REVERSE PAYMENT SETTLEMENTS UNDER COMPETITION LAW

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Introduction

Recent times have seen the rising importance of Intellectual Property ("IP") assets[1] across various economic sectors.

As a consequence, the undertakings increasingly engage in a strategic use of these IP rights aimed at protecting and, in certain cases, increasing the value attached to them.

One of the sectors mostly affected by this phenomenon is the pharmaceutical industry, where the costs to be borne for research and development are particularly high and only the exclusivity attached to IP rights can provide an adequate reward for these efforts.

A typical example of strategic use of IP rights in the pharmaceutical industry is represented by settlement agreements in which the parties provide for so called *"reverse payments"*: in these agreements, a pharmaceutical drug producer (originator), owner of a specific patent, pays a sum to one or more generic producers – potential competitors (allegedly infringing the former company's patent) and, in its turn, the generic company(ies) agree(s) to abstain from challenging the validity of the patent for a specific amount of time - usually 2-3 years - and therefore to delay the entry into the market.

The structure of such kind of settlement agreements is quite unusual, since it runs counter to the usual feature of settlements in IP law, in which the potential infringer of a right (the defendant at trial) pays the other party – the patent holder (the claimant) a fee to make use of the patent and thus being able to compete in the market.

This unusual aspect has attracted the attention of Competition Law enforcers, direct and indirect purchasers of prescription drugs, competitors and consumer advocacy groups, since the main scope of these settlements - the postponement of entry into the market by the generics in exchange of consideration - may clearly have anticompetitive effects.

The present thesis will therefore explore the characteristics of this type of agreements and how the US Courts, and subsequently the European Commission, have dealt with it. It will therefore develop its analysis around the following research question: what are the reasons of the different

[1] This is explained by some commentators by the fact that companies are increasingly giving a higher book value of intangible assets, including IP rights, and have therefore developed *"more imaginative uses for IPRs within their overall commercial strategies"*. See ANDERMAN S., *The IP and Competition interface: new developments*, in *Intellectual property and competition law, new frontiers*, 2011, Oxford University Press, p. 6.

approach emerging so far on the two shores of the Atlantic? These reasons will be investigated having regard to: (i) the attitude with respect to the interface between Competition Law and IP Law; (ii) the possibility to derive the illegality of a conduct based on the motives inspiring it; (iii) the policies, other than the ones inherently attached to IP Law and Competition Law, taken into account in the context of antitrust analysis.

I. Reverse payment settlements in the US case-law; the Actavis case

The United States have seen the first cases of reverse payment settlements, which, as in Europe, primarily concern the pharmaceutical industry[2].

The reasons for this lie in the particular features of the pharmaceutical industry[3] and, with regards to the US, in the peculiarities of the regulation concerning the marketing authorization of pharmaceutical drugs[4].

Therefore, before proceeding to analyse the main cases that have dealt with reverse payment settlements in the US, it is necessary to give a brief overview of the relevant US legislation.

In the United States, the marketing authorization of pharmaceutical drugs is mainly regulated by two regulatory "systems", orbiting around the United States Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA) respectively[5]. This regulatory framework was vastly reformed in 1984 by the Drug Price Competition and Patent Term Restoration Act 1984[6], most commonly known as Hatch-Waxman Act from the name of its legislative sponsors.

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[2] We do not have evidence of similar agreements in other sectors; this is also confirmed by the majority's opinion in the Actavis case (see below, p. 9 ff.). He held that *"Apparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation"* (par. I A).

[3] For a more detailed overview on this please refer to Chapter 2, *The pharmaceutical sector inquiry in Europe*.

[4] See HOVENKAMP, H. J., JANIS M. D., LEMLEY M. A., *Anticompetitive Settlement of Intellectual Property Disputes*, Minnesota Law Review, Vol. 87, p. 1719, 2003; UC Berkeley, Public Law and Legal Theory Research Paper No. 113, also available at SSRN: http://ssrn.com/abstract=380841 or http://dx.doi.org/10.2139/ssrn.380841 *"Practically, the problem of exclusion payments has arisen in antitrust law primarily in the pharmaceutical industry because of its unique patent rules"*.

[5] KARKI L., *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement, Journal of the Patent & Trademark Office Society* 87**,** 604.

[6] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in 21 U.S.C. § 355 (2006), 35 U.S.C. §§ 156, 271, 282 (2006)). The Act was amended in 2003 by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (also known as Medicare Modernization Act, or MMA), Pub. L. No. 108-173, tit. XI, subtits. A-B, 117 Stat. 2066, 2448-64 (codified at 21 U.S.C. § 355 (2006)).

The Hatch-Waxman Act was an attempt to reach a compromise between the often contrasting interests of the producers of branded drugs and the manufacturers of generic drugs (also *"generic producer(s)"* or, more synthetically, *"generic(s)"*).

In fact, in order to facilitate the entry of generic producers into the market and in this way to increase competition and lower prices' availability, the Hatch-Waxman Act provides a number of incentives to generics willing to market a generic version of a pharmaceutical drug. At the same time, the Act provides an extension of validity of the patents in order to allow the producer of the branded drug to recover, at least partially, the time lost during the approval process before the competent authority, the Food and Drug Administration ("FDA")[7].

Concerning the process of authorizations, instead of the expensive and time-consuming procedure requested for patentees (so called New Drug Application, hereinafter "NDA"), the generics can seek the authorization to market a generic version of an already authorized pharmaceutical product by filing an Abbreviated New Drug Applications (ANDA); in this way, they must simply demonstrate the bio-equivalence with a product already authorized and piggyback on the latter's examination results on safety and effectiveness already filed with the NDA. In this way, the system allows generics to avoid the repetitions of the expensive examinations already carried out for the bio-equivalent branded product and makes more expedite (and less expensive) the entry into the market of generics.

When certifying the bioequivalence with a product for which there is already an approved NDA, the generic producer has four options, the latter and relevant for the present analysis being to declare that the relevant "*patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the new application is submitted*[8].

The last option, often referred to as *"paragraph IV certification"*, is the most frequent case and it amounts to a sort of *"declaration of war"* against the patentee of the branded product, which, as a result, is expressly entitled by the Hatch/Waxman Act to suit the generic for infringement of the patent. Indeed, the Act provides that if, in this case, the patentee files a lawsuit against the

[7] The Hatch-Waxman Act provides the NDA applicant with a maximum extension period of validity of the patent of five years, for a total effective patent life (i.e. from the date of NDA approval until the end of enforceability period of the patent) not exceeding 14 years. See 35 U.S.C. (United States Code) §154 (b).

[8] The other available options are to state that: I) the information on the relevant patent has not been filed with the FDA; II) the relevant patent has expired; III) the relevant patent will expire on a certain date.

generic producer, the FDA will automatically not release any marketing authorization for the product concerned by the ANDA for a period of thirty months (so called *"thirty month stay"*)[9] or, at an earlier point, until a decision by the Court has been issued declaring the patent at stake invalid or not infringed.

On the other hand, in case of a successful ANDA, the generic producer will enjoy a 180-day exclusivity period to market the relevant pharmaceutical product. It is worth mentioning that such an exclusivity, which is worth millions of dollars[10], is solely reserved to the first ANDA filer.

While the Hatch-Waxman Act has proved to be quite successful in increasing the availability of generic products in the American pharmaceutical market[11], some of the characteristics outlined above appeared to be distortive and ultimately to have caused the rise of reverse patent settlements in the pharmaceutical industry (and, as we said, one of the causes of "confinement" of this phenomenon to such a sector).

On one hand the branded drug producer has an incentive to start litigation, due to the 30 month-stay period automatically applicable to the ANDA authorization and, more in general, to the high risk of losing market shares in case of entry into the market by the generic(s). On the other hand, the generic has an incentive to file a paragraph IV (and therefore to trigger the patentee judicial reaction), in order to take advantage of the 180-day exclusivity period in case of a successful ANDA. At the same time, the generic faces a low risk from litigation, because the lawsuit will not award, in any case, damages to the patentee, since the commercialization of the product has not started yet.

Alongside with the incentives to start litigation, the parties are also incentivized to settle, due to the usual uncertainty characterizing patent litigation, the high costs that litigation procedures

[9] The period can be shortened or extended by the competent Court where *"either party to the action failed to reasonably cooperate in expediting the action."* 21 U.S.C. § 355(j)(5)(B)(iii).

[10] SCOTT HEMPHILL C., *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N. Y. U. L. Rev., 126.

[11] The empirical evidence shows that in 1998 a generic version alternative was available to almost all most popular drugs with expired patents, up from 35% of cases before the entry into force of the Act. See BROWN M.J., *Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report: A Missed Opportunity to Benefit from U.S. Experience*, Columbia Journal of Law and the Arts, Vol. 33, Issue 3 (2009-2010), p. 381, citing Congressional Budget Office report *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry, July 1998,* available at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf

imply and the high interests at stake (namely the high profit potentially lost by the patentee in case of entry into the market by the generic and the high value of the 180-day exclusivity period for the first ANDA filer), which seem to provide the patentee and the generic with more incentives to settle than proceed with litigation.

In this way, the Act, despite its initial objectives, has caused a contingent alignment of settling interests between the patentees and generic producers and, as we said, a rise in number of patent settlements.

This, in turn, has triggered the reaction of the Federal Trade Commission and of other stakeholders (direct and indirect purchasers of prescription drugs, competitors and consumer advocacy groups) allegedly harmed by these practices, who sought to have these settlements be declared anticompetitive.

The US courts have judged these settlements in very different ways. In fact, the US case-law has experienced a split within the Circuits of the Court of Appeals. More specifically, the 6th Circuit and 3rd Circuit have considered reverse payment settlements as *per se* (or at least presumptively) unlawful under the Shearman Act, while the 2nd and the 11th Circuits have applied to such agreements the so called *"scope of the patent test"*[12]. As we will see, these different views have prompted the US Supreme Court to directly deal with the issue in the Actavis case: in that circumstance, the Court opted for a different text to perform the antitrust analysis of reverse payment settlements, based on a rule of reason approach. The US Supreme Court Actavis decision will be analysed in higher detail since, due to the *stare decisis* principle under US Law, this decision will bind and guide the future US litigation on reverse payment settlements.

With regard to the District Court's decisions, the 6th Circuit was the first to deal with the issue in the case *In re Cardizem Cd*, hearing on an appeal brought against an Eastern District of Michigan decision: it then considered the reverse payment settlement reached between Hoescht Marion Roussel Inc. and the generic producer Andrix Pharmaceuticals as a horizontal market allocation agreement, therefore *per se* invalid under the Sherman Act[13].

