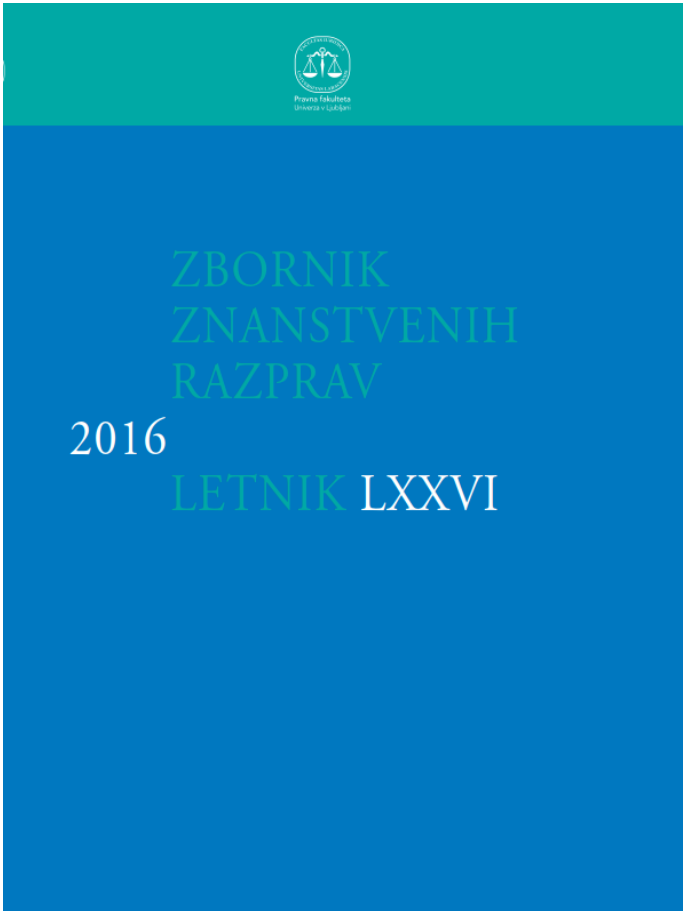

Zbornik znanstvenih razprav
Letnik 76 (2016) / Volume 76 (2016)
November 2016

Spletna stran / Web page:
http://zbornik.pf.uni-lj.si
http://journal.pf.uni-lj.si

9

UDC 347.77:347.9:061.1EU
347.77:347.9(73)

Joseph Straus[*]

"Pay for Delay" – A Subtly Hidden, Overlooked or Ignored Transatlantic Divide: Exemplified on the *Actavis* decision of the US Supreme Court and the *Servier* decision of the EU Commission

Judges are not mere rule appliers. They may to some extent renovate the law, but if they are to discharge this task properly, they must renovate it in the light of the true facts. If they proceed upon the basis of a reality which is untrue, then their formulations will not be soundly based.[1]

1. Introduction

Seldom, if at all, has a legal transaction at the crossroads of antitrust law and patent law attracted such an attention and triggered such highly motivated actions of competition authorities as patent settlement agreements between pharmaceutical – originator companies as owners of challenged drug patents, on the one hand, and generic drug producers as alleged infringers and challengers of those patents, on the other hand, if

[*] Dr. jur., Dres. jur. h.c., Professor of Law at the Universities of Munich and Ljubljana, NIPMO-UNISA Chair for Intellectual Property, University of South Africa (UNISA), Pretoria, Marshall B. Coyne Visiting Professor of International and Comparative Law, George Washington University Law School, Washington D.C. and Emeritus Director at the Max Planck Institute for Innovation and Competition, Munich. This contribution contains some information which the author gained when he submitted legal opinions in support of Les Laboratoires Servier in the European Commission Case COMP/39.612 – Perindopril (Servier), Doc. C (2012) 5513 final; Decision of July 9, 2014, AT.39612 – PERINDOPRIL (Servier). The information is used with the permission of Servier.

[1] Atiyah, Summers, Form and Substance in Anglo-American Law (1987), p. 158.

payments or other benefits accorded to the alleged infringer and challenger by the patentee are involved in the settlement. The contested aspect of such settlement agreements is that a potentially invalid patent remains in force, the generic company does not, or will only later enter the market, and the parties share the extra profits achieved at the expense of customers, who have to pay higher prices, which could not be charged without the patent. Such patent settlements have gained doubtful publicity in legal literature as "reverse payment" or "pay-for-delay" settlements.[2] At first glance every decent citizen and especially one who as patient has to pay higher prices for the medicine she is in need of, would certainly agree, that there is something wrong with such settlements and that therefore they should not be allowed. Only those closely familiar with complexities and uncertainties of patent litigation and also familiar with the role which patent exclusivity plays in the economic context, i.e. as an important incentive for the risky investment in drug development, will chose a more prudent and less pre-determined approach.

The relationship between antitrust law and intellectual property laws, especially patent law, has probably been tense and troubling since its very beginnings and characterized by a mutual distrust of protagonists of either discipline. According to the U.S. Department of Justice and the U.S. Federal Trade Commission,[3] however, antitrust enforcers and the courts have gradually come to recognize that intellectual property laws and antitrust laws share the same fundamental goals of enhancing consumer welfare and promoting innovation. The two U.S. agencies view this recognition as a signal for a

> "significant shift from the view that prevailed earlier in the twentieth century, when the goals of antitrust and intellectual property law were viewed as incompatible: intellectual property law's grant of exclusivity was seen as creating monopolies that

[2] For the abundant literature on this topic in Europe and in the US, reference is made only to Janis, Hovenkamp, Lemley, Anticompetitive Settlement of Intellectual Property Disputes (2003), (http://www.repository.law.indiana.edu/facpub/406); Drexl, "Pay-for-Delay" and Blocking Patents (2009), p. 751 ss.; Adkins, Beighton, Settling for Less? (2011), p. 71 ss.; Brown, Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report (2011), p. 377 ss.; Carrier, Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem (2012), p. 1 ss.; Gurgula, Restrictive Practices in Pharmaceutical Industry (2012), p. 58 ss.; Wooton, Schultz, Federal Trade Commission Continues to Put a Spotlight on Pharmaceutical Patent Agreements (2012), p. 15 ss.; O'Leary, Del-Greco, Reverse Payment Settlement Agreements in the Pharmaceutical Industry (2013), p. 195 ss.; Bagley, Patent Term Restauration and Non-Patent Exclusivity in the US (2013), p. 111 ss. and 117 ss.; Lim, Patent Misuse and Antitrust (2013), p. 252 ss.; Mungen, Reverse Payments, Perverse Incentives (2013), p. 1 ss.; Frank, Kerber, Patent Settlements in the Pharmaceutical Industry, https://leconcurrentialiste.files.wordpress.com/2013/09/patent-settlements-in-the-pharmaceutical-industry-an-antitrust-perspective1.pdf; Hemphill, Sampat, Drug Patents at the Supreme Court (2013), p. 1386 ss.

[3] Report "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition", April 2007 (accessible at http://www.justice.gov/atr/public/hearings/ip/222655.pdf; and www.ftc.gov/reports/index.shtm).

> were in tension with antitrust law's attack on monopoly power. Such generalizations are relegated to the past. Modern understanding of these two disciplines is that intellectual property and antitrust laws work in tandem to bring new and better technologies, products, and services to consumers at lower prices."[4]

Whereas no doubt should exist that the old generalizations about the relationship between the goals of the two disciplines were relegated, this does not necessarily mean that the praised modern understanding of these two disciplines leads to mutually shared legal assessment when specific facts have to be judged. This is true for the situation in the U.S. as well as in Europe. In Europe, however, not only the legal assessment of the relevant facts, but also of their identification and their adequate consideration in the context of the specifically applicable relevant laws gives cause for concern, as it will be discussed and exemplified with the current treatment of "reverse – payment – patent settlement agreements" by the EU Commission.

When I read the EU Commission's Press Release of 9 July 2014 on the fines which the Commission had imposed on the French drug manufacturer Laboratoires Servier and five generic companies,[5] I, as one being familiar with the facts of that case,[6] realized the deep wisdom of the above quoted statement of *P.S. Atiyah* and *Robert S. Summers*. After I read the interesting and well balanced article of my distinguished colleague *Josef Drexl* on the "Pay-for-Delay" Settlement Agreements,[7] in which he, mainly based on EU Commission's Press Release, also reports on and analyses the Servier case, and states that whereas the European Patent Office in 2006 rejected the opposition against Servier's patent, the England and Wales Court of Appeal in 2008 invalidated that patent with "des paroles bien étonnantes et extrêment claires" and quotes from that decision as follows:

> "The upshot of all this is that were the patent valid, Servier's monopoly in practice would last until 2020. But, as the Judge held and we confirm, it is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage."[8]

I felt the irresistible need to bring what I understood to be the "public perception" of the facts underlying the Servier case closer to what I have learned to be the "true reality" in that case. This, on the one hand, because the text quoted by *Josef Drexl*, from the

4 *Ibidem,* p. 1.

5 Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine (IP/14/799). On 9 July 2015, i.e. one year after this press release, the Commission made available "a provisional non-confidential version" of the decision (accessible under http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_11972_5.pdf).

6 See the asterix footnote *supra*.

7 Drexl, Les Règlements Amiables de Type 'Pay-For-Delay' (2015), p. 413 ss.

8 *Ibidem,* p. 414 and footnote 54 referring to the decision of May 9, 2008, *Les Laboratoires Servier and Servier Laboratories Limited v. Apotex Inc. Apotex Pharmachem Inc. Apotex Europe Limited and Apotex UK Limited* [2008] EWCA Civ. 445, para. 9 (Judge Jacob).

very beginning to the very end of Commission's proceedings against Servier has played a crucial role and was treated as a kind of obvious but untested "gold standard" for the assessment of the quality of the patent at issue, and, on the other hand, because very similar statements expressed by the same Lord Justice of the same Court of Appeal when revoking the UK parts of other European patents, have not prevented the UK House of Lords and its successor court, the UK Supreme Court, to reverse such decisions and uphold the respective European patents. For instance, in the *Eli Lilly v. Human Genome Sciences* case the UK Supreme Court in 2011 reversed the Appeal court's decision and upheld the European patent at issue,[9] although the appellate court when invalidating that patent stated:

> "if the patent were valid, […]. The patent system would not be working as it should. It would be operating to prevent research, not to encourage it."[10]

Obviously, the UK Supreme Court was neither impressed nor convinced by "such clear words" that the patent at hand was an invalid patent.

In the following a brief comparative analysis of the Landmark decision of the US Supreme Court of June 17, 2013, in the *Federal Trade Commission v. Actavis Inc. et al.* case (*Actavis*),[11] on the one hand, and of the EU Commission's decision of July 9, 2014 in the *Laboratoires Servier et al.* case,[12] on the other hand, shall be undertaken. Both decisions are dealing with antitrust aspects of "reverse-payment-patent settlement agreements", the so-called "pay-for-delay" issue. In contrast to contributions already published on this topic, [13] in the forefront of the interest of this paper will be the underlying facts of the two cases, i.e. what I understand as their "true reality", which is often and to a certain extent understandingly, missed in scholarly written articles, but has to be viewed as the only decisive basis for administrative and court decisions.[14] It should be added that the Servier decision as yet has been made accessible for the interested public in "a provi-

---

9 *Eli Lilly and Company v. Human Genome Sciences Inc.*, judgment of November 2, 2011 [2011] UKSC 51.

10 *Eli Lilly and Company v. Human Genome Sciences Inc.*, judgment of 9 February 2010 [2010] EWCA Civ. 33, at No. 68. When the Appeal Court reheard the case, the same Justice stated: "So far as the policy questions were concerned, they were the subject of the debate in the Supreme Court. Having lost the policy argument there, Lilly was not entitled to resurrect it in dealing with sufficiency." [2012] EWCA Civ. 33, at No. 69.

11 Case No. 12-146, 570 U.S. 756 (2013).

12 AT.39612 – PERINDOPRIL (Servier).

13 Cf., e.g., Lim, Reverse Payments (2014); Gürkayan, Güner, Filson, The Global Reach of *FTC v. Actavis* (2014), p. 128 ss.; Killick, Berghe, Applying by Object Test to Patent Settlement is Very Different from the Rule of Reason (2014), p. 21 ss.

