THE GENERICS (UK) CASE

A competition law analysis of patent settlement agreements in the pharmaceutical sector

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ABSTRACT

The pharmaceutical industry is responsible for the development, production, and marketing of medications. Up to this date, this industry continues to develop and manufacture drugs to control and eliminate diseases. The market is filled with pharmaceutical products from companies worldwide, which have lost their patent protection or are ready to lose it. Whenever this might happen, generic manufacturers are expected to produce the same but cheaper versions of the pre-patented drugs. Therefore, this situation that is beneficial for the consumer may pose tremendous competitive pressure to the originators who want to keep their blockbuster medicine's prolific dividends, hindering the competition by limiting the independent entry of the generics.

The generics usually start their preparations years before the originator's patent expiry date and try to enter the market the moment it expires. During this period, patent disputes arise, which are time-consuming, costly, and complex and bring along uncertainties for both parties. Therefore, parties are incentivised to settle their disputes with an agreement that would benefit them simultaneously. These settlement agreements are typical for the pharmaceutical world since these settlements involve a payment from the originator to the alleged infringer, the generic, who in return delays its plans to enter the market the moment the patent expires. These arrangements are known as either *reverse-payment* or *pay-for-delay* settlements.

The Commission only after 2009 has concluded that these settlements may restrict competition according to Article 101. After the inquiry, the Commission set out the three-step criteria, according to which the collusive settlements were considered restrictive by object within the meaning of Art. 101. According to the EU competition law, an agreement under restriction by object automatically is presumptively illegal, and as such, its background, motives, and effects are excluded from any further scrutiny.

Therefore the purpose of this thesis is to critically analyse the approach taken by the Commission and national authorities, by studying the *Generics (UK)* ECJ's judgment, in order to clarify whether other realistic factors that may induce parties to conclude a presumptively illegal settlement should be taken into consideration under EU Competition Law.

Keywords: Patent settlement, reverse payment, pay-for-delay, pharmaceutical, risk aversion, asymmetric information, competition law

ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
API	Active pharmaceutical ingredient
CA	Competition Act
CAT	Competition Appeal Tribunal
CHMP	Committee for Medicinal Products for Human Use
CJEU	Court of Justice of the European Union
CMA	Competition and Markets Authority
CP	Centralised Procedure
DCP	Decentralised Procedure
ECJ	European Court of Justice
EMA	European Medicines Agency
EU	The European Union
GSK	GlaxoSmithKline
IPR	Intellectual Property Right
MA	Market Authorisation
MRP	Mutual Recognition Procedure
NHS	National Health Service
OFT	Office of Fair Trading
R&D	Research and Development
TFEU	Treaty of the Functioning of the European Union
TTBER	The Technology Transfer Block Exemption Regulation
UK	United Kingdom
US	Unites States of America
VBER	Vertical Block Exemption Regulation

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INTRODUCTION

Intellectual property rights, such as patents, grant the holder of the right an exclusionary and sometimes exclusive right to exploit the human intellect's emanation. They are designed to provide an incentive for innovation and invention.

In the pharmaceutical sector, it is crucial to be vigilant of any exclusive property right granted by a particular institution to the patent holder. This sector deals with every citizen's health, who requires access to new, improved, and affordable medicine. These benefits would be impossible to achieve without R&D departments' immense efforts by pharmaceutical originator companies willing to take the financial risk of bringing new drugs to the market. After each cure is discovered and made available to the public, immediate imitation threats come from other generic companies. Therefore, this sector relies heavily on patents to protect the investments they made and also the regulatory framework applied differentiates this market from other markets.

Recently, due to patent validity expiry, several originator companies have lost patent protection of their most profitable medicines, so-called "blockbusters", and more are expected to do so soon.

From a competition point of view, patents, in general, serve as a barrier to entry since they grant the patent holder exclusive rights to the invention.[1] Thus, patent expiry affects the market structure typically and serves as a vital source for price competition. The loss of exclusivity in the pharmaceutical industry enables generic variants of products, i.e. drugs similar to pre-patented drugs from original companies, to enter the market. Generic companies differ from originator companies in that they are not required to spend substantial R&D efforts and costs; instead, they depend on the R&D efforts of originator companies, which are expressed in the patent. As a result, generic firms exert considerable pricing pressure on originator companies by offering generic versions of their products at considerably lower costs than the original products. This competitive pressure is often imminent before patent expiry when generic undertakings start their preparations for launching their generic version. As a result, patent disputes are common when generic entry is anticipated.

The European Commission has identified patent expiry and originator companies' struggle in pharmaceutical innovation as some of the underlying reasons originator companies have become

[1] Jones, Alison and Sufrin, Brenda, EU Competition Law: Text, Cases, and Materials (2019). EU Competition Law: Text, Cases, and Materials (Oxford University Press, 7th edn, 2019), p. 827-828 [cit. Jones & Sufrin].

increasingly dependent on the revenues gained from the current best-selling products blockbusters. Therefore, originators are inclined to take different actions to prolong their patented products' commercial lifespan for as long as possible to maintain their revenues. Simultaneously, the Commission has observed a delay of generic entry in the EU pharmaceutical markets after a settlement between the originator and the generic.

Although the Commission recognises the importance and benefits of settlements, it has become concerned about the *pay-for-delay* type of settlement agreements, otherwise known as *reverse payments*. These agreements are typically not based on a technology transfer but instead on a value transfer from the originator to the generic in exchange for the generic delaying the market's entry date.

In 2009, the Commission concluded an investigation into the pharmaceutical sector. In that report, they found out that many of these types of settlements potentially led to competition law distortions, which practices otherwise, could have led to innovative and cheaper generic medicine to the EU market. Therefore the Commission increased the attention level toward these agreements, including more vigorous enforcement and policy regulation of the competition law. Moreover, the Commission has remained concerned that settlements may eliminate potential competition and share the parties' resulting profits to the consumer's mere detriment.

After several investigations, the Commission has adopted three infringement decisions in which it found that the agreements at issue raised serious antitrust concerns by object in the *Lundbeck*[2], *Johnson & Johnson/ Novartis*[3], and *Servier/Perindopril*[4] cases.

The thesis, however, involves the most recent Generics (UK) case, which includes several patent settlement agreements. In this case, each settlement agreement involved monetary or other payments from GSK to the generic suppliers (referred to as '*value transfers'*) and a condition preventing the generic supplier from entering the market with its product for a set period of time (the restrictions). Nevertheless, there was a crucial difference from previous cases as these agreements allowed authorised generic entry. Once again, these reverse payments were

[2] COMP/39.226, Lundbeck Decision of 19 June 2013, and Case T-472/13, H Lundbeck A/S v Commission EU:T:2016:449.

[3] COMP/39.685 Johnson & Johnson/ Novartis Decision of 10 December 2013.

[4] COMP/39.612, Servier/Perindopril Decision of 9 July 2014.

considered a proxy for restriction by 'object' on the national and the EU level because they acted as incentives for the generics not to enter independently.

Importance of the Research

After knowing how complex this sector is, and the financial difficulties that each originator has to go with but a generic does not, it is crucial to study underlying factors. These factors push parties to settle to an agreement that involves a transfer of value that may be considered an indication for potential competition and as a proxy for restriction by *'object*' in the eye of the EU Competition Law.

The thesis on this topic will deal with the issues concerning transfers of value in patent settlement agreements, more precisely, pay-for-delay type of settlements. It will follow thorough research based on the practices of the Competition Appeal Tribunal of the UK, the Commission, and the CJEU. The main objective of the research is to address the following issue. In the light of the EU Competition Law, significantly large and unexplained value transfers are deemed to be seen as an anticompetitive part of the settlement. However, according to the ECJ, these transfers may be justified and necessary. The Courts base their assessment only on basic trading conditions, excluding realistic factors. As such:

(i) In assessing these settlements' competitiveness, should realistic factors such as risk attitude and asymmetric information be considered?

(ii) What is the role of these realistic factors in the parties' bargaining power when setting the settlement's terms and conditions?

(iii) How are these factors considered by the courts, and do they bring enough argument to legitimise restriction by 'object' and 'effect'?

Methodology of the Research

The thesis will aim to tackle issues coming out from both practical perspective and theoretical. For both reasons, the research will be primarily based on case law and the courts' arguments to find the relevant and coherent problems patent settlement agreements confer and how these issues may distort fair competition in the market. In addition, academic articles from scholars, policy papers or commentaries published by the EU Commission or IP organisations will be scrutinised and argued to answer the above-mentioned research questions.

The gathered data analysis will be interpreted concerning today's social context and difficulties patent settlement agreements have. Literary study will also be necessary to explain the theoretical approach taken under the thesis.

Outline of the Research

The dissertation is structured into three chapters. Chapter 1 introduces the reader to the EU regulatory framework, and the EU Commission works in the relevant legal areas; more precisely, it will discuss the main objectives and categorisation of these patent settlement agreements, providing the reader with the notion, goals, and types of patent settlement agreements.

The most recent case law, the *Generics(UK)* case, as the primary case law, will be scrutinised in the second chapter through the scope of both national and the EU competition laws, more precisely in the light of Article 101 of TFEU.

The thesis's main topic is 'transfers of value', so in this context, the final chapter is concerned exclusively with the models that describe how the national authorities and the courts view these transfers. It is crucial to study realistic factors such as risk attitude and asymmetric information as tools that may explain all parties' behaviour during the decision-making process and answer why they may include large and unexplained transfers of values to their agreements.

CHAPTER 1 - EU LAW ON PATENT SETTLEMENT AGREEMENTS

Agreements designed to resolve disputes concerning the validity or scope of IP, including an originator and a generic who agree to a transfer of value from the originator to the generic, as long as the generic agrees to delay the entry date are known as *Patent Settlement Agreements.* Other names used for this type of settlement agreements are *Reverse Payments* due to the inverted payment from the originator to the generic and not vice-versa; and *Pay-for-delay Agreement* due to the generic accepting the fee to delay the entry date of its product.

