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Opinion

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Temporary Relief of Pay-for-Delay: The ECJ as Specifically Different Antidepressant

Pay-for-delay agreements are increasingly scrutinised and sanctioned in the European Union (EU). The state of play so far has only made it possible to analyse such agreements as restrictions of competition by object under Art. 101(1) of the Treaty on the Functioning of the European Union (TFEU) and in some cases as abuses of a dominant position under Art. 102 TFEU. At the beginning of this year, the European Court of Justice (ECJ) gave its first ruling on this issue. The *Generics* judgment (C-307/18) deepens the reasoning and defined line of the General Court (EGC) and the Commission and deals with fundamental questions of competition law. To this end, the Court has extended the existing investigation criteria. Although the judgment consolidates the status of pay-for-delay, it fails to resolve important aspects and leaves only losers. This comment takes the ECJ's decision in *Generics* as an opportunity to analyse pay-for-delay agreements in the EU from a critical perspective.

I. Omnipresent pay-for-delay phenomenon

Imagine that you, an originator, are exposed to an imminent onslaught of competition. What can you do to maintain exclusivity? You have already spent countless sums on research and development (R&D). How can you ensure that your monopoly profits are maintained? Why not simply pay the generic competition to stay out of the market? This is precisely the strategy of pay-for-delay: a pay-for-delay agreement is a settlement where a value is transferred from a patent holder to a generic producer ('pay'). In return, the generic company delays market entry ('delay').[1] This type of agreement is also known as a 'reverse payment settlement'. While normally the alleged infringer pays damages and/or legal costs to the patent holder, the value here flows in the opposite direction, from the patent holder to the alleged infringer.[2] Reverse payments mainly concern pharmaceutical products whose patent on the active ingredient has expired but which are still protected by secondary patents. The difference between the pharmaceutical industry and other industries lies primarily in the regulatory burdens faced by innovators: The high costs of R&D and clinical trials have to be borne by the originators, while generic companies have a big cost advantage.[3]

The United States Federal Trade Commission and Circuit Courts dealt with pay-for-delay agreements as early as 2001,[4] while the first EGC decision was not issued until 2016.[5] Until then, reports from the Commission and national court decisions were the only legal guidance available. The examination of such agreements started with the Commission's inquiry into the pharmaceutical sector, which concluded that settlements are a generally accepted and legitimate way to end disputes.[6] They can even have a positive social impact by saving money and time for administrative authorities. However, the Commission warned that some settlements could also cause harm. It was therefore necessary to examine, first, whether patent settlements violated Art. 101 TFEU, and second, whether originators created artificial barriers to market entry by abusing patent rights or by engaging in sham disputes, thereby infringing Art. 102 TFEU.[7]

1. Bad medicine: the problem of pay-for-delay

The first problem raised by reverse payment settlements is the delay in the market entry of generics. One of the most important regulatory objectives is to encourage their early market entry to reduce health-care expenditure. The second problem is that these settlements can protect potentially weak patents against invalidation. Another problem involves the objective of keeping legitimate generics temporarily off the market. A value transfer from the originator to the generic company would only be expected if the

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1 Commission, 'Report to the Council and the European Parliament on Competition Enforcement in the Pharmaceutical Sector (2009-2017)' COM(2019) 17 final, 24; Sven Gallasch, 'A new dimension to EU pharma antitrust product hopping and unilateral pay for delay' (2016) 12 Eur. Compet. J. 137, 141.

2 Amalia Athanassiadou, *Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law* (Kluwer 2018).

3 Barbara Klaus and Matthias Derra, 'Kartellrecht im Pharma- und Gesundheitssektor' [2020] PharmR 115.

4 *Andrx Pharm Inc v Biovail Corp Intl*, 256 F.3d 799 (D.C. Cir. 2001); Federal Trade Commission, 'Pay-for-delay: when drug companies agree not to compete' <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay> accessed 25 December 2020.

5 Case T-472/13 *Lundbeck v Commission* ECLI:EU:T:2016:449.

6 Commission, 'Pharamceutical Sector Inquiry Final Report' (*European Commission*, 8 July 2009) 181-368 <https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 25 December 2020.

7 Commission, '3rd Report on the Monitoring of Patent Settlements (*European Commission*, 25 July 2012) <https://ec.europa.eu/competition/sectors/pharmaceuticals/archive/patent_settlements_report3_en.pdf> accessed 25 December 2020.

parties considered the patent invalid. By accepting a payment, the potential entrant recognises that it is valid.[8] This is particularly the case where the originator pays significant sums of money in return for restricting the other company's commercial activity. Various tactics allow companies to disguise the nature of the transfer, such as promises to promote or market other medicines, licensing agreements or agreements to share R&D tasks in future projects.

