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ANTITRUST RULES AND INTELLECTUAL PROPERTY RIGHTS IN THE EU AND THE US – TOWARDS CONVERGENCE?

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Abstract: *In light of the exponential increase of the number of investigations raising the issue of how to reconcile competition rules and Intellectual Property Rights (IPRs), it is now clear that the area of Antitrust/IP intersection is becoming the battleground of antitrust enforcers around the Globe. In some areas inherently prone to market power accumulation, antitrust rules tend to clash with IPRs and prevail over the latter, for the intensity in the application of competition rules increasingly depends on the strength of the IPRs at stake, as well as on the sector involved. Information Communication Technology and Pharmaceuticals are the sectors most affected by this trend, as they both display specific market features calling for intensive antitrust scrutiny. Surprisingly enough, in these areas the EU and the US agencies are heading towards convergence, in light of the decisions taken in cases such as the judicial injunctions sought by FRAND-pledged SEPs holders and the reverse settlements in the Pharma sector. The purpose of this article is to show that in those areas more exposed to tension between antitrust and IP rules, there is an increasing level of convergence between the US and the EU. In particular, it is submitted that, like in the EU, the US is departing from the traditional symmetry principle under which antitrust rules are applied to IPRs exactly the same way as other property rights. In this new framework, inconsistency is more likely to come from the enforcement activity of NCAs across Europe.*

1 INTRODUCTION[2]

In light of the exponential increase of the number of investigations raising the issue of how to reconcile competition rules and Intellectual Property Rights (IPRs), it is now clear that the area of Antitrust/IP intersection is becoming the battleground of antitrust enforcers around the Globe. It is no more a matter of a sporadic clash in few intellectually stimulating cases having little relevance for the purpose of the enforcement activity of competition agencies; it is rather a steadily growing conflict showing a discernible trend: in some areas inherently prone to market power accumulation, antitrust rules tend to clash with IPRs and prevail over the latter, for the intensity in the application of competition rules increasingly depends on the strength of the IPR at stake, as well as on the sector involved. Information Communication Technology (ICT) and Pharmaceuticals are the sectors most affected by this trend, as they both display

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[2] This article takes inspiration from another article by the same Author, forthcoming in the Antitrust Chronicle of Competition Policy International

specific market features calling for intensive antitrust scrutiny. Surprisingly enough, in these areas the EU and the US agencies are heading towards convergence, in light of the decisions taken in recent cases such as the judicial injunctions sought by Fair Reasonable And Non Discriminatory (FRAND) pledged Standard Essential Patents (SEPs) holders in the smartphone war, and the reverse settlements in the Pharma sector. A source of inconsistency, though, may come from the enforcement action of National Competition Agencies (NCAs) across the EU, for some of them are taking a far more intrusive attitude towards IPR.

The purpose of this article is to show that in those areas more exposed to tension between antitrust and IP rules, there is a increasing level of convergence between the US and the EU. In particular, it is submitted that, like in the EU, the US is departing from the traditional symmetry principle under which antitrust rules are applied to IPR exactly the same way as other property rights; quite the reverse, IPR deserve special attention due to their specific features and depending also on the relevant economic sector. In this new framework, Inconsistency is more likely to come from the enforcement activity of NCAs across Europe, which are very eager to aggressively enforce competition rules – come what may - in sectors which appear to be strategic for the economy and the consumer welfare.

2 BACKGROUND – ANTITRUST AND IP RIGHTS INTERSECTION – THE CLASSIC VIEW

Conventional wisdom has it that the approach of the US and the EU antitrust agencies when dealing with IPR is fundamentally different.

In the US, since long antitrust enforcement agencies and courts apply the principle of symmetry of IPR relative to other property rights, i.e. IPR do not deserve special attention more than other property rights, hence the same general antitrust principles should apply to conducts involving IPR that they apply to conduct involving any other form of tangible or intangible property[3]. This implies that there is no negative bias and no presumption that IP rights confer market power deserving special attention under antitrust rules.[4]

In the EU, instead, when enforcing antitrust rules the Commission and the EU Courts have traditionally shown less deference towards IP rights than the US. The typical approach spelt-out in the ECJ case-law consists of distinguishing between the existence and the exercise of IPR: conditions for granting an IP right as such (the existence) cannot in principle be challenged under Community Law, while the way such rights are exercised can indeed give rise to abusive exploitation of market

[3] See the 1995 Guidelines on IPR jointly issued by the Federal Trade Commission (FTC) and the Department of Justice (DOJ).

