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Who can compete?

- Analysing the concept of potential competition in reverse patent settlements

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Contents

Summary

After the General Court's (GC) decision in case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v Commission* it seems the concept of potential competition in the context of so-called 'pay-for-delay' agreements, or reverse patent settlements, might have been altered; that the bar in order for an undertaking to qualify as a potential competitor might have been lowered. This thesis aims to examine whether this is true, and if so to what extent. Starting with an introduction to competition law and the concept of patent settlements, followed by a description of the specifics of Article 101 TFEU, and the relationship between competition law and intellectual property rights, this essay aims to provide enough knowledge that the reader will have no trouble following the analysis of the case and its potential implications.

In 2010, the Commission launched formal proceedings against Lundbeck, a Danish pharmaceutical company, which in 2002 and 2003 had entered into agreements with four generic pharmaceutical undertakings concerning the anti-depressant citalopram. The four companies undertook to not enter the market with generic versions of citalopram for a certain period of time. In exchange, Lundbeck paid each sums which largely corresponded to the profits that the generic firms expected to make had they entered the market, or to the damages they would have obtained if they had been successful in litigation against Lundbeck. The agreements were all separately found, by the Commission and later also the GC, to infringe Article 101(1) TFEU by object as they restricted potential competition. At time the agreements were concluded Lundbeck's original compound patents had expired, however they still held a number of process patents. Had any of the four generic undertakings chosen to enter the market they might have done so at risk of infringing one of Lundbeck's patents. The Commission and the GC however still regarded the four companies to be potential competitors to Lundbeck, thus paying them to stay off the market was a restriction on competition.

Comparing the ruling in *Lundbeck* to previous case-law dealing with the concept of potential competition, and relying on comments and opinions by legal scholars and practitioners the analysis centres around whether the GC did right in defining potential competition as it did, and what the implications of the case might be in that regard. Many questions remain without answer in the GC's judgement, hopefully clarification will be provided for when the European Court of Justice reviews the case, which is currently under appeal.

Preface

Since starting my legal studies I have always known that I wanted to combine the Swedish law programme with courses which had a focus towards EU law. After my exchange semester at Maastricht Universiteit I had become even more sure of this, and had found my interest for EU competition law specifically. Finding a Master's programme at my home university in Lund has offered me a chance to deepen my knowledge in both EU law in general, as well as in specifically EU competition law.

My five years at Lund University have been a delight. Thank you all who have been a part, and a special thank you to my supervisor Justin Pierce for supporting me in the writing of this essay.

Sofie Olovsson, Lund, 2017.

Abbreviations

API	Active pharmaceutical ingredient
ECJ	Court of Justice
EU	European Union
GC	General Court
IPR	Intellectual property rights
NCA	National competition authority
SPC	Supplementary protection certificate
TEU	Treaty of the European Union
TFEU	Treaty on the functioning of the European Union

1 Introduction to the Research

This essay is focused around the concept of potential competition in reverse patent settlements under Article 101 TFEU. As the EU courts do not limit their investigations of what might amount to an infringement of Article 101(1) to only involving actual, but also potential competition, the notion, and its scope, provides for an interesting topic to analyse.

1.1 Purpose and Research Question

The overarching purpose of this essay is to review the concept of potential competition in the context of patent settlements containing reverse payments, so-called 'pay-for-delay' settlements or 'pay-for-delay' agreements. The research keeps focus on when these agreements should be found to infringe EU competition law, more specifically Article 101(1) TFEU. It is fairly easy to see how paying a potential competitor to stay off the market in which you are active may very well distort competition, and in the end harm consumers which may have to pay more for a product than they would had there been more competition. However, what happens if an undertaking enters into a pay-for-delay agreement with another company which might not have been able to enter the market due to e.g. legal obstacles, even if the agreement had not been in place? Has the agreement then actually amounted to an infringement of potential competition, and thus EU competition law?

With the recent Commission decision and General Court (GC) ruling in the *Lundbeck*-case[1] these questions have been raised. In this essay I attempt to look into the concept of potential competition and how far the notion stretches, in order to provide an answer to the question:

- *Given the ruling in Lundbeck, has the scope for who can be regarded as a potential competitor in pay-for-delay agreements been extended?*

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[1] Commission Decision C (2013) 3803 final, *Lundbeck*; Case T-472/13 *H Lundbeck A/S and Lundbeck Ltd v Commission.*

1.2 Research Aims

With a primary aim of answering the question posed above, this research centres around the Commission decision and GC ruling in the case of *Lundbeck v Commission.*[2] My aim is essentially to investigate what changes the ruling may have brought about as regards potential competition in patent settlement cases, and what possible positive or negative outcomes these changes might have for EU competition law, if any at all. Further, the aim is to investigate whether the conclusions drawn by the Court and Commission in *Lundbeck* can be applied in a general sense to the concept of potential competition or if they are so specific that they might only be applicable in the specific circumstances of the pharmaceutical sector, or even in the specific case itself. My hope is that this essay will facilitate access to information on the topic for students, as well as others who are new to the notions described.

1.3 Research Limitations and Delimitations

The focus of this essay lies solely on the concept of potential competition in pay-for-delay agreements under EU law. No wider comparisons will be made, not with Member State legislation, the situation and legislation in the United States, nor with the concept of potential competition in relation to other types of agreements or situations.

The concept will only be scrutinised under Article 101 TFEU, not under Article 102 as potential abuse of a dominant position. As regards Article 101, the main focus lies on the first paragraph as it is the one containing the prohibition. The possibility of being exempted under Article 101(3) is not elaborated on. As regards the restriction to competition law a pay-for-delay agreement might be regarded as, no deeper analysis is provided for on whether this should be deemed a restriction by object or effect. Concerning relevant case law and comments by legal scholars and practitioners a selection has been made, although my hope is I have chosen in a way which facilitates

[2] Case T-472/13.

the understanding of my thesis in an adequate way, and in a way which illuminates different aspects.

All limitations to this essay have been made in order to focus on, and analyse deeply enough, where the bar is set for potential competition in pay-for-delay agreements since the delivery of the *Lundbeck* ruling. In order to do so, and due to lack of space certain very interesting aspects surrounding the topic of this essay have been excluded, even though these aspects might have provided me with more context and a deeper understanding.

1.4 Selected Review of Literature

There is no lacking of literature in the field of EU competition law, meaning rather than having trouble finding material the challenge was to select what to include and what not to. For the more introductory and descriptive parts of this essay the works of Whish and Bailey, and Faull and Nickpay, have provided great help, as they present information in a well-structured and neutral manner. It is also to the works of these authors I have turned when attempting to describe the relation between competition law and intellectual property rights (IPRs). The more analytical sections specifically regarding the *Lundbeck* case include comments and papers by Dunne, Friend, and the trio Boehme, Frank and Kerber, which all tackle reverse patent settlements and present different views on the matter. In selecting these authors my goal has been to provide the reader with an assortment of opinions which can, hopefully, lead to a greater and more nuanced understanding of the concept of potential competition in pay-for-delay settlements, and what implications the ruling in *Lundbeck* might have in this regard.

1.5 Research Method and Materials

The materials used in this research are the main available sources of EU law; primary EU legislation (mainly Article 101 TFEU and the Regulation on Technology Transfer Agreements[3]), relevant case-law from the courts of the

[3] Commission Regulation No 316/2014, OJ [2014] L 93/17.

EU, related Commission Decisions, as well as relevant Guidelines from the Commission. Academic works, such as books, papers and commentaries are included as well, and have been helpful in providing context and a wider understanding for the issues related to my research question.

1.5.1 Legal Doctrinal Method

The chosen method is the legal doctrinal method (or legal dogmatics). The method aims to form a base which provides for an understanding and explanation of the existing law, while also providing for a further discovery and evaluation of the law, often leading it to change.[4] Legal dogmatics include the inquiry of the law as it is (*de lege lata*) , as well as the possibility to express an opinion of how the law should be (*de lege ferenda*).[5] In attempting to answer the main research question, both aspects of the legal doctrinal method provide useful. Any piece of legislation cannot be properly evaluated if separated from the context surrounding it, and the concept of potential competition in reverse patent settlements thus cannot be properly assessed without the overarching context of EU competition law and its purpose and goals.

