcare while at the same time wanting to have a creative and innovative pharmaceutical sector.64

Already in the introduction of the Sector Report the behaviour of the originator companies is suggested to contribute to the issues or problems that have been noted in regards to generic entry.65 At the same time it is noted that the regulatory framework

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60 Article 23 of Council Regulation No. 1/2003  
62 The Sector Report, para. 9  
63 The Sector Report, para. 14  
64 The Sector Report, para. 5  
65 A generic is defined in the Sector Report on page 7 as a medicinal product which has the same
might play a role, which also reveals that assessing the regulatory framework as a contributor to delayed generic entry does not lie within the scope of the Sector Report.

### 6.3. Competition between originator and generic companies

In chapter C of the Sector Report the competition between originator and generic companies is reviewed. The chapter is further divided into 7 subchapters that are based on the different instruments of the so-called "toolbox" that is used in the pharmaceutical industry to protect products.\(^{66}\) The thesis will discuss subchapter C.2.2 concerning patent-related exchanges and litigation and subchapter C.2.4 concerning settlements and other agreements of the Sector Report in particular.

#### 6.3.1. Chapter C.2.2. – Patent related exchanges and litigation

A variation of numbers are presented with among others the number of disputes that arose between originator and generic companies. According to the Sector Report disputes are defined as being an exchange of views between an originator and a generic company in which the actual or potential infringement, non-infringement or invalidity of one or several patents concerning a specific INN\(^{67}\) have been raised and has not yet ended in litigation\(^{68}\).

According to the Sector Report 187 patents\(^{69}\) of which only 8% of the disputes was ended with a settlement agreement in the period of 2000 to 2007. Based on this number it is concluded that patent-related disputes as a fact may affect generic entry.

 qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated. If these conditions are met, a generic applicant for marketing authorization is exempted from the requirement to prove safety and efficacy through pre-clinical tests and clinical trials, and the competent authority relies on the proof of safety and efficacy provided by the reference product. Generic entry is the point where the generic enters the market.

\(^{66}\) The Sector Report, para. 466

\(^{67}\) INN as defined in the Sector Report on page 8 is the international non-proprietary name for pharmaceutical substances.

\(^{68}\) The Sector Report, footnote 384

\(^{69}\) The Sector Report, para. 569. This includes different types of patents such as product patents, process patents and patent for first second medical use.
As the purpose of the chapter is to examine the delay of generic entry\textsuperscript{70}, one must assume that the effect in mind is a negative effect in the form of a delay.

In connection with the disputes the numbers regarding interim injunctions are examined. The reasons for requesting interim injunctions, the purpose of an interim injunction and what is generally required in order to obtain an interim injunction is explained in the Sector Report.\textsuperscript{71} One could be tempted to think that requesting an interim injunction is merely an instrument with which an originator can easily, compared to a full trial in court, stall a generic company in entering the market with their products. However, there is a risk for the originator company when requesting an interim injunction. An interim injunction is followed by a main case in which it is settled in court whether or not an infringement of some sort has taken place or not. If an originator has been granted an interim injunction and later loses the main case in court, the originator company shall pay damages to the generic company, which meanwhile has not been able to either sell or enter the market with their generic product. A decision to request an interim injunction is therefore not taken lightly.

In the Executive Summary of the Pharmaceutical Sector Inquiry Report\textsuperscript{72} (hereafter the Executive Summary) this aspect of requesting interim injunctions is not presented. When it is a summary report consisting of 30 pages summarizing a report of 533 pages it is expected that certain descriptions are left out and that some situations are simplified in order to include as much as possible. However, one shall not oversimplify matters in a way so that important aspects are left out or distorted.

To be fair the data concerning interim injunctions are presented objectively at first in the Executive Summary\textsuperscript{73}, but when presenting the final outcome of the cases where interim injunctions were granted, the Executive Summary misrepresents things slightly. Out of the 255 cases where originator companies had requested an interim injunction, 112 of them where granted.

\textit{“In 46\% of the cases in which injunctions were granted the subsequent court

\textsuperscript{70} The Sector Report, para. 466
\textsuperscript{71} The Sector Report, para. 640
\textsuperscript{72} Executive Summary of the Pharmaceutical Sector Inquiry Report of 8 July 2009
\textsuperscript{73} Executive Summary page 12

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proceedings in the main case ended either with final judgments favourable to the generic company, or settlements which appear to be favourable to the generic company as they allowed early entry for the generic company and/or foresaw a value transfer to it."^{74} (my underlining)

As it is presented in the citation above cases settled in court with a ruling against an originator company and a settlement outside court with an outcome that is seemingly favourable to a generic company are presented as more or less the same result. However, a final judgment that is favourable to a generic company would mean that the patent in question has been found either invalid or not covering the scope claimed by the patentee. If the result of such a final judgment and a patent settlement appearing to be favourable to a generic company are to be regarded as more or less the same, the underlying patent of such a patent settlement must be presumed to be either invalid or weak.

Of all the cases where an interim injunction was granted a high number of them were settled out of court. The cases that were closed with settlement agreements were furthermore divided in different categories, where a group of 23 cases is believed to be settlement agreements that appear to be favourable to the generic company because they included early entry for the generic company and/or a value transfer from the originator company.^{75}

In the Sector Report 10% of the cases that were closed with a settlement agreement are concluded to be favourable to the originator company because they include a value transfer to the originator company and/or a delayed generic entry. It is a curious choice of words when describing a successful settlement agreement for an originator company by using the words “delayed entry”. The words “delayed entry” suggest that the generic entry happens later than it should have. If a generic entry is delayed when entering the market at the expiration of the originator’s patent and thereby enters the market later than it rightfully should have, it is the strength of the underlying patent that determines whether that is the case or not. Such an examination should be made within the frames of European patent law, which does not lie within the scope of the

^{74} Executive Summary page 12
^{75} The Sector Report, para. 656, 44 out of 60 cases
Sector Report.\textsuperscript{76}

When cases are closed with a final judgment it is often easy to see which party the judgment is favourable to, but when a case is closed with a settlement agreement it is often not as “black and white” when it comes to naming a winner. The terms of a settlement agreement are often negotiated behind closed doors and consist of both give and take for each party or quid pro quo. The potential prize or cost of going through a full trial can often be bigger than what is at stake in a settlement, but a settlement is a way of reaching a final result “here and now”, and knowing what you are going to get.

This raises the question of how accurate the Sector Report is when it quite simply categorizes some settlement agreements as being favourable to either the originator or generic companies. The Sector Report does also categorize some of settlements in between though because it is not possible to determine which party the agreements are favourable to.\textsuperscript{77} It is noted that there is a tendency in the settled cases that the conditions are favourable to generic by allowing generic entry or a value transfer to the generic company. However, although the tendency is not regarded as conclusive in predicting the outcome of court cases, it is noted as an element to consider when viewing the amount of cases with interim injunctions that are won by originator companies.\textsuperscript{78}

\textbf{6.3.2. Chapter C.2.4 – Settlements and other agreements}

A total of 207 settlement agreements were concluded in the period January 2000 to June 2008. In this context it is important to note that the 207 settlement agreements include all patent settlement agreements with relevance to any of the EU27 Member States. This means that a patent settlement agreement where only part of the agreement relates to one of the EU27 Member States, is included in the 207 patent settlement agreements.\textsuperscript{79} Another thing to bear in mind is that this chapter of the

\begin{footnotesize}
\begin{tabular}{ll}
\textsuperscript{76} & The Sector Report, para. 654 \\
\textsuperscript{77} & The Sector Report, para. 654 \\
\textsuperscript{78} & The Sector Report, para. 656 \\
\textsuperscript{79} & The Sector Report, para. 740 \\
\end{tabular}
\end{footnotesize}
Sector Report is not based on the initial selection of 219 INNs as the rest of the Sector Report is. Both the originator and generic companies were asked to submit all settlements regardless of the INNs concerned and thereby expanding the scope of the Sector Report in that chapter.\textsuperscript{80}

