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Pay-for-Delay Arrangements in EU Competition Law

The Interface Between Patent Protection and Restrictions of Competition in the Pharmaceutical Sector

OT00BF60 Bachelor of Laws Thesis

Author:
Jerdi Skottman

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Abstract page

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Abstract: The pharmaceutical sector holds a special position in the EU internal market as an industry that is both highly regulated and heavily reliant on intellectual property rights. Patent protection and supplementary protection certificates safeguard originator companies' returns on costly research and development, but they also create tensions with competition law, which seeks to protect consumer welfare and access to medicines. One manifestation of this tension is the so-called pay-for-delay agreement, in which an originator transfers value to a generic competitor in exchange for delaying market entry.

This thesis analyses how EU competition law, in particular Article 101 TFEU, applies to such agreements, and how courts have drawn the line between legitimate patent settlements and unlawful restraints of competition. The study uses the legal dogmatic method (de lege lata), complemented by a critical de lege ferenda perspective to identify shortcomings and propose improvements. Sources include EU legislation, case law from the Court of Justice and the General Court, Commission decisions, and leading legal literature.

The findings show that while most patent settlements do not raise concerns, a small minority restrict entry and transfers value, thereby posing risks to competition and consumers. The thesis concludes that while "by object" assessment has an established role, cases involving genuine patent disputes or uncertainty would benefit from an effects-based approach, which would provide more precise guidance for both enforcement and industry.

Keywords: Competition law, intellectual property law, patent law, pay-for-delay agreements, pharmaceutical industry regulation.

Tiivistelmä: Lääketeollisuus on EU:n sisämarkkinoilla erityinen toimiala, joka on sekä tiukasti säännelty että vahvasti riippuvainen immateriaalioikeuksien tarjoamasta suojasta. Patentit ja lisäsuojatodistukset turvaavat alkuperäisvalmistajien investoinnit kalliiseen tutkimukseen ja tuotekehitykseen, mutta ne voivat olla ristiriidassa kilpailuoikeuden tavoitteiden kanssa, joiden ytimessä on kuluttajien hyvinvointi ja lääkkeiden saatavuus. Näiden jännitteiden näkyvin muoto on niin sanottu pay-for-delay-sopimus, jossa rinnakkaisvalmistajan markkinoille tulo viivästyy vastineeksi arvonsiirrosta alkuperäisvalmistajalta.

Tutkielma tarkastelee, miten EU:n kilpailuoikeus ja erityisesti SEUT 101 artikla soveltuvat tällaisiin sopimuksiin sekä miten tuomioistuimet erottavat hyväksyttävät patenttisovut kilpailunrajoituksista. Menetelmänä käytetään oikeusdogmaattista lähestymistapaa (de lege lata), jota täydennetään kriittisellä de lege ferenda -näkökulmalla. Lähteinä käytetään EU-lainsäädäntöä, unionin tuomioistuinten ja komission ratkaisuja sekä keskeistä oikeuskirjallisuutta.

Tutkielma päätyy siihen, että vaikka by object -arvioinnilla on vakiintunut asemansa, tapaukset, joissa on kyse aidosta patenttiriidasta tai epävarmuudesta, hyötyisivät vaikutusperusteisemmasta arvioinnista. Tämä antaisi selkeämpää ohjausta sekä viranomaisille että yrityksille.

Avainsanat: kilpailuoikeus, immateriaalioikeus, patenttioikeus, pay-for-delay -sopimukset, lääketeollisuuden sääntely.

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List of Abbreviations

API	Active Pharmaceutical Ingredient
CAT	Competition Appeal Tribunal (UK)
CJEU	Court of Justice of the European Union
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
FTC	Federal Trade Commission (US)
GSK	GlaxoSmithKline
SPC	Supplementary Protection Certificate
TFEU	Treaty on the Functioning of the European Union
US	United States

1 Introduction

1.1 Background

The pharmaceutical sector occupies a unique position within the European Union's internal market, as it is both one of the most heavily regulated industries and highly dependent on strong intellectual property protection. Patents and supplementary protection certificates grant originator companies exclusive rights over their products for an extended period, thereby safeguarding returns on expensive research and development investments. At the same time, competition law plays a crucial role in ensuring that these innovation incentives do not harm consumer welfare or access to affordable medicines.

A particularly contentious practice at the intersection of these two regimes is the so-called pay-for-delay arrangement, also known as a reverse payment patent settlement, whereby an originator pharmaceutical company pays or otherwise transfers value to a generic manufacturer in exchange for delaying the launch of a cheaper generic version. Such agreements have the effect of maintaining artificially high prices and limiting competition, while being defended by some companies as legitimate exercises of patent rights or as pragmatic settlements of patent disputes. A telling remark is cited in the book *The EU Law of Competition*, where a pharmaceutical executive stated that *"once the generic launches, the brand product is effectively dead."*[1]

The tension between these justifications and the aims of EU competition law has led to extensive enforcement action by the European Commission and significant case law from the Court of Justice of the European Union. It is noteworthy that these agreements are not unique to the European Union, as there have been many cases worldwide. Notably, the *Federal Trade Commission v. Actavis Inc*. case in the United States in 2013.[2]

This thesis aims to analyse how EU competition law applies to pay-for-delay agreements in the pharmaceutical sector, and how courts have delineated the boundary between legitimate patent

[1] Faull – Nikpay – Taylor 2014, p. 1886.
[2] FTC v Actavis Inc, 570 US 136, Judgment of the Supreme Court of the United States of 17 June 2013: FTC v Actavis Inc (2013) is the leading U.S. Supreme Court case on pay-for-delay agreements, holding that such settlements are not automatically lawful or unlawful but must be assessed under the antitrust "rule of reason." The Rule of Reason is an antitrust doctrine under US competition law that requires courts to assess the purpose and actual or potential effects of a restraint on competition, weighing its pro-competitive benefits against its anti-competitive harms, rather than deeming it automatically unlawful.

protection and unlawful restraints of competition. The primary focus is on the TFEU 101 article, with a brief discussion of the TFEU 102 article as well. The core research question is: to what extent can patent rights justify agreements that delay or restrict generic competition, and how does EU competition law resolve the tension between fostering innovation and ensuring consumer access to affordable medicines? This study intends to provide a structured review of relevant case law (*Lundbeck*, *Generics UK*, and *Servier*) and evaluate how the Court balances intellectual property rights with competition law within the framework of pharmaceutical regulation. This thesis does not primarily focus on the situation in the United States (US), though in a few sections, the EU framework is compared with that of the US.