[12] For more details about the scope of the patent test, please see page 7 *infra*.
[13] *Cardizem CD Antitrust Litig*., 332 F.3d 896 (6th Cir. 2003); the case concerned the agreement reached by the abovementioned companies pursuant to which Andrix Pharmaceuticals decided to refrain from marketing a generic

Following a different approach, the 11th Circuit, in the *Valley Drug Co. v. Geneva Pharmaceutical Inc.* case, excluded the anticompetitive nature of the reverse payment settlement agreements in which Abbott Laboratories and two generic firms (Zenith Goldline Pharmaceutical and Geneva Pharmaceuticals) entered into with regard to the drug Hytrin[14], due to the *"lawful exclusionary right"* granted to the patentee[15].

Consistently with this approach, the 2nd Circuit, in the *in re Tamoxifen Citrate antitrust litigation*[16], held that *"where there are legitimately conflicting patent claims, a settlement by agreement, rather than litigation, is not precluded by the Sherman Act"*. Therefore, in affirming the appealed district court decision, the 2nd Circuit excluded that the settlement agreement reached between Zeneca and the generic producer Barr was an infringement of the Sherman Act. Such a conclusion was also justified by the Court by considering that the settlement allowed Barr to introduce a generic version of Tamoxifen nine years before the Zeneca's patent date of expiration.

In the meantime, the 11th Circuit had provided an explicit formulation of the already mentioned *"scope of the patent test"* in the *Schering-Plough Corporation vs. FTC [Federal Trade Commission]* case[17]. More in detail, in this case the Court stated that the antitrust analysis of reverse payment settlements had to be performed having regard to: *"(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreement exceeded that scope; and (3) the resulting anticompetitive effects"*.

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version of Cardizem CD, a treatment for hypertension and angyna, as well as for the prevention of heart attacks and strokes, in exchange of a quarterly payment from Hoescht Marion Roussel Inc., the owner of the patent for Hytrin.

[14] *Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1311 n.27 (11th Cir. 2003).* Hytrin is a drug prescribed for the treatment of hypertension and enlarged prostrate. The settlement agreements under scrutiny provided, in exchange of a payment from Abbott Laboratories, the obligation on the generics not to sell any drug containing Hytrin's active ingredient until the relevant patent would have expired or would have declared invalid or a generic version of the drug would have been introduced by a third party. It is worth noting that both in the present case and in In re Cardizem Cd case quoted above the generics undertook not to transfer or sell rights to the 180-day exclusivity.

[15] *Valley Drug Co. v. Geneva Pharm., supra*, at 1335.

[16] *Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).* The Tamoxifen is a drug for the treatment of breast cancer. After the filing of an ANDA for Tamoxifen by Barr, Zeneca sued Barr for patent infringement, but the district court declared the patent invalid. However, pursuant to an agreement between the parties, Barr amended the ANDA by including a paragraph III certification and agreed that it would not have sold a generic version of Tamoxifen until the latter's patent expiration in 2002. The agreement was accompanied by the payment by Zeneca to Barr of 21 million $ and the grant to Barr of a non-exclusive licence to sell Tamoxifen generic sold by Zeneca.

[17] *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

Therefore, pursuant to the test above the Court analysed the settlement agreement and, founding its terms to be "*within the patent's exclusionary power*", excluded its anticompetitive nature.

The 11th Circuit followed again the scope of the patent test, as formulated in the Schering-Plough Corporation vs. FTC case, in the decision *FTC V. Watson Pharmaceutical*[18], affirming a decision of the Northern District of Georgia[19] dismissing a complaint by the FTC.

It is interesting here to note that, in the District Court decision affirmed by the 11th Circuit decision, the Court, similarly to the consideration expressed in the Tamoxifen case, considered that the settlement would have allowed the marketing of the generic at an earlier time (five years) than the date of expiration of the patents regarded by the settlement agreement and that, as a consequence, the agreement would not have had more anticompetitive effects than the ones already produced by the patent.

Quite surprisingly, the 3rd Circuit *in Re K-Dur Antitrust Litigation*[20] decided not to follow the apparently consolidated scope of the patent test and opted, instead, for a "*quick look rule of reason analysis"*, holding pay-for-delay settlements presumptively illegal; according to the Court such a presumption could be rebutted only by "*showing that the payment (i) was for a purpose other than delayed entry; or (ii) offers some pro-competitive benefits"*[21].

For the sake of abstraction, we can say that beneath the different approach followed by the Courts lie their different views about the relationship between IP Rights and Competition Law: in fact, while, in the case of the scope of the patent test, the Courts considered the presence of a patent a reason for derogating from antitrust rules, in the case of the 6th Circuit and the 3rd Circuit

[18] *FTC v. Watson Pharm., Inc.,* 677 F.3d 1298 (11th Cir. 2012).

[19] *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010). The agreement under scrutiny had been entered into between Solvay, the branded producer (and patentee) of Androgel, a prescription gel used to treat male hypogonadism, and two generic drug manufacturers, who had submitted ANDAs with a paragraph IV certification for a generic version of Androgen. Pursuant to the settlement of the patent infringement lawsuits started by Solvay against the two generic producers, the latter agreed to delay their entry into the Androgel market in exchange of a profit sharing arrangement conditioned upon their cooperation in Androgel promotion to urologists and primary care physicians.

[20] *In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012).* K-Dur 20 is a sustained-release potassium used to treat potassium deficiency. The agreement reached between Schering-Plough and the generic manufacturer Upsher contemplated the abstention by the latter from marketing its generic version of Androgel until September 2001; in addition Schering obtained the licences to market five Upsher products in exchange of up-front and *pro-rata* royalties.

[21] *In re K-Dur Antitrust Litig., supra,* at 218.

decisions the Courts appeared to have followed a sort of *"Antitrust-centric"* approach[22], consisting in qualifying reverse payment settlements according to ordinary competition rules. As we will see, these diverging views were also echoed, in some way, in the majority and dissenting opinions rendered in the Supreme Court Actavis case.

In fact, the diverging views outlined above prompted the US Supreme Court to grant, upon request of the Federal Trade Commission, a writ of certiorari with respect to the 11th Circuit decision in the aforesaid Watson Pharmaceutical case.

The US Supreme Court Actavis case

With its decision of 17 June 2013, the Court reversed the judgment of the 11th Circuit and remanded the case for further proceedings[23]. As a further evidence of the high sensitivity of the issue, it is worth noting that also the Supreme Court, similarly to the Courts of Appeals, experienced an internal split: the decision, in fact, was adopted with the favourable vote of five judges, while three other judges filed a dissenting opinion[24].

As already mentioned[25], the case concerned the patent settlements agreements entered into between Solvay, the branded producer (and patentee) of Androgel, a prescription gel used to treat male hypogonadism, and three generic drug manufacturers, Watson Pharmaceuticals (now Actavis Inc.), Paddock Laboratories and Generic Parr Pharmaceuticals. While the former two generics had filed ANDAs for a generic version of Androgel with a paragraph IV certification, Generic Parr Pharmaceuticals had agreed to share litigation costs with Paddock Laboratories in exchange of a profit-sharing agreement.

The patent settlement agreements provided for similar terms, including (i) the commitment by the generics not to enter the market before September 2015, i.e. more than five years earlier than the date of expiration of Androgel's patent (unless a generic would have been marketed earlier);

[22] The expression *"Antitrust-centric"* approach is used, with respect to the Actavis Supreme Court decision, by HOVENKAMP, H. J., *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision* (November 28, 2013). Minnesota Journal of Law, Science & Technology, Forthcoming; U Iowa Legal Studies Research Paper No. 13-35. Available at SSRN: http://ssrn.com/abstract=2286255 or http://dx.doi.org/10.2139/ssrn.2286255.

[23] FTC v. Actavis, Inc., 133 S. Ct., 2223 (2013), available at http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf (the number of pages quoted hereinafter refer to the document available at this link).

[24] The majority's opinion was filed by Justice Breyer, joined by Kennedy, Ginsburg, Sotomayor and Kagan, JJ. The dissenting opinion, also commented *infra*, was filed by Justice Roberts, joined by Justices Scalia and Thomas. Justice Alito took no part in the decision of the case.

[25] Please refer to footnote 19 *supra*.

(ii) the commitment by the generics to co-promote Androgel before urologist; (iii) the payment of (million-worth) sums by Solvay to the three generics.

At the beginning of 2009, the FTC filed lawsuits against all settling parties, arguing that the patent settlements were in breach of federal antitrust law. However, as we have already seen, the North District Court of Georgia dismissed the FTC claim, a decision later affirmed by the 11th Circuit of the Court of Appeals.

Unexpectedly the majority's opinion did not start with the description of the specific facts of the case, but opted for a general description of reverse payment settlements: this was based on the paradigmatic figures of Company A and Company B, settling a patent infringement case based on an agreement requiring *"(1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars"*[26].

As such, this description appears to be inaccurate, since it neglects the fact that, as we have seen, quite often reverse payment settlements, included the ones at stake in the Actavis case, allow the generics to enter the market *before*, and not necessarily after, the expiry of the patent (but nonetheless after the date originally planned by the generic).

After a short description of Hatch-Waxman's main features and of the specific facts at stake, the Court[27] went through the antitrust analysis of reverse payment settlements. First of all, it refused to follow the scope of the patent test, rejecting the view that a positive outcome to such a test could *"immunize the agreement from antitrust attacks"*[28].

On the contrary, according to the Supreme Court, the scope of the antitrust law immunity granted by a patent was to be determined taking into account both patent and antitrust policies[29].

[26] The "unexpected generality" of the incipit of the majority's opinion is also highlighted by HOVENKAMP H. J., *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, mentioned *supra*, p. 4. The description of the facts of the case and of the subsequent litigation brought by the FTC against the patent settlements is contained in the majority's opinion at pages 5-7.
[27] Thereinafter, except when otherwise specified, we will use "Supreme Court" or "Court" to refer to the majority's opinion rendered on the case.
[28] FTC v. Actavis, Inc., 133 S. Ct. (2013), majority's opinion, at 8.
[29] *Idem*, at 12.

The Supreme Court justified this view by also making reference to the Hatch-Waxman Act rationale, its *"general procompetitive thrust"* (…) and *"specific provisions facilitating challenges to a patent validity"*[30].

Thus, the Supreme Court, while recognizing the importance of settlements and the patent litigation problem, stated that these factors should not have been determinant in the case at stake; on the contrary, five sets of considerations should have pushed the Court to allow the Federal Trade Commission to prove its antitrust claim, namely:

1) the fact that the *"specific restraint at issue has the "potential for genuine adverse effects on competition""*[31];
2) that *"these anticompetitive consequences [would] at least sometimes prove unjustified"*[32]; and that
3) in these cases the patentee normally has the (market) power to bring into practice these anticompetitive consequences[33];
4) the ordinary possibility for the Courts to perform the antitrust analysis of a settlement agreement without litigating the patent validity, given that *"an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival"*[34];
5) the possibility for the litigating parties to settle their lawsuit without risking antitrust liability, by adopting solutions other than reverse payment settlements.

