Borbála Tünde Dömötörfy:

Competition Law in the Pharma Sector:

Pay-for-delay settlements in the EU and in the US

Abstract of the PhD Thesis

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I. SUBJECT AND RESEARCH OBJECTIVE OF THE THESIS

The title of this thesis refers to the competition law analysis of pay-for-delay patent settlements. Pay-for-delay, or reverse payment settlements raised antitrust scrutiny in the pharmaceutical sector first in the United States (US), and later also in the European Union (EU). These agreements are unique type of patent settlements and seem to be special features of the pharmaceutical sector exclusively, as result of its unique characteristics.[1]

In the pharmaceutical sector, the supply side of the market is dominated by two type of companies: originators and generics. The originators are the R&D based companies that carry out research and develop pharmaceuticals from the laboratory up to the stage of marketing authorisation. Generics produce and sell pharmaceutical products which are bioequivalents of an originators' product after the originators' patents expire. Generic products contain the same active pharmaceutical ingredients (APIs) as branded medicines and can therefore be used for the same treatments.

Pay-for-delay, or reverse payment settlements are therefore special patent settlements between originator and generic companies possibly delaying generic entry in return for a so-called reverse payment from the originator to the generic company. In the US, pay-for-delay agreements have been subject to antitrust scrutiny for more than a decade when the European Commission first identified them as potentially problematic in the framework of the Pharmaceutical Sector Inquiry.[2]

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[1] Herbert Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 14., C. Scott Hemphill: Collusive and Exclusive Settlements of Intellectual Property Litigation. Columbia Law School Working Paper No. 384. November 30, 2010. pp. 684-709. However, the opinion of the dissenting judges in Actavis differ in that point. (Roberts, C. J., dissenting 570 U. S.(2013) Ftc *v.* Actavis, Inc. Supreme Court of the United States No. 12-416 Chief Justice Roberts – Justice Scalia – Justice Thomas)

[2] Sector inquiries generally are investigations carried out by the European Commission (or by national competition authorities) into sectors of the economy and into types of agreements across various sectors, when the Commission (or the national competition authority) believes that a market is not working as well as it should, and breaches of the competition rules might contribute to this malfunctioning. For further details see the website of the Commission's

The thesis provides the analysis of pay-for-delay settlements from a competition/antitrust law point of view. However, even for a competition law analysis, intellectual property rules and sector specific regulation of the pharmaceutical sector shall be taken into account.

The thesis seeks to answer the following research questions.

Q1) *To what extent are pay-for-delay settlements the consequences of the sectoral regulation and/or intellectual property regimes?* In the US, reverse payment settlements are often called "Hatch-Waxman settlements" i.e. the Hatch-Waxman Act, a pharma sector specific rule is 'blamed' as main cause of the pay-for-delay settlements. [3] In the EU, the regulatory background relating to the pharmaceutical sector is different, no equivalent of the Hatch-Waxman Act can be identified, while pay-for-delay settlements were still found to be common types of agreements of the European pharmaceutical sector by the Pharmaceutical Sector Inquiry.[4] It should also be examined whether there are important differences between the types of EU and US settlements due to the differenced in the legal backgrounds.

Q2) *Should competition law play a role in overcoming the discrepancies of patent laws and sector specific rules?* Recent EU and US developments suggest that antitrust/competition law should correct the shortcomings and problems of the patent systems and of the sectoral regulations in the pharmaceutical industry. [5] This approach is based on the ECJ's AstraZeneca judgment, the statements of the monitoring reports[6], and the relevant US case law, especially the judgements

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Pharmaceutical Sector Inquiry. (Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/ Downloaded: 23 October 2018)

[3] A. B. Mehl: The Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive. Chicago-Kent Law Review, Volume 81. Issue 2. Article 13. January 2006.

[4] Final Report – Pharmaceutical Sector Inquiry Final (Available: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf, Downloaded: 6 February 2021)

[5] Case C-457/10 P, AstraZeneca/Commisson. ECLI:EU:C:2012:770, Valley Drug Company v. Geneva Pharmaceuticals Inc. 350 F3d 1181 (11th Cir. 2003), Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056 (11th Cir. 2005), Tamoxifen Citrate Antitrust Litigation 466 F.3d 187 (2d Cir. 2006)and Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008)

[6] European Commission: 6th Report on the Monitoring of Patent Settlements (period: January-December 2014) Published on 2 December 2015, European Commission: 5th Report on the Monitoring of Patent. Settlements (period: January-December 2014) Published on 5th December 2014, European Commission. 4th Report on the Monitoring of Patent Settlements (period: January-December 2012) Published on 9 December 2013, European Commission: 3rd Report on the Monitoring of Patent Settlements (period: January-December 2011), 2nd Report on the Monitoring of

which applied the "scope of the patent test". This approach suggests that competition law shall intervene, if the patent – or marketing authorization – is the result of sham litigation or fraud on the relevant authority.