14 However, one important reservation has to be made in this regard: The decision of the EU Commission in the Servier et al. case in the French version comprises 919 pages altogether. Thus, here only those facts can be addressed upon which the key legal assessments are based.

sional non-confidential" version, and even if and when it will become accessible in the "definitive non-confidential version", it will not reveal all the facts, which have formed an integral part of the case history, but for which the Commission has not found a place to refer to them and even less so to take them into account, in the 919 pages of the decision.

2. The *Actavis* Case

In the *Actavis* case the United States Court of Appeals for the Eleventh Circuit dismissed a Federal Trade Commission's (FTC) complaint that a reverse payment patent settlement agreement between an original drug producer (Solvay Pharmaceuticals), the patentee, and three generic drug manufacturers (Actavis, Inc. [originally Watson Pharmaceuticals], Paddock Laboratories and Par Pharmaceutical), according to which the generic companies agreed that they would not bring their generics to market until 65 months before the patent expires (unless someone else marketed a generic sooner) and the patentee agreed to pay a total of roughly US $ 252 million over nine years, violated the antitrust law.[15] In line with the case law of other U.S. Courts of Appeals,[16] the Eleventh Circuit held that such a patent settlement agreement, absent sham litigation or fraud in obtaining a patent, is generally "immune from antitrust attack so long as its anti-competitive effects fall within the scope of the exclusionary potential of the patent." Since the alleged infringer's promise not to enter the patentee's market expired before the patent's term ended, the Court of Appeals found the agreement valid.[17]

For a correct understanding of this decision of the Court of Appeals, it is necessary to add that, in 1999, Solvay Pharmaceuticals (Solvay) filed a New Drug Application for a brand-name drug AndroGel, which the Federal Drug Administration (FDA) approved in 2000. In 2003 Solvay obtained a respective patent and notified it to the FDA[18] as prescribed by the US Food, Drug and Cosmetics Act (the so-called Hatch-Waxman Act)[19] which FDA must publish upon submission as new patent information, also a requirement of that Hatch-Waxman Act provision. Later in 2003 Actavis, Inc., filed an Abbreviated New Drug Application (a so-called ANDA) under § 355 (j) [2] [a] [vii] [IV] Hatch-Waxman Act (a so-called Paragraph IV Certification), declaring that Solvay's patent is invalid or

15 *FTC v. Watson Pharmaceuticals, Inc.*, 677 F. 3d 1298 (2012).

16 For more on this case law cf. Gürkayan, Güner, Filson, The Global Reach of *FTC v. Actavis* (2014) (2014), p. 133 s. An exception was the Court of Appeals for the Third Circuit in *Re K-Dur Antitrust Litigation,* 686 F. 3d 197 (3d Cir. 2012), which held that reverse-payment agreements have to be treated as presumptively anticompetitive (for more see Gürkayan, Güner, Filson, The Global Reach of *FTC v. Actavis* (2014) , p. 135 s.

17 *FTC v. Watson Pharmaceuticals, Inc.*, 677 F. 3d 1298, 1312 (2012).

18 677 F 3d, at 1308 (2012).

19 21 U.S.C. § 355 (c) (2).

will not be infringed. The party which first files such an application, in this case Actavis, enjoys a 180 days exclusivity, calculated from the first marketing of the drug over all other generic applicants. This means that the FDA will not approve any subsequent ANDA made by another generic competitor until 180 days after either: (1) The first generic competitor commercially markets the generic product; or (2) a court rules that the originator company's patent is either invalid or not infringed by the sale of the generic product. Thus, the Hatch-Waxman Act enables a generic competitor to challenge an originator company's patent arising from infringement following market entry. This privileged position of the first generic ANDA filer is balanced by the entitlement of the originator company to challenge the "Paragraph IV Certification" by commencing a patent infringement action against the generic competitor within 45 days of filing. As a consequence, the originator company may obtain a 30-months stay in respect of the grant of the ANDA by the FDA. In other words, because Solvay initiated "Paragraph IV" patent litigation, it obtained a 30-months stay in respect of the grant of the ANDA by the FDA to Actavis. Actavis, indeed, received the FDA approval 30 months later as the first filer. However, as indicated above, the patent-litigation parties settled all in 2006 under the reported terms, i.e. that they will not bring their generics to market until August 31, 2015, meaning 65 months before Solvay's patent expired. The settlement with the three challengers of the validity of Solvay's patent thus resulted in an extended period of exclusivity of 9 years.

The US Supreme Court by a majority of five justices (Justice Breyer, who delivered the opinion of the Court, in which Justices Kennedy, Ginsburg, Sotomayor and Kagan, joined; Chief Justice Roberts filed a dissenting opinion, in which Justices Scalia and Thomas, joined. Justice Alito took no part in the consideration or decision of the case), however, rejected the view of the appellate court and held that reverse payment settlements such as the agreement in issue can sometimes violate the antitrust laws.[20] In its Writ of certiorari the Federal Trade Commission urged the Supreme Court to, in line with the Third Circuit, hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a "quick look" approach, rather than applying a "rule of reason". The Supreme Court, however, declined to apply that approach. With reference to its holding in *California Dental* case the Court pointed out that abandonment of the "rule of reason" in favor of presumptive rule is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arguments in questions would have an anticompetitive effect on customers and markets."[21] The Supreme Court then went on by stating:

> "We do not believe that reverse payment settlements, in the context we here discuss, meet this criterion. That is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for

[20] *Ibidem,* op.cit. footnote 3, at p. 2.

[21] *California Dental Assn. v. FTC*, 526 U.S. 756, at 775, n. 12, 781 (1999).

> which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases."[22]

Finally, in the *Actavis* dissent, the Chief Justice, joined by two further Justices, emphasized that correct approach of the Court should have been to ask whether the settlement gives the patentee monopoly power beyond what the patent already gave him. The dissent in its introductory note reasons:

> "The Court, however, departs from this approach, and would instead use antitrust law's amorphous rule of reason to inquire into the anticompetitive effects of such settlements. This novel approach is without support in any statute, and will discourage the settlement of patent litigation."[23]

Along the same lines the dissent also emphasized as follows:

> "A patent exempts its holder from the antitrust laws only insofar as the holder operates within the scope of the patent. When the holder steps outside the scope of the patent, he can no longer use the patent as his defense. The majority points to *no* case where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain. Not one. It is remarkable, and surely worth something, that in the 123 years since the Sherman Act was passed, we have never let antitrust law cross that Rubicon."[24]

If anything, the irreconcilable positions taken by the majority and the minority of the U.S. Supreme Court, demonstrate that despite certain approximation of views as regards the fundamental goals of intellectual property law, on the one hand, and antitrust laws, on the other hand, a deep divide continuous to exist as regards the means and ways how to achieve those goals. This although the majority of the Court even did not hold that reverse patent settlement agreements were presumptively unlawful and limited its departure from the settled case law, which had applied the "scope of patent approach", to the context of patent settlement under Hatch-Waxman Act.[25]

---

[22] Under III, at p. 20 of the Opinion.

[23] *Ibidem,* p. 1 of the Dissent. It should also be added here that the dissent made reference to the Court's own case law in which "The Court stressed, over and over, that patent holder does not violate the antitrust laws when it acts within the scope of its patent." *Ibidem,* p. 5 (referring to *Line Material* case, 333, U.S. at 305 and 310 (1948).

[24] *Ibidem,* p. 8. The reaction of the majority of the Court reads as follows: "The dissent does not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication. It would be difficult to reconcile the proposed right with the patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification'." (*Ibidem,* p. 12).

[25] However, Chief Justice Roberts in his dissent expressed the fear that this limitation "will not hold long" (*Ibidem,* p. 11).

3. The Servier Case

3.1. The Decision

With its decision AT.39612 – PERINDOPRIL (SERVIER) of July 9, 2014, addressed to: Servier SAS, Servier Laboratoires Ltd., Les Laboratoires Servier, Adir, Biogaran, KRKA, dd. Novo mesto, Lupin Ltd., Milan Laboratories Ltd., Niche Generics, Teva UK Ltd., Teva Pharmaceutical Industries Ltd., Teva Pharmaceutical Europe, B.V. and Unichem Laboratories Ltd., the European Commission imposed on Servier a fine in the amount of 330.997.200 € for the infringement of Article 101 of the Treaty of the Functioning of the European Union (TFEU) (settlements) and Article 102 TFEU (abusive strategy). The only focus, however, of this paper is the alleged infringement of Article 101 TFEU.

As regards patent settlement agreements Commission's decision emphasizes that Article 101 (1) TFEU prohibits all agreements between undertakings

> "which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market",

and which

> "limit or control production, markets, technical development, or investment"

or

> "share markets or sources of supply".[26]

Thereby the anti-competitive object and effect of an agreement are not cumulative but alternative conditions for assessing whether such an agreement comes within the scope of the prohibition set forth in Article 101 (1) TFEU.[27]

Under the case law to which Commission's decision refers, restrictions "by object" are those which, "by their very nature", can be regarded as being injurious to the proper functioning of normal competition.[28] According to the decision, it is sufficient for an agreement to have an anti-competitive object that it has the potential to have a negative impact on competition, i.e. must simply be capable in an individual case, of resulting in the prevention, restriction or distortion of competition within the internal market.[29]

The Commission emphasizes that, for the purpose of the application of Article 101 TFEU, there is no need to take into account the actual effects of an agreement which has

[26] Para. 1104.

[27] Para. 1109 referring to joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services et al. v. Commission et al.*, [2009] ECR I – 9291, para. 55.

[28] Para. 1110, with references to the case law (Case 19/77 *Miller International Schallplatten v. Commission* [1978] ECR I-131, para. 7 and Case C-209/07 *Beef Industry Development and Barry Brothers* [2008] ECR I-8637, para. 17).

[29] Para. 1111, referring to *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, para. 31; and *Allianz Hungária Biztositó and Others*, C-32/11, EU:C:2013:160, para. 35-38.

as its object the prevention, restriction or distortion of competition within the internal market. Therefore, it is not necessary to show actual anti-competitive effects where the anti-competitive object of the conduct in question is proved.[30] It further emphasizes that "an agreement that may affect trade between Member States and that has an anti-competitive object constitutes, by its nature and independently of any concrete effect that it may have, an appreciable restriction on competition."[31]

As the criteria for assessing the anti-competitive nature if an agreement involves a restriction by object, the Commission's decision enumerates, inter alia, the content of its provisions, the objectives it seeks to attain, the economic and legal context of which it forms a part,[32] and the parties' intention.[33] In this latter regard, the Decision emphasizes:

> "Thus the anti-competitive nature of an agreement may be deduced not only from the content of its clauses but also from the intention of the parties as it arises from the 'genesis' of the agreement and/or manifests itself in the '*circumstances in which it was implemented*' and in the '*conduct*' of the companies concerned."[34]

In principle, Commission's decision does not dispute that companies were entitled to settle litigation "including patent litigation", and that such settlements may benefit both the parties to the dispute, as well as the society at large, "by allowing for more efficient allocation of resources than if all litigations were to be pursued to judgment."[35] However, it emphasizes that holders of intellectual property rights, including patent rights, are not immune from the application of competition law,[36] and that also settlement agreements between competitors can fall within the prohibition of Article 101 (1) TFEU. In this context the Commission refers to the Court of Justice's statement in *Bayer AG and Maschinenfabrik Henecke GmbH v. Heinz Süllhöfer* that

---

30 Para. 1112, again referring to *T-Mobile Netherlands and Others*, *supra* footnote 29 at para. 31; *Allianz Hungária Biztositó and Others*, *supra* footnote 29, at paras. 28-30; and joined cases P *GlaxoSmithKline Services and Others v. Commission and Others,* C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU: C: 2009:610, *supra* footnote 27, at para. 55.

31 Para. 1112, quoting from *Expedia*, C-226/11, EU:C:2012:795, para. 37.

32 Para. 1113, referring to joined cases *GlaxoSmithKline Services and Others v. Commission and Others*, *supra* footnote 27, at para. 25 and *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paras. 16 and 21.

33 Para. 1113, with references to the joined cases in *IAZ International Belgium and Others v. Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paras. 23 to 25, and joined cases in *GlaxoSmithKline Services and Others v. Commission and Others, supra* footnote 27.