The patent settlement agreements were put into different categories with two main categories of A and B. A consisted of settlements that were not considered to limit generic entry or access. B was divided further into subcategory B.I, with patent settlements that were considered to limit generic entry or access, and B.II with patent settlements that were considered to limit generic entry or access including a value transfer from the originator to the generic.\textsuperscript{81} Of the 207 patent settlement agreements 99 of them fell into category B, being the category of agreements that limited generic entry. A limitation of generic entry is defined in the Sector Report to be when the patent settlement agreement limits the generic company’s ability to market its own product. 45 of the patent settlement agreements fell into the subcategory B.II. while both limiting generic entry and including a value transfer from the originator company to the generic company – a so-called reverse payment.\textsuperscript{82}

There was some concern about the categorisation of the patent settlement agreements which was expressed in connection with the public consultation. The concern was that all the patent settlement agreements that belong to category B.II. would automatically be considered to be anticompetitive. As a response to these concerns it is emphasized in the Sector Report that whether a patent settlement agreement is anti-competitive or not requires an in-depth analysis, taking into account the factual, economic and legal background.\textsuperscript{83}

\textbf{6.3.2.1. Motives for entering patent settlement agreements}

The Sector Report starts of by stating that a sort of “main motive” for entering a patent settlement agreement is to save both money and time. In addition to these

\textsuperscript{80} The Sector Report, para. 714
\textsuperscript{81} The Sector Report, para. 741 and 472
\textsuperscript{82} The Sector Report, para. 743 and figure 106
\textsuperscript{83} The Sector Report, para. 763
factors a patent settlement agreement can also be advantageous compared to a full trial in court because the outcome can be more predictable for the parties. The parties will also have the freedom to choose what terms they agree to with a patent settlement. The Sector Report also states that patent settlement agreements generally are an accepted way of ending disputes.\textsuperscript{84}

Another reason for choosing to enter a patent settlement agreement that appears repeatedly is the complexity of the patent litigation cases. A generic company is quoted:

\begin{quote}
"Patent litigation can be so complex and technical [...] We can never know the ultimate outcome when a patent litigation begins, even though we may have undertaken prior IP review and evaluation. This is because the evaluation of the risk may evolve from one month to another, according to internal assessments, as well as external circumstances [...]"\textsuperscript{85}
\end{quote}

However, the interest in choosing to settle because of complexity and the technical aspect of such cases is an argument that is used by both the generic and the originator companies. In a category B.II. patent settlement, an interim injunction had been granted, prohibiting the generic company in entering the market. The interim injunction was followed by a judgement that was not favourable to the originator company. The originator company was therefore ordered to pay the loss of profits to the generic company for the period when the injunction was in place.\textsuperscript{86} The parties then decided to settle:

\begin{quote}
"... in order to avoid excessive costs and time-consuming litigation (particularly in view of the number of expert witnesses that were required in order to determine the potential lost profits due to the generic company)."
\end{quote}

In another example an originator company states that,

\textsuperscript{84} The Sector Report, para. 707
\textsuperscript{85} The Sector Report, p. 263
\textsuperscript{86} The Sector Report, p. 279
"We often settle not because we think we have a weak case, but because it would have been impossible to obtain an interim injunction against a generic company. Thus, there is no longer any significant commercial benefit in continuing litigation, in particular after the entry of other generic companies."\(^87\)

The practical advantage of entering a patent settlement agreement in order to avoid highly complex and time-consuming litigation seems to play an important role on both the generic side and the originator side.

In order to learn how the companies evaluate the pros and cons when considering to enter a patent settlement agreement, a questionnaire was sent to the companies asking which factors played a role in such a decision.

The companies were asked to make a prioritized list of the five most important factors that are considered when entering a patent settlement. Based on the replies Table 21 in the Sector Report\(^88\) presents the different considerations as a prioritized list of all the companies' answers. However, Table 21 does not take into consideration that the companies could give more than one answer of the most important considerations.\(^89\)

It can can seem a small point to make, but it is a misrepresentation when the strength of the company's own position is presented as the single most important factor that is considered. The same method is applied in relation Table 22 with the generics' answers.\(^90\) In addition it is mentioned that some of the companies were not able to make a prioritized list as asked to because patent settlements are highly subjective and case specific.\(^91\) The point is still important though because the more examples of presenting data with a slight twist in order to illustrate what is believed to be a trend in a bigger context, the more damage is done to the credibility of the Sector Report.

\(^{87}\) The Sector Report, p. 263
\(^{88}\) The Sector Report, p. 266
\(^{89}\) The Sector Report, para 735
\(^{90}\) The Sector Report, p. 267
\(^{91}\) The Sector Report, footnote 470
6.4. Reports on the Monitoring of Patent Settlements

After the Sector Report was finished the Commission wished to follow up on the Sector Report by monitoring patent settlement agreements between originator and generic companies. This has so far resulted in four reports with the latest report being published on 9 December 2013.\(^2\) All four reports are based on the same categorisation of the patent settlements as in the Sector Report, dividing the agreements according to whether or not there was a limitation of the generic company and if so, whether a value transfer from the originator to the generic company had taken place.

The first monitoring report published on 5 July 2010\(^3\) covered the period from mid-2008 to the end of 2009. A total of 93 patent settlements were concluded in that period. 53 of the 93 patent settlements contained no limitation, falling into category A, leaving 40 patent settlements which limited the generic company’s ability to market their own product freely and thereby falling into category B. 9 of those 40 patent settlements fell into category B.II because of including a value transfer from the originator to the generic company.

The numbers are compared to the findings in the Sector Report showing that there has been an increase in the number of patent settlements, while there simultaneously has been a decrease in the number of settlements that could attract competition law scrutiny. Based on these numbers the report concludes that the Sector Report has not had a discouraging effect on companies in regard to entering patent settlements contrary to statements made by stakeholders during the inquiries for the Sector Report.\(^4\)

The Commission continued to monitor patent settlements and published the second monitoring report on 6 July 2010\(^5\) which covered the period January to December 2011. A total of 89 patent settlements were concluded whereof only 3 limited the generics’ ability to market their own products including a value transfer from the

\(^3\) 1st Report on the Monitoring of Patent Settlements of 5 July 2010
originator to the generic company. The number of patent settlements was still higher than what was registered in the Sector Report, but there the report continued to show a decrease in the number of patent settlements that were potentially problematic in relation to competition law.

On 25 July 2012 the Commission published their third report on patent settlement monitoring, which showed that 120 patent settlements had been concluded in the period January to December 2011. There was a slight increase in the patent settlements belonging to category B.II but with 13 of the 120 settlements belonging to this category the number was still low.96

The latest report on monitoring of patent settlements was published on 9 December 2013. The report covered the period January to December 2012 and in this period 183 patent settlements were concluded with 12 of them belonging to category B.II.97

All four monitoring reports on patent settlements are based on the same structure referring to the Sector Report and e.g. categorising patent settlements according to either A, B.I or B.II type of agreements. There is a definite increase in the amount of patent settlements that are concluded and based on these numbers the Commission concludes that the Sector Report and the following reports have not caused a decrease in patent settlements with a corresponding increase in litigation. However, the reports also show an increase in the number of INN’s that are subject to patent settlements98 and additionally there has been an increase in the amount of patent applications99, which are likely to be part of the explanation for the increased amount of patent settlements.

Despite the increase of the number of patent settlements the simultaneous decrease in patent settlements belonging to category B.II is notable. Although the Sector Report and the following monitoring reports do not provide a lot of guidance to this relatively new or at least untested area, there is no doubt that the Commission is intent on

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reaching its goal of eliminating any patent settlements that distort the market in the pharmaceutical sector.


