The *Lundbeck* Case through the Lens of Probabilistic Patents

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I. Introduction: pay-for-delay agreements and the balance between patent law and competition law

Pay-for-delay agreements, or patent settlement agreements with reverse payment, are agreements concluded between the holder of the patent (originator firm) and the generics supplier in the pharmaceutical industry. They are entered into before the date of the expiry of the patent to avoid litigation concerning the validity of the patent and involve the transfer of value to the generics firm. In addition, they may also cover the delay of the entry of the generic version of the patented drug into the market after the expiry of the patent. Although patent settlement agreements can save cost and time, and promote innovation, they might also raise antitrust concerns. For instance, the prices of the drugs may increase, since the monopoly of the former patent holder is preserved. Consumers may be harmed and innovation hindered.[117] Scrutinising the effects of patent settlements with reverse payments is clearly relevant from a consumer welfare perspective, so that the effects of the conduct in prices and innovation may be monitored by antitrust authorities. Moreover, such arrangements also have significant implications for the application of patent law. In particular, issues might arise in the context of so-called 'weak patents'—that is, those patents that might not be indisputably invalid, 'but nobody knows for sure without conclusive litigation'.[118] In fact, it has been pointed out that patent settlements with large reverse payments will only occur where weak patents exist.[119] Both the consumer welfare and patent law dimensions should, therefore, be considered closely linked in the analysis of this type of agreements.

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[117] For an analysis of the contrasting the approaches taken in the EU and in the USA with regard to reverse patent settlement agreements, see D. Geradin, D. Ginsburg and G. Safty, Reverse Payment Patent Settlements in the European Union and the United States, *George Mason University Legal Studies Research Paper Series* LS 15-22, 2015. See also W. Choi, B. den Uyl and M. Hughes, Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and Others, 5 (1) *Journal of European Competition Law & Practice*, 2014, 44.

[118] J. Farrell and C. Shapiro, How Strong are Weak Patents? 98 *American Economic Review* 4, 2008, 1347-1369, at p. 1347.

[119] See W. Kerber and S. Frank, Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis? *Philipps-Universität Marburg, MACIE Paper Series,* No. 2016/1, p. 2.

The study of patent settlements in the pharmaceutical industry cannot ignore the evidence that suggests that patents are sometimes granted erroneously. While only a small number of patents—about 0.1 per cent—is challenged in court, of those that are challenged around 50 per cent are deemed to be invalid in patent litigation.[120] Such statistics encourage the patent holder to settle if its patent is indeed facing legal action.[121] These patent settlements may have the positive effect of avoiding litigation costs, but they may also create barriers to market entry and hinder competition.

The majority of scholars argues that pay-for-delay agreements must be assessed under competition law. However, there is no consensus as to the most adequate legal solution. Some advocate for a presumption of illegality for pay-for-delay agreements,[122] while others argue that they should be *per se* illegal.[123] Some voices defend analysing them under the rule of reason,[124] and there are also those scholars who propose the application of a structured effects-based approach instead of considering those agreements restrictions by object.[125] The difficulties in striking the right balance between the interests of patent law—in increasing the incentives given to pharmaceutical firms to innovate—and the interests of competition law—in avoiding consumer harm—are, therefore, particular visible in this kind of agreements.

The goal of this article is to analyse the *Lundbeck* case through the lens of probabilistic patent rights theory. As stressed above, the actual scope of a patent right, its commercial value and its validity are contingent questions. These uncertainties are an inherent part of the patent system which require rethinking not only several of the solutions offered by patent law, but also the limits of competition law when it comes to patent settlements. The purpose here is to reflect on the new approach followed by the GC in the *Lundbeck* case, taking into account the theory of probabilistic patent rights. The article first explores the essentials of probabilistic patents theory (part II). It then goes on to discuss the *Lundbeck* case (part III), and the concept of potential competitor that the GC seems to adhere to (part IV). Subsequently, the judgment is placed in the context of previous developments in the EU and

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[120] Furthermore, it has been argued that proving validity and infringement is more difficult for process claims, see, for example, O. Zafar, Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 'Pay-for-Delay' Decisions, 5(4), *Journal of European Competition Law & Practice*, 2014, p. 207.

[121] As Kerber and Frank pointed out, 'from an economic perspective, policy solutions for the weak patent problem in competition law and in patent law are alternative options'. Kerber and Frank (2016) above, p. 26

[122] See H. Hovenkamp et al., *IP and Antitrust,* 2d ed. (Wolters Kluwer, 2010) §15.3a1(C).