1.6 Outline and Disposition

This thesis leads with an introduction to EU competition law and the concept of patent settlements, followed by an introduction to Article 101 TFEU, and an overview of the relationship between competition law and intellectual property rights. The concept of potential competition is introduced, including relevant case law on the topic. Lastly the Commission decision and GC ruling in *Lundbeck* are presented, along with as well positive as critical comments by legal scholars and practitioners, before a final analysis is made with a focus on providing an answer to the research question.

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[4] Stelmach, Jerzy & Brozek, Bartosz, *Methods of legal reasoning*, Dordrecth: Springer, 2006, pp 17-19.

[5] Eng, Svein, *Fusion of Descriptive and Normative Propositions. The Concepts of 'Descriptive Proposition' and 'Normative Proposition' as Concepts of Degree*, Ratio Juris Issue 3, 2000, pp 236-260.

2 Introduction to EU Competition Law

The European Union (EU) is established by two Treaties: these are the Treaty of the European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU). Through these Treaties, the Member States entrust the EU with certain competences, in order for the Union's objectives to be fulfilled.[6] One of these objectives is the establishment of an internal market, which shall work for a highly competitive social market economy.[7] Protocol 27 to the Treaties[8], having the same force[9], states that the internal market as set out in Article 3 TEU includes a system ensuring that competition is not distorted. Hence, competition law is an important part of EU law, and a large portion of EU law is aimed at eliminating possible obstacles to free movement, and promoting competition within the Union.[10]

The main EU competition rules, which the EU has an exclusive competence in establishing[11], are contained in Articles 101-109 TFEU and the EU Merger Regulation[12]. The focus of the essay remains on Article 101 TFEU, which through its first paragraph prohibits agreements, decisions by associations of undertakings and concerted practices that have as their object or effect the restriction of competition, unless certain conditions set out in the third paragraph are met.

The EU institution with the main responsibility as regards competition law is the European Commission (the Commission).[13] The Commission carries out investigations, and is the body which will take action against infringements

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[6] Article 5 TEU.
[7] Article 3(3) TEU.
[8] Protocol (No 27) on the internal market and competition.
[9] Article 51 TEU.
[10] Whish, Richard & Bailey, David, Competition Law (8th Edition), Oxford Competition Law [OCL], July 2015, p 52 f; Craig, Paul & de Búrca, Gráinne, EU Law: Texts, Cases, and Materials, (6th edition) Oxford University Press, 2015, pp 1001-1002.
[11] Article 3(1)(b) TFEU.
[12] Council Regulation 139/2004 on the control of concentrations between undertakings, OJ [2004] L 24/1.
[13] Article 17(1) TEU.

of competition law through adopting decisions and imposing penalties on breaches. It is the Commission which adopts block exemption regulations, develops policy and legislative initiatives, and cooperates with National Competition Authorities (NCAs). [14] A party subject to a Commission decision can however submit an appeal against such a decision. In that case the GC will review the legality of the decision in accordance with the relevant provisions in TFEU.[15] The GC can assess evidence, annul a contested decision and alter the amount of a fine.[16] A decision from the GC can in turn be appealed to the Court of Justice (the ECJ), however only on points of law.[17]

2.1 Introduction to Patent Settlements

The Commission, having a leading role in EU competition policy, can also conduct so-called sectoral inquiries. During recent years the pharmaceutical sector has been given much attention.[18] Especially reviewing settlements of patent disputes has been highly prioritised. Patent settlements are, as other settlement agreements, agreements which aim to settle a dispute between two parties, thus avoiding litigation in front of a court.[19] Specific for patent settlements is that they will settle a patent dispute. The certain kind being relevant for this essay is pay-for-delay settlements, also called reverse patent settlements. These are agreements where the owner of an IPR (typically a patent) will transfer value, usually in the form of a monetary transfer, to another undertaking. In exchange the latter offers a commitment to delay entry into, or not enter, the market with a generic product at a lower price.[20] The value transfer being the 'pay' for the commitment to 'delay' entry explains the name.

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[14] On the powers of the Commission, see Council Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.
[15] Article 261 (penalties); Article 263 (actions for annulment); Article 265 (failures to act).
[16] C-386/10 P *Chalkor AE Epexergasias Metallon v European Commission*, para 67.
[17] Whish & Bailey, p 58.
[18] See the Commission's *Pharmaceutical Sector Inquiry Report* of 8 July 2009.
[19] Whish & Bailey, p 838.
[20] Faull, Jonathan & Nikpay, Ali, The EU Law of Competition (3rd Edition), Oxford Competition Law [OCL], March 2014, pp 1888 -1889; Guidelines on the application of Article 101 to technology transfer agreements, para 238.

3 Article 101 TFEU

In order to understand why pay-for-delay settlements can harm competition, one must study the rule which they are in danger of breaching. As stated this essay focuses only on the probability of breaching Article 101 TFEU, therefor this is the rule which needs to be considered. Breaking down the article the first paragraph states the prohibition, paragraph two declares all actions in breach of paragraph one to be automatically void, and the third paragraph offers a possibility to be exempted from paragraph one if certain criteria are fulfilled. This essay, and particularly this chapter, focuses only on the first paragraph.

3.1 What does Article 101 prohibit?

Article 101 (1) TFEU states:

The following shall be prohibited as incompatible with the internal market: 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…

By looking at the wording it can be noted that there are quite a few criteria to be met in order for the article to be applicable. Firstly, the parties to the agreement must be undertakings. The Court of Justice has defined an undertaking as 'every entity engaged in an economic activity regardless of the legal status of the entity and the way in which it is financed'[21]. The offering of goods or services on a given market constitutes an economic activity,[22] leading a pharmaceutical company to fulfil the first criteria in Article 101(1) TFEU.

[21] Case C-41/90 *Höfner and Elser v Macrotron GmbH*, para 21.
[22] Joined Cases C-180/98 to C-184/98, *Pavel Pavlov and others v. Stichting Pensioenfonds Medische Specialisten*, para 75.

Secondly, the actions of the undertakings concerned must amount to an agreement, decision or concerted practice. Article 101(1) covers agreements[23] both on a horizontal and vertical level, meaning both agreements between competitors as well as between non-competitors; actors on different levels of the market, for example a supplier and a distributor, are included under the article.[24]

What does then constitute an agreement which is at risk of being caught by Article 101(1)? The ECJ has stated that the important factor is 'the existence of a concurrence of wills'[25], however how this is manifested or formulated is not what is of importance. Consequently an agreement may take a variety of shapes and forms; an oral agreement[26], the exchange of correspondence[27], or a so called gentlemen's agreement[28] have all been deemed by the GC or the ECJ to constitute an agreement within the meaning of Article 101(1) TFEU. As regards judicial settlements; agreements between undertakings to settle litigation, e.g. on matters of intellectual property as is the case with pay-for-delay agreements, these may very well fall under Article 101(1).[29]

Concerted practices entail conduct which does not stem from an agreement or decisions but which can nevertheless come to be caught by Article 101(1). In a leading case on the matter, commonly referred to as the *Dyestuffs* case[30], the ECJ upheld a Commission decision where the Commission found an infringement of Article 101(1) through looking at things such as informal contact, timing of price increases and instructions going out from parent to subsidiary. The Court stated in its ruling that concerted practices falling with the scope of Article 101(1) aim to prohibit 'a form of coordination between undertakings which, without having reached the stage where an agreement

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[23] I will use the term agreement short for agreements, decisions and concerted practices.
[24] Joined Cases 56 and 58-64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission*; Whish & Bailey, p 103.
[25] Case T-41/96, *Bayer v Commission*.
[26] Case 28/77 *Tepea v Commission*; Cases T-25/95 etc *Cimenteries CBR SA v Commission.*
[27] Case C-260/09 P Activision Blizzard Germany GmbH v Commission.
[28] Case 41/ 69 *ACF Chemiefarma NV v Commission*; Case T-53/03 *BPB plc v Commission*.
[29] Faull & Nikpay, p 217; Commission Decision C (2013) 3803 final, *Lundbeck*; Commission Decision OJ 1982 L379/19, *Toltecs-Dorcet*.
[30] Case 48/69, *ICI v Commission.*

properly so-called has been concluded, knowingly substitutes practical cooperation between them for the risks of competition.'[31] In a situation where all incriminating evidence may have been destroyed by the parties it is important that the Commission be able to rely on even a thing such as parallel behaviour on the market in order to capture illegal conduct.[32] However, as patent settlement agreements, such as pay for delay agreements, are formal, written agreements it is not necessary for the sake of this essay to further examine the notion of concerted practices.