The Sector Report is repeatedly presented as a mere fact finding and objective presentation of the information submitted by the various pharmaceutical companies. It is not the object of the Sector Report to make any conclusions regarding the information it is based on. Having this in mind it is important to remember that the outset of the Sector Report was a decrease in new pharmaceutical products entering the market and a registered delay in generic entry. There was an initial suspicion that some of the company behaviour in the pharmaceutical sector was violating competition rules, which is also reflected in the Sector Report.

Although it was made clear that no conclusions were made in the Sector Report of the compatibility of company behaviour and the competition rules, the Sector Report is not objective, which is reflected in the way the data is presented. There is a lot of focus on the patent settlement agreements and, as pointed out above, it seems there is an underlying presumption in the Sector Report that patents subject to these agreements are either weak or invalid.100

It is more than likely that some of the patent settlement agreements grant originator companies rights that go beyond the scope of their patent and thereby delay generic entry. This is of course an important restriction of competition that is to be dealt with, but the importance of presuming a patent to be valid until the contrary is proven should also be recognised and not underestimated. Patent settlements are a natural and necessary part of the pharmaceutical sector and should continue to be so.

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100 Nordlander, Kristina & Harrison, Patrick: "Pharmaceutical Patent Settlements – A Presumption in Reverse", The Online Magazine for Global Competition Policy (2009) http://www.sidley.com/files/Publication/af1a23084-a887-402b-8a60-cfd721a3d3a5/Presentation/PublicationAttachment/bd3f5692-f1f7-4635-8bb6-5959a8b68d8/Nordlander-AUG-09_1_.pdf latest access 29 January 2014
The existence of patent settlement agreements and the risk of some these agreements being anti-competitive should be monitored carefully, but with a balanced approach. The indications of the Sector Report and the choice of how to present data is troubling because it seems that it is biased or based on an agenda of reducing patent settlements just to ensure that competition is not restricted.

Another issue is the categorisation of the patent settlement agreements which seems simplified and potentially over inclusive. Both originators and generics consider patent disputes to be fact-intensive and legally complex and enter patent settlements on a case-by-case basis.101 In addition the number of different ways to structure a patent settlement agreement are almost non-exhaustive. With this in mind it is surprising that the Sector Report only divides the patent settlement agreements in three different categories.

The point of these comments on the Sector Report is not to discredit the Sector Report, for it contains important information about the pharmaceutical sector and its structure. The intention is, however, to point out that when reading the Sector Report it should be borne in mind the context in which it has been produced and the position of or the interest of the Commission.

101 The Sector Report, para. 718-719
7. Patent Settlements in the EU

Until now the only case in which a decision has been reached is in the Commission’s case against the Danish pharmaceutical company, Lundbeck. The case with the Commission’s decision and the general reaction to the case will be described.

7.1. The Lundbeck case

7.1.1. Background and process of the case

The Commission finished the Sector Report in July 2009 and based on the findings announced on 7 January 2010 that it had opened formal antitrust proceedings against the Danish originator Lundbeck. The investigation was based on a suspicion of Lundbeck’s behaviour in regard to their best-selling blockbuster antidepressant, Citalopram.

The legal basis for the Commission to initiate antitrust proceedings is found in Article 11(6) of Council Regulation 1/2003 according to which the Commission relieves the national authorities of their competence to apply Articles 81 and 82 of the Treaty (now Articles 101 and 102 of the TFEU). The legal basis also includes Article 2(1) of Commission Regulation 773/2004 according to which the Commission may decide to initiate proceedings with a view to adopting a decision pursuant to chapter III of Council Regulation 1/2003.

The formal proceedings against Lundbeck were followed by a Statement of Objections which was announced on 5th July 2012. The Commission was of the preliminary view that Lundbeck had entered agreements with a number of generic companies with the purpose of preventing an entry of cheaper generic medicines that

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102 European Commission press release IP/10/8 of 7 January 2010
103 According to the Sector Report page 6 a blockbuster medicine is defined as being a medicine which achieves an annual revenue of more than US$ 1 billion at global level over US$ 1 billion at global level.
104 European Commission press release IP/12/834 of 25 July 2012
would compete with Citalopram. The Commission believed these agreements to include substantial value transfers from Lundbeck to four generic competitors, which included both direct payments and purchase of generic citalopram stock for destruction or guaranteed profits in a distribution agreement.\textsuperscript{105}

On 19th June 2013 the Commission had reached a decision in the case. The Commission imposed a fine of € 93.8 million on Lundbeck for entering agreements to delay the entry of cheaper generic versions of Lundbeck’s medicine Citalopram. The agreements were found by the Commission to be anticompetitive and thereby in violation of Article 101 of the TFEU.\textsuperscript{106}

Lundbeck has now appealed the Commission’s decision to the General Court as they believe that the decision of 19 June 2013 contains several factual and legal errors.\textsuperscript{107}

The only public information available so far about the Lundbeck case are the press releases concerning the Commission’s investigation of Lundbeck, the result of the investigation and Lundbeck’s own corporate release of 19 September 2013.

Lundbeck has on 30 August 2013 brought an action to annul the Commission’s decision. In the action for annulment Lundbeck makes ten claims through which they argue why the Commission’s decision should either be annulled or the fine should be reduced. Among other things Lundbeck claims that the Commission has applied the established principles of “restriction by object” wrongly. In addition Lundbeck alleges that the relevance of the value transfers were assessed wrongly and that the parties to the agreements were not actual or potential competitors.\textsuperscript{108}

Based on Lundbeck’s appeal of the Commission’s decision it appears that the assessment of specific agreements in the case has not been based on determining the scope of Lundbeck’s patent. On the contrary it appears that the Commission has found the agreements to restrict competition by object, which would mean that the effect of the agreements will not have been assessed.

\textsuperscript{105} European Commission press release IP/12/834 of 25 July 2012
\textsuperscript{106} European Commission press release IP/13/563 of 19 June 2013
\textsuperscript{107} Corporate release nr. 506 of 19 September 2013 from Lundbeck A/S
\textsuperscript{108} Case T-472/13 H. Lundbeck and Lundbeck v Commission

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The Commission’s press release announcing the Commission’s decision in the case also seem to support that the agreements were considered to be restrictions by object,

"Internal documents refer to a "club" being formed and "a pile of $$$" to be shared among the participants. Lundbeck paid significant lump sums, purchased generics’ stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement."\textsuperscript{109} (my underlining)

The Commission is currently working on making a public version of the decision that does not contain business secrets or other confidential information.\textsuperscript{110} Since the Commission’s decision has not been published or the appeal of the case has not been tried, further speculation of the Commission’s reasoning will not be discussed.

7.2. Reactions in connection with the Lundbeck case

The decision in the Lundbeck case had been anxiously awaited. Since the Sector Report was published in July 2009 with following Reports on the Monitoring of Patent Settlements, case law has been sought after in order to connect the observations in the Commission’s reports to some actual case law.

Even though there is no public version of the decision available yet, the decision of the case and the size of the fine imposed on Lundbeck have received significant attention.

As a reaction to the decision the European Federation of Pharmaceutical Industries and Associations (hereafter ”EFPIA”) issued a statement the same day as the Lundbeck decision was announced on behalf of the pharmaceutical industry operating in Europe. The statement criticized the EU patent system claiming that,

\textsuperscript{109} European Commission press release IP/13/563 of 19 June 2013
\textsuperscript{110} \url{http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39226} latest access 29 January 2014
"Patent settlements are a symptom of the failure of Europe’s patent litigation."\textsuperscript{111}

As the details of the decision in the Lundbeck case have not yet been published, the EFPIA refrained from commenting on the Lundbeck case specifically. The EFPIA has previously issued a "position paper" on 15 May 2013 stating the EFPIA’s position on patent settlements and how they think they should be approached,

"A nuanced fact-specific approach is required in situations that may merit review. Those situations should be limited to circumstances in which a patent has been obtained fraudulently or where a settlement includes restrictions that manifestly go beyond the exclusivity conferred by the disputed patent."\textsuperscript{112}

Irrespective of any truth in the EFPIA’s criticism of Europe’s patent litigation, the Lundbeck case is a result of the current system. The Commission itself has also stated its criticism of the current system, but the Commission’s criticism has its focus on the effectiveness of the competition rules and the more short term benefits for the consumers and the national healthcare systems. In connection with the Lundbeck case Commission Vice-President Joaquin Almunia was adamant in his statement,

"Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices."