Pay-for-delay agreements are not provided for in the patent system. A patent does not give its holder the right to exclude firms other than by asserting it against any possible or actual infringement. The issue of pay-for-delay involves a crucial conflict between patent and competition law: Without adequate protection, innovation is not sufficiently generated ('underprotection'). At the same time, too much protection restricts the innovation scope of other market participants ('overprotection').[9] The result is a static conflict. In dynamic terms, patent and competition law complement each other in that both aim to generate innovation. The more a holder is restricted in the exercise of his rights, the lower the value of the intellectual property (IP) right. This value is thus not only determined by IP law but also depends on competition law. The task of IP law is to define and protect IP rights, while the task of competition law is to ensure that IP rights are not exercised at the expense of third parties. What is particularly problematic is the assessment of behaviour which constitutes an infringement under competition law but which may at the same time be covered by patent law. Consequently, the exercise (but not existence) of a patent can be subject to antitrust scrutiny. This is in line with the widespread theory of complementarity between the two areas of the law.[10]

Pay-for-delay agreements are not ordinary settlements. It would, in principle, not be necessary for the originator to make a substantial value transfer to the generic company if its patent were strong and valid. He is faced with the uncertainty of patent infringement litigation and has a lot to lose.[11] Nevertheless, the public remains the biggest loser, with settlement agreements often having a negative impact on consumers since, under normal circumstances, the generic company could have entered the market and given consumers a choice of medicines. Settlements should therefore not be regarded as the ultimate goal or a 'carte blanche' for the parties. It is not surprising, therefore, that the negative effects of agreements have led to increased, albeit delayed, sanctions.

II. Outline of pay-for-delay in the EU legal system

Lundbeck and *Servier* were the first Commission and court decisions on anti-competitive patent settlements between originator and generic companies. Both decisions have been challenged by the parties before the ECJ.

1. *Lundbeck* and *Servier*: non-categorical condemnations and abusive monopolies

The Commission noted in *Lundbeck* that it made economic sense for an originator to prevent generic entry. By reaching a settlement, the originator avoids the risks of (1) failure to obtain injunctions, (2) patent invalidation, (3) non-infringement of the patent, and (4) significant losses upon generic entry. The Commission linked the probability of patent invalidity to the amount paid: the higher the probability of invalidity, the higher the amount. The patent scope test was explicitly rejected, since such a test would reduce competition and preserve high costs.[12] In 2016, the EGC published its first judgment on pay-for-delay, dismissing all claims, upholding the Commission's fines and ruling that the settlements constituted restrictions of competition by object. The EGC stressed that the presumption of patent validity could not be equated with a presumption of the illegality of generics. The Court largely confirmed the Commission's rejection of the patent scope test and found that the existence of a reverse payment settlement was not always problematic and could not be categorically condemned.[13] The Court benefited from US experience and was strongly influenced by the reasoning of the US Supreme Court in *Actavis*,[14] an approach favouring the objectives of competition law over those of patent law. The most significant result of *Actavis* is the rejection of per se legality and the application of the rule of reason.[15] As guidance, the EGC made it clear that the likelihood of anti-competitive effects depends on the method of payment, its amount, its scope in relation to future legal costs and other criteria. Accordingly, lower courts may rely on the amount of the payment to determine patent strength. The EGC also emphasised that the amount may give an indication of how the parties perceive this strength and of the doubts as to the chances of success in a patent infringement case.[16] The Court did not limit its judgment to cash payments, but held that the replacement of uncertainty by the certainty of market exclusion generally constitutes a restriction by object. The most remarkable aspect of *Lundbeck* is that the agreements would have been a restriction of competition even if they had dealt with a 'genuine' patent dispute. According to the standard set, a settlement agreement with a disproportionately high payment raises a red flag. However, the judgment does not address the question whether such agreements constitute a restriction by effect or an abuse of a dominant position.

