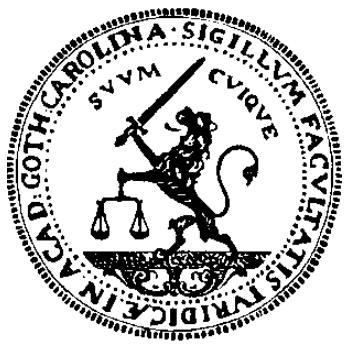

FACULTY OF LAW
Lund University

ALEKSANDAR ARANĐELOVIĆ

EU competition law perspective on "pay-for-delay agreements" in pharmaceutical industry

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At the start I would like to express my gratitude to all those that were responsible for making this two-years stay in Sweden a truly memorable experience.

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Sist men inte minst, ***TACK SVERIGE***!

Summary

This thesis' topic represents author's academic interest, in view of the various normative perspectives, in the allegedly anti-competitive practice of concluding pay-for-delay agreements in the EU pharmaceutical industry.

Chapter I of the thesis analyses the EU normative framework in which pay-for-delay agreements occur. Emphasis is firstly made on the interrelation between the EU competition law and the intellectual property law since these agreements lay at their intersection. The EU pharmaceutical market and the way in which it is regulated are further discussed to the extent to which they affect and prompt the conclusion of these agreements. Special focus is placed upon patent litigation and settlement of patent disputes by means of an agreement that contains provisions restrictive of competition. Finally, parties' incentives for the conclusion of the controversial agreements are addressed.

Chapter II analyses the content of the three decisions adopted by the European Commission with regards to pay-for-delay agreements. The particular provisions of each of the agreements made between the originator and generic pharmaceutical undertakings are displayed and commented upon. Similarities and differences between the three cases are further outlined in the attempt to identify factors which are relevant for developing a common approach for the enforcement of the EU competition rules in this area. Finally, a general assessment is made of pay-for-delay agreements in the context of Article 101 (1) TFEU where the stress is placed on the two main criteria responsible for the agreements being perceived as anti-competitive conducts: namely the consensual acceptance of the restriction of potential competitors entry and the inducement to do so in the form of a value transfer from the originator to the generic undertaking.

Chapter III contains a more profound analysis of the specific legal concepts particularly relevant for the Commission's finding of the anti-competitive character of the agreements in question. Primarily, it is speculated on the probability of the CJEU's ruling on the absolute immunity from the competition law enforcement for pay-for-delay patent settlement agreements. Thereafter, discussion includes the question of the ambivalent state of the patent claim and its relevance for the competition law assessment. The central part of the analysis is reserved for two most controversial issues: firstly, whether the Commission's argumentation with respect to the qualification of the infringement as 'restriction by object' is convincing, secondly, whether the Commission managed to substantiate its claim that the generic undertakings are potential competitors to the originator market incumbents.

Preface

Pharmaceutical sector is characterised by a number of different factors such as high level of investments and significant developing costs, lengthily market authorisation procedures, government regulated prices of pharmaceutical products and fierce competition. This inter-brand competition manifests through extremely costly[1] yet uncertain competitive race between originator companies to be the first in placing a new drug on the market. However, the effort is generously rewarded by a period of exclusivity warranted by a patent. Patent can relate to a specific compound or to a production process and has to satisfy all patentability criteria. Valid patent secures the developing "originator" company the right to sell, distribute or license patented medicine for a limited period of time, more or less on its own terms, thus yielding significant profits. This specific kind of a legal monopoly obtained through possession and enforcement of intellectual property (hereinafter 'IP') rights, more specifically patents, makes up for abundant R&D investments, and is a way by which society secures, praises and supports innovation as an important factor for social and economic growth.

Selling medicines is a lucrative business attracting not only those market players with capacities and economic means to develop new drugs. Once the medicine was successfully developed the costs of producing a bio-equivalent are significantly lower. Therefore, there are those undertakings which business model includes patiently waiting for a compound patent expiry date to approach before engaging in activities necessary for placing a generic, bioequivalent drug on the market. Sales of generic medicines are done at considerably lower prices thus allowing generics to successfully compete with the originator companies and in a short time acquire high market shares. However, in certain cases these generic companies even step forward to challenge the validity of the patent or simply launch a generic product on the market, anticipating that in the case they have been sued for patent infringement they will be able to oppose the validity of the patent or successfully claim non-infringement.

On the other hand, the introduction of generic drugs to the market is gladly welcomed by both consumers and states.[2] Through competitive pressure the prices of medicine decrease

[1] Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, *"The price of innovation: new estimates of drug development costs"*, Journal of Health Economics 22 (2003), 151–185, at pp. 151-152 et sqq, at 172-173.
[2] *Fentanyl case*, Statement by Joaquín Almunia the Vice President of the European Commission responsible for Competition Policy on EbS, Strasbourg, 10 December 2013, European Commission press release database, at http://europa.eu/rapid/press-release_SPEECH-13-1053_en.htm.

which necessary reflects on purchasers' expenditures.[3] Sales of blockbuster medicines secure originator companies most of their annual profits. Hence, they have abundance of reasons to try to delay the generic entry.[4] One of the legal means recognised in the European Union (hereinafter 'the EU') includes the application for a supplementary protection certificate. Other methods depend on each company's commercial strategy and have on few occasions caught the ever vigilant eye of the European Commission (herein after 'the Commission').

One specific practice involves conclusion of agreements between generic and originator companies, mostly in the context of the alleged patent litigation, which contain provisions raising serious competition law concerns. Following an extensive pharmaceutical sector inquiry in 2008 the Commission has in the last three years managed to tackle a number of these agreements in its decisions concerning companies Lundbeck[5], Servier[6] and Johnson&Johnson[7]. In the decisions involving the aforementioned companies the Commission found the agreements incompatible with Article 101 TFEU. Two former decisions, Lundbeck and Servier, have been challenged and appealed before the Court of Justice of the European Union (hereinafter 'the CJEU') but to the present day no judgment has been delivered. Until the final judgment on the legality of pay-for-delay agreements is delivered, the status quo is maintained followed by expectation, impatience and uncertainty, which represents a rather fertile ground for academic discussions and a headache for practitioners and relevant market players.

Purpose

This thesis scrutinises competition law issues raised with regards to pay-for-delay agreements entered into by originator and generic pharmaceutical companies operating their businesses within the EU[8]. Arising in most cases as the end result of the pending patent dispute these agreements contain a number of provisions, commitments accepted on behalf of

[3] The European Commission Communication COM (2008) 666 of 10 December 2008, acknowledged that "[c]ompetition with off-patent products enables sustainable treatment of more patients with less financial resources", to the effect that "[t]he generated savings create financial headroom for innovative medicines".
[4] The European Commission Communication of 8 July 2009, Executive Summary of the Pharmaceutical Sector Inquiry Report, (hereinafter 'Final Report'), para 65.
[5] Commission Decision, Case AT.39226 – LUNDBECK, Brussels, 19.6.2013 C (2013) 3803 final. (hereinafter '*Lundbeck'*)
[6] Commission Decision, Case AT.39612 – PERINDOPRIL (SERVIER), Brussels, 9.7.2014 C (2014) 4955 final. (hereinafter '*Servier'*)
[7] Commission Decision, Case AT.39685 – FENTANYL, Strasbourg, 10.12.2013 C (2013) 8870 final. (hereinafter '*Fentanyl'*)
[8] Some of the agreements concern non-EU states but nonetheless within European Economic Area (EEA) to which essentially same provisions on restriction of competition apply.

the concluding parties, including a value transfer, that in the European Commission's view appear to be in breach of EU competition rules, mostly Article 101 TFEU. The research will focus on three decisions concerning the following medicines: citalopram ('*Lundbeck'*), perindopril ('*Servier'*) and fentanyl ('*Johnson&Johnson'*). First two decisions have been appealed and in the anticipation of the judgment by the CJEU the author wishes to *examine and compare the economic and legal context* in which each of the agreements concerned by three decisions were made. The author will further make inquiries with regards to why are these "reverse patent settlement" agreements under the current EU doctrine considered by the Commission to be restrictive of competition. Special attention will be drawn to similarities and differences between the agreements in each of the decisions in an attempt to find a common standard. Additionally, Commission's approach to specific competition law concerns will be scrutinised against the legal standards developed thus far by the CJEU. Finally, an assertion shall be made to whether that specific approach shall be deemed justified and upheld on the appeal.

Method

In order to give an answer to the research question the systematic analysis of the three decisions adopted by the European Commission will be undertaken. In identifying the particular provisions of the agreements and providing an answer to the question why they raise competition law concerns it will be necessary to identify the applicable law and further examine the circumstances in the light of the developed legal standards and principles of EU competition law. The author will acknowledge number of conflicting views of the commentators, practitioners or academics, and analyse hypothetical cases and scenarios based on the preceding EU case law dealing in principle with the matter. This shall be achieved through the use of the traditional dogmatic legal method.

The economic impact of generic drug entry into the pharmaceutical market to a great extent explains why the concerned undertakings resorted to the allegedly anti-competitive behaviour. To demonstrate what commercial interests were at stake and how does the generic entry affect the originators profits prompting them to develop strategies aimed at delaying that entry the author will provide an economic perspective on the matter.

Delimitations

Pay-for-delay agreements have only just recently been in the focus of the EU competition authorities. The Commission has done an extensive investigation followed by lengthily, detailed and reasoned decisions. Unfortunately, it is impossible to make neither common nor definite conclusions on the matter without the cases being settled by the CJEU.

The extent of the analysis is further constrained by the not so immense number of available scholarly interpretations of the issues hereby discussed.

Additionally, it shall be observed that although in its *Servier decision* the Commission raised arguments concerning the abuse of dominant position and breach of Article 102 TFEU thesis will focus only on the alleged violations of Article 101 TFEU.

Chapter I: Pay-for-delay agreements in the European Union regulatory framework

Pay-for-delay agreements in most cases[9] concern issues that might be scrutinised both from IP and competition law perspective. This section shall therefore, as a matter of general background assessment, primarily address the relation between these two legal fields. It will be demonstrated that although competition law and IP law at first glance seem to have divergent goals they are interrelated and together attend important social and economic purpose. Towards the end of this Chapter the focus will shift to the EU pharmaceutical industry and in particular to pharmaceutical innovation, together with the predisposed role that patents and competition law play in its promotion. A review of EU legal framework in pharma industry which has considerable influence on the conclusion of pay-for-delay deals will follow.

1.1. Interrelation between IP and competition law

Intellectual property rights are to the greatest extent regulated by national legal norms. The ever closer cooperation among nations and increasing international trade nonetheless called for the establishment of certain level of standardisation. This standardisation can be particularly evidenced in the EU where considerable differences in national norms may seriously impair the functioning of the single market. The CJEU at an early stage and in an attempt to preserve the single market recognised in *Deutsche Grammophon*[10] the so called dichotomy between the existence and exercise of IP rights, where the former remains under the respective Member State's jurisdiction while the latter can be affected and restricted by the provisions in the Treaties[11]. Legal protection of intellectual property in the EU still does not manifest the elements of a harmonised yet even less of a unitary system. However, numerous harmonisation instruments have been adopted by the European Council and

[9] IP law issues did not arise in the context of *Fentanyl* decision given that the pharmaceutical drug was never patented.
[10] Case C-78/70, *Deutsche Grammophon v Metro*, ECLI:EU:C:1971:59, para 11.
[11] The use of expression the Treaties in the thesis refers to both Consolidated Version of the Treaty on European Union [2008] OJ C 115/13 (hereinafter 'TEU') and Consolidated Version of the Treaty on the Functioning of the European Union, 2008 O.J. C 115/47. (hereinafter 'TFEU')

Parliament in an attempt to tone down the divergences present between different national IP legislation.[12]

In the sphere of patents, which is the sole relevant IP right for the discussion in this thesis, the EU is still struggling to reach a consensus. There are currently two regulations[13] and the Agreement on a Unified Patent Court[14] which is supposed to provide a unitary patent system to be placed under a single, specified EU Patent Court's jurisdiction is not yet in force. The most significant instrument in Europe that regulates patent protection is the European Patent Convention[15] (hereinafter 'the EPC'). It is characteristic of every single patent system that it confers on the inventor, the 'patentee', an exclusivity right which manifests in different ways. Namely, patent can concern both product and a process. Accordingly the patentee is authorised to prevent any third party from putting on a market a patent protected product or using the same patented production method to develop its own product.[16] It is precisely the scope of this exclusivity that allegedly clashes with the competition law policy which seeks to maintain the market open for competitors' products. This allegation is faced with much criticism and it is becoming widely accepted that both areas of law only complement each other in the realisation of one of their intended purpose – innovation boost.

It must primarily be observed that exclusivity does not necessary entail monopoly. In many instances, the capacity to deny others the ability to use a species of IP does not confer substantial market power upon the rights-holder.[17] Patent policy encourages prospective inventors to invest time and money in inventions, because a patent's grant of the exclusive right to make, sell, and use the invention for a certain period of time can allow inventors to realise returns sufficient to encourage the initial investments.[18] Competition on the contrary manifests in a consumer benevolent race, in terms of price and quality, to be the first undertaking in the market to bring about a new product. It further seeks to maintain fair

[12] For example see: Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015, OJ [2015] L 341/21; Community Designs Regulation 6/2002of 12 December 2001, OJ [2002] L 3/1.
[13] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, *OJ* [2012] L 361/1 and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, *OJ* [2012] L 361/89.
[14] Agreement on a Unified Patent Court, *OJ* [2013] C 175/1.
[15] Convention on the Grant of European Patents of 5 October 1973, 13 INT'L LEGAL MATS. 268 (1974). (hereinafter 'EPC').
[16] EPC, Art. 64.
[17] William E. Kovacic, Andreas P. Reindl, *An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy*, Fordham International Law Journal Vol. 28 Issue 4, [2007], p. 1064.
[18] *To Promote Innovation: The Proper Balance of Competition and Patent Law and* Policy, Federal Trade Commission Report, October 2003, p. 1.

competition on the market and ensure that the timely and genuine market entry is a plausible option. Together, both mechanisms as evidenced nurture innovation. In fact, the European Commission's Technology Transfer Guidelines[19] notes the following: "both bodies of law share the same objective of promoting consumer welfare and efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open competitive market economy."[20]

Finally, it is to be understood that in order for both systems to co-exist peacefully a proper balance needs to be maintained. This balance is maintained due to the limits imposed on the exclusivity period enjoyed by a patentee, as well as through the establishment of clear limitations on discretionary conducts enjoyed by these innovators. It is a job conferred upon Competition authority not to allow any kind of abuse of the patent system that might be detrimental for competition on the market. As an example of an alleged misuse of a system mandated and encouraged legal actions, such as settlements of patent disputes, sprouted the practice of conclusion of pay-for-delay agreements which found especially fertile soil in the pharmaceutical industry.

1.2. EU Pharmaceutical sector: competitive race between generics and originator companies

Pharmaceutical innovation is of crucial importance when it comes to increasing public health and public welfare.[21] In view of the high economic interests involved innovating companies intensely struggle for strong and far-reaching industrial property protection and use of patents as essential tools in order to generate market exclusivity.[22] The regulatory framework for EU pharmaceutical sector is highly complex and consists of a bundle of national, international and EU legal norms. As such it is aimed at removing obstacles to the free movement of medicinal products and ensuring their quality, safety and efficacy while stimulating innovation and ensuring access to affordable medicines.[23] More about its concrete implications and effects on the conclusion of pay-for-delay agreements will further be explained in the following sub-headings.