Patent settlements which are detrimental to consumers and exert additional strain on the national healthcare systems should not be agreed upon. However, with the seemingly hard or sceptical line that the Commission has chosen in approaching patent settlements, the outcome might end up being a more short term improvement with a long term loss of innovation. On 13 September 2013 Joquin Almunia said,


\textsuperscript{112} EFPIA position paper of 15 May 2013 \url{http://www.efpia.eu/uploads/Modules/Mediaroom/patent_settlements_150513.pdf} latest access 27 January 2014
"IPRs result from public-policy decisions that create incentives for innovation by rewarding the bright people and companies that make it happen in the first place. So far, so good. But the protection of intellectual property – like any other form of legal protection – may also find limits in the interest of the general public."\(^{113}\)

This wording seems to confirm that Commission’s focus is on ensuring the benefits of competition law at the expense of intellectual property rights.

Time will tell what kind of precedent the Lundbeck case will set. It could be argued that the Commission was keen to make an example of Lundbeck because it was the first case, which may have caused some goal fixation from the Commission’s side. On the other hand according to the press release in connection with the Lundbeck decision the Commission stated that the agreements were different from other patent settlements because the generic companies were simply paid off to stay out of the market for the duration of the agreements.\(^{114}\)

The next decision of the Commission concerning a patent settlement with a reverse payment will most likely be in the case concerning Servier. On 30 July 2012 the Commission announced that it was of the preliminary view that the patent settlements agreed upon by Servier and other generic companies were aimed at delaying generic entry.\(^{115}\)

The fact remains that so far guidance on patent settlements with reverse payments is still conspicuous by its absence.

\(^{113}\) European Commission SPEECH/13/697 of 13 September 2013
\(^{114}\) European Commission press release IP/13/563 of 19 June 2013
\(^{115}\) European Commission press release IP/12/835 of 30 July 2012
8. Approach according to Article 101 of TFEU

This chapter will if considering patent settlements with a reverse payment to restrict competition by object is reasonable approach and it what cases it could be applied. It is also discussed what the advantage and disadvantage will be if such agreements’ effect on competition is to be assessed.

8.1. Do patent settlement agreements restrict competition by object?

According to article 101(1) of TFEU agreements that have as their object to restrict competition are automatically void and the effect of the agreement does not need to be assessed. It is worth considering whether aspects of patent settlements with reverse payments could be considered a restriction by object, which would make the treatment of these agreements a lot easier and quicker. However, as discussed in chapter 5 the fact that a reverse payment has taken place does indicate the intention or aim of the agreement.

In the case where it is established that a reverse payment has taken place, it is necessary to look at what the reverse payment has paid for. If the exchange for the reverse payment is an agreement by the generic to hold its product off the market for a certain period, it makes more sense to begin to consider the possibility of the agreement having restriction of competition as its object.

In the case Windsurfing\textsuperscript{116} the Court stated regarding an agreement containing a non-challenge clause that,

\textit{"Such a clause does not fall within the specific subject matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent’s validity, in view of the fact that it is}

\textsuperscript{116} C-193/83 Windsurfing International Inc. v Commission of the European Communities
public interest to eliminate any obstacle to economic activity which may arise where a patent is granted in error.\textsuperscript{117}

A rigid approach as the one in Windsurfer does take in to account the potential pro-competitive effects that a patent settlement can have by e.g. generic entry before patent expiration. For a patent settlement to restrict competition it is inevitable that some consideration of the patent is taken. As long as a patent settlement with a reverse payment confers the same rights to the originator – or patentee – as the patent, the patent settlement does not limit the rights of the generic and the agreement does not restrict competition. The reasoning in Windsurfer can therefore only be applied when the patent settlement goes beyond the exclusionary zone of the patent. The issue of the validity and scope of the patent is therefore the potential causal link to the settlement restricting competition.\textsuperscript{118}

The question is then if a patent settlement with a reverse payment can result in situations where either the validity or the scope of the patent can lead to restriction by object.

If a patent settlement is believed to restrict competition the agreement can do this in two ways. First of all the patent can be invalid, which means that the originator or the patentee has no exclusionary right and accordingly no right to exclude a generic from the market. If the originator knowingly has obtained its patent by providing wrong information or in some other way has information that its patent is invalid, it could be reasonable to consider a restriction by object. The knowledge of the patent’s invalidity must be able to be proven to be more than an insecurity of whether the patent will stand a challenge in court, because even strong patents do not guarantee the outcome of litigation. An example could be internal documents where the patent invalidity is acknowledged or in the case of a patent settlement being found invalid in the first instance where the parties during the appeal enter a patent settlement.\textsuperscript{119}


Another situation could be if the patent settlement clearly goes beyond the scope of the patent by e.g. agreeing to a generic entry date later than the date of the patent expiration.

The situation where the patent settlement clearly goes beyond the scope of the patent or where the originator positively knows that its patent is invalid both show an intent to limit the rights of the generic. If such an intent can be proven it seems reasonable that a restriction by object is applied. As it is described here the assessment of the intent to limit generic access would be based on the patent and not on the existence of a reverse payment. As long as the originator enters agreements within the limitations of its patent, it should be up to the originator in which way they wish to defend their exclusionary right, and also how much they wish to spend on it.

8.2. Case by case analysis

Based on the EU competition rules the alternative to an anti-competitive agreement being found void due to restriction by object, is if the effect of the agreement is found to restrict competition. This approach would effectively require a more extensive review of the agreement.

With the lack of case law so far the Commission’s communication through the Sector Report and the following Reports on the Monitoring of Patent Settlements must be relied upon as a valid indication of how patent settlements will be reviewed. During the public consultation some stakeholders expressed concern that the consequence of some of the patent settlements would be presumed to be in violation of competition rules. The Commission responded to this in the Sector Report,

"Such an assessment would require in-depth analysis of the individual practice taking into account the factual, economic and legal background."\(^\text{120}\)

\(^{120}\) The Sector Report, para. 463
This statement is followed by a similar statement in the fourth and latest Report on Monitoring of Patent Settlements,

“There is no presumption of violation of competition rules. A case by case analysis would be required. For instance, in some instances, an early entry may be pro-competitive when compared to the parties’ anticipated outcome of the litigation. In other instances, the conditions attached to the early entry (through a licence or a distribution agreement) may cancel out any positive effect on competition.”121

As argued earlier a review of a reverse payment alone does not suffice to explain what it is paying for and under what circumstances. No matter what the outcome of a patent settlement is, it will almost certainly represent a result of give and take between the originator and the generic. If the generic has entered its product at a risk or intends to do so, but refrains from this because of a patent settlement, the generic is more than likely to have received some sort of compensation in order to enter the agreement. On the other hand if the originator has in some way paid the generic it will want something in return e.g. maintain market exclusivity. The point is that a patent settlement is the result of negotiation and that the parties will only enter if it can be made worth their while. Each value that is transferred and every term of the patent settlement can therefore not be reviewed as isolated terms. In order to fully understand the result of a patent settlement, whether anti-competitive or not, the full agreement must therefore be reviewed and broad generalisations will be inadequate.122

A quick glance at the Sector Report shows that the different ways of structuring a patent settlement are many and the approach of an in-depth analysis would ensure the necessary flexibility that patent settlements demand. If the necessary thoroughness and time is not spent on assessing patent settlements, it would result in a higher

number of false negatives or false positives depending on the underlying presumption. 123

However, the disadvantage to applying an in-depth case by case analysis is that it would be very time consuming and complex. The Sector Report shows that the originators, their associations and lawyers await some guidance on the potential limitations of patent settlements between originators and generics. 124 By applying a more thorough approach to the patent settlements the configuration of guidelines might be prolonged even further.