[4] On the symmetry principle in the US, see J. Wright, D. Ginsburg "*Whither symmetry? Antitrust analysis of intellectual property rights at the FTC and DOJ*", CPI,9. 2 (2013): 41.

power or exclusionary forms of unilateral conducts contrary to article 102 TFEU. This has led the Commission to challenge even the most typical way of exercising an IP right, and therefore its very essence.

The relationship between antitrust rules and IPR in the EU has been historically influenced by two main factors: first IP rights have been traditionally tainted with a negative bias given their potential to cause market segmentation along national borders and frustrate the internal market. Second, the traditional form-based approach[5] in the assessment of unilateral conducts combined with the special responsibility principle incumbent upon dominant firms, has resulted in the Commission aggressively enforcing competition rules under Article 102 TFUE, including in those areas of intersection between competition rules and IPR.

This is particularly visible in the area of refusal to deal with rivals, where the distance existing between the US and the EU systems, following the *Microsoft* case (Microsoft I[6]), could not be wider.[7]

Under US antitrust law, as a general principle there is no duty to deal with rivals (see *inter alia* S. Ct. in *Trinko*), even less so when IP rights are involved, for anticompetitive effects stemming from a unilateral refusal to license a valid IPR are a natural consequence of IP Laws themselves.[8]

Under EU antitrust law, the reverse is true, because of its "special responsibility", a dominant firm has in principle a duty to give its rivals access to an input it controls, if its refusal results in a significant elimination of competition in the market dependent upon that input. The same principle tends to apply in case the refusal is based on the exercise of a legitimate IP right,[9] although under more exceptional circumstances. The *Magill/IMS*[10] line of jurisprudence had indeed established that a refusal to grant a license by a IPR holder may amount to an abuse of dominance when: the IPR owner enjoys market power; access to the IPR/input is indispensable in order for competitors to operate in a market dependent

[5] Over the last years, the Commission has increasingly departed from a formalistic assessment of unilateral conducts, moving towards an effect based analysis. See Commission's guidance paper on the application of Article 102 TFEU.

[6] See Commission Decision 2007/53 EC of 24 March 2004; Case COMP/C-3/37.792, *Microsoft* [2007] OJ L32/23 available at: http://ec.europa.eu/competition/antitrust/cases/dec_docs/37792/37792_4177_1.pdf

[7] For a review of the substantive Law applicable in the US and the EU to the refusal to deal in the area of antitrust/IPR intersection, see A. Arena, B. Bergmann, J. L. Himes "*Two bodies of Law separated by a Common Mission: Unilateral Conducst by Dominant firms at the IP/antitrust intersection in the EU and the US*" European Competition Journal 9. (2013), p. 623.

[8] For an extensive review of the topic, see H. Hovenkamp, M. Janis, M. Lemley, *IP and Antitrust*, Aspen, 2004.

[9] For a review of the topic, see V. Korah, *"The interface between intellectual property and antitrust: The European experience"*, in Antitrust Law Journal 69. (2002), p. 801.

[10] See joined cases C-241/91 and C-242/91 P, *RTE and ITP v Commission,* [1995] ECR I-00743 (Magill); case C-418/01, *IMS Health GmbH v NDC Health GmbH,* [2004] ECR I-05039 (IMS Health).

upon such input; refusal to grant a license risks eliminating all competition from such a market; there is no objective justification; the refusal to deal prevents the appearance of a new product.