As the concept of decisions between associations of undertakings is relevant mainly when dealing with trade associations this will not be examined here.

3.2 Restriction by Object or Effect

A third criteria is that the agreement at issue must have as an object or effect the prevention, restriction or distortion of competition. The two conditions are alternative, meaning only when it is not clear that an agreement has as its object to restrict competition is it necessary to consider if it might have such an effect.[33]

As regards restrictions by object this means such restrictions which 'by their very nature have the potential to restrict competition within the meaning of Article 101(1)'.[34] From the wording in the article it can be gathered that if an anti-competitive object is found there is no need for an actual anti-competitive effect. This has been repeatedly stated by the ECJ in a number of cases.[35] However in order to determine this every agreement must be looked at in the

[31] Case 48/69 *ICI v Commission*, para 64.
[32] Whish & Bailey, p 117.
[33] Case 56/65 *Société Technique Minière v Maschinenbau Ulm*, p 249.
[34] Case C-8/08 *T-Mobile Netherlands and Others v Raad van bestuur van de Nederlandse Mededingingsautoriteit*, para 29; Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (Guidelines on Cooperation Agreements), OJ [2011] C11/1, para 24; Guidelines on the application of Article 81(3) of the Treaty, OJ C101/97, para 21.
[35] Such as Joined Cases 56 and 58-64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission*, Case C-501/06 P, *GlaxoSmithKline Services Unlimited v Commission* and Case C-8/08 *T-Mobile.*

light of its objectives, context – legal as well as economic, the intent of the parties , as well as the agreement's content and way of implementation.[36]

For some time it seemed the test for what amounted to a restriction by object was expanding to be wider and wider; for example in *T-Mobile*[37] the ECJ stated that it is sufficient that a concerted practice, as the case was dealing with, has the potential to have a negative impact on competition in order to be ascribed an anti-competitive object.[38] However, in *Groupement des Cartes Bancaires*[39] the ECJ made an important clarification, saying that the GC had been erring in law when concluding that restriction by object was not a concept which needed to be interpreted restrictively. Rather 'the concept of restriction of competition 'by object' can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects'.[40]

If there is no restriction to competition by object 'the consequences of the agreement should then be considered and for it to be caught by the prohibition it is then necessary to find that those factors are present which show that competition has in fact been prevented or restricted or distorted to an appreciable extent. The competition in question must be understood within the actual context in which it would occur in the absence of the agreement in dispute'.[41] This means that the Commission at first hand, and in later instances the European courts, must assess whether there has been an infringement to competition law by the effects of an agreement, decision or concerted practice. In making this assessment one must look at the market as it behaves and contrast this with what could have been the situation had the agreement under scrutiny not been in effect. If the conclusion is that there would have

[36] Faull & Nikpay, p 235.
[37] Case C-67/13 P.
[38] Case C-8/08 *T-Mobile Netherlands and others v Raad van bestuur van de Nederlandse Mededingingsautoriteit*, para 31.
[39] Case C-67/13 P.
[40] Case C-67/13 P, *Groupement des cartes bancaires (CB) v European Commission*, para 58.
[41] Case 56/65, Société Technique Minière v Maschinenbau Ulm GmbH pp 249-250.

been appreciably more competition in the absence of the agreement, the agreement is having an anti-competitive effect and therefor is in breach of Article 101(1) TFEU.[42] The question of when this is the case, and how this is to be measured generally centres around two things. The first is the impact of the agreement on the internal market, and the second is the impact of the agreement on the process of rivalry, both between the parties to the agreement and/or from third parties.[43]

How the agreements in *Lundbeck* specifically were assessed relating to infringement by object or effect is discussed further down, and the information provided for in this chapter will hopefully serve as a good base for the discussion to follow.

3.3 An Effect on Competition

As stated above Article 101(1) prohibits agreements which have as their object or effect the prevention, restriction or distortion of competition. In order to know when something distorts competition one must first know what is meant by competition in this case. As regards Article 101(1) the notion covers not only restrictions of actual but also of potential competition.[44] This means that in terms of competitors it does not suffice to look at those already active on the relevant market. One must also factor in what effects the agreement at hand has on new potential actors on the market – is it creating barriers to entry or aggravating market circumstances in any other way? It is however important to note that in making this assessment, the view on what qualifies as potential competition is to be realistic; neither too speculative nor too theoretical.[45]

According to the Commission's Guidelines on cooperation agreements, a company is to be treated as a potential competitor of another company if, in absence of the agreement, it would be likely that in the case of a small but

[42] Faull & Nikpay, p 237.
[43] Ibid.
[44] Case T-504/93 *Tiércé-Ladbroke v Commission*, paras 158-159; Case T-461/07 *Visa Europe Limited and Visa International Service v Commission*, paras 127, 131, and 146.
[45] Guidelines on Horizontal Cooperation Agreements, para 10.

permanent increase in relative prices the former company would undertake the necessary additional investments or other necessary switching costs to enter the relevant market on which the latter is active, within a short period of time.[46] The concept of potential competition specifically in pay-for-delay situations will be examined in Chapters 4 through 6.

3.4 *De Minimis* & Effect on Trade between Member States

In addition, for Article 101(1) to be applicable, there is a rule of double appreciability which needs to be satisfied. The effects of an agreement must have an appreciable effect on competition as well as on trade between Member States. Agreements which effect competition and would normally be caught by Article 101(1) will nevertheless not be caught if they lack having an appreciable impact either on competition or on inter-state trade.[47] This doctrine, called the *de minimis* doctrine, was formulated in *Völk v Vervaecke*[48] and has since then been repeated a number of times. The recent ruling in *Expedia Inc v Autorité de la Concurrence*[49] has however provided for a significant clarification. As restrictions by object are 'by their very nature…injurious to the proper functioning of normal competition'[50], an agreement restricting competition by object is automatically in violation of Article 101(1) TFEU, as long as it may effect trade between Member States.[51] This clarification eliminates the burden on the Commission of proving double appreciability when dealing with object restrictions.

The criteria of affecting trade between Member States has historically been interpreted widely, thus giving Article 101(1) a large scope.[52] Today, when all Member States have effective competition rules of their own, abusive behaviour can be caught without the help of EU competition law. However,

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[46] Guidelines on Horizontal Cooperation Agreements, para 10.
[47] Case 5/69, *Völk v Vervaecke* p 295.
[48] Case 5/69.
[49] Case C-226/11.
[50] Ibid, para 36.
[51] Case C-226/11, *Expedia Inc v Autorité de la Concurrence,* para 37.
[52] Whish & Bailey, p 154.

determining whether an agreement or practice has an effect on trade between Member States is still of importance, because this is turn impacts how national law and EU competition law should work together; e.g. when a NCA is obliged to apply Article 101 and 102[53], how communication between NCAs and the Commission should work[54], and when stricter national rules are allowed[55].