34 Para. 1113 (emphasis in the original), referring to joined case*s IAZ International Belgium and Others v. Commission*, *supra* footnote 33, paras. 23-25; and, *inter alia*, *Société Technique Minière v. Maschinenbau Ulm*, 56/65, EU:C:1966:38; joined cases in *CRAM v. Commission*, 29/83 and 30/83, EU:C:1984:130, para. 26.

35 Paras. 1102 and 1118.

36 Para. 1119 with some case law references in footnote 1570.

> "In its prohibition of certain 'agreements' between undertakings, Article 85 (1) makes no distinction between agreements whose purpose is to put an end to litigation and those concluding with other aims in mind."[37]

As regards patent settlement agreements Commission's decision on the one hand admits that although where parties can reasonably disagree on the validity of a particular patent or whether that patent has been infringed and there is genuine uncertainty as to the outcome of litigation, it could be reasonable to reach a patent settlement, notwithstanding the utility of having judicial decisions,[38] but on the other hand considers that,

> "depending on the specific circumstances of the case, a patent settlement agreement by which a generic company accepts restrictions on its ability and incentives to compete in return for a value transfer (either in the form of significant sums of money or other significant inducements) can be a restriction of competition by object contrary to Article 101 of the Treaty."[39]

The Commission argues that a patent litigation settlement between originator and generic companies which is reached on the basis of each party's assessment of the patent case before them, even though it may contain a non-compete, or a non-challenge clause, were unlikely to infringe competition, because the resulting limitations on the commercial behaviour of the generic undertaking are a direct and exclusive result of the strength of the litigated case, as perceived by each party and are not the result of an additional transfer of value from the originator to the generic.[40] That such circumstances were lacking in the Servier case the Commission fleshed out by characterizing Servier's patent using the pejorative quote from the decision of the England and Wales Court of Appeal[41] according to which it was

> "the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. But this is not one of them. … *The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest.*"[42]

---

37 Case 65/86, [1988] ECR I-5249, para. 15. Reference is also made to Case 35/83 *BAT Cigaretten-Fabriken GmbH v Commission* [1985] ECR 363, para. 33 (footnote 1575).

38 Para. 1133.

39 Para. 1134.

40 Para. 1136.

41 *Supra,* footnote 8.

42 Para. 1132 and footnote 1584 (emphasis added by the Commission). It is a matter of serious concern that the Commission misses entirely to mention that the "only solution" identified by Jacob LJ are not decisions of lower courts, but of courts of last instance, which, as exemplified above (footnotes 9 and 10, and the accompanying text) can well differ from those of appellate courts.

Presumably in view of the perceived facts in issue, the Commission goes on by emphasizing that the situation were very different when the settlement has been affected by elements extraneous to the dispute / litigation. According to the Commission

> "This is notably the case where the originator pays significant sums of money, or offers other compensation (for example, a market sharing arrangement), to the generic company as consideration for a significant restriction of the generic company's commercial behaviour, limiting its independent efforts to enter one or more EU markets with a generic product (a "reverse payment" situation). This is not foreseen by the patent system. While a patent holder has the right to oppose possible infringement of his patent, patent law does not provide for a right to pay actual or potential competitor to stay out of the market or to refrain from challenging a patent prior to entering the market. The means used by patent holders to defend their rights matter. It is not because the patent, if valid and infringed, grants the patent holder certain rights to exclude that any means used to obtain the exclusionary result would necessarily be compatible with competition law. In particular, payments made by patent holders to generic challengers aimed at persuading them to stop or delay their independent efforts to enter the market may well, in certain specific circumstances, fall afoul of Union competition law. Indeed, even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they constitute a breach of Article 101 of the Treaty when those limitations cannot be justified and do not result from the party's assessment of the merits of the exclusive right itself but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market."[43]

Commission's decision further holds that patent settlements by definition avoid an authoritative, judicial decision on the merits. Therefore, the outcome of litigation cannot be established with certainty. It was obvious that a settlement prevents a patent dispute/litigation from reaching an authoritative judicial decision on merits. The question of whether the agreements entailed actual effects was not relevant for the purpose of competitive assessments (of restriction by object).[44] What, according to the Commission matters,

> "is if a reverse payment settlement collusively removes a potential competitor and affects the structure of the market,"

because Article 101 TFEU also protects the structure of the market and thus competition as such.[45] It was therefore, in the case at issue, not only inappropriate, but also unnecessary, for the Commission to rely on posterior court decisions or perform an own assessment, of the likely outcome of the patent dispute / litigation.

---

[43] Para. 1137.

[44] Para. 1144.

[45] Ibidem, with reference to the ECJ judgment in *T-Mobile Netherlands and Others, supra* footnote 29, paras. 38-39.

Eventually, Commission's decision sets forth that the assessment of whether the patent settlement agreements at issue are restrictions by object will depend on the facts relating to each agreement, which will be examined on a case-by-case basis. In order to identify whether each agreement had the potential to restrict competition by its very nature, the analysis will in particular take into account whether:

– the generic undertaking and the originator undertaking were at least potential competitors
– the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EU markets with a generic product, and
– the agreement was related to a transfer of value from the originator undertaking as a significant inducement which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter one or more EU markets with the generic product.[46]

The Commission, in principle, suggests that a generic drug producer in possession of a marketing authorization should launch the product "at risk," if it in its own assessment believes that the patents are not valid and not infringed. In its view such a launch *per se* is neither "illegal" nor unlawful, and the marketing authorization approval does not depend on the patent status of the originator. It is for the courts to establish infringement and it is on the patentee to prove the infringement. The Commission does not entirely put into question that in the case at hand such risks existed, [47] but then uses the ex post experience of Apotex' of how well such an approach could work:

> "By way of example, it cannot be said that Apotex' entry at risk in summer of 2006 violated Servier's patent rights, although Servier alleged patent infringement and even obtained an interim injunction. The ensuing patent litigation namely resulted in a judgment invalidating the '947 patent in the UK, and the corresponding award of damages to Apotex."[48]

What is missing in the arguments used by the Commission is a reference to cases in which "risk taking" under comparable circumstances ended with an exactly opposite result because they were litigated to the end and were decided by the House of Lords, respectively the UK Supreme Court.[49]

---

[46] Para.1154.

[47] Para.1176.

[48] Para. 1177 of the Decision.

[49] In addition to the UK Supreme Court Decision in *Elli Lilly v. Human Genome Sciences* (see *supra* the text accompanying footnotes 9 and 10) reference can be made, e.g. to the judgment of the UK House of Lords of 9 July 2008 in *Conor MedSystems Inc. v. Angiotech Pharmaceuticals* ([2008] R.P.C. 28, p. 716), in which the same Lord Justice to whose assessment of the contested Servier patent the Commission repeatedly referred to and, actually, based its entire case on it, when revoking the European patent at hand, first criticized the Dutch Court which had upheld the Dutch part of that

3.2. Servier's Patent – "The Stumbling Block" – and its Invention

Servier's contested patent relates to a specific crystalline form of perindopril tert -butylamine salt. The substance perindopril, which belongs to a so-called third generation of angiotensin-converting enzyme (ACE) inhibitors, was first synthesized in 1982 by Servier researchers. After several years of pre-clinical research and intensive development, perindopril was made available for treatment of hypertension throughout the European Community in 1988. Two patents for the synthesis of building blocks of perindopril were granted by the EPO and expired in 2008. It should be noted and emphasized that apart from the methods for synthesis of perindopril patented for Servier, alternative methods for synthesizing the two key intermediaries of perindopril existed long before the expiry of the two patents.

Since 1988 Servier has concentrated its efforts on improving, inter alia, the crystallization reaction of the perindopril tert-butylamine salt, whose operation conditions were suboptimal due to small variations, which had the potential to influence its crystalline morphology, with the consequence of great variability between batches in terms of cycle time (filtration and drying) as well as particle size. For instance, the variability in cycle times made it impossible to plan the production of one batch per day. The variability of particle size distribution, on the other hand, had caused problems in tableting, where particle size distribution is of special importance. The reproducibility of particle size distribution is an essential factor in guaranteeing the content uniformity and in vitro dissolution speed of tablets. Since certain countries, as for instance Japan, have stricter particle size requirements than others, the observed variability in particle size meant that specific batches had to be selected for some countries, creating expensive storage constraints. Furthermore, a product that was off-specification with regard to its crystalline morphology, had to be re-crystallized, adding an extra cost.

In order to overcome the deficiencies of the crystallisation, filtration and drying steps of perindopril tert-butylamine salt, Servier in 1997 entered into a collaboration with a

European patent, that it formed its view "with the hindsight knowledge that Taxol stents work", and then reasoned his annulment of the patent, *inter alia* by stating: "But this is miles away from indicating that Taxol is a particularly suitable anti-angiogenic for a drug eluting vascular stent or that the CAM assay is a test for a drug which will actually work to prevent restenosis in a drug eluting vascular stent." When the House of Lords reversed that decision of the Court of Appeal and upheld the patent, Lord Hoffmann commented, first, "I do not think that this is a fair criticism. The Dutch court was not addressing…" As to the quote from the reasons of the decision of the Appellate Court, Lord Hoffmann stated:
"If, by using the word 'indicating', Jacob LJ meant 'proving', then of course I agree. The specification did not prove that Taxol would work. If, however, he meant that it did not claim that Taxol would work, then I would regard it as a very narrow approach to the meaning of the patent, more suitable to old-fashioned statutory construction than to what the skilled practitioner in cardio-vascular intervention would have understood." ([2008] R.P.C. 28, paras. 38-39 at p. 729).

crystallization laboratory at the University of Rouen. After three years of cooperation the outcome was the invention, eventually protected by the vilified patent. As the respective patent documents reveal, Servier as applicant and patentee indicated as inventors three employees of the University of Rouen and one of its own employees. The joint inventors of the University of Rouen and Servier succeeded in finding a special salt of perindopril, which can be obtained in a well-defined crystalline form, which is perfectly reproducible and has in particular interesting characteristics as regards filtration, drying and the ease of formulation. Thus, this should be made clear, whereas the "stumbling block" patent covered a special salt of perindopril, all product patents related to the substance perindopril had expired. In other words, only the special salt of perindopril was protected by a so-called "secondary patent", the compound perindopril could be freely produced, used, etc.

3.3. Opposition Against EP '947

Servier's patent was opposed by altogether ten parties, Niche Generics Limited, Quimica Sintetica S.A., Norton Healthcare Ltd., Glenmark Pharmaceuticals Ltd., Polpharma, Mieszkowska, Agnieszka, AMCA Consulting, Lupin Limited, Hetero Drugs Limited, Krka Tovarna Zdravil, d.d. and Ratiopharm GmbH.

The Opposition Division of the EPO (OD) has carefully examined all arguments raised by opponents, including those raised by opponent Niche, who in the course of opposition proceeding withdrew its opposition, and found in its decision of July 27, 2006 all objections raised by opponents against sufficiency of disclosure (Article 83 EPC), lack of novelty (Article 54 EPC), and lack of inventive step (Article 56 EPC) unfounded.

3.4. UK Infringement and Validity Suits between Servier and Apotex and between Servier and Krka

Five days after the decision of the Opposition Division of the EPO by which its patent was upheld, Servier launched patent infringement proceedings against the Apotex Group in the High Court of Justice Chancery Division, Patents Court.[50] Pending trial, on August 8, 2006, Servier obtained an interim injunction against Apotex, preventing it from importing, offering to sell or selling its perindopril in UK.[51]

On August 2, 2006 Servier launched patent infringement proceedings before the High Court of England and Wales also against Krka and filed a motion for grant of an interim injunction. On September 1, 2006 Krka counter-claimed for invalidity of Servier's patent. On October 4, 2006, the UK High Court granted Servier's motion for

[50] Case No. HC06CC3050, before Mr. Justice Mann, [2007] EWHC 1538 (Pat).