1.2 Research materials and methods

This thesis[3] applies the legal dogmatic method, which means interpreting and systematising the current state of the law, in other words, a de lege lata[4] approach.[5] The aim of analysing legal sources is to identify results that reflect the content of the applicable law and can be used to resolve concrete legal problems. In addition, the thesis also takes a critical perspective, described as de lege ferenda,[6] which seeks solutions to possible gaps or shortcomings in the law. When the law is shown to lead to unsatisfactory outcomes in light of particular objectives or principles, the legal dogmatic method goes beyond describing the law as it stands and becomes a means of assessing how it should be developed.[7]

The sources used include EU law, both primary and secondary, international treaties, the case law of the Court of Justice of the European Union and the General Court, publications and decisions of EU institutions, legal literature, and official online sources. With the help of these sources, the thesis provides a coherent and reliable account of the tension between competition law and patent law, as exemplified by pay-for-delay agreements.

The content of this thesis is structured as follows. After the introduction, which presents the background, research materials, and methods, the study first examines the regulatory and legal framework, focusing on pharmaceutical regulation, patents, and EU competition law. It then

[3] In the writing of this thesis, artificial intelligence has been used solely and in a limited manner for language editing and terminology translation, in accordance with the University of Turku's policy on the use of artificial intelligence in teaching and studying.
[4] Latin for "the law as it exists".
[5] Smits 2015, p. 8-9.
[6] Latin for "what the law should be".
[7] Smits 2015, p. 10-11.

turns to pay-for-delay agreements, beginning with their definition and main features, and continuing with an analysis of key cases, including *Lundbeck*, *Generics UK*, and *Servier*. Building on these cases, the thesis identifies the main lessons that can be learned. Finally, the conclusion brings together the findings of the study.

2 Regulatory and Legal Framework

2.1 Pharmaceutical regulation and patents

Patent protection forms the bedrock of the pharmaceutical industry, as it grants originator companies a limited-term but legally enforceable monopoly over their innovations. A patent is an exclusive legal right granted for an invention, enabling the patent holder to prevent others from making, using, selling, or importing the invention without authorisation, for a limited period, in exchange for disclosure of the invention.[8] To be patentable, an invention must generally meet three core criteria: novelty, inventive step, and industrial applicability.[9]

In the European Union, patents generally last for twenty years from the date of application. Pharmaceutical patents can extend for twenty-five years with supplementary protection.[10] This exclusivity is justified by the need to incentivise costly and risky investments in pharmaceutical research and development. Developing a new drug can take more than a decade and often involves billions of euros in expenditure, with a high risk of failure during clinical trials.[11] Without strong intellectual property rights, companies would lack the economic motivation to pursue such uncertain projects.

Supplementary Protection Certificates (SPCs), introduced by Regulation (EC) No 469/2009[12], extend the effective patent life by up to five years to offset time lost during regulatory approval processes.[13] For each medicine, an SPC may only be granted once.[14] In some cases, a further six-month extension may be granted for conducting paediatric studies.[15] This system reflects the EU's effort to maintain incentives for innovation while recognising that lengthy approval procedures reduce the period during which a company can commercially exploit its patent.

It should be noted that there are different types of patents in the pharmaceutical sector. Basic, or primary, patents protect the core invention of a medicine. In pharmaceuticals, this usually

[8] Spiers 2009, p. 43–44.
[9] Spiers 2009, p. 43–44.
[10] Spiers 2009, p. 43–44. See also European Patent Convention, Article 63 and Finnish Patent Act (550/1967), Section 40.
[11] Philipp 2011, p. 18.
[12] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1.
[13] Frankel 2019, p. 228–229.
[14] Faull – Nikpay – Taylor 2014, p. 1873.
[15] Frankel 2019, p. 228–229.

means the active pharmaceutical ingredient (API), the chemical compound that delivers the therapeutic effect. These patents are generally considered the strongest because they cover the very substance of the medicine and usually withstand legal challenges more effectively. Process patents protect the methods used to manufacture the API or to produce the finished medicinal product. Their strength depends on how difficult it is for competitors to find alternative production methods; they can be effective but are often less robust than basic patents, as generics may be able to design around them. Secondary patents, sometimes called follow-on or evergreening patents, cover additional or modified aspects of a medicine, such as new formulations, dosage regimens, combinations with other active ingredients, or new medical uses.[16] These are usually the weakest type of patent, since they often face more legal uncertainty and are more frequently challenged in court by generic manufacturers.[17] While basic patents provide the primary and most reliable exclusivity, process and secondary patents can extend protection in practice, though with varying degrees of legal certainty.[18]

Accordingly, pharmaceutical patents are not unlimited in scope or duration.[19] As a counterbalance to exclusivity, the EU has established regulatory mechanisms that encourage market entry by generic medicines once patent rights expire. Generic medicines can enter the market once the molecule patent and any SPCs have expired.[20] Generics are approved based on bioequivalence studies rather than full clinical trials, which enables them to be available more swiftly and at significantly lower costs.[21] In other words, generic medicines only need to demonstrate equivalence to the originator medicine in terms of efficacy and safety. Their introduction typically results in steep price drops, leading to substantial savings for healthcare systems and better access to affordable medicines for patients.[22] The EU regulatory framework thus aims to balance: providing strong protection for originators to encourage innovation, while supporting timely generic competition to benefit public health and economic sustainability.