The effect on trade criterion is fulfilled when an agreement may affect trade between Member States, and the effects are appreciable.[56] Trade between Member States is a wide concept and covers all cross-border activity as well as activities which affect the competitive structure of the market, meaning a situation where only parts of states are affected is enough.[57] The notion 'may affect' means that, on the basis of a set of objective factors of law or fact, it must be possible to foresee that the agreement or practice may have an influence on the pattern on trade between Member states. This influence may be direct or indirect, actual or potential.[58] As regards appreciability a presumption can be made that the stronger a position on the market the undertakings concerned hold, the more likely it is that their actions will have an appreciable effect on trade between Member States.[59] The Commission's Guidelines on inter-state trade[60] provide two rebuttable presumptions, based on market shares and annual turnover, as guidance for when an agreement or practice is likely to have or not have an appreciable effect on trade between Member States.[61] Examining these further, however, is not within the scope of this research.

As a final comment for this chapter, important to note is that Article 101 TFEU does not cover unilateral conduct. As you cannot enter into an

[53] Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, Article 3(1).
[54] Ibid, Article 11.
[55] Ibid, Article 3(2).
[56] Article 101(1) TFEU; Whish & Bailey, pp 154-155.
[57] Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ [2004] C 101/81 (Guidelines on inter-state trade), paras 19- 20, 30.
[58] Ibid, para 23.
[59] Ibid, para 45.
[60] OJ [2004] C 101/81.
[61] Ibid, paras 52-53.

agreement with yourself, two or more parties are required for Article 101 to be applicable. Unilateral conduct can still be caught by EU competition rules, however that is not something this essay has room to elaborate on.

Having examined Article 101, with a focus on paragraph 1, the following chapter studies the relationship between competition law and intellectual property law.

4 Competition Law and Intellectual Property Rights

In order to understand why and how pay-for-delay settlements can infringe competition law, and more specifically Article 101(1) TFEU, it is necessary to have some insight into the relationship between competition law and intellectual property rights. At first glance, it might seem that these two branches of law will inevitably conflict with one another. IPRs grant their owners exclusive rights, legal monopolies, e.g. through patents, copyrights and trademarks, whereas competition law has an open market as its goal. However, as has been explicitly stated – presuming such a conflict proves a lacking in nuance, and would be incorrect.[62] Rather the two legal areas can support one another, and share the common goal of protecting consumer welfare. The Guidelines on the application of Article 101 to technology transfer agreements[63], which are examined in the following section, state the following: 'Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy'.[64]

Still, there are ways in which the usage of IPRs may harm competition. As this essay focuses on Article 101(1) TFEU this article is the only piece of legislation examined in this context. The main way in which Article 101(1) can come into play when dealing with intellectual property is through different types of licencing agreements, they can be patent licences granting a territorial exclusivity, licences granting design rights, or software licences, to mention a few.[65] The Commission has adopted a Regulation[66] exempting

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[62] Whish & Bailey, p 812; Jacob, Robin *Competition Authorities Support Grasshoppers: Competition Law as a Threat to Innovation*, Competition Policy International, vol 9 nr 2 2013, pp 15-29.
[63] Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements OJ [2004] C101/2 (Technology Transfer Guidelines).
[64] Ibid, rec 7.
[65] Whish & Bailey, pp 819-821.
[66] Regulation 316/2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements (Regulation on Technology Transfer Agreements).

many of these so-called 'technology transfer agreements' from Article 101(1) in the same way as Article 101(3) can do. Many of such agreements will however not infringe Article 101(1) at all and do not need this block exemption, but are regarded as pro-competitive and believed to have the effect of improving economic efficiency.[67]

However, in a pay-for-delay settlement there is no intent or will to licence, the agreement instead serves to settle a dispute between two parties. Can such an agreement benefit from the Block Exemption Regulation or will it inevitably be caught by Article 101(1) TFEU?

4.1 Patent Settlements & the Technology Transfer Guidelines

The Commission has along with the Regulation on Technology Transfer Agreements also developed Guidelines on the Application of Article 101 TFEU to Technology Transfer Agreements.[68] Whilst there is no mention in the Regulation of settlement agreements the Guidelines provide some assistance on how these are to be viewed as regards the relationship between intellectual property rights and competition law.

In principle, a settlement agreement is a legitimate way of finding a mutually acceptable compromise to a legal dispute.[69] This goes for disputes regarding technology as well as for disagreements in several other commercial areas. It can save time and money for the disputing parties, at the same time as saving a court or competent administrative body the effort in deciding on the matter.[70] However, there is a difference to be made between settlement agreements which do in fact contain a licensing agreement, and pay-for-delay agreements which commonly do not involve any transfer of technology rights. Settlement agreements of the pay-for-delay type are based on a value

[67] Regulation on Technology Transfer Agreements, rec 4.
[68] OJ [2004] C101/2.
[69] Technology Transfer Guidelines, para 235.
[70] Ibid.

transfer from one party to the another, in return for a limitation on the entry and/or expansion on the market of the latter. The Guidelines state that these type agreements may very well be caught by Article 101(1).[71]

If such an agreement does include a licensing of the technology rights concerned by the underlying dispute, the agreement can still be caught under Article 101(1) after being assessed in the light of the hard-core restrictions provided for in Article 4 of the Regulation on Technology Transfer Agreements, if it leads to a delayed or otherwise limited ability for the licensee to launch the product on any concerned market.[72]

Having established that pay-for-delay agreements may very well come to be caught by Article 101(1) TFEU, the following chapter focuses on one criteria laid down in that same article in particular – namely the distortion of competition, more specifically the notion of potential competition. What does the concept entail, and how far does it stretch?

[71] Technology Transfer Guidelines, para 238.
[72] Ibid, para 239.

5 Potential Competition

5.1 Who can be a potential competitor?

As described in chapter 2 the Commission and the EU Courts will take into account the possibility that an agreement will affect not only existing, but also potential, competition when deciding whether Article 101(1) TFEU has been infringed.

It is well established that potential competition is one of the relevant parameters to include when making an assessment under Article 101(1). In analysing the conditions of competition within which an agreement is to be implemented, the GC has stated that the examination is to be 'based not only on existing competition between undertakings already present on the relevant market but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are 'real concrete possibilities' for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market and compete with established undertakings'.[73] In order to demonstrate that an undertaking has such 'real concrete possibilities' to enter the relevant market there is a need for support in form of factual evidence or an analysis of the structures of said market.[74] Consequently, an undertaking can only be regarded as a potential competitor if its entry into a market is an economically viable strategy.[75] Important to bear in mind is that in assessing whether or not an undertaking can be regarded as a potential competitor is that it is never the intention of a potential competitor which is determinative. Whether an undertaking wishes to enter the market or not is irrelevant. The key criterion is simply whether there is a de facto ability for an undertaking to enter the relevant market.[76] This means that the mere existence of an

[73] Case T-374/94 *European Night Services v Commission*, para 137
[74] Case T-360/09, *E.ON Ruhrgas and E.ON v Commission*, para 86.
[75] Ibid; Case T-461/07, *Visa Europe and Visa International Service v Commission*, paras 166-167.
[76] Case T-360/09, *E.ON Ruhrgas and E.ON v Commission*, para 86; Case T-461/07, *Visa Europe and Visa International Service v Commission* paras 168-169.

undertaking currently outside a given market may give rise to competitive pressure on the undertakings currently operating in that market.[77] This competitive pressure is linked to the probability that such a new competitor will enter the market in the case that it becomes more attractive for it to do so.[78]

Should one as an active participant on the relevant market however be obliged to take into account a potential competitor if, say, that potential competitor has been in a position of having 'real concrete possibilities' to enter for several years and still not entered? Would this not have a negative impact on competition at large? The Commission Guidelines on cooperation agreements at Paragraph 10 state, as mentioned above, that 'a company is treated as a potential competitor of another company if… it is *likely* that the former, *within a short period of time*, would undertake the necessary additional investments or other necessary switching costs to enter the relevant market' (emphasis added). What qualifies as a 'short period of time' has been discussed by both the Commission in its Guidelines, more specifically in the footnotes, as well as by the GC in e.g. case *Visa.*[79]

In *Visa* reference is made to the previous version of the Guidelines on cooperation agreements[80], which stated that a likely market entry had to happen sufficiently fast that the threat of a potential entry would be a constraint on the behaviour of the undertakings active on the market. This would normally mean a period of maximum one year, though longer time periods could be taken into account in individual cases.[81] The GC did however come to find the period of one year as being merely illustrative.[82] The Guidelines have since been revised and in the present time a period of not more than three years is considered a 'short period of time'. Still, it is important to bear in mind that this does not mean that a potential competitor must enter the market within three years of having the ability to do so. All it

[77] Case T-461/07, *Visa Europe and Visa International Service v Commission*, para 169.
[78] Ibid.
[79] Case T-461/07, *Visa Europe and Visa International Service v Commission.*
[80] OJ 2001/C 3/02.
[81] Ibid, footnote no 9.
[82] Case T-461/07, *Visa Europe and Visa International Service v Commission* para 189.

means is that if in the absence of the possibly anti-competitive agreement, in case of a small but permanent increase in relative prices, it is *likely* that an undertaking would enter the relevant market within a 'short period of time', then it should be regarded as a potential competitor.