[123] M. A. O'Rourke and J. F. Brodley, An Incentives Approach to Patent Settlements, 87 *Minnesota Law Review,* 2003, p. 1767.

[124] R. D. Blair and T. F. Cotter, Are Settlements of Patent Disputes Illegal Per Se? 47 *Antitrust Bulletin,* 2002, p. 491.

[125] S. Gallasch, Activating *Actavis* in Europe – the Proposal of a "Structured Effects Based" Analysis for Pay for Delay Settlements, *University of East Anglia Centre for Competition Policy Working Paper* 15-3, 2016.

US relating to the concept of potential competitors (part V), and conclusions are drawn (part VI).

II. The theory of probabilistic patents explained

The uncertainties as to the commercial significance of patents and as to their validity has been clearly stressed by Mark Lemley and Carl Shapiro in the theory of probabilistic patent rights. They challenge the traditional view that sees patents as well-defined property rights giving their owners a monopoly over a market and competitive advantages. According to the conventional position, once issued patents should be presumed valid, and the owner could, therefore, exclude rivals. Moreover, patents would be issued without engaging in extensive evaluation, which would increase the likelihood of invalidity and put into question the commercial value of the patents. Taking into account these uncertainties, the authors concluded that a 'patent does not confer upon its owner the right to exclude but rather a right to *try* to exclude'.[126] The patent legal framework would thus encourage firms to settle either using reverse payments or other solutions. Among the latter would be licensing agreements with small royalties, for instance. Since some of these agreements should be presumed anticompetitive, particularly patent settlements with large reverse payments, probabilistic patent rights theory suggests that antitrust limits on these settlements are needed.

According to the probabilistic patents theory, the owner of a patent only has a probabilistic right, and is not entitled to conclude an agreement that would harm consumers. It is not easy, however, to identify the agreements that might have such effects. The legal standard proposed by Shapiro compares the welfare for consumers in the case of patent settlements with the one that would be achieved with patent litigation. As he puts it, 'a settlement must leave consumers as well off as they would have been from ongoing patent litigation'.[127] If consumer welfare is lower in the case of patent settlements than in the case of patent litigation, the agreement should be considered anticompetitive and prohibited. In this context, the existence of large reverse payments in excess of the expected costs of litigation leads to the presumption that the patent is weak and that the settlement should be considered anticompetitive.[128]

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[126] M. A. Lemley and C. Shapiro, Probabilistic Patents, 19 (2), *Journal of Economic Perspectives*, 2005, pp. 80, 94-95. See also D. Encaoua and Y. Lefouili, Licensing Weak Patents, 57 *Journal of Industrial Economics*, 2009, pp. 492-525.
[127] C. Shapiro, Antitrust Limits to Patent Settlements, (2003) 87 *RAND Journal of Economics*, 391.
[128] Ibid, pp. 397-408. Shapiro's theory has, however, been criticized, because it cannot be applied to all types of agreements. See P. Régibeau, 'Pay-for-Delay': What Do We Disagree On? 9 (2) *Competition Policy International,* 2013, p. 122.

In addition, if we accept Shapiro's normative standard, the concept of potential competitor under article 101 TFEU should also be redefined. Traditionally, patents were presumed valid until considered void by the competent authorities; generics producers could not, therefore, be considered potential competitors, as patents were well-defined rights and the entry of competitors could only occur in violation of the patents. Through the lens of the probabilistic patent rights theory, potential competitor must be redefined and should also be considered probabilistic: 'a generic entrant would still be seen as a potential competitor if there is a sufficiently high probability that it would actually prevail in litigation and therefore be able to enter the market'.[129]

The probabilistic patent rights theory was also considered by the Supreme Court in the USA. The US pharmaceutical sector is regulated by the Hatch-Waxman Act.[130] The purpose of this Act is encouraging generics manufacturers to challenge invalid patents from the originator firm by offering a 180-day market exclusivity for the first producer challenging the patent to enter the market and to offer generic drugs at a cheaper price. Although in the EU there is no equivalent to the Hatch-Waxman Act, pay-for-delay agreements have also been used frequently in Europe to buy the originator company time to establish a new version of its drug. Such use of pay-for-delay contracts clearly raises antitrust concerns.[131]