There is a distinction between these terminologies: *Reverse payment* means that the originator makes a payment to the generic, which asserts patent protection. On the other hand, *Pay-for-delay* implies that the originator pays the generic for the generic to delay market entry artificially. [5]

Patent settlement agreements bring new competitors to the market, resolve disputes concerning the validity or scope of IP, and increase innovation rewards. In essence, these agreements open up the market and do not restrict competition. It should not, therefore, infringe Art. 101(1). However, these agreements may contain provisions or clauses beyond bare permission for the originator to exploit the right. Competition law, in this case, has to decide whether and in what circumstances these provisions have the effect of restricting competition.

Patent litigation between originator and generic companies usually involves two systems run simultaneously, with the originator company accusing the generic company of infringement. As a result, the generic company may seek to invalidate the patent in a cross-action, alleging, for example, that the patent fails to meet one or more patentability criteria.[6]

This chapter will illustrate an overview of patent settlement agreements through the EU policy regulations and the EU Commission inquiry within the scope of Art. 101 solely. Furthermore, it will discuss these settlements' backgrounds, objectives, categories, and types by distinguishing patent settlements from pay-for-delay agreements.

[5] Case 1251-1255/1/12/16, Generics (UK) Ltd Glaxosmithkline PLC (1) Xellia Pharmaceuticals APS, (2) Alpharma LLC, Actavis UK Limited, Merck KGAA v Competition and Markets Authority, London, 8 March 2018 [cit: Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018].

[6] Domeij, Bengt, Patenträt Iustus, Förlag, AB Stockholm, 2007, pg. 117-120 and Case AT. 39226 - Lundbeck, para. 73

1.1 REGULATORY FRAMEWORK GOVERNING THE PLACING ON THE MARKET OF PHARMACEUTICAL PRODUCTS

In the pharmaceutical industry, rivalry typically exists at two stages. The first stage is a rivalry between various originator companies that compete by participating in the same R&D activities in order to be the first to introduce a cure for a specific disease or a replacement product for already existing products.[7] In the second stage, rivalry exists in the same product markets between originator firms and generic rivals aiming for the same customer demand. The application of EU competition law and regulatory framework to the exercise of patent rights on both levels is possible. However, for the following review, the operation on the second stage is of concern.

The EU regulatory framework is based on Regulation No 726/2004 and Directive 2001/83 as amended by subsequent legislation[8].

To market a pharmaceutical product, a brand-name drug manufacturer must obtain a marketing authorisation (MA) covering the Member States in which the drug will be marketed. Applicants may apply for a national authorisation to the concerned Member State or may apply for Union authorisation[9]. There are three methods of obtaining such Union authorisation:

1. the centralised procedure (CP),
2. the mutual recognition procedure (MRP), and
3. the decentralised procedure (DCP).

The first procedure is used to obtain a marketing authorisation valid in all EU countries and is mandatory for biotechnology medicinal products, orphan medical products and products containing new active substances to treat specific diseases.[10] The applications are sent to the European Medicines Agency (EMA) and reviewed by the Committee for Medicinal Products for

[7] European Commission, Pharmaceutical Sector Inquiry Final Report, 8 July 2009 [cit. Final report of the Pharmaceutical sector inquiry] pg. 379, https://bit.ly/3xAVrky.

[8] See Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, 67, and subsequent amending legislation; and, Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, 1, and subsequent amending legislation.

[9] In addition, see Article 6(1), second subparagraph, of Directive 2001/83/EC.

[10] See Article 3(2) of Regulation (EC) No 726/2004.

Human Use (CHMP), which has 210 days to apply its opinion to the European Commission for final approval.[11]

The other two procedures both concern the applications for MA in more than one Member State.[12]

If the MA is requested for a generic product of a previously authorised drug, the applicant can file a so-called "*abridged*" application exempting him from the requirement to prove safety and efficacy. In this case, the EMA relies on the tests and trials for the reference product but only after the reference product's data exclusivity period expiry. In that regard, the current framework provides the so-called 8+2(+1) formula. According to this scheme, a generic product licensed based on an abridged application cannot be put on the market until ten years have passed since the reference product was first approved (period of so-called "market protection", which can be extended by one year in the case of new indication with a significant clinical benefit approved for the reference product). Furthermore, after eight years from the original authorisation of the reference product, legitimate applications for generic products can be submitted, leading to a marketing authorisation granting.[13]

Since there is no competition during the patent protection era, the originator company can charge more than the marginal cost of production. When a medication achieves large sales, such as with blockbuster drugs, several pharmaceutical companies begin planning to launch generic versions just before the patent expires. As a result, generic firms compete to be the first to reach the market after a patent expires. For future gains to be made, the time of generic entry is critical. As more generic market players enter the market, the first generic company to introduce a generic version of a drug will charge the highest price, which will eventually decrease as more generic market players enter the market. [14]

However, generic producers are permitted to conduct studies and trials necessary to prepare for an MA application without infringing IP rights on the reference product: the rationale of this

[11] Colangelo, Margherita, Reverse Payment Patent Settlements in the Pharmaceutical Sector Under EU and US Competition Laws: A Comparative Analysis (May 1, 2017). World Competition: Law and Economics Review, Vol. 40, No. 3, 2017, Available at SSRN: https://bit.ly/3xx25sc, [cit: Colangelo].

[12] Colangelo, pg. 3

[13] These new rules have been introduced by Directive 2004/27 amending Directive 2001/83, and Regulation (EC) No 726/2004.).

[14] Case AT.39226 – Lundbeck, para. 69.

provision is to apply for the MA immediately after the originator's patent protection has elapsed.[15]

Given that preparations are often made prior to the expiration of a patent, one would assume that, even if the launch is expected after the expiration of the patent, the generic companies' preparatory activities will be considered patent infringement[16], mainly if there is a valid substance patent with a scope of protection. However, the preliminary activities such as studies, tests, and experiments carried out by generic undertakings to receive approval for sale (e.g. Marketing Authorization) are exempted from the exclusive right conferred by a patent.[17]

Therefore, it is essential to note that MAs are based on scientific standards for the medicinal product's consistency, protection, and efficacy.[18] In other words, non-infringement of a patent is not a requirement to obtain a marketing authorisation, nor does a generic undertaking have to prove that it is not infringing any patent before it can market its products. [19]

However, generic companies' full-scale production of patent-protected drugs before patent expiry would constitute an infringement. This is, of course, highly dependent on whether the patent covers a substance or process. There would not be any legal way for competitors to produce the API before patent expiry if there were a valid substance patent. However, when a process patent only protects a drug, the scope of protection is limited. In theory, generic companies can use other production methods to produce a generic version of a particular API.[20] Whether the generic undertaking succeeds in discovering a different approach or not, they are easy targets for patent

[15] Article 10(6) of Directive 2001/83.

[16] In the US the act of infringement is considered the moment the generic files for permission to get the data already registered by the originator about the branded drug, for the generic to avoid safety and effectiveness, which usually causes high costs and takes a vast amount of time. For more see Ioannis Lianos, Pre-published version of Chapter 13 in I. Lianos & V. Korah with P. Siciliani, Competition Law: Analysis, Cases and Materials (forth. Hart Pub, 2017)

[17] Directive 2004/27/EC art. 10(a).

[18] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, 1).

[19] Colangelo, pg. 6.

[20] Case AT.39226 – Lundbeck, para. 72.

disputes launched by aggressive originator firms seeking to protect their interests against any potential new market entrant.[21]

1.2 AGREEMENTS BETWEEN COMPETITORS: APPLICATION OF ARTICLE 101 TFEU AND INTELLECTUAL PROPERTY RIGHTS

Article 101 (1) TFEU[22] aims to protect competitors and consumers' interests and the market's competitive structure.[23] This article declares "*all agreements between undertakings [...] that may affect trade between the Member States and have as their purpose or effect the avoidance, limitation, or distortion of competition within the internal market incompatible with the internal market."* If an agreement is found to limit competition under Article 101 (1), it is declared null and void under Article 101 (2) unless the parties can show that the agreement creates efficiencies that outweigh the adverse effects and is therefore exempted under Article 101 (3). EU competition law's efficiencies deem legitimate to outweigh any negative effects pre-defined in a closed list under article 101 (3).[24]

The Commission sets out the general principles by which it approaches the application of Art. 101 to IPRs. A few points of general importance are noted as follows:

i) There is no presumption of illegality for a technology transfer agreement falling outside the TTBER as long as it does not contain hardcore restrictions on competition;[25]

ii) The Commission accepts the fact that a technology transfer agreement, which does not contain hardcore restraints, is unlikely to infringe Art 101 where four or more independently controlled substitutable technologies exist in addition to those controlled by the parties;[26]

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[21] Selenhag, 2019.

[22] Consolidated Version of the Treaty on the Functioning of the European Union, OJ 2012, C 326/49 [cit. TFEU].

[23] C-8/08, T-mobile Netherlands and T-Mobile Netherlands BV, KPN Mobile NV, Orange Nederland NV and Vodafone Libertel NV v Raad van bestuur van de Nederlandse Mededingingsautoriteit, 4 June 2009, ECLI:EU:C:2009:343, , para. 38.

[24] Bernitz U., & Kjellgren A., Europarattengrunder, 5th ed., Nordstedts Juridik, Stockholm, 2014 [cit: Bernitz].

[25] Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, para. 9 [cit: Guidelines on TFEU]

[26] Ibid, para. 157.

iii) Application of Art. 101(1) to technology transfer agreements is concerned with both *restriction on inter-technology competition (*competition between the undertaking that uses different technology*)* and *restriction on intra-technology competition* (competition between the undertaking that uses the same technology).

1.2.1 Settlement Agreements under Art. 101 of TFEU

The TTBER[27] covers settlement agreements involving a transfer of technology, designed to resolve disputes concerning the validity or scope of IP, as long as they do not contain hardcore restrictions.

Outside the safe harbour, the general approach of the Commission is explained in the Guidelines:

"Licensing of technology rights in settlement agreements may serve as a means of settling disputes or avoiding that one party exercises its IPR-s to prevent the other party from exploiting its technology rights."[28]

"Settlement agreements in the context of technology disputes are, ..., in principle a legitimate way to find a mutually acceptable compromise to a bona fide legal disagreement. The parties may prefer to discontinue the dispute or litigation because it proves to be too costly, time-consuming and/or uncertain as regards its outcome. Settlements can give rise to welfare-enhancing benefits. On the other hand, it is in the general public interest to remove invalid IPR-s as an unmerited barrier to innovation and economic activity."[29]

Although the Commission recognises the importance and benefits of settlements, it has become concerned about *pay-for-delay* settlements, or *'reverse payments.'*[30] These settlements generally do not involve the transfer of technology rather of value from the originator to the generic "*for a limitation on the entry and/or expansion on the market of the other party and may be caught by Article 101(1)."*[31]

[27] Guidelines on TFEU.