Having looked into the qualifications of potential competition the following section presents some important case law revolving around the concept.

5.2 Pre-*Lundbeck* Case Law

5.2.1 *European Night Services and others v Commission*

European Night Services Ltd ('ENS') was a joint venture set up by four railways companies, which intended to operate night passenger services through the Channel Tunnel in conjunction with its parent companies. Following notification of the agreement, the Commission concluded that the so-called ENS agreements had the potential of restricting actual or potential competition between the parent companies, between the parent companies and ENS, as well as vis-a-vis third parties.[83]

The GC however rejected this conclusion. The Commission's finding was merely a hypothesis 'unsupported by any evidence or any analysis of the structures of the relevant market from which it might be concluded that it represented a real, concrete possibility'[84] The Commission had failed to make a correct and adequate assessment of the economic and legal context in which the ENS agreements were concluded[85]. It therefore did not demonstrate the existence of restrictions of potential competition within the meaning of Article 101(1) TFEU.

[83] Case T-374/94 *European Night Services v Commission*, para 135.
[84] Ibid, para 142.
[85] Ibid, para 144.

5.2.3 *Visa Europe Ltd v Commission*

In *Visa Europe Ltd v Commission*[86] Morgan Stanley, a financial institution, was denied Visa International membership in the 'European Union' region, on the ground that Morgan Stanley then owned the Discover Card network, considered to be a competitor of the Visa network. The refusal lasted from 2000 until 2006, when Morgan Stanley was granted membership and withdrew its complaint to the Commission. The Commission however decided to nonetheless fine Visa International and Visa Europe.[87]

According to the Commission, the result of the refusal was the prevention of a new potential competitor entering a market in which there was scope for further competition, despite it being marked by a high degree of concentration.[88] The refusal to admit Morgan Stanley had not only prevented it from providing services for the acceptance of Visa cards, but also excluded it from transactions effected using MasterCard cards. Since merchants prefer to conclude a single contract covering all their transactions, they want to enter into contracts for acceptance of Visa and MasterCard with one and the same acquirer. Being refused Visa International membership thus put Morgan Stanley at a disadvantage also in the market for transactions effected using MasterCard.[89]

As regards the assessment whether Morgan Stanley qualified as a potential competitor the GC stated that an undertaking's intention to enter a market may be relevant to consider, however this is not the essential factor. The essential factor is instead the actual ability of an undertaking to enter that market.[90] Entry into the market must be an economically viable strategy.[91] In the case at hand Morgan Stanley's entry into the market was not merely a theoretical hypothesis, rather it was a plausible assumption that the

[86] Case T-461/07.
[87] Commission Decision C (2007) 4471 final, *Morgan Stanley*.
[88] Ibid, para 22.
[89] Ibid, para 23.
[90] Ibid, para 168.
[91] Ibid, para 167.

undertaking would enter. This meant the Commission had done rightly when describing Morgan Stanley as a potential competitor.[92]

5.2.4 *E.ON Ruhrgas and E.ON v Commission & GDF Suez SA v Commission*

In Joined Cases *E.ON Ruhrgas and E.ON AG and GDF Suez SA v Commission*[93] the Commission had fined the two energy companies E.ON and GDF Suez (GDF) for infringing EU competition law, due to a market-sharing agreement regarding the French and German markets for natural gas.[94] When the two companies in 1975 decided to together build a pipeline importing Russian gas to Germany and France the two also decided to divide the market amongst themselves and agreed not to sell gas conveyed by that gas pipeline on each other's national markets.[95]

In France GDF had a legal monopoly on importation and supply of gas, until 2000, meaning that up until then the conduct as issue could not have restricted competition. Thus the infringement on the French market began in August 2000, at the time when competitors could have started supplying customers in France. In Germany however there was no monopoly in place, meaning the infringement began in 1980 when the pipelines became operational.[96] In 2004 the companies had confirmed that they had since long regarded the anti-competitive provisions of their agreement as 'null and void'.[97] Yet the Commission concluded that the agreement had, in fact, produced effects until at least the end of September 2005.[98] The companies both brought actions against the decision.

The GC mainly confirmed the Commission decision, however noting an error in the assessment of potential competition. Even though there was no

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[92] Case T-461/07 *Visa Europe Ltd v Commission*, paras 186-187.
[93] Joined Cases T-360/09 and T-370/09.
[94] Commission Decision C (2009) 5355 final, *E.ON/GDF.*
[95] Joined Cases T-360/09 *E.ON Ruhrgas and E.ON AG* and T-370/09 *GDF Suez SA v Commission*, paras 21-23.
[96] Ibid, para 38.
[97] Ibid, para 25.
[98] Ibid, para 40.

monopoly on the German market, there were other agreements in place, covered by an exemption until 24 April 1998, which had the effect of establishing *de facto* a system of areas of exclusive supply.[99] This meant, that up until the date when these agreements seized to be exempt there were *de facto* territorial monopolies covering the German gas market.[100] These agreements were likely to have as a result an absence of competition, both actual and potential, on the relevant market.[101] The Commission did not manage to show that, up until 24 April 1998, there would have been 'real concrete possibilities' for GDF to enter the German gas market, had the agreement at issue not applied.[102] Consequently, the Commission failed to establish the existence of potential competition between the companies on the German market for gas between 1 January 1980 and 24 April 1998, which could have been adversely affected by the agreement between them.

5.2.5 Summary

To summarise some of the leading case law pre-*Lundbeck* the GC has been consistent in demanding that the Commission show that, had the agreement at issued not applied, there would have been 'real concrete possibilities' for an undertaking to enter the relevant market, and compete with established undertakings. Such a demonstration must be supported by evidence or an analysis of the structures of the relevant market, and not be based on a mere hypothesis. Accordingly, it is not the will or intention to enter a market which is essential for deciding who is a potential competitor or not – it is the ability to enter. Having established this the following chapter presents the *Lundbeck* case, with a focus on the view of the Commission and the GC on the concept of potential competition.

[99] Joined Cases T-360/09 *E.ON Ruhrgas and E.ON AG* and T-370/09 *GDF Suez SA v Commission*, para 100.
[100] Ibid, para 102.
[101] Ibid, para 103.
[102] Ibid, para 104.

