

e-Competitions

Antitrust Case Laws e-Bulletin

Patent
Settlements

Patent Settlements: An overview of US, EU and national case law

INTELLECTUAL PROPERTY, PHARMACEUTICAL, SETTLEMENT, BARRIERS TO ENTRY, FOREWORD, EFFECT ON COMPETITION, PAY-FOR-DELAY

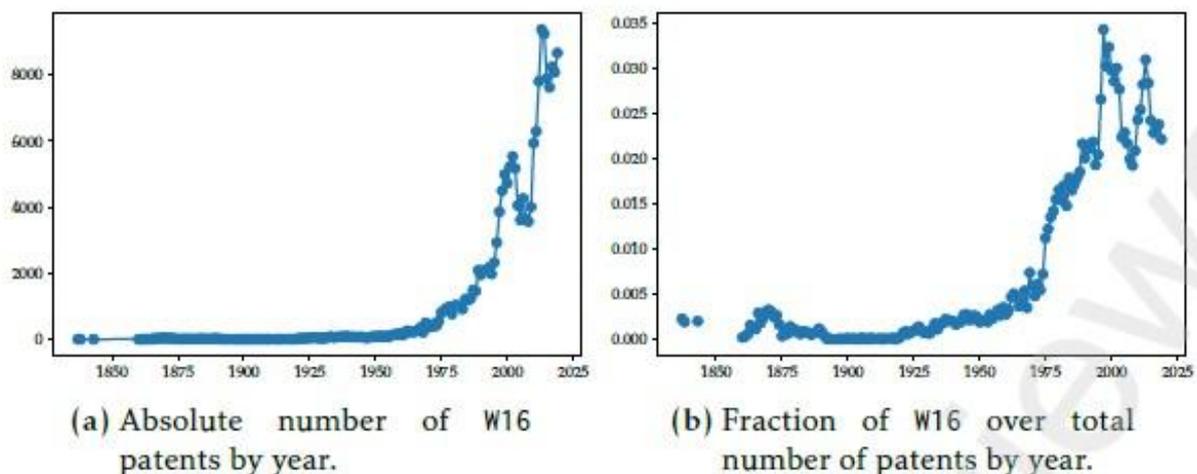
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1. Introduction: the pharma sector as a cornerstone in the interplay between Patent Law & Competition Law

A picture is worth a thousand words, the adage says: for the sake of brevity, let's then start with two images taken from a recent paper devoted to pharmaceutical Intellectual Property Rights (IPRs). [7]



Source: G. Dosi, L. Marengo, J. Staccioli & M. Virgillito, *supra* note 1.

The two charts depict the patenting trend related to the World Intellectual Property Organization (WIPO) technical field 16 (i.e., pharmaceuticals), referring to a database containing 177,040 patents published since 1837. Pharmaceutical activities have always been patent-sensitive, according to applicable legal frameworks (e.g., in many European countries, several content limitations on patenting medical discoveries were strictly maintained until at least the mid-20th century). However, the vertical increase in W16 patenting since the 1980s has transformed the industrial and competitive dynamics of the sector, making it fundamentally Intellectual Property Rights (IPRs) intensive.

Add to this impressive trend the extraordinarily complex and expanding web of market exclusivities associated with IPRs based on specific therapeutic features (say, the growing relevance of orphan drugs for treating rare diseases), and it is easy to understand how patent litigation – and related settlement opportunities – has become a central battleground for pharmaceutical companies.

Accordingly, and proportionally to the number of patents, the possibility of using patents in an anti-competitive manner has been unleashed, with IPRs becoming a formidable tool (also) for defending monopolistic positions far beyond the original intentions of the patent system envisaged for the sector.

As a general remark, it can be said that a well-functioning patent system can promote competition by encouraging firms to invest in innovation, and that a dynamic competition policy helps to create the right framework conditions for innovators, combat dominant positions and promote market entry. With specific regard to the pharma sector, competition between original drugs (so-called originators) and their legal copies that can be marketed after the exhaustion of IPRs (known as equivalents or generics) is also a dynamic force that stimulates pharmaceutical companies to continue to invest in research and development (R&D) of innovative treatments, as they cannot rely on their “blockbuster” products forever.