In parallel with intellectual property rights, pharmaceuticals are subject to a complex regulatory framework before they can be marketed. Marketing authorisations ensure that medicines sold in the EU meet high safety, efficacy, and quality standards. There are several authorisation

[16]Burdon, M and Sloper, K 2003, p. 228.
[17] Seitz 2017, p. 463-464.
[18] Burdon, M and Sloper, K 2003, p. 228.
[19] Vinje 2017, p. 45 and Faull – Nikpay – Taylor 2014, p. 1872.
[20] Fimea, *Generic products* (Fimea 2025) https://fimea.fi/en/for_public/what-is-a-medicine-/generic-products accessed 12 October 2025.
[21] Faull – Nikpay – Taylor 2014, p. 1873-1874.
[22] Faull – Nikpay – Taylor 2014, p. 1896 and Dylst – Simoens 2011, p. 876.

routes: the centralised procedure administered by the European Medicines Agency (EMA), which grants EU-wide approval for specific categories of drugs; the decentralised and mutual recognition procedures, which enable authorisation in multiple Member States; and purely national authorisations.[23] These mechanisms and processes guarantee patient safety but also extend the time between the initial patent filing and the product reaching the market, thereby increasing the importance of SPCs for originator companies, as the time between the patent filing and reaping the earnings from the patent is long. It can be said that these lengthy processes also increase the originator companies' willingness to protect their patents aggressively, as it entails significant costs and lost sales revenues.

Indeed, the interaction between patent rights and regulatory requirements has led to vast and complex legal and economic strategies within the industry. For example, originator companies have sometimes been accused of abusing the regulatory framework through practices such as "evergreening" (filing follow-on patents to prolong protection), data exclusivity claims, or litigation aimed at delaying generic entry.[24] These strategies, while grounded in the lawful exercise of intellectual property rights, raise competition concerns when they result in unfair restrictions on market access for generics. There are different views on these practices, both among scholars and in the pharmaceutical industry, where generic producers strongly oppose the protective strategies of originator firms. This grey area, where patent rights overlap with anti-competitive conduct, has become increasingly crucial under EU competition law, as shown by the focus on pay-for-delay agreements. We can say that pay-for-delay agreements lie precisely within this grey area.

2.2 EU competition law

Competition law is a fundamental part of the European Union's legal system, designed to ensure the proper functioning of the internal market.[25] Its main provisions are outlined in the Treaty on the Functioning of the European Union (TFEU). Article 101 TFEU prohibits agreements between businesses that aim to or have the effect of preventing, restricting, or distorting competition within the internal market. This includes practices such as price fixing, market sharing, and anti-competitive cooperation between competitors. Conversely, Article 102 TFEU

[23] Donghi 2014, p. 19. See also European Medicines Agency, *What we do: Authorisation of medicines*, https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines accessed 12 October 2025.
[24] Donghi 2014, p. 42–44: defending the legitimacy of originator companies' patent evergreening strategies. See also Burdon, M and Sloper, K 2003, p. 226-238, for different secondary patenting strategies.
[25] Frenz 2016, p 14.

forbids the abuse of a dominant position, which can occur through practices like exclusionary conduct, excessive pricing, or refusal to supply. Together, these provisions form the core of EU competition enforcement and apply across all sectors, including the highly regulated pharmaceutical industry.

Under Article 101 TFEU, the definition of an agreement is interpreted broadly. It encompasses any form of coordination between two or more independent undertakings that reflects a concurrence of wills to conduct themselves on the market in a particular way.[26] The concept does not require a formal or legally binding contract; informal arrangements, oral understandings, exchanges of letters, or so-called "gentlemen's agreements" are sufficient.[27] What matters is the existence of a mutual intention that might restrict competition, regardless of the form or enforceability of the arrangement.

In EU competition law, agreements can be classified as restrictions "by object" or "by effect" under Article 101 TFEU.[28] A restriction by object refers to agreements whose very nature reveals a sufficient degree of harm to competition, such as price fixing, market sharing; in such cases, it is unnecessary to demonstrate actual effects on the market. Thus, for an agreement to fall under the category of a "by object" restriction, it must inherently display a degree of harm to competition that is considered significant. By contrast, a restriction by effect requires a detailed assessment of the agreement's economic and legal context, and proof that the arrangement has, in practice, appreciable anticompetitive consequences.[29] The distinction is crucial in the pharmaceutical sector, since the Court of Justice (CJEU) has confirmed that pay-for-delay agreements can amount to restrictions by object, thereby allowing competition authorities to address them without undertaking a complete effects-based analysis.[30]

However, Article 101(3) TFEU provides an exemption to the general prohibition in Article 101(1). Agreements that restrict competition may still be allowed if they generate efficiencies, benefit consumers, are essential to achieve those benefits, and do not eliminate competition in

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[26] Bailey – John 2018, p. 107.
[27] Bailey – John 2018, p. 108.
[28] European Commission 2023, *Communication from the Commission — Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements* (2023/C 259/01), p. 10.
[29] European Commission 2023, *Communication from the Commission — Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements* (2023/C 259/01), p. 11–13.
[30] They are not, however, always classified as restrictions by object; see Nagy 2024, p. 130.

a significant part of the internal market. But the agreement must meet each condition specified in Article 101(3). This could be a relevant argument for a shift towards more effects-based analysis of agreements between undertakings, such as between originators and generic companies.

The interaction between competition law and sectors governed by strict regulation, such as pharmaceuticals, raises particularly complex questions. On the one hand, regulatory frameworks and intellectual property rights grant undertakings legal exclusivity, which may lawfully limit competition. On the other hand, the Court of Justice of the European Union has consistently emphasised that the exercise of intellectual property rights does not exempt undertakings from compliance with competition rules.[31] In the pharmaceutical sector, this principle means that patent holders may enforce their rights to exclude competitors but cannot use those rights as a pretext to engage in conduct whose object or effect is the artificial delay of generic entry.