6 H. Lundbeck A/S and Lundbeck Ltd v European Commission

6.1 Facts and Circumstances

In 2002 and 2003, the Danish pharmaceutical company Lundbeck entered into agreements with four separate generic pharmaceutical companies concerning the anti-depressant citalopram, a product responsible for 85% of Lundbeck's turnover[103]. The product came both in the form of an active pharmaceutical ingredient (API) and in the form of a medicinal product. When the agreements were concluded Lundbeck's compound patents and data protection as well as the two original production process patents had expired. They did however still own a number of other process patents, including patents protecting the crystallisation process method ('crystallisation patents'), with one granted in the United Kingdom 30 January 2002[104], and one granted by the EPO on 22 September 2002.[105] These process patents granted Lundbeck exclusive rights on certain new ways of producing the product.[106] Yet, in principle, any undertaking using either the original production processes or a production process not covered by the still valid process patents could freely enter the EEA market with generic citalopram, provided they met the applicable regulatory requirements.[107]

Since Lundbeck had not managed to introduce citalopram onto the larger European market until till middle of the 1990's, but had patented the compound as early as 1976, the time available to commercially exploit the product was not very long.[108] The possibility of competitors entering their generic products into the European market, which was considered possible as

[103] Commission Decision C (2013) 3803 final, *Lundbeck,* rec 623.
[104] Ibid, rec 275.
[105] Ibid, rec 342.
[106] Ibid, rec 3.
[107] Ibid.
[108] Ibid, rec 123.

of year 2000[109], embodied the greatest threat to Lundbeck, given the company's strong dependence on sales of citalopram.[110]

At the time of the conclusion of the agreements, there was at least the potential of a patent dispute between each of the generic undertakings concerned and Lundbeck regarding the generic companies' intentions to sell citalopram in a specific area[111], mainly the UK market[112]. The companies with which the agreements were entered into had already begun the process of entering the market for generic citalopram, one had even succeeded.[113] Instead of trying to enforcing its process patents before national courts Lundbeck entered into patent settlement agreements with each of the generic undertakings.[114] The agreements each involved a transfer value from Lundbeck, to a value of around EUR 66.8 million in total[115] in return for the generic undertaking's promise not to sell generic citalopram in a certain geographical area for the duration of the agreement. This prevented the generic companies from marketing generic citalopram, regardless of whether such a product would have been produced in a way which infringed Lundbeck's process patents or not.[116] However, none of the agreements actually resolved a patent dispute; they merely postponed generic entry for a certain period of time.[117]

6.2 The Commission Decision

The agreements were brought to the Commission's attention by the Danish Competition Authority in 2003, after which the Commission began its investigation. In January 2008, the Commission decided to launch a broad inquiry into the pharmaceutical sector[118], and once the final report[119] of the

[109] Commission Decision C (2013) 3803 final, *Lundbeck*, rec 127-129.
[110] Ibid, rec 133.
[111] Ibid, rec 4.
[112] Ibid, rec 195.
[113] The generic undertaking Merck had successfully entered the Swedish market, see case T‑472/13, *Lundbeck v Commission, para 165.*
[114] Commission Decision C (2013) 3803 final, *Lundbeck*, rec 6.
[115] Ibid, rec 193.
[116] Ibid, rec 6.
[117] Ibid.
[118] Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003.
[119] Commission's *Pharmaceutical Sector Inquiry Report* of 8 July 2009.

sector inquiry had come out in 2009 formal proceedings against Lundbeck were launched in 2010.

As regards potential competition and whether or not the generic companies could be regarded as potential competitors the Commission stated in its decision that 'the agreements in the case at hand were agreements between undertakings that were at the time of events at least potential competitors'.[120]

The Commission took into account the specific characteristics of the pharmaceutical sector in doing its assessment, and found that the sector is characterized by a highly dynamic competitive process due to the holding and expiry of patents.[121] Generic undertakings will make hard efforts to be the first to compete with a generic version of an originator medicine,[122] and the process to do so may start well in advance of the actual patent expiry. The company which manages to be first may profit from high profit margins until competition is intensified through the entry of more generic competitors, when prices will tend to drop.[123] Because of this generic suppliers may be willing to make substantial investments as well as undertake certain risks, including that of infringing valid process patents that an originator undertaking might hold or might be applying for, in order to be the first to enter the market with a generic product.[124] Through time the market will saturate and prices usually drop significantly compared to what the originator undertaking could charge, a process which can take up to five years according to the Commission's assessment.[125]

In the view of the Commission a generic undertaking has the potential of becoming a competitive threat to an originator undertaking even years before a compound patent expires. The Commission in its decision recited the ECJ in *AstraZeneca*[126] where it stated that supplementary protection certificates

[120] Commission Decision C (2013) 3803 final, *Lundbeck*, rec 610.
[121] Ibid, rec 615.
[122] Ibid, rec 69.
[123] Ibid, rec 615.
[124] Ibid.
[125] Ibid, rec 124, 615.
[126] Case C-457/10 P, *AstraZeneca v Commission*.

(SPCs), which extend with a maximum of five years the patent protection of medicinal products that are protected by a basic patent in the territory of a Member State, and are subject to a marketing authorisation before being placed on the market, are liable, though adversely affecting potential competition, to alter the structure of the market even before the expiry of the basic patents.[127] According to the Commission this meant that the ECJ considers, in the pharmaceutical sector, that potential competition is likely to exist well before a basic patent expires, even when process patents are still in force.[128]

When the agreements between Lundbeck and the generic companies were concluded in 2002 and 2003 Lundbeck's basic patent on the citalopram compound had lapsed in most of the EEA area.[129] This meant that at that time, given that regulatory requirements as to quality, safety and efficacy were met, the market was open for generic citalopram medicine.[130] Hence, in the view of the Commission, generic undertakings with a market plan to sell citalopram that had a realistic prospect of obtaining supplies of generic citalopram and receiving marketing authorisation all in the near future, were potential competitors both to each other and Lundbeck.[131] According to evidence found by the Commission, Lundbeck had foreseen such competition from generic companies already in 1998. In November that year Lundbeck wrote: 'Generic competition is foreseen on markets where the product patent has expired or where generic suppliers may invent a new manufacturing process.'[132]

However, it was Lundbeck's opinion that companies which could compete on the market with products whose manufacturing was infringing Lundbeck's process patents could not be regarded as potential competitors, and held that this was the case at hand.[133] Hence, Lundbeck had a right to exclude these

[127] Case C-457/10 P, *AstraZeneca v Commission*, para 108.
[128] Commission Decision C (2013) 3803 final, *Lundbeck* rec 619.
[129] Commission Decision C (2013) 3803 final, *Lundbeck* rec, 621.
[130] Ibid.
[131] Ibid.
[132] Commission Decision C (2013) 3803 final, *Lundbeck,* rec 127, referencing Lundbeck's Budget and Activity Plan 1999.
[133] Ibid, rec 629, 672.

companies from the market.[134] The Commission did not accept this view. The Commission did agree that it is true that 'When granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right.'[135] However, it is not until a patent infringement has been proven, the generic undertaking has been injuncted by a court not to sell their product, and no possibilities of legal challenge remain, that a generic undertaking will seize to be regarded as a potential competitor of the originator undertaking.[136]

Launching a product at risk of facing litigation from Lundbeck for patent infringement hence constituted, according to the Commission, a 'real concrete possibility' to enter the market.[137] As patent litigation is very common in the pharmaceutical sector[138], the Commission stated that patent challenges, which were present in the case[139], are in fact also an expression of potential competition. They are an essential part of the competitive process between generic undertakings looking to enter the market for compounds that are no longer patent-protected and originator undertakings that invoke e.g. process patents against such market entry.[140]

Lundbeck was not, in the Commission's view, holding any right connected to its process patents to exclude the four generic competitors from the market though paying them as much as or more than they could possibly earn in profit from a market entry thus removing any incentive to compete with Lundbeck.[141] The Commission considered that in absence of the agreements

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[134] Commission Decision C (2013) 3803 final, *Lundbeck*, rec 672.
[135] Ibid, rec 628; Case T-321/05, *AstraZeneca AB and AstraZeneca plc v Commission*, para 362.
[136] Commission Decision C (2013) 3803 final, *Lundbeck,* rec 624.
[137] Ibid*,* rec 635.
[138] Ibid, rec 625.
[139] From e.g. the generic undertaking Merck which Lundbeck entered into two pay-for-delay agreements with in 2002, see Commission Decision C (2013) 3803 final, *Lundbeck,* rec 247.
[140] Commission Decision C (2013) 3803 final, *Lundbeck*, rec 626; Commission's *Pharmaceutical Sector Inquiry Report* of 8 July 2009, p 10-15 & 195-383.
[141] Ibid, rec 676.

at issue ‘there would have been real concrete possibilities for the generic undertakings to enter the market. The possibility of entering represented a plausible assumption and not a merely theoretical hypothesis.’[142] Consequently, the agreements amounted to four separate infringements by object of Article 101(1) TFEU[143], and the Commission imposed fines on all parties to the agreements at issue.