[19] Commission Communication of 28 March 2014, Guidelines on the application of Article 101 of the Treaty of the Functioning of the European Union to technology transfer agreements, OJ [2014] C 89/3. (hereinafter "TTG")
[20] TTG, para 813.
[21] Final Report, para 1.
[22] Josef Drexl and Nari Lee (eds), *Pharmaceutical Innovation, Competition and Patent Law. A Trilateral Perspective*, (Edward Elgar Publishing, 2013), Cheltenham, UK, ISBN 978-0-85793-245-7, p. 54.
[23] *Servier*, para 62.

1.2.1. Relevant market players and EU legislation in pharmaceutical sector

The competition in pharmaceutical sector occurs on two levels: between originator companies and between the former and their generic competitors. While the agreements entered into between different originator companies are open to the application of the EU competition law norms they are not relevant for the present discussion.

Originator companies are pharmaceutical undertakings investing significant means in developing new active pharmaceutical ingredients and bringing them to the market.[24] Investment in R&D is recouped from the period of exclusivity enjoyed after successful filing of patent application for the specific product or production process. Given that the period of protection covered by patents is limited to 20 years[25] in EU jurisdiction the originator companies tend to develop a number of late "life-cycle management" strategies for their bestselling, blockbuster pharmaceutical products intended to secure high revenues for as long as possible.[26] Some of these strategies are considered legitimate such as application for supplementary protection certificate,[27] filing of the so called "secondary patent" applications for production processes or the protection offered through the data exclusivity period.[28] Many more practices are employed and some of them were already flagged by the CJEU as incompatible with competition law, such as e.g. the one dealt with in *Astra Zeneca*[29].

Generic companies specialise in production of generic versions of patented medicines after the period of exclusivity has expired.[30] Placing their bioequivalent versions of originator's medicinal products on the market these companies offer them for a fraction of their former monopolistic price. It is usually more than one generic company that enters the market with their own versions of the patented drug. The number of entrants will depend mostly on the profitability of a certain medicine. Generic entry initiates a competitive race eventually allowing these companies to acquire a significant part of the market. The prices of

[24] Final Report, para 51.
[25] Article 63 (1) of the EPC provides that the term of a European patent is 20 years from the date of filing of the application.
[26] Final Report, para 166.
[27] Supplementary protection certificate can be obtained for a an additional period of 5 years under the conditions contained in Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, *OJ* [1992] L 182/1.
[28] See *infra* note 31.
[29] Case C-457/10, *Astra Zeneca v Commission*, ECLI:EU:C:2012:770; In this case the ECJ was called to give its opinion on whether strategic use of procedures before patent offices and marketing authorisation agencies, in order to delay generic's market entry, could be considered a violation of EU competition law.
[30] Final Report, para. 89.

medicine drop considerably which positively affects the consumers and Member States' national health care budgets.

EU legislation relevant for better understanding of the concept of pay-for-delay agreements includes rules on patent law, marketing authorisation and price and reimbursement of medicinal products. Principally pertinent are the norms of the *Directive 2004/27/EC* allowing generics to conduct tests and trials that are paramount for the demonstration of bioequivalence before the patent exclusivity period had lapsed.[31] The directive ensures that generics can make use of a two year period prior the expiry of data exclusivity to apply for marketing authorisation for their generic product.[32] This technically allows the originator to identify future generic competitors prior to the end of the exclusivity period. Based on their application for marketing authorisation the originator may identify the process used for the production of the medicinal product in question. The originator may initiate litigation against generic competitor as a mean of enforcing its patent rights. Patent holders are in general free to rely on their patents to exclude competitors from practising the patented invention.[33] It may nonetheless be the case that the validity of the originator's patents is contested or that the originator have difficulties proving that the generic's process infringes its remaining patents. By resorting to litigation in those cases the originator's primal intention is to frighten away the potential competitor and influence it to reconsider its strategy. Frequently, the parties conclude settlement agreements some of which may appear as anti-competitive, in case where decision to settle is not solely made on the parties' appraisal of the strength of the patent, but induced by other, often financial, means.

1.2.2. Competitive pressure and patent litigation

As noticed above, patent challenges are quiet common part of the competitive process between originator and generic companies in the pharmaceutical sector. As the Commission explains, expiry of exclusivity of the compound patent bestows to suppliers of generic medicines a number of options to attempt market entry in the face of process patent obstacles created by the originator undertaking.[34]

[31] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, [2004] OJ L 136/3, art. 10(a)
[32] Ibid, para 10.
[33] *Servier*, para 1118; Case T-111/96, *ITT Promedia v Commission*, ECLI:EU:T:1998:183, para. 60 ; Case T-119/09, Protégé International v Commission, ECLI:EU:T:2012:421, para. 49.
[34] *Lundbeck*, para 618.

Generic companies interested in entering the market despite the remaining patents may decide to, apart from making an attempt to invent around the patents, oppose or invalidate remaining patents. In addition, they can seek declaration of non-infringement from a competent court in a Member State of primary interest. A more risky strategy presupposes that the generic undertakings launch their products exposing themselves to the potential patent challenge by the originator company. In the course of the ensuing lawsuit they may counterclaim invalidity or attempt to prove non-infringement. All these possible scenarios, in spite of the fact which one makes the first move, originator or generic company, lead to an expensive patent litigation with a number of consequences which may seriously affect each of the company's business.

Alternatively to the option of waiting for the matter to be finally decided by the designated patent court the parties may enter settlement agreements. Originator companies are aware that generic companies, mostly SMEs,[35] may try to mitigate litigation costs and that they are likely to settle the claim. In that, it became obvious to originator companies that they may use patent litigation and the possibility of settlement to try and induce the generic undertakings to delay their market entry. That is why despite the insecurity about the strength of the patents originator companies may initiate the dispute, waiting to open-handedly offer alternative or complementary incentives that may sweeten the deal for the generics.

1.3. Settlements of patent based disputes and EU competition law concerns

Settlements are means to end litigation in court and are generally regarded as favourable, as they are cost-saving and provide legal certainty.[36] This especially applies with respect to patent litigation, as these litigations are regarded as remarkably complex and require high level of expertise, which makes them particularly expensive and long lasting. Moreover, in the EU, in spite of having the single market, the absence of the unitary patent protection system does not allow for patent disputes to be resolved by only one instance. On the contrary, patents must be enforced or challenged in multiple jurisdictions which increases the overall costs and thus makes the settlements of disputes even more appealing. It is therefore legitimately expected and moreover generally encouraged that the parties settle those disputes on the terms acceptable to both sides. This view is also shared by the European Commission.[37]

[35] Final Report, para. 88.
[36] Carl Shapiro, *'Antitrust limits and patent settlements'* (2003) 34 Rand Journal of Economics, p. 394.
[37] Final Report, para. 704.

The expected outcome of the settlements between concerned parties, in a standard scenario, can be twofold. First scenario revolves around the case where the parties consider the patent to be valid and infringed or likely to be infringed by the expected generic entry. Under those circumstances it is expected that the generic company acknowledges the validity of the patent, offers commitments not to enter the market before patent expiry and in specific cases cover the damages sustained by the originator company due to the patent infringement.[38] Alternative scenario connotes that the parties to the agreement consider the patent invalid or non-infringed in which case an originator company is likely to license the patent to generic on favourable terms and cover any costs it might have inflicted, in exchange for the generics dropping their patent invalidity claim.[39]

If the settlement of patent dispute is a legitimate, welcomed and encouraged practice one may be interested in which case the conclusion of these agreements can be controversial from the EU competition law perspective. Shall the competition law artillery be unleashed against these companies who are trying to settle their intellectual property conflicting claims?

One of the reasons for putting these agreements under the scrutiny of EU competition law is the fact that a patent does not confer on its proprietor the right to impose a restriction on other market players or interested parties from challenging its validity. A patent allows the patentee to prevent third parties from making, using, offering for sale, selling, importing, distributing or stocking the product (including the product obtained directly by a patented manufacturing process) without the patent holder's consent.[40] However, every interested party shall have the opportunity to oppose patent registration, or seek its invalidation when it considers the patent to be illegitimately obtained, whether through misrepresentation of facts or by an administrative error. Additionally, the CJEU considered in *Windsurfing International* that "it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error".[41] That is due to the fact that unjustified conferral of monopoly power shall not be maintained in the interest of fairness of competition on the relevant market. In as much as the conclusion of the agreements of this kind determines the dispute without the competent court's examination and its final say on the

[38] *See* Final Report, section 2.2.
[39] *Ibid*.
[40] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) Article 28(1) ('TRIPS Agreement')
[41] C-193/83, *Windsurfing International v Commission*, ECLI:EU:C:1986:75, paragraph 92.

validity of the patent the uncertainty remains present and credibility of either claim is questioned.

Secondly, the Commission alleges that "limitations on competition cannot be justified when they do not result from the parties' assessment of the merits of the exclusive right itself but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market"[42] It is necessary to deter, by virtue of competition law enforcement, any attempt of an illegitimate patent holder to use certain means, such as value transfer in case of the contested agreements, to allegedly defend the rights it might unduly enjoy. What is evidently clear is that the Commission tries to convey a message that originator companies may not legitimately make use of any means they deep appropriate to achieve the exclusionary outcome.

Finally, patent settlement agreements may contain provisions which conflict with the interests protected by competition law; they obstruct competitive process[43] or have negative repercussions for consumers.[44] Commission precisely argues that pay-for-delay agreements manifest certain characteristics which run counter both of these legitimately protected interests. In reverse patent settlement agreements[45], as its name suggests, although generic company acknowledges the strength of the patent and agrees to stay out of the market, the value is transferred from the originator to the generic which resembles a clear "buy-off" situation.[46] In the words of one respected practitioner, it is the payment that "flew the wrong way".[47] This unexpected and non-deliberated payment casts a shade on the legality of the agreements.

[42] *Servier*, para. 1137; *Lundbeck*, para. 641.
[43] More about competitive process as a goal of EU competition law enforcement in: Andriychuk, O. (2010), *Rediscovering the spirit of competition: on the normative value of the competitive process*, European Competition Journal, 6(3) p. 575-610.
[44] "Maximization of consumer welfare is an objective of antitrust policy and could serve as the benchmark to assess the lawfulness of settlements" at Stanislas de Margerie, *'Pay-for-Delay' Settlements: In Search of the Right Standard*, World Competition Law and Economics Review, Kluwer Law International 2013, Volume 36 Issue 1, pp. 85 – 97; Commission Guidelines on the application of Article 101(3) of the Treaty [2004] OJ C 101/97, para. 13.
[45] Alternative term used to for the most pay-for-delay agreements.
[46] The term "buying off" of competition was used in a similar context by Advocate General Trstenjak Opinion delivered on 4 September 2008 in Case C-209/07*Beef Industry Development and Barry Brothers*, EU:C:2008:643, para 77.
[47] Kevin D McDonald, *'Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea'* , (2002) Vol. 15/4 Antitrust Health Care Chronicle, p. 3.

1.4. Incentives for the conclusion of pay-for-delay agreements

Settlement of the opposing patent claims by means of conclusion of an anti-competitive pay-for-delay agreement benefits both parties. Originator companies get to stay exclusive suppliers on the market, reaping monopolistic profits for a while longer. On the other hand, generic companies are given opportunity to gain significant amount of money without even entering the market. They get to avoid, for the duration of the agreement, the efforts and risks attached to market entry, including the risks of litigation with the originator undertaking, risks associated with the likelihood of obtaining the regulatory approval, and risks of competition from other generic undertakings and/or the originator undertaking.[48] For both parties, conclusion of such an agreement appears to be a 'win-win' situation. Technically, the parties have agreed to share for the certain time the monopoly profits of the originator company to the detriment of final consumers which are unable to profit from the benefits indispensable to a generic entry. The Commission explains the economic incentive for the conclusion of the agreements in the following way:

> "reason why both (potential) competitors can be better off at the same time is that the profits the generic undertaking could make from entering the market will be lower than the loss in profits that would likely result for the originator undertaking from generic entry."[49]

Primal factor relevant for the conclusion of pay-for-delay agreements is associated therefore with the inevitable decrease in annual revenues generated by originator undertaking. The introduction of a generic version of the branded drug into the market has a twofold effect: it affects the sales volume of a product and its price.[50] The effects are more notable with respect to the so called blockbuster medicines that account for the most of the annual turnover of the originator companies.[51] After the generic drug has been authorised for sale reimbursable price is adjusted downwards to meet new market conditions, namely it takes into consideration the increase in the number of market players as suppliers of the designated medicine. The studies have shown that the prices at which generics enter the market are on average 25 % lower than that of the originator prior the loss of exclusivity while after two

[48] *Servier*, para 1150.
[49] *Servier*, para 1147.
[50] Final Report, para 209.
[51] Final Report, para 188.

years they decrease down to 40% from the original price.[52] Within one year after generic entry, generic companies have been known to acquire on average a market share by volume of 30%, and of 45% after two years.[53] Following from the statistics it becomes obvious that any successful delay in generic entry will profoundly benefit originator companies as it maintains the level of revenue prior the loss of exclusivity.

One shall further refer to a number of factors inciting the parties towards conclusion of settlement agreements in the course of their ongoing patent disputes. The fundamental consideration for the originator undertakings is the self-evaluation of the strength of the patent. The lack of confidence in the strength of its patent may trigger a risk-managing strategy through an attempt of striking a settlement with its generic competitors. Important part in the assessment of the benefits for the originator undertaking from conclusion of a patent settlement is the competitive pressure created by the plausibility of multiple generics entry.[54] The more generic companies attempt to enter the market the incentive for conclusion of new arrangements or maintaining in force the old one decreases. Additional factor that has conflicting influence on both sides determination of whether or not to conclude an agreement is the possibility of a grant of an interim injunction.[55] Generic companies, on the other hand, are mostly concerned about litigation costs and the effects potential damages claim may have on their ability to operate their business.[56] Even though the invalidity or a non-infringement claim of a generic company may be strong there is still uncertainty that they may lose the litigation. It is precisely that uncertainty that the originator company relies on when trying to induce the generic company to agree to terms of the agreement which significantly limit its independent efforts of entering the market.

These factors are closely tied with the legislative framework peculiar to each specific market. One of the specificities of the EU market is that besides the constant attempt to create the ever closer, jointly functioning single market, some industries, such as pharmaceutical industry, remain closely tied to the national legal framework. Primarily, the grant of patents falls under the national jurisdiction and is subjected to national laws of Member States.[57] Subsequently, the enforcement of patent rights and any challenges concerning patent's validity have to be brought before the national courts.[58] This necessarily calls, in order for an

[52] Final Report, p. 94.
[53] *Ibid*.
[54] *Ibid*, para. 724.
[55] *Ibid*, para. 723.
[56] *Ibid*, para. 721.
[57] *Ibid*, paras 267-268.
[58] *Ibid*, para. 284.

effective enforcement of rights, for the initiation of a number of litigations in multiple jurisdictions against potential infringers. Naturally, this entails much higher costs for parties involved and is an incentive to rather reach a settlement than pursue litigation.