[28] Ibid, para. 234.

[29] Ibid, para. 235.

[30] Jones & Sufrin, pg. 854.

[31] Guidelines on TFEU, para. 238

In addition, "*if the parties to such a settlement agreement are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing."*[32]

Patent settlement agreements, as usual settlements, involve a "*non-challenge clause*", which in the eyes of Commission has been seen as a form of restriction of competition, although the Guidelines consider these clauses to fall outside Art. 101(1)[33] because the settlement implies that the parties agree not to challenge each other, which is the very purpose of the agreement, to settle existing disputes and avoid future disputes.

However, there are specific circumstances when these clauses can be anticompetitive and caught by Art.101(1). The restriction of freedom to challenge is outside of the scope of exclusive rights that a patent holder has. Therefore, since it falls out of the patent subject-matter right, it can be caught under Art 101. In addition, if, after further scrutiny, the Authority concludes that a sum was transferred to induce the other party not to challenge, it is seen as an infringement of Art. 101.[34]

1.2.2 Pay-For-Delay Arrangement vs Patent Settlement Agreements

The Commission does not believe that agreements resolving disputes and including a licensing term in which the originator grants the generic undertaking a contested patent license is anticompetitive as it is possible that the generic undertaking will be forced out of the market without the license.[35] That is when the generic product would infringe the original's patent if it did not have a license. In these cases, the Commission believes that a license term is procompetitive because it encourages all parties to use their technology after the settlement agreement is finalised.[36]

Settlement arrangements, as previously stated, are not forbidden in and of themselves. In some instances, settlement agreements can be the best option for resolving conflicts over patent validity or violation of those rights. Although these arrangements can be a valuable tool for

[32] Ibid, para. 239

[33] Ibid, para. 240

[34] Ibid, para. 241

[35]Ibid, para. 236.

[36] Selenhag, 2019.

resolving disputes, they can also be used to cover collusive transactions between originator and generic firms, resulting in gains for the parties involved at society's expense. Regardless of the validity of the underlying legal dispute, the agreement and its terms are subject to competition law regulations.[37]

Different agreements between the originator and generic firms may be used in a pay-for-delay deal.[38] The generic company agrees to restrict, postpone, or entirely suspend its market entry in return for a value transfer from the originator company, which is common to all agreements.[39] As a result, the goal of a pay-for-delay agreement can be defined as limiting market competition.[40]

When one or more pay-for-delay deals are reached, the originator company will take advantage of the additional profits generated by its extended exclusivity on the market and keep or even raise the drug's price. The benefit transferred to the generic business may be a small price to pay for the loss of sales that the originator would have experienced if the generic entry had occurred.[41]

These collusive transactions, however, will help more than just originator firms. There could be good incentives for generic firms to enter into pay-for-delay contracts. The generic business may make substantial profits without even entering the market by sharing the profits generated by the originator's extended exclusivity.[42] Entering a pay-for-delay agreement eliminates any risks for the generic undertaking failed market entry or costs associated. Nevertheless, when so is done, these benefits are made at the expense of society's welfare and diminishes citizens accessibility to affordable substitute medicines. Consequently, these agreements contradict the goals and objectives of competition law, making it evident that such arrangements cannot and have not been permitted by competition law.[43]

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[37] See Anderman, S., & Schmidt, H., EU Competition Law and Intellectual Property Rights - the Regulation of Innovation, 2nd ed., Oxford University Press, 2011, in Selenhag, 2019.

[38] European Commission, Competition Enforcement in the Pharmaceutical Sector (2009-2017), COM (2019) 17 final, Brussels, 28 January 2019 [cit. Competition Enforcement in the Pharmaceutical Sector (2009-2017)], p. 24

[39] Ibid

[40] See Selenhag, 2019.

[41] Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 25.

[42] Ibid, p. 26.

[43] See Selenhag, 2019.

1.3 THE EU COMMISSION'S INQUIRY

1.3.1 General remarks

In 2017, the Commission completed the eighth pharmaceutical sector monitoring exercise[44], which covered the period from January 1, 2016, to December 31, 2016. The original conclusion of this study was that these settlements might be problematic because, in the end, the consumer could be the one who pays the price for the market entry delay. Thus the adverse effects of these agreements between potential competitors outweigh any social benefit. The adverse effects implied are a distortion of competition, delays in accessing new, innovative and cheaper generic medicines to the EU market.[45] Furthermore, they suggested a case-by-case assessment of settlement agreements.

Prior to 2009, there was no guidance or case law concerning patent settlements' legality containing reverse payments under EU competition law.[46] Although the final report to the pharmaceutical inquiry was not meant to provide any guidance on patent settlements' compatibility with EU competition rules, it was nowhere indicated that the Commission would view settlements containing reverse payments as restrictions by '*object*'.[47] Quite the contrary, the Commission announced that whether it would deem certain patent settlement agreements as anticompetitive or not would require an in-depth case-by-case assessment.[48] Some critics mean that this suggested that the agreements' assessment was to be made based on an effect-analysis, which was wrong considering the outcome of the several hundred pages long decisions in *Lundbeck* and *Servier*.[49] However, concern has been raised contending that there is an absence of

[44] Competition Enforcement in the Pharmaceutical Sector (2009-2017).

[45] Jones & Sufrin, pg. 854.

[46] Gerardin, D., Ginsburg, D.H., & Safty, G., 2.07: Reverse Settlements in the EU and the US, in Giovanni Pitruzella and Gabriella Muscolo (eds), Competition Law Series, Volume 65, Kluwer Law International, 2016 p. 137 [cit: Gerardin]

[47] Final report of the Pharmaceutical sector inquiry, p. 15.

[48] Ibid, p. 20.

[49] Bruzzone, G., & Capozzi, S., The Procompetitive and Anticompetitive Impact of Patent Settlements, in Giovanni Pitruzzella and Gabriella Muscolo (eds), Competition and Patent Law in the Pharmaceutical Sector: An International Perspective, International Competition Law Series, Volume 65, Kluwer Law International, pp. 15–30, 2016, p. 18 [cit. Bruzzone & Capozzi].

sufficiently clear guidelines of the competitive assessment made on patent settlements, ultimately creating legal uncertainty.[50]

1.3.2 Categorisation of Patent Settlement Agreements

From a Competition Law perspective, the EU Commission[51] has classified settlement agreements into two categories. The date of entry to the market for a generic can be limited in several ways. One limitation could be an explicit moratorium for a generic not to challenge a patent's validity, thus having a "*non-challenge clause*". Other restraints could involve a delay to market entry for a generic until the patent has expired, thus having a "*non-compete clause*".[52]

Even a license granted by the originator company allowing the generic to be on the market is also categorised as limiting generic entry. Another form of limitation refers to parties agreeing that the generic will distribute the originator's product in the market.[53]

The value transfer from the originator to the generic, other than a direct monetary transfer, can also be in a "*side-deal*" form. The originator would allow the generic to enter the market earlier than the patent expiry date, but in a different geographic area or with a different product marketed by the originator.[54]

Therefore, the EU Commission has sorted these settlement agreements into two categories, as shown in *Table 1*[55] below.

[50] Bruzzone & Capozzi, p. 18.

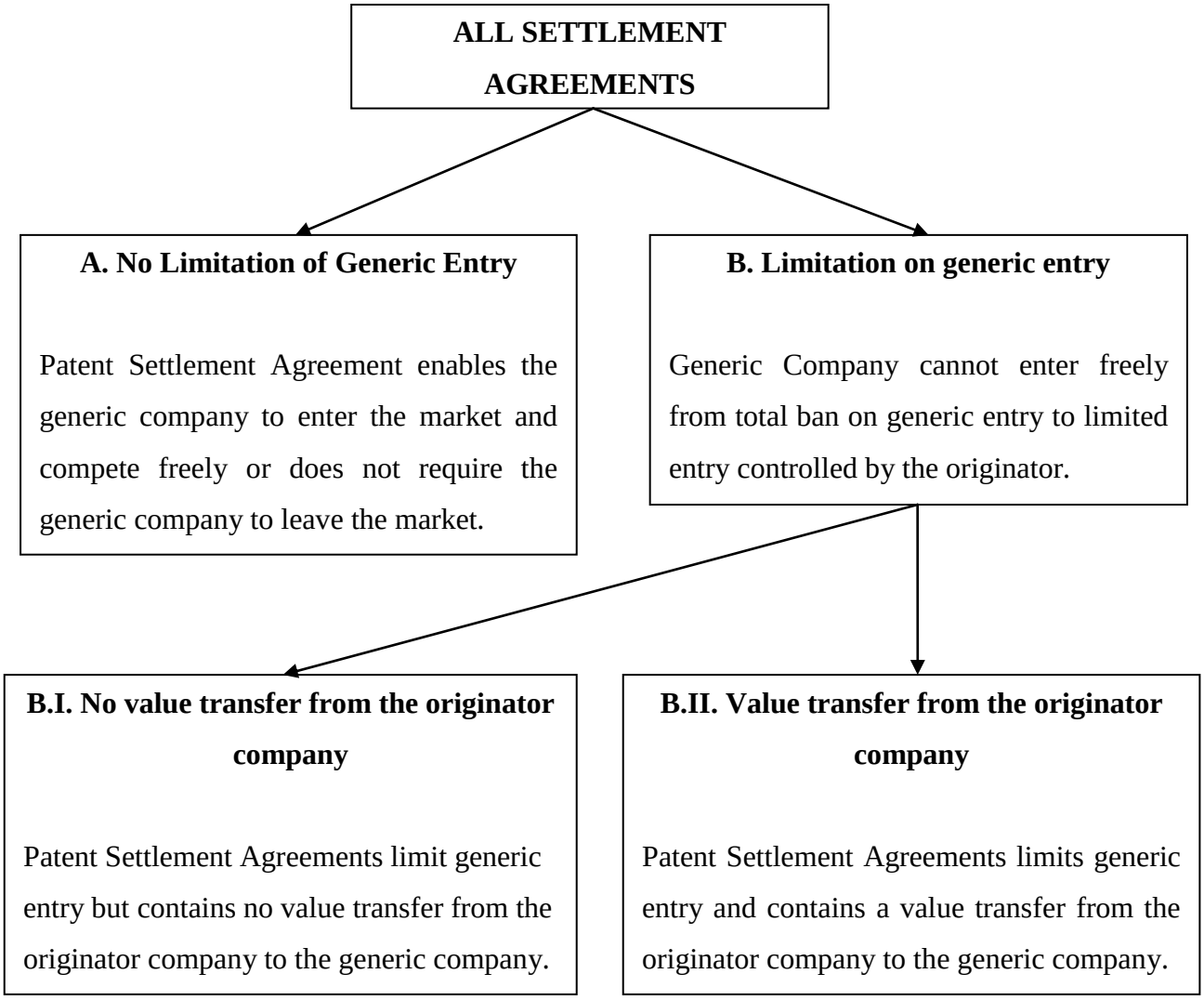
[51] See Competition Enforcement in the Pharmaceutical Sector (2009-2017).