The reasoning in *Servier* is very similar to that in *Lundbeck*. In principle, the decision does not deny that companies are entitled to settle disputes. Settlements can benefit both the parties and society by allowing a more

8 Mark Lemley and Carl Shapiro, 'Probabilistic Patents' (2005) 19 Journal of Economic Perspectives 75, 92.
9 cf Wernhard Möschel, 'Gibt es einen optimalen Schutzumfang für ein Immaterialgüterrecht?' in Knut Lange, Diethelm Klippel and Ansgar Ohly (eds), *Geistiges Eigentum und Wettbewerb* (Mohr Siebeck 2009) 126 ff.
10 Ansgar Ohly, ',,Patenttrolle" oder: Der patentrechtliche Unterlassungsanspruch unter Verhältnismäßigkeitsvorbehalt?' [2008] GRUR Int 787, 793.
11 Robin Feldman and Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (CUP 2017) 37.
12 *Lundbeck* (Case AT.39226) Commission Decision C(2013) 3803 final [2013] OJ C80/13, paras 640, 659, 698 and 708.
13 *Lundbeck v Commission* (n 5) paras 61 ff, 117 ff, 332 ff, 388, 401 and 414.
14 ibid paras 352 ff; *FTC v Actavis, Inc.* 570 U.S. 136 (2013).
15 Gönenc Gürkaynak, Ayse Güner and Janelle Filson, 'The Global Reach of FTC v. Actavis – Will Europe Differ from the US Approach to Pay-for-Delay Agreements?' (2014) 45 IIC 128, 142.
16 *Lundbeck* (n 12) paras 353, and 360 ff.

efficient allocation of resources. However, the Commission stressed that patent rights were not excluded from the application of competition law, and held that a pay-for-delay settlement in principle constituted a restriction of competition by object. The complexity of the *Servier* agreements was probably one of the main reasons for the Commission's impact assessment. It was the first decision to argue that an agreement can constitute a violation of both Arts.101 and 102 TFEU simultaneously.[17] The competition analysis largely evolved from *Lundbeck* to *Servier*: While in both decisions the Commission found that the agreements had as their object the restriction of competition, the *Servier* decision contains a detailed analysis of the effects. The EGC further accepted an analysis under Art. 102 TFEU, affirming a restriction by object and confirming the three criteria used by the Commission in its findings: (i) the generic producer and the originator are potential competitors, (ii) the generic producer is restricted from entering a market in the EU, and (iii) there is a transfer of value. The EGC ruled that the nature, amount and justification of the transfer should be examined.[18]

2. Full application of EU competition law

According to *Lundbeck*, pay-for-delay agreements must be considered as anti-competitive infringements of Art. 101(1) TFEU. Based on US experience and case law, the EGC rejected the application of the patent scope test and refused to grant competition immunity for patent settlements.[19] Faced with the task of unravelling different agreements, some US courts began to use the patent scope test (inherency doctrine) to legitimise exclusionary agreements if they did not go beyond the patent scope, if patent infringement suits were not unfounded and if the patents were not fraudulently obtained. In essence, the question was whether agreements imposed a restriction going beyond the patent's exclusion zone. This test was a rule of per se legality, which protected all reverse payments from antitrust scrutiny.[20] In *Actavis*, the Supreme Court finally rejected this test in favour of the rule of reason. Thus, the scope of protection of IP rights is no longer relevant, and instead an overall analysis of the legal and economic context is required. This case-by-case analysis, as also practised in the EU, aims at a more precise determination of the effects on competition. The EGC referred not only to cash payments but to transfers of value in general.[21] As confirmed in *Servier*, such settlements can be considered as part of a broader abuse strategy contrary to Art. 102 TFEU. These findings were recently confirmed in *Generics*.

III. The ECJ and *Generics*

The ECJ delivered its first judgment on this issue in January 2020 (C-307/18). An originator had reached a number of settlements with several generic companies regarding the antidepressant paroxetine. The preliminary questions focus on three main aspects, namely (i) whether originator and generic companies can be considered as potential competitors, (ii) whether a settlement agreement can be considered as an infringement of competition by object or effect, and (iii) whether such conduct infringes the prohibition of anti-competitive agreements and at the same time the prohibition of abuse of a dominant position. The ECJ largely followed the line previously set out by the Commission, the EGC and the Advocate General.