A significant step in addressing competition concerns in the pharmaceutical industry was the Pharmaceutical Sector Inquiry in 2009.[32] The inquiry's monitoring period was 2000–2008. According to the Commission, one of its main objectives was to identify the reasons why generic medicines were entering the market only slowly.[33] The inquiry examined whether originator companies were creating barriers to generic market entry. In this context, the investigation uncovered numerous pay-for-delay agreements between originators and generics, which raised serious concerns about anti-competitive practices.[34]

Thus, agreements between originator companies and generic manufacturers have been scrutinised for their potential to impede competition by delaying market entry. These "pay-for-delay" agreements have been evaluated under Article 101 TFEU as potential restrictions of competition "by object". Furthermore, cases such as *AstraZeneca* have demonstrated that the misuse of regulatory procedures or patent systems can also fall within the scope of Article 102 TFEU as an abuse of dominance.[35]

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[31] Hull – Clancy 2019, p. 646.
[32] European Commission 2009, *Pharmaceutical Sector Inquiry: Final Report.*
[33] Faull – Nikpay – Taylor 2014, p. 1877.
[34] Faull – Nikpay – Taylor 2014, p. 1894.
[35] See the case C-457/10 P, *AstraZeneca AB and AstraZeneca plc v European Commission*, 2012

The application of EU competition law to the pharmaceutical sector can be said to be serving a dual purpose: ensuring that innovation is rewarded correctly, while also preventing companies from exploiting regulation and intellectual property rights in ways that harm consumer welfare.[36] This duality is central to the case law on pay-for-delay agreements, which demonstrates how the CJEU balances the need to protect incentives for investment with the necessity of maintaining effective competition and affordable access to medicines.

[36] European Commission 2009, *Pharmaceutical Sector Inquiry: Final Report*, p. 10-12

3 Pay-for-Delay Agreements

3.1 Definition and characteristics of pay-for-delay arrangements

Pay-for-delay arrangements, also known as reverse payment settlements, are agreements between an originator pharmaceutical company and a generic manufacturer that resolve a pending or potential patent dispute.[37] The Commission's Pharma Sector Inquiry defines these agreements as commercial arrangements made to resolve existing or potential disputes concerning patents.[38] They are typically concluded to settle claims arising in patent disputes, opposition proceedings, or pending litigation where no final judgment has yet been delivered or, in some cases, before formal court proceedings have even begun. The core purpose of such agreements is to bring the dispute, opposition process, or litigation to an end.

The main feature of these arrangements is that the patent-owner provides monetary compensation or another benefit to the generic company in exchange for its agreement to delay or drop its market entry.[39] In essence, the agreement turns what could be a competitive challenge into a mutually beneficial settlement for both parties. The compensation granted to the generic may be relatively modest compared to the substantial profit losses the originator would have incurred had the generic entered the market.[40]

These agreements are called "reverse payments" because, unlike traditional settlements where the alleged infringer compensates the patent holder, the payment flows in the opposite direction: from the originator to the generic. This reversal emphasises the unique dynamics of the pharmaceutical sector, where generics are typically ready to compete as soon as the exclusivity period ends or the patent is successfully challenged. In practice, such settlements may involve direct cash payments, licensing arrangements, distribution agreements, or other forms of value transfer that motivate the generic manufacturer to delay launching its product.[41]

As stated earlier, in its 2009 pharmaceutical sector inquiry, the European Commission examined the reasons for delays in the entry of generic medicines into the market and the apparent decline in innovation. A central issue was how disputes between originator and generic

[37] Bayrak 2025, p. 336–337.
[38] EU Commission 2009, *Pharmaceutical Sector Inquiry: Final Report,* p. 254, para 704.
[39] Zelger 2021, p.279.
[40] Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 25
[41] European Commission 2009, *Pharmaceutical Sector Inquiry: Final Report*, p. 269.

companies were resolved through settlement agreements. The Commission identified two main categories of such agreements. Category A agreements allow generics to enter or remain on the market, while Category B agreements restrict or delay their entry.[42] Within Category B, the decisive factor is whether there is a value transfer from the originator to the generic company, such as payments, distribution rights, or licences. Agreements without value transfer, referred to as Category B. I, were considered less problematic, whereas those involving value transfers, Category B.II, raised more serious competition concerns.[43] Since the sector inquiry, the Commission has monitored these agreements and taken enforcement action, particularly in relation to Category B.II.

Following the pharmaceutical sector inquiry, the European Commission has continued to monitor patent settlements between originator and generic companies. Since then, it has published annual reports to understand better how these agreements are used in the European Economic Area and to identify those that may delay generic entry to the detriment of consumers.[44] For example, the European Commission's eighth monitoring report on patent settlements, covering 2016, identified 107 agreements involving 46 active pharmaceutical ingredients.[45] Of these, 27% imposed no restrictions on generic entry (category A), 62% limited entry without any value transfer (category B.I), and only 11% both restricted entry and involved a value transfer from the originator to the generic (category B.II).[46] Compared to the sector inquiry period (2000–2008), when such agreements accounted for 22%.[47] Therefore, the data suggest a clear decline, and overall, the majority of settlements appear unproblematic from a competition law perspective. In conclusion, the Commission's monitoring has either deterred companies from entering into such agreements or left some of them outside its oversight.

On the other hand, a key weakness of the European Union's approach lies in the absence of a statutory notification system for patent settlements, in stark contrast to the United States. In the

[42] Bailey – John 2018, p. 841.
[43] Bailey – John 2018, p. 841.
[44] European Commission, *Pharmaceutical sector inquiry* (Overview page, updated 2024) https://competition-policy.ec.europa.eu/sectors/pharmaceuticals-health-services/pharmaceutical-sector-inquiry_en accessed 25 October 2025.
[45] European Commission 2018, 8th Report on the Monitoring of Patent Settlements (period: January–December 2016).
[46] European Commission 2018, 8th Report on the Monitoring of Patent Settlements (period: January–December 2016).
[47] European Commission 2018, 8th Report on the Monitoring of Patent Settlements (period: January–December 2016).