In defence of its agreements with generic manufacturers before the General Court (hereinafter 'the GC'), Lundbeck offered couple of other justifications for engaging in the disputable dealings. It submitted that the agreements were made in order to prevent 'irreparable' harm to its business, including the reduction in reimbursements which national healthcare systems would make for a branded drug following entry by generic manufacturers.[59] Lundbeck also submitted that generic manufacturers exploit the existence of asymmetrical risks in order to 'hold up' originators, which, Lundbeck argued, are 'at risk of sustaining considerable and irreversible damage as a result of the infringement by the generic undertakings, whereas the latter undertakings faced little or no risk at all'.[60]

Finally, an interesting theory has been developed to explain the reasoning behind the agreements. The theory is behavioristic in nature in as much as it is based on the risk and people's attitudes towards it. Theory revolves around the assumption that most individuals are 'risk averse' in as much as they value outcomes that are inherently uncertain less than outcomes that can be known with certainty.[61] As explained, faced with the uncertainty of litigation outcome and possibility of 'losing it all' the risk averse patentee would be willing to sacrifice some of its monopolistic profit in exchange for reducing the uncertainty attendant upon litigation.[62] The same stands for the generic undertaking which rather than risking infringement agrees to accept a generous payment and thus eliminate all the risk, not just that associated with litigation but also commercial risks related to market entry. The theory may further be backed by a study proving that announcement of settlements with indication of reverse payment had a significant positive effect on stock prices of originator companies.[63] These results may be seen not only as a proof that shareholders evidently prefer certainty but also can indicate their reliance on continuation in gathering of monopolistic profits thanks to the agreement.

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[59] Report of the Hearing (26 November 2015), Case T-472/13 Lundbeck v European Commission, paras 172-174.
[60] *Ibid*, para. 171.
[61] Sumanth Addanki, Alan J. Daskin, *Patent Settlement Agreements*, Chapter 85 in ABA Section of Antitrust law, *Issues in competition law and policy*, ABA Book Publishing, Chicago, 2008, p. 2130.
[62] *Ibid*, p. 2131.
[63] Keith M. Drake, Martha A. Starr & Thomas G. McGuire, *Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?*, International Journal of the Economics of Business, 22:2, (2015) 173-200, at p. 194.

Chapter II: Decisions of the European Commission dealing with pay-for-delay arrangements

Pay-for-delay agreements have caught the attention of the Commission by means of reference from a number of national competition authorities in the early 2000's.[64] However, it was not until the big 2008 Pharmaceutical Sector Inquiry[65] that the Commission officially raised concerns about their legality from the competition law perspective. The aim of the inquiry was to identify the practices of originator companies that might be responsible for the notable delay in the entry of generic medicines to the EU market.[66] The results of the inquiry together with the conclusions reached by the European Commission are presented in its Final Report published on the 8th of July 2009.

Considerable space in the Final Report is committed to the patent settlement agreements between originator and generic companies concluded in the time span from January 2000 to June 2008.[67] The Commission therein categorised patent settlement agreements on the basis of two main criteria. First one concerns the occurrence of a certain degree of limitation on the generic company's ability to market its own generic product in the market concerned by the settlement.[68] Second one rests on the finding of any type of value transfer made from the originator company to the generic company.[69] If the agreement involved both limitation on entry and the value transfer it was flagged by the Commission as potentially infringing. It is emphasized that no presumption of illegality exists and the finding of each of the agreement's incompatibility with the EU competition norms is to be assessed with regards to its own factual, economic and legal background.[70] On this basis the Commission initiated a number of separate investigations into the dealings of some of the biggest market players in the pharmaceutical industry. A thorough investigation was undertaken pursuant to the broad investigative competences conferred to the Commission by Council Regulation 1/2003/EC.[71]

The following text is an overview of the Commission's findings in the three so far announced decisions in which the Commission fined the originator companies Lundbeck,

[64] *Lundbeck*, paras 8-9.
[65] Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).
[66] Final Report, paras 3 and 14.
[67] Final Report, 740.
[68] Final Report, para 741.
[69] Final Report, para 742.
[70] Final Report, para 763.
[71] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 101 and 102 of the Treaty, *OJ* L 1, 4.1.2003.

Servier and Johnson&Johnson, together with their generic counterparts. The focus of Chapter II of the Thesis is firstly placed on the specific provisions of the pay-for-delay agreements that according to the Commission pose restrictions on competition within the single market. Further on, the focus tilts to the general assessment of the agreements under Article 101 TFEU while the specific, controversial issues shall be assessed in the following third Chapter. Finally, this Chapter discusses differences between the agreements that might pose a barrier towards establishing a uniform policy towards the EU competition law assessment of pay-for-delay agreements.

2.1. Topical cases in the EU: Legal and economic background to the three cases: Lundbeck, Servier, Johnson&Johnson

On 19 June 2013, the European Commission announced that it had imposed fines totalling €146 million upon Lundbeck and a number of producers of generic medicines in respect of infringements of Article 101 TFEU. In December of 2013 Johnson&Johnson and Novartis were fined €16 million for delaying market entry of generic pain-killer fentanyl. Finally, the following year the Commission imposed a fine upon Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine perindopril. Each of the decision is hereby analysed taking into consideration the legal and economic background to the agreements concluded between these competitors.

2.1.1. Lundbeck decision: legal consequences of "the art of playing a losing hand slowly"[72]

Lundbeck addresses six agreements concluded on behalf of Lundbeck, a Danish originator pharmaceutical undertaking, and four other generic counterparts Merck, Arrow, Alpharma and Ranbaxy. Time period concerned is January 2002 to December 2003. The subject matter of each of these agreements is the limitation of trade in generic versions of Lundbeck's blockbuster anti-depressant medicine – citalopram.

Internal documents seized by the Commission during the inspections of Lundbeck's facilities show that the company was aware of the consequences of inevitable and rather soon generic entry on the citalopram market after their compound patent expires.[73] Statistics show that at a time the agreements were concluded Lundbeck's revenue was highly dependent on

[72] Lundbeck's strategy regarding citalopram explained in Lundbeck Business Development document with the title "Generic citalopram update 22 11 02", ID 847, pages 50-51 in *Lundbeck*, para 131.
[73] *Lundbeck*, para 124.

sales of citalopram.[74] Therefore, in an attempt to secure their profits the company developed a number of strategies aimed at postponing generic entry.[75] The strategy involved three main tactics – influencing the authorities, defensive patenting through mainly process patents and deal making.[76] With regards to the named strategies *Lundbeck* solely addresses the practice of concluding agreements aimed at delaying generic entry and including significant value transfer from Lundbeck to the four aforementioned generic undertakings. Other practices are only mentioned in order to clarify the context and the background from which these agreements transpired.

The absolute exclusivity that Lundbeck enjoyed with regards to the manufacture and sales of the concerned medicine ceased upon the expiry of the patent and data protection on the citalopram compound and accompanying two original production methods. The uncertainty for the generic companies nonetheless lied in the fact that Lundbeck was still in possession of certain process patents (including but not limited to the most disputed crystallisation method). However, process patents do not convey the same kind of exclusivity in production, marketing and sale of pharmaceuticals as patents covering the active ingredient itself. In *AstraZeneca* on a related matter the Court duly noted that: "the ability of a formulation patent to confer exclusivity on a product is not equivalent, in any event, to that of a substance patent, since an active substance can be incorporated into different formulations."[77] Commission in *Lundbeck* takes the view that the same can be said of process patents, in cases where an active substance can be produced by different processes.[78] Although the risk of patent infringement was present, generic companies were nonetheless able to use two original production processes and in general free to develop their own ways of manufacturing generic citalopram.

What is characteristic of this case is that all the agreements that are subjects of the decision and flagged by the Commission as anti-competitive were concluded in the context of a prospective patent litigation. Parties disagreed on the matter of possible infringement of Lundbeck's process patents by generic undertakings' marketing and manufacturing of generic citalopram. The most controversial one was the crystallization patent granted as a utility model in the Netherlands. Lundbeck claimed that this method, unlike any other processes, was perfectly suitable for eliminating certain impurities from the molecule in a very efficient

[74] *Lundbeck*, para 26.
[75] *Lundbeck*, para 127.
[76] *Lundbeck*, para 131.
[77] Case T-321/05, *AstraZeneca v Commission*, ECLI:EU:T:2010:266, para. 607.
[78] *Lundbeck*, para 71.

and cost-effective manner to levels below regulatory requirements in the EEA.[79] On the other hand, generic competitors referred to this method as "high school chemistry" and contested its validity on the basis of not fulfilling the novelty criterion.[80]

Disputes between the parties ended upon conclusion of the so called "settlement agreements" in which they supposedly settled their opposing patent claims. The Commission considered that these agreements were not a genuine dispute settlement instruments and that they encompassed hidden restrictions on competition. In the Commission's view, by agreeing not to place on the market their generic versions of citalopram for the duration of the agreement and in the territory concerned, in return for a value transfer, generic companies and Lundbeck jointly encroached upon EU competition rules by preventing entry of the potential competitors.[81] The assumption is based on a solid amount of evidence, some of the Commission's arguments being that the parties did not resolve or terminate any patent dispute but rather agreed on a period in which the generic company would be excluded from the generic market, without any guarantee of unrestricted market entry upon contracts' termination, in exchange for a considerable sum of money from the originator company.[82] The specificities of the agreements Lundbeck concluded with each of the generic companies shall further be disclosed together with certain comments.

2.1.1.a. Lundbeck's agreements with Merck

There are in total two agreements between Lundbeck and Merck that are covered by the Decision. First of these two, so called "Settlement and Supply Agreement", was concluded on the 24 January 2002. The agreement covered the territory of United Kingdom and was in force for one year, but subsequently got prolonged till 1 November 2003. As noted by the Commission, agreement itself uses a rather vague terms that make it hard to identify its actual scope.[83] Its provisions nevertheless unambiguously oblige Merck to deliver all their stocks of tablets and bulk generic citalopram to Lundbeck in consideration for payment of a sum.[84] Particularly interesting is that Article 2.7 creates an obligation for Merck "not to grant duplicates in favour of any third party of its marketing authorisation during the Term for marketing use in the Territory."[85] Its connection to the settlement of the patent

[79] *Lundbeck*, para 149.
[80] *Ibid*.
[81] *Lundbeck*, para 6.
[82] *Lundbeck*, para 80.
[83] *Lundbeck*, para 267.
[84] Article 2.2 of "Settlement and Supply Agreement", as stipulated in *Lundbeck*, para 267.
[85] *Ibid*.

dispute is not straightforward. The agreement also included a supply arrangement whereby Merck agreed to exclusively purchase its requirements of citalopram from Lundbeck for resale in the UK.[86] Therein, instead of supplying its customers with the generic version of the drug produced with the API supplied by Natco (Indian API producer and supplier of Merck for EEA), Merck distributed Lundbeck's citalopram and did so at a higher price. Further on, a notice shall be taken of the Article 6.2. by which Lundbeck guarantees Merck a certain amount of Net Profits on those sales.[87] The notion is that by agreeing to this Merck wanted to secure that it will no matter what generate profits which are equivalent to those it expected to make from the sales of generic citalopram.

Second agreement that was concluded among the two undertakings concerned the rest of the EEA, excluding UK. What is particularly peculiar is that during the internal considerations within both companies, in the anticipation of the outcome of negotiations, neither of them discussed thoroughly the benefits of settlement such as the amounts saved in litigation costs nor they discuss in detail their positions regarding the outcome of the possible litigation. Instead, internal correspondence focuses primarily and in detail on the expected profits and other solely monetary benefits of striking a deal.[88] When an acceptable amount was finally set and agreed by both parties, they entered into the agreement on 22 October 2002.[89] Parties agreed on an immediate cessation of sales and supplies of generic citalopram to Merck's affiliates and third parties in the EEA.[90] Apart from that, given that Merck was not an exclusive buyer of Natco's APIs, Merck undertook an additional obligation to use all reasonable efforts to ensure that Natco ceases to supply citalopram and products containing citalopram. Even the payment of the monthly instalments, as agreed between the parties, was conditional upon the event that Natco does not supply any citalopram on the market. Contrary to the agreement for the United Kingdom, the EEA agreement did not provide for Merck (GUK) to distribute Lundbeck's citalopram.[91]

Most intriguingly Article 4 of the agreement provided: "…upon the effective date of termination of this Agreement for whatever reason, any party shall be entitled to exercise and prosecute any intellectual property rights owned by or licensed to such party as such party sees fit.[92] It may be argued that this kind of provision indicates that the agreement did not

[86] *Lundbeck*, para 272. Article 3.2. of "Settlement and Supply Agreement".
[87] *Lundbeck*, para 268.
[88] See e.g. *Lundbeck*, para 345.
[89] *Lundbeck*, para 348.
[90] *Lundbeck*, para 348.
[91] *Lundbeck*, para 353.
[92] *Ibid*.

manage to provide a definite resolution of any of disputed patent claims and that the intention of the parties was divergent. However, after the termination of the agreement Lundbeck did not initiate any infringement proceedings against Merck.[93]

2.1.1.b. Lundbeck's agreements with Arrow regarding the United Kingdom and Denmark

The agreement itself was concluded on the same day as the above mentioned one with Merck. It does not finally settle the patent dispute but rather allows the companies to, for the duration of the agreement, discuss and attempt to resolve their issues. The literal interpretation of article 2.1. connotes that the parties conceded to a possibility of opening of endless number of future disputes to be resolved by a patent court. Namely, it stated that Lundbeck would commence legal infringement proceedings on the merits as soon as possible "with the aim to establish whether ARROW has, is or would infringe Lundbeck's Proprietary Rights.[94] This provision runs against the very purpose of the patent settlement agreement.

As summarised by the Commission, in the United Kingdom Arrow was prohibited from making, importing or selling citalopram which Lundbeck alleged to be infringing or from dealing in any marketing authorisations pertaining to such citalopram.[95] The agreement was prolonged on two occasions second of which, interestingly enough, tied the termination of the contract with the outcome of Lundbeck v Lagap litigation and not on the ongoing one between the parties, which was at that point clearly neglected.[96] This is extremely interesting given that Lagap litigation was about the production process developed and used by Matrix[97] and not Cipla which was Arrow's supplier[98] and therefore the decision that the former process was or was not infringing should not have born any effect on the latter.