1. Finding: adoption of a strict standard

a) Potential competition

The prohibition of the restriction of competition under Art. 101 TFEU applies to actual and potential competitors. Whether a generic company that has not yet entered the market is to be considered a potential competitor depends on its firm intention and ability to enter the market. Two dimensions are relevant: the likelihood of market entry and its timing. As regards the first dimension, the question arises whether there is a real and concrete possibility of entry. Such a possibility presupposes that the generic company has taken sufficient preparatory steps to enter the market (e.g. through applications for authorisation, patent disputes or marketing initiatives). Furthermore, there should be no insurmountable obstacles to market entry.[22] As regards the second factor, the prospect of entry must be sufficiently short term and rapid to constrain the behaviour of existing players. The analysis of this factor requires a case-by-case assessment of the economic and legal context.[23] In the pharmaceutical sector, generic companies are considered as potential competitors of originators. They have a number of concrete possibilities to enter the market, e.g. by entering at risk or by applying for patent revocation. The need to conclude an agreement is a strong indication that a competitive relationship exists.[24]

b) Restriction of competition by object or effect

A large part of the judgment is devoted to the question whether the disputed settlements fall into the category of restriction by object under Art. 101(1) TFEU. The ECJ previously emphasised that this concept can only be applied to agreements which are so damaging to competition that it is not necessary to examine their effects.[25] A sufficient degree of harm is present if the parties' sole commercial intention is to avoid competition. The fact that the scope of the patent is exceeded is irrelevant. With regard to the transfer of value, the amount must be

17 *Perindopril (Servier)* (Case AT.39612) Commission Decision C(2014) 4955 final [2014] OJ C393/7.
18 Case T-691/14 *Servier and Others v Commission* ECLI:EU:T:2018:922, paras 267 ff and 368.
19 cf Juliane Langguth, *Pay-for-Delay-Vereinbarungen im transatlantischen Vergleich* (Nomos 2018) 110-126; Alexander Eufinger, 'Buchbesprechung: Pay-for-Delay-Vereinbarungen im transatlantischen Vergleich' [2018] GRUR Int 1226, 1226 f.
20 *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (2012), 214; Joshua Davis, 'Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal' (2010) 41 Rutgers Law Journal 255, 277, 284 ff.
21 The EGC thereby avoided fierce debates; for more on the interpretation of 'payments' in *Actavis*, see Herbert Hovenkamp and others, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (3rd edn, Wolters Kluwer 2020), 36 ff.
22 Case C-307/18 *Generics (UK) and Others* ECLI:EU:C:2020:52 = [2020] GRUR International 1071, paras 32, 37 and 44 ff.
23 Commission, 'Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements' Communication 2014/C 89/03, paras 31 ff.
24 *Generics* (n 22) para 55.
25 Case C-67/13 P *CB v Commission* ECLI:EU:C:2014:2204, paras 53 and 57 ff.

sufficiently high to provide an incentive.[26] In summary, the determination of the purpose of an agreement is a case-specific analysis and does not automatically lead to a classification.

The ECJ further examined whether the agreements in question could be classified as restrictions by effect. To do so, the counterfactual situation would have to be established, i.e. the market structure without the agreement's existence. Neither the parties' prospects of success in the patent nullity proceedings nor the possibility of a less restrictive settlement were decisive.[27] The ECJ offered only a very brief analysis.

The ECJ decided that pro-competitive effects can be taken into account under Art. 101(1) TFEU. However, it made it clear that EU law does not recognise a US-like rule of reason.[28] According to this rule, a case-by-case analysis is carried out which aims to weigh anti-competitive effects against pro-competitive benefits. The analysis is reserved for practices that potentially cause damage to competition but also have possible social benefits. The test involves complex economic analyses, requires extensive information and follows an amorphous set of standards.[29] In its *Actavis* judgment, the Supreme Court opened the door to such rule of reason.[30] The Commission had already stressed that this approach would risk distracting Art. 101(3) TFEU from its purpose, especially since it already contains all the elements of a rule of reason.[31] The *Generics* judgment clearly demonstrates that pro-competitive effects are not only to be considered under Art. 101(3) TFEU, but may well be relevant for a classification under Art. 101(1) TFEU. Accordingly, pro-competitive effects of an agreement can be taken into account if they raise sufficient doubts as to whether competition is affected. A reliable indicator is the analysis of efficiency gains. In the present case, the ECJ considered that a slight reduction in the price of medicines would not have a sufficiently positive effect.[32]