EU, information is collected only through ad hoc[48] monitoring exercises in which certain companies are asked to submit their agreements, resulting in data that is periodic, less comprehensive, and inevitably retrospective. By comparison, the US system obliges pharmaceutical companies to notify every settlement directly to the Federal Trade Commission and the Department of Justice, ensuring continuous oversight and enabling timely enforcement.[49] The EU's reliance on irregular inquiries not only reduces transparency but also weakens deterrence. This structural gap implies that in the EU, certain settlements may never be disclosed, leaving potentially anticompetitive arrangements outside the scope of scrutiny. The reliance on periodic inquiries not only limits transparency but also creates uncertainty about the effectiveness of enforcement, as problematic agreements may remain undetected. Thus, it can be said that reliable data might not be available in the EU, as it is not difficult to imagine reasons why companies might want to hide these agreements from authorities if they assume they will be labelled as illegal pay-for-delay agreements in the first place. Accordingly, it may be reasonable for the EU to move towards a solution resembling the mandatory notification model applied in the United States.

Having said that, the underlying economic reasoning is based on the high profitability of pharmaceutical patents, especially those covering so-called blockbuster drugs. A blockbuster drug is a widely used medicine that generates exceptionally high revenues, typically defined as over one billion dollars in annual global sales.[50] Perhaps the best-known example of a blockbuster medicine is Pfizer's cholesterol-lowering drug Lipitor (atorvastatin). At its peak in 2011, global annual sales exceeded USD 12 billion, demonstrating the extraordinary profitability such products can generate for the originator company.[51] Thus, originator companies have strong incentives to safeguard market exclusivity for as long as possible, since the entry of a single generic competitor can cause a sharp decline in prices. Conversely, generic companies may consider litigation costly and uncertain, with the outcome depending on the strength of the originator's patent. A guaranteed financial transfer may therefore seem more appealing than risking an adverse judgment or engaging in a lengthy legal process.

[48] Latin for "for this purpose".
[49] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub L No 108–173, 117 Stat 2066, §1112 (2003).
[50] European Commission 2009, *Pharmaceutical Sector Inquiry: Final Report*, p. 6.
[51] The Lancet 2011.

The key feature of pay-for-delay arrangements is their dual impact: they resolve disputes in a way that removes the immediate threat of generic competition, while also extending the period during which consumers are kept from accessing cheaper alternatives.[52] Although such agreements may provide short-term stability for the parties involved, they are often criticised for skewing the balance between protecting innovation and encouraging competition, as they delay the societal benefits that typically come from the timely introduction of generics.[53]

3.2 Case law

The Commission and the courts of the European Union have delivered multiple rulings concerning the pay-for-delay agreements, and these rulings shed light on how these agreements are qualified in practice and how the lawful practices are determined from the unlawful ones.

There is no definitive test for establishing whether reverse payment patent settlements fall within the scope of Article 101(1) TFEU. Nevertheless, three core elements appear to indicate the existence of an anti-competitive settlement agreement.[54] First, the parties must be at least potential competitors, meaning that the generic manufacturer has a realistic possibility of entering the market. Second, the generic undertaking must agree to restrict or delay its independent efforts to introduce a competing product in one or more EU markets. Third, the originator company must transfer value to the generic firm as an inducement to accept those restrictions. Beyond these criteria, other considerations may also be relevant.[55] For example, it is significant whether the settlement payment reflects the expected profits from market entry rather than the mere costs of litigation. If the payment is essentially designed to exclude competitors from the market, rather than to resolve legitimate patent disputes, the agreement may be characterised as a restriction of competition "by object." In such cases, the decisive factor may be evidence that the patent holder's true intention was to prevent competitive entry. However, undertakings can still attempt to justify such agreements under Article 101(3) TFEU by demonstrating that the arrangement provides sufficient benefits to competition and consumers.[56]

[52] Palikot – Pietola 2023, p. 387–389.
[53] Anderman – Schmidt 2011, p. 22–23.
[54] Bailey – John 2018, p. 842-843.
[55] Bailey – John 2018, p. 843.
[56] Bailey – John 2018, p. 843.

Generally, it can be said that arrangements of this kind often require, or should require, at least a preliminary assessment of their likely effects to determine whether they should be classified as restrictions of competition "by object."[57] The fact that a generic manufacturer agrees not to produce or market a medicine, combined with a transfer of value from the originator, may suggest an intention to reduce or eliminate competitive pressure. However, such agreements can also result from a genuine attempt to resolve complex intellectual property disputes.[58] For this reason, the mere existence of a value transfer is not enough to conclude that competition has been restricted "by object." What is crucial is whether the circumstances of the settlement indicate that the transfer of value has no credible justification other than to prevent competition on the merits. Therefore, a contextual analysis of the agreement and its functioning in the market is necessary to establish whether it reveals a sufficient degree of harm to competition. After all, the agreement can be a legitimate bona fide[59] patent dispute between two companies.

The following section examines three significant cases and their specific features, after which a synthesis is provided on how such agreements are addressed within the European Union legal framework. The synthesis illustrates how the EU courts have, in practice, assessed such agreements.

3.2.1 Lundbeck

The Lundbeck case arose after the expiry of the basic patent for the antidepressant citalopram in 2002 in the United Kingdom.[60] Once this protection ended, several generic companies prepared to enter the market. Lundbeck still had secondary process patents, for example, for specific methods of producing citalopram, but these patents were not sufficient to prevent generics from at least trying to launch or to challenge the patents in court.

In 2002 and 2003, Lundbeck signed settlement agreements with four generics: Merck (Generics UK), Arrow, Alpharma and Ranbaxy. Lundbeck transferred significant sums of money and other benefits, such as supplies of active ingredients, to the generics. In return, the generics

[57] van de Gronden – Rusu 2024, p. 65-66.
[58] van de Gronden – Rusu 2024, p. 65-66.
[59] Latin for "in good faith".
[60] Case C-591/16 P, *Lundbeck v Commission*, ECLI:EU:C:2021:243, Judgment of the Court (Grand Chamber) of 25 March 2021.

agreed not to sell their own citalopram products for a defined period and not to attack Lundbeck's patents.