[51] Except for fulfilling some old contractual obligations (No. 43 of the Judgment).

preliminary injunction against Krka and rejected Krka's summary judgment motion of September 1, 2006 for invalidation of the patent, as insufficient to avoid a full trial.[52]

In the decision of the UK High Court by which Servier was granted motion for preliminary injunction and in which the motion of Krka for summary judgment was rejected, Mr. Justice Kitchin, a very experienced patent judge with high international reputation (now Lord Justice at UK Court of Appeal), stated as regards the question of the validity of EP '947 *inter alia*:

– In the light of all this evidence it is, in my judgment, impossible to say that there is no issue to go to trial on the question of anticipation or obviousness of the Patent over 341. I reach this conclusion for all of the following reasons.[53]
– First, there is clearly an acute conflict on the evidence as to whether the skilled person would implement the teaching of Stage 3D of 341 by actively cooling the solution or by letting it cool naturally.[54]
– Second, the experimental evidence relied upon by Krka only goes so far as to show that the alpha crystal form of perindopril is produced when the solution is cooled naturally.[55]
– Third, it is true to say that the Patent discloses a method of making the alpha crystalline form which involves a particular controlled cooling regime. The cooling regime is, however, a slow one.[56]
– Fourth, it is at least arguable in the light of the evidence of Professor Motherwell that the skilled person would be concerned to cool the solution as quickly as possible to avoid adverse side reactions of the kind which he has described.[57]
– Fifth, there is no evidence before me upon from which I can safely conclude at this stage that such rapid cooling will necessarily produce the alpha crystal form. On the contrary, the evidence filed by Servier suggests that rapid cooling to a low temperature will produce something other than the alpha crystalline form, namely, a form similar to the beta crystalline form.[58]
– It is admitted that Servier sold Coversyl tablets before the priority date. However, it is not admitted that the tablets contain the alpha crystalline form of perindopril, nor that the disclosure was enabling.[59]

---

52 Case No. HC06C03051, before Mr. Justice Kitchin, [2006]. EWHC 2453 (Pat).

53 Ibidem, No. 45.

54 Ibidem, No. 46.

55 Ibidem, No. 47.

56 Ibidem, No. 48.

57 Ibidem, No. 49.

58 Ibidem, No. 50.

59 Ibidem, No. 53.

– This is, to my mind, powerful evidence. But it proceeds on a number of assumptions. First, it is important to have in mind that the tablet itself reveals nothing about the crystal form of the perindopril it contains. At the priority date of the Patent, there was no knowledge or understanding of the different crystal forms of perindopril and there is no disclosure of these different forms or how to make them in 341.[60]
– To my mind, an important point emerging from this evidence is that it is far from clear that it would occur to the skilled person to carry out the reverse engineering process that Mr. Ward described. Whether or not it would be possible to make it work in practice is one issue. As I have indicated, I certainly have powerful evidence to suggest that it would. However, another issue is whether or not the skilled person would embark upon the task at all. It is on this point that I understand the opinions of the experts differ.[61]

Such a detailed reproduction of reasons for a summary judgment in a contribution dealing with antitrust aspects of patent settlement agreements may seem superfluous and odd, but appears necessary because it reflects the true facts of the case, which should be made known to all interested and discussing the case, but cannot be found in the 919 pages of Commission's decision, where Mr. Justice Kitchin's judgment the Commission, based on a secondary source (!), has summarized as follows:

> "However, the High Court found in October 2006 that Krka had strong arguments with which to question the validity of the patent, and that certain of its evidentiary assumptions were compelling [reference to ID 0103, p. 75]. The judge found that it was impossible to say that there is no issue to go to trial on the question of anticipation or obviousness of the Patent over 341' and thus ordered a full trial, it also considered that Krka had 'a powerful base for the attack on the validity of the patent for lack of novelty or obviousness over 341'."[62]

In the light of the numerous arguments which Mr. Justice Kitchin found in support of potential validity of Servier's patent, reproduced above, it does not seem unfair to characterize the summary provided by the Commission as "a reality which is untrue" in the sense of the quote from Atiyah and Summers.[63] And the idea suggests itself, how could Mr. Justice Kitchin, whose competence has brought him to the UK Court of Appeal, overlooked that he brought forward so many detailed arguments speaking in favour of the validity of a patent, which was not only invalid but "the sort of patent which can give the patent system a bad name" and should be revoked "before it does too much harm to the public interest"? In fact, Mr. Justice Kitchin's appraisal of the chances that Servier's patent will be held valid, was certainly shared by patent granting authorities of Australia,

60 Ibidem, No. 61.

61 Ibidem, No. 66.

62 Para. 904 of the decision.

63 *Supra*, footnote 1.

Croatia, Estonia, Hong Kong, Japan, Mexico, Montenegro, Morocco, New Zealand, Norway, Republic of Korea, Serbia, Tunisia, Ukraine and the Eurasian patent authority, where Servier was granted the patent.[64]

In the *Servier v. Apotex* case on July 6, 2007, i.e. six months after Servier and Krka have settled,[65] the UK Patents Court by Mr Justice Pumfrey held Servier's patent invalid for lack of novelty and inventive step. Mr. Justice Pumfrey in his decision made no single reference to the decision of the Opposition Division of the EPO, but permitted the appeal.[66] Servier appealed the Patents Court judgment to the Court of Appeal (Civil Division) which on May 9, 2008 dismissed the appeal.[67] As regards the substantial reasons given by Lord Justice Jacob for the revocation of Servier's patent, but which somehow went lost in the general outrage about the bad patent, they appear, prudently judged, relatively thin:

> "I agree it is not permissible to do that. But I do not begin to see why taking into account the post-claim knowledge that only three forms have been discovered, when trying to decide whether a particular crystalline form is the claimed product, involves hindsight construction. You know that the claimed product is to have the properties shown in the table, give or take a bit. You have a product whose properties are close to those specified. Knowing that that there are only three possibilities and that the other two are very different leads you to the conclusion that the one you have is that of the claim – it cannot be anything else."[68]

3.5. Revocation of Servier's Patent by the EPO Board of Appeal

On the appeal from the decision of the Opposition Division, filed originally by ten opponents and still pursued by six of them, on May 6, 2009 the Technical Board of Appeal (TBA) of the EPO revoked Servier's patent.[69] Norton Healthcare Ltd., a subsidiary of the Teva Group, which also settled its patent litigation with Servier,[70] and one of the remaining six opponents, submitted the judgements of the UK courts by which the UK part of Servier's European patent was revoked. The TBA revoked Servier's patent for lack of novelty and for obviousness and explicitly emphasised that it had to take

---

64 For the sake of completeness only, it should be noted that where the patent was subsequently revoked, the act of revocation followed the revocation by the EPO Board of Appeal.

65 See *infra* 4. Servier – Krka Patent Settlement and other Agreements.

66 [2007] FSR 37 at No. 10.

67 Case No. A 3/2007/1715 [2008] EWCA Civ. 445.

68 Ibidem, No. 32 and No. 33.

69 T 1753/06 – 3.3.01.

70 The Settlement and Exclusive Purchasing Agreement which Teva signed with Servier on June 13, 2006 (see *infra* 6. Commission's New Approach), did not prevent Teva to oppose Servier's patent in the EPO.

into account all arguments brought forward against the validity of the patent, i.e. also by those opponents which withdrew their oppositions. The TBA, which needed some 60 pages to reason its decision (!), also rejected Servier's request to refer the case to the Enlarged Board of Appeal of the EPO, because according to Servier the intention of the TBA to take into consideration facts and evidence (faits et preuves), which constituted part of the UK judgments would contradict the established EPO case law. In this respect the Board stated:

> "Cependant, la chambre ne fonde pas sa décision sur le raisonnement ou la conclusion des jugements britanniques, mais seulement sur les faits et les preuves y mentionnés. Elle les examine et tire ses propres conclusions en application de la CBE, particulièrement les articles 54 et 56 CBE. Cependant, la chambre ne dévie pas de la jurisprudence constante des chambres de recours, comme établie notamment dans la décision T 452/91."[71]

It is a matter of great concern that UK courts can invalidate European patents, i.e. their UK part, before the final decision on their validity is taken in opposition and opposition appeal proceedings in the EPO.[72] If judgments of the UK lower courts, which maybe would not stand scrutiny by the UK Supreme Court, are submitted in the EPO opposition proceedings, this indirectly can lead to final revocation of a European patent for all designated states, including the UK, without any possibility to reach the UK Supreme Court! The EPO Boards of Appeal, no matter how highly regarded, and also no matter what they explicitly state as regards their independence, are faced, as in the case of Servier, with a situation, in which, for instance, concurring with the EPO Opposition Division and its objective arguments, and upholding the patent, would signify to contradict a UK Lord Justice, who not only revoked the UK part of that patent, but had characterized it as "the sort of a patent which can give the patent system a bad name" and which should be revoked "before it does too much harm to the public interest." Members of the Boards of Appeal of the EPO, with all due respect for their high quality expertise,[73]

---

[71] Ibidem, 12.4. Cf. on this practice also Stothers, EPO Revokes Patent in Record Time (2012), p. 880 ss.

[72] It should be noted that under Section 81 (2) of the German Patent Act, an action for revocation (nullification) of the German part of a European patent cannot be filed with the German Federal Patent Court as long as the opposition and opposition appeal proceedings before the EPO can be filed or are still pending. Because of the so-called bi-furcated German system, which does not allow the alleged patent infringer to challenge the validity of the allegedly infringed patent by counterclaiming invalidity in the infringement litigation, but has to file the nullity action in the Federal Patent Court, she is prevented to file any such action pending opposition proceedings in the EPO.

[73] It should be emphasized that the UK House of Lords has explicitly recognized the high quality of decisions of the EPO Boards of Appeal. In the *Merrell Dow Pharmaceutical Inc. v. H.N. Norton & Co., Ltd.*, Lord Hoffmann stated as follows:
"It is therefore the duty of the United Kingdom Courts to construe Section 2 so that, so far as possible, it has the same effect as Article 54. For this purpose, it must have regard to the decisions

do not dispose of the sovereign thinking and even less so sovereign acting as the UK law lords, who "stand above the things", only committed to law and their persuasion and who are not exposed to unqualified criticism.

4. Servier – Krka Patent Settlement and other Agreements

The literal reproduction of arguments which Mr. Justice Kitchin put forward in favour of the validity of Servier's patent, however is also a must, because it presents, together with the decision of the Opposition Division of the EPO, the only objective and impartial yardstick for perceiving "the strength of the litigated case," which Servier and KRKA had at their disposal when they concluded the patent settlement agreement on October 27, 2006.

Prior to addressing some details of that agreement it seems appropriate to point out how difficult and risky it is to "perceive" the strength of a patent infringement case, and why parties have good reasons to settle despite their possibly positive "perception". This has been impressively explained by the US Court of Appeals for the Eleventh Circuit in the *FTC v. Watson Pharmaceuticals, Inc.* case.[74] When the Court rejected the Federal Trade Commission's antitrust claim based on allegation that Solvay was "not likely to prevail" in the underlying infringement action against Watson, Par and Paddock, the Court stated, *inter alia*:

– The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is 'likely' to fail actually will fail. 'Likely' means more likely than not, and that includes a 51% chance of a result one way against a 49% chance of a result the other way around.
– Giving the word its plain meaning, as many as 49 out of 100 times that an infringement claim is 'likely' to fail it actually will succeed and keep the competitor out of the market. Our decisions focus on the potential exclusionary effect of the patent, not the likely exclusionary effect…
– In few cases that are settled is the probability needle pointing straight up, one side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty. Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not only for the side that is likely to lose but

of the European Patent Office ("EPO") on the construction of the EPC. These decisions are not strictly binding upon courts in the United Kingdom but they are of great persuasive authority; first, because they are decisions of expert courts involved daily in the administration of the EPC and secondly, because it would be highly undesirable for the provisions of the EPC to be construed differently in the EPO from the way they are interpreted in national courts of a contracting state." [1996] R.P.C. 76 at 82 (H.L.).