Q3) *Is there room for two different legal standards analysing the legality of pay-for-delay agreements?* The third research question seeks to compare the US and EU approaches about the applicable standards. Understanding the exact meaning of the EU concepts “restriction by object or effect” and the similar US terms of “rule of reason and per se” illegality is crucial for this analysis.

Q4) *What sort of pay for delay agreements are lawful?* Both the US and the EU approaches agree that not all value transfers are illegal between the originator and the generic, even in the context of patent settlements. Generally, payments up to the amount of the (expectable) litigation costs are accepted in both jurisdictions. "[P]ayment for real service" is also accepted in both the EU and the US. *But what is considered as genuine service and what price can be demanded accordingly? When is a reverse payment excessive and thus unjustified?*

Patent Settlements (period: JanuaryDecember 2010) Published on 6 July 2011, 1st Report on the Monitoring of Patent Settlements (period: mid 2008 - end 2009) Published on 5 July 2010

II. BRIEF SUMMARY OF THE RESEARCH OBJECTIVES AND METHODOLOGY

Right after "setting the scene", i.e. introducing the main features of pay-for delay settlements, and listing the research questions, the thesis dives into the topic by reviewing the pharmaceutical market's characteristic and its sector specific regulation in the EU and in the US. Since one important hypothesis of the thesis is that the sectoral regulation plays a role in shaping not only the background, but also pay-for-delay settlements themselves, the careful examination of such rules is vital for the research. The relevance of the market characteristics lies in the fact that not only the regulation itself, but also its "background", i.e. the real life situation what it regulates should be taken into account. Otherwise, it cannot be totally excluded that not only the regulation, but the market characteristics themselves are the main causes of pay-for-delay settlements.

After discussing the main features of the market and the pharmaceutical sectoral regulations, intellectual property right (IP rights) in the EU and in the US come to the focus of attention. IP rights in the EU are going to be subject to more detailed examination, since in the legal literature it is assumed that the fragmented patent and patent enforcement systems play a major role in incentivizing pay-for-delay settlements.

The third major group of rules, antitrust/competition rules are introduced after sector specific regulations and IP rules. This placement might seem strange due to the fact that competition/antitrust laws – as it is stated – are the main focus of the thesis. However, competition/antitrust laws never act in vacuum – these "omnipotent" rules are subtle enough to be applied in completely different segments of the economy – although the characteristics and sectoral etc. regulations should never be ignored. By applying general competition rules, the other regulations and market characteristics are always taken into account – even if competition rules sometimes seem to collude with other regulations, as it is the case with the IP-competition intersection introduced next.

Therefore, in the first part, the thesis examines the EU and US regulatory backgrounds including the relevant IP regime, the sectoral regulation and antitrust competition laws in order to set up the background of pay-for delay settlements. The introductory part also introduces the main market players and driving forces of competition and its dynamics on the typical relevant markets of the pharma sector, as well as main economic theories in a nutshell.

After discussing the above topics, the firs part concludes by seeking to answer research questions 1 and 2. As far as the regulatory background is concerned, different factors were identified with a potential to encourage companies to participate in pay-for-delay settlements in the EU and in the US. Due to these differences, the respective settlements differ in these two jurisdictions. While it was found that an Act embedded in the sector specific regulation, the Hatch-Waxman Act is mainly responsible for reverse payment agreements in the US, in the EU, it seems to be the fragmented patent and patent litigation system – taking also into regard certain shortcomings of the sector specific regulations – which might be identified as the root cause behind pay-for-delay settlements. Although even certain element of the pharmaceutical sector specific regulation could be improved (e.g. by accepting a new Transparency Directive[7]) in the EU, no one specific element of the sectoral rules can be blamed for incentivizing pay-for-delay settlements, unlike in the US. On the other hand, the patent system does not relate only to pharmaceuticals, while pay for delay settlements are industry specific features also in the EU. The thesis found that cumulated effect of the sector specific regulation, the special characteristics of the pharma industry, and the patent system – including the fragmented patent enforcement system – may be behind European pay-for-delay settlements.

Although identified root causes seem to be totally different, their effect – and consequently their role in pay-for-delay settlements – seem to be quite similar in creating uncertainties and asymmetric risks.