At the same time, the Supreme Court declined to follow the view of the Federal Trade Commission to hold reverse payment settlements presumptively unlawful and to analyse them pursuant to a *"quick look"* approach[35]. In this regard, the Court held that the use of a quick look approach could be justified only when the ability of a conduct to produce anticompetitive effects

[30] *Idem*, at 13.
[31] *Idem*, at 14, quoting *Indiana Federation of Dentists*, 476 U. S., at 460–461.
[32] *Idem*, at 17.
[33] *Idem*, at 18.
[34] *Ibidem*.
[35] *Idem*, at 20.

was remarkably evident[36]; a situation that the court failed to recognize in the case of reverse payment settlements.

Conclusively, the Supreme Court opted for a rule of reason approach, according to which reverse payment settlements should be analysed on a case-by-case basis. To this end, the Court specified a number of indices upon which it could assess the anti-competitiveness of a settlement agreement, including the size of the reverse payment, *"its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification[37]"*.

These views were not shared by the dissenting opinion of Justice Roberts (joined by Justices Scalia and Thomas).

This started with the assumption that *"a patent carves out an exception to the applicability of antitrust laws"*[38].

Then, the dissenting opinion, echoing the scope of the patent test, held that if the conduct of the patentee was not *beyond the scope* of its patent, this had to be considered a lawful exercise of the monopoly rights granted by the law, while the contrary could occur only if the patent was invalid or infringed[39]. Curiously, the opinion supported this conclusion by making reference to the same case-law quoted by the majority's opinion, reading this case-law as limiting antitrust scrutiny to the case *"a patent holder acts outside the scope of its patent"*[40].

Subsequently, the opinion rejected the argument of the majority's opinion based on the pro-competitive intent of the Hatch-Waxman Act *("no legislation pursues its purposes at all costs")*[41] and refused to accept as evidence of the weakness of the patent the large sum paid by

[36] *Ibidem*. For instance, the remarkably evidence of anticompetitive effects was rendered through the reference - contained in *California Dental Association v. FTC*, 526 U. S., at 770 - to the figurative image of *"an observer with even a rudimentary understanding of economics"* able to understand that the conduct in the case at stake *"would have an anticompetitive effect on customers and markets"*.
[37] *Idem*, at 20.
[38] *FTC v. Actavis, Inc*., 133 S. Ct. (2013), dissenting opinion, at 1.
[39] *Idem*, at 5.
[40] *Idem*, at 6.
[41] *Idem*, at 8, 9.

the patentee to the generic manufacturer, holding that such a situation could arise from the particular risk (or litigation) adversity of the patentee[42].

The dissent finally expressed two concerns with regard to the rule of reason approach chosen by the majority's opinion: in its view, such an approach would discourage settlement of patent litigation and would lead to an increasing uncertainty in the antitrust analysis of reverse payment settlements, also due to the difficult administrability of this rule by lower courts, called to weigh *"likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances"*[43].

It is worth noting that the Actavis decision has been welcomed by branded and generic pharmaceuticals associations, as well as consumer advocates[44], while at the same time has attracted the critics of prominent scholars for its vagueness and potential uncertainty for future litigation[45]. Other scholars have finally criticized the judgment deeming the rule of reason approach a non-effective tool for enforcement purposes approach, since it would give rise to highly expensive and risky cases, with consequent deterrent effect on litigation[46]: this appears quite strange, if we consider that the judgment marked a sort of discontinuity with the previously dominant approach based on the - less enforcement favourable - scope of the patent test.

It will be interesting to see how the US lower courts will apply in the future the rule of reason test to reverse payment settlements and if the uncertainty surrounding this test will cause, as feared by many[47], diverging decisions.

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[42] *Idem*, at 13.
[43] *Idem*, at 15, quoting the majority's opinion at 9, 10.
[44] See CHAO I., *Supreme Court, in FTC v. Actavis, rejects the "scope of the patent" test, holding that antitrust law's "rule of reason" analysis can pierce the shield of patent rights*, available at http://www.lexology.com/library/detail.aspx?g=1985e3e6-5e3d-4c7b-af7c-c81333167814
[45] *Ex multis*, see CLANCY M. J., GERADIN, D., LAZEROW, A., *Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law* (October 27, 2013), at 9. Available at SSRN: http://ssrn.com/abstract=2345851 or http://dx.doi.org/10.2139/ssrn.2345851 .
[46] PERITZ R. J.R., *A Brief Introduction to Competition Concerns in 'Pay-for-Delay' Settlement Agreements Between Brand-Name and Generic Drug Companies (December 1, 2010)*, New York Law School Legal Studies, Research Paper Series 10/11 # 10, available at SSRN: http://ssrn.com/abstract=1718517, p. 9.
[47]CLANCY M. J., GERADIN, D., LAZEROW, A.., *Reverse-Payment Patent Settlements in the Pharmaceutical Industry*, mentioned *supra;* CROUCH D., *Supreme Court Adds Antitrust Consideration to Patent Settlements.* available at *http://patentlyo.com/patent/2013/06/supreme-court-adds-antitrust-consideration-to-patent-settlements.html;*
GRAVELINE B., DRISCOLL-CHIPPENDALE J., *FTC v. Actavis: What Does It Mean for Reverse-Payment Settlements?, available at http://www.fdalawblog.com/2013/06/articles/ip-and-technology-transactions/ftc-v-actavis-what-does-it-mean-for-reverse-payment-settlements/*

II. The EU Pharmaceutical Sector Inquiry; the Lundbeck decision and other EU pending cases

1) Introduction

As we have seen, some of the features of the United States' medicine marketing regulation or, at least, of the Hatch-Waxman Act would be one of the reasons of the emergence of reverse payment settlements in the US pharmaceutical sector[48].

However, the phenomenon of reverse payment settlements, as explained in this chapter, is not only confined to US, but is also taking place in Europe[49]. In fact, according to some authors, the differences between the US and the EU (including Member States') regulation would not be so important[50], since the two systems would share the main features. For instance, in Europe the originators must also perform, before requesting the authorisation of a new medicine, clinical trials concerning safety and efficacy of the product; and, like in the case of ANDAs[51], any generic manufacturer is allowed to submit abridged applications for a generic version of an already authorized brand-name medicine[52].

At the same time, while certainly not unknown to Europe, reverse payment settlements appear to be less prominent than in the US[53]: this could be partly explained by the lower development of

[48] See HOVENKAMP H. J., *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, mentioned *supra*, p. 16, according to whom, based on the evidence submitted before the Supreme Court in the Actavis case, *"pay-for-delay seems to be predominantly if not exclusively a feature of the Hatch-Waxman Act"*.

[49] For instance, according to Lim, the presence of similar cases in Europe would be *"evidence that reverse payments occur outside the setting of the Act" (*LIM D., *Reverse Payments: Life after Actavis (November 27, 2013). International Review of Intellectual Property and Competition Law (IIC), Forthcoming,* p. 2, *available at SSRN: http://ssrn.com/abstract=2360795).*

[50] See BROWN M.J., *Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report: A Missed Opportunity to Benefit from U.S. Experience*, *Columbia Journal of Law and the Arts*, Vol. 33, Issue 3 (2009-2010), p. 397 (*"That both European and American settlements include otherwise counterintuitive reverse payments suggests that their respective regulatory environments extend similar incentives and pressures on the parties involved"*).

[51] ANDA stands for Abbreviated New Drug Application in the US system (see Chapter 1, page 5, *supra*).

[52] It is worth noting that in Europe two marketing authorisation procedures exist, i.e. (i) a centralized application before the European Medicines Agency; and (ii) a decentralized application before the Member State's relevant agency, whose results can be used in other EU jurisdictions pursuant to a Mutual Recognition Procedure.

[53] TREACY P., LAWRANCE S., *Intellectual property rights and out of court settlements*, in Intellectual property and competition law, new frontiers, 2011, Oxford University Press, p. 201. The lower value of reverse payment settlement in Europe compared to US is highlighted by PARCU L., ROSSI M. A., *Reverse Payment Settlements in the Pharmaceutical Sector: A European Perspective*, in *European Journal of Risk Regulation*, Vol. 2011, Issue 2 (2011), p. 262.

the pharmaceutical industry in Europe[54]; however, certain peculiarities of the Hatch-Waxman Act could also have played a role in creating some of the distortions that would have ultimately aligned the interests of originators and generics with regard to settlements of patent disputes. In fact, despite the similarities outlined above, the European regulation does not provide the first generic applicant with the 180-day exclusivity period, nor with the automatic 30-month stay further to the filing of a patent infringement suit against a generic abridged application. In addition, in Europe, unlike in the American system, the filing of a generic drug application does not require affirmation of a patent status, with consequent authorisation of the originator to sue the generic, as in the case of paragraph IV certification[55]: for this reason, the generic will be allowed to entry the market, but with the risk that an infringement action may be brought against it after the start of production and marketing of the relevant product (with consequent risk to pay high damages in case the action by the originator is successful). This could obviously make the generic more cautious about launching a new product into the market and therefore decrease the number of patent infringement actions and related settlements[56].

In 2003, the European Commission had the first direct experience with reverse payment settlements, when, together with the Danish Competition Authority, reviewed a series of settlement agreements between Lundbeck, a Danish pharmaceutical manufacturer, and a number of generics involving reverse payments; due to their relatively new nature, the authorities stated that these agreements fell into a *"legal grey zone"* and that, as a consequence, the European Commission would have started a general analysis of these cases in order to develop a general standard[57].

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[54] In this regard it is worth noting that in 2012 North America accounted for 41% of world sales in the pharmaceutical sector, while Europe for only 26.7%. In addition, in 2012, the US market accounted for 62% of world sales of new medicines, compared to 18% of Europe. Please refer to *The Pharmaceutical Industry in Figures – Key Data* 2013, EFPIA, available at http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf

[55] See Chapter 1, page 4, *supra*.

[56] However, according to some scholars, other legal and factual elements of the European situation would contribute to incentivize originators and generics to enter into patent settlement agreements. Please refer to CLANCY M. J., GERADIN D., LAZEROW A., *Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law*, mentioned *supra*, p. 9 ("*Due to the cumbersome system for enforcing patents in the EU and the automatic price reductions triggered by the entry of a generic supplier, originator companies have very strong incentives to settle, even in cases where they hold strong patent rights"*).

[57] Danish Competition Authority, Press Release, Investigation of Lundbeck, Council Meeting, 28 January 2004. The case is quoted in CLANCY M. J., GERADIN, D., LAZEROW A., *Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law*, mentioned *supra*, p. 10.