The European Commission decided in 2013 that these were not ordinary patent settlements but "reverse payment" agreements whose real object was to keep generics out of the market.[61] The Commission stressed that the payments were not linked to any genuine licensing or service but only to delay entry. It considered this a restriction of competition by object under Article 101 TFEU. The Commission imposed fines totalling about €146 million.

The General Court confirmed the Commission's reasoning in 2016.[62] It agreed that the generics were potential competitors because they had real and concrete possibilities of entering the market. Even if their entry might have been followed by patent litigation, this was part of normal competitive rivalry. By paying the generics to remain outside the market, Lundbeck eliminated this potential competition.

In 2021, the Court of Justice also confirmed the decision.[63] It emphasised that agreements of this type restrict competition "by object" because their very purpose is to remove rivals from the market. The Court underlined that the existence of secondary patents does not remove potential competition: a generic producer can still be considered a competitor if it is ready and able to enter and possibly to challenge the patents. The Court's reasoning made clear that patent law cannot justify agreements that involve paying rivals not to compete.

3.2.2 Generics UK

The *Generics UK* case involved the antidepressant paroxetine produced by GlaxoSmithKline (GSK). The basic patent had expired, and generics such as Generics UK, Alpharma and IVAX were preparing to enter. Between 2001 and 2004, GSK signed settlement agreements with these companies. The agreements included transfers of value from GSK to the generics, and in return, the generics delayed entry and abandoned challenges to GSK's patents.

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[61] European Commission, *Lundbeck*, Case AT.39226, Commission Decision of 19 June 2013, available at https://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_8310_11.pdf.
[62] Case T-472/13, Lundbeck v Commission, ECLI:EU:T:2016:449, Judgment of the General Court of 8 September 2016.
[63] Case C-591/16 P, *Lundbeck v Commission*, ECLI:EU:C:2021:243, Judgment of the Court (Grand Chamber) of 25 March 2021.

The UK Competition and Markets Authority investigated these arrangements.[64] The matter was referred to the Court of Justice to clarify how such cases should be treated under EU competition law. Thus, the Generics UK case reached the Court of Justice of the European Union through a preliminary reference from the UK Competition Appeal Tribunal (CAT). The CJEU set out the principles under Articles 101 and 102 TFEU for assessing pay-for-delay agreements, while the CAT remained responsible for resolving the case on the facts, considering that guidance.[65]

In its 2020 judgment, the Court of Justice developed its reasoning carefully.[66] It stated first that generic companies are potential competitors if they have a real intention and concrete ability to enter, even if their entry depends on resolving patent issues. The Court rejected the idea that the existence of secondary patents automatically excludes competition.

Second, the Court explained that agreements may restrict competition by object under Article 101 if the payments are sufficiently large to convince the generics not to enter the market. It underlined that these payments must be examined considering their size, their relation to potential profits, and their lack of justification beyond excluding competition. By contrast, settlements that only resolve disputes without payments designed to exclude entry might not be problematic.

Third, the Court added that such agreements may also fall under Article 102 if the originator holds a dominant position. By using financial inducements to prevent market entry, a dominant company can reinforce its market power and protect its monopoly artificially.

The reasoning shows that the Court wanted to set a clear legal framework. It stressed that potential competition must be protected and that agreements which serve no purpose other than to delay cheaper medicines harm consumers and are serious violations of competition law.

3.2.3 Servier

The Servier case concerned the French company Servier and its cardiovascular medicine perindopril. Servier's basic patent expired in 2003, and generics were preparing to launch. Servier held certain secondary patents, but their validity could be contested. Servier concluded agreements with companies such as Krka, Teva, Lupin, Matrix and Niche. The agreements

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[64] Paroxetine: anti-competitive agreements and conduct, CMA Decision of 12 February 2016, Case CE/9856-12.
[65] Competition Appeal Tribunal, *Paroxetine*, [2021] CAT 4, Judgment of 10 May 2021.
[66] Case C-307/18, Generics (UK) Ltd and Others v Competition and Markets Authority, ECLI:EU:C:2020:52, Judgment of the Court (Grand Chamber) of 30 January 2020.

involved large payments or other benefits in exchange for delaying entry and refraining from legal actions against the patents.

In 2014, the European Commission found that these agreements restricted competition by object under Article 101 TFEU.[67] It also concluded that Servier had abused its dominant position under Article 102, because it used these agreements to strengthen its market position and to exclude rivals. The fines totalled more than €330 million. The Commission's reasoning was that these agreements served no legitimate settlement purpose but were aimed at preserving Servier's monopoly after the expiry of the basic patent.

The General Court partly agreed in 2018 but annulled important parts of the Commission's decision.[68] It confirmed that the agreements infringed Article 101, but it found errors in the Commission's definition of the relevant product market for Article 102. The Commission had defined the market too narrowly, focusing only on perindopril and not considering other medicines that might compete. Because of this, the General Court held that dominance and abuse had not been proven.

The case then went to the Court of Justice, which gave its final rulings in 2022.[69] The Court confirmed the Commission's view that the agreements restricted competition by object under Article 101, stressing again that potential competition existed and was unlawfully removed. On Article 102, the Court corrected the General Court's errors and partly restored the Commission's decision. It emphasised that careful market definition is necessary, but it also underlined that such exclusionary agreements can amount to abuse when a dominant position is correctly established.

The reasoning of both the Commission and the courts shows that Servier's conduct was assessed as a deliberate attempt to protect monopoly profits after the expiry of basic patents. The case highlights both the seriousness of pay-for-delay agreements under Article 101 and the central role of market definition when applying Article 102.