[52] Ibid, pg.2.

[53] Ibid, pg. 3.

[54] Ibid, pg. 4-5.

[55] See Clancy M, Geradin D, Lazerow A. Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of U.S. Antitrust Law and EU Competition Law. The Antitrust Bulletin. 2014;59(1):153-172. doi: https://bit.ly/2QDZNa0.



From a competition law perspective, Category A settlements usually should be unproblematic as they allow immediate market entry by the generic company. The same applies to B-I settlements, although they require further competition law scrutiny. On the other hand, B-II agreements are subject to the most intense antitrust scrutiny because they restrict market access and provide a benefit shift from the originator to the generic. [56]

[56] According to the US scholars Langenfeld & Li, reverse settlement agreements are categorised into two types: complete and partial or interim settlement agreements. Complete settlement agreements involve a value transfer from the originator to the generic companies to ultimately settle the patent litigation, with specific agreed entry dates for the generics. Partial or interim settlement agreements include payments from the originator to the generic manufacturer in exchange for the generics not entering the market before a final resolution of patent litigation. These types of settlements do not specify a fixed date for generic entry. For more see James Langenfeld & Wenqing Li,

According to the Final Report[57], out of 107 patent settlement agreements, 27% of the settlement agreements reached within 2016 were A-type settlements; 62% were B-I type settlements; 12% were B-II types settlements.

1.4 DECISIONS OF THE EUROPEAN COMMISSION ON PAY-FOR-DELAY AGREEMENTS

The Commission has played an influential role in developing policy in this field, especially since there have been very few cases that the ECJ has released a decision. The few judgments that the Court has given are of great importance and significance in developing the law on patent settlements and the question of what amounts to a restriction of competition for Art. 101(1) generally.

The Commission's early attitude toward agreements involving a patent licensing, analogously a patent settlement, was that these agreements do not fall within Art. 101(1) as long as the restrictions did not go beyond the *'scope of the patent'*. Consequently, the Commission became aware of the potential that these exclusive agreements have for isolating the market.

The Commission has remained concerned with pay-for-delay settlements, particularly "B-II" types, eliminating potential competition and sharing the parties' resulting profits to the consumers' detriment.[58] It has conducted several investigations and has now adopted some infringement decisions in which it found that the agreements at issue infringed competition by object, hence imposed fines.

> *Lundbeck*[59] - The Commission imposed fines on both the originator and the generic *for delaying a cheaper drug entry.* The settlement had as an object a process patent, where the generic agreed not to enter the market in return for substantial pay and other inducements by Lundbeck. The Commission found that this settlement infringed 101(1) by object and did not satisfy 101(3).

Economic Analyses of Patent Settlement Agreements: The Implementation of Specific Economic Tests, the Evaluation of Dynamic Efficiency, and the Scope of Patent Rights https://bit.ly/3eH3ovX, date 10.09.

[57] See Competition Enforcement in the Pharmaceutical Sector (2009-2017).

[58] Bokhari, Farasat A. S., What Is the Price of Pay-to-Delay Deals? (November 24, 2012). Journal of Competition Law & Economics, 9(3), 739-775, 2012, Available at SSRN: https://bit.ly/3vnR3n6, dt. 13.09 [cit: Bokhari, 2012].

[59] COMP/39.226, 9 /June 2013.

Johnson & Johnson/Novartis (Fentanyl)[60] - The Commission fined both for deterring the entry of a new generic by Novartis through a co-promotion agreement.

Servier/Perindopril[61] - The Commission fined all parties because the settlement agreements contained non-challenge and non-competition clauses, which restricted competition and excluded the generics from the market. The initial patent had expired, but the secondary ones were still active. Here the Commission held that this settlement restricted the competition by object and by effect.

In its decisions, the Commission relied on mainly three cumulative conditions to establish that the agreements between the originators and the generic contenders constituted by object restrictions in the meaning of Article 101 (1) TFEU. The Commission considers a settlement agreement restrictive of competition by object where the undertakings to the agreement were: (i) at least potential competitors, (ii) the generic undertaking committed itself in the agreement to restrict its entry and (iii) the agreement was related to a value transfer from the originator to the generic undertaking which substantially reduced the incentives of the generic undertaking to enter the market.[62]

In *Lundbeck,*[63] the Court confirmed that they were potential competitors because the generics had real and concrete possibility to enter the market.

The Court affirmed the argument that Art. 101 could apply to a patent settlement when it went beyond the patent scope and held that large payments operated as a deal-clincher would restrict competition by object.[64]

Replacing the uncertainty of litigation with the certainty that the generic would not enter the market constitutes a restriction by object since this was obtained through a reverse payment.[65]

This agreement was analogous to *market-sharing agreements*, thus had no aim of achieving legitimate objectives (the protection and enforcement of patent).[66]

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[60] COMP/39.685, 10 December 2013.

[61] COMP/39.612, 9 July 2014, IP14/799.

[62] See e.g. Final report of the Pharmaceutical sector inquiry, p. 269; Commission decision, AT. 39226 – Lundbeck, para. 661 and Case AT.39612 – Perindopril (Servier), para. 1154.

[63] Case T-472/13, H Lundbeck A/S v Commission EU:T:2016:449.

[64] Ibid, para. 361-365.

[65] Ibid, para. 336, 363.

[66] Ibid, para. 458-464.

In *Servier*[67], the Commission repeated the importance of Lundbeck's criteria in determining whether the content, aims, and legal and economic context of the patent settlement agreements concluded between Servier, and other generics justified a conclusion that they restricted competition by object. The Commission moreover, rejected their claims that a presumption of legality should be applied to patent settlement agreements remaining within the scope of the patent even if it includes a transfer of value, where:

i) The patent has not been obtained by fraud

ii) The settled litigation was not fictitious

iii) Settlement terms do go beyond the exclusionary scope of the patents.[68]

In these cases[69], the Commission's findings set out a plausible theory of harm, which is contingent on several assumptions, that entry would have been attempted and would have succeeded in bringing down the market price.[70] According to the Commission's careful contextual analysis of the patent settlement agreements, there is sufficient ground to establish that the purpose of the agreements was to restrict competition by object, if between potential competitors and where payments were made to induce delay of market entry.[71]

[67] COMP/39.612, 9 July 2014, IP14/799.

[68] Jones & Sufrin, pg. 856-857.

[69] COMP/39.226, 9 /June 2013, COMP/39.685, 10 December 2013, and COMP/39.612, 9 July 2014, IP14/799.

[70] Dunne, Niamh, The Lundbeck Case and the Concept of Potential Competition, The Chinese University of Hong Kong Faculty of Law Research Paper No. 2017-05.

[71] Jones & Sufrin, pg. 858.

CHAPTER 2 - THE GENERICS (UK) CASE

The case relates to a complete patent settlement agreement between GlaxoSmithKline (GSK), Paroxetine product Seroxat supplier, GUK, Merck, IVAX/TEVA, Alpharma, Xellia and Actavis - suppliers of generic drugs. GSK settled with each of them in separate agreements that usually involved:

- monetary or other payments from GSK to the generic suppliers (referred to as '*value transfers*'); and
- a condition preventing the generic supplier from entering the market with its product for a set period of time (*the restrictions*).

This categorises these settlements into *Category B.II type*[72] according to the EU Commission categorisation. However, a key difference in Paroxetine is that the generic firms entered into individual supply agreements with GSK to supply an alternative version of GSK's product instead of their independent product. These supply agreements led to the entry of multiple authorised generic suppliers, which captured over 50 per cent of the market in the two years following the settlement. This contrasts with the facts of the Servier and Lundbeck cases, where there was no authorised entry.[73] According to the CAT[74], the agreements delayed generic entry in the supply of Paroxetine in the UK, which consequently delayed the price reduction.

This chapter will deal directly with the *Generics (UK)*, which will be observed through the decisions of the Competition Authority in the UK and through the ECJ's preliminary ruling, which gives detailed interpretation on potential competition, restriction by object, and for the first time, on restriction by effect. Furthermore, it will assess the economic impact on price-effect.

2.1 COMPETITION APPEAL TRIBUNAL ASSESSMENT OF THE CASE

GlaxoSmithKline (GSK) was the genuine patent holder whose patent protection lasted until January 1999, whereas data protection until December 2000. GSK held three patents:

[72] See, Chapter 1, table 1.

[73] Avantika Chowdhury, Helen Jenkins, Inference or Evidence? The Uncertain Fate of Patent Settlement Agreements, Journal of European Competition Law & Practice, Volume 9, Issue 7, September 2018, Pages 449–453, https://bit.ly/2PCj1wq, pg. 449-450 [cit: Avantika & Jenkins, 2018].

[74] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018.