Second agreement that concerned the sales of generic citalopram in the territory of Denmark was mostly identical with the one concerning UK. As a matter of difference, it did not provide for the testing of samples on the base of which Lundbeck would be able to initiate litigation should it considers it to be infringing its patents.[99] The most prominent addition to the UK version of the agreement is its provision 4.2 stating that in case a third party tries to market generic citalopram in Denmark, Lundbeck is to pursue such action based

[93] *Lundbeck*, para 372.
[94] *Lundbeck*, para 396.
[95] *Lundbeck*, para 432.
[96] *Lundbeck*, para 438.
[97] *Lundbeck*, para 152.
[98] *Lundbeck*, para 379.
[99] *Lundbeck*, para 457.

on its patents. In case the legal action comes out unsuccessful, Arrow reserved a right to annul the agreement following the repayment of certain sums of money it had received in advance.[100]

2.1.1.c. Lundbeck's agreement with Alpharma regarding the EEA

This agreement was concluded 22 February 2002 and was meant to expire on 30 June 2003.[101] It covered the entire EU but also included Norway and "[third country]". Unlike previously mentioned agreements where generic companies deny the possibility of the infringement Alpharma acknowledges that Lundbeck's findings regarding the likelihood of infringement are correct before it agrees to refrain from marketing its product.[102] Another more significant difference lies in the fact that Alpharma agrees not to sell or manufacture *any pharmaceutical product containing citalopram* therefore not exclusively the ones produced by the disputed process.[103] The limitation on its commercial freedom regarding the sales of Citalopram is therefore undoubtedly absolute and goes beyond the effects that could have been achieved if Lundbeck successfully defended its patent in litigation. The numbers show that Lundbeck purchased for EUR 11.6 million 25.4 million tablets which Alpharma originally paid EUR 3.7 million.[104] This shows, in Commissions view, that Lundbeck paid Alpharma roughly the expected resale value of the tablets in the market, not the purchase cost which is in turn indicative of the "buy-off" scenario.[105]

2.1.1.d. Lundbeck's agreement with Ranbaxy

Lundbeck's deal with Ranbaxy including the transfer to Ranbaxy of the settlement amount was concluded for a one year period on 16 June 2002 and covered the EEA (it was subsequently extended till December 2003).[106] The agreement also presupposes that Ranbaxy would sell on the monthly bases, during the duration of the agreement and solely in the UK territory, Lundbeck's citalopram in the quantity equivalent to 10 % of Lundbeck's last month's sales.[107] The price at which Ranbaxy would acquire that citalopram is Lundbeck's then estimated ex-factory price less 40 %. Ranbaxy was indeed only generic to develop its

[100] *Lundbeck*, para 463.
[101] *Lundbeck*, para 521.
[102] *Lundbeck*, para 522.
[103] *Lundbeck*, para 523.
[104] *Lundbeck* para, 528.
[105] *Lundbeck*, para 528
[106] *Lunbeck*, para 567.
[107] Article 1.3. of the agreement between Lundbeck and Ranbaxy; *Lundbeck*, para 571.

own production method. In that, parties further agreed not to initiate any legal proceedings against each other with regards to their respective patents.[108]

2.1.2. Johnson&Johnson decision: an ill-orchestrated attempt to feast on a part of J&J's cake

The decision focuses on the anti-competitive character of the so called "co-promotion" and "supply" agreements concluded on behalf and between Dutch subsidiaries of Johnson&Johnson's and Novartis, Janssen-Cilag and Hexal/Sandoz respectively. The effect of the agreement was a successful delay in entry on the Dutch market of a generic version of Johnson & Johnson's high-sale medicine fentanyl in its patch depot form after its data exclusivity in the Netherlands expired on 4 March 2004.[109] Fentanyl depot patch was never patent protected. Accordingly the agreements did not transpire in the context of patent litigation. Sandoz agreed in exchange for monthly payments not to launch its version of the product as long as the Dutch market remains free from generic entry. The period during which the agreement was in force is the time span between 11 July 2005 and 15 December 2006. A value of approximately EUR 5 million was transferred to Sandoz on the basis of the alleged performance of co-promotional activities, which the Commission finds never to have taken place.

2.1.2.a. The co-promotion and supply agreements

The Preamble to the agreement stresses the importance that the promotional activities play with respect to sales of medical products, emphasising on the role and habits of pharmacists and general practitioners in prescribing particular drugs for the treatment of various diseases.[110] It is to be assumed that parties' intention was to elaborate on the supposed need for the conclusion of the agreement whereby Sandoz shall be paid to assist Janssen-Cilag in its promotional activities. The Commission takes the view that the terms of the agreement related to the co-promotional duties of Sandoz are rather vague and described in a general way.[111] The agreement unequivocally prohibits Sandoz from selling or entering any negotiations for the sale of the Product.[112] The Product however is defined with regards

[108] *Lundbeck*, para 572.
[109] *Fentanyl*, para 33.
[110] *Fentanyl*, para 154.
[111] *Fentanyl*, para 159.
[112] *Fentanyl*, para 158. Agreement Article 3.1.

to Johnson&Johnson's own brand - *Durogesic*.[113] In that, it may be argued that the agreement itself does not contain a specific provision prohibiting Sandoz from marketing and selling its own generic version of fentanyl. Sandoz nevertheless did not launch its generic medicine in the Netherlands while the co-promotional agreement was in force, while the placement occurred in August and September 2005 in at least 7 other Member States.[114] An internal email explained the rationale behind the co-promotional agreement providing that entering the agreement was a more lucrative option for Sandoz than launching its own generic product.[115]

In addition to the co-promotion agreement the above mentioned companies concluded a supply agreement that entered into force on 1 January 2007 and was initially intended to last for a period of 2 years.[116] The agreement allowed for the sale, on non-exclusive basis, of the transdermal fentanyl patches in the Netherlands under the generic companies' (Sandoz and Hexal Pharma) respective brand.[117] This right was nonetheless conditional upon the entry into the Dutch market of a competing generic version of the specified product.[118] The generic product was launched in January 2007; one month before a generic company Ratiopharm launched their generic product.[119]

The most positive effect from this cooperation was the avoidance of any reduction in the price of Janssen-Cilag's fentanyl patch in the Netherlands which manifested in a surplus in profit estimated at EUR 5.9 million on an annual basis.[120] Additionally, J&J maintained its position of a sole supplier throughout duration of the "co-promotion agreement" thus avoiding the predicted loss of 25% of its market share in the event of generic entry.[121] Thanks to the later supply agreements with Hexal/Sandoz, Janssen-Cilag was still able to supply approximately 90% of the Dutch market with its fentanyl patches in spite of the generic entry.[122]

[113] *Fentanyl*, para 155.
[114] *Fentany*l, paras 175, 177.
[115] *Fentanyl*, para 177
[116] *Fentany*l, para 195.
[117] *Fentanyl*, para 197.
[118] *Ibid*.
[119] *Fentanyl*, para 198.
[120] *Fentanyl*, para 201.
[121] *Fentanyl*, para 201.
[122] *Fentanyl*, para 203.

2.1.3. Servier decision: An infamous story behind Servier's "dairy cow"[123]

Servier Decision (hereafter *Servier*) is chronologically the third one enforced by the Commission, following *Lundbeck* and *Johnson&Johnson*, tackling pay-for-delay agreements. The decision was published on 9 July 2014 and in addition to the assessment of the settlement agreements as anti-competitive dealings under Article 101 TFEU, it accuses Servier for the abuse of dominant position. Alike Lundbeck, Servier was also preparing for the generic entry following the expiration of the perindopril compound patent (Servier's top-selling blood pressure control medicine) which including the period covered by the SPC was expected to happen on its most significant markets (UK and France) in 2003/2005.[124] Its defensive mechanism against generic entry included filing numerous applications for "secondary patents" of which, in the view of generic companies, the most significant obstacle to market entry was patent for the "alpha crystalline form".[125] With limited amount of options, i.e. attempts to invent around Servier's patents, the only remaining possibility for the generic companies was to challenge their validity. This, together with Servier's enforcement of its patent rights by means of initiating injunction procedures[126] created high level of insecurity for the generic companies thus making the pay-for-delay arrangement with Servier a desirable option for those undertakings.

The agreements entered into by Servier and five producers of generic perindopril (Niche/Unichem, Matrix, Teva, Krka and Lupin) that delayed their entry to the relevant markets for a significant period of time remain the sole focus of this thesis excluding other practices that might present an abuse of dominance in breach of EU competition norms. These agreements were concluded in the period between 2005 and 2007 and include significant payments, or other inducements, to the generic companies.[127] They further oblige Servier's generic competitors not to challenge Servier's patents and not to enter the market for the agreed period.[128] The particularities of each of the agreements entered into shall further be presented.

[123] Servier referred to and described its medicine perindopril as its "dairy cow" thus emphasising on the significance that this product had for its profits and the business.
[124] *Servier*, para 4.
[125] *Servier*, para 5.
[126] *Servirer*, para 7
[127] *Ibid*.
[128] *Ibid*.

2.1.3.a. Niche/Unichem and Matrix settlement agreements

The Commission considered these two settlements together explaining that the companies were contractually linked cooperation partners for perindopril and hence there is evident interdependence between two contractual arrangements.[129] The initial settlement discussions between Servier and Niche (Matrix was Niche's API supplier) were not successful and, ultimately, Servier decided to bring a patent suit against Niche before the High Court.[130] The two parties however managed to settle their differences before the High Court was in position to deliver a final judgment. Settlement agreements were signed on February 2005.[131]

These settlement agreements prohibit Niche/Unichem and Matrix from entering the relevant product market before September 2008, and even then only in the case they do not infringe Servier's patent.[132] Two generic companies also agreed not to challenge any of Servier's main patents (or seek a declaration of non-infringement).[133] In exchange for a generous payment they agreed to additionally cancel, terminate or suspend all customer relations associated with perindopril until the expiry of the process patents and refrain from applying for regulatory approval.[134]

Commission further in detail explains the cooperation between Niche and Matrix regarding the development of the generic perindopril and the stages of progress including all the hurdles and technical hitches. It nonetheless concludes that the two companies were, despite them advocating to the contrary, actively involved in finding solutions and none of the encountered barriers seemed to have been "insurmountable".[135] In Commission's view companies planed product launch during the course of 2005 which would make them pioneers on the generic market for perindopril.[136]

[129] *Servier*, para 421.
[130] *Servier*, para 497.
[131] *Ibid*.
[132] *Servier*, para 422.
[133] *Servier*, para 422.
[134] *Ibid*.
[135] *Servier*, para 479.
[136] *Ibid*.

2.1.3.b. Teva settlement agreement

Out of the three options to enter the UK market with generic perindopril,[137] Teva opted for a deal with Servier. A settlement agreement was concluded between Servier and Teva on 13 June 2006 and unlike other agreements assessed in *Servier,* which are valid for the entire EU, solely concerns the UK market.[138] Under the terms of the agreement Teva bound itself for a period of three years to exclusively purchase perindopril from Servier for distribution purposes in the UK market.[139] Teva also agreed to refrain from offering on the relevant market any generic perindopril (other than that supplied by Servier) and from challenging Servier's patents.[140] For the said commitments Servier agreed to make a significant payment.[141]

2.1.3.c. Krka settlement and acquisition agreements

Negotiations between Krka, a Slovenian based company developing its own version of perindopril (both API and formulation), and Servier resulted in the conclusion of three agreements concerning perindopril.[142] The first two which are both dated 27 October 2006 bring an end to the disputes and based on a licence allow Krka to sell perindopril in seven Central and Eastern Europe Member States while restricting its entry to the markets of 20 other EU Member States.[143] What makes this arrangement somewhat different from the previously mentioned dealing of Servier is that the third and final agreement dated 5 January 2007, provided that Krka shall assign to Servier, within one year, two patent applications concerning perindopril.[144] For this transaction it shall be compensated with EUR 30 million and a back-licence with no right for Krka to sub-license it.[145]

[137] Paras 720-722 of Servier decision explain that Teva was considering to a) enter the market with its self-developed product for which it lacked marketing authorisation, b) enter into a supply agreement with Krka, which had obtained MA for its generic version of perindopril and c) to become Servier's authorised generic/distributor.
[138] *Servier*, paras 651 and 653.
[139] *Servier*, para 652.
[140] *Ibid*.
[141] *Ibid*.
[142] *Servier*, paras 821-822.
[143] *Servier* para 822.
[144] *Ibid*.
[145] *Servier* para 822.

2.1.3.d. Lupin settlement and acquisition agreement

On 18 October 2006, Lupin turned to the High Court claiming that Servier's '947 patent (the one causing the most controversy between all of the relevant market players) was invalid and seeking a declaration that Lupin's product that was to reach UK market was non-infringing.[146] This dispute never came to be resolved given that patent settlement agreement between the parties was concluded on 30 January 2007.[147] By virtue of this agreement Servier in exchange for payment of EUR 40 million acquired ownership over Lupin's three patent applications for perindopril, licensed them back, but gained assurance that Lupin will not enter the market with the generic perindopril as long as the market is free from the third party entry or until expiry/invalidation of Servier's patent.[148] The payment of the sum was not conditional upon approval of a patent.[149] Moreover, the agreement foresaw that in the case of generic entry the concluding parties shall give their best to strike a deal that will include distribution of Servier's perindopril on Lupin's behalf.[150]

2.2. Divergences between the agreements signed by Servier, Lundbeck, and Johnson&Johnson

In its 2009 Final Report the Commission has expressed the view that patent settlement agreements shall be assessed on a case by case basis[151] and the figures showed that the majority of these agreements do not raise any competition law concerns.[152] It has further classified these agreements in few categories, according to the likeliness of raising competitive concerns, type B.II agreements being the most contentious.[153] In the period that followed, as seen in the previous heading, the Commission fined the companies that entered into this kind of anti-competitive deals on three occasions. Each of the previously discussed decisions contains results of a long lasting investigation and gathers immense amount of evidence on which the Commission bases its claims of infringement of Article 101 TFEU. The agreements assessed by the Commission in the here mentioned decisions manifest certain similarities and transpire as a result of a more or less similar negotiation processes. Namely,

[146] *Servier*, para 1015.
[147] *Servier*, para 975.
[148] *Servier*, para 975.
[149] *Servier*, para 1040.
[150] *Ibid*.
[151] Final Report, para 763.
[152] Final Report, para 743.
[153] *See* Figure 106, Final Report, p. 270.

all of the agreements concerned by the decisions follow the same logic: an originator company pays its generic competitors to postpone their entry on the market with the generic version of its high-profit-generating drug. Likewise, motives behind the conclusion of the agreements are more or less identical. Originator companies get to maintain their exclusivity on the market and secure that no loss in profits affiliated with generic entry shall transpire. Generic companies on the other hand receive direct payments in the amount approximate to expected profit margins from the sales of generic drugs without risk inherent to market entry and without having to bear any litigation costs. However, certain differences can also be evidenced. This heading is meant to address those differences in an attempt to answer the question whether given the non-uniform character of the agreements a single common legal approach can be taken with regards to these Commission flagged anti-competitive conducts.

In the first place one shall notice that both *Lundbeck* and *Servier* involved an apparent "patent settlement", in contrast to *Johnson&Johnson* which does not refer to any intellectual property dispute. In fact, there were no hindrances present on a Dutch market that would prevent Novartis from launching its generic product. The dealing was made based on solely commercial considerations of both parties and disguised behind the co-promotion agreement by which the transferred amount was a reimbursement for the promotional services. Hence, this agreement falls out of the taxonomy witnessed in the Commission's 2009 Report. It nonetheless exhibits all the other characteristics akin to a pay-for-delay arrangement.

Lundbeck and *Servier* and the agreements referred to therein involve an alleged dispute over the validity or /and infringement of the so called "secondary" process patents. They differ in as much as to whether or not any proceedings involving the patents have been initiated before relevant instances. Lundbeck agreements were concluded before any actual litigation has taken place and some agreements involved a clause obliging the generic counterpart to submit to voluntary injunction. Servier's agreements on the other hand settle either the patent litigations initiated before the High Court in UK or they provide for generic company's withdrawal from the opposition procedure before European Patent Office. As can be seen, no common standard can be inferred from the fact weather the agreements were concluded pre or post-litigation was initiated. This factor may nonetheless play a role with regards to determining the level of competitive constraint exercised by the generics as potential competitors.