c) Abuse of a dominant position

Until *Generics*, pay-for-delay agreements were analysed almost exclusively under Art. 101(1) TFEU. With the development of pay-for-delay, Art. 102 TFEU has become increasingly important for a global analysis of strategies to delay market entry. The ECJ has made it clear that a certain behaviour may lead to an infringement of both provisions.[33] Consequently, original and generic products may be considered as substitutes and thus included in the definition of the product market. Finally, the ECJ ruled on whether the overall strategy could amount to an abuse of dominance. It pointed out that the exercise of a patent does not in itself constitute an abuse unless such conduct effectively denies market access.[34] The agreements delayed the market entry of generics and thus also the fall in prices of paroxetine on the British market to the detriment of the National Health Service and end consumers. It therefore had anticompetitive effects. Once an abuse has been established, justifications allow the dominant producer to protect its commercial interests. However, it would be difficult to prove that the use of delaying tactics is not specifically aimed at strengthening or abusing his position. Finally, in the context of the efficiency defence, he must prove that the measures are justified by future efficiency gains. Referring to its *Intel* judgment, the ECJ held that the assessment of whether the conduct is justified requires a balancing of pro- and anti-competitive effects.[35] In this case, efficiency gains were unlikely to outweigh the negative effects. The analysis under Art. 102 TFEU thus allowed for a review of the entire conduct (and not only isolated practices).

2. Evaluation of *Generics*

a) Competition and IP law: convergence or divergence?

According to the ECJ, uncertainty about the strength or validity of patents is not relevant for the assessment of pay-for-delay.[36] The core of IP rights remains unaffected, while competition law restricts their exercise. It has been consistently held that the existence of an IP right does not equal protection from competition law. The relationship between competition and IP law has always been strained, with a tension between the fundamental right of the patentee to exclusion and the antipathy of competition policy towards exclusionary behaviour. The moral basis of patents rests on a reward function for the genius of individual imagination and inventiveness. In other words, the basic idea of patent protection is the need to reward successful innovation and provide incentives for further R&D with the ultimate aim of increasing social well-being. However, behaviour that delays competition is contrary to EU law. As previously indicated, pay-for-delay tends to settle litigation over secondary patents usually covering the manufacturing process or ancillary aspects of a drug. They are a powerful instrument for achieving an extension of exclusivity and are therefore often filed at a later stage of the product life cycle. A firm is less likely to win on these patents than it is on active ingredient patents.[37] Thus, secondary patents may overreward the actual innovative contribution with strategic but unwarranted extensions of protection. In this way, agreements boost the tension between static and dynamic efficiency, diluting the dual objective of innovation incentive and price competition. Patent laws have traditionally been understood to promote long-term and dynamic efficiency. Hence, they protect a patent holder's incentive to

26 *Generics* (n 22) paras 85 ff and 90 ff; Pablo Ibáñez Colomo, 'Pay-For-Delay and the Structure of Article 101(1) TFEU: Points of Law Raised in *Lundbeck* and *Paroxetine*' (2019) 10 JECLAP 591, 608.
27 *Generics* (n 22) paras 118 ff.
28 ibid paras 103 ff.
29 Herbert Hovenkamp, 'The Rule of Reason' (2018) 70 Florida Law Review 81; cf Martin Adelman, 'A Safe Harbor for Pay for Delay Pharmaceutical Settlements in the United States' [2018] GRUR Int 1112, 1113.
30 *FTC v Actavis* (n 14) para 2237.
31 Commission, 'White Paper on modernisation of the rules implementing Articles 85 and 86 of the EC Treaty' No 99/027 [1999] C132/01, para 57.
32 *Generics* (n 22) paras 103 and 107 ff.
33 ibid paras 131 ff and 146; cf Case C-85/76 *Hoffmann-La Roche v Commission* ECLI:EU:C:1979:36, para 116.
34 *Generics* (n 22) paras 150 ff.
35 ibid paras 162 and 165-171 relating to Case C-413/14 P *Intel v Commission* ECLI:EU:C:2017:632 = [2018] GRUR Int 69.
36 ibid para 50; cf Joined Cases C-56/64 and 58/64 *Consten and Grundig v Commission* ECLI:EU:C:1966:41; Juliane Langguth, 'Pay for Delay-Vereinbarung - (k)ein Auslaufmodell' [2020] NZKart 235, 236.
37 Christina Raasch, *Der Patentauslauf von Pharmazeutika als Herausforderung beim Management des Produktlebenszyklus* (2nd edn, Springer 2010); Scott Hemphill and Bhaven Sampat, 'When Do Generics Challenge Drug Patents?' (2011) 8 Journal of Empirical Legal Studies 613, 615.

innovate by allowing him to recoup the investment through a period of exclusivity.[38] Competition law, on the other hand, primarily promotes static efficiency through short-term price and output competition. To a certain extent, it also promotes dynamic efficiency by stimulating investment in new medicines in response to the threat of competition.[39] Consumers benefit from lower prices and more choice. Competition law objectives therefore favour the eradication of weak patents and the identification and punishment of horizontal market-sharing agreements. In principle, the laws of both fields pursue the same goals, the promotion of consumer welfare and innovation.