With respect to the latter requirement, in *Microsoft* for the first time the Commission argued that the test would be met not only in those cases where competitors were prevented from marketing products having specified innovative features relative to the existing ones, but also when the refusal to deal prevented rivals from generically innovating through the introduction of competing products; and the General Court upheld the Commission's view: "preventing the appearance of a new product" is nothing else than limitation of technical development in the broad sense.[11]

The case, which to date still epitomizes the gap existing between the US and the EU in the area of antitrust/IP intersection, raised massive criticism especially on the other side of the Atlantic because of, inter alia, the ever increasing intrusive approach over IP rights being endorsed by the EU Judges. In this respect, there is no doubt that the EU decision has lowered the thresholds for antitrust intervention in case of clash with IPR. Not only does *Microsoft* confirm the *Magill/IMS* doctrine in that, behind the prevalence of competition rules over IP rights there is also an implicit judgement over the intrinsic quality of the IP rights at stake (in this case finally judged unworthy of protection). It also expands the *Magill/IMS* doctrine, for the legal test is now less demanding: it suffices to prove that a refusal to license an IPR prevents any competing product from entering the market in order for the "new product" test to be fulfilled and the sphere of legitimate IPRs be invaded.

3 THE AREAS OF CONVERGENCE

Although admittedly the duty to deal principle set forth by the *Microsoft* doctrine is still good law in the EU and may potentially still have far-reaching implications in future cases, the noise made and the visibility of this case have largely contributed to divert the attention from other important areas of antitrust/IPR intersection where the US and the EU systems appear to head towards convergence.

Interestingly, it is the US System which is coming closer to the EU and moving towards a more interventionist approach,[12] possibly under the influence of some distinguished scholars who have started to challenge the idea of IP rights' untouchability and parity with other property rights. First, it has been argued, IPRs are probabilistic in nature, i.e. they contain a

[11] Case T-201/04, *Microsoft Corp v Commission,* [2007] ECR II-03601 (Microsoft). For a comment, see D. Geradin, "*Limiting the scope of Article 82 of the EC treaty: What can the EU learn from the US SC judgment in Trinko in the wake of Microsoft, IMS and Deutsche Telekom*", Common Market Law Review 41. 6 (2004): 1519.

[12] This is not to say that the US has followed the EU, quite the opposite, US has typically been at the forefront of the debate on the antitrust/IP intersection, with the EU Commission being quicker to put in practice the US principles, also because of the different enforcement models (administrative in the EU).

strong element of uncertainty; many rest on shaky grounds, are issued after a limited examination process and would not stand scrutiny if litigated[13]. Second, IPRs cannot be treated like other property rights since the former may in some circumstances confer market power, sometimes even extraordinary market power. Accordingly, strong antitrust enforcement is needed in presence of strong IPRs.[14] These ideas may have created the favorable intellectual background for a more assertive antitrust intervention in areas such as SEPs in the ICT sector and patent rights in the pharmaceutical sector, as it will be seen in the following.

3.1 Patent hold-up cases

The first important area of convergence concerns the issue of the deceitful acquisition of SEPs and the problem of patent hold-up[15]. A patent hold-up occurs when a patent holder takes part in a standard setting process conducted by a Standard Setting Organization (SSO) to establish an industry standard, and after having had its patent included in the technology standard retained by the SSO, once the standard is in place, threatens to enforce its patent rights to extract supra-competitive prices from firms producing goods which use the standard.

The hold up problem typically occurs in two scenarios: the patent holder takes part in the SSP and fails to disclose to the SSO the existence of relevant IPR, and then once the standard is set, attempts to extract large royalty payments under threat of an injunction (the so called patent ambush); the patent holder first agrees to have its patent included in the standard retained by the SSO in exchange for a commitment to license its patent under FRAND terms, and then attempts to charge to locked-in standard compliant manufacturers much higher rates than FRAND terms.[16]

Deceitful acquisition of patents

The first prominent case investigated by both the US and the EU dealing with the issue of the deceitful acquisition of SEPs is Rambus. The

[13] On the topic, see M. Lemley, C. Shapiro "*Probabilistic patents*" J. Econ. Persp. 19. (2005), p. 75.

[14] On the topic, see M. Lemley, "*New balance between IP and antitrust*", Sw.J L & Trade Am. 13. (2007), p. 237.