III. The *Lundbeck* case: background

On 8 September 2016, the General Court (GC) ruled in *Lundbeck* that competition law rules, namely Article 101 TFEU, apply to patent settlement agreements with reverse payment, and that these should be considered restrictions of competition by object.[132] Lundbeck is a Danish pharmaceutical company which manufactures citalopram, a blockbuster antidepressant. The protection afforded by the firm's compound patent had expired by 2002 in most countries, but over time the company developed other more effective processes for the production of citalopram. Nevertheless, several generics producers were preparing their entry into the market. Lundbeck claimed an infringement of its intellectual property (IP) rights and concluded six agreements concerning citalopram with four generics manufacturers active in the production and/or sale of generic medicinal products. In those agreements, the generics

[129] Ibid, p. 122.
[130] *Drug Price Competition and Patent Term Restoration Act* of 1984, Public Law 98/417.
[131] European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009), para. 1010.
[132] *H. Lundbeck A/S and Lunbeck Ltd v European Commission*, Case T-472/13, 8 September 2016.

producers committed not to enter the market, and Lundbeck offered substantial payments in return.

The GC upheld the European Commission's approach to pay-for-delay agreements. In fact, in the cases *Fentanyl* and *Servier* the Commission had also applied EU competition law provisions to those agreements.[133] In *Lundbeck*, it found that the originator firm and the generics producers were at least potential competitors in the European Economic Area (EEA). Moreover, the agreement involved making significant payments to the generics producers, which were approximately equivalent to the profits expected with the successful entry of the generics into the market. It also restricted market entry for generic producers. As a result, the agreement infringed Article 101 TFEU, and the Commission imposed fines on all the firms involved. The decision was upheld by the GC in September 2016 and, on 18 November 2016, Lundbeck filed an appeal before the Court of Justice against the judgment of the GC.[134]

It should be noted, however, that the principle laid down by the GC in the *Lundbeck* case is that reverse payments are not always problematic. This is particularly the case when that payment is linked to the strength of the patent and does not intend to delay the market entry of generics.[135] That was also the stand taken by the Commission in the *Annual Pharmaceutical Sector Inquiry*, which referred agreements with limitation on generic entry with value transfer as the only ones raising antitrust concerns. Other types of settlements, such as agreements with no limitation on generic entry—so that the generics firm can enter the market freely—or agreements with limitation on generics entry without value transfer from the originator firm—for instance, allowing the generic firm to distribute the drugs of the originator—were not problematic.[136]

Therefore, both the Commission and the GC focused principally on the size of the payments, seemingly leaning on the lessons of the probabilistic patent rights theory. Large reverse payments, unexpectedly high litigation costs and the generics firms' expected market profit, were considered proof that the parties believed the patent was likely to be invalid or at least not infringed by the generics manufacturers, and the main goal of the agreement was the exclusion of potential competitors.[137] In other words, when the reverse payment amount

[133] Case AT.39685 - *Fentanyl* and case AT. 39612 - *Perindopril* (Servier).
[134] Case C-591/16 P, Appeal brought by H. Lundbeck A/S, Lundbeck Ltd against the judgment of the General Court (Ninth Chamber).
[135] *Lundbeck* judgment, para. 350.
[136] European Commission, *6th Report on the Monitoring of Patent Settlements (period: January-December 2014)*, 2 December 2015.
[137] Carl Shapiro, Antitrust Analysis of Patent Settlements Between Rivals, *Antitrust Magazine*, 2003, pp. 70-77, at p. 72.

exceeds the originator's anticipated litigation costs, it will not only delay the expected market entry of the generics firm, but it will also exceed 'the probabilistic patent scope according to the patent holder's own probability estimate'.[138] This test would have the advantage of not requiring an assessment of the patent's merits, which is extremely hard for antitrust authorities, while providing an easy and practical criterion of legality.

Taking this test into account, and considering that Lundbeck's agreements were similar to market-sharing deals,[139] the GC applied Article 101(1) TFEU. The Court concluded that those agreements were restrictive of competition by object.[140] Since the originator firm blocked all competition during a specified period, the arrangements allocated time instead of a territory (as in traditional market-sharing).[141] The examination of the hypothetical counterfactual scenario was considered irrelevant *in casu*, as the CG did not find it necessary to analyse the effects of the agreements on the market under 101(1), and the legal exception of Article 101(3) TFEU was found to be inapplicable.[142]