Similar considerations can be applied to standard-essential patents. In this case, too, a tension is apparent. They are essential IP rights for the use of processes or the manufacturing of products that meet a certain technical standard[40] that ensure that labour is minimised, production costs are reduced and competition is encouraged. In return for standardisation, patent holders undertake to license the right to use the patent to any interested third party on fair, reasonable and non-discriminatory (FRAND) terms. There is a restriction of competition if a FRAND licensing agreement has been concluded and the holder nevertheless files an injunction.[41] Injunctions give far-reaching exclusive rights, which are often abused. The competitive risk is that standard-essential technologies are licensed at prices that do not reflect market values. This relationship of dependency has led to legal disputes for years such that, despite the availability of injunctions, the holder of a weak patent will accept any conditions, especially if litigation costs are high.[42]

Analogous behaviour can be observed in trademark delimitation agreements, whose function is to settle or avoid conflict situations between trademarks. If they refer in a similar way to similar products, there is a risk of confusion. Trademark owners are anxious to prevent a weakening or exploitation of their trademark by delimiting the scope of protection accordingly.[43] As is the case with patents, it is not always clear that a trademark has been infringed, and an agreement is a good alternative in order to avoid expensive legal proceedings. Despite competition-law neutrality towards the exercise of a trademark, agreements fall under Arts.101 and 102 TFEU if they constitute measures restricting competition. They are only permitted if they serve the interests of both parties in determining the extent to which their trademarks are used.[44] An agreement on the market behaviour therefore raises the same competition concerns as pay-for-delay.

38 Steven Anderman and Ariel Ezrachi (eds), *Intellectual Property and Competition Law* (OUP 2011) 248.
39 Feldman and Frondorf (n 11) 138.
40 Commission, 'Guidelines' (n 23) para 252.
41 See Case C-170/13 *Huawei Technologies* ECLI:EU:C:2015:477 = [2015] GRUR Int 942, para 53.
42 For an overview of the main judicial decisions see Clemens-August Heusch, 'Missbrauch marktbeherrschender Stellungen (Art. 102 AEUV) durch Patentinhaber' [2014] GRUR 745; Jeffery Atik, 'The FRAND Ceremony and the Engagement of Article 102 TFEU in the Licensing of Standard Essential Patents' (2019) 42 Fordham Int. Law J. 949.
43 Dietmar Althaus, *Markenrechtliche Abgrenzungsvereinbarungen* (Peter Lang 2010) 49 ff; Philipp Lehmann, 'Kartellrechtliche Grenzen markenrechtlicher Abgrenzungsvereinbarungen' (2017) 6 MarkenR 241.
44 *Consten and Grundig* (n 36) para 580.

b) Patent strength and validity

Judicial practice has repeatedly held that IP rights raise competition concerns only in exceptional situations.[45] If companies unduly delay or hinder the entry of generics, this behaviour is contrary to the open and competitive market environment. The application of competition law to reverse payments is a necessary remedy to market failures: The best economic option for pharmaceutical companies is detrimental to competition, consumers and national health systems. IP rights should by no means be incontestable and should not be excluded from competition law scrutiny, and hence a patent holder should not be able to invoke the exclusionary nature of the patent.

There are therefore good reasons against but also in favour of attacking agreements on the basis of patent strength or validity. Patent strength is important as it gives an idea of the survival rate, and is defined by two main criteria. First, it includes the strength of the legal position (e.g. status in the licensing procedure, scope of protection, available instruments). Secondly, the strength of the patent holder is of relevance (e.g. available financial and personal resources).[46] Although the burden of proof in the assessment of patent solidity and its scope would lie with the Commission, it is not in a good position to do this.[47] Pharmaceutical patents are complex and require extensive chemical knowledge. There simply are no weak or strong patents, only patents. The Commission would have to predict the outcome of a patent dispute. However, pharmaceutical patents are sophisticated and disputes are often dealt with in specialised courts, making prediction unsound. Further, patents are national rights and subject to specific rules and procedures in each Member State,[48] which would undermine legal certainty in pay-for-delay cases and the value of the decision itself. Conversely, the mere fact of this uncertainty about strength or validity suggests that the payments are anti-competitive, that they exclude at least some generics which would actually have a right to compete. In this context, the amount of the payment is closely related to strength: the lower the chances of winning, the greater the willingness to pay. It must therefore be assessed whether the presumably valid patent rights should be examined in terms of value transfer.