2) General overview of the Sector Inquiry

The need to gather more information on the issue, together with other concerns (barriers to entry into the pharmaceutical market created by misuse of patent rights, vexatious litigation or other means), pushed the European Commission to launch, on 16 January 2008, a sector inquiry into the pharmaceutical sector (hereinafter the "Sector Inquiry")[58]. This inquiry, which started with unannounced inspections at the premises of several pharmaceutical companies, was launched pursuant to Article 17 of Regulation 1/2003[59]: this provision allows the European Commission to conduct a general investigation in particular sectors of the economy or particular types of agreements, "*where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market*".

As such, the Sector Inquiry did not (nor could) aim at examining and sanctioning specific infringements of EU Competition Law, but only at assessing the general competitive structure of the pharmaceutical market and, in this context, identifying categories of conducts potentially problematic by a EU Competition Law viewpoint.

With regard to the scope of the Sector Inquiry, this focused on the market of prescription medicines for human use in the (then) 27 EU Member States during the period 2000-2007[60].

After collection of information through questionnaires sent to industry players, release of a preliminary report on November 2008 with subsequent public consultation between different kind of stakeholders (pharmaceutical companies, industry associations, public authorities, insurance companies, doctors' associations, law firms and academics), the Sector Inquiry was finally concluded in July 2009, when the European Commission issued its final report (the "Final Report")[61].

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[58] See press release http://europa.eu/rapid/press-release_IP-08-49_en.htm?locale=en

[59] *Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty*, OJ L 1, 04/01/2003, pp. 1–25.

[60] More specifically, subject to the Sector Inquiry were 43 originators and 27 generic manufacturers (which overall considered accounted for 80% of EU turnover of prescription medicines for human use during the relevant period) and 219 substances (accounting for 50% of the same EU turnover).

[61] See press release of 8 July 2009 *Antitrust: shortcomings in pharmaceutical sector require further action.* The text of the final report is available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

With regard to the assessment of competition between originators and generics, the Final Report identified a number of strategies mostly used by the former in order to block or delay the development of competition from generics. Between these strategies, which include patent clusters/thickets, voluntary divisional patents[62], intervention of originators before public bodies in the context of authorization of generic drugs, "lobbying" before medical doctors and other health care professionals, the Final Report found that a major role was played by litigation brought by originators against generics and by the related settlements entered into between the parties[63].

With regard to the litigation between the two industry players, the Final Report, while recognizing the importance of the right to enforce patent rights in court, stated that, however, litigation, in certain circumstances, can be deployed as a means of hindering market entry by generic companies or, at least, as a deterring signal. The Final Report also provided interesting statistics regarding litigation between originators and generic manufacturers during the relevant period: these statistics showed, in line with the US experience, a prevalence of positive outcomes for generics, despite the fact that most claims had been brought by originators, thus implicitly showing the weakness of most of such patent claims[64].

3) *The assessment of patent settlements*

The Sector Inquiry identified during the period at stake 207 settlements between originators and generic companies, mostly in the context of litigation[65]. The EU Commission found that, as in

[62] Patent thickets (or patent clusters) consist of numerous patent applications filed for the same technology; while generally a legitimate conduct, it can make more difficult entry into the market by new undertakings by raising the risk that the product to be marketed (e.g. a generic drug) will actually infringe one of the patents composing the thickets; similar issues arise with regard to voluntary divisional patents, consisting of various applications, someway related to a previous patent application (parent application), filed in order to support new claims regarding the patent (e.g. new invention uses of the patent). Divisional patent applications extend the examination period by the competent patent office, also in case the parent application is withdrawn or revoked, and this, in the case of the pharmaceutical sector, can create legal uncertainty for firms willing to market a generic version of the product.

[63] Most cases of patent settlements were reported to have been entered in the context of litigation, see footnote 13 *infra*.

[64] More specifically, the Final Report specifies that during the period 2000-2007 the total number of cases of patent litigation between originator companies and generic companies regarding the medicines investigated in the Sector Inquiry was 698: of these, 223 cases were settled, whereas in 149 cases a final judgement was rendered; in these latter cases, generic companies won 62% of cases. Concerning the remaining 326 cases, these were either pending or had been withdrawn at the moment of the release of the Final Report. See Final Report, p. 238. Similar outcomes were also reported with regard to *interim* injunctions.

[65] Final Report, § 740.

the classical case of reverse payment settlements, these settlements provided in slightly less than half of cases (99) a restriction on the possibility of the generic to market its medicine, while, at the same time, a significant proportion (45) of these latter cases provided a value transfer from the originator company to the generic company[66] (*sub specie* of a direct payment, licence, supply/distribution agreement or "side-deals")[67].

The Final Report expressed some concerns with regard to these settlements containing a value transfer from the originator company to the generic company, arguing that these could *"be used to delay the market entry of the latter"* or make the entry of the generic company *"in a more limited fashion than it would have done in the absence of a settlement, for example as a licensee (…) or a distributor of the originator company"*[68].

However, in line with the nature of the Sector Inquiry as a general investigation on the competitive structure of the market, the Final Report did not provide a conclusive view on the anti-competitiveness of reverse payment settlements; instead, it suggested that a case-by-case approach should have to be adopted in such cases, stating that:

"Any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background"[69].

This case-by-case approach seemed to suggest that this kind of agreements could only constitute a restriction by effect, rather than by object, under EU Competition Law, similarly to the rule of reason approach followed by the US Supreme Court with the Actavis decision.

However, in other parts, the Final Report seems to take a more "hostile" view with regard to *"settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies"*, arguing their potential anti-competitiveness *"in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets"*[70].

[66] *Idem*, § 743.
[67] *Idem*, § 765.
[68] *Idem*, § 769.
[69] *Idem*, § 1530.
[70] *Idem*, § 1573.

4) *The periodical monitoring exercises on patent settlements*

Due to these concerns, the European Commission decided to launch, after the conclusion of the Sector Inquiry, periodical monitoring exercises on patent settlements between originators and generic companies. The reports issued at the end of these monitoring exercises - which now account to 4 (covering the periods (i) mid 2008 – end 2009; (ii) January – December 2010; (iii) January – December 2011; (iv) January – December 2012) – all showed a proportionate rise in the overall number of patent settlements while, at the same time, a trend of decline of settlements potentially problematic under EU antitrust rules[71], as showed in the table below.

	Sector inquiry (7,5 years)	**1st monitoring** (18 months)	**2nd monitoring** (12 months)	**3rd monitoring** (12 months)	**4th monitoring** (12 months)
(a) Total no. of patent settlements	207	93	89	120	183
(b) Problematic patent settlements	45	9	3	13	12
Ratio (b)/(a)	22%	10%	3%	11%	7%

As we can see, the reports show a proportional increase of the overall numbers of patent settlements from 203 during the 7,5 year-period taken under consideration by the Sector Inquiry to 183[72] of the 4th monitoring exercise (regarding the twelve month-period January 2012 -

[71] All reports on the monitoring exercises and the press release thereof are available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

[72] According to the European Commission the latter figure was affected by the introduction of specific provisions in Portugal. Without considering the effect of these provisions, the total number of settlements would be 125, showing, in any case, a little increase with regard to the previous year. See press release on 4th monitoring exercise of 9 December 2013, *Antitrust: Commission welcomes continued low level of potentially problematic patent settlements in EU pharma sector.*

December 2012), while the ratio problematic settlements/total number of settlements fell from 22% of the Final Report of the Sector Inquiry to 7% of the 4th monitoring exercise. In addition, the data available for the Sector Inquiry and the first monitoring exercise showed a remarkable decrease (from € 200 million to € 1 million) in the amount of money involved in the value transfer from the originators to the generics[73].

The data above were interpreted by the European Commission with a supposed *"increased awareness of the industry of which settlement agreements might attract competition law scrutiny"*[74]; at the same time the European Commission referred to the rising number of overall patent settlement to assert that, unlike feared by many, *"the heightened scrutiny of the sector did not hindered out-of-court settlement of litigation"*[75].

This idyllic view and in particular the contrast between the rise in the overall number of patent settlements and the parallel decline in the number of problematic settlements, however, could be misleading, since it could be (partially) due to the fact that the parties in the settlements make more frequently use of side deals and other instruments providing for a value transfer less apparent that direct payments[76].

5) *The Lundbeck decision; other cases in Europe*

The investigation on the agreements between Lundbeck and a number of generics[77], which, as we mentioned above, contributed to triggering the Sector Inquiry, led to the first decision on reverse payment settlements in Europe. Curiously, one of the generics, party to the agreements, Arrow Group ApS, has been subsequently acquired by Actavis group, one of the protagonists of the Actavis Supreme Court's decision in the United States.

The aforesaid agreements concerned the main patent related to Citalopram, a Lundbeck blockbuster anti-depressant medicine: as in the most classic pay-for-delay settlement, before

[73] See press release on 1st monitoring exercise of 5 July 2010, *Antitrust: Commission welcomes decrease of potentially problematic patent settlements in EU pharma sector.* Data related to the subsequent monitoring exercises were not provided.
[74] *Ibidem.*
[75] *Ibidem.*
[76] PARCU L., ROSSI M. A., *Reverse Payment Settlements in the Pharmaceutical Sector: A European Perspective*, in *European Journal of Risk Regulation*, mentioned *supra*, p. 262.
[77] Please refer to page 16, *supra*. The generics were notably Alpharma (now part of Zoetis), Merck KGaA/Generics UK Ltd (the latter now part of Mylan), Arrow Group ApS (now part of Actavis Group), Products LLC and Xellia Pharmaceuticals ApS, Zoetis Ranbaxy Laboratories Limited and Ranbaxy (UK) Limited.

Citalopram's patent expiration in 2002, Lundbeck paid the generics a substantial amount of money in exchange of their commitment not to enter the market with their generics. In addition, Lundbeck purchased the generics' stock in order to proceed to its destruction and entered into a distribution agreement with the generics with a profit-sharing clause.

With its decision of 19 June 2013 the European Commission found the agreements between Lundbeck and the generics in breach of Article 101 TFEU and, as a consequence, sanctioned Lundbeck with a fine of € 93.8 million and imposed on the generics an overall fine of € 52.2 million[78].

The conclusions of the European Commission were also based on the internal documents collected during the inspections, which, by referring to a "*club*" formed by the parties and to *"a pile of $$$"* to be shared among them, showed a sort of anti-competitive state of mind of the parties[79].

Since the decision is still confidential, it is not possible to conduct a detailed examination of it. However, from the information provided in its press release on the case and the relevant commentaries by legal scholars, the European Commission seems to have considered such agreements as a violation per object of Article 101 TFEU[80].

If this is confirmed, the EU Commission will have adopted a stricter approach to reverse payment settlements than US, where, as we have seen, the Supreme Court rejected the view, "sponsored" by the FTC, that such agreements should be considered *per se* illegal[81].