In this context, antitrust enforcement intervenes only when the patent rights are abused or used as a cover-up for anti-competitive conducts. The mentioned balance between patents and competition is disrupted when companies don't play by the rules.

The patent settlement agreements should be framed in the same way: the overwhelming majority of patent settlements are entirely legitimate as they do not involve any payments by originators to exclude generic companies. By avoiding the costs of market uncertainty and/or expensive litigation they may bring real benefits.

However, sometimes patent settlements involve a value transfer from the originator to the generic with the aim of limiting the generics' market entry and may constitute a restriction of competition by object, as well as part of an abusive anti-competitive strategy. Finally, it should be noted that in certain cases settlement agreements in the pharmaceutical sector do not involve patents at all.

Indeed, disrupting the balance is especially harmful in the field in question, due to the essential role played by pharmaceuticals in the fulfilment of the fundamental right to health: consumers in both developed and developing countries are harmed, with the latter suffering to an even greater extent as a result of these anticompetitive practices because of the economic and capacity expenditure constraints that are inherent to their current conditions [2].

At the same time, from a pharmaceutical business perspective, the possibility of using IPRs barriers to insulate a blockbuster product from competitors for longer can lead to further support for the R&D of other drugs thanks to the stream of revenue it secures.

Antitrust law neatly establishes the rules of the competition game by taking into account illicit anticompetitive agreements and abuses of a dominant position. However, where to draw the line in practice between lawful and illegal conducts, between the use and abuse of a right (in the specific cases discussed here, of intellectual property), is a much more complicated matter.

2. Patent Settlements and the dilemma: freedom to contract or pay-for-delay?

We assume that the U.S Supreme Court's decision in *Diamond v Chakrabarty* (1980), the *Bayh-Doyle Act* (1984), and the *Hatch-Waxman Act* (1984) are the triad commonly believed to be responsible for the patent explosion that occurred in the US and eventually spread to the rest of the world in the following decades. [3] These three legal interventions opened the patent genie bottle, respectively, by encompassing living organisms at the very dawn of the biological drugs era, fostering R&D by transferring IPRs from academia to commercial enterprises, creating unprecedented patent-related litigation – and, in turn, settlement opportunities – for the market entry of generic drugs due to the so-called “Paragraph IV” certification scheme.

All this happened in the US. It should therefore come as no surprise that the anticompetitive use of patents and the resulting antitrust concerns also first emerged as an American specialty. Rather, what is surprising is that it took so long for theorists and practitioners to become fully aware of the issue. The 2000s, faced with a scattered jurisprudential landscape and often heated interpretive contrasts, became a laboratory for reaching a practical understanding of the possible negative consequences of “astute” patent settlements, both in the U.S and in Europe. In fact, due to the natural temporal course of the first patents filed beginning with the boom of the 1980s, the question of defining the illegality of agreements between companies to conclude patent disputes arose with increasing frequency in both Courts and Competition Authorities in the early 2000s.

From the outset, the patent settlement issue has been one of competitive conflict between companies holding patents registered to protect the exclusivity of the originator and those seeking to enter the profitable drug market, hitherto protected by IPRs, as quickly as possible by means of equivalents or generics. It has taken long and as yet unexhausted work to draw a clearer distinction in the neutral set of patent settlement agreements, which are in themselves a legitimate expression of freedom of contract, between the two far more critical and only partially overlapping subsets of reverse-payment agreements and pay-for-delay agreements. [4] Provided that both types of subsets are inherently connected to the generics-originator competition, at least the latter could also exist without a patent dispute as a reason for being. However, an IPR-centric ecosystem, such as that of today's pharma industry, could only facilitate the referral to these rights as an operational “cover” for these types of agreements.

Concerns about problematic horizontal agreements from a competition law perspective were finally echoed both by the EU Commission in its 2009 EU pharmaceutical sector inquiry, and the FTC in a 2010 staff study. [5] The year 2013 then became the real turning point, with the Supreme Court's *Actavis* ruling, on one side, and, on the other side (of the pond), the EU Commission's *Lundbeck* decision [6].