Judging by the decrease of patent settlements that according to the Commission potentially conflict with EU competition rules, it seems that the Commission’s inquiry in the pharmaceutical sector with the following reports has resulted in fewer potentially problematic patent settlements. From the Commission’s point of view this can be seen as positive because this should lead to earlier generic entry. However, from a legal point of view it is not all positive. The Commission should still make sure to provide the pharmaceutical sector with some guidelines in the future cases, as an increase in the legal certainty regarding patent settlements should be desirable for all. The decrease in potentially problematic patent settlements should not be caused by a limitation of originator and generics’ freedom to contract because of legal uncertainty, but it should rather be based on the parties knowingly negotiating within the law.

124 The Sector Report, para. 1346
9. Possibility of guidance from the US and a "rule of reason" approach

Despite all the attention that patent settlements have received, the only conclusion so far is, that some of the patent settlements potentially violate the competition rules in Articles 101 and 102 of TFEU, but with the lack of case law further guidelines are still missing. The chapter will consider and discuss if the EU can draw on the experience of the US and its approach to patent settlements. In line with this it will be discussed whether a "rule of reason" exists in the EU and its potential applicability to patent settlements.

9.1. Can the US be used as guidance?

Patent settlements are an integrated part of settling commercial disputes in the pharmaceutical sector, but in spite of their establishment there is hardly any case law in the EU concerning patent settlements with reverse payments and their relation to competition law. So far the only case is the Commission's decision in the Lundbeck case but the reasoning in the decision has yet to be published and in addition, the decision has been appealed by Lundbeck.\footnote{Case T-472/13 H. Lundbeck and Lundbeck v Commission}

In the US the issue of patent settlements with reverse payments has been a topic for discussion since the introduction of the so-called "Hatch-Waxman Act".\footnote{Drug Price Competition and Patent Term Restoration Act, Public Law 98-417, 24. September 1984, 98 Stat.1585} It was introduced to improve the amount of generic products that were being entered on the market by making the process of obtaining approval for generic drugs easier through an "abbreviated new drug application". If the generic can prove that its product is bioequivalent to the originator drug, the drug will be approved for marketing. The "Hatch-Waxman Act" also provides a possibility for the generic to challenge the originator's patent without having to enter its generic product at risk first. This leads to the financial risk of the generic to be limited to the litigation costs. Although the...
"Hatch-Waxman Act" generally has led to an increase in the generic sector of the pharmaceutical industry, it has also led to many patent settlements with reverse payments.

Some different approaches have developed in the US in the different circuits resulting in a so-called "scope of the patent" test and a more traditional antitrust approach with the principle of "rule of reason." However, they share a common ground in the sense that the Federal Trade Commission has been advocating a presumption of illegality for reverse payments, which has yet to be adopted. Despite the Federal Trade Commission’s efforts, the US Courts of Appeal have preferred a presumption of patent validity.

9.1.1 The Actavis Case

Until recently the question of the approach to patent settlements with reverse payments had not yet been heard by the Supreme Court of the United States (hereafter "Supreme Court"). On 17 June 2013 the Supreme Court’s ruling in the case "Federal Trade Commission v. Actavis" (hereafter "Actavis case") was published.

The Actavis case concerned a patent settlement with a reverse payment, where the settlement agreement previously had been reviewed under the "scope of the patent" test. However, a 5-3 majority of the Supreme Court held that the antitrust "rule of reason" was the correct approach to the settlement agreement. By applying the "rule of reason" the anti-competitive effects of an agreement are compared with pro-competitive effects. If the pro-competitive effects outweigh the anti-competitive effects, the agreement can/will be allowed.

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127 Chao, Isaac: "Supreme Court, in FTC v. Actavis, rejects the "scope of the patent" test, holding that antitrust law's "rule of reason" analysis can pierce the shield of patent rights" http://www.lexology.com/library/detail.aspx?g=1985c3e6-5e3d-4c7b-af7c-c81333167814 latest access 29 Januar 2014
129 Supreme Court of the United States, Federal Trade Commission v. Actavis, Inc. of 17 June 2013, liutra e of the syllabus
Although applying a "rule of reason" approach where the reverse payment will be reviewed in the context of the patent settlement, the Supreme Court also noted that the size of a reverse payment can be an indication of the likelihood of the patent settlement having anti-competitive effects. In addition the size of the reverse payment could be an indication of the strength of a patent. The Supreme Court justified this interpretation with the reverse payments in the Actavis case being so disproportionately large compared to the actual worth of the patents.\textsuperscript{130}

Consequently, the Federal Trade Commission is left with the task of proving the anti-competitive effects of patent settlements with reverse payments in the future. In the cases where the Federal Trade Commission is able to lift the burden of proof, the patentee will have to establish that the settlement produces pro-competition effects that outweigh the anti-competitive effects in order to uphold the patent settlement. Even though the burden of proving the pro-competitive effects of an agreement is a lot heavier compared to the "scope of the patent" approach, the decision promotes a more flexible approach than a presumption of illegality for reverse payments would constitute.

9.1.2. Similarities and differences in the US and EU legislation

Both the US and the EU share the aim of wanting to secure an efficiently competitive market that can provide patients with innovative and cheaper medicines. The basis for the "Hatch-Waxman Act" was to generate more generic products and thereby bring down the prices. The basis for the Sector Report was the fact that the Commission had registered a decrease in the number of novel medicines entering the market and a delay in the entry of generic products.\textsuperscript{131}

However, there are some differences in the legislation that is set out to secure these goals. When a generic applies for approval of a new drug in the US based on the "Hatch-Waxman Act" the generic is granted a market exclusivity period of 180 days. If a dispute arises regarding a potential infringement of the patent, it will initially

\textsuperscript{130} Supreme Court of the United States, Federal Trade Commission v. Actavis, Inc. of 17 June 2013, lira b of the syllabus
\textsuperscript{131} European Commission press release IP/09/1098 of 8 July 2009
postpone the approval of the generic medicine with either 30 months or until it is established that the patent is not infringed.

If the originator and generic enter a patent settlement instead of the originator challenging the generic in court, the delay of the approval can be avoided and the generic will enjoy 180 days of market exclusivity. The 180 days of market exclusivity are granted to the first generic to apply for approval, which effectively means that the generics to come after the "first applicant" are not able to enter the market when the patent expires. This means that the patent settlement agreed upon by the originator and the first generic to apply for approval for its product does not only affect the parties to the agreement, but effectively will have an impact on the remaining generics that wish to enter the market. The fact that a patent settlement can have an impact on a third party magnifies the anti-competitive effect of the patent settlement if it goes beyond a justifiable defence of the patent. This is a consideration that does not exist in the EU.\textsuperscript{132}

A consideration or goal that does exist in the EU, but which does not exist in the US, is the goal of ensuring an effective single market within the EU which plays a role in the assessment of whether or not a patent settlement has an anticompetitive effect. In addition article 101(3) of TFEU, although narrow, allows for exemptions of hard core restrictions, which is not the case in the US.\textsuperscript{133}

Following the Actavis case the future approach of patent settlements with reverse payments in the US is set out to be the "rule of reason". When applying the "rule of reason" it is the sum of the negative and positive competitive effects that decide whether the agreement can continue to be considered legal.\textsuperscript{134} The "corresponding" relevant EU competition legislation are the articles 101 and 102 of TFEU, where article 101 is the general provision. The wording of article 101 describes the specific exemptions to agreements that are considered anti-competitive. Whether or not the

\textsuperscript{133} Callery, Craig: "Should the European Union embrace or exercise Leegin's "rule of reason"?", (2011) in "Cartels and Anti-competitive Agreements, Volume I" edited by Sandra Marco Colino, Ashgate Publishing Limited (2012)
\textsuperscript{134} Heide-Jørgensen, Caroline et al:"Konkurrenceretten i EU", 3rd edition, Jurist – og Økonomforbundets Forlag (2009), p. 128
structure of article 101 can accommodate the potentially very broad scope of a "rule of reason" is a question that has been raised before, but which is even more relevant after the ruling in the Actavis case. The further discussion of the applicability of a "rule of reason" demands a more concrete review of the application of article 101 of TFEU, which will be continued in the following section.