However, from the information available it is not clear whether the settlement agreements were entered into in the context of litigation or not. If this was not the case, the settlements under consideration could not be considered a proper reverse payment settlement and therefore the

[78] http://europa.eu/rapid/press-release_IP-13-563_en.htm
[79] *Ibidem*.
[80] *Ibidem*. Please refer, in particular, to the statement by the EU Commissioner in charge of competition policy Joaquin Almunia, who declared *"It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices"*.
[81] For the sake of clarity, it must be specified that illegality *per se* under US Antitrust Law and incompatibility per object under EU Competition Law are similar, yet slightly different concepts, since the former conducts are conducts always illegal in the end, while conducts anti-competitive per object can, in principle, be "redeemed" by virtue of the exemptions provided under Article 101.3 TFEU.

position of the EU Commission would appear more justified, since the agreement could not take advantage of the potential redeeming virtue of avoiding litigation costs.

After the Lundbeck decision, a similar case was dealt with by the European Commission.

In fact, with its decision of 10 December 2013 the European Commission sanctioned Johnson and Johnson ("J&J") and Novartis, jointly and severally with their respective Dutch subsidiaries Janssen-Cilag B.V. ("Janssen-Cilag") and Sandoz B.V. ("Sandoz"), with a fine for an alleged pay-for-delay agreement: according to the Brussels' officials the parties concluded an agreement aimed at delaying the marketing by Novartis of a generic version of Fentanyl, a pain killer medicine owned by J&J and generally used for patients suffering from cancer[82].

More in detail, the parties concluded a co-promotion agreement conditioned upon the non-entry into the market of a generic version of Fentanyl. The European Commission estimated that the monthly payments pursuant to the co-promotion agreement exceeded the profits that Sandoz could have gained from marketing a Fentanyl generic and therefore were aimed at disincentivising Sandoz's entry into the market. In other words, the European Commission seems to have considered the payments arising from the co-promotion agreement as a hidden value transfer from the originator (Janssen-Cilag) to the generic (Sandoz), whose real intent was to remunerate Sandoz for not entering into the market[83].

This last mentioned case was different from the Lundbeck decision – and from the classical reverse payment settlement-type cases – since it did not relate to actual or potential IP infringements (J&J's relevant patent had already expired); however, the European Commission deemed that in both cases the parties' conducts shared a similar logic, consisting on the payment by *"a company [to] its competitor to delay the entry on the market of the generic version of its drug"*[84]. Nevertheless, in the J&J/Novartis case the agreement was undoubtedly entered into

[82] More in detail, J&J was sanctioned, jointly and severally with its subsidiary, with a fine of € 10,798,000, while Novartis with its subsidiary Sandoz with a fine of € 5,493,000. Also in this case the decision is still not available for confidentiality reason, therefore it is only possible to make reference to the press release on the case at http://europa.eu/rapid/press-release_IP-13-1233_en.htm

[83] The agreement was eventually terminated in December 2006 when a third party was going to launch a generic version of Fentanyl in the Netherlands.

[84] See EU Commissioner Joaquin Almunia's speech on the case, available at http://europa.eu/rapid/press-release_SPEECH-13-1053_en.htm

outside a litigation, which would again justify the strict approach adopted by the European Commission.

In addition to the Lundbeck and the J&J/Novartis decisions, the European Commission is also conducting other investigations on reverse payment settlements, which are still pending.

On 8 July 2009 the EU Commission opened a formal proceeding against Les Laboratoires Servier group (hereinafter "Servier") and several generics with regard to patent settlements and other alleged anticompetitive practices concerning Perindopril, a cardio-vascular medicine. On 30 July 2012 the EU Commission sent to the parties the statement of objections[85], alleging that:

- the reverse patent settlement concluded between the parties could have aimed at delaying the market entry of generics into the market and therefore could run afoul of Article 101 TFEU;
- the acquisition by Servier, which was assumed to have had a dominant position in the market of production and distribution of Perindopril, of key competing technologies necessary to produce Perindopril could constitute an infringement of Article 102 TFEU (prohibition of abuse of dominant position)[86].

On 28 April 2011 the EU Commission opened an investigation on the settlement agreement between Cephalon Inc., an American pharmaceutical producer, and Teva Pharmaceutical Industries Ltd. ("Teva"), an Israelian generic manufacturer, concerning the pharmaceutical drug Modafinil, marketed under the commercial name of Provigil®, a treatment for sleeping disorders. With the settlement agreement, which is also under investigation in the United States by the FTC, the parties agreed a series of side deals along with the commitment by Teva not to sell its generic version of Modafinil in the EEA before October 2012[87].

[85] See press release of 30 July 2012 *Antitrust: Commission sends Statement of Objections on perindopril to Servier and others*, available at http://europa.eu/rapid/press-release_IP-12-835_en.htm

[86] It is worth noting that Servier had also been accused by the EU Commission to have provided misleading and inaccurate information in the context of the requests of information sent during the Sector Inquiry; however, these accusations have been subsequently dropped by the EU Commission (see press release about closing of procedural case http://europa.eu/rapid/press-release_IP-12-43_en.htm?locale=en).

[87] See press release of 28 April 2011 *Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva*, http://europa.eu/rapid/press-release_IP-11-511_en.htm

It is worth noting that Cephalon was subsequently acquired by Teva and that the acquisition was cleared by the EU Commission conditioned upon the divestment of Cephalon's generic Modafinil pipeline product and related rights[88].

Finally, the issue of reverse payment settlements has also been recently addressed by the new Technology Transfer Guidelines ("Guidelines")[89], adopted by the European Commission on 21 March 2014. The Guidelines explicitly mention pay-for-delay settlement agreements as a type of agreements which could run afoul of Article 101 TFEU[90], also when the value transfer is represented by a licence, presumably provided at a lower than commercial price (*rectius*, fees and royalties) in exchange of the commitment by the licensee to delay its entry into the market.

III. The reasons of the divergent approach US/EU

As we have seen, with regard to the antitrust assessment of reverse payment settlements the United States and the European Union seem to have, at present, a different view: moreover, the different approach adopted by the US Supreme Court (rule of reason) and by the European Commission (infringement per object) does not only imply a different conception of the conduct at stake (only potentially anticompetitive in the former case, presumptively illegal in the latter case), but has also important consequences in term of burden of proof upon the enforcement agencies or the plaintiff(s). In fact, while the illegality per object allows the European Commission to - automatically, unless the defendant is able to prove that its behaviour meet the conditions set forth by Article 101(3) TFEU - sanction a certain conduct without the need to prove its effects on the market, the rule of reason approach requires, in any case, an assessment on a case-by-case basis of the characteristics of the conduct, of the circumstances in which it occurred and of its effects on the market.

As such, the approach chosen by the Supreme Court could give rise to higher uncertainties and inconsistencies in its interpretation and application, as proven by one of the first cases dealt with by the lower courts after the Actavis decision: this appears to have followed a very narrow

[88] See text of the decision at http://ec.europa.eu/competition/mergers/cases/decisions/m6258_20111013_20212_3496467_EN.pdf

[89] *Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements*, OJ 2014/C 89/03.

[90] Please refer to §§ 238, 239 of Guidelines. The reference to the case of licence is compatible with the scope of the Guidelines, which is to provide a guide for the assessment of agreements involving a transfer of technologies and therefore focus on licences and other kind of agreements generally used for this purpose.

interpretation of the test adopted by the US Supreme Court, inclined to exclude any infringement of the antitrust law whenever the settlement does not contain any payment from the originator to the generic[91].

However, it is still too early to say if this different approach would amount to a new transatlantic "fault" that will further increase the number of antitrust issues (e.g. predatory pricing, resale price maintenance, essential facility doctrine) in which Europe and US present a different view or if this divergence will only be temporary, since the position of the European Commission (as expressed, in particular, in its Lundbeck decision) has not been tested yet by the Courts[92]: in this sense, the interpretation of reverse payment settlements by the European Commission would be in line with the one of its counterpart in US, the FTC, which has always claimed that reverse payment settlements should be considered as infringement *per se* of antitrust law. Therefore, the situation could obviously vary if the European Courts adopted a different approach, an event which however is far from likely to occur given the more deferring attitude of the European Courts, compared to the US Courts, towards the antitrust enforcement agencies[93].

Some may argue that the US and EU approaches are eventually not so distant, especially considered the possibility, just mentioned, that the Lundbeck decision is overturned by the EU Courts. However, it is necessary to bear in mind that, before the Actavis decision, the view predominant on the US Courts (also affirmed in the case then judged by the US Supreme Court in the Actavis decision) was the one based on the scope of the patent test, that, if confirmed, would have obviously marked a stronger difference between US and Europe. While, due to the *stare decisis* principle, it is now necessary to only consider the position taken by the Supreme Court, the test previously dominant in the US case-law may nevertheless be seen as evidence of a different sensibility compared to Europe.

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[91] Please refer to *In Re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-cv-995 (D.N.J. Jan. 24, 2014). The case concerned so called "no-authorized generic commitments", consisting in agreements between originators and generics that include the originator's commitment not to market its own "authorized generic" during the 180-day exclusivity period available to the generic. The decision has been appealed to the Court of Appeals and the FTC has filed *amicus curiae* briefs, arguing that the commitment by the originator not to entry into the market with its generic is a form of consideration in exchange of the commitment by the generic to delay its entry into the market. Similar *amicus curiae* briefs were filed by the FTC in: *In re: Effexor XR Antitrust Litigation case* no.: 3:11-cv-05479 (D NJ 14 August 2013); and *In re: Wellbutrin XL Antitrust Litigation* case no.: 2:08-cv-2431 and case no.: 2:08-cv-2433.

[92] CLANCY, M. J., GERADIN, D., LAZEROW, A., *Reverse-Payment Patent Settlements in the Pharmaceutical Industry*, mentioned *supra*, pp. 15-16.

[93] *Idem*, p. 16.

Secondly, it is true that, in theory, the rule of reason approach – at least in the form adopted by the US Supreme Court, for which payment of a large sum is a presumption of the anticompetitive nature of the patent settlement - and the qualification chosen by the European Commission – i.e. infringement per object (therefore presumptively illegal, but, in principle, redeemable by meeting the conditions set forth by Article 101.3 TFEU)[94] – could appear not so distant, or at least not diametrically opposite. However, as some commentators acutely observed[95], in practice the difference would be much wider, due, on one hand, on the heavy burden of proof imposed on plaintiffs by the rule of reason standard in US[96], and, on the other hand, on the low chances of successfully applying Article 101.3 TFEU in infringement per object cases.

The current stricter European approach appears to be quite paradoxical, since, as we know, the EU regulation does not have some of the features of the Hatch/Waxman Act, namely the 180-day exclusivity period accorded to the first ANDA generic filer and the 30 month-stay period, that, as we said, have been blamed to have created an alignment of interests between originators and generics and, ultimately, incentivized the rise in reverse payment settlements in US[97].