It is not disputed that reverse payment settlements are – at least partially – the consequences of the shortcomings of the regulation – both in the EU and in the US. However, this fact does not mean that they would be out of the scope of competition/antitrust law, as it is proven by the relevant EU and US cases.

After understanding the background and the main rules affecting the reverse payment settlements – and also other types of pharmaceutical patent settlements – the main US and EU pay-for-delay cases are discussed.

[7] To replace the current one, Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinaI products for human use and their inclusion in the scope of national health insurance systems (“Transparency Directive”)

The EU and the US cases are presented in different chapters of the thesis, and also the style of their discussion is somewhat different: in the US, several cases are introduced while in the case of the EU, fewer cases are subject to more detailed discussion.

Important to note that this thesis is not a comparative research, its aim was not to compare the US and EU similarities and differences, rather to introduce some of the relevant similarities and differences. The thesis focuses on European law, and on European patent settlements, the discussion of the US parts rather refers to the need for an example. Since the US had long-term experiences in handling reverse payment patent settlement when the EU started to scrutinize them, knowledge of the US cases was unavoidable for the European enforcers, lawyers and scholars, as it is presented by the fact that the EU cases contain references to the US cases and state-of-the-art literature.

Therefore, the role of discussion of the US rules, cases and literature is to introduce them in the necessary depth to find important conclusions for the EU. Although certain parts of the thesis compare EU and US approaches, this fact does not make the thesis a comparative research. The EU law focused nature of the thesis also explains why the European cases are discussed in more details, although it is not the only cause: the published European judgments and administrative decisions simply let us know more details of the cases compared to the US ones.

In the US, the short review of types of pay-for-delay settlements is followed by the introduction of the evolution of the FTC's and DoJ's approaches. The US cases are divided into three groups: pre-Actavis cases, detailed discussion of the Supreme Court"s Actavis judgment and analysis of different legal tests, selected post-Actavis cases. The chapter is closed by conclusion on the US experiences, and also seeks to answer research question four, at least, partially. The most detailed assesment of what constitutes a payment is still provided by the US case law. In Actavis, the Supreme Court stipulated that payment for real services, and up to the value of the avoided litigation costs is lawful. One of the most important question of post-Actavis cases is the exact meaning of this. Furthermore, while the first pay-for-delay cases of the US were pretty straitforward, due to antitrust scrutiny and enforcement result, later cases became more and more subtle. In the newer cases, the courts often face the question what exactly constitutes a payment. Settlements therefore become more and more complex and complicated. Discussion of the fourth question is provided in this part, since US cousrts have been the most active in this field. However,

one of the newest EU judgments, the General Court's judgment in Servier provides some insights to this question, which will be discussed in the European part, until now no answer has been provided which would make easier the task of drafting lawful settlements.

The third, and last part of the thesis focuses on the EU. This part mainly deals with cases of the European Commission and of the European courts, and one pre-Brexit UK case, Paroxetine. Even though Brexit put the UK developments out of the scope of this research, the importance of Paroxetine is provided by the fact that the only preliminary ruling occured in this case. Paroxetine preliminary ruling is and important element of the develoment of EU competition law, therefore, I find it necessary to discuss it in details. The construction of this part follows the structure of the US part, except of certain, already mentioned differences. First the point of view of the European Commission is introduced, in chronological order: first the Pharmaceutical Sector Inquiry. In the framework of its Final report, the European Commission divided patent settlements between originator and generic into three categories; and this structure of typology has been followed since then. After that, the thesis introduces the relevant competition authorities' decisions: four of the European Commission[8], and two of the CMA[9]. This is followed by discussion of the court cases. First, a short discussion of the evolution of the object/effect dichotomy is provided, with special emphasis on two important, not pharma secrtor related case, Cartes Bancaires[10] and Budapest Bank[11]. They have important implications for the pay-for-delay cases. The next step is discussion of Lundbeck[12] and Servier[13] judgments. Preliminary ruling of the General Court in British Paroxetine case[14] is also introduced in this chapter.

[8] Case AT.39226 – Lundbeck, Case AT.39612 – Perindopril (Servier), Case AT.39685 – Fentanyl, Case AT.39686 – Cephalon

[9] Case Nos: 1251-1255/1/12/16. Competition Appeal Tribunal, Paroxetine. Pending CMA case number: 50277-2 – Concordia.