Hemihydrate patent, which was protected until October 2006 and was not a process patent; *Anhydrate Patent* lasted until 2016 and was a process patent; *Dry Tabletting Patent* lasted until 2008 also was a process patent.[75]

Seroxat between 2000 and 2001 would profit £71.6 million, whereas 27% of all NHS (National Health Service) expenditure was used to buy Seroxat between 2001 and 2002. Doctors in their prescriptions usually wrote Paroxetine instead of Seroxat 90% of the times. Imported drugs sold 30-40% of Paroxetine in the UK. [76]

As for *Data Exclusivity*, IVAX applied in June 2000 in Ireland; GUK in April 2001 in Denmark; whereas Alpharma in May 2001 in the UK. [77]

i) The GSK/IVAX Agreement

IVAX appeared to be aggressive and risk-neutral and was ready to launch at risk; therefore, GSK wanted to defend the patent since IVAX's MA posed significant damage to GSK.

They reached an agreement before starting any litigation whatsoever. This agreement entered on October 3 2001 and expired on June 29 2004, and appointed IVAX as *'sole distributor'* in the UK of 20mg Paroxetine Hydrochloride, to a maximum 770,000 packs of 30 tablets, to be sold as authorised generic medicine, in return for an annual *'promotional allowance'* of £3.2 million paid by GSK.[78]

ii) The GSK/GUK Agreement

GUK had the financial means, the investment, its customers, and it was the first generic, but the injunction stopped them from entering the market.[79]

GUK intended to enter the market at its own risk, but immediately GSK sought an injunction against GUK to impede the latter from launching its generic product because if GUK entered the market, GSK product price would significantly fall. On the other hand, GUK could have had the validity issue resolved by the time it launched its generic product, but this never happened. The

[75] Ibid, para. 10-15.

[76] Ibid, para. 16-17.

[77] Ibid, para. 18-20.

[78] Ibid, para. 21-27.

[79] Ibid, para. 28.

manager of GUK and the head of GUK's R&D department claimed damages of £6 million, including API (raw material) cost and a decent profit.[80]

Meanwhile, GSK started different proceedings against GUK on the Hemihydrate patent, but later in Feb 2002, GUK re-evaluated its chances of prevailing at Court, which led to a distribution agreement of API between GUK and GSK while GSK waived all the damage claims. This agreement entered on March 13 2002, and expired on July 1 2004, which included "*Marketing Allowance*", for which GSK paid GUK £1.65 million per year, whereas GUK's annual Market budget was £0.4 million. GSK paid GUK a total amount of £21.3 million over three years.[81]

Launching at risk would be late December 2003, and with the API GUK possessed, they would last only until December 2004. In reality, had GSK not gotten an injunction against GUK, GUK could have been ready to launch at risk.[82]

iii) The GSK/Alpharma Agreement

Alpharma sourced Paroxetine API from BASF. GSK commenced infringement proceedings against Alpharma for both Anhydrate and Hemihydrate Patents. The main issue was whether Alpharma's process was the same as in GSK's process patent. Hence, the Court granted GSK interim relief. After GSK lost its Anhydrate Patent in BASF Judgment, it waived its process claims against Alpharma. Afterwards, GSK dropped the charges for any infringement on Hemihydrate Patent since there was no trace of Hemihydrate in Alpharma's sample tablets.[83]

Although Alpharma was not able to launch at risk, as GUK was, it is believed by the experts that Alpharma could have used that time to prepare for launch, but with an injunction on the table, Alpharma was not allowed to take any preparation for launch until final adjudication.[84]

GSK and Alpharma agreed to settle to a £19 million agreement with a 12-month delay of entry entered on November 12 2002, and expired on February 13 2004.

The CMA's evaluation is that Alpharma could have gone forward with litigation, although aware of the risk imposed, because the trial was expected to be short, lasting from December 2002 until

[80] Ibid, para. 29-30.

[81] Ibid, para. 31-33.

[82] Ibid, para. 34-35.

[83] Ibid, para. 37-39.

[84] Ibid, para. 40-42.

January 2003. Even the appeal could have happened earlier since the trial concerned only the Anhydrate patent. Finally, if anything went in Alpharma's favour, it could have launched it in the UK since it had all the necessary arrangements with Delta and BASF for production. Alpharma was more risk-averse, which had real chances to prevail in uncertain litigation within a month, but still chose to settle under no pressure. The CMAs findings show that the Alpharma settlement was a simple commercial deal from which both gained certain profits. As for this settlement's legality, the settlement was not an agreement for excluding a potential competitor. [85]

iv) The BASF Trial and the Apotex Judgment

The BASF trial went on to a final adjudication, which invalided most of the Anhydrate patent.

After a partial invalided patent because of the BASF trial, the Apotex Judgment invalided the whole Anhydrate Patent. Thus there was no infringement by Apotex. In addition, GSK never appealed. GSK never settled with Apotex, whom they lost in Court because of Apotex's aggressive behaviour outside the UK, but this does not change anything.[86]

Although the Apotex product was found not to infringe the Anhydrate Patent, this does not necessarily mean that the GUK or Alpharma products would similarly have been found not to infringe since this was a process patent and a different procedure may have made those products.[87]

2.2 OTHER NATIONAL DECISIONS ON THE CASE

The EU Commission drew the agreements' attention to the Office of Fair Trading ("OFT"), the CMA's precursor after its report was released in 2009. Furthermore, provided it with copies of the agreements in July 2010. After a preliminary investigation, the OFT opened a formal investigation under sect 25 CA on August 11 2011, and finally stated objections on April 19 2013. Following further information gathered by the OFT and then the CMA and extensive representations from the various parties, the CMA concluded that there were no grounds for action regarding the IVAX agreement and adopted the Decision on February 12 2016.[88]

[85] Ibid, para. 44-45.

[86] Ibid, para. 36.

[87] Ibid, para. 47-49.

[88] Ibid, para. 58.

The decision contains parts on market classification and domination, object assessment, consequences assessment, misuse of a dominant position assessment, and responsibility attribution.[89] The CMA imposed penalties totalling £44,990,421 on the addressees. GSK received the most significant penalty, fined £37,606,275 for its infringement of Chapters I and II prohibitions.[90]

The CMA found that GUK and Alpharma were potential competitors of GSK, which was treated as a condition for concluding that the respective Agreements had the object of restricting such competition. The appellants challenged this finding of potential competition.[91] All the appellants challenged the finding that the relevant agreement was a restriction by 'object'; to the contrary, they argued that the agreements brought about procompetitive effects.[92]

In summary, the CMA found that the GUK-GSK agreement and the Alpharma-GSK agreement revealed, in and of themselves, a sufficient degree of harm to competition and therefore had the object of restricting competition.

All the appellants challenged the finding that the relevant agreement was a restriction by 'effect'.[93]

As stated above, all of the appellants were found to have infringed the Chapter I prohibition; subsequently, GSK and GUK were also found to have infringed Art 101 because of the GUK agreement lasting beyond May 1 2004, when EU Regulation 1/2003 entered into force. However, that infringement of Art 101 is of only peripheral relevance since it effectively overlaps with the Chapter I prohibition.[94]

The Chapter I prohibition is prescribed by sect 2 CA[95], which states, insofar as material:

Agreements between undertakings, decisions by associations of undertakings, or concerted practices which:

(a) may affect trade within the United Kingdom, and

[89] Ibid, para. 59.

[90] Ibid, para. 60.

[91] Ibid, para. 90.

[92] Ibid, para. 160.

[93] Ibid, para. 327.

[94] Ibid, para. 70.

[95] The Competition Act, Chapter 41, Published in 1998

(b) as their object or effect, the prevention, restriction, or distortion of competition within the United Kingdom is prohibited unless they are exempt under this Part's provisions.[96]

(2) Subsection (1) applies, in particular, to agreements, decisions or practices which—

(b) limit or control production, markets, technical development or investment;

(c) share markets or sources of supply."[97]

Further, sect 10 CA provides for "*parallel exemptions*" whereby, if an agreement is exempt from Art 101 because of an EU block exemption regulation (or would be if it affected trade between the EU Member States), it will similarly be exempt from the Chapter I prohibition. In this case, GSK contends that the agreements fell within Regulation (EC) No 2790/1999 (the "Vertical Block Exemption Regulation" or "VBER").[98] The CAT dismissed this ground.

The Chapter I prohibitions are substantively the same as, respectively, Art 101 TFEU, with the difference that they require an effect on trade in the UK as opposed to an effect on trade between the EU Member States, and the conditions for individual exemption under sect 9 CA mirror those in Art 101(3). Therefore, the domestic provisions' application should be based on the Commission's decisions and judgments of the EU Courts.[99]

In that regard, sect 60 CA provides:

At any time when the Court determines a question arising, it must act to secure that there is no inconsistency between:

(a) the principles applied, and a decision reached, by the Court in determining that question; and

(b) the principles laid down by the Treaty and the European Court and any relevant decision of that Court, as applicable at that time, determine any related question arising in EU law.[100]

[96] Ibid, para. 78.

[97] Ibid, para. 79.

[98] Ibid, para. 80.

[99] Ibid, para. 83.

[100] Ibid, para. 86.

2.3 PRELIMINARY RULING BY THE COURT OF JUSTICE

All of the companies affected by the CMA's decision appealed to the CAT. [101] The CAT found that the current appeals and the *Lundbeck* and *Servier* cases had many issues in common. Rather than deferring further argument, on whether any principles enunciated in those cases are directly applicable or distinguishable, and, if distinguishable, what the applicable principles may be in light of those eventual judgments, the CAT believed it was appropriate for this Tribunal to refer the relevant questions of EU law interpretation arising out of those cases to this Tribunal right now.[102]

On this matter, the CAT decided to make a preliminary reference to the CJEU on crucial issues such as potential competition, restriction by object, and for the first time, restriction by effect. Meanwhile, in the judgment, the CAT dealt with all questions of fact and decided those issues on which either no question of the interpretation of EU law arises or on which CAT considered it unnecessary to seek a ruling from the CJEU.[103]

2.3.1 Potential Competition

In the case law, it has been established that to define whether an undertaking qualifies as a potential competitor, the Commission must prove that there would have been "*real concrete possibilities*" to enter the market and compete with actual competitors absent the agreement.[104] The intention of an undertaking to enter the market is not sufficient to determine potential competition unless such intention derives from the undertaking's ability to fulfil its intention to enter the market.[105] The second condition other than the ability to enter the market is for the undertakings not to encounter any *insurmountable barriers* that would hinder the undertaking's ability to enter the market.[106]

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[101] Ibid, para. 5-7.