Therefore, the different regulatory environment present in Europe and in US cannot be held responsible for the abovementioned different attitude towards reverse payment settlements and this leaves us with the task of investigating the actual reasons at the basis of this different approach.

Such an investigation will be, hereinafter, carried out along the following lines:

1) the different approach of US and EU in the antitrust enforcement of cases involving an interface between Competition Law and IP Law;

[94] The EU jurisprudence has confirmed that the conditions for exemption provided by Article 101.3 may, in some cases, be invoked to conducts in principle qualified as infringement per object. See Court of Justice, Judgment of 13 October 2011, Case C-439/09.

[95] See LAMADRID A., *Reverse payments (Pay for delay settlements) in EU and US antitrust law (Part I)*, in Chillin' Competition blog (http://chillingcompetition.com/2013/07/02/reverse-payments-pay-for-delay-settlements-in-eu-and-us-antitrust-law/)

[96] On the deterrent effect of the rule of reason approach on litigation see also Chapter 1, p. 13 and footnote 46 *supra*, making reference to PERITZ R.J.R., *A Brief Introduction to Competition Concerns in 'Pay-for-Delay' Settlement Agreements Between Brand-Name and Generic Drug Companies (December 1, 2010)*, mentioned *supra*, p. 10.

[97] See chapter 1, pp. 5-6, *supra*. As we also pointed out, however, these distortions do not appear to have been the only causes of the rise of reverse payment settlements, considered the presence of similar arrangements in Europe. See chapter 2, pp. 14-15, *supra*.

2) connected with the previous explanation, the different (and predominant) role that Competition Law has always had *vis à vis* of IP Law in Europe, compared to US;

3) the fact that in US (and, more in general, in Common Law systems) the doctrine of abuse of rights has always played a minor role, compared to Europe;

4) the policies, other than IP Law and Competition Law, taken into account in the assessment of reverse payment settlements.

1) *The different approach of US and EU with regard to the interface between Competition Law and IP Law*

Dealing with the first reason of "divergence" requires providing a short introduction about the general role of Competition Law and Intellectual Property (IP) Law, before turning to how their interactions have been "managed" in Europe and in US.

In fact, Competition Law and IP Law are two contiguous fields of law, having as their aim the promotion of competition and innovation in the market respectively[98].

If we look at their intrinsic nature, we can see how these aims are normally consistent, since they both converge to the goal of increasing the consumer welfare and the efficient allocation of resources[99]: innovation being, with the words of the European Commission, *"an essential and dynamic component of an open and competitive market economy"*[100].

[98] Such a conclusion is perfectly summarized by Justice Roberts' dissenting opinion in the Actavis case (I, 2, see Chapter 1 *supra*), where it is stated that *"The point of antitrust law is to encourage competitive markets to promote consumer welfare. The point of patent law is to grant limited monopolies as a way of encouraging innovation"*.

[99] The convergence of competition in the market and innovation has been questioned by Joseph Schumpeter and other economists, who claim that innovation would be better fostered by monopoly, since the monopoly profits would provide a higher rewards for innovation, therefore making the latter more attractive for companies. Moreover, especially in high tech industries, the cost of research requires huge amounts of capital, which are normally available to large companies or require cooperation between companies. Therefore, according to this view, the struggle of the competition authorities against monopoly and creation of market power would focus on static efficiency at the expense of dynamic efficiency as arising from innovation. However, Kenneth Arrow and other economists have challenged this view, since it would undermine the important incentives for innovation arising from competition, in particular for what it concern the possibility of new entrants to gain market share by offering new products on the market. For a more detailed overview about this opposing views, see Madero VILLAREJO C., KRAMLER T., *Intellectual property rights and competition rules, a complex but indispensable coexistence*, in *Intellectual property and competition law, new frontiers*, Oxford University Press, p. 62.

[100] *European Commission's Guidelines on the application of Article [101 TFEU] to technology transfer agreements*, OJ [2004] C 101/2, par. 7.

The convergent role of Competition Law and IP Law has also been recognized by the current EU Commissioner in charge of Competition Policy[101], as well as by the US case law[102].

Nonetheless, their aims can occasionally appear to be in contrast, since the promotion of innovation is mainly pursued by IP Law through the grant of an exclusivity (e.g. a copyright, a patent) to the innovator; this, in turn, causes a "suspension" of competition with regard to the area covered by the right from the time of validity of the latter.

Therefore, in these specific cases it is necessary to reconcile IP Law with Competition Law.

This issue has normally been solved by the EU Courts (the EU Court of Justice and the Court of First Instance[103]) by reserving to IP Law a deferent role with regard to Competition Law, in cases where the two systems appeared to be in contrast[104].

In this sense, the EU Competition Law is seen by some scholars as a system of regulation of intellectual property rights, providing *"a set of outer limits to the exploitation and licensing of intellectual property rights (IPR) by IPR owners which can override their entitlements under IPR legislation"*[105]. Such a system would act both in a negative sense (by restricting, as we will see, the possibility of exercising the IP rights in certain ways) and in a positive sense (by providing, for example with the Block Exemption on Technology Transfer Regulation[106], a list of conducts

[101] ALMUNIA J., Speech of 9/12/2013, *Intellectual property and competition policy*, available at http://europa.eu/rapid/press-release_SPEECH-13-1042_en.htm : in this speech, Mr. Almunia, after denying that *"competition policy enforcement and the protection of IP rights have mis-aligned objectives"*, stated that *"In their different ways, both the patent system and the system that enforces competition law in the EU pursue common goals. A well-functioning IPR system can in fact promote competition by encouraging firms to invest in innovation. And both competition policy and the intellectual-property protection system do contribute to create the right framework for innovators"*.

[102] See *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990):*"[t]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are complementary, as both are aimed at encouraging innovation, industry and competition"*.

[103] Now the General Court.

[104] See ANDERMAN S. D., SCHMIDT H., *EC competition law and intellectual property rights: the regulation of innovation*, Oxford University Press, 2011, p. 19.

[105] See ANDERMAN S. D., *EC competition law and intellectual property rights: the regulation of innovation*, Oxford University Press, 1998, pp. 3-4.

[106] *Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements*, in OJ L 93, 28/03/2014, p. 17–23.

in intellectual property licensing agreements which are considered compatible with the EU Competition Law[107]).

In this regard, the settled EU case-law[108] draws a distinction between grant/existence of IP rights, whose conditions and procedures remain a matter for national law[109] and are irrelevant for antitrust enforcement purposes[110], and exercise of IP rights, that in exceptional circumstances can give rise to a breach of antitrust rules.

As the distinction drawn above clearly shows, the exercise of the IP right shall not obviously be deemed anticompetitive as such, but only when this appear to be an *"instrument of abuse"* of a dominant position[111] or able *"to serve the effect to"* or *"be the means of"* a restrictive agreement, decision or concerted practice prohibited under Article 101 TFEU[112].

Between the most significant examples in which the EU Commission and EU Courts have applied this principle, we can mention:

- the Grundig/Consten case, in which the use of a trademark to enforce a sole distribution agreement between a German TV manufacturer, Grundig, and a French distributor, Consten, was considered to prevent the parallel import within the European market and was therefore qualified as an anticompetitive restrictive agreement[113];
- the Magill case, in which the refusal by TV broadcasters to grant a license necessary to allow a company to market a new product (for instance, a *weekly guide to television*

[107] Likewise, the Technology Transfer Agreement Guidelines (mentioned *supra*, footnote 89) provide a sort of guidance on the compatibility of certain conducts (for instance concerning transfer of technology) with EU Competition Law.
[108] Please refer to *AB Volvo v Erik Veng (UK) Ltd.* Case 238/87, ECR **[**1988] 6211 parr. 7-9; *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH vs. European Commission*, Cases 56 and 58-64, ECR [1966], 299, parr. 49, 50; *Parke Davis v. Probel*, case 24/67, ECR [1968] 55; *Deutsche Grammophon GmbH v. Metro SB Grossmarkte GmbH*, case 78/70, ECR [1971] 487.
[109] An exception to this principle can be found in the European Union Patent set forth by Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012, in OJ L 361, 31/12/2012, p. 1–8, still to enter into force, whose conditions for granting are set forth by the Convention on the grant of European Patents (European Patent Convention) of 5 October 1973.
[110] The Astra Zeneca case (see page 31 below) seems to constitute a partial exception (the case referred to conducts aiming at extending the validity of a patent, and not at obtaining the grant of the patent) to this principle.
[111] *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, case 85/76 [1979], ECR 461.
[112] *Coditel v. Cinè Vog Films (Coditel II)*, Case 262/81, ECR [1982] 3381, paragraph 14: the example to which the present and the previous footnote refer to are reported in ANDERMAN S. D., SCHMIDT H., mentioned *supra*, p. 22.
[113] *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH vs. European Commission*, Cases 56 and 58-64, ECR [1966], 299.

programs), for which there was a potential demand by consumers, was considered an abuse of dominant position[114];

- the Microsoft case, in which the refusal by Microsoft to provide the competitors with information related to its operating system source code, which was necessary for the development of competing software products in the group server market, was considered in breach of Article 82 of EC Treaty[115] (now Article 102 TFEU[116])[117];
- the Astra Zeneca case, in which a number of conducts by Astra Zeneca[118], aiming at fraudulently extending the period of validity of patents and preventing entry into the market by generic producers, was considered an unlawful exploitation of dominance on the market[119].

It is worth noting that the cases in which the exercise of IP rights can give rise to antitrust liability are, in the words of the EU Commission itself, quite exceptional[120] and indeed are statistically not frequent; however, some scholars warn against the undesirable effect that these enforcement actions, though rare, may have on the conducts of the economic actors, and, in particular, of those operating on high-tech industries[121].

The situation is in sharp contrast with the US, where IP rights are regarded in a much higher sacrosanct esteem[122] and, especially in the last two decades, have been afforded with a higher protection against antitrust scrutiny[123].