IV. The concept of 'potential competitor' in the *Lundbeck* case

Ruling that pay-for-delay agreements are restrictions of competition by object was only possible because the GC considered generics producers and Lundbeck to be potential competitors. According to the Court, the generics firms had real concrete possibilities and capacity to enter the market and to compete with established undertakings.[143] Their entry was an economically viable strategy, supported by factual evidence. In fact, the generics producers had taken steps, before the expiry date of the patent, to develop viable production processes and obtain marketing authorizations, and they had already concluded contracts for the supply of generics products.[144] As confirmed by the GC, potential competition takes place in two phases in the pharmaceutical sector. The first phase may start several years before patent expiry on an active pharmaceutical ingredient (API), when generic firms start developing viable production processes. In the second phase, generic firms prepare for actual

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[138] E. Elhauge and A. Krueger, Solving the Patent Settlement Puzzle, 91 *Texas Law Review*, 2012, p. 282.
[139] The uncertainty of patent litigation was replaced by the certainty of delaying generic entry against a large payment.
[140] *Lundbeck* judgment, paras. 161, 355. For a critical view of this solution, see R. Subiotto QC and J. Figus Diaz, *Lundbeck* v *Commission*: Reverse Payment Patent Settlements as Restrictions of Competition by Object, 8(1) *Journal of European Competition Law & Practice*, 2017, p. 27.
[141] See *FTC v. Watson Pharmaceuticals, Inc*.et al., Supreme Court, N0.12-416, On Writ of Certiorari to the US Court of Appeals for the Eleventh Circuit, Brief Amicus Curiae., January 29, 2013. See, however, K. D. McDonald noting that the mere 'existence of the patent right destroys any analogy with market division'. K. D. McDonald, Because I Said So: On the Competitive Rationale of *FTC v. Actavis*, 28 (1) *Antitrust*, 2013, p. 37.
[142] *Lundbeck* judgment, paras. 473, 720.
[143] Ibid, para. 128.
[144] Ibid, paras. 100, 104, 131.

market entry by making applications for marketing authorisations (MAs) and establishing distribution networks. Lundbeck's process patents were not, therefore, capable of blocking all possibilities of market entry open to the generics firms.

As the GC mentioned in that case, according to the undertakings involved the crystallisation patent on which Lundbeck relied in order to close the market entry in the United Kingdom had a good chance (around 60 per cent) of being held invalid by a court.[145] In addition, generics producers did not consider the product as novel. Generic undertakings could thus 'enter the market 'at risk'',[146] and this type of conduct, which has been criticised for endorsing potentially unlawful conduct,[147] should not be considered an infringement of patent law according to the GC.

VI. The *Lundbeck* approach in the light of the previous *praxis* on exclusive rights: what is new?

The solution held by the GC in the *Lundbeck* case has been criticized for being seemingly at odds with the approaches followed by the Commission and the EU courts in their previous decisions.[148] The Commission had already decided that generics firms could not enter the market in a sustainable way if patent litigation was ongoing.[149] The GC, on its part, had already decided in cases involving exclusive rights that potential competition could be set aside. This appears to be the case, for instance, in *E.On Ruhrgas*,[150] which dealt with market-sharing agreements between energy distribution companies by which the undertakings involved agreed not to supply electricity or gas in each other's territories. Here, the GC appeared to suggest that firms could not be considered potential competitors if there were territorial monopolies granted by the State. In *Lundbeck*, however, the GC pointed out that the *E.On Ruhrgas* case should be seen as a totally different matter. In the latter case the national legislation created a *de facto* monopoly, and undertakings were not treated as potential competitors because market entry was not an economically viable strategy.

[145] Ibid, paras. 122, 254.
[146] Ibid, paras. 96, 281.
[147] S. Lawrence, E. Bond, and M. Hunt, Survey - Genentech, Lundbeck, Paramount and Others: A Survey of Cases at the Intersection Between Competition Law and IP Law in the Past Year, 8 (1) *Journal of European Competition Law & Practice*, 2017, p. 66.
[148] Ibid, p. 70.
[149] See Case No COMP/M.6258 - *TEVA/ CEPHALON*.
[150] Case T-360/09 *E.ON Ruhrgas and E.ON v Commission*, ECLI:EU:T:2012:332, para. 84.