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[67]Case AT.39612, Perindopril (Servier), Commission Decision of 9 July 2014 (summary OJ C 393, 25.10.2016, p. 5).
[68] Case T-691/14, Servier and Others v Commission, ECLI:EU: T:2018:922, Judgment of 12 December 2018.
[69] Court of Justice (Final, multiple joined appeals):
Joined Cases C-176/19 P, C-201/19 P, C-202/19 P, C-264/19 P and C-271/19 P, Servier and Others v Commission, ECLI:EU:C:2024:553, Judgments of the Court (Grand Chamber) of 27 June 2024.

4 Key lessons from case law

4.1 Overview

This chapter provides an overview of the key lessons that can be drawn from the study. It brings together the main findings, introduces some additional reflections, and highlights their relevance. The purpose is to guide the reader towards a more comprehensive understanding of the themes discussed and to prepare the ground for the concluding remarks.

4.2 Key Takeaways

As we can see, the judgments complement each other and establish a coherent line of reasoning. The European Commission and later the EU Courts have developed and confirmed a test for identifying when settlement agreements between originator and generic companies amount to restrictions of competition by object under Article 101(1) TFEU. This test rests on three cumulative elements. First, the parties must be at least potential competitors. A generic company is considered a potential competitor if it has both the real intention and the concrete ability to enter the market, provided that there are no insurmountable barriers. The mere existence of patents, especially secondary process patents of limited scope, does not in itself exclude the possibility of generic entry. Second, the agreement must restrict the generic's incentives or ability to compete, usually by postponing or preventing market entry. Third, the settlement must involve a transfer of value from the originator to the generic, such as cash payments, licences, or other benefits, that are significant enough to remove or weaken the generic's commercial incentive to compete.[70]

If these three conditions are met, the Commission considers the agreement to restrict competition by object, without the need to show concrete effects on the market. This approach has been applied in practice in *Lundbeck*, *Generics UK* and *Servier*. In each of these cases, the Commission and the courts underlined that protecting potential competition is essential. If generics are ready and able to enter, they may be competitors even before they actually launch.[71] Originator companies have often argued that their patent portfolios shielded them from competition, but the courts have consistently rejected this reasoning. They pointed out that the

[70] Hull – Clancy 2019, p. 648.
[71] Hull – Clancy 2019, p. 648. See also case T-691/14, Servier v. Commission, EU:T:2018:922, paras. 356 and 360.

relevant secondary and process patents were often narrower, less robust or more uncertain than claimed, and could have been challenged or invalidated. In *Lundbeck*, the Court even stated that competition may already exist before a patent's expiry, because the prospect of generic entry and patent challenges exerts pressure on the originator.

The case law places particular emphasis on the purpose of reverse payment agreements and their economic context.[72] The EU courts have stressed that settlements must be assessed not only by their wording but also by their timing, their connection to patent expiry, and the scale of any value transfer. Where a settlement coincides with the expiry of a basic patent and effectively extends the originator's exclusivity, this is seen as strong evidence of anticompetitive intent. Likewise, payments beyond what can be justified by litigation costs, licensing, or genuine commercial transactions are treated as clear indications that the aim was to buy delay. The courts, therefore, look closely at the motives and incentives of the parties. If the economic reality shows that the real purpose of the settlement was to neutralise generic competition rather than resolve a legitimate patent dispute, the agreement qualifies as a restriction of competition by object under Article 101 TFEU. This reasoning reflects a consistent policy choice: competition law must intervene whenever patent settlements are used to protect monopolies beyond their lawful term and block cheaper medicines from reaching consumers.

In *Generics UK*, which came before the Court of Justice by way of a preliminary reference from the UK Competition Appeal Tribunal, the Court confirmed this three-step framework but also clarified the limits of the by-object approach. It explained that not every settlement involving a payment is automatically a restriction by object. Where an agreement is genuinely linked to a bona fide[73] patent dispute and payments can be explained by normal litigation or commercial considerations, a more detailed effects-based analysis may be required. In other words, the Court of Justice clarified that the mere presence of a payment in a settlement does not automatically transform it into a restriction of competition by object. Competition authorities must assess whether the payment has any legitimate explanation other than excluding competition. If the value transfer can reasonably be justified by factors such as covering litigation costs, compensating for goods or services genuinely provided, or settling a genuine

[72] Nagy 2024, p. 130.
[73] Latin for "in good faith".

patent dispute without removing the generic's incentive to compete, then the agreement cannot be presumed anticompetitive by its very nature.[74]

In such situations, a more detailed effects-based analysis is required to determine whether the arrangement in fact produces appreciable harm to competition. This distinction is crucial because it prevents an overly rigid application of the "by object" category and ensures that only those settlements whose purpose and structure reveal an anticompetitive intent are caught automatically. It also reflects the Court's broader concern to strike a fair balance between patent law, which allows companies to enforce and defend their intellectual property rights, and competition law, which prevents the misuse of those rights to unjustifiably delay generic entry.

Servier illustrates both the strength and the limits of the Commission's approach. The Commission applied its three-step test and found multiple restrictions of competition by object under Article 101, as well as an abuse of dominance under Article 102. The General Court in 2018 upheld most of the Article 101 findings but annulled the Article 102 part, because the Commission had defined the relevant market too narrowly. In 2022, the Court of Justice corrected the General Court's errors, confirming that the agreements fell under Article 101 and partly restoring the Commission's reasoning under Article 102. This shows that while the by-object classification has been accepted, proper market definition remains crucial for establishing dominance and abuse.