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[114] *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v European Commission*, joined cases C-241/91 P and C-242/91 P, ECR [1995] I-00743.
[115] *Treaty establishing the European Community*, as amended by the *Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and related acts*, OJ C 340, 10 November 1997.
[116] *Treaty on the Functioning of the European Union*, OJ 2012/C 326/01, 47.
[117] *Microsoft Corp. vs. European Commission*, Case T-201/04, ECR [2007] II-03601. The case also concerned the tying by Microsoft of its Windows Media Player software with its PC operating system.
[118] More in detail the undertakings under scrutiny were Astra Zeneca and Astra Zeneca plc.
[119] Court of Justice, judgment of 6 December 2012, case C-457/10 P, available on http://curia.europa.eu
[120] Please refer to the Final Report (par. 1568) "*If the existence and exercise of an industrial property right are not of themselves incompatible with competition law, they are not immune from competition law intervention. However, certain practices can only be an infringement in exceptional circumstances*". *See also* BANASEVIC N., *Global Competition Review*, 8 October 2013 (*"It's important to remember that antitrust intervention in IP is very rare" "Some of the cases [at the moment] are very high-profile, that's why they get more prominence. But [antitrust intervention] is over-stated"*).
[121] PETIT, N., *"Stealth Licensing" - Or Antitrust Law and Trade Regulation Squeezing Patent Rights* (April 19, 2014), pp. 20-21, available at SSRN: http://ssrn.com/abstract=2426782 or http://dx.doi.org/10.2139/ssrn.2426782
[122] KOBAK J.B., *Running the Gauntlet*: *Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic*, in 64 Antitrust Law Journal, 1996, p. 353.

Indeed, in US the antitrust intervention in IP-related cases has been much more limited in scope compared to EU; for instance, the possibility of antitrust scrutiny of conducts such as refusals to licence, enforcement of IP rights (with the exception of sham litigation), as well as the application of the essential facilities doctrine to IP rights, even if not excluded altogether, is considered possible only in very limited circumstances[124]. In this sense, only cases involving sham litigation or the use of invalid/fraudulently obtained IP rights seem to give frequently rise to antitrust liability[125]: this is often justified with the fact that these conducts clearly lack any efficiency considerations, but, at the contrary, seem to run counter the underlying objective of IP protection, i.e. incentivizing innovation[126].

2) The different role and importance of IP Law and Competition Law in Europe and in US

Some may wonder why the interface between IP rights and Competition Law is so differently dealt with in Europe and in US. The explanation, in my opinion, must be traced in the different role and importance that these two fields of law have on the two sides of the Atlantic.

In fact, in Europe Competition Law has a predominant role since it constitutes a primary policy of the EU, recognized as an aim of the European Union (and, before, of the European Economic Community) since its founding Treaty[127] and now by the Treaty on European Union[128]; in addition, Competition Law is a policy directly enforced by the European Commission (through its Competition General Directorate) and whose rules are directly - and mainly – provided at the EU level[129]; by contrast, the protection of intellectual property is, at most, a right recognised

[123] For a general overview about the evolution of antitrust enforcement towards IP rights in US and Europe, see KOBAK J.B., *Running the Gauntlet*: *Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic*, mentioned *supra*, pp. 341-366.

[124] CZAPRACKA, K. A. (2007) *Where antitrust ends and IP begins - on the roots of the transatlantic clashes*, Yale Journal of Law and Technology: Vol. 9: Iss. 1, p. 93. See also KOBAK J.B., *Running the Gauntlet*: *Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic*, mentioned *supra*, p. 354.

[125] *Idem*, p. 99.

[126] *Ibidem.*

[127] Please refer to Article 3.1 g) of the Treaty establishing the European Community, mentioned *supra*.

[128] *Consolidated version of the Treaty on European Union*, OJ 2012/C 326/01, p. 13. Kindly note that the recognition of the role of the Competition Law is now contained in Article 3.3 of this treaty (stating that *"the Union (…) shall work for the sustainable development of Europe based on (…) a highly competitive social market economy")*, to be read in conjunction with Protocol no. 27 (specifying that *"the internal market as set out in Article 3 of the Treaty on European Union includes a system ensuring that competition is not distorted"*).

[129] Please refer to Article 3(1)(b) of the Treaty on the Functioning of the European Union, mentioned *supra* (*"the European Union shall have the exclusive competence in establishing the competition rules necessary for the functioning of the internal market"*).

under the Charter of Fundamental Rights of the European Union[130] and whose regulation and enforcement are mostly reserved to the competence of the single Member States.

Such a privileged status is not enjoyed by antitrust law in US, in which the interest towards IP rights has grown in the last decades up to the point to reserve to these rights, as we said, a sort of *"sacral importance"*.

No wonder, thus, if the European Commission and the EU Courts have generally applied Competition Law in IP-related cases in a much rigorous way compared to their American counterparts and interpreted IP Law objectives as being subordinated to Competition Law concerns[131].

3) The different success of the abuse of rights doctrine

Another possible explanation for the divergence at stake might be, in principle, the different success of the notion of abuse of rights.

In fact, the abovementioned EU case-law imposing limits to certain exercises of IP rights may be seen as a projection of the abuse of rights doctrine in the antitrust enforcement of IP-related cases.

Indeed, as for the concept of the abuse of rights, the anticompetitive exercise of an IP right implies that the enforcement of a valid right can nonetheless be deemed illegal when contrasts with the purposes for which the right was granted or occurs in an "antisocial" way. In Europe the notion of abuse of rights, though still largely uncodified, has always enjoyed a wide recognition through its different national declinations (*abus de droit* in France, *abuso del diritto* in Italy, *Rechtmissbrauch* in Germany); more recently it has also been expressly recognized at the EU

[130] See Article 17(2) of the *Charter of Fundamental Rights of the European Union*, OJ 2012/C 326/02, p. 391.

[131] The "subordinated" role of IP Law in the context of EU Law is well summarized by the words of the Court of First Instance in the case Radio Telefis Eireann v. Commission, in which it stated that when an IP right is exercized in a manner contrasting with the objectives of Article 86 of the Treaty (now Article 102 TFEU) "*the primacy of Community Law, particularly as regards principles as fundamental as those of the free movement of goods and freedom of competition, prevails over any use of a rule of national intellectual property in a manner contrary to these principles*". See Court of First Instance of 10 July 1991 cases T-69/89 RTE v Commission [1991] ECR II-485 and in Case T-76/89 ITP v Commission [1991] ECR II-575.

level by the EU Courts[132] and as a fundamental right of the European Union under Article 54 of the Charter of Fundamental Rights[133].

By contrast, under US Law and, more in general, in the common law systems the concept of abuse of rights has always enjoyed a lower success.

The reason for this must be linked with the general aversion of common law systems towards indefinite legal concepts, such as the principle of good faith (from which indeed the concept of abuse of rights originated) and with the traditional restraint against judging the motives inspiring (legitimate) conducts of individuals and entities. So, with the words of Judge Lord Watson in the context of a famous English case:

"the law of England does not . . . take into account as constituting an element of civil wrong the existence of a bad motive, in the case of an act which is not in itself illegal, will not convert that act into a civil wrong for which reparation is due" [134].

Notwithstanding with this, certain scholars warn against excluding altogether the presence of the concept of abuse of rights in US law, arguing that the concept, although not directly employed (nor mentioned) as such, would underlie more specific legal principles, such as nuisance, duress, good faith, economic waste, public policy[135].

A particular declination of this concept in the field of intellectual property law can be identified in the notion of misuse of patent doctrine.

In general, a misuse of patent arises when a patentee exercises the rights connected with the patent in a fashion involving an infringement of antitrust laws or the patentee improperly seeks to expand the scope of the patent[136].

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[132] See ECJ judgement of 21 February 2006, case C-255/02 (Halifax) and ECJ judgment of 12 May 1998, case C-367/96 (Kefalas) on VAT taxes; ECJ judgement of 21 June 1988, case C-39/86 (Lair) and ECJ judgement of 19 October 2004, case C-200/02 (Chen) on free movement of persons or workers.

[133] *Charter of Fundamental Rights of the European Union*, mentioned *supra*, Article 54 (Prohibition of abuse of rights): *"Nothing in this Charter shall be interpreted as implying any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms recognised in this Charter or at their limitation to a greater extent than is provided for herein"*.

[134] *Allen v Flood* [1898] AC 1, at 92; the case is mentioned in REID E., *The doctrine of abuse of rights: Perspective from a Mixed Jurisdiction*, available at http://www.ejcl.org/83/abs83-2.html

[135] BYERS M., *Abuse of Rights: An Old Principle, A New Age*, (2002) 47 McGill LJ, pp. 395, 396.

[136] See *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318 (Fed. Cir. 2010) ("*Princo II*"). For the sake of completeness, kindly note that misuse is only an affirmative defence, that can only be used by a defendant in an IP-infringement case and not as a basis for seeking an affirmative relief through an award of damages (in an often used

As we can see, misuse of patent may therefore be strictly related to an anti-competitive behaviour carried out through an IP right: in this sense, the concept presents a strong similarity with the aforesaid examples of (abusive) exercise of IP rights under EU law.

Due to the presence of an analogous figure in US law[137], it becomes hard to claim that the alleged lower success of the concept of abuse of rights contributes to explain the divergent view of US and Europe on reverse payment settlements.

Still, this hypothesis cannot be completely ruled out.

In this regard, it is worth noting that in the last decades, consistently with the more favourable approach adopted by the US Courts towards IP rights, the vigour of the doctrine of misuse of patent had been constantly weakened, as it has been narrowly interpreted and enforced by the American judges. A restriction of its application was also pursued at the legislative level, with the enactment in 1988 by the Congress of a Statute (1988 Patent Misuse Reform Act[138]) expressly shielding certain behaviours, such as refusal to licence and tying by non-dominant firms, from the application of the doctrine.

Echoes of this restrictive trend in restricting the interpretation of the misuse of patent doctrine can be found in the scope of the patent test developed by the 2nd and the 11th Circuits, as well as in the dissenting opinion filed in the Actavis case; in these cases, as we have seen, the judges argued against the possibility of antitrust liability arising from the exercise of a patent apart from the case of a conduct exceeding the scope of the exclusionary powers granted with the patent[139].

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figurative sense we could say that it cannot be used as a sword, but only as a shield); the effect of successfully arguing a misuse is to render the patent unenforceable for the period during which the misuse lasts.

[137] With regard to the similarities between the doctrines of misuse of patent and abuse of rights Please refer to FLANAGAN A., MONTAGNANI M.L., *Intellectual Property and Social Justice: a law and economics approach*, Edward Elgar Publishing (2010) (*"In the EU there is no equivalent to IPR misuse per se; however, there is a recent jurisprudential development within which IPR misuse may fall: the emerging Community "abuse of rights" doctrine"*).

[138] See 35 U.S.C. § 271(d) (1994).

[139] Please refer to the following part (at paragraph I, page 3) from Justice Roberts' dissenting opinion: "*the key, of course, is that the patent holder - when doing anything, including settling - must act within the scope of the patent. If its actions go beyond the monopoly powers conferred by the patent, we have held that such actions are subject to antitrust scrutiny (…). If its actions are within the scope of the patent, they are not subject to antitrust scrutiny, with two exceptions concededly not applicable here: (1) when the parties settle sham litigation, cf. Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U. S. 49, 60–61 (1993); and (2) when the litigation involves a patent obtained through fraud on the Patent and Trademark Office. Walker Process Equipment, supra, at 177"*.