All in all, both decisions helped clarify fundamental issues related to the practical understanding of anticompetitive patent settlements. *Actavis* dismissed the “scope of the patent” test supported by some US Circuit Courts, as well as a presumptive illegality test adopted by the FTC, introducing a new rule of reason approach while better re-focusing the interpretative analysis on competition issues first.

Lundbeck, in turn, firmly established the notions of “by object” restrictions when dealing with pay-for-delay deemed to be disconnected from genuine, more complex cooperative relationships. In addition, EU jurisprudence firmly supported potential competition as a fundamental asset for the protection of competition in the pharmaceutical field by establishing that a valid patent does not preclude its holder and a prospective entrant from being potential competitors.

As for the abuses of dominant position related to the distorted use of IPRs, these are apparently more clearly distinguishable from unilateral conduct. However, there have been cases where, as the EU Commission’s experience with the *Servier* [7] case discussed below shows, the scenario is anything but straightforward, where multilateral agreements and unilateral abuses are combined.

2.1 Weaponizing IPRs and patent settlements: the special case of sham litigation

Sham litigation [8] constitutes a very particular case of anticompetitive patent use, which has become relevant in practice, especially in connection with pharmaceutical patents, and is intertwined with the issue of patent settlements. A few years ago, when we looked at abusive litigation in the pharmaceutical sector, we wondered whether sham litigation and its related legal “doctrine” was still relevant in the IPRs field: the answer was affirmative, because at that time attention was focused on new cases of abuse, including reverse payments. [9] A second question followed: is there anything peculiar to the sham litigation doctrine when applied to the pharmaceutical sector, and more in particular to patent settlements? [10] Recent case law indeed shows that the abuse of pharmaceutical patents may also be pursued by means of judicial protection.

For instance, in the public enforcement *Servier* case [11] in the EU, the Commission faced the issue of the abuse of litigation in the context of a pay-for-delay case; more specifically, vexatious litigation appeared as a means to delay the market entry of competitors [12].

On the other side of the Atlantic, the Humira private enforcement case [13] appears as a landmark ruling purely about settlement agreements as a means for sham litigation, although it is not exempt from criticism. [14] It also recalls several principles from the Actavis case, though the Actavis doctrine has been considered as misinterpreted by commentators. [15]

3. Conclusion: some open issues

Much has become clearer over recent decades, but unfortunately some issues remain to be clarified. For instance, as a result of the reasonability approach being fully embraced in the US and somewhat accepted also in the EU in the wake of the national post-*Lundbeck* litigations, [16] pharma companies are now much more cautious about using specific patent settlement clauses, and are following a case-by-case approach that tries to safely navigate ambiguous situations by adopting a more conservative approach, especially in their communication strategies when it comes to publicly stating the closing of patent settlements.

Also, the issue of non-monetary but valuable transfers occurring among settlers from an originator to a genericist remains, well, unsettled. As underlined above, the EU General Court partly overturned the Commission decision on the *Servier* saga because it was not considered demonstrated that the value transfer in question effectively induced non-entry. [17] As for the US, recent case law shows persisting contrasts regarding the need for value transfers and its magnitude when assessing the legitimacy of patent settlements. [18]

To add to the complexity, patent rights will certainly continue to be the place of choice for sham litigation, and subsequent settlements are often difficult to distinguish from the dark side of such practice.

Today, it is safe to say that the field of action of dubious patent settlements is being redefined, as competition between originators and generic companies has changed over time due to the increasing structural relationships between these once fiercely hostile industries following the massive mergers and acquisitions activities of the last decade. At the same time, the increased complexity of R&D paths along the frontiers of therapeutic innovation – with mRNA vaccines being a poster child for these new trends – requires cross-licensing agreements (with FRAND-like agreements possibly on the horizon) much more frequently than ever before, as well as ways to solve patent interferences issues; this is likely the area that antitrust theorists and practitioners will need to pay attention to in the coming years.

Again, in the interest of sparing a thousand words, we report here below a table of patent interconnections in the field of anti-Covid19 mRNA vaccines, taken from a recent study [19]. It clearly shows how competition between originators is now intrinsically characterized by strong design and production links between competing products, with high risks of related litigation.