[102] Ibid, para. 87.

[103] Ibid, para. 88.

[104] Case T-461/07, Visa Europe Ltd and Visa International Service v European Commission, 14 April 2011, ECLI:EU:T:2011:181, para. 166.

[105] Ibid, para. 167 and Case T-177/04, Easyjet Airline Co. Ltd v Commission, 4 July 2006, ECLI:EU:T:2006:187, para. 123-125.

[106] Case T-519/09, Toshiba Corp. v. Commission, 21 May 2014, ECLI:EU:T:2014:263, para. 230 and Case T-208/13, Portugal Telecom SGPS v. Commission, 28 June 2016, ECLI:EU:T:2016:368 para. 181.

Considering previous cases such as *Lundbeck and* Servier, the ECJ held that the Commission was right to consider them potential competitors[107]. However, according to the undertakings, the process patents posed insurmountable entry barriers since patents confer exclusive rights to their owners, hindering "*real concrete possibilities*" of entry. The parties also asserted that the lack of an MA is also an insurmountable obstacle, which the authorities rejected to justify that the generics could achieve market entry since they were pursuing efforts to obtain regulatory approvals.[108]

The Commission argued that as long as the generic companies can challenge the validity of the originators' process patents, these patents could not constitute insurmountable barriers to entry.[109]

In the *Generics (UK)* case, the CMA found that GUK and Alpharma were potential competitors of GSK.[110] However, GUK and Alpharma contended, with GSK's support, that the interim injunction meant that irrespective of their intention or strategy, there was an insurmountable barrier to their entry and that they are therefore not to be regarded as potential competitors when assessing the agreements in the light of competition law.[111]

Indeed interim injunctions prolonged generic entry, but their duration was only up to the final judgment. In contrast, the settlement caused a delay, which lasted for a much more extended period than any injunction would have extended.[112] In the light of the *Lundbeck* judgments, the block on entry imposed by short-term interim relief pending trial should not be regarded as precluding the generic company being regarded as a potential competitor.[113]

As for the generics' intention to enter the market, the ECJ evaluated that transfers of value from an originator to a generic under the premises of a delay of market entry strongly indicate that they are potential competitors—furthermore, the greater the transfer of value, the stronger the

[107] General Court of the European Union, press release No 194/18 regarding Judgment T-691/14, Servier et al v. Commission, 12 December 2018, and press release No 90/16 regarding Judgment T-472/13, Lundbeck v. Commission, 8 September 2016.

[108] Case AT.39226 - Lundbeck, para. 1038 and Case AT.39612 - Perindopril (Servier), para. 1181.

[109] Case AT.39226 - Lundbeck, para. 628 and Case AT.39612 - Perindopril (Servier), para. 117, and T-691/14, Servier et al v. Commission, para. 368.

[110] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018, para. 90.

[111] Ibid, para. 137

[112] Ibid, para. 141

[113] Ibid, para. 156

indication. Transfer of value is a strong indication since it discloses the originator's perception of the risk that the generic may pose to the originator's commercial interests; therefore, this perception is relevant to assess the potential competition.[114]

The ECJ responded that the originator and the generic, although in an ongoing dispute, are potential competitors, where it is established that *the generic has a firm intention and an inherent ability to enter the market*, and that *market entry does not meet the barriers to entry that are insurmountable*, which the national courts assess. [115]

2.3.2 Restriction by Object

The referring Court sought to ascertain several issues related to limitations to entry, non-challenge clause, the transfer of value, and the procompetitive effects of the agreements, but for the dissertation's purpose, transfer of value is going to be discussed.

The referring Court sought, in essence, to ascertain whether a settlement agreement that involves a transfer of value, which may be significantly large and unexplained, that exceeds the litigation costs without covering any goods or service, infringe Art. 101 by object, in circumstances when the patent strength outcome is uncertain. In addition, does the response change if the amount of the value transfer to the generic is less than the amount the generic would have made had it prevailed in the litigation and entered the market with the generic medicine?

In this sense, the CMA's overall analysis[116] was that:

- GSK paid GUK and Alpharma to remove the risk of them entering the market;
- The value transfer included cash payments, profit margin, distribution agreement;
- Parties share the profit from high prices, whereas customers are deprived of lower prices;
- For the originator, there was a risk of patent invalidity or not infringement. Thus, a high-profit loss at stake was more inclined to pay the generic companies part of that lost money.
- For the generic, the value transfer was higher than the returns from entering the market. Generic independent profit was lower than the lost profit of originator if generic entered.

[114] Case C-307/18, Generics (UK) and Others v Competition and Markets Authority, 30 January 2020, ECLI:EU:C:2020:52, para. 56.

[115] Ibid, para. 58.

[116] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018, para. 166-167.

Had the generics entered the market, the market shares and/or price level of the originator product would have fallen because of intense price competition.

Professor Shapiro commented that the value of transfer should amount to the legal costs and the management time and disruption involved in pursuing a patent infringement case. Any other reason is not a legitimate one, such as avoidance from potential competition.[117]

The ECJ responded that the fact that such an agreement involves transfers of value, either monetary or non-monetary, made by the originator to the generic is not sufficient ground to classify it as a '*restriction by object'*, since those transfers of value may prove to be justified, that is, appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement.[118]

In conclusion,[119] in the light of the preceding, Article 101(1), TFEU must be interpreted as meaning that a settlement agreement between potential competitors constitutes an agreement that has as its object the prevention, restriction or distortion of competition:

- if it is clear from all the information available that the net gain from the transfers of value by the originator in favour of the generic can have no other explanation than the commercial interest of the parties not to engage in competition on the merits;
- unless the settlement agreement is accompanied by proven procompetitive effects capable of justifying the reasonable doubt of a sufficient degree of harm to competition (that the settlement may have caused).

2.3.3 Restriction by Effect

The CAT found that if an agreement in its economic and legal context could show that the counterfactual was appreciably more competitive than limited competitive benefits that may have resulted from the reverse payment agreement, the CAT did not consider that those benefits precluded a finding of infringement by effect.[120]

[117] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018, para. 168.

[118] Case C-307/18, Generics (UK) and Others v Competition and Markets Authority, 30 January 2020, ECLI:EU:C:2020:52, para. 85.

[119] Ibid, para. 111.

[120] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018, para. 328-329.

The Decision of CMA says that had GUK and Alpharma entered the market independently, any following settlement would not have involved a transfer of value to delay entry because only in this case the real uncertainties on GSK's patent strength or weakness would have been revealed.[121]

As for the exclusive patent right, paying a potential competitor a sum of money in order for them not to try to enter the market is not an exclusive right granted by any patent law, nor does it show patent strength. As a result, it is not a legitimate means to defend one's patent rights.[122]

The referring Court, in trying to ascertain *'restriction by effect'* in the circumstances mentioned in previous paragraphs or does its existence depend on the Court's finding that in the absence of the settlement:

i) The generic would have prevailed in the patent proceedings; alternatively

ii) The parties would probably have entered into a less restrictive settlement?

The ECJ responded that, when the concerted practice does not reveal a sufficient degree of harm to competition, it is then necessary to examine the effects of that practice and, in order to classify that practice as a *'restriction of competition'* within the meaning of Article 101(1) TFEU, to identify the factors which establish that competition was, prevented, or restricted, to any appreciable extent. [123]

In conclusion,[124] in the light of the preceding, in defining '*restriction by effect*' in this context, Article 101(1) must be interpreted as meaning that if a settlement agreement is to be demonstrated to have appreciable potential or actual effects on competition, then, is to be characterised as a 'restriction by effect'. Therefore, there is no need to find that either the generic would probably have been successful in the absence of that agreement or that the parties would probably have concluded a less restrictive settlement agreement.

[121] Ibid, para. 331-333.

[122] Ibid, para. 338-339.

[123] Case C-307/18, Generics (UK) and Others v Competition and Markets Authority, 30 January 2020, ECLI:EU:C:2020:52, para. 120-121.

[124] Ibid, para. 122.

CHAPTER 3 - TRANSFER OF VALUE AS A PROXY FOR ANTICOMPETITIVE PATENT SETTLEMENTS

Reverse payment's size and direction are factors that have been relied upon as a proxy to justify a finding that a genuine dispute is restrictive by object. If the amount were too large, the argument would go, as it would indicate that the *'precise purpose'* of the settlement is to share the profits with the generic producer.[125]

Large and economically unexplained value transfer could be explained as paying off the generic to delay the entry. If this payment is above the litigation costs and delays entry and restrictions on the generic, it is considered anticompetitive.[126]

In the perfect scenario, the framework of the settlement is based on the following assumptions:

- Both parties are risk-neutral
- Both have common (symmetric) and complete information
- Any negotiation between parties is efficient (efficient bargaining).[127]

However, if parties have asymmetric information, they may be risk-averse, meaning friction in the bargaining process. The settlement can be procompetitive with a significant and unexplained value transfer (above litigation costs).[128]

Therefore, this chapter will explain how the transfers of value are treated under basic and realistic models to provide a thorough resolution on how these transfers should be treated.

3.1 TRANSFERS OF VALUE IN DIFFERENT PATENT SETTLEMENT MODELS

According to most of the contributions from legal and economic academics, transfers of value are scrutinised from a basic patent settlement model lens.[129] This Chapter analyses both basic and realistic patent settlement models' assumptions, reasoning, and conclusions.

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[125] Ibáñez Colomo, Pablo, Pay-for-Delay and the Structure of Article 101(1) TFEU: Points of Law Raised in Lundbeck and Paroxetine (November 28, 2019). Available at SSRN: https://bit.ly/3nv3CKR.

[126] Case C-307/18, Generics (UK) and Others v CMA, ECLI:EU:C:2020:52, para. 80-84.

[127] Avantika & Jenkins, 2018, pg. 451.

[128] Ibid, pg. 449–453.