However, there is no doubt that the Commission is paying attention to the activity in this area in the US. When the Commission announced the decision in the Lundbeck case the ruling in the Actavis case was mentioned,

"[...] we are in good company in this approach: in a long-awaited ruling, the US Supreme Court has just concluded two days ago the these "pay for delay" deals should be open to antitrust scrutiny. As the judge noted in its opinion, under such agreements the patentee and the challenger gain, the consumer loses."

Although the "EU approach" to patent settlements with reverse payments has yet to be determined, the Commission has welcomed the ruling in the Actavis case, because it undoubtedly lies closer to the Commission's view of such agreements.

9.2. Does a rule of reason exist in the EU?

It has often been discussed whether the EU should adapt to US approach when it comes to assessing whether agreements are compatible with EU competition law. In the US there are two classifications of agreements or approaches to agreements in the antitrust areas. One is the per se approach which covers agreements that are anti-competitive once the agreement is proven to exist. In these cases it is not necessary to assess the effect of the agreement because it is illegal by its mere existence. The other approach is the previously mentioned rule of reason. As explained, the concept of the rule of reason approach can be explained quite simply. It is a specific assessment of whether the positive competitive effects outweigh the negative competitive effects.

135 Joaquín Almunia speech/13/553 of 19 June 2013
However, this assessment is often highly complex and difficult when carried out in real life.  

When describing the "per se" and "rule of reason" approach it leads to the natural question of a comparison with the EU approach where an agreement that has as its object to restrict competition is a "restriction by object" and the potential effects of the agreement do not have to be assessed. With the "rule of reason" containing an assessment of the effect, negative and positive, of the agreement it raises the question if a comparison can be made with the assessment regulated in article 101(1) of TFEU where,

"The following shall be prohibited as incompatible with the internal market: all agreements between undertakings [...] which have as their object or effect the prevention, restriction or distortion of competition within the internal market [...]"

The speculation of an applied "rule of reason" in the EU has existed for a long time before patent settlements with reverse payments became a hot topic. One of the reasons for wanting to introduce a rule of reason approach in the EU is that the Commission initially interpreted the scope of the then Article 81 of the EC Treaty too broadly. The result was that too many agreements fell within the scope of the then Article 81 (now Article 101 of TFEU) with the narrow exemption in the then Article 81(3) (now Article 101(3) of TFEU).

In the case Métropole télévision the Court denied that a "rule of reason" existed in the EU. The case was about a partnership of six companies, Télévision per Satelite or TPS, who entered the pay-tv market, which was very much dominated by Canal+. Two of the contract terms were especially interesting with the Court finding that they

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136 Heide-Jørgensen, Caroline et al:"Konkurrenceretten i EU", 3rd edition, Jurist – og Økonomforbundets Forlag (2009), s. 128
138 The Treaty on the European Union and of the Treaty establishing the European Community
140 T-112/99 Métropole Télévision (M6), Suez-Lyonnaise des eaux, France Télécom and Télévision francaise 1 SA (TF1) v. The Commission of the European Communities (Métropole Télévision)
fell within the scope of the then Article 85. The contract terms were a clause containing a right of priority and a right of final refusal regarding production of special interest channels and an exclusivity clause regarding general interest channels.

The applicants submitted that a rule of reason had already been confirmed by the Court of Justice in previous cases and that Article 85(1) should have been applied in the light of a rule of reason in Métropole, which would have led to the positive effects of the clauses to outweigh the negative by allowing a new operator to gain access to a market which until then, was dominated by a single operator.\textsuperscript{141}

However, the Court denied that a rule of reason had been established and that in the assessment of the applicability of Article 85(1) to agreements:

\begin{quote}
    \textit{“... account should be taken of the actual conditions in which it functions, in particular the economic context in which the undertakings operate, the products or services covered by the agreement and the actual structure of the market concerned ...”}\textsuperscript{142}
\end{quote}

The Court furthermore specified that the above mentioned approach did not mean that the pro - and anti-competitive effects of an agreement should be weighed against each other.\textsuperscript{143}

Although the Court explicitly stated that pro-competitive effects could outweigh anti-competitive effects, Métropole télévision was subsequently followed by three other cases that kept the discussion of a "rule of reason" alive.

The Wouters\textsuperscript{144} and Meca-Medina\textsuperscript{145} followed the Métropole case. The application or existence of a rule of reason was not mentioned in these cases but the approach that was taken in the two cases is interesting when read in the light of the Métropole case.

\textsuperscript{141} Métropole Télévision, para. 68 and 69
\textsuperscript{142} Métropole Télévision, para. 76
\textsuperscript{143} Métropole Télévision, para. 77
\textsuperscript{144} C-309/99 J.C.J. Wouters and Others v. Algemene Raad van de Nederlandse Orde van Advocaten (hereafter Wouters)
\textsuperscript{145} C-519/04 David Meca-Medina and Igor Majcen v. the Commission (hereafter Meca-Medina)
In Wouters the Court of Justice found that a prohibition of multi-disciplinary partnerships of members of the Bar and accountants, as was laid in the national legislation, was liable to limit production and technical development within the meaning of the then Article 85(1)(b) of the Treaty. However, the Court of Justice stated that an agreement did not necessarily fall within the scope of the then Article 85(1), but that account must be taken of the overall context in which the decision was taken in order to ensure that the ultimate consumers are provided with the necessary guarantees in relation to integrity and experience. It has then to be considered whether the consequential effects restrictive of competition are inherent in the pursuit of those objectives.\textsuperscript{146} The Court went on to state that the effects restrictive of competition did not go beyond what was necessary in order to ensure the proper practice of the legal profession.\textsuperscript{147}

The same reasoning is used in the Meca-Medina case, where account must be taken of the overall context in which the decision was taken and its objectives. Once the decision is taken it has then to be considered whether the consequential effects restrictive of competition are inherent in the pursuit of those objectives and are proportionate to them.\textsuperscript{148}

There is no mentioning of Métropole in Wouters and Meca-Medina so it is unclear if there is a “hidden agenda” or “other agenda” in the approach to then Article 81(1) in its relation to then Article 81(3).

The structure of article 101(1) and article 101(3) of TFEU is that article 101(3) describes the possibility of exemption from article 101(1) if an agreement,

\textit{“[...] contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit [...]”}

From the wording of article 101(3) the type of effects that can exempt an agreement

\textsuperscript{146} Wouters, para. 97
\textsuperscript{147} Wouters, para. 109
\textsuperscript{148} Meca-Medina, para. 42
from being invalid according to article 101(1) must be assessed from an economic point of view. In addition to the economic assessment it is also a requirement that the consumers benefit from the agreement. However, in Wouters the reasoning that allowed the restriction was based on ensuring the proper practice of the legal profession.

If the application of article 101(1) does not include a pro and con assessment of the competitive effects of an agreement and the exemption in article 101(3) is purely an economic one, the case is significant in the consideration of a "rule of reason" in the EU.

It is argued that based on the current structure of article 101, if a "rule of reason" were to be adopted it would effectively render the exemption in article 101(3) useless. A "rule of reason" would be a way of introducing other considerations than the purely economic ones in article 101(3), but it is still tricky to see how a "rule of reason" can be explicitly incorporated while maintaining the current structure of article 101.