[10] Case C-67/13, Groupement des Cartes Bancaires v Commission, EU:C:2014:2204

[11] Case C-228/18, Budapest Bank at all. v. Gazdasági Vesenyhivatal. ECLI:EU:C:2020:265

[12] Case T-472/13, Lundbeck v Commission, ECLI:EU:T:2016:449, Case C-591/16 P, Lundbeck k. Commission, ECLI:EU:C:2021:243

[13] Case T-691/14, Servier and others k European Commission. ECLI:EU:T:2018:922

[14] C-307/08, GUK at all v. CMA ECLI:EU:C:2020:52

After the EU cases the third research question is examined, i.e. whether pay-for-delay settlements infringe competition law by object? As the General Court highlighted in Lundbeck and Servier, assessment of potential competition is relevant here. Pursuant to the courts' views, if the generic and the originator involved in the pay-for-delay settlements are (potential) competitors, the agreement raises scrutiny. The originators' willingness to pay a large amount can be assessed as indicator of potential competition, how the General Court found in Lundbeck and Servier, and the US Supreme Court in Actavis. The General Court interpretation in Lundbeck – confirmed by Servier – of what constitutes potential competition can be criticized as contradictory, and not providing sufficient guidance to companies for self-assessment. Competition law and IP law advocates certainly will be on different opinions. Yet, one thing is sure: courts and authorities should take into account the specificities of the pharmaceutical sector in order to ensure that the "*antitrust doctrine [will be] supple enough, and its commitment to economic rationality strong enough*" to handle the challenges posed by pay-for-delay agreements.[15] However, this requirement seems to be fulfilled by the fact that competition law analysis always have to take into account the economic and legal context behind the examined agreements.

In Lundbeck –and later confirmed in Servier – the General Court found that the market conduct at issue was harmful enough to meet the Cartes Bancaires test, the examined market conduct caused a harm reaching the sufficient degree to European consumers and healthcare systems, to identify the conduct as by object restraint. In Fentanyl[16], where no patent dispute was involved, the infringement was assessed as a pure market sharing agreement. In Lundbeck, Servier, and the other discussed European cases the main difference compared to Fentanyl is the existence of (boundle of) patents, i.e. while roughly the same type of conduct takes place, it seems to be covered by a patent for the first sight. If the incumbent provides value transfer to a competitor to stay out of the market, it is market sharing. If however the incumbent is a patent holder, who provides incentive to a generic company, the question is more complex, even though the European courts pointed out now several times that paying a (potential) competitor to stay out of the market – in which market

[15] R. A. Posner: Antitrust in the new economy. John M. Olin Program in Law and Economics Working Paper No. 106, 2000. Available at: https://chicagounbound.uchicago.edu/law_and_economics/58/ Downloaded: 27 November 2018) p. 2.

[16] Case AT – 39685 Fentanyl

the patent holder anyway has a patent protected position – has never been a patent protected right. It eliminates the incentives to challenge weak patents, which is not beneficial for public welfare. If we examine this by keeping in mind that patents are exclusive rights provided to the inventor in return for delivering something new and valuable to the public, and their role is to ensure a fair return for an investment which provides something valuable to the public, it makes sense that eliminating weak patents is important, not only for social welfare but also to enhance other players possibilities and incentives to innovate.

However, especially in the pharma sector – due to the authorization system and sectoral regulations – it cannot be doubted that originator companies often cannot use a sufficient part of the patent protection to recover their investments due to the long gap between the granting of the patent and of obtaining the marketing authorization. Partially as a consequence, evergreening strategies are common. Partially, because it is highly questionable that e.g. starting the patent protection time only from the date the originator started to sell the drug would make an end to evergreening strategies. Nevertheless, such strategies are not illegal – but competition rules should be respected.

The same is true in the case of reverse payment settlements, which are not generally considered as infringement on competition law, especially not are identified automatically as a by object restraint. The cases raising competition scrutiny are subject to a case-by-case analysis, as it might be concluded after Lundbeck and Servier. Although some guidelines are provided to assess cases similar to the already examined ones, pay-for-delay settlements surely stay a challenging area both for enforcers and compliance experts. At the end of the day, it can be concluded that both the US and EU judgments can be criticized for not providing sufficient guidance for companies to draft lawful settlements, and especially for not elaborating what is the lawful amount of a payment. However, due to the diversity and nuances of the settlements, and the evolving nature of the industry – and of the business practices – it is probably impossible.

In order to properly understand the different approaches in the US and in the EU, and to answer the third research question, I compared the similar legal concepts of per se illegality/rule of reason and by object/effect infringements. This is of great relevance as to the standard of proof rules. With regard to Actavis, it was found that the Supreme Court accepted the continuum theory, and did not suggested either a quick look, or a full rule of reason approach to assess pay-for-delay settlements, but something in-between. It was discussed that per se illegality and rule of reason are not

considered as a dichotomy, but rather as a sliding scale. Actavis is somewhere in-between its endpoints.