Secondly, some of the agreements involve distribution of the originator company's either own generic or original pharmaceutical product, in certain cases with the guaranteed profits. Some agreements make this option conditional upon entry of other generic companies

therefore the co-operation between contracting parties is further deepened as they jointly try to protect originator's market shares and artificially high prices.

Finally, the payments to the generic companies are made in exchange for different kinds of prestations. Lundbeck transferred the value to Merck and Alpharma by virtue of purchasing for destruction their stocks of generic citalopram.[154] Lundbeck's deal with Ranbaxy presupposes that it supplies Ranbaxy with citalopram for distribution purposes at a price below the ex-factory costs thus indirectly transferring the value in the form of losses incurred.[155] Servier in its agreements with Krka and Lupin pays the alleged purchase price for the two companies' patent applications.[156] Compensation to Teva is made as a clear up-front payment[157] and through the agreed liquidated damages in case of no-supply of Servier's perindopril for distribution purposes.[158] With regards Niche/Unichem and Matrix the payment covered for their "costs of development" and legal costs as well as for the compensation payments incurred due to the breach of contracts with their customers.[159] Sandoz as noted received from Johnson&Johnson EUR 5 million purportedly in exchange for promotional services.

Bearing this in mind, it becomes evident that none of the specificities singled out in the preceding text may be taken as a defying factor or a norm when it comes to the nature of pay-for-delay agreements and their non-compliance with EU competition law. Clear case scenarios like Johnson&Johnson leave not so much room for controversies and steamed academic discussions. That might just as well be the reason why this decision was not appealed by the parties. Two other cases which involve patent disputes, for which reason the agreements are also known as "reverse patent settlement agreements",[160] make them somewhat more interesting and susceptible to theoretical discussions. They also display wider range of similarities that might be used for drafting EU competition authorities' single, uniform approach with regards to treatment of pay-for-delay agreements. For the said reason the next section of the thesis will more closely concentrate on the two criteria that the

[154] *Lundbeck*, paras 267 and 528.
[155] *Lundbeck*, para 572.
[156] *Servier*, paras 923 and 1040.
[157] *Servier*, para 739.
[158] *Servier*, para 749.
[159] *Servier*, para 548.
[160] "Agreements which may contain a non-challenge clause to protect the patents held by the originator company, which are frequently concluded in the context of patent infringement or invalidity actions, are commonly referred to as a reverse payment settlement agreements." See Mark A. Lemley and Carl Shapiro, *"Probabilistic Patents"*, 19(2) Journal of Economic Perspectives (2005), p. 92.

Commission singled out and used as the basis for demonstrating the restrictive nature of dubious agreements.

2.3. Assessment of Pay-for-delay agreements under the EU Competition law

Article 101(1) of the TFEU prohibits as incompatible with the internal market "all agreements between undertakings […] 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.[161] Agreements explicitly prohibited by Article 101(1) include those which "limit or control production, markets, technical development, or investment" or "share markets or sources of supply".[162]

The notion of an agreement as contained within the Article 101(1) TFEU presupposes that the undertakings in question have expressed their joint intention to conduct themselves on the market in a specific way.[163] The Commission assumes that patent settlement agreements are, just like any other civil law contracts, voluntarily concluded by a meeting of the free will of two or more parties.[164] Indeed, agreements thus concluded represent the conviction of the litigating parties that, being aware of the plausible outcome of the proceeding, pursuing the litigation towards its end may not be the most desirable option, in terms of both resources and time efficiency. Therefore, the Commission duly recognizes that not all patent settlement agreements represent a potential threat to the competitive structure of the market.[165] Likewise, it is not to be presumed that patent settlements between competitors, or in these cases only potential competitors, constitute antitrust infringements.[166] Even the existence of any kind of value transfer does not necessarily connote the violation of competition rules and each agreement must be assessed in detail to determine its allegedly harmful nature.[167] What is it then, that disturbs the balance and qualifies the conduct as anti-competitive?

An anti-competitive agreement connotes a concurrence of wills on the very principle of a restriction of competition without essentially displaying all of its specific features.[168]

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[161] TFEU, Art. 101(1).
[162] *Servier*, para 1104; Art. 101(1) TFEU para b) and c).
[163] Case T-7/89, *Hercules Chemicals v Commission*, ECLI: EU:T:1991:75, paragraph 256; Case T-9/99, HFB and Others v Commission, ECLI: EU:T:2002:70, paragraph 199.
[164] *Lundbeck*, para 600.
[165] Commission Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014/C 89/03), para. 235.
[166] *Servier*, para 1102.
[167] *Servier*, para 1102.
[168] *HFB and Others v Commission*, paragraphs 151 to 157 and 206.

Restriction of competition in pay-for-delay agreements is evidenced by a common decision that independent efforts of a generic company to bring its product to a market shall be abandoned in exchange for a payment from the originator company corresponding with the profits generic expected to make from the sales of the said product.

Based on the Commission's findings evidenced in the three abovementioned decisions we can identify the two main constituents of a pay-for-delay agreement a) a prohibition for generic company on entering the market with the generic version of the drug b) a value transfer from an originator undertaking to its generic counterpart. Both of these may vary based on the specific situation on the relevant market and the negotiation process between the parties but the common prerogative of each pay-for-delay agreement is that these two provisions are always present notwithstanding their specific formulation or additional, supplementary prestations. The following part shall address each of these two criteria the presence of which must be evidenced in the agreement to classify it as anti-competitive.

2.3.1. Exclusion of a generic competitor from the market

The inducement of a generic company to abandon its efforts to place its generic product on the market in competition law terms amounts to exclusion of a potential competitor. Based on the variations witnessed in the different agreements this prohibition may exclusively relate to the products manufactured by the disputable processes or prohibit all dealing in any generic product notwithstanding weather it might be infringing the patent or not. The latter dealing is evidently exclusionary and undoubtedly goes beyond the effects that an originator company may achieve by relying on its patents.[169] As a matter of fact it does not seem at all reasonable for these companies to claim that they were simply enforcing their valid and infringed patents, where it is evident that in practice the effects of the agreements went beyond the scope of the patent. However, are we to assume that the former case, where exclusion from the market does not relate to the entry with another non-infringing product, is in line with competition law? As thigs stand, that cannot probably be accepted either.

Primarily, there is only limited amount of processes available for the production of a generic version of a drug. Secondly, as a matter of fact, every generic company opts for one or mostly two suppliers of either API or the product itself. Issuance of marketing authorisation and other regulatory approvals needed for placement of a pharmaceutical

[169] "A process patent does not give the patent holder rights outside the patent's scope, which for process patents is limited to the particular process covered by that patent and products directly obtained by the patented process", *Lundbeck*, para 642.

product on the market are in most jurisdictions long lasting processes that need to be undertaken all over again in case of switching to an alternative supplier. Additionally, agreement can contain a provision by which generic undertaking accepts not to take any steps towards getting a regulatory approval for their product throughout the duration of the agreement.[170] That means that in a realistic scenario, after the originator acquired certain number of these technologies or otherwise by virtue of agreements prohibited companies from using them the probability of entering with a non-blocked process are close to zero. Finally, it is essential for the originators' overall plan to make sure that that entry shall not occur. It is therefore clear that even in the former case where it does not seem from the specific provisions of the agreement that the limitation on entry is absolute, it will *de facto* be the case.

Furthermore, the fact that the companies entered into a supply arrangement[171] whereas generic company agrees to distribute originator's products and technically gets on the market does not mean that competition has not been restricted. Namely, in such arrangements the generic distributor will offer the product in quantities and at a price set by the originator which will not be equivalent to the effect produced by the genuine generic entry. All the benefits such as significant price reduction and supplier diversity will be absent. The same scrutiny under competition law shall apply to those agreements such as the ones between Servier and Krka where by virtue of a licence a single market is divided between competitors while each one gives commitments not to deal in the market of the other.[172] The Court has already held that market-sharing agreements constitute particularly serious breaches of the competition rules.[173] Furthermore, the agreements which aim to share markets have, in themselves, an object restrictive of competition.[174]

As witnessed, the commitment to abstain from market entry can be manifested in various forms, which nonetheless does not change the reality in which the entry of potential competitor is unquestionably precluded. This outcome does not follow from the parties' conviction of the strength of the originator's patent or the evidence of patent infringement. It

[170] *E.g*. Lundbeck's agreement with Merck or Servier's agreement with Niche/Unichem.
[171] *E.g.* Lundbeck's agreement with Merck and Ranbaxy.
[172] On a number of occasions the CJEU has considered agreements aimed at partitioning national markets according to national borders as agreements whose object is to restrict competition, see e.g. Joined Cases C-468/06 to C-478/06 *Sot.Lélos kai Sia and Others*, ECLI:EU:C:2008:504, para 65; Joined Cases C-501/06, C-513/06, C-515/06, C-519/06, *GlaxoSmithKline Services v Commission*, ECLI:EU:C:2009:610, para 61.
[173] Case C-449/11 P, *Solvay Solexis v Commission*, ECLI:EU:C:2013:802, para. 82; C-408/12 P, *YKK and Others v Commission*, EU:C:2014:2153, para 26.
[174] Joined Cases C-239/11 P, C-489/11 P and C-498/11 P, *Siemens and Others v Commission*, ECLI:EU:C:2013:866, para 218.

is a limitation on the generic's right and obligation to determine its commercial strategy free from influence of any of its competitors. The practice involving conclusion of agreements among competitors with the objective of excluding some of them from the market by virtue of an inducing payment is not uncommon in EU competition law. Namely, *Irish beef* is a case that dealt with the agreements aimed at sharing profits among the undertakings staying on the market and those agreeing to leave it. The conclusion of the agreement enables participating undertakings to implement a common policy which has as its object the encouragement of some of them to withdraw from the market.[175] This contrasts with the very *raison d'etre* of competition law which is to ensure that each economic operator is independently determining the policy it intends to adopt on the common market.[176] Similarly, in the pay-for-delay cases, in absence of the agreements, the originator companies could not rely on any legitimate means, or they would be potentially proven ineffective, in order to repel generic competitors and would necessarily loose the profits due to price reductions and loss of market shares. The Court of Justice in *Irish Beef* took a stand that the arrangements in question were a "restriction by object."[177] Given the high resemblance of the situations in *Irish beef* and cases at hand, by virtue of analogy, it would be safe to assert that the same treatment shall be applied with respect to pay-for-delay agreements.

2.3.2. The value transfer from the originator company

Originator companies are well-aware that generics' profits depend mostly on the timely entry into the market with own generic version of the drug. The first company to enter the market will be able to charge the highest price before it gradually starts to decrease as the competition on generic market grows. In that, there is a strong incentive for the generics to attempt to be market pioneers. Given that the main aim and effect of the pay-for-delay agreements is to postpone this entry for the duration of the agreement, originator companies must counter offer a significant inducement. As the economics of pay-for-delay explained originators can afford to share their profits with the generics with the greatest odds of entering the market. Therefore, they agree to "pay-off" the competition. The value transfer in pay-for-delay agreements flows from the originator to the generic undertaking. As evidenced from the agreements above it can take different form and can be well or ill-disguised from the

[175] Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, ECLI:EU:C:2008:643, para 33. (hereinafter '*Irish Beef*')
[176] *Irish Beef*, para 34.
[177] *Irish beef*, para 40.

competition authority. The creativity and subtlety of the drafter of the agreements deserves more or less praise but in the end the true nature of the commitment resurfaces.

The Commission in its 2009 report identifies multiple variations of value transfer.[178] The most obvious one is direct monetary transfer, a straight up front payment of a full lump sum or in monthly constellations. More subtle alternatives include monetary transfer that takes the form of compensation for the generic company's patent litigation and/or other legal costs or are disguised behind the purchase of the allegedly infringing stock of a generic product supplies. Other types of agreements include value transfers indicated as payments for a certain service performed by the generic undertaking such as distribution of the originator's product or co-promotion services. Further on, value transfer could consist in granting a patent licence to the generic company which enables it to enter a market with a product. Nonetheless, as previously explained, the commercial freedom of the generic undertaking remains limited by the terms of the licence agreement and as such the generic entry in its true sense is lacking.

The Commission seems to identify the value transfer from the originator as one of the indicators of the existence of a reason (e.g. the invalidity of the patent) that would justify immediate generic entry.[179] More generous the amount it is more likely that the assumption is correct. Nonetheless, the Commission affirms that each value transfer shall be investigated on a case by case basis in terms of verifying the net amount and any potential justifications for it.[180] What is nonetheless controversial is the question of when does a payment exceed a threshold and becomes an anti-competitive inducement for the delay in market entry. How does the Commission determine, for example, that the value transfer exceeds the genuine consideration for the services provided by generics? The Commission in the three decisions strongly values the argument that the size of the payment reflects the estimated profits of the generic companies in the case of entry. These profits are determined based on the companies' own predictions expressed in the internal documents seized during the course of the Commission's investigation.

How much value can be given to the Commission's argument is highly expected to be determined in the CJEU's decision on Lundbeck's and Servier's appeal. In the meantime some conclusions may be drawn from the *FTC v Actavis*[181] judgment of the US Supreme

[178] Final Report, p. 269.
[179] Stefano Barazza, *Pay-for-Delay Agreements in the Pharmaceutical Sector: Towards a Coherent EU Approach?*, 5 Eur. J. Risk Reg. 79 2014, p. 85.
[180] European Commission, 6th Report on the Monitoring of Patent Settlements, 2 December 2015, para 13.
[181] *Federal Trade Commission v Actavis*, 133 S. Ct. 2223 (2013). (hereinafter 'Actavis')

Court. The conclusion of the Supreme Court's judgment in *Actavis* is that "the presence of a 'large, unexplained' payment from the brand to the generic deserves legal scrutiny but is not by itself conclusive regarding anticompetitive delays in generic entry.[182] The US Court implied that there might be normal business purposes which are remunerated by the originator-to-generic payment. It also held that the size of a reverse payment settlement may provide a "workable surrogate for a patent's weakness".[183] Personally, one of the most interesting features was the Court's notion that "the [reverse] payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." This question is necessarily tied with the question of the scope of the process patent, and weather the commitments of the generic company go beyond that scope. It can also be understood as the legitimate purchase of legal certainty, the argument previously raised when the incentives for conclusion of pay-for-delay agreements were discussed.

[182] Keith M. Drake, Martha A. Starr & Thomas G. McGuire, *Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?,* (2015) International Journal of the Economics of Business, 22:2, 173-200, p. 174.
[183] *Actavis*, p. 19.