74 677 F. 3d 1298 (2012); 102 USPQ 2d 1561 (at 1571).

also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking…

– …That companies with conflicting claims settle drug patent litigation in these circumstances is not a violation of the antitrust laws.[75]
– That reality and those risks are precisely why a party is likely to choose to settle a patent dispute even if it might well prevail. When hundreds of millions of dollars of lost profits are at stake, 'even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.'…
– Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects.'[76]
– There are other reasons to reject the FTC's approach. It would require an after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled. Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages.[77]

As a consequence, the ability to terminate a legal dispute by a settlement is viewed as the most basic element of the power of disposal of the parties to a civil law suit.[78] *Eike Ullmann* (later on Presiding Judge at the German Federal Supreme Court), specifically stated in the context of direct interest here:

> "If one would require objective accuracy as the yardstick for an effective injunctive agreement admissible under the anti-trust law, this would result in a fundamental denial of a dispute mediating regulation of the patent infringement litigation through such an agreement. In the majority of patent infringement litigations an interpretation is required, the result of which is not above any reasonable doubt. Existing doubts could only be removed by judgments of the courts of the last instance. Making their assessment (in way of the validity control of the injunctive settlement) to the standard of the antitrust admissibility, would lead to the unreasonable, and the doctrine of party control in civil litigation contradicting result, that the parties had to desist from peaceful resolution of the law suit."[79]

---

75 *Ibidem*.

76 *Ibidem,* pp. 1571-1572.

77 *Ibidem,* p. 1572.

78 Ullmann, Gedanken zur Partei Maxime in Patentverletzungsstreit (1985), p. 811 [English translation J.S.].

79 1985 GRUR, 812 [English translation J.S.].

It is, therefore, not surprising that in the periods from 2001 to 2006 of the 308 patent cases pending before the German Federal Supreme Court only 111 were resolved by a judgment.[80]

In the patent settlement agreement of October 27, 2006 Servier and Krka essentially agreed that, on the one hand, Servier will withdraw litigation against Krka based on claims of infringement of its patent, including motions for interim injunctions, worldwide. On the other hand, that Krka will withdraw any claims against the validity of the two patents. As a consequence, UK patent infringement proceedings were discontinued and the preliminary injunction was lifted. On the same date Servier and Krka also signed a "License Agreement" and on January 5, 2007, an "Assignment and License Agreement".

Under the "License Agreement" Servier granted to Krka the exclusive, irrevocable license on its patent, to use, manufacture, sell, offer to sale, promote and import products which contain crystalline form α of perindopril tert-butylamine salt in Czech Republic, Hungary, Lithuania. Latvia, Poland, Slovakia and Slovenia. Servier thereby retained the right to directly or through one of its affiliates or through solely one third party also serves those markets. As remuneration Krka had to pay Servier 3% royalties on its net sales prices. The validity of the "License Agreement" was directly linked to the validity of the licensed patent.

Under the "Assignment and License Agreement" Krka transferred and assigned to Servier two PCT patent applications. One related to an invention of "A process for preparing a solid pharmaceutical composition of perindopril or a salt thereof", the other to "A process of the preparation of Perindopril and Salts thereof." As consideration for the transfer of property rights in these two PCT applications, Krka received in total € 30 Million. Moreover, after the ownership title was transferred to Servier, Servier granted to Krka a non-exclusive, irrevocable, non-assignable, royalty free license with no right to sublicense (other than to Krka's affiliates) on the two applications, ensuing patents. Krka committed itself, not to challenge the validity of either of any patents granted on the basis of either of the two PCT applications. It should be added that Servier prosecuted the two PCT applications in a great number of countries and was granted patents, *inter alia*, in Australia, Canada, Japan, South Africa, Ukraine, the USA and by the Eurasian patent authority.

5. Other Contested Servier Agreements with Generic Drug Producers

Servier concluded patent settlement agreements as well as license and/or assignment agreements related to patent applications and/or patents or product portfolios also with

[80] See for details Mes, Reflections on the German Patent Litigation System (2009), p. 401 ss. (at p. 409 and footnote 32).

other generic drug producers as already mentioned at the outset of this paper.[81] It goes without saying, that neither the specific facts underlying those agreements, nor any of their details can be reported and analysed here. It should suffice and satisfy the purpose of this contribution to only generally touch upon some of their essential aspects.

Except for Krka, those generic companies had no marketing authorisation for selling a generic form of perindopril in the European Union. In fact, for technical problems, they were quite far from obtaining the necessary approval when they signed the agreement(s). None of the agreements had any impact on the pending opposition and later on opposition appeal proceedings in the EPO,[82] thus has in no way prevented a judicial test of validity of Servier's patents. Servier was fully aware of this fact, as it was of the fact of the pending litigation with Apotex in the UK courts, that was equally entirely unaffected by the settlement agreements. Servier never either approached any of the opponents or Apotex suggesting a settlement. In no single of those agreements has a contracting party entered in any obligation beyond the scope of Servier's patents. Thus, there was no delay as regards entry into the market agreed upon beyond the validity of the patent. All payments or other benefits which Servier accorded to the contracting parties of those agreements were as a rule a consideration for acquired technology and/or intellectual property rights. As in the case of acquired Krka's PCT applications, Servier prosecuted the acquired IP rights worldwide and was granted patents, e.g. in Australia, Canada, Israel, Japan, New Zealand, South Africa, the USA and by the EPO and in Eurasian patent procedure.[83] Thus, the acquired IP rights have strengthened Servier's global competitiveness.

---

81 *Supra* 3.1.

82 According to Rule 84 (2) of the Implementing Regulations to the EPC, the Opposition Division can continue the opposition proceedings of its own motion even when the opposition is withdrawn. Under the established case law of the EPO Boards of Appeal, the situation differs at the opposition appeal level in case the only remaining opponent withdraws opposition. Such a withdrawal is interpreted as the withdrawal of the appeal by the opponent and therefore terminates the proceedings when the opponent in question is the only appellant (cf. Singer, Stauder, Günzel, The European Patent Convention (2003), Art. 101, note 92 and Singer, Stauder, Bostedt, Europäisches Patentübereinkommen (2016), Art. 101, notes 87-90). As it is well known, 6 opponents/appellants were involved in the pending opposition and opposition appeal proceedings even after Servier settled with some opponents. Also, in opposition and opposition appeal proceedings, the Opposition Division and the Board of Appeal of the EPO have to take into account also arguments brought forward by those opponents who withdrew their opposition.

83 For the sake of completeness it has to be noted that not for all acquired patent application have patents been granted in all the named countries. The main issue, however, is, that Servier has with considerable financial means and human resources prosecuted worldwide the acquired rights and considerably improved its competitiveness.

6. Commission's New Approach

In the Servier decision the Commission, as a matter of principle, decided that settlements of patent disputes involving "reverse payments" constitute a restriction of competition "by object" under Article 101 (1) TFEU with all the far reaching legal consequences. The three criteria developed by the Commission[84] which, if met, examined on the facts of each settlement, lead to a restriction of competition "by object", irrespective of whether those settlements had in fact restrictive effects on competition. The Commission has rejected the "scope-of-the-patent" test as the basis for judging whether a patent settlement agreement constitutes a restriction by object. In the Commission's view this would not be in the interest of competition in the pharmaceutical sector and would tend to perpetuate very high costs to consumers for medicine compounds whose patent protection has expired.[85]

The Commission was keen to demonstrate that its approach is supported by the case law of the Court of Justice of the European Union. It uses as evidence for instance the early judgment of the Court in *BAT Cigaretten-Fabriken GmbH v. Commission* case.[86] Whereas it is correct that the court in *BAT* held that "delimitation agreements", although lawful and useful for the parties, were not excluded from application of Article 85 of the Treaty, if they also have the aim of dividing up the market or restricting competition in other ways,[87] plainly invoking this holding as being to the point raises concerns: Apart from the fact that the *BAT Cigaretten-Fabriken GmbH* case related to a trademark "delimitation agreement", the restrictions accepted by one of the parties were clearly not covered by the trademark law provisions, which means that they were outside the "scope-of-the-trademark". This, because *BAT* was the proprietor of an unused, dormant trademark, which was liable to be removed from the register upon application by any interested party. Therefore, the opposition of *BAT* formed part of its efforts to control the distribution of the competitor, with whom it settled the case, and constituted an abuse of the rights conferred upon it by its trademark ownership.[88] Thus, an absolute certainty existed that the *BAT's* trademark would have been removed from the register, had the case not been settled. Moreover, the settlement agreement contained a "no-challenge" clause, by which, the parties admittedly intended "to consolidate the position" of the *BAT* trademark "even after it had ceased to be legally protected."[89]

84 See *supra* text accompanying footnote 46.

85 Para. 1193.

86 Case C 35/83, *ECR 1985: 00363.*

87 *Ibidem,* para. 32.

88 *Ibidem,* para. 35.

89 *Ibidem,* para. 26. It should further be observed that Segers, as the party to the settlement agreement with *BAT* also waived his right to claim priority for his trademark even after the expiry of the legal protection period of five years (*Ibidem,* para. 34).

When applying the restriction "by object" rule under Article 101 (1) TFEU to patent settlement agreements it has also to be borne in mind that such findings have immediate criminal consequences.[90] In view of such severe consequences Article 101 (1) TFEU with its open list of the respective types of such restrictions, requires, as put forward by Advocate General Wahl, a relatively prudent attitude for determining a restriction of competition 'by object'.[91] Such an attitude will by necessity qualify an agreement as restriction 'by object' only if it intrinsically presents a certain degree of harm. Advocate General Wahl explicitly emphasized in this regard:

> "Ne devraient donc être considérés comme restrictifs de concurrence par objet que les comportements dont le caractère nocif est, au vu de l'expérience acquise et de la science économique, avéré et facilement décelable, et non les accords qui, au vu du contexte dans lequel ils s'insèrent, présentent des effets ambivalents sur le marché ou qui sont porteurs d'effets restrictifs accessoires nécessaires à la poursuite d'un objectif principal non restrictif de concurrence."[92]

The interpretation of Article 101 (1) TFEU by Advocate General Wahl, has been, in principle, confirmed by the Court of Justice of European Union in its decision of September 11, 2014 in the same case.[93] Therein, the Court, fully relying on its established case law, clarified the circumstances under which the concept of restriction of competition by "object" can be applied. It, first, emphasized that such a restriction is at hand only if the coordination [i.e. agreement] reveals in itself a sufficient degree of harm to competition.[94]

The Court then went on in stating:

> "Secondly, in the light of that case law, the General Court erred in finding, […], that the concept of restriction of competition by "object" must not be interpreted 'restrictively'. The concept of restriction of competition 'by object' can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects, otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which are in no way established to be, by their very nature, harmful to the proper functioning

---

90 Cf. opinion of Advocate General Sharpston in case C-272/09, *KME Germany AG v. Commission,* para. 64.

91 Opinion of Advocate General Wahl in case C-67/13 *Groupement Cartes Bancaires v. Commission*, para. 58.

92 *Ibidem,* para. 56.

93 Case C-67/13P *Groupement des Cartes Bancaires (CW) v. European Commission*.

94 *Ibidem,* para. 57, referring to Case C-56/65 *LTM v. Maschinenbau Ulm,* EUC:C:1966:38, para. 359 and 360 , Case C-209/07 *Competition Authoritiy v. Beef Industry Development Society Ltd. and Barry Brothers (Carrigmore) Meets Ltd.,* EU:C:2008:643, para. 15; Case C-32/11 *Allianz Hungária Biztositó and Others*, EU:C:2013:160, para. 34 with further case law references.

> of normal competition. The fact that the types of agreements covered by Article 81 (1) EC do not constitute an exhaustive list of prohibited collusion is, in that regard, irrelevant."[95]

It has to be observed that this criticism of the Court relates, inter alia, to the statement of the General Court that "… it is sufficient that the agreement…has the potential to have a negative impact on competition. In other words, the agreement or decision must simply be capable in the particular case…"[96], which implies that "a potential", or a "simple capability" do not suffice, rather the respective type of agreement as such must reveal a sufficient degree of harm to competition.

In criticizing the findings of the General Court the CJEU made two further statements of interest in the context at hand. It criticized that although the General Court took the view that the restrictive object of the measures at issue could be inferred from their wording alone, but that it did not at any point explain, in the context of its review of the lawfulness of the decision at issue, in what respect that wording could be considered to reveal the existence of a restriction of competition "by object" within the meaning of Article 81 (1) EC.[97]

Finally, the Court also criticized that the General Court, although it set out the reasons why the measures at issue, in view of their formulas, are capable of restricting competition and, consequently, of falling within the scope of the prohibition laid down in Article 101 (1) EC,

"it in no way explained – contrary to the requirements of the case law referred to… – in what respect that restriction of competition reveals a sufficient degree of harm in order to be characterized as a restriction 'by object' within the meaning of that provision, there being no analysis of that point in the judgment under appeal."[98]

The reasons given by the CJEU for its holdings in the Groupement Cartes Bancaires Case[99] specify, in principle, the Commission's Guidelines on the application of Article 101 (3) TFEU, which in para. 21 characterizes the restriction of competition "by object" as

> "...restrictions which in light of the objectives pursued by the Community Competition Rules have such a high potential of negative effects on competition that it is unnecessary for the purposes of applying Article 81 (1) [101 (1)] to demonstrate any actual effects on the market. The presumption is based on the serious nature of the restriction and on experience showing that restrictions of

[95] *Ibidem,* para. 58.