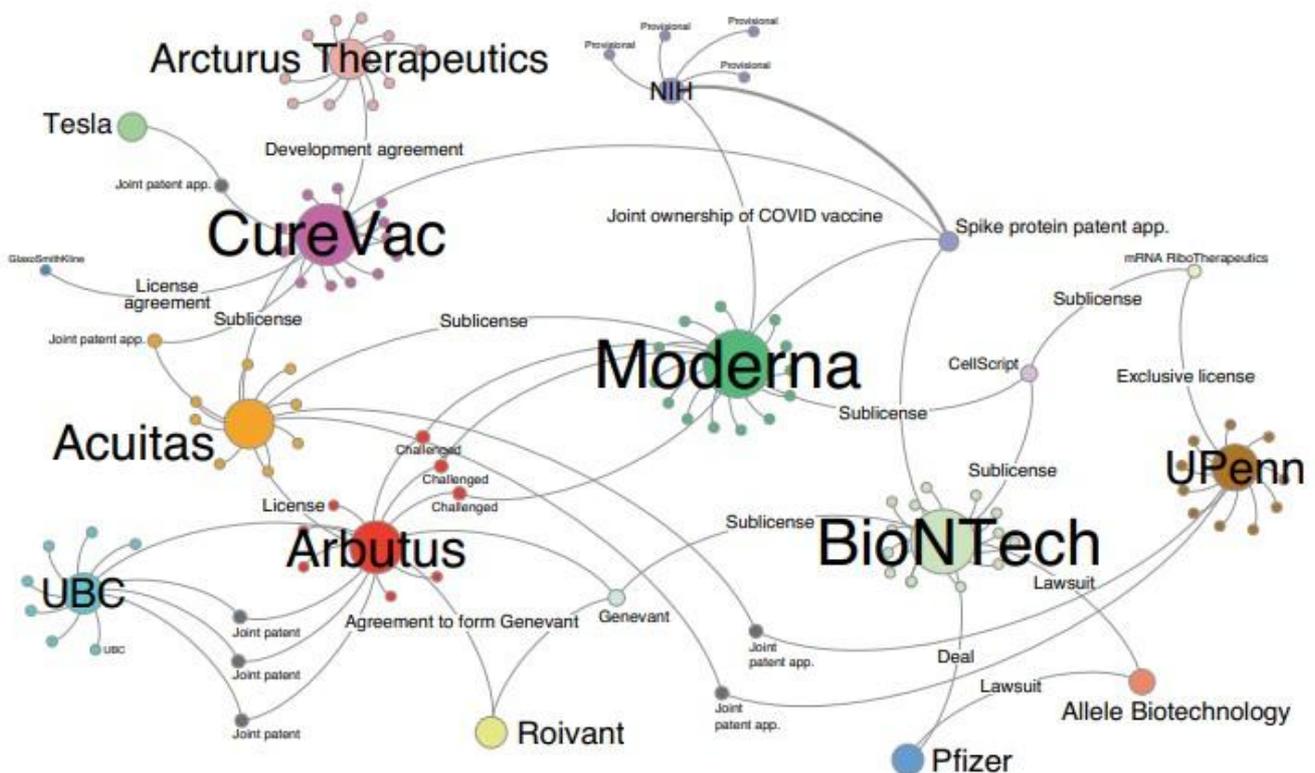


Fig. 1 | Patent network analysis of mRNA-based vaccine candidates for COVID-19. Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology (Supplementary Information). The network analysis was developed using Gephi²³. UPenn, University of Pennsylvania; UBC, University of British Columbia; app., application.

Source: M. Gaviria & B. Kilic, *supra* note 19.

The e-Competitions Special Issue now available provides readers with a synthesis of both EU and US antitrust developments over the last few years in the shadow of Actavis and Lundbeck, in preparation for the complexity of future challenges. For instance, it provides an analysis of the first fully litigated FTC decision following Actavis (the Impax case [20]), as well as the EU Court of Justice's final dismissal of the appeals brought against Lundbeck.

The contributions included in the Special Issue offer a useful guide to the subtle and potentially dangerous interplay between competition and IPRs in a sector such as that of pharmaceuticals, where the recent Covid-19 pandemic has directly affected public health and thus contributed significantly to our understanding of its importance and sensitivity from a human rights perspective.