[129] Frank & Kerber Wolfgang, "Patent settlements in the pharmaceutical industry: What can we learn from the economic analysis?", November 2015, pg. 7 [cit: Frank & Kerber].

3.1.1 The Basic Patent Settlement Model

In a basic patent settlement model, parties know the strength of a patent, are risk-neutral, and provide scholars with a perfect scenario; thus, this model is considered a reference point.

From this basic model, several conclusions[130] can be derived that have been very influential in the policy discussion:

(1) The normative criterion that patent settlements should not harm consumers compared to patent litigation translates into the standard that generic entry should not be later than the agreed time of generic entry, which should be strictly proportional to patent strength.

(2) If there were no reverse payments, the bargaining would lead to a settlement range around an optimal entry date. As soon as the reverse payment is larger than the originator's litigation costs, the agreed entry date is later than the optimal entry date and therefore anticompetitive.

(3) Reverse payments are a very effective instrument for restricting price competition through generic entry. Increasing reverse payments leads directly to later entry dates and higher joint profits, and higher welfare losses for consumers than patent litigation.

(5) This model also suggests that patent settlements without reverse payments are not anticompetitive because they usually lead to the correct entry date.

Under these assumptions, parties can legally reach settlements. According to the case law, the transfer of value should be in the sum that corresponds:

i) to compensation for the costs or disruptions caused by the litigation;

ii) to remuneration (payment) for the actual supply of goods and services to the originator;

iii) to justify the existence of any waivers undertaken by the generic, besides when the generic discharges the originator from a cross-undertaking in damages.[131]

Generally, scholars and judges have based their articles and decisions on this basic model. The starting point is '*potential competition*', in which transfers of value under the promise of an entry delay are seen as an indication of potential competition. Moreover, the higher the transfer, the stronger the indication since the transfers imply risk perception.

[130] Frank & Kerber, pg. 8-9.

[131] Case C-307/18, Generics (UK) and Others v CMA, ECLI:EU:C:2020:52, para. 86.

'*Restriction by object*' goes further and qualifies any transfer of value that is greater than the sum of the costs or disruptions caused by the litigation as '*large*' and '*unexplained*'. The logic is that such an unexplained payment is in return for delayed entry by the generic. This logic is based on this simplistic patent settlement model, which implies that whenever the originator pays such an amount to the generic that surpasses the litigation costs to delay market entry, it is likely that this agreement is anticompetitive.[132]

A settlement has two dimensions in this simplified model: *a value transfer* and *an agreed date of independent entry* before patent expiry. The transfer of value included in the settlements usually involves the litigation costs incurred had the settlement not been concluded. This is the central concept that legitimises the agreement as procompetitive.[133]

As long as the settlement's total monetary value is greater than the expected profit under litigation, the generic firm will settle. This illustrates the concern related to the patent settlement agreements with large value transfers. In this simple approach, without a reverse payment, the generic would demand an earlier entry date. Therefore the originator would offer compensation to delay that date. In conclusion, a lower reverse payment is more competitive because it would be accompanied by earlier entry date.[134]

The Commission has categorised these settlements into A and B types, in which reverse payments are seen as means of limitations on generic entry, so every patent settlement that involves a transfer of value is qualified under B.II category, which is further scrutinised for infringements. [135] Such an approach by the Commission renders all reverse payment settlements as initially anticompetitive because they delay entry based on a simplistic settlement model. Such a reverse payment could be justified when used not to delay entry but to compensate for delayed entry caused by a too optimistic belief in the parties' patent validity.[136]

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[132] Avantika & Jenkins, 2018, pg. 451

[133] Shapiro, Carl, Antitrust Limits to Patent Settlements (May 1, 2001). Available at SSRN: https://bit.ly/32YoSiB dt. 13.09 [cit: Shapiro, 2001].

[134] Ibid, pg. 452

[135]Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.4

[136] Frank, Jonas, Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics Perspective (2016). Part of cumulative dissertation University Marburg 2017, Available at SSRN: https://bit.ly/3aP2rAO, [cit: Frank, Jonas] pg. 14

Therefore, this shows how the basic model is irrespective of the complex nature that patent settlements have. Since these settlements include worldwide companies and influential people with different risk-attitude, they may possess different information that leads to frictions in the bargaining process.

3.1.2 The Realistic Patent Settlement Model

In the basic model, it was assumed that both parties are risk-neutral. In risk-averse originators or entrants settlement, economics shows that the settlement ranges and the agreed entry dates and reverse payments change.[137] Even in the case of no reverse payment when the reality assumptions are taken into account, we cannot expect the patent settlement outcome to correspond to the outcome of patent litigation.[138]

Economists also would agree that in reality, the bargaining situations between originator and generic firms are much more complex and might suffer from several imperfections not considered in this basic model.[139]

Several factors need to be considered for the parties to decide to settle patent litigation during a trial. According to a *study*[140] conducted in Germany settlements, within-trial usually happens because new evidence or information may lead to changes in the parties' expectations or stakes. In this context, the role and impact of asymmetric information and risk aversion are crucial in the realistic model of reverse settlement agreements.

3.1.2.1 Asymmetric Information

On the economic analysis of legal disputes, settlement and trial are considered a cooperative and non-cooperative solution of a bargaining game between the plaintiff and defendant driven by

[137] Willig RD, Bigelow JP. Antitrust Policy toward Agreements that Settle Patent Litigation. The Antitrust Bulletin. 2004;49(3):655-698. doi: https://bit.ly/3sY4dWl [cit: Willig & Bigelow, 2004].

[138] Davis, Joshua P. (2009): Applying Litigation Economics To Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, in: Rutgers Law Journal, Vol. 41, Issue 1/2, [cit: Joshua, 2009], pp. 255-307.

[139] Frank,& Kerber.

[140]Cremers, Katrin and Schliessler, Paula, Patent Litigation Settlement in Germany - Why Parties Settle During Trial (2012). ZEW - Centre for European Economic Research Discussion Paper No. 12-084, Available at SSRN: https://bit.ly/3nw4sqA date 10.09.

different asymmetries.[141] In the absence of asymmetries between parties, a settlement is most likely to happen.[142]

One party may have only private information about its probability of prevailing at Court, while the other party only knows the distribution of win probabilities. The uninformed party makes only a take-it-or-leave-it settlement offer. In contrast, the party that knows its win probability may reject this offer and follow up with litigation if the win probability is high. The estimated payoffs from litigation are higher than the settlement amount.

In the context of patent settlements, any wrong and/or different predictions and other information asymmetries will lead to different settlement outcomes regarding agreed entry, which might be far from the optimal entry date (as derived in the basic model). [143]

They can show that a procompetitive settlement is only possible with a reverse payment in a case of asymmetric information about a patent's value. [144]

3.1.2.2 Risk Aversion

Risk aversion[145] has been identified as a justification for pay-for-delay settlements, especially the originator company's risk aversion. Regarding different types of reverse payment agreements as complete and partial, risk aversion may have a different impact.

Risk aversion has a significant impact on reaching a final complete settlement but does not necessarily justify the settlement's reverse payment. It is the asymmetry in risk aversion that makes a reverse payment justifiable and necessary in a settlement. [146]

In patent settlement agreements, if both parties are risk-averse, then the originator company that values certainty will agree on an earlier generic date of entry acceptable for the generic; therefore, no reverse payment is needed to fill in the settlement gaps.[147]

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[141] Ibid, pg. 4.

[142] Ibid, pg. 5-6.

[143] See Willig & Bigelow, 2004.

[144] Ibid, pg 655-698.

[145] Li, Wenqing. "The Role of Risk Aversion in Reverse Payment Agreements." The Antitrust Bulletin 63, no. 2 (June 2018): 237–45. https://bit.ly/3aOltXM dt: 10.09, [cit: Wenqing, 2018].

[146] Ibid.

[147] Ibid.

If the parties overestimate the patent strength, then even without reverse payments, the agreed entry date will be later than the normatively optimal one, rendering patent settlements anticompetitive. Vice versa, in the case of underestimating the patent strength, the agreed entry date will be earlier than the optimal one, which would allow positive reverse payments (beyond litigation costs) without making the patent settlement anticompetitive.[148]

In other words, if there is an asymmetry in risk aversion, the risk-neutral party may insist on litigation which to his calculations would bring prolific benefits. On the contrary, it could turn negative, therefore lose the chance to offer or accept a reasonable entry date. Whereas the risk-averse party would like to settle to reduce the risk of losing money in costly litigations, but since there has already been a gap created for an apt entry of date, reverse payment is more than necessary to close this gap and reach the settlement.[149]

3.2 THE GENERICS (UK) CASE UNDER PATENT SETTLEMENT MODELS

In Generics(UK) case, we encounter a more realistic model in which GSK and the generics had different information and estimations on patent strength and their win chances, so all settlements were concluded under asymmetric information, without considering their risk-attitude.

In this context, there are three agreements reached by the generics and the originator, GSK, which appeared to be risk-averse and confident only of the Hemihydrate but not of Anhydrate patent.[150]

In the first agreement, IVAX appeared risk-seeking and ready to launch at risk, but GSK seemed risk-averse, which GSK confirmed at Court. They reached an agreement benefiting IVAX in the long run since IVAX became the sole distributor for GSK in the UK even after GSK concluded other agreements with other generics.

The second agreement was reached between GSK as reasonably risk-averse and GUK as fairly risk-neutral and highly confident in their win chances, 110% as its head of the R&D department stated[151], so they sent the case to Court. GUK had enough raw materials to enter the market on its

[148] Frank & Kerber, pg. 10.

[149] Wenqing, 2018, dt: 10.09.

[150] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018, para. 108.

[151] Ibid, para. 105.

own, so they were ready to launch.[152] Meanwhile, GUK reassessed their chances against the most potent patent of GSK, the Hemihydrate Patent, and afterwards, GUK became risk-averse and settled. GSK paid GUK a total amount of £21.3 million between March 2002 and July 2004. Launching at risk would be late December 2003, and with the API GUK possessed, they would last only until December 2004.[153] Since there were no indications on the Hemihydrate patent's strength and any party conducted no investigation, it is difficult to conclude whether this settlement was a better decision than going through with litigation.