Chapter III: Challenges to the Commission's findings on anti-competitive pay-for-delay

Commission's approach to pay-for-delay agreements was summarised by then incumbent Director General Alexander Italianer as a three-pronged test encompassing the following: i) originator and generic manufacturer must be potential competitors, ii) the agreement must provide for a limitation on generic's attempt on entry and iii) a substantial value transfer from the originator to the generic producer.[184] Judgment by the General Court is impatiently awaited but it is the assumption that all three elements need to be evidenced cumulatively in the agreements and substantiated by reference to the legal and economic context to those agreements in order to constitute restriction of competition by object. In the anticipation of the judgment some scepticism has been evidenced in academic circles with regards to each of these specific elements. Firstly, uncertainty is expressed with regards to the general character of settlement agreements which, if the patent is deemed valid, necessarily involve a commitment from the generic undertaking not to encroach upon patent rights when entering the market. Secondly, great uncertainty is expressed as to whether the Court will support the Commission in asserting that pay-for-delay agreements restrict competition by object. Finally, it is argued that the Commission's arguments on potential competition do not fully comply with the previous jurisprudence, in as much as a generic manufacturer not yet in possession of the requisite marketing authorisation and which, when challenged by an originator, loses a critical patent dispute have 'real, concrete possibilities' to enter the relevant market within the requisite 'short period of time'.[185]

The purpose of this Chapter is to present the arguments both in favour and against the Commission's approach and consider the likelihood that they will be upheld by the CJEU.

3.1. An unlikely case for immunity from competition law enforcement

European Commission in its *Lundbeck* and *Servier* decisions seems to unambiguously pursue the line of reasoning that the fact that the respective pay-for-delay agreements are concluded in the course of an ongoing patent dispute and represent the way that the patent litigation has been settled by the concerned parties makes no difference for the competition

[184] Speech by Director General Alexander Italianer, *Competitor agreements under EU competition law*, 40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute New York, 26 September 2013, p. 9.
[185] Patrick Harrison; Kristina Nordlander, *EU / US Patent Settlements: An overview of leading cases*, e-Competitions, No. 58749, Institute of Competition Law, p.4.

law purposes. In that, the Commission seems to have orthodoxly accepted that the agreements which subject matter concerns patent law shall not be immune from competition law scrutiny. However, these arguments seem to have caused some controversy on the other side of the Atlantic. Namely, in the US Supreme Court's *FTC v Actavis*, a dissenting minority of judges disagreed with the majority opinion, claiming that reverse patent settlement agreements shall be immune from the competition rule, in as much as they remain in the sphere of the exclusivity monopolistic rights conferred by a patent.[186] Is it possible and likely that the CJ EUwill follow the same reasoning in the impatiently awaited judgments on appeal?

Part of the answer to this question lies in the previous jurisprudence of the CJEU. General Court has defined the agreements for the purpose of Article 101 TFEU as "concurrence of wills between at least two parties… [in as much as] it constitutes the faithful expression of the parties' intention."[187] Likewise, the GC in *Bayer v Heinz Süllhöfer* expressed its view that Article 101(1) TFEU [then article 85(1)] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind."[188] The Court thus endorses a rather wide interpretation of what can be considered an agreement in the sense of Article 101 TFEU. Accordingly, there seem not to be a reason to assume *a priori* that pay-for-delay agreements shall be immune from the application of competition law.

It is true that competition law shall not negate the effects that transpire from the patent rights held by the originator. For example, according to the CJEU the right of the patentee to oppose infringements is inherent to the possession of a patent.[189] In that, specific steps taken by Lundbeck or Servier such as informing generic undertakings of the existence of a patent and possibilities of infringement, the initiation of infringement proceedings or request for interim injunction do not go beyond the legitimate rights assigned to the patentee. However, the restriction of the freedom to challenge an intellectual property right is not part of the specific subject-matter of an intellectual property right and may restrict competition.[190] Such

[186] *FTC v Actavis*, 133 S. Ct. 2223 (2013). (Roberts, C.J., dissenting), pages 1 and 3.
[187] Case T-41/96, *Bayer v Commission*, ECLI:EU:T:2000:242, para 69; for discussion see Oliver Black, *Agreement: Concurrence of Wills, or Offer and Acceptance?* (2008) European Competition Journal Volume 4, Issue 1, 2008, p. 103.
[188] Case C-65/86, *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer,* ECLI:EU:C:1988:448, paragraph 15.
[189] Case C-15/74, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, ECLI:EU:C:1974:114, paragraphs 7 to 9.
[190] TTG, para 243.

commitment which is in the context of a pay-for-delay agreement most likely induced, financially or otherwise, is likely to breach competition law.[191]

Hereby, an important difference between *Actavis* and both *Lundbeck* and *Servier* must be noted. The patent challenge in the former case concerns the compound patent while in two latter cases the controversy revolves around process patents. While the compound patent does provide the patentee with the absolute legal monopoly, the process patents relate only to certain ways of manufacturing the substance. The exclusivity enjoyed in the latter case is significantly lesser. To prove the infringement the originator has to firstly make evident that the generic is using precisely the patent protected technology, which may not be an easy task. Even if the originator succeeds, relaying on its patents will never be enough to achieve absolute exclusionary effect. In that, the commitment not to enter the market which is not limited solely to the products covered by the disputed patents goes beyond the patents' scope. Even the dissenting minority in *Actavis* concedes that in a case where the actions of the originator go beyond monopoly powers conferred by the patent those actions shall be subjected to competition law scrutiny.[192]

In addition, the decision on behalf of generics to refrain from market entry needs to be made solely on the assessment of the strength of the originators' patents and not made against compensation. If it appears to the generic undertaking that the process might indeed be infringing it is in the interest of that undertaking to settle the litigation and avoid further costs. In case where the entry has not yet taken place, the generic undertaking would not be liable for any damages and no payment shall be evidenced in the agreement. It is nonetheless reasonably expected that the generic undertaking that settled the dispute would continue with its attempt to enter the market by looking for different arrangements, i.e. new suppliers of API or the generic product itself, attempting to invent itself a non-infringing process or acquire a licence. The commitment to abstain from all efforts to enter the market through use of the alternative, available and non-infringing production methods justifiably raises competition law related concerns.

The facts in *Lundbeck,* including the wording of provisions of the agreements in question, connote that generic undertaking in most cases agreed to the restrictive terms that go beyond the scope of the disputed patents. Four out of six Lundbeck's agreements exceeded the scope of patent law in as much as they relate not solely to the citalopram

[191] *Ibid*.
[192] Actavis, dissenting opinion, p. 3; The dissenting judges additionally refer to the case *United States v. Singer Mfg. Co.*, 374 U. S. 174, 196–197 (1963).

product the generics produced by the allegedly infringing processes, but also to any future citalopram products that could have been produced in a non-infringing manner. This was the case for Lundbeck's agreements with: i) Merck agreement regarding other EEA Contracting Parties than the United Kingdom[193] ii) Arrow regarding both the United Kingdom[194] and Denmark[195] and iii) Alpharma regarding the EEA.[196]

Given the circumstances, one may assume that the CJEU will most unlikely find on the appeal that the agreements covered by the Commission's *Lundbeck* and *Servier* decisions may be excused from the EU competition law scrutiny.

3.2. Unresolved patent dispute and legal uncertainty

The specific situation of legal uncertainty, in which a patent appears as only potentially infringed, is one of the peculiarities characteristic of the legal and economic context analysis and especially for determining whether generics can be seen as potential competitors. What clearly separates the situation in question from the regular monopoly owed exclusion of competitors from the market is the high level of ambiguity as to whether the disputed patent is strong and valid. The settlement has the effect of substituting the final judgment on the infringement or patent validity. It is widely accepted that such settlement in general carries pro-competitive effects.[197] But are we to believe that the parties to Lundbeck's and Servier's agreements actually settled patent litigation? What is the significance of the non-challenge clause in patent settlement agreements and does the existence of such a clause presume anti-competitive effects?

The Commission acknowledges that the content of individual settlements may vary according to the circumstances of the case. It however stresses that the common aim of a settlement is to end the disagreement.[198] But the agreements considered in *Servier* and *Lundbeck* in fact did not settle any intellectual property issue but solely postponed the conflict in the financial interest of both parties. Parties in all but one[199] of the Lundbeck's settlement agreements do not seem to have a common approach towards the validity of the disputed patent. Preambles to these agreements acknowledge that while the originator

[193] *Lundbeck*, para 348.
[194] *Lundbeck*, para 394.
[195] *Lundbeck*, para 457.
[196] *Lundbeck*, para 523.
[197] Sumanth Addanki, Alan J. Daskin, *Patent Settlement Agreements*, Chapter 85 in ABA Section of Antitrust law, *Issues in competition law and policy*, ABA Book Publishing, Chicago, 2008, p. 2127.
[198] 6th Monitoring Report, para 2.
[199] Lundbeck's agreement with Alpharma.

undertaking considers the patent to be infringed the generic company disagrees with that claim but still decides to settle.

Patent settlement agreement in which any one of the parties fails to acknowledge the validity of the other party's claim is a logical nonsense, it is paradoxical. This phenomenon can indeed be compared to the 'Schrödinger's Cat' experiment.[200] Following the conclusion of the agreement the patent remains in a state referred to in the experiment as a "quantum superposition", meaning it may be both valid and invalid. The only purpose the agreement achieves is therefore to delay the "random subatomic event" that may or may not occur – court's ruling on the validity of the patent.

Particular impact to the anti-competitive conduct comes from the inclusion of a non-challenge provision in the agreements. Said provision without exception forbids the generics from challenging originator's patents or provide for the mutual refrainment from challenging each other's patents. Non-challenge provisions are clauses typically forming part of licence agreements aimed at avoiding a licensee from 'biting the hand that feeds it' and challenging the intellectual property rights that have been licensed to it.[201] These clauses also form an essential part of genuine settlement agreements, which are regarded as not being able to fulfil their intended purpose, putting an end to litigation, if a non-challenge provision relating to the litigated patents is omitted.[202] However, this can be accepted solely in cases where the parties actually settled by agreeing on the patents validity or the non-infringement.

The parties in *Lundbeck* and *Servier* agreed to mutually refrain from challenging each other's patents for the duration of the agreement or abandon any litigation or opposition procedures that might have been initiated. Without the possibility of challenging the patent potential generic competitors will not have a chance of entering the market without risking the infringement and potential liability for damages. Therefore, generic's acceptance of a non-challenge and/or non-compete obligation (generic company refrains from entering the market until the patents have expired) in a pay-for-delay agreement is equivalent to the limitation on entry.[203] No guarantees on behalf of the originator that it shall not initiate litigation upon termination of the agreements are provided nor did they agree on a date of an "early entry" (entry before originators' process patents expired). This means that after the agreements have been terminated generic companies would still have to litigate on the

[200] That is, they might prove ultimately valid or invalid if litigated: R Stern, *FTC v Actavis: Patent Validity, Schrödinger's Cat and Reverse Payments,* (2013) 12 EIPR 743.
[201] Sophie Lawrance, *The competition law treatment of no-challenge clauses in licence agreements: an unfortunate revolution?* Journal of Intellectual Property Law & Practice, 2014, Vol. , No. 0, p. 1.
[202] TTG, para 242.
[203] 6th Monitoring Report, para 9.

validity or seek declaration of non-infringement if they want to launch their product before the patents have expired.

This practice evidently contrasts with the public interest which according to the CJEU in *Windsurfing* is "to eliminate any obstacle to economic activity which may arise where an intellectual property right was granted in error."[204] The conclusion of settlement agreement with a non-challenge clause, where induced financially or otherwise, removes or simply delays the chance of determining the validity of the right, given that such agreement substitutes a final judicial decision.

This argument, in my opinion, makes a strong case for the object based approach toward the pay-for-delay agreements that include a non-challenge and/or a non-compete clause.

3.3. Pay-for-delay agreements as restrictions of competition by object: reasonable approach or a manifest error in assessment

In its Final Report the Commission concluded that, it will indulge into "an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background" when assessing the legality of pay-for-delay agreements.[205] According to some authors[206] this can be understood either as the Commission opting for an effects-based approach or that the Commission is referring to the object restriction based on the extended contextual analysis in line with the Court's interpretation in *Allianz Hungaria*.[207] Furthermore, Commission stated in its Technology Transfer Guidelines that pay-for-delay settlements "are based on a value transfer from one party in return for a limitation on the entry and/or expansion on the market of the other party and *may* be caught by Article 101(1)".[208] From the use of the word *may* in this definition one can infer that the Commission does not find these agreements to be *per se* or *ab initio* restrictions of competition.

However, the three decisions concerning pay-for-delay agreements confirm that the Commission finally opted for "the object restriction" approach. The Commission therein argues that the clear objective of the pay-for-delay agreements was to block the imminent market entry of a generic company for the duration of the agreement. Generic counterpart is

[204] Case C-193/83, *Windsurfing International*, para 91.
[205] Final Report, para 574.
[206] Petar Cimentarov, *Expanding the "Object Box" and its Perverse Effects. Does EU Competition Law Condemn Innocent Behaviour?*, Mayer Brown, in association with the College of Europe, 2014, p. 21
[207] Case C-32/11, *Allianz Hungária Biztosító Zrt and Others v Gazdasági Versenyhivatal*, ECLI:EU:C:2013:160. (hereinafter 'Allianz Hungaria')
[208] TTG, para 238.

financially induced to abandon its independent efforts of bringing its own generic product to the market. The agreement ensures that an originator company maintains its monopoly prices while its monopoly rent is shared with the closest potential competitors.[209] Lundbeck in its appeal of the Commission's decision alleges that the conclusion that the patent settlement agreements restricted competition by object under Article 101(1) rests on a wrongful application of the established principles on restrictions by object.[210] Servier along the same line argues that in order to classify the restriction agreements 'by object', the Commission relied on three factors, so broadly defined that they are ineffective, to distinguish legitimate amicable settlements from anti-competitive agreements.[211] In addition, a number of academics are of the opinion, which is partly influenced by US Supreme Court's *Actavis case*,[212] that these agreements shall be regarded as anti-competitive solely after their anti-competitive effects have been assessed and substantiated.[213]

How consistent is the Commission's analysis with the CJEU's jurisprudence on restrictions of competition by object? Why should the CJEU support the Commission's classification of these agreements as restrictions by object? Would the interpretation of restriction by object be unduly broadened? Finally, are the suggested threshold criteria by the Commission sufficient and acceptable? These are the questions the author is looking forward to address in the following headings.