Disclaimer from the Authors: this article represents the opinions of the authors and is the product of academic research, it is not meant to represent the position of any of the institutions mentioned above. The authors wish to thank Carmine Di Sanza for his extensive survey work of case law and his invaluable help in reviewing the final text.

Note from the Editors: although the e-Competitions editors are doing their best to build a comprehensive set of the leading EU and national antitrust cases, the completeness of the database cannot be guaranteed. The present foreword seeks to provide readers with a view of the existing trends based primarily on cases reported in e-Competitions. Readers are welcome to bring any other relevant cases to the attention of the editors.

[1] G. Dosi, L. Marengo, J. Staccioli & M. Virgillito, *Big Pharma and Monopoly Capitalism: A Long-Term View*, research paper, April 2022, p. 9 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4092494 ↗).

[2] V. Guimarães de Lima e Silva, *Sham Litigation in the Pharmaceutical Sector (2011)*, 7 *European Competition Journal*, 455-503, 2011 (<http://ssrn.com/abstract=1994461> ↗).

[3] Cf. B. Hall, *Exploring the Patent Explosion*, 30 *Journal of Technology Transfer*, 35–48, 2005.

[4] For a classical piece of literature, see H. Hovenkamp, M. Janis & M. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 *Minnesota Law Review*, 1719-1766, 2003 (<https://www-cdn.law.stanford.edu/wp-content/uploads/2015/06/Anticompetitive-Settlements-of-Intellectual-Property-Disputes.pdf> ↗). For an updated, comparative analysis, see now G. Gabison & Z. Tameez, *Reverse Payment: A comparative Study*, 19 *Indiana Health Law Review*, 21-45, 2022 (<https://journals.iupui.edu/index.php/iHLR/article/view/26084/24161> ↗).

[5] As for the EU sector inquiry, a historical perspective was offered by the EU Commission 8th Report on the Monitoring of Patent Settlements (period: January-December 2016), March 2018 (https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report8_en.pdf ↗); see also FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010 (<https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staffstudy/100112payfordelayrpt.pdf> ↗).

[6] US Supreme Court, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); EU Commission, AT.39226

– Lundbeck, June 19, 2013. For Actavis, see e.g. **Michael A. Carrier**, *The US Supreme Court issues first ruling on antitrust legality of reverse-payment drug patent settlements (Actavis)*, 17 June 2013, e-Competitions June 2013, Art. N° 53120, **Christopher Sagers**, *The US Supreme Court reverses the judgment of the Court of Appeals for the Eleventh Circuit and leaves the structuring of the rule of reason antitrust litigation to the lower courts (Actavis)*, 17 June 2013, e-Competitions June 2013, Art. N° 54663, and **Athina Tsitsou**, *The US Supreme Court rules that the “pay-for-delay” settlements in the pharmaceutical sector are to be analyzed under the rule of reason (Actavis)*, 17 June 2013, e-Competitions June 2013, Art. N° 57706. For Lundbeck, see e.g. **European Competition Network Brief**, *The EU Commission fines pharmaceutical companies for delaying market entry of generic medicines through pay-for-delay agreements (Lundbeck)*, 19 June 2013, e-Competitions June 2013, Art. N° 53279.

[7] EU Commission, AT.39612 – Perindopril (Servier), available at https://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12448_6.pdf . See, e.g. European Court of Justice, *The EU Court of Justice AG Kokott proposes that the Court should set aside the ruling of the General Court and declare that the pay-for-delay agreements concluded by a pharma constituted an abuse of dominance (Servier)*, 14 July 2022, e-Competitions Preview, Art. N° 107752.

[8] On the topic, for an institutional perspective to be coupled with a growing academic literature, see WIPO, *Study on the Anti-Competitive Enforcement of Intellectual Property (IP) Rights: Sham Litigation*, CDIP/9/INF/6, February 22, 2012 (https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=199801).

[9] See G. Muscolo, *Abuse of litigation, abuse of Patent and abuse of dominance: where do we stand?* in G. Pitruzzella, G. Muscolo; *Competition and Patent Law in the Pharmaceutical Sector. An International Perspective*, The Netherlands-London, 2016, p. 107.