4.3 Criticism

However, criticism of this line of cases remains. Some scholars argue that the Commission's reliance on a by-object approach risks condemning agreements that may in fact be legitimate settlements, and that the three-step test can be too abstract or simplistic.[75] Others point out that "by object" is not a shortcut: in practice, proving that an agreement is inherently anticompetitive often requires detailed and complex factual analysis, similar to an effects-based assessment.[76] The CJEU itself in *Generics UK* acknowledged that where there is a genuine patent dispute, competition authorities may need to conduct a more thorough effects analysis.[77] I agree with

[74] Case C-307/18, *Generics (UK) Ltd v Competition and Markets Authority*, Judgment of the Court of Justice of the European Union (Grand Chamber), 30 January 2020.
[75] For example, Bayrak 2025, p. 354–355 and Killick – Jourdan – Kickinson 2014, p. 7.
[76] Ibáñez 2024, p. 230. (Treacy – Lawrance – Henry 2020, p. 463: on the other hand, they argue that it is nevertheless more burdensome.)
[77] Nagy 2024, p. 83. See also Zelger 2020.

the critics' view that the Commission's by-object test for pay-for-delay arrangements is somewhat too simplistic. Many reasonable and lawful settlements may be classified as restrictions by object under this approach, without the need for a more nuanced effects-based analysis. Therefore, I would consider it more appropriate to adopt an effects-based assessment, at least in cases where the agreements cannot be regarded as prima facie[78] motivated by anti-competitive intent: in other words, it would therefore be possible that there is a genuine patent dispute in the background.[79]

It can be said that all patents contain an inherent degree of uncertainty regarding both their validity and their scope. From my point of view, the key question for competition law is how this uncertainty should be taken into account. The mere existence of a patent cannot in itself prevent potential competitors from entering the market. This raises the question of whether a patent holder should always be required to pursue litigation to its conclusion or if they are entitled to settle disputes to avoid lengthy and costly proceedings.

The European Commission has argued that pay-for-delay agreements generally have the potential to infringe competition law. However, this approach is open to criticism because it does not always take into account the circumstances of the specific case or the relative strength of the patent in question. The earlier-mentioned distinction between so-called "strong" and "weak" patents is particularly relevant here. A "strong" patent is one that is broadly recognised as valid and enforceable, with a low likelihood of being invalidated. In contrast, a "weak" patent is vulnerable, for example, because of overly narrow claims, and therefore carries a higher risk of being struck down in litigation. A typical example from the case law is a process patent: while it protects only a specific method of manufacturing a substance, it does not prevent competitors from using alternative processes to reach the same end product. This often makes process patents less robust and more open to challenge in litigation.

From a competition law perspective, settlements concerning weak patents are far more problematic, since they may serve mainly to protect a right that would not have survived judicial scrutiny. In these cases, pay-for-delay agreements can be viewed as an artificial extension of monopoly power at the expense of consumers. By contrast, when a strong patent is at stake, the concerns are less straightforward. If the patent would likely have been upheld, then preventing

[78] Latin for "at first sight".
[79] See also Zelger 2021, p. 279-281.

generic entry through litigation could have been entirely lawful. In such circumstances, a settlement does not necessarily alter the competitive outcome, although payments to delay entry must still be carefully scrutinised to ensure they are not excessive or unjustified.

The difficulty in distinguishing between weak and strong patents ex ante[80] is rarely simple. Unless a patent has already been challenged and tested in court, its actual strength remains uncertain. This is precisely what makes the assessment of pay-for-delay agreements complex. Once litigation is settled, the opportunity to test the validity of the patent in open court is lost, and competition authorities are left to reconstruct whether the settlement reflected genuine patent strength or whether it was essentially a means to buy time and exclude generic competition. The real validity of the patent can be revealed only ex post[81].

Nevertheless, the overall policy direction is clear. Competition law must intervene when patent-related settlements go beyond resolving disputes and instead become tools for excluding generic competitors. The rulings in *Lundbeck*, *Generics UK* and *Servier* show the willingness of the EU courts to scrutinise the interaction between intellectual property rights and competition law. At the same time, they expose the unresolved tension between respecting legitimate patent settlements and condemning those that artificially extend monopoly power. The result is a coherent but still developing framework in which companies must tread carefully, balancing the need for legal certainty in patent litigation with the fundamental EU objective of ensuring timely access to affordable medicines for consumers.[82]

[80] Latin for ”before the event”.
[81] Latin for ”after the event”.
[82] Hull – Clancy 2019, p. 659.

5 Conclusion

This thesis examines the legal treatment of pay-for-delay agreements under EU competition law and their relation to patent protection in the pharmaceutical sector. The analysis of the *Lundbeck*, *Generics UK*, and *Servier* cases shows that such agreements are generally seen as restrictions of competition by object when they involve value transfers that delay the entry of generic medicines, regardless of the strength or scope of the underlying patent rights. The case law also confirms that patents cannot act as a shield for anti-competitive behaviour, especially when they are weak or limited in scope, such as process patents that can easily be challenged in court.

At the same time, the Courts have been careful to acknowledge the broader policy dilemma: while originator companies require sufficient incentives to invest in costly and risky pharmaceutical research, consumers and health systems depend on timely access to affordable generic medicines. This tension lies at the heart of the debate on how far competition law should reach into the exercise of patent rights. The Commission's three-step test has provided a structured framework for assessing whether agreements constitute restrictions by object, yet its application continues to raise concerns about legal certainty, over-enforcement, and the risk of condemning legitimate settlements.

From a critical perspective, these cases emphasise that the balance between innovation and competition remains a moving target. The Courts' willingness to classify reverse-payment settlements as restrictions by object reflects a broader commitment to consumer welfare, but it also leaves unresolved questions about the appropriate role of patent law in shaping competition outcomes. In this sense, the jurisprudence contributes not only to legal clarity but also to ongoing policy debates about the future of pharmaceutical innovation in Europe. Ultimately, the case law illustrates the EU's effort to prevent collusive practices that distort the competitive process, while still grappling with the challenge of safeguarding the incentives needed to bring new medicines to the market.

There is also a broader debate that the EU should reconsider its institutional framework for monitoring patent settlements. Given existing shortcomings, it is questionable whether the current approach provides sufficient transparency or deterrence. The absence of a statutory notification system leaves oversight fragmented and reactive, allowing potentially anticompetitive agreements to escape scrutiny. A stronger model would be to move closer to

the United States, where companies are legally required to notify every settlement to the authorities. Adopting a similar mechanism in the EU would enhance transparency, enable earlier intervention, and better safeguard both competition and consumer welfare. Of course, even then, the problem of what constitutes a pay-for-delay agreement remains.