3.3.1. The CJEU's general approach towards object-based infringements

Restrictions of competition by object are considered as those which, in light of the objectives pursued by the EU competition rules, have a high potential of negative effects on competition.[214] In as much as it is argued that the agreements in focus are generally pro-competitive, patent litigation settling mechanisms, we may recall that an agreement can be restrictive by object, even if its object is not solely anticompetitive but also serves legitimate aim.[215] In line with the CJEU's jurisprudence, "restrictions of competition by *object* and *effect*" are not cumulative, but alternative conditions in assessing compatibility of agreements

[209] *Fentanyl*, paras 329-331.
[210] Case T-472/13, *H. Lundbeck and Lundbeck v Commission*, 30 August 2013, third plea in law.
[211] Case T-691/14, *Servier SAS and Others v Commission*, 21, September 2014, fourth to twelfth pleas in law.
[212] *Actavis*, p. 20.
[213] Stefano Barazza, *Pay-for-Delay Agreements in the Pharmaceutical Sector: Towards a Coherent EU Approach?*, 5 Eur. J. Risk Reg. 79 2014, at p. 86; Osman Zafar, *Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 'pay-for-delay' decisions*, Journal of European Competition Law & Practice, Oxford University Press, 2014, p. 2.
[214] *Irish Beef*, para. 17; European Commission, Guidelines on the application of Article 101 (3) (formerly Article 81(3) TEC)of the Treaty [2004] OJ C 101/97 para. 21.
[215] Case C-551/03, *General Motors BV v Commission*, ECLI:EU:C:2006:229, para. 64.

with the prohibition enclosed in Article 101 TFEU.[216] In that, it is redundant to examine the effects of an agreement once its anticompetitive object has been demonstrated.[217] This approach is rather favorable for the Commission which needs not indulge into complex and costly economic analysis of the market *ex post* conclusion of the relevant agreements.[218]

According to CJEU in *Cartes Bancaires*, which has been the most topical recent case of *"object-effect"* saga, the essential legal criterion for ascertaining whether coordination between undertakings restricts competition by object is the finding "that such coordination reveals in itself a sufficient degree of harm to competition."[219] Where conduct reveals such sufficient harm the Commission may find that there is no need to examine its effects.[220] The previous shall be established on the basis of the extensive analysis of the content of the agreement's provisions, its objectives and the economic and legal context of which it forms part.[221] Additionally, the parties' intention does not necessary form part of the assessment of the restrictiveness of a certain conduct on competition, but the competition authorities are not precluded from taking account of that factor.[222]

Finally, all pay-for-delay decisions were delivered in the period after the CJEU's judgment in *Allianz Hungária*. Accordingly, it has been accepted by the CJEU that the Commission, when determining the economic and legal context of the agreements as a part of the object analysis, may draw conclusions from the detailed consideration of the nature of the goods at issue, as well as the real conditions of the functioning and structure of the markets.[223] The same statement is repeated by the Court in *Cartes Bancaires*[224] in spite of the notion that there is a need to keep a restrictive approach to the object classified restrictions.[225]

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[216] *GlaxoSmithKline Services v Commission*, para 55.
[217] *Ibid*.
[218] Sven Patrick Gallasch, *The Anticompetitive Misuse of Intellectual Property Rights in the European Pharmaceutical Sector*, Thesis submitted for degree of Doctor of Philosophy University of East Anglia, UEA Law School, April 2014, p. 149.
[219] Case C-67/13 P, *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, para 57; C-382/12 P - *MasterCard and Others v Commission*, ECLI:EU:C:2014:2201, para 139; Case C-226/11, *Expedia Inc. v Autorité de la concurrence*, ECLI:EU:C:2012:795, para 36.
[220] *Groupement des Cartes Bancaires*, paras 52, 58, 69.
[221] *Groupement des Cartes Bancaires*, para 53; *GlaxoSmithKline Services and Others v Commission*, para 58; Case C-172/14, *ING Pensii*, EU:C:2015:484, para 33.
[222] *Groupement des Cartes Bancaires*, para 54; *Allianz Hungária,* para 37.
[223] *Allianz Hungária*, para 36.
[224] *Groupement des Cartes Bancaires*, para 78.
[225] *Groupement des Cartes Bancaires*, para 58.

3.3.2. Advocating in favour of the Commission's restriction by object classification

Based on the consideration of the Commission's arguments in the three cases it is submitted that pay-for-delay arrangements, except in some exceptional circumstances, meet the appropriate standard for being regarded as object restrictions. Effects-based analysis of pay-for-delay settlements is redundant.

3.3.2.a. Commissions assessment of restriction by object is consistent with the case law on the matter

In line with the above mentioned legal test, the author argues that the Commission properly conducted the assessment of all the previously noted criteria necessary for classifying a certain conduct, in this case pay-for-delay agreements entered into by Lundbeck, Servier and Johnson&Johnson, as restrictions by object.

Commission's findings are presented in systematic and consistent way. The analysis of the economic and legal context acknowledges the nature of the goods in question, namely pharmaceutical drugs. Accordingly, it takes into account in particular the EU regulatory framework for pharmaceutical industry together with the implications of the system to the market structure and real conditions of competition and functioning on the market. The analysis further contains a presentation of the negotiating process between the parties that led to the conclusion of the agreement. It reveals parties' motives for the conclusion of the agreements, their predictions of profits and perception of competition. It also exhibits in great detail and with respect to each generic competitor, their strategies for market entry. On the basis of those considerations the Commission concludes that the originator and generic undertakings were at least potential if not actual competitors.

Commission further discusses specific provisions of the agreements as a part of content and objective analysis. It concludes that the agreements had as their objective to ensure that the generic party stayed out of the market for the duration of the agreement. The former effect is achieved through different variations of provisions characteristic for the each generic undertakings position with regard to the originator. These specific provisions have been discussed in detail in Chapter II. What they have in common is that, as the consequence of the commitments accepted by the generic undertakings, potential competitors were excluded from the market when their entry was imminent. These commitments were undertaken in exchange of a significant value transfers that occurred in different forms but

served as the substantial inducement for the anti-competitive conduct. The Commission finally submitted considerable amount of material evidencing parties' intentions to restrict competition which compliments its analysis of the objective elements.

3.3.2.b. Pay-for-delay settlements cause presumably harmful effects

The primary argument of the author relies on the economic theory of harm. It is presumed that sufficient degree of harm can be inferred with a high degree of certainty from the absence of immediate or imminent generic entry. Namely, the positive effects on the market resulting from generic entry have been presented in Chapter I. Delay in the occurrence of these positive outcomes, owed to the conclusion of the agreement, inherently carries negative effects that harm consumers and public health authorities. These effects on prices, output, innovation or the variety or quality of goods, can be inferred with a reasonable degree of probability. The argumentation is therefore based on the theory of inherent consumer harm of pay-for-delay agreements.

Further conclusion can be drawn from the comparison of the current practice with the conclusion of the so called "BIDS arrangements" in *Irish Beef*. In as much as the overcapacity on the beef market, which was the reason in this case to resort to the anti-competitive practice, affected undertaking's profitability by preventing them from achieving economies of scale[226] a very similar effect on originator's profitability transpires from the generic entry. The originator companies face significant profit losses due to the fact that they are no longer in position to impose monopolistic 'supracompetitive' prices. Their capability of determining prices for goods on the market is strangled by generic competition. Any agreement which objective is to prevent the occurrence of price competition on the market for a certain product is by its nature sufficiently harmful for competition.[227] Experience shows that these dealings are detrimental particularly to consumers.[228]

3.3.2.c. Pay-for-delay agreements hinder competition from new entrants

An anti-competitive measure will be classified as object restriction in case where it hinders competition from new entrants. The agreements in questions produced precisely the said effect with respect to the generic undertakings involved in their conclusion. The assumption of the GC in *Cartes Bancaires* was that the measures at issue have as their object

[226] *Irish Beef*, para 33.
[227] Case C-123/83, *Clair*, ECLI:EU:C:1985:33, para 22.
[228] *Groupement des Cartes Bancaires*, para 51.

the restriction of competition within the meaning of Article 101(1) TFEU in that, essentially, they hinder the competition of new entrants on the market for the issue of payment cards in France.[229] The ECJ did not find GC's argumentation consistent with the case law on restriction by object. We must nonetheless make a distinction between that case and hereby discussed decisions. While sufficiently harmful exclusionary effects in *Cartes Bancaires* might not have been induced from the measures such as 'payment of a fee or limiting the issue of CB cards'[230] without examination of the effects, it is more than certain that these effects transpire from the generic's *explicit* commitment to abstain from market entry.

Furthermore, the presumption is that "cumulative effect of all the agreements" concluded by a single undertaking was to completely foreclose the market to any kind of competition. As previously argued, the agreements concluded between the parties exceed the scope of protection owed to the possession of the process patents in that their effect is to prolong market exclusivity on the compound beyond the compound patent expiry. The originator's monopoly is thus maintained which allows it to charge monopolistic prices. Market foreclosure in this case may not be absolute but nonetheless it is sufficient to generate negative effects on competition. Namely, the peculiarities of the EU pharmaceutical market neither allow absolute market foreclosure nor do they exclude the possibility that it happens. Whether or not such foreclosure is likely to occur will depend on the assessment of the competitive environment within the relevant market.

Negative repercussions of such arrangements have been discussed by the CJEU in *Delimitis v Henninger Brau*.[231] Although this is an effects-based case the author emphasises on the previously noted peculiarity that post *Allianz Hungaria*, identical assessment of the competitive environment is possible within the analysis of legal and economic context of which the presumably anti-competitive agreement forms part. The Court's examination in *Henninger Brau* of whether it was difficult for competitors to gain access to the market in the light of the economic and legal context of the agreement at issue[232] is essentially similar to the Commission's finding that pay-for-delay agreements restrict potential competition. The judgment in this case is acknowledgment that even agreements with pro-competitive features can potentially give rise to significant anticompetitive effects when considered in their legal and economic context in the relevant market.

[229] *Groupement des Cartes Bancaires*, para 60.
[230] *Groupement des Cartes Bancaires*, para 82.
[231] Case C-234/89, *Delimitis v Henninger Bräu* ECLI:EU:C:1991:91. (hereinafter '*Henninger Bräu')*
[232] *Henninger Bräu*, para 27.

3.3.2.d. Restriction by object classification enhances legal certainty

The classification of a certain type of collusive conduct between competitors as the object-based infringement inherently carries certain advantages such as that it undoubtedly creates legal certainty, enabling undertakings to predict the legal consequences of some of their actions, and to modify their conduct accordingly.[233] It further has a deterrent effect thus helping in the prevention of the anticompetitive conduct.[234] The annual monitoring reports on pay-for-delay settlements conducted by the Commission manifest a trend of downfall in the number of problematic patent settlements while recording increase in the overall number of settlements.[235] This means that the enforcement of competition rules in the three decisions, including the classification of anticompetitive conducts as restrictions by object, indeed served the designated purpose.

3.4. The challenge to the interpretation of the concept of potential competitors

Potential competition is seen as one of the three main sources of competitive constraints together with demand and supply substitutability.[236] Commissions' examination of conditions of competition on a given market must include the assessment of potential competition in order to ascertain whether there are *real concrete possibilities* for the relevant undertakings to compete among themselves or to determine the odds for the entry of a new competitor.[237]

The legal concept of potential competition has a vital role in the Commission's assessment of pay-for-delay agreements. These agreements are in most cases concluded before any actual generic product placement on the market had transpired. In that, we can only talk of the generic and originator undertakings being potential competitors for the specific pharmaceutical product for which the period of patent exclusivity on the compound had lapsed or whose validity is challenged. The prospective of a successful market entry is further blurred by the notion that the originator company is still in possession of some patents over the manufacturing processes, claiming that the production of the generic drug would inevitably infringe those patents. This was precisely the case in *Lundbeck and Servier*. Both

[233] Case C-67/13, Opinion of AG Wahl in *Groupement des Cartes Bancaires*, ECLI:EU:C:2014:1958, para 35.
[234] *Ibid*.
[235] 6th Monitoring Report, p.p. 14-15.
[236] Commission's Notice on the definition of the relevant market for the purposes of Community competition law, OJ 1997 C 372, p. 5.
[237] Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services and Others v Commission*, ECLI:EU:T:1998:198, para 137.

of these originator companies challenged in their appeals the Commission's findings, claiming that it misinterpreted the main criterion to determine whether an agreement restricts potential competition.[238]

In the light of the previous, it is necessary to proceed by examining Commission's arguments on the matter in the light of the criteria developed through the practice of the CJEU. Did the Commission apply a correct legal test in order to assess generics prospects of entering the market in question?

3.4.1. Entry into the market as an economically viable strategy

At first we may examine how Commission's approach matches the assessment of potential competition as suggested in *Visa* case. Legal test to be applied when determining whether a certain undertaking can be regarded as potential competitor requires the Commission to demonstrate that "in the absence of the anti-competitive conduct there would have been *real concrete possibilities* for that undertaking to enter the market and to compete with market incumbents."[239] An undertaking cannot be regarded as potential competitor unless its entry into a market is not an '*economically viable strategy'*.[240] Commission's consideration of an undertaking as a potential competitor may be based on that undertaking's intention but more essentially it must derive from its assessment of undertaking's ability to enter the market.[241]

In the pharmaceutical sector the notion of a 'viable strategy' entails a fulfilment of a number of steps before the generic undertaking can be considered ready to place the product on the market. As the Commission stipulates, this process starts when a commercially viable production process is found and it leads to a product that meets regulatory requirements.[242] The following phase encompasses steps such as applying for marketing authorisations, ordering supplies, developing strategies for commercial market entry and obtaining price and reimbursement levels.[243] The biggest hurdle however is the need to overcome potential intellectual property barriers deriving from not yet expired process patents which is the precise issue with pay-for-delay agreements.

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[238] Lundbeck's Corporate Release No 5092, *Lundbeck appeals European Commission decision*, Valby, Denmark, September 2013, at http://investor.lundbeck.com/releasedetail.cfm?releaseid=788105 (last accessed on 9 May 2016).
[239] Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, ECLI:EU:T:2011:181, para 166. (hereinafter 'Visa')
[240] *Visa*, para 167; Case T-177/04, *easyJet* v *Commission*, ECLI:EU:T:2006:187, paragraphs 123 to 125.
[241] *Visa*, para 168.
[242] *Lundbeck*, para 616.
[243] *Ibid*.

Can a company in a situation where a possibility of interim injunction against it is present and pending be regarded as a potential competitor? Can there be potential competition when generic undertaking does not at the moment of conclusion of the agreement possess marketing authorisation? At which stage of the entry process is the threshold satisfied? The answer to these questions may not be of a wide-general character. Whether or not a specific generic undertaking can be identified as potential competitor is a task for the Commission to assess based on the analysis of the economic and legal context of each of the agreements entered into.[244]

The Commission in all three decisions identifies a number of factors relevant for such assessment and indeed individually examines each of the agreements with reference to specific conditions, provisions of the agreement and negotiating process.[245] Thus, it seems to be acting accordingly with the requirement that the demonstration of real concrete possibilities of entering the market must not be based on a mere hypothesis, but must be supported by evidence or an analysis of the structures of the relevant market.[246]

The Commission has built a strong argumentation based on the assumption that the potential threat from the generic competitors may be derived from the perceptions of the market incumbents. For that purpose in both Decisions it refers to numerous statements of originator companies' officials, patent experts and legal advisors in which they express concern that the generic competitors might be on the virtue of entering the market at risk or that they might be up to acquiring the API synthesised by use of a non-infringing process. The outcome of patent litigation is however unpredictable to either of the parties involved and they equally share their concerns. The strong determination of generics to nonetheless launch the product and take the risk might be taken as a signal that the patents were not considered an unsurmountable burden. Indeed in its assessment of generics chances of penetrating the market the Commission takes into account that the parties had strong incentives for launching at risk given that they considered their chances of invalidating a patent or escaping injunction as high.[247] Some of them even had an option of switching to alternative supplier with what was considered a non-infringing process.[248]

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[244] *GlaxoSmithKline*, paragraph 58; Case C-403/08, *Football Association Premier League*, ECLI:EU:C:2011:631, paragraph 136; Case C-8/08, *T-Mobile Netherlands BV*, ECLI:EU:C:2009:343, paragraph 27.
[245] *Lundbeck*, section 12.
[246] *Visa*, para 167; *European Night Services and Others* v *Commission*, paragraphs 142 to 145.
[247] *Lundbeck*, para 1038.
[248] *Ibid*.