c) Transfer of value

In *Generics*, the ECJ dealt intensively with the question of the classification of the transfer of value. In summary, once the transfer is sufficiently advantageous to dissuade the generic company from entering the market, it constitutes a restriction by object.[49] An assessment in the light of the value transfer seems fair, as it covers the behaviour of both companies, and is also the meeting point of mutual interests and an indication of possible collusive behaviour. If the transfer exceeds the likely profits of

45 eg Case C-418/01 *IMS Health* ECLI:EU:C:2004:257 = [2004] GRUR Int 644, para 35.
46 Heinz-Georg Baum, Adolf Coenenberg and Thomas Günther, *Strategisches Controlling* (5th edn, Schäffer-Poeschel 2013) 262 ff.
47 Case C-193/83 *Windsurfing International v Commission* ECLI:EU:C:1986:75, para 26.
48 Pat Treacy and Sophie Lawrance, 'Intellectual Property Rights and Out of Court Settlements' in Anderman and Ezrachi (n 38) 296.
49 *Generics* (n 22) para 95.

generics, it is an indication that the settlement is anti-competitive,[50] since an originator will only accept the cost of a large transfer if it expects its patent to be revoked. However, if the payment is lower than the expected return, this does not directly mean that the settlement is in line with competition law. Not all agreements contain merely a transfer of value, they may also be accompanied by ancillary agreements, such as licensing or distribution agreements.[51] From an economic point of view, there are also pro-competitive reasons to conclude an agreement involving a large amount of money. It should be borne in mind that litigation is inherently uncertain and that an originator can be particularly risk-averse when the profitability of its medicines is at stake. In such a context, it does not seem implausible that the party most at risk will offer the other a large payment. Nor does the settlement of patent disputes prevent subsequent challenges and the entry of generics. For this reason, the author agrees with the ECJ that the value transfer should be included in the assessment of such deals. It is rather obvious that substantial payments are an indication that the aim is not to settle disputes but rather to buy the competition. A large amount of money presupposes a weak patent and the wish to maintain dominance at any price. Nevertheless, the decision should not be based solely on the transfer, but on a case-by-case analysis of all relevant circumstances. It is thus important that courts carry out at least some investigation into the merits of a settlement or claim to ensure that a legitimate dispute is settled.

d) A real legal dispute?

The number of patent disputes being settled is increasing and is having an ever-greater impact on competition. The purpose of a settlement is precisely to resolve existing conflicts or avoid future ones. In the view of the Commission and the Court, a lawful settlement agreement requires actual litigation. The ECJ has not commented on possible justifications. One reason put forward by the companies was that the case involved a 'real' patent dispute. However, the ECJ considered that this was rather evidence of the existence of a potential competitive relationship.[52] *Lundbeck* and *Generics* suggest that even a settlement dealing with a genuine patent dispute may infringe Art. 101(1) TFEU. In *Generics*, there had been litigation between the originator and the generic companies and an interim injunction had been obtained. Such circumstances suggest that there indeed was a genuine dispute. Consequently, it has not been fully clarified to what extent companies can be held accountable. Nor has there been any reference to a wider context, including the assessment of non-aggression agreements. Pay-for-delay agreements often contain non-aggression clauses, in which the generic company undertakes not to challenge the IP right in invalidity or cancellation proceedings. The agreement prevents the generic company from removing a barrier to its economic activity.[53] The same applies to licensing agreements, in which the generic producer is also prevented from entering the market with its own product.

IV. Conclusions

It is legitimate in both the EU and US to pay the generic company the expected legal costs and damages if it is excluded from the market without justification. Patent settlements can be legitimately combined with other types of commercial side deals. Pharmaceutical undertakings must therefore carefully examine each element before entering into a new type of settlement. They should focus on the potential impact on generic entry, which does not mean that originators are not entitled to use legitimate means to protect their rights or monopoly. Furthermore, they are not obliged to facilitate the market entry of generics. Nevertheless, the buying up of generic competition or the creation of artificial barriers will not be tolerated, irrespective of the form of behaviour. A case-by-case analysis is in line with the Court's and the Commission's position that not every settlement can be considered as anti-competitive. The serious disadvantage of this approach is that it deprives companies of legal certainty. The content of their agreements would be revealed by an examination without a foreseeable outcome as to its legality.