In this sense, the different approach followed by the Actavis decision can be seen as a sort of reaction to the trend of restricting the scope of the misuse of patent doctrine and, more in general, the imposition of limits to the exercise of IP rights. Unsurprisingly, the decision has been hailed by some as a revitalization of the misuse of patent doctrine and as a move towards a *"realistic compromise on how the rules that affect [patent and antitrust spheres] should look like and function"*[140].

Nonetheless, we cannot exclude that the abovementioned reticence of the US courts to apply the misuse of the patent doctrine (or, at least, to enforce it in a narrow way) and, more in general, to impose limits to the lawfulness of conducts based on their "motives" may have influenced not only the dissenting opinion, but also the majority opinion in the Actavis case, preventing it from going "too far" in assessing reverse payment settlements. Finally, this must also be coupled with the current favour, in US antitrust enforcement, for the rule of reason approach[141], that may also have contributed to persuade the US Supreme Court not to follow the *per se* approach sponsored by the FTC.

4) The other policies taken into account in the assessment of antitrust cases

Another possible explanation of the current divergent views about reverse payment settlements can be identified in the policies, other than the ones strictly connected with IP Law and Competition Law (e.g. policies related to the promotion of innovation, economic efficiency and consumers welfare), that are sometimes taken into account in the analysis of antitrust cases.

Also in this case, a general different attitude distinguishes the two sides of the Atlantic. In fact, US antitrust legislation appears a purer[142] and auto-sufficient system, with its internal principles and coherent rules, which at most encounters as limits to its application other binding rules such as IP Law or other State/Federal laws. By contrast, European antitrust system appears as a

[140] LYM D., *The Pendulum Swings: Patent Misuse and Antitrust*, available at http://elgarblog.wordpress.com/2014/02/28/the-pendulum-swings-patent-misuse-and-antitrust-by-daryl-lim/

[141] KOBAK J.B., *Running the Gauntlet*: *Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic*, mentioned *supra*, p. 346 (*"apart from the hard-core horizontal violations, under U.S. antitrust law the rule of reason has again become largely the rule, and the per se rule the exception, for evaluating most conduct"*).

[142] Please refer to AMATO G., *Antitrust and the Bounds of Power* (Oxford, Hart, 1997), p. 116, expressing the desire that EU Competition Law be freed *"from the multiple purposes it has served in the past, enabling it to be, as in the USA, antitrust law pure and simple"*.

system often communicating with various policies, other than the ones strictly related to antitrust rules.

This is consistent with the fact that EU Competition Law was "born" as part of a general legal instrument, a treaty, as such "*involving other considerations of industrial and political policy*"[143]. In addition, EU Competition Law has never been an instrument pursuing only its own intrinsic objectives, but has always been put in connection with the goal of internal market integration[144].

As other examples of non-antitrust specific goals that have been taken into account, from time to time, in the application of EU Competition Law legal scholars quote, among others, industrial policy[145], defence[146], health policy[147], culture, consumer protection[148], unemployment and regional policies[149].

It is worth noting that this apparent completeness and over-inclusivity of the European system carries with it two major risks.

First of all, taking into account other objectives in the antitrust enforcement risks undermining the internal coherence of antitrust law and, since it relies on vague and sometimes arbitrary concepts, creating legal uncertainty[150].

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[143] KOBAK J.B., *Running the Gauntlet*: *Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic*, mentioned *supra*, p. 352. The interference of other policies on the application of EU Competition Law and its connection with the other aims of the European Treaties is well exemplified by the words of the then EU Commissioner charged of Competition policy, Mr. Karel Van Miert, according to whom *"The aims of the European Community's competition policy are economic, political and social. The policy is concerned not only with promoting efficient production but also achieving the aims of the European treaties: establishing a common market, approximating economic policies, promoting harmonious growth, raising living standards, bringing Member States closer together"*. JEBSEN P., STEVENS P., *Assumptions, Goals, and Dominant Undertakings: The Regulation of Competition Under Article 86 of the European Union*, 64 ANTITRUST L.J. 443 (1996), p. 450.

[144] See footnotes 128 and 129 *supra*. It is also worth noting that Articles 101 and 102 TFEU justify the prohibitions of restrictive agreements and abuses of dominant position, thereby set forth, *"as incompatible with the common market"*.

[145] KINGSTON S., *The Role of Environmental Protection in EC Competition Law and Policy*. Doctoral Dissertation, 17.2.2009, University of Leiden, the Netherlands, p. 97, available at https://openaccess.leidenuniv.nl/bitstream/handle/1887/13497/Suzanne%20Kingston%20PhD%20Thesis.pdf?sequence=1

[146] *Idem*, p. 98.

[147] *Idem*, p. 100.

[148] WHISH R., BAILEY D., *Competition Law*, Oxford, Oxford University Press, 2012, pp. 21-25.

[149] *Idem*, p. 23.

[150] Amato also warns against the risk that, due to the fact that the EU Commissions and the national authorities are not qualified, nor entitled, to carry out an analysis of other policy implications, this could lead to economically

Secondly, considering other deserving policies, such as industrial policy, health protection, regional policy, contrast to unemployment and so on, may bring with it the risk of decisions influenced by political considerations: a possibility not so remote in Europe, given the pressures from national governments that antitrust decisions may sometimes be subject to[151] and the fact that the administrative agency mainly charged of antitrust enforcement at the EU Level, the European Commission, is undoubtedly (also) a political body.

The possibility of influence of other policies is not negligible in cases affecting the pharmaceutical industry, due to the fact that such a sector is at a meeting point of different policies and legal issues, including, in addition to Competition Law and Intellectual Property Law, State regulation, health policy and social welfare[152].

In the case of reverse payment settlements, we can assume[153] that the European Commission has been influenced, in its Lundbeck decision and the other relevant cases[154], by the goals of ensuring a viable access to health treatments and of limiting public expenditure. In this regard, it must not be forgotten that the Sector Inquiry, which was the antecedent and the basis of the aforesaid cases, was launched by bearing in mind the needs of ensuring access of consumers to the most advanced medicines and limiting *"health spending by individuals, private health schemes and government health services in Europe"*[155].

Consideration of these purposes could have, therefore, influenced the European Commission in adopting a stricter approach towards reverse payment settlements, seen as instruments

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inefficient decisions and to usurp duties belonging to the legislative bodies. See AMATO G., *Antitrust and the Bounds of Power*, mentioned *supra*, p. 123.

[151] See FOX E. M., *US and EU Competition Law: A Comparison*, in Global Competition Policy, p. 353. The author does not exclude that also US antitrust enforcement may be subject to political influences, but it argues that these would consist more in the effect produced *"by the political philosophy current in the administration rather than [in the] direct interference in particular cases*" (*ibidem*).

[152] PRIDDIS S., CONSTANTINE S., *The pharmaceutical sector, intellectual property rights, and competition law in Europe*, in *Intellectual property and competition law, new frontiers*, mentioned *supra*, p. 241.

[153] The considerations hereinafter reported must be considered assumptions, due to the persistent unavailability of the public version of Lundbeck and the other EU decisions on the subject.

[154] Please refer to Chapter 2, pp. 20-24.

[155] Press release related to the launch of the Sector Inquiry of 16 January 2008, available at http://europa.eu/rapid/press-release_IP-08-49_en.htm?locale=en ; See also Final Report, Introduction, parr. 11-16.

necessarily delaying the availability of newer and cheaper medicines for patients and leading to higher spending for national health systems[156].

On the contrary, in United States the relevant case-law did not generally take into account other policies, apart from the ones strictly related to IP Law and Competition Law. In the case of reverse payment settlements, the only exception could be seen in the frequent references that some courts (basically the ones adopting the scope of the patent test) made to the general interest of the promotion of litigation settlements, seen as an important tool to deal with the high costs, complexity and uncertainty of patent litigation[157]. However, the favour for litigation settlements must be interpreted, more than as a separate policy deserving due consideration in the context of an antitrust assessment, as an economic justification of reverse payment settlements, redeeming its potential anticompetitive effects.

On the other hand, other courts (in a diametrically opposite way, the ones which did not adopt the scope of the patent test) tried to restrict the importance of the promotion of settlements, arguing, for instance, that this should be balanced with other *"countervailing public policy objectives"* and that *"litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers"*[158].

In this regard, it has been interestingly observed that the generics exert a competitive pressure on originators *"not only on price, but also in litigation to challenge patent validity and scope"*, a role that reverse payment settlements seem to irredeemably frustrate.

The reference to the aforesaid *"public policy objectives"* seems at odd with the already mentioned reluctance of US courts to take into accounts other policies in the context of antitrust cases; however, this was echoed in the Actavis case, where the US Supreme Court, while not

[156] In this regard, it is possible to refer to the declaration released by the EU Competition Commissioner Joaquin Almunia in relation to the Lundbeck decision (see footnote 78 *supra*) arguing that *"It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices".*

[157] See, for instance, *Valley Drug Co. v. Geneva Pharm., Inc.; FTC v. Watson Pharm., Inc.,* both mentioned *supra.* See also Justice Roberts' dissenting opinion in the Actavis case, par. IV, p. 17.

[158] *In re K-Dur Antitrust Litig.*, mentioned *supra.*

explicitly mentioning health policy purposes, justified, as we have seen[159], its position on reverse payment settlements by also considering the Hatch-Waxman rationale.

In this sense, the Actavis decision shows again a sort of discontinuity with regard to the previous jurisprudence and has been welcomed as one of the most important decisions on the antitrust/IP interface[160].

Conclusion

Reverse payment settlements, by providing a transfer of a sum (or other economic advantage) from the owner of a right to its alleged infringer, challenge the ordinary features of litigation settlements, in which the transfer of money flows in the opposite direction. Depending on the point of view, this kind of settlements could be regarded as an anticompetitive mean to delay the entry into the market by a competitor (for instance, a generic manufacturer) or as a legitimate way for a patent owner to settle an expensive and uncertain litigation.

At present, the US Supreme Court and the European Commission seem to have a different view on the issue, based on a rule of reason approach and on the qualification of the conduct as an infringement per object respectively. This divergent view has important consequences not only on the qualification of the conduct at stake, but also on the burden of proof upon enforcement agencies and plaintiffs.

While it is still too early to know if the gap between these different approaches will close, I tried to explore in the present thesis the reasons of the current different attitudes of US and Europe: these must be explained, in my opinion, on the ground of the different approach with regard to the interface between Competition Law and IP Law, the minor role played in US by the abuse of rights doctrine or similar concepts and by the more limited consideration of external policies in the context of antitrust analysis under US Antitrust Law.

[159] See page 11, *supra*.
[160] LIM D., *The Pendulum Swings: Patent Misuse and Antitrust*, mentioned *supra*.

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