6.3 General Court Ruling

Lundbeck challenged the Commission decision before the GC[144], however without success. The company’s claims relating to potential competition were that the launch of generic products that infringed their IPRs could not be an expression of potential competition[145], that the Commission had been relying on subjective assessments when determining whether the generic undertakings were actual or potential competitors of Lundbeck[146], and that challenging a valid patent did not constitute such a ‘real concrete possibility’ of entering the market as demanded by settled case law[147].

The GC rejected all Lundbeck’s arguments, stating that the presumption of validity of a patent does not automatically equate a presumption of illegality of generic products which are claimed by the patent holder to infringe the patent.[148] The Court also pointed out that the original patents had expired and the UK crystallisation patent had not yet been granted at the time for two of the agreements at issue.[149] Furthermore, the GC said, it was not clear that Lundbeck would actually have initiated patent infringement proceedings if any of the generic undertakings had entered the market, as they knew their crystallisation patent was “not the strongest of all patents”.[150] The aforementioned meant that the generic companies actually had several ‘real

[142] Commission Decision C (2013) 3803 final, *Lundbeck*, rec, 636.
[143] Ibid, rec 824.
[144] Case T‑472/13, *Lundbeck v Commission*.
[145] Ibid,
[146] Ibid,
[147] Ibid,
[148] Ibid, para 121.
[149] Ibid, para 127.
[150] Ibid, para 126.

concrete possibilities' of entering the market when the agreements at issue had been concluded, including the launch of a generic product that might have led to facing litigation from Lundbeck.[151] According to the Court, that possibility represented an expression of potential competition.[152]

The GC found no evidence to the fact that the Commission had not been objective enough in its assessment of whether the generic undertakings constituted actual or potential competition to Lundbeck. The examining of whether the generic undertakings had 'real concrete possibilities' of entering the market had been carried out carefully by the Commission, and relied on objective evidence, in the view of the Court.[153]

Lastly, in response to Lundbeck's argumentation that the Commission excessively stretched the boundaries of potential competition by considering the challenging of Lundbeck's valid patents as 'real concrete possibilities' of entering the market the GC stated that 'the Commission did not take the view… that the mere possibility of challenging the validity of a patent before a court or before the competent authorities suffices to establish the existence of potential competition.'[154] They had rather taken several factors into consideration when reaching this conclusion, such as the efforts and investments made by the generic undertakings in order to be able to enter the market, and the fact that some of Lundbeck's process patents might not be valid. Also, the fact that Lundbeck had decided to pay the companies to stay off the market showed that the generic undertakings were potential competitors, as Lundbeck actually perceived them to be a competitive threat on the market, the Court claimed.[155] The Court also pointed out that the sums paid by Lundbeck largely corresponded to the profits that the generic firms expected to make had they entered the market, or to the damages they would have obtained if they had been successful in litigation against Lundbeck. This

[151] Case T‑472/13, *Lundbeck v Commission*, para 128.
[152] Ibid, para 129.
[153] Case T‑472/13, *Lundbeck v Commission,* paras 141-142.
[154] Ibid, para 157.
[155] Ibid.

removed any incentive for the generic undertakings to contest the validity of Lundbeck's patents. [156]

The Court upheld the Commission's finding that the agreements at issue all amounted to restrictions to competition by object. However, this does not mean all patent settlements containing reverse payments should be regarded as restrictions by object within the meaning of Article 101(1) TFEU, only that the disproportionate nature of such payments, in combination with several other factors led to the conclusion that the agreements in *Lundbeck* had as their object the restriction of competition, within the meaning of Article 101(1) TFEU.[157] The GC dismissed Lundbeck's action before it in its entirety.[158] Lundbeck has appealed the judgement to the ECJ.[159]

Following the Commission decision and GC ruling, opinions have been raised regarding the *Lundbeck* case. The following section presents a few of these.

6.4 Opinions and Comments

6.4.1 Niamh Dunne

Niamh Dunne, Assistant Professor, London School of Economics and Political Science, has commented on to what extent the concept of potential competition, as used by the Commission and Court in *Lundbeck* to help reach the conclusion that the agreements at issue amounted to restrictions by object, has a grounding within the framework of EU competition law. Restrictions by object are such which can be regarded as being harmful to the proper functioning of competition by their very nature.[160] When examining a pay-for-delay agreement, whether such a harm will actually be realised depends to a large extant on antecedent assumptions, such as that market entry actually

[156] Case T‑472/13, *Lundbeck v Commission*, paras 398-399.
[157] Ibid, paras 354-355.
[158] Ibid, para 845.
[159] Case C-591/16 P: Appeal brought on 18 November 2016 by H. Lundbeck A/S, Lundbeck Ltd against the judgment of the General Court (Ninth Chamber) delivered on 8 September 2016 in Case T-472/13: *H. Lundbeck A/S, Lundbeck Ltd v European Commission.*
[160] C-67/13 P *Cartes Bancaires v Commission*, para 50.

will be attempted, and that the entry will be successful in lowering market prices, thus proving beneficial to consumers.[161] However, there is no requirement as to succeeding on the market in order to qualify as a potential competitor, only 'real concrete possibilities' for entry are needed.[162] Should an agreement with a potential competitor which might, in absence of the agreement, not have succeeded and furthered competition on the market, really qualify as harmful 'by its very nature'?[163] Dunne finds that since the ruling in *Cartes Bancaires*[164] where the ECJ held that an agreement should be assessed in light of the 'content of its provisions, its objectives and the economic and legal context of which it forms a part'[165], the ruling in *Lundbeck* is in fact compatible with Article 101(1) TFEU as the context provided for in the case confirmed the probability that the agreements at issue would in fact harm competition.[166]

6.4.2 Mark Friend

Mark Friend provides a different view in his commentary on the ruling.[167] As previously stated, 'real concrete possibilities' for entry, is the decisive factor when determining potential competition. But what happens, Friend asks, in a situation as in *Lundbeck*, where the patents held by the originator might actually have been infringed by entry into the market by generic undertakings? Were there in fact 'real concrete possibilities' for entry if such entry was potentially unlawful, and likely to provoke litigation?[168]

Friend finds the logic behind the statement from the GC that the presumption of validity of a patent 'cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent', and the view that "at risk" entry (entry at risk of

[161] Dunne, Niamh, *The Lundbeck Case and the Concept of Potential Competition,* Concurrences Review, No. 2, 2017, p 18.
[162] Dunne, p 19.
[163] Ibid.
[164] C-67/13 P.
[165] Ibid, para 53.
[166] Dunne, p 19.
[167] Friend, Mark, *Reverse Patent Settlements and EU Competition Law,* The Cambridge Law Journal*,* 76(1), 2017
[168] Friend, p 30.

infringing valid patents) actually was an expression of potential competition, to be hard to follow.[169] The fact that it is up to the patent holder to prove patent infringement does not exclude that entry would be unlawful if the patent holder is successful in challenging the generic entry.[170] With a restriction to competition by object the anti-competitive effects can be presumed, meaning there is never a need to prove actual effects or to consider the counterfactual (the situation in absence of the agreement). Accordingly, assessing a potential restriction to competition by effect demands a demonstration of anti-competitive effects, through contrasting the situation at hand with the situation in absence of the agreement.[171] Friend is of the opinion that the GC blurred the distinction between the two in its assessment of potential competition. The assessment of whether the generic companies had 'real concrete possibilities' to enter the market unavoidably infers some consideration of the counterfactual, however the Court fails to recognise this.[172] Referencing *Cartes Bancaires*[173], where the ECJ rejected arguments for a wide interpretation of the concept of restriction by object, Friend concludes that the GC has done exactly that. Generally, the judgement leaves many questions unanswered and provides very little guidance for those involved in negotiating patent settlements.