[15] For an extensive comment on the patent hold-up issues and the Rambus case, see J. M. Wallace, "*Rambus v. F.T.C. in the Context of Standard-Setting Organizations, Antitrust, and the Patent Hold-Up Problem*", Berkeley Technology Law Journal 24. (2009), pp. 661-693; B.H. Kobayashi and J.D. Wright, "*Federalism, Substantive Pre-Emption, and Limits on Antitrust: an Application to Patent Holdup*", Journal of Competition Law & Economics 5. 3 (2009), pp. 469-516; J. Farrell, J. Hayes, C. Shapiro, T. Sullivan, "*Standard setting, patents and hold-up*", Antitrust Law Journal 74. (2007), p. 603.

[16] The issue of patent trolls and patent holds-up had been long debated in the US which has put forward a two-fold approach to address the problem from a competition stand-point: an ex ante solution, i.e. SSOs should be antitrust exempted if they agreed upon the FRAND terms to which the patents included in the technology (SEPs) would be licensed to standard compliant manufacturers; ex-post intervention, meaning that a deceitful acquisition of a SEP with a view to extorting exorbitant royalties from standard users should be treated as a form of unlawful monopolization caught by S. 2 of the SA, as well as unfair trade practice hurting consumers under section 5 of the FTC Act. A similar approach has been endorsed by the EU Commission, see Guidelines on horizontal agreements.

facts investigated by the two agencies were exactly the same: Rambus was a patent troll (i.e. non practicing entity) which engaged in a so-called patent ambush strategy in the context of the US-based standard setting organisation JEDEC. It intentionally concealed its SEPs relevant to technology used in the JEDEC standard for DRAMs (chipset memories), and subsequently claimed excessive royalties for those patents from JEDEC compliant DRAM manufacturers.

The case started first in the US, where the FTC challenged Rambus deceptive behavior as form of unfair competition (S. 5 FTC Act) and as an attempt of unlawful monopolization (S. 2 SH. Act). However, the FTC decision was quashed by DC Circuit Court of appeal on the ground that the FTC had not demonstrated that Rambus deception of Jedec SSO had directly caused the latter unlawful acquisition of monopoly power.[17]

In the EU, the case was investigated later and assessed on a different legal standard. Since Article 102 prohibition does not include conducts resulting in an unlawful acquisition of market power (only the abuse of dominant position can be challenged and not the creation of dominance as such), the Commission challenged Rambus behavior as a form of exploitative abuse, i.e. a deceptive conduct aimed at extracting monopoly profits from royalties paid by SEPs licensees. However, finding evidence of an exploitative abuse is a very difficult exercise and this case proved to be no exception.[18] This is why at the end, *in dubio* as to having collected sufficient evidence to the requisite legal standard, the Commission opted for settlement (Commitment decision): Rambus committed to license patents relating to DRAM technology at FRAND conditions.[19]

The interest of this case lies in the fact that the patent hold-up theory of harm inspiring the investigations on both sides of the Atlantic was developed in the US and then imported and applied in the EU– although under somehow different legal grounds. Despite the different outcomes, in fact Rambus is the first case showing a similarity of approaches between EU and US agencies in dealing with SEPs corrupted by an element of deception.

SEPs and judicial injunctions

Similar convergence is emerging in the way US and EU agencies are dealing with the

[17] *Rambus Inc. v FTC* 522 F 3d 456 (DC Cir 2008).

[18] A price can be deemed excessive under the EU case law when it has no reasonable relation to the economic value of the product supplied. This requires a two-stage analysis aimed at examining whether the difference between the costs actually incurred and the price actually charged (the profit margin) is excessive. Investigating a case of excessive prices thus requires the following analytical steps: collecting costs and revenues of the dominant firm in the relevant market; calculating profits of the dominant firm in the relevant market; comparing such profits to the profits generated either by a competitor in the same relevant market or by the dominant firm in a different (geographic) market acting as competitive benchmark; demonstrating the disproportion between the dominant firm's profit margins in the relevant market and the fair benchmark profit margin.

[19] Commitment Decision of 9 December 2009, Case COMP/38.636, *Rambus*, available at: http://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pd

injunctions sought by SEPs' holders vis-à-vis willing licensees in the context of the smartphone war.[20]

The facts investigated are the same: all these cases are about the recourse (and enforcement) to injunctions by the owners of SEPs, towards potential licensees willing to enter into a license on FRAND terms.