A number of legal practitioners[249] support Commission's argument that the entry was not just purely theoretical by referring to the specific terms in the documents seized and analysed by the Commission such as 'generic companies competing for being in the "*pole position"* for generic entry' or the reference to the *"race against Tiefenbacher"*.[250] There are nonetheless those who take the view that the Commission's understanding of potential competition is too broad to be acceptable.[251]

The greatest enigma however remains with the question whether Lundbeck's patents were an obstacle that was impossible to overcome. While it is undisputed that Lundbeck and Servier were in possession of process patents their validity was speculative. Moreover, the patents on the molecules themselves have expired. Therefore, one can at least argue that it was feasible for the generics to enter the market with the generic version of the product produced by the non-infringing methods. The economic viability of that option may nevertheless be contested and might be something General Court would consider in its judgments on the appeals.

3.4.2. Perception of market incumbents

Special consideration shall be given to the General Court's notion in *Visa* of the competitive pressure that transpires from a mere existence of a potential competitor.[252] The competitive pressure felt towards the termination of exclusivity period indeed triggers a defence mechanism on behalf of the originator undertaking which resort to different kind of strategies in an attempt to retain high profits as long as possible. The weight of that exact competitive pressure triggered Lundbeck and other originators to engage into discussions with specific generic competitors and offer or accept to share a significant piece of their profits in exchange of obtaining certainty that the generic products will not reach the market as long as the agreements are in force.

The selective targeting of certain generic undertakings is also evident from the case files.[253] It is the careful consideration of market conditions and generic's readiness to launch its product that were a determining factor in choosing the generic counterparts with which

[249] Andrea Zulli, Anne Robert, Cynthia Burton, Peter Bogaert, *The Commission's Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis?- A review of the Commission's assessment of reverse patent settlements in the Lundbeck citalopram case*, Covington & Burling LLP, 2015.
[250] *Lundbeck*, para 622.
[251] James Killick, Jérémie Jourdan & Jerome Dickinson, *The Commission's Lundbeck decision: A critical review of the Commission's test for patent settlement agreements*, Competition Policy International Europe Column, February 2014, p. 5.
[252] *Visa*, para 169.
[253] *Lundbeck*, para 622.

originators wanted to strike a deal. For example, Lundbeck was convinced at the time that "[g]eneric competition is foreseen on markets where the product patent has expired", which was for most EEA Contracting Parties at January 2002 the latest.[254]

The Court found in *Hitachi*[255] and *Visa* the assessment of the competitors as an important factor in determining the likelihood of entry and therefore the potential competition on the market. With this regard, General Court in *Hitachi* acknowledged that the willingness of the market incumbent undertaking to conclude restrictive agreement in the first place demonstrates that it considers the entry of the new undertaking most probable and therefore identifies that undertaking as a potential competitor.[256] What degree of potential competition did the originator companies feel threatened by can best be deducted from their conducts. The Commission has built more than solid argumentation in support of its claim that Lundbeck perceived the generic companies as potential competitors. Therefore, I must side with the Commission[257] in asserting that the perception of market incumbents compliments the finding that generics were indeed potential competitors with the highest probability of entering the market and initiating competitive race.

3.4.3. Patent litigation as an indicator of competitive constraints

Patent litigation on its own can be regarded as a manifest of competitive pressure evidenced on the market. The Commission in Lundbeck observes that the mere fact that legal challenges were possible and that both Lundbeck and the generic companies were in fact assessing the option of challenging the process patents, is in itself an expression of potential competition.[258] It further notes that generic companies had several alternatives open to them that could lead to market entry even in the presence of Lundbeck's process patents.[259] The Commission asserts in Servier that in the pharmaceutical sector, patent challenges are an essential, and at times unavoidable, part of the competitive process.[260] Denial of potential competition in those situations undermines the very business strategy of generic pharmaceutical industry and generics' considerable efforts to establish themselves on the market.[261]

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[254] *Lundbeck*, paras 127 and 622.
[255] Case T-112/07, *Hitachi v Commission*, ECLI:EU:T:2011:342.
[256] *Hitachi v Commission*, paragraph 226.
[257] *Lundbeck*, para 614.
[258] *Lundbeck*, para 633.
[259] *Lundbeck*, para 635.
[260] *Servier*, para 1131.
[261] *Ibid*.

Based on the preceding considerations as well as the points discussed in the sub-heading 1.1.2, I concur with the Commission in assuming that the competitive pressure generics exert on the originator industry when expiry of exclusivity looms is derived precisely from the perspective of potential challenges to originator's patent. In that, the possibility of recourse to the legal artillery for challenging the patent, at the generic's disposal when considering market entry, shall be regarded as an expression of potential competition.

3.4.4. Barriers to entry and their effect on potential competition

Barriers to entry exercise significant constraints on the potential market entrants in their attempt to penetrate the market. Some of these barriers are generated by the legislative framework itself, some derive from the practices of market incumbents. The effects of legislative barriers may be so far-reaching that it may raise doubts with regards to whether the sector was open to competition. When the sector is considered closed for competition there can be no notion of potential competition. Two most notable hurdles for any generic company are the existing patents and administrative procedures such as requirement to obtain market authorisation. The Commission in *Servier* indeed contemplates on the potential market foreclosure due to the exclusivity rights generated by the originator's patent. It also expresses its conviction that the non-possession of marketing authorisation at the point when the agreements were concluded does not weaken the notion that generics were indeed potential competitors. Each of these peculiarities will be separately addressed and commented.

3.4.4.a. Process patents as barriers to entry

For the assessment of potential competition in pay-for-delay cases, when applicable, it is necessary to establish whether the process patents in question create an absolute barrier to entry and in that preclude all competition, both potential and actual.

With that regard, the General Courts' opinion in *GDF/Ruhr gas* may be of relevance for the discussion.[262] Two undertakings, one German and other French, concluded agreements with the purpose of constructing and managing a joint gas pipeline. The controversial provisions of the agreements were those that obliged each party to refrain from penetrating the other one's market. The Commission considered that those commitments

[262] Case T-360/09, *E.ON Ruhrgas and E.ON v Commission*, ECR, EU:T:2012:332. *(hereinafter GDF/Ruhr gas*)

limited the commercial conduct of those undertakings and were thus anti-competitive.[263] It also observed that as a result of the legal monopoly which existed on the importation and supply of gas, the conduct at issue could not have restricted competition before the liberalisation of the gas market.[264] This can be interpreted as to mean that as long as the legal monopoly exists, there can be no notion of competition, actual or potential. The extent of that legal monopoly may nonetheless be put into question. Namely, the Commission argued that no official monopoly power was conferred to the German market players. Hence, it claimed that the barriers to entry, created by the dealings between market incumbents which were exempt from competition law rule, were not such as to completely foreclose the market from potential competitors.[265] The applicants conversely submitted that there was no actual, concrete and realistic possibility of access to the market and therefore potential competition was excluded.[266]

The same dilemma may *mutatis mutandis* arise in the context of reverse patent settlement agreements. The legal monopoly associated with the possession of a patent (together with the legal presumption of its validity) creates legitimate barriers to entry for the potential competitors, generic API producers or suppliers. But is the market truly impenetrable with the serious doubt as to the validity of the process patent, its strength, and overall with a high plausibility of inventing around the patent?

The Commission in its pay-for-delay decisions asserts that the parties regarded one another as potential competitors otherwise they would have not entered into the agreements in the first place. Similar argument was unsuccessful in the *GDF*. In particular, the Commission's attempt at claiming that the potential competition existed because if there wasn't one there would be no need to include the non-compete commitments in the agreement did not pass the scrutiny of the GC. The GC reiterated that when the existence of monopoly is implied due to legislative arrangements, the Commission must demonstrate on the objective basis the real, concrete possibilities to enter the market. The GC in *GDF* held that the Commission failed to prove that the entry was not merely a hypothesis but real concrete possibility.[267] Nonetheless, the GC sustained, if it successfully achieves so, it will

[263] *GDF/Ruhr gas*, para 35.
[264] *Ibid*, para 38.
[265] *Ibid*, para 94.
[266] *Ibid*, para 96.
[267] *Ibid*, para 114.

result in the finding that the fact that potential competition is precluded on account of a monopoly will be irrelevant.[268]

The differences in the factual, legal and economic context might be enough to persuade the General Court in *Lundbeck* and *Servier* to back the Commission's argument in spite of its earlier decision to the opposite. The Commission in *Servier* stated that the fundamental difference between the two cases is that unlike in pay-for-delay cases, the legal barriers to entry in *GDF/Ruhr gas* were not readily challengeable.[269] It alleged that the market for the generic product is in principle open for competition once the compound patent had lapsed as well as SPC.[270]

3.4.4.b. Absence of marketing authorisation

Servier claimed that the existence of potential competition shall be ruled out in cases where the generic companies had not yet obtained the marketing authorisation.[271] It assumes that the application for a regulatory approval merely manifests generic undertaking's intention but does not speak of its capacity to obtain the authorisation.[272] In that, Servier seems to essentially claim that uncertainty necessary attached to the process of regulatory approval averts the finding that the entry may be perceived as a *'real, concrete possibility'* which is a case law requirement. The Commission on the other hand emphasises that the use of the word 'possibility' in the CJEU's standard reflects the Court's position that the entry does not need to be expected with *'certainty'*.[273] It further recalls the judgment in *Toshiba* where General Court confirmed that the existence of barriers to entry do not preclude a finding of potential competition, unless such barriers are *'insurmountable'*.[274] The Commission does not consider the absence of marketing authorisation as an absolute bar to entry. This is a well-argued point given that the recent legislative activity in the EU, as argued in heading 1.2.1. perceptibly manifests a trend that favours generic undertakings as it simplifies the MA procedure. Furthermore, the MA approval is autonomous from any considerations of the validity of the originator's patent. This fact removes from the scope of the present assessment all the claims associated with the alleged infringement of the patent.

[268] *Ibid*, para 105.
[269] Servier, para 1166.
[270] *Ibid*.
[271] Servier's reply to the Statement of Objection, paragraph 150, in *Servier*, para 1180.
[272] *Ibid*.
[273] *Servier*, para 1181.
[274] Case T-519/09, *Toshiba v Commission*, ECLI:EU:T:2014:263, para 230.

3.4.5. Potential competition and sustainability of market entry

Some shadow may nonetheless be shed upon the foregoing argumentation. Contrary to what the Commission argued in *Ludbeck* and *Servier*[275] it assumed in *Teva/Cephalon* merger that the two generic companies[276], which entered at risk and which market entry it thus characterised as *'unsustainable',* are not to be regarded as potential competitors. The Commission as well disregarded the fact that Cephalon launched patent infringement lawsuits against both these companies, but its application for interim injunction was rejected in Denmark.[277] Teva, which was indeed the first generic to launch, on the other hand sometime prior the merger concluded a patent settlement agreement with Cephalon which provided for early entry (it agreed to postpone entry until three years prior to patent expiry) and appointed Teva as Cephalon's exclusive distributor in the UK.[278]

The Commission was uncertain if, given that patent litigation is ongoing in a number of countries, generic companies would be able to exert a significant competitive pressure on the originator's product.[279] It assumed that Cephalon would be successful in its claim that its patent was valid and infringed by the generics. The decision notes that the generics' access to the market was not guaranteed to be "sustainable" and thus they shall not be regarded as potential competitors.[280] On the contrary, in its pay-for-delay decisions the Commission argues that the generics are potential competitors even in cases where the market entry had not yet occurred and there were many, prospective or ongoing, patent litigations involved.

Is there an explanation for the discrepancy in the Commission's approach? Given the very limited scope of the analysis the Commission conducted with respect to other generic competitors but Teva, the only notable difference between two cases is that while Cephalon was in possession of the patent covering the compound, Lundbeck and Servier had only process patents which scope of protection is limited and which presumption of validity is considered easier to reboot. It might be interested to see if the GC will find this difference substantial to justify the divergence in the Commissions approach.

[275] *See e.g.* para 1176.
[276] Generis Farma in Portugal and Orifarm in Denmark and Sweden.
[277] *Teva/Cephalon*, Case No COMP/M.6258 , European Commission, Brussels, 13.10.2011 C(2011) 7435 final para 94.
[278] *Teva/Cephalon*, para 95.
[279] *Teva/Cephalon*, para 98.
[280] *Ibid*, paras 99 and 126.

Conclusion

Patent settlement and other agreements between originator and generic pharmaceutical undertakings restrict competition in the internal market or its substantial part in as long as they delay generic entry to the detriment of consumers providing for the share of monopoly profits between the parties. This normative assumption, based on the views expressed by the European Commission, has not yet been clarified by positive EU competition law, as the appeals from the affected companies were not to the present day addressed by the Court of Justice of the European Union.

However, the foregoing analysis of the normative and economic context in which the agreements transpire allows us to extract the essence of the anti-competitive conduct. It is the lucrative agreement that influences the commercial strategy of the generic undertaking inducing it to abandon its independent efforts to enter the market with the generic version of the drug.

The expiry of the compound patent and the limited scope of protection and exclusivity stemming from the possession of patents over certain manufacturing processes undermine the arguments in favour of the exemption of patent settlement agreements from the scrutiny of EU competition law. The absence of a genuine patent settlement and the ambiguity with regards to the validity of the process patents, which persists in spite of the agreements and contrary to the public interest, further account for the anti-immunity approach.

The object based approach towards the assessment of pay-for-delay agreements is justified, fitted and sufficient and shall be reiterated by the CJEU. The ‘sufficient level of competitive harm’ can be inferred from the absence of imminent generic entry. The economic theory on effects of generic entry allows the Commission to assume with high degree of probability the negative repercussions for consumers caused by the delay of such entry. In addition, it may be presumed that cumulative effect on competition from all the agreements of a single originator will be manifested either as a market foreclosure[281] or market-sharing arrangement, depending on the market circumstances acknowledged through legal and economic background assessment. Both situations are considered hard-core restrictions as they allow for the share of monopolistic profits among originators and generics to the detriment of final consumers of patent protected medicine.

[281] Market foreclosure will with a high degree of certainty transpire at least for the limited but significant time period. This may in turn allow the originator as well to implement a wider ‘end of life-cycle’ strategy.

Process patents owned by the originator do not represent ‘unsurmountable obstacles’ to generic entry and therefore do not foreclose the market to actual or potential competition. It is nonetheless essential that the Commission demonstrates, on the objective grounds, that the market entry for the specific generic undertaking was a ‘real, concrete possibility’ hence the anti-competitive conduct was the sole reason why the entry did not occur. The complexity of the normative and factual background justifies the strong reliance by the Commission on the subjective elements such as parties’ intentions with regards to the settlement or perceptions by market incumbents of the competitive threat akin to generic entry. These subjective elements may nevertheless be used solely as the ancillary tools in the overall assessment of the anti-competitive nature of the agreements. Overall, in the course of three decisions concerned by the analysis the Commission provided sufficient justification for its claim that generic and originator undertakings are to be regarded as potential competitors.

Finally, the legal discussion surrounding pay-for-delay agreements and herein addressed controversial concepts are yet to get profound once the CJEU delivers its first judgment on the two appeals. There are also issues not covered by this thesis that spark further interest. For example, we may not forget about the pro-competitive effects stemming from the conclusion of the patent settlement agreements and therefore the caution shall be exercised when the assessment is made. In that, The Commission shall attempt to create a systematic approach to pay-for-delay that would in turn allow for the effective use of Article 101(3) efficiency defence. The constructive role of the CJEU in assisting the process is further expected.

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