[96] *Ibidem,* para. 55, reproducing para. 125 of the decision of the General Court.

[97] *Ibidem,* para. 65.

[98] *Ibidem,* para. 69.

[99] See *supra* 14.5.1.

> competition by object are likely to produce negative effects on the market and to jeopardize the objectives pursued by the Community Competition Rules."[100]

Thus, a "high potential of negative effects" can only be affirmed if the agreement in itself reveals a sufficient degree of harm to competition.[101] As a consequence of this judgment, apart from the so-called hardcore anti-trust cases, the Commission will be faced with high hurdles for qualifying agreements as intended restrictions of competition, especially by invoking internal documents of participating companies.[102]

Because the patent settlement agreements are at issue and in view of the fact that the Commission's Decision makes a great number of references to the established case law, emphasizing that the exercise of intellectual property rights is not immune against the rules of antitrust law, it is necessary not only to point out the exceptional importance of patents, especially in the area of pharmaceuticals, for incentivizing and shielding the risky R&D activity in drug development, but also to emphasize that the established case law of the ECJ and also of the General Court repeatedly held that intellectual property rights may only be made to yield to competition concerns in exceptional circumstances.[103] As the Grand Chamber of the General Court in the Microsoft Corp. v. Commission decision of 2007 summarized the respective case law of the ECJ, thereunder even

> "the refusal by an undertaking holding a dominant position to license a third party to use a product covered by an intellectual property right cannot in itself constitute an abuse of dominant position within the meaning of Article 82 EC. It is only in exceptional circumstances that the exercise of the exclusive right by the owner of the intellectual property right may give rise to such an abuse."[104]

Finally, the Commission's new Guidelines on The Application of Article 101 TFEU to Technology Transfer Agreements of 2014[105] put the interplay between competition rules and intellectual property rights into a clear and balanced perspective. Para. 7 sets forth:

---

[100] Guidelines on the application of Article 81 (3) of the Treaty (2004/C101/08, OJ No. C101/97 of 27.4.2004.

[101] Sina Tannebaum (Tannebaum, The Concept of Restriction of Competition 'By Object' and Article 101 (1) TFEU (2015), p. 138 ss.), observes in this regard: "The judgment clarifies that the Commission must show likely effects on competition unless it is clear that the anti-competitive behaviour sufficiently harms competition by its very nature. Complex measures might not be subject to the 'by object' standard because the contextual analysis is not suitable for determining in what respect a certain restriction of competition reveal a *sufficient* degree of harm in order to be characterized as 'restriction by object' under Article 101 (1) TFEU. A more detailed effects-based analysis has to be carried out especially if no precedent exists." Ibidem, p. 148.

[102] Cf. von Köckritz, Comment on the CJEU Judgment (2014), p. 908 s.

[103] See eg. case C-418/01 *IMS Health v. NDC Health* [2004] ECR I-5039, para. 35.

[104] Case T201/04 *Microsoft Corp. v. Commission*, Reports of cases 2007 II-036001, para. 331.

[105] OJ No. C89/3 of 28.3.2014.

> "The fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention. Article 101 of the Treaty is in particular applicable to agreements whereby the holder licenses another undertaking to exploit its intellectual property rights. Nor does it imply that there is an inherent conflict between intellectual property rights and the Union Competition Rules. Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof."

Commission's new Guidelines also cover the treatment of so-called non-challenge clauses in settlement agreements. Para. 242 provides that in the context of a settlement agreement, non-challenge clauses are generally considered to fall outside Article 101 (1) of the Treaty. It were inherent in such agreements that the parties agree not to challenge ex post the intellectual property rights which were the center of the dispute, because it were the very purpose of the agreement to settle existing disputes and/or to avoid future disputes.

In the following Para. 243 the Guidelines, however, first lay down that under certain specific circumstances such clauses in settlement agreements can be anti-competitive and may be caught by Article 101 (1) TFEU. The reason being that the restriction of freedom to challenge an intellectual property right is not part of the specific subject-matter of an intellectual property right and may restrict competition. Such could be where an intellectual property right was granted following the provision of incorrect or misleading information [here referring to Case C-457/10P, AstraZeneca v. Commission], or if the licensor, besides licensing the technology rights, induces, financially or otherwise, the licensee to agree not to challenge the validity of the technology rights or if the technology rights are a necessary input for the licensees production.[106]

7. Concluding Remarks

Whether the patent settlement agreements which Servier concluded with other addressees of the Decision fall under Article 101 (1) TFEU, i.e. constitute a restriction "by object", depends on whether each agreement reveals in itself a sufficient degree of harm to competition that it may be found that there is no need to examine their effects. In order to make such findings, it is, however, necessary to establish that they are, by their

[106] Para. 243 of the Guidelines.

very nature, harmful to the proper functioning of normal competition.[107] As the Court in Groupement des Cartes Bancaires emphasized, in this context it is also necessary to explain in what respect the wording of the settlement agreements could be considered to reveal the existence of a restriction of competition "by object" within the meaning of Article [101 (1) TFEU].[108]

Next, the question arises, whether on the basis of the three criteria developed by the Commission[109] the required tests under Groupement des Cartes Bancaires can be properly performed. When applying that test, it certainly can either be ignored that all obligations the parties entered into were within the scope of the patent (EP '947) or that the non-challenge clauses, in view of the procedural rules controlling the opposition and opposition appeal proceedings under the EPC, had no impact on the ongoing challenge of the validity of EP '947. Moreover, all payments which Servier, either directly agreed upon in settlement agreements or in separate licensing or assignment agreements of patent applications and patents respectively, under the given circumstances, can neither be characterized as "reverse payment", nor as an "inducement" to agree to a proposed settlement, nor can they be by their very nature harmful to the proper functioning of normal competition.[110]

Reducing the ability of originator and generic undertakings to settle patent litigation and agree on "non-infringement", or on, inter alia, "non-challenge" clauses only in cases where the settlement is a "direct and exclusive result of the strength of the litigated case, as perceived by each party and are not the result of an additional transfer of value from the originator to the generic"[111], practically prevents parties at hand to make any reasonable settlements, because they are divested of any reasonable possibility to settle based on their technical, commercial, financial and other realities. As the Servier case blatantly demonstrates, the parties can even not rely on the appraisal of the litigated case by a most experienced judge, such as the present Lord Justice Kitchin!

It seems as if the test whether the third requirement under the test developed by the Commission, i.e. that the agreement was related to a transfer of value from originator undertaking as a significant inducement which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter the market with the

[107] CJEU Case C-67/13P *Groupement des Cartes Bancaires v. Commission*, para.s 57 and 58.

[108] *Ibidem,* para. 65.

[109] Para. 1154 of the Decision (see *supra* text accompanying footnote 46).

[110] To license a valid patent for the term of its validity to only some of the EU Member States, as in case of the license agreement between Servier and Krka, cannot by the very nature of such an agreement be harmful to the proper functioning of a normal competition. If so, such license agreements could not be explicitly allowed under Article 3 (2) third subparagraph of the Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of unitary patent protection (OJ EU No. L 361/1 of 31.12.2012).

[111] Para. 1136 of the Decision.

generic product[112] is to be found in para. 1188 of the Decision. Thereunder, in the context of interest here, in case that "value transfer" between originator and generics consists "of a series of two-way transactions", a reverse payment to the generic company is represented by a difference between the value flowing from the originator to the generic company and the flow of value from the generic to originator, which may represent the "inducement" for the generic company to settle, instead to, relying on own assessment of the validity of the patent in suit, its potential infringement and the strength of the parties involved.

To the understanding of this writer, a patent litigation settlement agreement which provides that, for instance the originator – patent owner – whose allegedly infringed patent's validity has been challenged by the alleged infringer – the generic company, will be granted a license in one or more patents, patent applications, etc. of the generic company, or will acquire such rights against consideration, whatever form it may have, i.e. lump sum, royalties, milestones, etc., and that, e.g. the generic company will not challenge the contested patents, cannot by itself be qualified as a "type of coordination which reveals a sufficient degree of harm to competition that it may be found that there is no need to examine their effect", i.e. as by their very nature be harmful to the proper functioning of normal competition.[113]

The position taken by the Commission that such settlements were no longer based on the party's assessment of the validity of the patent, its alleged infringement and the corresponding strength, meaning the strength exclusively rooted in the party's assessment to win or to loose, in other words in the "probability to prevail", or having "genuine doubt", does not stand scrutiny. Such an understanding of the complexities of patent litigations, and especially those in the area of pharmaceuticals, obviously either ignores or at least overlooks real and legitimate interests of the parties involved in such litigation. Those interests may reflect, literally speaking, a plethora of very real technical, financial, commercial or even human resources problems, which may, even combined, play a decisive role when such settlements are agreed upon. The so-called "two-way transactions" may be "induced" by any of those factors and may, or may not be linked entirely, partly, or not at all to the difficult prediction on the merits of the patent in suit, but do not and cannot, as a so called "value transfer" and inducement have the consequence that agreements involving such transaction, be qualified as a type of coordination, which in itself reveals a sufficient degree of harm to competition and by this very motive, be harmful to the proper functioning of the normal competition, as required under Groupement des Cartes Bancaires judgment. In this context it has to be explicitly emphasized that a restriction of competition, which may result from such settlements, under Groupement Cartes Bancaires judgment is by no means sufficient to be qualified as restriction "by

[112] Para. 1154.

[113] ECJ C-76/13P., *Groupement Cartes Bancaires* paras. 57 and 58.

object" under Article 101 (1) TFEU. This is only the case if it is established "in what respect that restriction of competition reveals a sufficient degree of harm." Thus, neither the restriction of competition as such, nor a restriction of competition causing some harm meets the standard for being qualified as restriction "by object". Instead, in addition to the restriction of competition it must reveal also a sufficient degree of harm.

It does not seem redundant to recall that the US Supreme Court in Actavis, despite the Hatch-Waxman Act "factor", which because of its direct impact on the date of entry of generics into the market, could, if anything, make "reverse payment settlements" between originators and generic companies appear as a special type of patent settlements, with an impact alien to and beyond the reach of patent settlements in other areas, has refused to treat "reverse payment patent settlements" as "presumptively unlawful".[114]

Treating patent settlement agreements with "value transfer" as restriction "by object" under Article 101 (1) TFEU, has far reaching and immediate criminal consequences. It should be beyond doubt that this requires particularly high standards as regards legal certainty. Insofar the criteria set forth by the Commission for the settlement agreements to be qualified as restriction "by object" can be viewed as an invitation for using discretionary power, leaving the parties involved in the dark. If, as assumed, para. 1188 of the Decision constitutes a decisive yardstick for finding a patent settlement agreement with "two-way transactions" as a restriction "by object", this would certainly result in the opposite of what is to be understood legal certainty. According to that test, only the circumstances directly linked to the, not really predictable, merits of the case count, all other relevant and legitimate circumstances co-responsible for the parties to settle are ignored. Moreover, and not less important, the "inducement", the actual "bone of contention", should be established as "difference between the value flowing from the originator to the generic company and the flow of value from the generic to originator." Quite apart from the more than challenging issue of calculating such a difference, which would have to take into account flows of often very dissimilar means, a calculation of a difference, which would not and probably could not take into account all motives of the parties involved, which were legitimately decisive for the settlement, would ultimately link the calculated difference – i.e. the inducement – to be in fact arbitrary judgement on the "genuine doubt" on the validity of the patent in suit.

Lastly, but of crucial importance: If the Commission is about to adopt a new approach in a context which touches upon fundamental issues not only of patent law but also of fundamental rights of litigating parties, i.e. to renovate in an area of law in which no real precedents exist, the least what is required is that it "must renovate in the light of true facts" and not "proceed upon the basis of a reality which is untrue."[115] The main aim of this contribution was to bring to the light a number, although by no means all

[114] See *supra* 2.