In relation to patent settlements with reverse payments the main reasons for wanting to eliminate the agreements that restrict competition is to limit the expenses for the consumers and the national health care systems. The cases of patent settlements with reverse payments might therefore not be the best suited occasion to suggest an implementation of a "rule of reason".

With the ruling in the Actavis case, though the discussion has re-entered, if it ever really left, and at a first glance it can seem like a well-developed and balanced approach that even if the actual assessment is complicated, the result will be fair in some way because despite an agreement having anti-competitive effects, these will only continue to exist if they are outweighed by the positive competitive effects.

In the reports on the monitoring of patent settlements that have followed the Sector Report the choice of words do seem to have an inherent "rule of reason",

"Ultimately, it may be the consumer in such cases who pays the price for such a delay in market entry and therefore any benefits to society identified above are more than outweighed by the negative effects of the agreement between potential competitors. In this context, obviously, an assessment of each individual case would be necessary." 150

It is argued that the patent settlements within the pharmaceutical sector are highly complex and therefore need a concrete and in-depth review of the agreement.151 This is also supported by the Commission in the Sector Report,

"Such an assessment would require in-depth analysis of the individual practice taking into account the factual, economic and legal background."152

A "rule of reason" would basically accommodate any effect in an assessment once its existence is proven. Therefore a "rule of reason" might be an approach that would be able to also accommodate the special relationship between the considerations and aims of patent law and competition law. However, the benefits of patent law are more, if not only, long term in comparison with the benefits of competition law. A "rule of reason" approach would mean a concrete assessment of the specific case, which would make it difficult to include a long term benefit as a pro-competitive effect that could outweigh a negative competitive effect.

It is also important to remember that the principle is developed in the US, and although the US has and still provides inspiration to the competition law in the EU, the legislation and considerations are not identical.153 By simply adopting an approach that is developed in a different legal system, it might be wiser to consider a vocabulary of our own in the EU and determining its content rather than a principle with the content being already established.

150 1st Report on the Monitoring of Patent Settlements of 5 July 2010, para. 4
152 The Sector Report, para. 463
10. Discussion

This chapter will discuss the legal status of patent settlements with a reverse payment including the unsolved issues at present as well as a proposal for a reasonable approach in the way forward for such agreements.

10.1. Legal status of patent settlements with reverse payments

From the Sector Report it appears that both the Commission, the originator and generic companies agree that patent settlements is an efficient way of solving patent disputes between originator and generic companies. The point where opinions begin to differ is first when the patent settlements limit the generic companies’ access to the market and especially if the patent settlement includes a value transfer from the originator to the generic company.

However, the object and even less the effect of a patent settlement cannot be assessed based on the fact that a value transfer has flowed from an originator to a generic company alone. The limitation of the terms of a patent settlement with a reverse payment lies at the interface between patent law and competition law, which effectively is the limitation of the patent through its scope. Although the approach of how to best determine where the interface lies is still unresolved, it is unsettling when the Commission classifies patent settlements as limiting generic access when the generic cannot enter the market until after patent expiry.

Regardless of the uncertainty that the Commission’s classification of patent settlement might cause, the reports following the Sector Report have shown an increase in the number of patent settlements concluded between originator and generic companies. At the same time a decrease in the number of patent settlements limiting generic access with a value transfer from the originator to the generic company has been registered. The development is welcomed by the Commission and

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154 The Sector Report, para. 1344 and para. 1347
the Commission goes even further by concluding that the companies are aware of the competition concerns and that companies are able to find solutions that are unproblematic under EU antitrust rules.\textsuperscript{157}

It appears as if the Commission is satisfied with the decrease of the number of potentially problematic patent settlements, but as long as the guidance that is provided in the Commission’s reports consists of certain types of patent settlements being "problematic"\textsuperscript{158}, the Commission should not be content with the result.

There is a real risk that a decrease in patent settlements with reverse payments could be caused by the lack of certainty of their legal status in the EU, leaving the decrease in the number of such patent settlements to be based on caution of the liability of antitrust scrutiny by the Commission rather than consciously abiding by the competition rules.

The Commission considers the development in patent settlements to be good news for the consumers and the tax payers because of the potential delay in generic access that some patent settlements can cause.\textsuperscript{159} However, even though the monitoring of patent settlements does not question patent system\textsuperscript{160}, the reports should still take into account the considerations of the patent system.

Patent settlements should not be concluded to the detriment of the consumers and the national healthcare systems, but focusing on this issue from a point of view that mainly considers the effects on competition will not necessarily benefit the consumers in the long term. These patent settlements are located at the interface of competition law and patent law and that part of finding the balance between these two systems is keeping in mind that they ultimately share the same goals.

The first decision concerning a patent settlement with a reverse payment in the EU has been made by the Commission in the Lundbeck case. As the decision has been appealed by Lundbeck, the case is not finally settled and the public still awaits a

\begin{itemize}
\item \textsuperscript{157} European Commission press release IP/13/1228 of 9 December 2013
\item \textsuperscript{158} 4th Report on the Monitoring of Patent Settlements of 9 December 2013, para. 4
\item \textsuperscript{159} European Commission press release IP/13/1228 of 9 December 2013
\item \textsuperscript{160} 4th Report on the Monitoring of Patent Settlements of 9 December 2013
\end{itemize}
public version of the Commission’s decision.\textsuperscript{161} This leaves the pharmaceutical industry with the Commission’s view of patent settlements with reverse payments being "problematic". Until further guidance, such as a public version of the Commission’s reasoning in the Lundbeck case, the legal status of these patent settlements continues to be uncertain and "problematic".

10.2. Proposal for an approach

10.2.1. Guidance from the US

With the lack of guidance in terms of case law in the area of patent settlements with reverse payments it leaves room to discuss a possible approach and what benefits and challenges it could lead to. The discussion of patent settlements and the potential collision with the goal of having an efficient and competitive market has existed for a long time in the US compared to the relatively recent attention in the EU. EU competition law has in general been inspired by the US and still is\textsuperscript{162}, which also makes it natural to consider the applicability of a "US approach" in the EU.

In relation to patent settlements there has been two ways of approaching these agreements. Previously the US Courts of Appeal had preferred a strong presumption of a patent’s validity to an assumption of reverse payments being illegal.\textsuperscript{163} The alternative to basing the assessment on the patents validity was applying the principle of "rule of reason". The rule of reason requires a balanced assessment of the negative and positive effects of an agreement. If the positive effects of an agreement outweigh the negative, the agreement can be considered legal.\textsuperscript{164} On 19 June 2013 the US Supreme Court considered the approach to patent settlements and reverse payments in the Actavis case and found that applying the "rule of reason" is the correct approach.

\textsuperscript{161} http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39226 accessed on 29 January 2014


If the Commission and the European Courts were to adopt the principle of "rule of reason" it would entail a balanced assessment of the patent settlements which, although likely to be extensive and time consuming, would ensure that only agreements with predominantly positive competition effects would be upheld. However, in this context it is important to keep in mind that patent settlements are not required to be pro-competitive in order to be legal. Patent settlements that are neutral in their effect on competition do not violate the prohibition in Article 101 of TFEU.

When considering an implementation of the principle of "rule of reason" in relation to patent settlements in the EU, the background in which the principle was developed and currently exists must be taken into account. In the US the approach of presuming the validity of a patent has only recently been changed by a decision of the US Supreme Court deciding that this is not the correct approach. In deciding that the "rule of reason" is the correct approach, the US Supreme Court has in addition stated that the fact that a reverse payment has taken place, can indicate the strength of the underlying patent. The US Supreme Court goes on to state that the size of the reverse payment can also be viewed as an indication of the strength of the patent.

Although it appears that the US and the EU are moving closer towards each other in this point, their outsets lie directly opposite each other. For the EU to adopt the US principle of "rule of reason" it would be adopting a vocabulary with a predetermined content.