The *Generics* judgment is the first time that the ECJ has dealt comprehensively with several concepts of competition law in a pay-for-delay agreement. At this stage, the existence of a patent right as such is not called into question. Accordingly, the analysis of whether a practice amounts to a restriction of competition is made on the assumption that the underlying IP right is valid. However, it must be noted that patent strength is not an insignificant factor, revealing much about the parties' perceptions and intentions. A patent holder cannot legitimately use a large transfer to exchange uncertainty about patent validity or strength for certainty about an extension of his monopoly and the prevention of competition. The element of uncertainty is at the heart of the relationship between patent and competition law, directly affecting the negotiating position of the parties and the timing and conditions for generic entry. European courts are likely to consider factors such as the amount of the payment. The prohibition of large transfers and the insistence on fair patent settlements are necessary steps to restore the balance between patent protection and competition.

It should be noted that a pay-for-delay agreement must be considered both as a restriction by object or effect and as an abuse of a dominant position, particularly where the sole purpose is to delay market entry. It seems clear that non-cash transfers are no longer immune from scrutiny. Agreements that involve large transfers from the originator to the generic company and that (1) are disproportionate to likely legal costs, (2) are very close to or exceed the generic company's potential profits, (3) are independent of other goods or services offered by the generic company, and (4) serve as an incentive not to enter the market are contrary to competition law. In the absence of a legitimate justification, such agreements

50 Jonas Welge, 'Generics (UK) u.a.: EuGH nimmt Stellung zu Pay-for-Delay-Vereinbarungen' [2020] WuW 120, 122.
51 Avantika Chowdhury and Helen Jenkins, 'Inference or Evidence? The Uncertain Fate of Patent Settlement Agreements' (2018) 9 JECLAP 449, 452 ff.
52 *Generics* (n 22) para 52.
53 *Windsurfing International* (n 47); Fabian Böttger and Jan Kresken, 'Nichtangriffsklauseln, Kündigungsrechte und andere Sanktionsklauseln in Lizenz- und Streitbeilegungsvereinbarungen nach EU- und US-Recht' [2014] EuZW 653, 653 ff.

constitute restrictions by object.[54] Hence, it is expected that agreements will be caught under either provision. EU law is unlikely to allow for a full rule of reason method. Defendants in the US are likely to have more arguments to justify why such agreements do not harm consumers, which limits the impact of the *Actavis* decision. Although the Court argues for a non-categorical condemnation of such agreements, in practice it always amounts to a restriction by object. In particular, whenever generic companies take preparatory measures, this will automatically lead to a firm intention. It is impossible for companies to prove pro-competitive effects. The effective enforcement of competition law, however, necessarily requires some assessment of the likelihood of different future outcomes and the balancing of advantages and disadvantages. Before *Generics*, efficiency claims were exclusively assessed under Art. 101(3) TFEU. Fortunately, the ECJ has now extended the analysis to Art. 101(1) TFEU. This is a good step in the right direction, as parties are now able to argue that their agreement is objectively necessary to attain pro-competitive aims or that its pro-competitive potential rules out it being qualified as restrictive by object. The practical impact is likely to remain limited though.

As patent regulations and strategies develop in the pharmaceutical industry, legal analysis and standards will also evolve. It is necessary to adjust competition law in such a way that, on the one hand, the incentive of innovation will not be diluted and, on the other hand, the promotion of an efficient allocation of IP is ensured. It is to be expected that originators will face increasing pressure. The judgment encourages an intensive pursuit of pay-for-delay agreements.[55] The recourse to the value transfer as an essential element will provide authorities with a criterion for review and avoids their interference with IP law. Nevertheless, the Court failed to furnish clear assessment criteria. The *Lundbeck* and *Servier* cases are under appeal and the ECJ will have to rule on two further pay-for-delay cases. It remains to be seen whether the Court will clarify remaining opaque issues or maintain its generic reasoning and wording.

54 Sophie Lawrence and Edwin Bond, '"Reverse-payment" patent settlement agreements: non-cash value transfers are not immune from competition law scrutiny' (2018) 13 JIPLP 552, 554.

55 See also Marc Holtorf and Julia Traumann, 'Zur Wettbewerbswidrigkeit einer Vereinbarung zur Verzögerung einer Generika-Einführung' [2020] GRUR-Prax 132; Christian Burholt, 'Bericht der Europäischen Kommission zur Kartell-und fusionskontrollrechtlichen Entscheidungspraxis im Arzneimittelsektor' [2019] PharmR 95.