Nonetheless, in *Lundbeck* the legal monopoly granted to the patent holder was not considered sufficient to block the potential entrance of generic firms into the market.[151]

Following this logic, it would seem that not all exclusive rights can be considered equal as regards potential competition. While some exclusive rights granted by the State exclude potential competition, the validity of others – such as patents – is uncertain. If the outcome of patent litigation is unclear, the patent holder does not have the right to exclude rivals who are allegedly infringing competition (the alternative could be to seek a preliminary injunction).[152] To put it differently, although there is a *presumption* of patent validity, there is no *certainty* as to the result of the patent litigation. Any decision on that issue would consequently be purely speculative. Moreover, it has been suggested that potential competition could not exist where market entry depends on the infringement of an intellectual property right. For example, in the *Teva/Cephalon* case, as the patent litigation was ongoing, the Commission assumed that the generics firms could not have entered the market in a sustainable way.[153] A similar approach was followed by the Commission in the *Guidelines on the application of Article 101 TFEU to technology transfer agreements*, which confirmed that the possibility that existing IP rights act as a barrier to entry should be considered. The licensee is not a potential competitor if it cannot enter the market without infringing the IP rights of the other party.[154]

The GC ignored all these arguments and clarified that Lundbeck's patents were not considered to constitute a barrier to entry. Therefore, potential competition may exist before the expiry of a patent, as the Court of Justice had already established in the *AstraZeneca* judgment.[155] Although the solution presented has been criticised for rendering the presumption of validity afforded to patents by statute meaningless,[156] the strength or weakness of the patent is still relevant. In fact, the weakness of the patent is evidenced when the originator firm is paying the generic firm large amounts of cash to avoid the risk of litigation. Large reverse payments are thus inconsistent with a claim by the patent holder that its patent would probably be found valid if litigated, and should be presumed to be anticompetitive.

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[151] Ibid, paras. 100 and 816.
[152] Lemley & Shapiro (2005) above, p. 94.
[153] Case No COMP/M.6258 - *TEVA/ CEPHALON*, para. 98.
[154] Communication from the Commission, *Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements*, (2014) C89/03, paras. 129-132.
[155] T-321/05 *AstraZeneca v Commission*, ECLI: EU:T:2010:266, paras.121, 163.
[156] K. D. McDonald (2013) above, p. 74.

Finally, it should be mentioned that the *Lundbeck* analysis set aside the approach taken in the *Windsurfing* case,[157] which accepted the scope of the patent test. This test is somewhat problematic from the point of view of competition law, as it leads to the presumption that the generic product infringes the patent when the issue was not decided. Moreover, it suggests that patents are immune to antitrust laws. Yet the case law of the Court of Justice followed a quite different approach and never exempted patent settlements from antitrust scrutiny.[158] The scope of a patent is not, it appears, immune to antitrust laws; on the contrary, antitrust laws and patent laws should work together to define that scope. Setting aside the scope of the patent test, and allowing competition law to intervene along with patent law in the definition of the scope of the patent, would seem like the best solution.

The approach followed by the GC in the *Lundbeck* case is therefore coherent with the dominant economic literature and particularly with the theory of probabilistic patents rights. In fact, the GC acknowledged the uncertainties inherent to the patent system, as patents are issued with little examination and they will probably be invalid. It held that 'the presumption of validity cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent' and that ''at risk' entry is not unlawful in itself'. [159] Moreover, the GC has relied in the previous case law of the Court of Justice and confirmed that, given the economic and legal context, 'there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market'.[160] Furthermore, the GC decided that there is a high probabilty that generic firms would prevail in litigation: the parties 'estimated the probability that its crystallisation patent would be held invalid at 50 to 60 per cent'.[161] In addition, the GC appears to have accepted that the 'size of a reverse payment may constitute an indicator of the strength or weakness of a patent, as perceived by the parties to the agreements',[162] and that the higher the originator firm estimates the chances of its patent being found invalid, 'the more money it will be willing to pay the generic undertakings to avoid that risk'. [163]

In conclusion, the Court held that it was the 'disproportionate nature of such payments', combined with several other factors , that led to the finding that the agreements at

[157] C-193/83, *Windsurfing International v Commission*, 193/83, ECLI: EU:C:1986:75, para. 26.
[158] C-65/86, *Bayer and Maschinenfabrik Hennecke,*, ECLI:, EU:C:1988:448.
[159] *Lundbeck* judgment, paras. 121 and 122.
[160] Ibid, para. 123.
[161] Ibid, para.122.
[162] Ibid, para. 353.
[163] Ibid.

issue had as their object the restriction of competition.[164] Moreover, the transfer of value 'replaces the autonomous assessment, by the parties, of the strength of the originator undertaking's patents and the assessment of their chances of succeeding in potential litigation based on those patents or concerning their validity'.[165] This means that the GC, without entering into an assessment of the validity of the patent, applied a test which is easy to perform, [166] benefiting from the theoretical framework developed in the context of probabilistic patents rights.[167]