[10] In the *Pharmaceutical Sector Inquiry Report of the EU Commission* par. from 3.2.2. to 3.2.4. are entitled to different cases of Patent related abusive litigation (available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>)

[11] In the *Servier* case the Commission has imposed fines totalling Euros 427.7million on the French pharmaceutical company Servier and five producers of generic medicines-namely Niche/Unichem, Matrix (now part of Mylan), Teva, Krka and Lupin - for an illicit agreement aimed at protecting Servier bestselling blood pressure medicine, perindopril, from price competition by generics in EU. Through a technology acquisition and a series of patent settlements with generic rivals, Servier implemented a strategy to exclude competitors and delay the entry of cheaper generic medicines to the detriment of public budgets and patients in breach of EU antitrust rules. Damages actions were pending in the United Kingdom concerning Servier’s practices in the market for perindopril. See, e.g. **Elvira Aliende Rodriguez, James Webber, Ozlem Fidanboyly, Susanna Charlwood, Jonathan Swil**, *The UK Supreme Court hands down a judgment in a competition damages lawsuit and makes key observations on when a judicial decision of the EU courts is binding in other proceedings (Secretary of State for Health / Servier Laboratories)*, 6 November 2020, e-Competitions November 2020, Art. N° 97904.

[12] More in detail, when Servier learned about generic companies that were preparing for market entry, it sent them warning letters with the aim of deterring them from launching their generic versions of perindopril. These warning letters often invoked as many as thirty-five patents, including those that Servier internally qualified as “barrage patents” and patents with “zero inventive activity”. Servier made clear that it would exhaust all means to defend its product: in a number of cases where the warning letter did not produce the desired results, Servier sought an

injunction. Servier contested the Commission's Decision before the General Court, which ruled on the case on the 12th of December 2018. The GC confirmed that the pay-for-delay agreements concluded by Servier with several generic drugs manufacturers constituted restrictions of competition by object. See, e.g. Peter L'Ecluse, The EU General Court offers a mixed review of patent settlement agreements in the pharmaceutical sector (Servier), 12 December 2018, eCompetitions December 2018, Art. N° 88976. However, the GC also found that the Commission had committed an error in the assessment of the relevant market (for the purpose of applying Art. 102 TFEU), which had been wrongfully limited only to the brand-name drug perindopril and to its generic counterparts. Lastly, the GC found that an agreement concluded between Servier and generic drug manufacturer Krka did not constitute a restriction of competition. Both Servier and the Commission brought appeals against the judgment (respectively, case C-201/19 P and case C176/19 P). In its appeal, Servier claims that its agreements with generic drug companies should not have been qualified as by-object restrictions. In its appeal, the Commission challenges the findings of the GC concerning the lawfulness of the agreement concluded between Servier and Krka and concerning the definition of the relevant product market. On the 14th of July 2022, Advocate General Kokott issued her opinion on both appeals. Concerning the appeal brought by Servier (C-201/19 P), the AG disagrees with Servier and believes that the agreement between Servier and Krka constituted a reverse-payment agreement, and therefore should have been considered a by-object restriction. Moreover, the AG believes that the agreement should be also qualified as a restriction by effect, since the Commission had demonstrated that it had the actual effect of keeping Krka out of the perindopril market. The AG also believes that the GC erred in law in overturning the Commission's definition of the relevant product market. Concerning the appeal brought by the Commission (C-176/19 P), the AG obviously agrees with the Commission on the qualification of the agreements concluded between Servier and the generic drug manufacturers. According to AG Kokott, the GC decision on the issue is consistent with the caselaw of the ECJ, according to which, in order to qualify a reverse-payment settlement as a restriction by object, it is necessary to consider the justification of the transfer of value that is made from the originator to the generic companies. In this case, AG Kokott believes that the GC correctly found that the transfer was justified solely by the companies' intention not to compete against each other. See European Court of Justice, The EU Court of Justice AG Kokott proposes that the Court should set aside the ruling of the General Court and declare that the pay-for-delay agreements concluded by a pharma constituted an abuse of dominance (Servier), 14 July 2022, eCompetitions Preview, Art. N° 107752.