[115] In the sense of the quote of Atiyah and Summers (see *supra* footnote No. 1).

important and relevant facts and highlight some aspects of the Servier case, which cannot be found in the decision of the EU Commission. It is hoped that this will allow or even incentivize a more in-depth and objective fact based analysis of the new approach applied by the Commission.[116] Finally, it is also hoped that this paper will contribute to a better understanding of the main differences which exist between the relevant provisions of the EU law and the US law, as interpreted and applied by the EU Commission and the US Supreme Court, respectively.

Bibliography

Adkins, Bernadine; Beighton, Sam: Settling for Less? "Reverse Payment Settlement" Agreements Under US and EU Competition Law, in: Bio-Science Law Review 11 (2011), pp. 71–77.

Atiyah, P.S.; Summers, Robert S.: Form and Substance in Anglo-American Law, A Comparative Study in Legal Reasoning, Legal Theory and Legal Institutions, Clarendon Press, Oxford 1987.

Bagley, Margo A.: Patent Term Restauration and Non-Patent Exclusivity in the US, in: Pharmaceutical Innovation, Competition and Patent Law (Ed. Drexl, Lee), Edward Elgar Publishing, Cheltenham (UK), Northampton, MA (USA) 2013, pp. 111–141.

Brown, Melanie J.: Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report: A Missed Opportunity to Benefit from U.S. Experience, in: Columbia Journal of Law & the Arts, 33 (2011), pp. 377–407.

Carrier, Michael A.: Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem, in: Stanford Technology Law Review, 16 (2012), pp. 1–8.

Drexl, Josef: "Pay-for-Delay" and Blocking Patents – Targeting Pharmaceutical Companies under European Competition Law, in: International Review of Intellectual Property and Competition Law, 40 (2009), pp. 751–755.

Drexl, Josef: Les Règlements Amiables de Type 'Pay-For-Delay': Playdoyer Pour Une Reforme du Systeme Reglementaire des Brevets Pharmaceuticques en Europe, in: Droit, Économie et Valeurs – Hommage à Bernard Remiche (Eds. Autenne, Cassier, Strowel), Larcier, Brussels 2015, pp. 413–437.

[116] There are many important issues in the Servier case worth an in-depth research, but not at all touched upon in this paper, such as for instance: how can a drug which can easily be substituted by at least twenty other equally efficient or even better drugs and which in most EU Member States has a market share below 5% have a dominant market position?

EU Commission Press Release of 9 July 2014, Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine (IP/14/799).

Frank, Jonas Severin; Kerber, Wolfgang: Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective, in: Wettbewerb und Regulierung in Medien, Politik und Märkten, Festschrift zum 65. Geburtstag von Jörn Kruse (Ed. Dewenter, Haucap, Kehder), Baden-Baden, Nomos, 2013, pp. 385–413. Accessible at: https://leconcurrentialiste.files.wordpress.com/2013/09/patent-settlements-in-the-pharmaceutical-industry-an-antitrust-perspective1.pdf (last visited 11 June 2015).

Gurgula, Olga: Restrictive Practices in Pharmaceutical Industry: Reverse Payment Agreements – Seeking for a Balance Between Intellectual Property and Competition Law, The Interdisciplinary Center for Competition Law and Policy (ICC), in: Global Antitrust Review, 5 (2012), pp. 58–105.

Gürkayan, Gönenç; Güner, Ayşe; Filson, Janelle: The Global Reach of *FTC v. Actavis* – Will Europe Differ from the US Approach to Pay-for-Delay Agreements?, in: International Review of Intellectual Property and Competition Law, 45 (2014), pp. 128–160.

Hemphill, C. Scott; Sampat, Bhaven: Drug Patents at the Supreme Court, in: Science, 339 (2013) 1386, pp. 1386–1387.

Janis, Mark D.; Hovenkamp, Herbert J.; Lemley, Mark A.: Anticompetitive Settlement of Intellectual Property Disputes, in: Minnesota Law Review, 87 (2003), pp. 1719–1766. Faculty Publications, Paper 406, accessible at: http://www.repository.law.indiana.edu/facpub/406 (last visited 11 June 2015).

Killick, James; Berghe Pascal: Applying by Object Test to Patent Settlement is Very Different from the Rule of Reason, in: Concurrences, (2014) 2, pp. 21–24.

Lim, Daryl: Patent Misuse and Antitrust, Edward Elgar Publishing, Cheltenham, UK, Northampton (MA) 2013.

Lim, Daryl: Reverse Payments – Life after *Actavis*, in: International Review of Intellectual Property and Competition Law, 45 (2014), pp. 1–5.

Mes, Peter: Reflections on the German Patent Litigation System, in: Patents and Technological Progress in a Globalized World – Liber Amicorum Joseph Straus (Prinz zu Waldeck and Pyrmont, Wolrad *et al.* (eds.)), Springer, Heidelberg 2009, pp. 401–411.

Mungen, Murat C.: Reverse Payments, Perverse Incentives, in: Harvard Journal of Law & Technology, 27 (2013) 1, pp. 1–48.

O'Leary, Julianne; Del-Greco, Joseph: Reverse Payment Settlement Agreements in the Pharmaceutical Industry: Settling the Debate Between Pro-Exclusivity and the Pro-Competition Principles of Antitrust Law, in: Bio-Science Law Review, 13 (2013), pp. 195–203.

Singer, Margarete; Stauder, Dieter (Bostedt, Frédéric): Europäisches Patentübereinkommen, 7th ed., Carl Heymanns, Cologne, etc. 2016.

Singer, Margarete; Stauder, Dieter (Günzel, Brigitte): The European Patent Convention, Vol. II., 3rd ed., Thomson, Sweet & Maxwell, Carl Heymann, Cologne, Berlin, Bonn, Munich 2003.

Stothers, Christopher: EPO Revokes Patent in Record Time. Relying on Documents Disclosed in the UK, 2012 PTCJ, pp. 880–883.

Tannebaum, Sina: The Concept of Restriction of Competition 'By Object' and Article 101 (1) TFEU, in: Maastricht Journal of European and Comparative Law, 22 (2015) 1, pp. 138–148.

U.S. Department of Justice and the U.S. Federal Trade Commission, Report "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition", April 2007 URL: http://www.justice.gov/atr/public/hearings/ip/222655.pdf; and www.ftc.gov/reports/index.shtm (6 June 2016).

Ullmann, Eike: Gedanken zur Partei Maxime in Patentverletzungsstreit – Geständnis, Anerkenntnis, Prozessvergleich (Deliberations on Parties Disposal in Patent Infringement Litigation – Guilty Plea, Acknowledgement, Litigation Settlement), 1985 GRUR, pp. 809–813.

von Köckritz, Christian: Comment on the CJEU Judgment, in: Europäische Zeitschrift für Wirtschaftsrecht, (2014), pp. 908–909.

Wooton, Barbara H.; Schultz, Matthew: Federal Trade Commission Continues to Put a Spotlight on Pharmaceutical Patent Agreements, in: Intellectual Property & Technology Law Journal, 24 (2012) 12, pp. 15–20.

Pay for Delay (plačilo za zakasnitev) – subtilno skrita, spregledana ali ignorirana čezatlantska »razpoka«: Obravnavana na osnovi sodbe ameriškega zveznega Vrhovnega sodišča v zadevi *Actavis* in odločbe Evropske komisije v zadevi *Servier*

(Povzetek)

Na področju, na katerem se soočata antimonopolno (kartelno) pravo in patentno pravo, so v preteklosti pravni posli redko pritegnili tako veliko pozornost organov, pristojnih za varovanje konkurence, kot pogodbe, s katerimi t. i. inovativna farmacevtska podjetja kot lastniki patentov, katerih veljavnost je izpodbijana, poravnajo spore s proizvajalci t. i. generičnih zdravil, toženih za kršitev teh patentov, katerih veljavnost oni izpodbijajo, če so na podlagi poravnave upravičeni do denarnih plačil ali drugih koristi. Oblasti takim poravnavam očitajo predvsem: 1. da je njihova posledica nadaljnja veljavnost potencialno neveljavnih patentov; 2. da generična oziroma cenejša zdravila na trg sploh ne pridejo ali pa se to zgodi z veliko zamudo; in 3. da si stranke takih pogodb delijo dodatne dobičke na račun potrošnikov, ki morajo plačati višje cene, kot bi jih lahko proizvajalci zahtevali brez patentov. Take poravnave so na obeh straneh Atlantika v strokovni literaturi poimenovane plačilo za zakasnitev (angl. *pay for delay*) ali poravnave patentnih sporov z obratnim plačilom (angl. *reverse payment patent settlement agreements*) – plača torej tožnik, lastnik patenta, ne pa toženi, kot bi bilo običajno –, pridobivajo pa vprašljiv sloves. Vsak razumen človek, predvsem bolniki, ki plačujejo višje cene zdravil, bi menil, da bi morale biti take pogodbe prepovedane, tisti, ki poznajo kompleksno problematiko patentnih sporov in njihov nepredvidljiv izid in ki jim je poznana pomembna vloga patentov kot spodbude za in varstvo visokih ter zelo tveganih investicij za raziskave in razvoj novih zdravil, pa zavzemajo previdnejše in manj vnaprej opredeljeno stališče.

Razmerje med kartelnim pravom in pravom intelektualne lastnine, predvsem patentnim pravom, ki podeljuje izključne pravice, je od nekdaj napeto in prežeto z medsebojnim nezaupanjem ter nerazumevanjem protagonistov obeh disciplin. Šele v zadnjem desetletju se je uveljavilo prepričanje, da kartelno pravo in pravo intelektualne lastnine delujeta kot tandem v korist novih in boljših tehnologij, izdelkov in storitev, ki so na voljo potrošnikom po nižjih cenah. Sodno in upravno obravnavanje t. i. pogodb *pay for delay* pa razodeva, s kakšnimi zapleti in s koliko težavami je obremenjena uporaba kartelnega prava pri pravnih poslih na področju, na katerem se soočata obe pravni disciplini, in kako težko je najti dobro uravnotežene rešitve, ki upoštevajo cilje tako patentnega kot tudi kartelnega prava.

Prispevek obravnava predstavljeno tematiko predvsem na primeru dveh odločb: sodbe ameriškega Vrhovnega sodišča v zadevi *Actavis* in odločbe Evropske komisije v zadevi *Servier*. Pri tem namenja posebno pozornost ne samo primerjalnopravnim vidikom problemov, obravnavanih v obeh zadevah, temveč tudi dejanskemu stanju, na podlagi

katerega so ali naj bi bile, kot v primeru *Servier*, odločbe sprejete. Slednje predvsem zato, ker Evropska komisija v odločbi v zadevi *Servier*, ki obsega več kot 900 strani, ni samo neupoštevala več patentno pravno relevantnih dejstev, temveč jih sploh ne omenja. Eden od ciljev prispevka je zato med drugim seznaniti zainteresirane strokovne kroge in tudi širšo javnost z dejstvi, relevantnimi za pravno presojo zadeve, ki pa niso bila upoštevana ali niso bila niti omenjena.