On a more specific level the current structure of the prohibition against restriction of competition in the EU would not be able to accommodate the application of a "rule of reason". It is explicitly explained by the Commission that the assessment of whether an agreement falls within the scope of Article 101(1) does not include potential benefits that are assessed according to Article 101(3).166

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166 Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, 2011, para. 29
If a principle of "rule of reason" as developed in the US should be implemented in EU competition law, it would require a change in the current structure of Article 101. It has been considered whether an adoption of the principle can be said to have been implemented through case law, but so far this has been denied. For the legal security of the EU citizens it would be desirable that the implementation went via legislation and not case law alone.

10.2.2. Approach based on Article 101 of TFEU

Based on the structure of Article 101(1) of TFEU an agreement can restrict competition either by object or by effect.

A patent settlement with a reverse payment that is based on a valid patent and the scope of the specific patent is mere enforcement of the patentee’s rights conferred by the patent, and the agreement is a result of the parties’ freedom to enter an agreement. If on the other hand a patent settlement with a reverse payment is based on an invalid patent or if the patent is valid the settlement goes beyond the scope of the patent, the agreement is limiting the generic companies’ rights to freely access the market. Such an agreement is without a doubt not acceptable according to the competition rules.

Does the potential damage to the consumers and healthcare systems justify a strict approach where a patent settlement with a reverse payment is considered to restrict competition by object? In the cases where the patent is invalid or the agreement goes beyond its scope it would be an efficient way of eliminating such anti-competitive agreements. If such an approach was chosen there would be a risk of limiting the right of the patent holder to defend his/her right and it would also limit the parties’ freedom to enter agreements. As previously discussed in chapter 5 the intent or object of an agreement cannot be determined by establishing that a reverse payment has taken place alone. Although consumers would easily benefit from an approach of considering a reverse payment a restriction by object, the price of limiting originator and generics companies the right to freely conclude patent settlement is too high.
If, however, it can be established that the object of the reverse payment is to protect a patent that is known to be invalid or to expand the scope of the patent, the agreement is of course restricting competition by its object alone. Determining the object of such a patent settlement could be found in e.g. internal documents, but in such cases a careful distinction must be made between knowing that a patent is invalid and assessing the risks of defending the patent through litigation.\textsuperscript{167}

It could appear that this has been the case in the Lundbeck case when reading the Commission’s press release and Lundbeck’s arguments in their appeal of the decision. Until the Commission’s decision is published, interpreting the Commission’s reasoning remains pure speculation.

The Commission itself has indicated that the assessment of patent settlements should be a case by case analysis that takes into account the factual, legal and economic background of each case.\textsuperscript{168} The more specific an assessment is of the facts of a case, the more difficult it is to derive more general guidance from an eventual decision. With such an approach it will therefore take longer to provide more general guidance on the legal status of reverse payments in patent settlements. Some argue that the Commission might have to distance itself from this approach in order to efficiently succeed in eliminating the patent settlements that are anti-competitive.\textsuperscript{169} Maybe the Commission already has in the Lundbeck case.

The Commission must follow its own statements and the case by case approach taking the factual, legal and economic context into account follows not only from the Commission’s reports\textsuperscript{170} but also from its own guidelines on the application of Article 101.\textsuperscript{171}

\textsuperscript{168} The Sector Report, para. 463
\textsuperscript{171} Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, 2011, para. 29
From the point of view that the pharmaceutical sector, the Member States and the consumers are entitled to a certain level of legal certainty, the consideration of the future decisions concerning patent settlements with reverse payments being assessed correctly must outweigh a desire to reach a quick decision.
12. Conclusion

The relevant legislation and considerations of both EU competition law and patent law have been explained in order to examine the legal status of patent settlements with reverse payments in the pharmaceutical sector in the EU.

The basic and most common terms of patent settlements has been described with focus on patent settlements including a reverse payment. A distinction between the term "reverse payment" and "pay-for-delay" has been made. An analysis has been made of the incentives for both originator and generic companies to enter patent settlements with reverse payments. The assumption that the incentive for an originator company to enter such an agreement is stronger, the weaker the patent is, has been considered. Although this will be true in some cases it is not an assumption that can safely be assumed in every case. Based on an economic risk assessment the incentive to enter such an agreement with a strong patent can be just as strong. There is always a risk of losing when going to court, which also exists even when a strong patent is being defended. The commercial uncertainty and the risk, although it may be small, of losing in court is therefore also a valid incentive for originator companies with valid patents to enter patent settlements with a reverse payment. From the generic companies’ point of view reverse payments in patent settlements is considered to be a way of balancing out the difference there may be in the parties’ assessment of winning a patent dispute in court. It has therefore been concluded that an assessment of a patent settlement’s effect on competition cannot be based alone on the fact that a reverse payment has taken place.

The Commission’s Sector Report and the following reports monitoring patent settlements has been analysed with focus on the agreements concluded between originator and generic companies. It is recognised that the work done in connection with these reports is an important instrument in understanding the pharmaceutical sector in the EU. However, criticism has been raised of some of the ways in which the data is presented in the Sector Report. Specifically the comparison of judgements being favourable to the generic company with patent settlements appearing to be
favourable to the generic because of including early entry and/or a reverse payment is criticized. Also the presentation of the companies' considerations when entering a patent settlement gives rise to criticism.

The analysis of the Sector Report and following monitoring reports has led to the conclusion that an underlying presumption exists of the object of patent settlements with a reverse payment being anti-competitive. Although the Sector Report clearly states that it does not question the patent system, it leaves an impression of not taking the considerations of the patent system into account.

It has been discussed if patent settlements with reverse payments could be efficiently approached by considering the agreements to restrict competition by object. Based on the analysis of the incentives to enter patent settlements with reverse payments it is concluded that considering such agreements to restrict competition by object will not be a reasonable approach. In the event that it can be determined with a high level of certainty that an originator company as a patent holder knowingly defends an invalid patent through such an agreement, or effectively expands the scope of the patent, such an agreement may be considered to cause a restriction of competition by object.

The approach of proving the effect of patent settlements with a reverse payment according to Article 101(1) of TFEU has been analysed. It is concluded that the advantage of such an approach is that the agreements will be assessed in their factual, legal and economic background, which is considered necessary to establish the full outcome of a patent settlement. The disadvantage of such an approach is that such an assessment will be time consuming, which will delay the guidance that is needed in this area. In addition the more fact specific the approach, the less predictable case law might be. However, based on the factual complexity of patents in the pharmaceutical sector, it is concluded that the consideration of reaching well founded decisions should outweigh the desire to eliminate patent settlements that restrict competition as quickly as possible.

Furthermore it has been discussed whether US case law and its experience with patent settlements can be used in the EU. It has also been discussed whether the principle of "rule of reason" which is developed in the US exists or should exist when applying
EU competition rules. It is concluded that the US’ experience with patent settlements can be used as inspiration but that the legal systems and their histories in the US and the EU are too different to justify a more direct application of the reasoning in US case law. Regarding the existence of a "rule of reason" sufficient support of is not found in previous case law and it is concluded that the current structure of Article 101 of TFEU does not accommodate a "rule of reason" approach. It also concluded to be preferable that the EU chooses its own vocabulary and defines its content to adopting a pre-determined principle.

Finally the legal status of patent settlements with a reverse payment in the EU is discussed. It is concluded that the legal status is still uncertain and that the guidance that the Commission has provided so far is not satisfactory. Although the Sector Report was published over four years ago and the first decision has been reached by the Commission in the Lundbeck case, guidance on the matter does not seem to have been developed. A registered decrease in the number of potentially problematic patent settlements will benefit the consumers. However, it is considered that the decrease might be occurring because of the legal uncertainty and if that is the case, a continued lack of guidance and legal uncertainty will ultimately harm the consumer by resulting in a decrease in/of innovation.
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