[13] See *In re Humira (Adalimumab) Antitrust Litigation*, 465 F. Supp. 3d 811, 835 (N.D. Ill. 2020) and *Mayor and City Council of Baltimore v. AbbVie Inc.* (7th Cir. 2022). In the Humira case, AbbVie engaged in litigation against the generic companies, which led to settlements. The generic companies agreed to enter the market in 2023 in the US and in 2018 in Europe. According to the plaintiffs, AbbVie induced the generic companies to delay their entry in the American market by offering them an early entry in the European market. The plaintiffs claimed that AbbVie's conduct before the US Patent Office, the FDA and in litigation, amounted to sham conduct. However, the District Court disagreed, and stated that the fact that there were flaws in AbbVie's patents did not demonstrate that their enforcement was baseless, since more than half of the company's patent applications resulted in patents. The Court also stated that the lawsuits initiated by AbbVie were settled on terms that foreclose a finding of objective baselessness". Therefore, the Court excluded that AbbVie's could amount to sham litigation, since the settlements concluded with generic manufacturers included concessions from both sides. In addition, the Court affirmed that settlement did non concern cash payments and considered the settlement to be lawful according to the Actavis case-law. The decision of the lower court was confirmed by the Court of Appeals stating that the settlements concluded by AbbVie and the generic companies did not amount to pay-for-delay agreement. More in detail the plaintiffs claimed that the reverse-payment could be identified in the fact that AbbVie allowed the generic companies to enter the market early in Europe and the Court explained that this was "a use of the economic concept of opportunity cost,

which treats a forgone earning opportunity (fewer years of monopoly profit in Europe) as equivalent to a payment out of pocket". However, the Actavis ruling itself had excluded the possibility to equate an opportunity cost with a reverse-payment. The Court concludes, therefore, that AbbVie's settlements were not unlawful.

[14] See **Michael A. Carrier**, *The US District Court for the Northern District of Illinois dismisses antitrust case challenging patent thicket (Humira)*, 8 June 2020, *e-Competitions June 2020*, Art. N° 96364.

[15] *Id.*

[16] See EU Court of Justice, C307/18 – GSK, January 30, 2020 (paroxetine case). See, e.g. **Sandrine Mathieu, Amélie Lamarq**, *The EU Court of Justice clarifies the conditions under which pay-for-delay agreements preventing generic versions of a patented medicine from entering the market or delaying such entry may constitute a restriction of competition 'by object' or 'by effect' as well as an abuse of dominant position (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpha)*, 30 January 2020, *e-Competitions January 2020*, Art. N° 94657, **Lesley Hannah, Ann-Christin Richter**, *The EU Court of Justice provides guidance on patent settlements between manufacturers of the originator and generic medicines (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpha)*, 30 January 2020, *e-Competitions January 2020*, Art. N° 96452, and **Donald Slater**, *The EU Court of Justice clarifies the conditions for a pay-for-delay agreement to be qualified as a restriction of competition by object (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpha)*, 30 January 2020, *e-Competitions January 2020*, Art. N° 95834.

[17] See EU General Court, T684/14 – Krka, December 12, 2018. See also footnotes 12 and 13.

[18] See *In re Humira (Adalimumab) Antitrust Litigation*, 465 F. Supp. 3d 811, 835 (N.D. Ill. 2020) For a joint survey, cf. J. Blumenfeld, L. Blad Jr, Z. Jaramillo, and J. Lewis, *Status of Reverse Payment Cases against Pharmaceutical Companies*, *Global Competition Review*, July 19, 2021 (<https://globalcompetitionreview.com/review/us-courts-annual-review/2021/article/status-of-reverse-payment-cases-against-pharmaceutical-companies#footnote-036>). See also footnotes 15 and 16.

[19] **M. Gaviria & B. Kilic**, *A network analysis of COVID-19 mRNA vaccine patents*, 39 *Nature Biotechnology*, 546–548 (2021).

[20] See, e.g. **US Federal Trade Commission**, *The US FTC charges 2 pharmaceutical companies for the second time with preventing competition in the national market for oxycodone (Endo / Impax)*, 25 January 2021, *e-Competitions January 2021*, Art. N° 98900.