Po uvodni razlagi pravne problematike so predstavljene poravnave patentnih sporov *pay for delay* v praksi ameriške *Federal Trade Commission* in ameriških instančnih sodišč. Slednja, vključno s *Federal Circuits* in *Courts of Appeals*, so z eno samo izjemo obravnavala take poravnave po *Sherman Act*. Če so bile obveznosti strank v okviru veljavnosti patenta, katerega kršitev je bila uveljavljana oziroma izpodbijana, je *Federal Trade Commission* zastopala stališče, da take poravnalne pogodbe *per se* pomenijo kršitev *Sherman Act* in morajo biti prepovedane. Tudi v zadevi *Actavis*, ki jo je obravnavalo Vrhovno sodišče ZDA, je *U.S. Court of Appeals for the Eleventh Circuit* zavrnil tožbo *Federal Trade Commission* in potrdil veljavnost sporne poravnave. Sporno poravnavo je sklenilo podjetje Solvay Pharmaceuticals kot lastnik patenta za zdravilo AndroGel s tremi proizvajalci generičnih zdravil (Actavis Inc., Paddock Laboratories in Par Pharmaceutical). Ti trije proizvajalci generičnih zdravil so se v poravnalni pogodbi obvezali, da zdravila ne bodo prinesli na trg do 65 mesecev pred iztekom patenta, torej še med veljavnostjo patenta. Za pravilno razumevanje tega spora je pomembno, da je Solvay leta 1999 pri *Federal Drug Administration* (FDA) vložil zahtevo za izdajo dovoljenja za prodajo AndroGela. Ta mu je bila izdana leta 2000. Leta 2003 je ameriški patentni urad (*US Patent and Trademark Office* – USPTO) podjetju Solvay podelil patent za AndroGel zdravilo in, kot to zahteva *US Food, Drug and Cosmetics Act* (znan kot *Hatch-Waxman Act*), o tem obvestil USPTO. Pozneje v letu 2003 je Actavis vložil t. i. skrajšano zahtevo za podelitev dovoljenja (*Abbreviated New Drug Application* – ANDA) za prodajo generičnega AndroGela in se pri tem skliceval na § 355 (j) (2) (a) (vii) (IV) *Hatch Waxman Act* (t. i. certifikat po četrtem paragrafu), da je patent firme Solvay neveljaven, oziroma da s tem ne bo kršen. Po *Hatch-Waxman Act* uživa stranka, ki kot prva vloži zahtevo ANDA, torej konkretno Actavis, 180 dni izključnosti nasproti vsem drugim proizvajalcem generičnih zdravil, računano od prvega dneva trgovanja s tem zdravilom. To pomeni, da FDA pred iztekom 180-dnevnega roka nobenemu drugemu proizvajalcu generičnih zdravil ne bo podelila dovoljenja za prodajo tega zdravila: 1. odkar je prvi proizvajalec generičnih zdravil – konkurent prvič trgoval s tem zdravilom, ali 2. je sodišče ugotovilo, da je patent neveljaven ali da ga generični produkt ne krši. *Hatch-Waxman Act* proizvajalcem generičnih zdravil tako omogoča izpodbijanje veljavnosti patenta proizvajalca originalnega zdravila, ki bi bil s prihodom generičnega zdravila na trg kršen. Ta privilegiran položaj stranke, ki prva vloži zahtevo ANDA *Hatch-Waxman Act* uravnoteži tako, da lastniku patenta da možnost, da v 45 dneh, odkar je bila vložena prva zahteva ANDA, vloži tožbo zaradi kršitve patenta proti

vlagatelju ANDA. Posledica take tožbe je, da FDA 30 mesecev ne bo odobrila zahteve ANDA, zaradi česar bo lahko generično zdravilo v najboljšem primeru prišlo na trg šele po dveh letih in pol. Poravnave med lastnikom izpodbijanega patenta in stranko, ki je prva vložila zahtevo ANDA, imajo torej dolgoročne posledice, ki jih v Evropi ne more biti, ker pravo Evropske unije nima določb, primerljivih s *Hatch-Waxman Act*. Ameriško Vrhovno sodišče ni sledilo niti *Federal Trade Commission* niti prizivnemu sodišču. Z večino pet proti tri je ugotovilo, da poravnave, taka kot je, v presoji včasih kršijo kartelno pravo, da pa niso *per se* nezakonite (angl. *unlawful*). Odločilno vlogo za to novo stališče sodišča so imele posebnosti *Hatch-Waxman Act*. Prispevek daje podroben vpogled v argumente večine in tudi manjšine sodišča, ki je podala obširno odklonilno ločeno mnenje.

Drugače kot ameriško Vrhovno sodišče je Evropska komisija v zadevi *Servier*, ki jo obravnava naslednji del prispevka, zavzela stališče, da poravnave tipa *pay for delay* pomenijo kršitev 101. člena Pogodbe o delovanju Evropske unije (PDEU). Po mnenju Komisije, ki je kaznovala Servier in sopogodbenike, med njimi tudi slovensko Krko, s skupaj več kot 300 milijonov evrov, pomenijo take poravnave kršitev konkurence glede na predmet, torej *per se*, ne da bi bilo treba ugotavljati, ali dejansko preprečujejo, omejujejo ali izkrivljajo konkurenco na notranjem trgu. Komisija sicer načelno ne zanika, da imajo lahko tudi poravnave patentnih sporov pozitivne učinke za skupnost, poudarja pa, da niso imune pred uporabo kartelnega prava. Pri tem se Komisija sklicuje na sodno prakso Sodišča Evropske unije. Prispevek podrobneje analizira stališče Evropske komisije glede na kriterije, ki jih uporablja, in tudi glede na opiranje njenih argumentov na sodno prakso Sodišča EU.

Eden glavnih ciljev prispevka je predstavitev dejstev, ki jih bralec ne more najti v 900 strani dolgi odločbi Evropske komisije. V središču pozornosti in pravi »kamen spotike« je pri tem patent Serviera za sol farmacevtske učinkovine perindopril, ki kot taka ni bila več zavarovana s patentom. Dodati je treba, da je bil Servierjev izum rezultat sodelovanja z laboratorijem Univerze v Rouenu in da so trije imenovani izumitelji uslužbenci univerze ter le eden uslužbenec družbe Servier. To je še ena od podrobnosti, ki je ni v odločbi, glede na polemiko okoli patenta, ki je v odločbi vseprisotna, pa ni nepomembna. Tretji del prispevka prikazuje, da je Ugovorni oddelek Evropskega patentnega urada z obsežno obrazložitvijo zavrnil vse ugovore številnih nasprotnikov, med njimi tudi Krkinega, proti veljavnosti patenta za perindopril in da je Servier šele po tej odločbi začel postopke zaradi kršitve patenta na primer v Angliji, tudi proti Krki. Eden glavnih motivov Komisije, da je sprožila postopek proti Servierju in sopogodbenikom je bila sodba angleškega *Court of Appeal*, v zadevi *Servier proti Apotex*, v kateri sodnik ni samo razveljavil patent za perindopril, temveč ga je označil kot vrsto patenta, ki daje patentnemu sistemu slab sloves in ki naj bi bili razveljavljeni, še preden lahko oškodujejo skupnost. Prispevek ne prikazuje samo tega, da podobne pripombe istega sodnika v drugih zadevah na Lordsko zbornico oziroma Vrhovno sodišče Združenega kraljestva, ki nista sledila sodnikovim argumen-

tom in razsodila v prid veljave zadevnih patentov, niso naredile posebnega vtisa, temveč tudi podrobno pokaže, da je drugi sodnik angleškega sodišča, ki je obravnaval spor med Servierjem in Krko, naštel več razlogov, ki so govorili v prid veljavnosti patenta, vendar jih v odločbi Evropske komisije ni mogoče najti. Prispevek tudi kritično obravnava patentno pravo Združenega kraljestva, ki angleškim sodiščem omogoča, da odločajo o veljavnosti »angleškega dela« evropskih patentov in ga lahko razveljavijo, še preden je bil v Evropskem patentnem uradu v pritožbenem postopku dokončno podeljen. V primeru Servier je to vodilo do tega, da je bila sodba angleškega sodišča, vložena pri Pritožbenem senatu, ki je obravnaval še več drugih pritožb proti patentu za perindopril in ga, potem ko so mu predložili angleško razveljavitveno sodbo, končno tudi razveljavil, vendar je za to potreboval 60 strani. Prispevek kritično obravnava tudi dilemo Pritožbenega senata, da objektivno odloča v takih okoliščinah.

Prispevek posebno pozornost namenja tudi poravnavi in drugim pogodbam, ki sta jih Servier in Krka sklenila po odločbi Ugovornega oddelka Evropskega patentnega urada in angleškega sodišča, ki je izdalo začasno odredbo, s katero je Krki prepovedalo prodajo perindoprila v Združenem kraljestvu in zavrnilo zahtevo Krke za sodbo brez obravnave (angl. *summary judgment*), še preden je *Court of Appeal* v zadevi *Servier proti Apotex* razveljavil patent za perindopril. Kratko omenjene so tudi poravnave med Servierjem in drugimi sopogodbeniki, kaznovanimi z odločbo Komisije. Pri tem je poudarek na tem, da so bile vse obveznosti sopogodbenikov v okviru veljavnosti patentov družbe Servier in da glede na viseče ugovorne pritožbene postopke pred Pritožbenim senatom Evropskega patentnega urada in postopek *Servier proti Apotex*, poravnave na noben način niso preprečile, in ob poznavanju okoliščin tudi niso mogle imeti namena preprečiti, sodni preizkus veljavnosti patenta za perindopril ali imele za posledico zamudo dostopa na trg za generično sol perindoprila.

Septembra 2014 je Sodišče EU v zadevi *Groupement des Cartes Bancaires* razsodilo, da je Splošno sodišče napačno odločilo, da koncepta omejitve konkurence po predmetu ni treba restriktivno razlagati. Sodišče je poudarilo, da se sme ta koncept uporabiti samo za nekatere tipe pogodb med podjetji, ki kažejo zadostno stopnjo oškodovanja (angl. *harm*) konkurence, tako da ni treba ugotavljati njihovih dejanskih učinkov. Komisija sicer ne bi bila obvezana dokazati dejanske učinke pogodb na trgu, čeprav za take pogodbe nikakor ni bilo ugotovljeno, da so glede na njihovo naravo škodljive za pravilno delovanje konkurence. Sodišče EU je tudi zavrnilo stališče Splošnega sodišča, da je dovolj, da ima pogodba potencialno negativen vpliv na konkurenco, prav nasprotno, pogodba ali odločba mora biti v konkretnem primeru preprosto sposobna, da omeji konkurenco. V luči te sodbe Sodišča EU prispevek analizira odločbo Komisije Servier na podlagi relevantnih dejstev, ki jih Komisija v svoji odločbi ni upoštevala ali pa jih je premalo upoštevala.

Prispevek sklene z ugotovitvijo, da je vprašanje, ali pogodbe, ki jih je Servier sklenil z drugimi kaznovanimi z odločbo, izpolnjujejo pogoje prvega odstavka 101. člena PDEU

v smislu omejevanja konkurence po predmetu, odvisno od tega, ali vsaka pogodba kot taka razkriva zadostno stopnjo oškodovanja konkurence. Zato je mogoče sklepati, da ni treba ugotavljati njihovih dejanskih učinkov, in to na podlagi pravilno ugotovljenih dejstev. Za to pa je nujno, da so te pogodbe po svoji naravi take, da oškodujejo. Kot je poudarilo Sodišče EU, je za to treba obrazložiti, v kakšnem smislu bi bilo lahko samo besedilo poravnave razlagano, da razkriva obstoj omejitve konkurence po predmetu v smislu prvega odstavka 101. člena PDEU. Licenčna pogodba, kot je bila na primer sklenjena med Servierjem in Krko in po kateri je Krka dobila pravico prodaje patentiranega zdravila samo v določenih državah EU, po mnenju avtorja ne more biti taka pogodba, saj 3. točka drugega odstavka 3. člena Uredbe (EU) št. 1257/2012 Evropskega parlamenta in Sveta z dne 17. decembra 2012 izrecno dovoljuje licenciranje patentov tudi samo za ozemlje dela članic EU. Po mnenju avtorja ni sprejemljivo stališče Komisije, da bi bile poravnave patentnih sporov med proizvajalci originalnih zdravil in proizvajalci generičnih zdravil s klavzulami, da ne izpodbijajo patentov samo takrat v skladu s prvim odstavkom 101. člena PDEU, kadar je poravnava neposreden in izključen rezultat moči sporne zadeve, kot jo presojata obe stranki, in ne rezultat dodatnega prenosa koristi od proizvajalca originalnega zdravila k proizvajalcu generika. Taka razlaga strankam onemogoča poravnavo glede na tehnične, komercialne, finančne in druge odločilne okoliščine. Prispevek ob koncu spominja, da je ameriško Vrhovno sodišče, čeprav imajo v ZDA pogodbe *pay for delay* mnogo dolgoročnejše učinke kot v Evropi, zavrnilo uporabo pravila *per se* omejevanja konkurence in uporabil pravilo razuma (angl. *rule of reason*), ki zahteva ugotavljanje dejanskih učinkov takih pogodb na konkurenco.