6.4.3 Enrico Böhme, Jonas Severin Frank and Wolfgang Kerber

Another interesting contribution, with a different focus, is that of Böhme, Frank and Kerber. Their paper[174] in MAGKS Joint Discussion Paper Series in Economics examines how antitrust assessments of patent settlements might influence the incentives for challenging patents, and whether such assessments should also consider their possible impact on the enticements to

[169] Friend, p 31.
[170] Ibid.
[171] Ibid.
[172] Ibid.
[173] C-67/13 P.
[174] Boehme, Enrico, Frank, Jonas Severin & Kerber, Wolfgang, *Optimal Incentives for Patent Challenges in the Pharmaceutical Industry*, MAGKS Joint Discussion Paper Series in Economics, 2017.

challenge potentially invalid patents. As patent systems rely on private litigation to challenge patents an interesting question to consider is when firms consider themselves to have enough incentive for challenging potentially invalid ('weak') patents.[175] One issue is that the challenging undertaking is not able to internalize all benefits from invalidating such a weak patent, since other competitors will also benefit from the removal of an unjustified monopoly.[176] This 'public good problem' can lead to inefficiently small challenging incentives for individual firms.[177]

There is a consensus that patent settlements with reverse payments from originators to generics can function as an effective tool for protecting weak patents against patent challenges which might lead to invalidation.[178] Using pay-for-delay agreements, originator undertakings will pay companies for not challenging their weak patents in front of a court, and consequently market entry and price competition will be delayed, which harms consumers.[179] As such, reverse patent settlements can function as an instrument for avoiding patent litigation and solving the issue of holding a weak patent.[180] A concern expressed by the authors is that too restrictive an antitrust policy against patent settlements, prohibiting reverse payment settlements could result in a decrease in generic firms' incentives for challenging weak patents.[181]

In the view of the authors, the present-day discussion almost exclusively focuses on on the effects of patent settlements on consumer welfare through their effects on prices, in the way that a later generic entry into the market will lead to an inefficiently late start of price competition and thus a decrease in prices.[182] However, this is not the only way in which patent settlements

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[175] Boehme, Frank, and Kerber, p 2.
[176] Ibid.
[177] Ibid; Farrell, Joseph & Merges, Robert, *Incentives To Challenge And Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors And Why Administrative Patent Review Might Help*, Berkeley Technology Law Journal, Vol 19, 2004; Farrell, Joseph, Shapiro, Carl, *How Strong Are Weak Patents?* American Economic Review, Vol. 98, No 4, 2008.
[178] Boehme, Frank, and Kerber, p 6.
[179] Ibid, p 2.
[180] Ibid.
[181] Ibid, p 3.
[182] Ibid, p 6.

can affect consumer welfare.[183] One should also take into account the effects of antitrust assessments of patent settlements on the incentives for generics to challenge patents. Simply stated, the assessment is that limiting the possibility for generics to engage in patent settlements which delay generic entry will reduce the incentives to challenge patents, since this would limit the possibilities for them to profit from patent settlements.[184] In this context it is interesting to note that the Commission in its Technology Transfer Guidelines has expressed that it is in the public interest to remove wrongly granted patents to promote competition and innovation.[185] A second, more far-fetching, argument against too strict antitrust limits on pay-for-delay agreements are that such limits might decrease incentives for originator firms to innovate. Since antitrust limits for patent settlements influence originators' profits a possible effect is the development of fewer pharmaceuticals, which would end up harming consumers.[186] This does however not seem to be an outcome competition authorities need to worry too much about.[187]

Through an existing model framework, the authors do however discover that allowing reverse patent settlements which delay the market entry of generic firms, compared to the expected market entry under patent litigation, can in fact increase consumer welfare under certain conditions. The outcome is dependent on e.g. the intensity of competition, the size of the challenging costs, and the duration of the delay of the generics' market entry compared to what it would have been in absence of the agreement.[188] In conclusion, taking into account challenging incentives when assessing pay-for-delay agreements under competition law does not alter the need for critical scrutiny in order to further elimination of the possibility to protect potentially unjustified and

[183] Boehme, Frank, and Kerber p 6; Frank, Severin & Kerber, Wolfgang, *Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?* MAGKS Joint Discussion Paper Series in Economics No. 01-2016.
[184] Boehme, Frank, and Kerber p 6; Dickey, Bret, Orszag, Jonathan & Tyson, Laura, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, Annals of Health Law, Volume 19, Issue 2 2010, Article 5, p 399.
[185] Technology Transfer Guidelines, rec 235.
[186] Boehme, Frank, and Kerber, p 6.
[187] Ibid; Elhauge, Einer & Krüger, Alex, *Solving the Patent Settlement Puzzle*, Texas Law Review, Vol. 91, 2012; Woodcock, Ramsi, '*Innovation, Litigation, and New Drugs*, 2016; Woodcock, Ramsi, *'Innovation and Reverse Payments'*, Florida State University Law Review, Vol. 43, 2017.
[188] Boehme, Frank, and Kerber, p 1.

weak patents that can harm consumers. Considering challenging incentives can however, as demonstrated, help optimize the antitrust assessment of patent settlements.[189]

Drawing on this, too harsh scrutiny of pay-for-delay agreements, e.g. consequently deeming restricting potential competition as restrictions by object, will probably provide for less incentives to challenge weak patents, something which in the end can harm consumers. Thus, extending the possibility to consider an undertaking as a potential competitor even when its market entry could infringe valid patents can, depending on circumstances in each case, actually have a negative effect on consumer welfare.

[189] Boehme, Frank, and Kerber, pp 24-25.

6 Final Analysis

To conclude, it seems that extending the scope for who is to be considered a potential competitor, and at the same time opening up the possibility for pay-for-delay agreements restricting potential competition to amount to infringements of competition law by object, might not only hold positive side-effects. Even though innovation incentives do not seem to be at risk, challenging incentives might be. With no room to settle, litigation is a riskier venture for generic undertakings, and the enticements to pursue weak patents are likely to drop. With a larger number of wrongly granted patents in place, consumers will most likely be forced to pay more for a product protected by such, than if generic undertakings had been present on the market, delivering competing products.

This essay has presented opinions both to the agreement with, and in objection to, the Commission's and Court's reasoning regarding potential competition in *Lundbeck*. In one view the ruling follows the ECJ's reasoning in *Cartes Bancaires,* as each agreement was assessed in light of the 'content of its provisions, its objectives and the economic and legal context of which it forms a part'. Another observation, drawing on the same judgement, is that the ECJ has already found the GC to be erring in law once when concluding that restriction by object was not a concept which needed to be interpreted restrictively. Perhaps a similar correction will come after appeal in *Lundbeck*.

The discussion regarding potential competition has not been possible to completely separate from the one regarding the agreements' restrictions on competition to be by object. The two aspects of the ruling in combination is probably what may have an impact on future assessments regarding reverse patent settlements, as I see it. In my interpretation the case has the potential of lowering the bar for what is considered potential competition, through deeming entry at risk of infringing patents as a 'real concrete possibility' to enter a market. However, in order to be certain of this some answers need to be provided for. As Friend points out, there are many questions which remain unanswered in the GC's ruling. How important are the specific facts and context of the case, and the specific circumstances of the pharmaceutical sector – characterised by highly dynamic competitive process due to the holding and expiry of patents? Does the ruling set a new standard for who can be regarded as a potential competitor when assessing pay-for-delay agreements? Or is the judgement in fact so dependent on circumstances, such as disproportionally large payments, other possibilities to enter the market than "at risk" entry, and weak patents, that no broader conclusions can or should be drawn from it? Hopefully the ECJ will deliver some answers.

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