In the third agreement, we have a different scenario. Both parties GSK and Alpharma, appeared to be moderately risk-averse since Alpharma was not ready to launch at risk, and the case involved a process patent, which had been already in the trial in the Apotex case.[154] GSK initiated the litigation on this patent, and Alpharma conducted its investigations and waited for the Apotex trial. Although the Apotex trial invalidated the Anhydrate patent, which increased Alpharma's win chances and made them more risk-averse than initially, Alpharma did not go through its trial against GSK. On the contrary, Alpharma being so risk-averse, settled with GSK under no pressure and thus lost its upper hand to ask for better conditions. Alpharma got a 12-months delay condition. However, the trials would never have delayed Alpharma for more than six months.[155]

Addanki & Daskin[156] argue that a risk-averse might be willing to sacrifice a portion of his return from a venture in exchange for a reduction of the uncertainty associated with the venture. As attractive as it may sound for the entrant, he may have liquidity issues that would pose difficulties in sustaining the activities until the entry date. Therefore a "*cash infusion*" in the form of a reverse payment by the originator would help the entrepreneur survive in the market. In this sense, an earlier date would be infeasible for the entrant to survive.[157]

This scenario happened in the Alpharma settlement in which Alpharma was not ready to launch and needed time and more preparatory measures before launch. Therefore, a part of the transfer

[152] Ibid, para. 96.

[153] Ibid, para. 109-113

[154] Ibid, para. 50-53

[155] Ibid, para. 130

[156] Addanki, Sumanth & Daskin J. Alan, Patent Settlement Agreements, Issues in Competition Law and Policy, Chapter 85, 2006, https://bit.ly/2Rae3Hq.

[157] Ibid, pg. 2131

of value made by GSK under the name of "*production and preparation*" was paid to Alpharma to make it feasible for Alpharma to survive the market after independent market entry.

In the Generics(UK), the ECJ based on the simplistic model confirmed that the transfer of value should be in the sum that corresponds:

i) to compensation for the costs or disruptions caused by the litigation; and

ii) to remuneration for the actual supply of goods and services to the originator.[158]

Nevertheless, the Court made some advancement by not excluding these possibilities from the assessment. The ECJ even justifies the generic that decides to refrain itself from entering the market as a sign that the generic may have gotten the right information about its win probabilities. In addition, the Court argues that the mere existence of the transfer of value is not sufficient ground to classify the settlement as restrictive by object, since this may be *justified, appropriate and strictly necessary*[159] considering the parties' risk-attitude and the possession of information, also having regard to the legitimate objectives of the parties. Even when considering the case's uncertainty, it is not essential if the transfers of value are more significant than the generic profits had it won the litigation. Instead, it is crucial to determine whether this enormous sum was an incentive for the generic to refrain from entering the market.[160]

However, the Court restricts the deliberate substitution of competition risks with a practical agreement, including an economically unexplained sum with no other explanation that the parties' plain commercial self-interests not to engage in competition infringe Art. 101(1) by object.[161]

3.3 PRICE-EFFECT ANALYSIS OF TRANSFERS OF VALUE IN GENERICS (UK)

Patent settlements implicate competition between rivals and tend to affect third parties such as the consumers. These settlements could either lead to higher-quality products when both parties cross-license each other, or they could enable competition restrictions between them to the

[158] Case C-307/18, Generics (UK) and Others v Competition and Markets Authority, 30 January 2020, ECLI:EU:C:2020:52, para. 86.

[159] Ibid, para. 85.

[160] Ibid, para. 94.

[161] Ibid, para. 87.

detriment of consumers. Even a non-litigation of patent validity is harmful to consumers because it deprives them of competition.[162]

In reality, the basic model's assumptions are not fulfilled due to information inadequacy, different risk attitudes, market conditions, strategies, and bargaining powers. We can expect that in most cases, the patent settlement outcome will not correspond to the outcome of patent litigation, even when there is not a reverse payment included. [163] Since the agreed entry date could be earlier or later, consumer welfare is also affected in terms of price effect. [164]

Bokhari[165] conducted a simulation with the data gathered for a sub-segment of drugs used to treat deficit hyperactivity disorder (ADHD) and computed market equilibrium prices under three counterfactuals.

There was a significant increase in the price of ADHD drugs in all three counterfactuals, but the percentage increase was 4 to 4.5 times larger in the case of a missing drug compared to when Adderall and its generic versions jointly set profit maximising prices. Both features may be present in a typical pay-to-delay deal: a two to a three-year delay in any generic entry followed by a term of licensed entry and joint profit maximisation.

In *Generics(UK)* case, before the settlements, GSK sold Seroxat for £17.76 per pack, whereas the PIs in the UK were selling Paroxetine for £13.00 per pack.[166] After the IVAX agreement, GSK agreed to supply IVAX the generic version of Paroxetine for £8.45 per pack. Even after the settlement agreements, the generics had to sell GSK's version at a price range between £8.45 and £12.25 per pack. Once the average sell price fell under the price of £8.45 within three consecutive months, the generics could terminate their agreements.[167]

The Apotex Judgment opened the market, allowing the generic companies to enter the market, which happened only one year after this judgment. Alpharma finally entered the market on its own after terminating the IVAX-Alpharma agreement. Consequently, GUK and IVAX

[162] See Shapiro, 2001.

[163] Joshua, 2009, pp. 255-307.

[164] Frank & Kerber, pg. 11.

[165] See Bokhari, 2012.

[166] Case 1251-1255/1/12/16, Generics (UK) & Others v CMA, London, 2018, para. 266.

[167] Ibid, para. 188-189.

terminated their contracts with GSK and entered the market, whereas GSK had to pay IVAX £2.3 million.[168]

In a short period, prices fell by 34%, followed by a fall of 69% after a year, respectively from £12.95 to £3.97 per pack. The average price as shown in the fall by December 2005 was 75%. In addition, the market share of GSK dropped from 75% to 40% between 2000 and 2003.[169]

In conclusion, the Bokhari simulated study compiled with the Generics(UK) case indicates that a product's price is affected even when the originator and the generic share the profits, rather than when the generics are inexistent. In the Generics(UK), had the generics never existed, the price of Seroxat would have remained at the cost of £17.76, but even after controlled competition by pay-for-delay settlements, the price fell from £17.76 to an average price between £8.45 and £12.25, which was partly beneficial for the consumer nonetheless. In the light of the ECJ's ruling, although the agreements lowered the market prices and were partly beneficial for the consumer, these agreements controlled and limited the market resulting in restriction by object. Thus, instead of paying a price range of £8.45 and £12.25, the consumer would have paid £3.97 per pack had the independent entry been allowed.[170]

[168] Ibid, para. 50-53.

[169] Ibid, para. 54-55.

[170] Ibid, para. 56.

CONCLUSIONS

An agreement limiting competition by object is called a hardcore restriction since it reveals that its anticompetitive consequences are believed to have a sufficient degree of harm. When determining whether the purpose of an agreement is to limit competition, the agreement's content, aims, and the economic and legal context of which it forms a part must be taken into account. According to the research questions posed in this dissertation, I have come to certain conclusions described as follows.

In the pharmaceutical sector, after each discovery made through R&D departments, the originator company has to deal with all the necessary procedures, including testing, checking for side-effects, safety and security issues, and so on, which are costly and consume a lot of time. In comparison, the generics do not have to go through all these processes to get an MA grant. Therefore, the generics have the advantage in the market to compete with lower prices than the originator.

The originator, who has gone through an arduous period to secure its patent, wants to prolong its expiry date as long as possible since that patent has been prolific by creating a monopoly in the market. Concluding several agreements that include 'non-challenge clause' and 'transfer of value' with other generics only helps the originator preserve that monopoly profit by sharing its market with other generics under *'authorised generic entry'*.

The primary explanation for the excluded party's agreement to remain out of the market is that the party found it more beneficial to share the existing market's monopoly profits than to follow its market entry plans. The purpose of the agreement is indeed to restrict competition.

These restrictions fall within the scope of Art 101 since no patent-holder has the exclusive right to pay a potential competitor a sum of money for them not to try to enter the market. The patent holder has the inherent right to exclude any product that infringes on his patent, but a settlement cannot be used to remove a generic from the market. This is not an exclusive right granted by any patent law, nor does it show patent strength; as a result, it is not a legitimate means to defend one's patent rights.

Nevertheless, according to the ECJ in the *Generics (UK)* case, these pay-for-delay settlements, although restrictive, can be justified as appropriate and strictly necessary if risk aversion and asymmetric information of the parties can be proven. If parties have asymmetric information, they tend to be risk-averse therefore conclude settlements with transfer values above the

litigation costs. A risk-averse originator is willing to sacrifice a portion of its venture to reduce any uncertainty involving its patent validity. Otherwise, if they had the correct information, the settlement would be concluded under the scholars' concepts, including a transfer of value and early independent entry. Large transfer of values may have another legitimate reason if its role is to act as a cash infusion for the generics with liquidity issues. This situation could be witnessed in Alpharma's case when GSK had to transfer a particular value under the new clause of '*production and preparation*' only to help Alpharma develop sufficiently to enter the market independently after the agreement termination.

Concerning the effects via prices, a basic settlement model with simplified assumptions will demonstrate that the agreed date of generic entry in patent settlements without reverse payments would lead to settlement outcomes whose consumer welfare implications would be closer to litigation outcomes. However, the bargaining situation between originator and generic firms is much more complicated in practice. It can contain various imperfections that lead to settlement dates far from the normatively ideal entry dates. Even in a limited and controlled competition, the settlements affect the market price by dropping the price to a certain level which may not be ideal for the customer but still is beneficial.

Finally, the pharmaceutical industry's competitive framework remains intact by distinguishing between valid agreements and those invalid, which ultimately favour customers' well-being and human health security. The Commission and national competition authorities have to balance a patent settlement and the customer's well-being. After all, even a settlement agreement that is considered restrictive by object is not entirely harmful to the customer since it allows the prices to drop but only in a controlled manner. Therefore, the authorities should consider the realistic factors, which determined the actual fate of the settlements. Concluding that a settlement agreement is restrictive by object without considering the parties' risk-attitude, their information on the cases, and the effect after the settlement is a strict policy that may discourage the generics from innovating and developing new ways of producing medicine.

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