To fully understand the *Lundbeck* judgment, a brief reference to the approach taken in the United States is necessary. Since a detailed analysis is provided elsewhere in this on-topic paper,[168] the focus here will be simply on some those developments that are of particular relevance to this discussion. After a long period of inconsistent case law and conflicting views between the FTC and some courts, the Supreme Court held in *Federal Trade Commission v. Actavis* that large payments made to a generic firm to prevent it from entering the market infringed antitrust rules, subject to a rule of reason analysis. This is so even if the patent settlement is within the scope of the patent, excluding only products allegedly infringing a presumptively valid patent. According to the Supreme Court, the presence of a significant reverse payment in a patent settlement agreement can provide a "workable surrogate for the weakness of a patent, without a court having to carry out a detailed analysis of the validity of that patent".[169] The Supreme Court thus rejected, both the scope of the patent test, and the quick look test.[170] It left, however, several questions unanswered. For instance, it did not clarify whether reverse payments should also include value transfer, such as distribution or license agreements, and it did not detail when a payment is large and unjustified, or how to assess the benefits of the settlement.

Some of these issues were addressed by the Third Circuit Court in the *King Drug* decision in June 2015, and the First Circuit Court in the *Loestrin* decision of February 2016. Those judgments confirmed that the principle laid down *Actavis* can be applied to payments

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[164] Ibid, para. 354.
[165] Ibid, paras. 354 and 360.
[166] On the perception of the probabilistic patents by the GC, see I. Lianos and V. Korah with P. Siciliani, *Competition Law: Analysis, Cases and Materials* (Hart, 2017), Chapter 13.
[167] It should also be noted that the GC follows the principle that competition law only protects lawful competition, and is not intended to protect firms that might infringe IP rights when entering into the market. As Judge Posner put it, "[w]e do not want an efficient market in stolen goods. Cf. Richard A. Posner, *Economic Analysis of Law*, 5th ed. 1998, 91.
[168] K. Fournier, The Notion of 'Potential Competitor' in US Antitrust Enforcement: Pragmatism and Legal Certainty, *Concurrences* No. 2-2017.
[169] Judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission v. Actavis*, 570 U.S. (2013).
[170] *Federal Trade Commission v. Actavis Inc. et al*. Certiorari to the United States Court of Appeals for the Eleventh Circuit, p. 122. See also Schering-Plough Corp. v. FCT 402 F.3d 1065, 1076 (11th Cir.2005), which proposed a test of presumptive illegality followed by a 'quick-look; analysis.

in forms other than cash. The Supreme Court was asked to review and reverse the Third Circuit's unanimous panel decision in *King Drug*, which considered that a no-authorized generic deal (that is to say, the originator firm agrees not to launch its own authorized-generic alternative when the first generic company begins to compete) can be considered a transfer of value to the generic firm and can be scrutinized under antitrust law.[171]

Notwithstanding the questions left unanswered, the approach followed in *Actavis* also takes into account the probabilistic patent rights theory, and the results achieved are not very different from those obtained in the EU context. In fact, in spite of the different regulatory context, the solution proposed by the GC in *Lundbeck* is consistent with the one followed by the Supreme Court: both considered that patent settlements with a high level of value transfer should be subject to antitrust scrutiny, setting aside the scope of the patent test, and both insisted on the uncertainties of this type of IP rights and the specificities of the pharmaceutical sector, calling into the equation the probabilistic patent rights theory.

VII. Conclusion

The specific solution followed in the *Lundbeck* case for pay-for-delay agreements in the pharmaceutical sector must be considered through the lens of probabilistic patents. The GC appears to propose a new approach regarding to the concept of potential competitors. It applied Article 101 TFEU to pay-for-delay agreements and explained that the legal monopoly granted to the patent holder will not exclude potential competition if generics firms have the ability and capacity, in a short period of time, to enter the market. In fact, potential competition may exist even before the exerted patent has expired. Additionally, apparently inspired by the probabilistic patent rights theory, the GC moved away from the traditional view of potential competitor, and decided that generic firms could be potential competitors, if there was a high probability that they would prevail in litigation. Finally, the GC accepted that the existence of large reverse payments should be seen as an indicator of the weakness of the patent and of the anticompetitive nature of patent settlements.

[171] *King Drug Company. of Florence, Inc. v. SmithKline Beecham Corp*., 791 F.3d 388 (3d Cir. June 26, 2015). and *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co.* (In re Loestrin 24 FE Antirust Litig.), 2016 U.S. App. LEXIS 3049 (1st Cir. February 22, 2016).