On the other hand, it should not be forgotten that while the US Supreme Court creates precedent for lower courts, i.e. it did so also in Actavis, the General Court – and the ECJ in Paroxetine – delivered their judgments in the cases under examination, and decided that pay-for delay settlements should be assessed on a case-by-case basis.

III. PREVIOUS PUBLICATIONS OF THE DOCTORAL CANDIDATE

In English:

- Balázs Bartóki-Gönczy – Borbála Dömötörfy: Net Neutrality and Competition Law. Presented at CLaSF Workshop, 26th January 2012, London.
- Borbála Dömötörfy: Misuse of procedures as an Abuse of Dominant Position. Presented at Fourth Annual International Conference on Competition Enforcement in the Central and Eastern European Region. 7th December 2012, Budapest.
- Balázs Bartóki-Gönczy – Borbála Dömötörfy: Net Neutrality and Competition Law: New Business Models and Changing Regulatory Approach in the European Union. US-China Law Review, Vol. 11, No. 4, in April, 2014
- Tihamér Tóth – Botond Horváth – Pál Szilágyi – Borbála Dömötörfy: Cases and Materials on EU and Hungarian Competition Law and Policy. 5th Chapter: Exploitation of Market Power, Abuse of Dominant Position. Teaching Material, Competition Law in English for Foreign and Hungarian Students, Pázmány Péter Catholic University. Budapest. 2014.
- Borbála Dömötörfy: The Metropolitan Court of Budapest upholds the decision of Hungarian Competition Authority almost in its entirety in the "Baker cartel" case (Hungarian Baker Association) 2012. http://www.concurrences.com/Bulletin/News-Issues/November-2011/TheMetropolitan-Court-of-Budapest?lang=en
- Judit Firniksz – Borbála Dömötörfy, Information Exchange Going Digital – Challenges to Hungarian Competition Law Enforcement. YARS 2019 vol 12(19)
- Borbála Tünde Dömötörfy – Barnabás Sándor Kiss – Judit Firniksz: Ostensible Dichotomy? By object and by effect restraints in EU competition law, with special regard to the Budapest Bank case. Competition and Regulation 2020. (English version)

In Hungarian:

- Borbála Dömötörfy: The Future of Private Enforcement of Antitrust Claims in the European Union. Presented at Jánossy Ferenc Emlékkonferencia, 18th March 2011, Budapest.
- Borbála Dömötörfy: Parental Liability for a Wholly Owned Subsidiary – The Recent Case Law of the Courts of the European Union. Versenytükör, 2/2011.
- Borbála Dömötörfy: Competition Law and Arbitration in the European Union. Iustum, Aequum, Salutare, 2/2012.
- Borbála Dömötörfy: The Applicability of EU Competition Law by Arbitral Tribunals. Presented at the Legal Committee of Hungarian Chamber of Commerce, on 19th April 2012. Budapest.

- Borbála Dömötörfy: Price Discrimination and Parallel Trade in the Pharmaceutical Sector: Application of Competition Law in Innovative Industries. Versenytükör, 2/2012.
- Borbála Dömötörfy: The Possible Role of ADR in the Enforcement of Self-Regulation. Versenyjogi Kutatóközpont, Versenyjogi Tanulmányok, 4/1012.
- Borbála Dömötörfy: Consumers ADR in the EU – Recent Developments. Presented at MOE Conference, 8th June 2012.
- Borbála Dömötörfy: The possible role of ADR in the private enforcement of competition law. 2013. http://www.rezler-foundation.hu/
- Borbála Dömötörfy: Competition Law for the Associations of Undertakings. Teaching materials. 2012.
- Borbála Dömötörfy: Competition Policy and the Economic Crisis. In: Válságban az EU. Edt.: Dr. P. LÁNCZOS. Komáromi Nyomda és Kiadó Kft. Budapest, 2014.
- Borbála Dömötörfy: The judgement of the ECJ about due process and parental liability for a wholly owned subsidiary. (JeMa, 2015/1.)
- Borbála Dömötörfy: Pay-for-delay in the pharmaceutical sector: rule of reason v. by object restriction? (Versenytükör, 2015/1.)
- Borbála Dömötörfy: The judgement of the General Court in the Lundbeck case. (Versenytükör, 2016/2.)
- Borbála Tünde Dömötörfy – Barnabás Sándor Kiss – Judit Firniksz: Ostensible Dichotomy? By object and by effect restraints in EU competition law, with special regard to the Budapest Bank case. Competition and Regulation 2020. (Hungarian version)