The theory of harm behind the agencies' interventions on both sides of the Atlantic is by and large the same: since injunctions generally involve a prohibition of the product infringing the patent being sold, by seeking or enforcing injunctive relief in court against a willing licensee, a SEP holder can impose unfair or unreasonable licensing terms to the licensee and cause significant foreclosure by forcing competitors out of the market. Such a threat can therefore distort licensing negotiations and lead to anticompetitive licensing terms that the licensee of the SEP would not have accepted absent the seeking of the injunction.[21]

The legal grounds on which these conducts are challenged are partly different (like in Rambus): in the US the agencies treat these conducts as either an act of unfair competition under section 5 FTC A, or as an attempt of willful monopolization under S. 2 SA. The EU Commission seems to oscillate between qualifying these behaviors as either a form of exploitative abuse (i.e. an attempt by a dominant firm to extract from its clients supra competitive profits along the lines of Rambus) or as cases of indirect refusals to deal (exclusionary abuses) causing foreclosure.[22]

The outcomes are by and large consistent with only some caveats: while the US investigations have been closed with settlements,[23] the EU investigations have just ended with a commitment decision[24] and a prohibition

[20] In more general terms, the same approach in dealing with FRAND-encumbered SEPs has also been clearly spelt out in the guidelines respectively issued by the EU Commission and the US agencies in this area. See EU *Guidelines on horizontal cooperation agreements*, and DOJ and FTC *Antitrust guidelines for collaboration among competitors.*

[21] As to the US position on the topic, see *Prepared Statement of The Federal Trade Commission Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights Concerning "Standard Essential Patent Disputes and Antitrust Law"*, Washington, D.C., July 30, 2013.

[22] The recent Motorola decision, not yet available, will cast light on what legal standard the Commission has applied to these cases. For an extensive comment on the legal test applicable to such conducts in the EU, in particular whether the strict test laid down in the *ITT Promedia* jurisprudence (T-11/96) should apply, see N. Petit "*Injunctions for FRAND-pledges SEPs: the quest for an appropriate test of abuse under article 102 TFEU"*, European Competition Journal 9. 3 (2013), p. 677. See also M. Rato, N. Petit "*Abuse of dominance in technology-enabled markets: established standards reconsidered*?" European Competition Journal 9. 1 (2013), p. 1.

[23] In the US Google has committed to cease seeking injunctions against a willing licensee, either in US federal courts or at the ITC, to block the use of any standard-essential patents that the company has previously committed to license on FRAND terms. See Motorola Mobility LLC and Google Inc., F.T.C. File No. 121-0120 (July 22, 2013) at 5, available at http://ftc.gov/os/caselist/1210120/130724googlemotorolacmpt.pdf

[24] See Commission decision of 29 April 2014, not yet available. Samsung has committed not to seek any injunctions in the European Economic Area (EEA) for a period of five years on the basis of any of its SEPs, present and future, that relate to technologies implemented in smartphones and tablets against any

decision – without fine – respectively. In the Motorola case, in particular, the Commission has ultimately taken a more radical approach than the US counterparts, holding that not only the threat of the enforcement of an injunction vis-à-vis Apple, but also Motorola insistence that Apple gives up its rights to challenge the validity by Apple's mobile devices of Motorola SEPs should be regarded as abusive.[25]

Besides confirming that the US and EU agencies agree on how to treat patent holds-up, these cases show that the level of convergence has significantly escalated, i.e. antitrust rules can now encroach upon what is an essential feature of full fledged IPR, that is to protect the property right vis-à-vis potential infringers through recourse to justice, which is a fundamental right.

It is true that in the current debate over the legality of injunctions sought by SEPs holders, a prominent role is played by the origins of these rights, that is the FRAND commitments taken in the context of the SSO as a precondition for the patent owner to have its patent inserted in the technology selected as a standard. This would confer a somewhat deceptive connotation to the behavior of a SEP holder who first seems to agree on, and then reneges his commitment and tries to extort better licensing terms to locked-in rivals. This is to say that stronger enforcement of antitrust rules – up to impinge upon the very essence of IPR, would be justified only by the original sin of the IPR at stake, and not under ordinary circumstances.

On the other hand, unlike the most blatant forms of patent ambushes,[26] in such cases the allegedly deceptive nature of the conduct taken by the FRAND-pledged SEP's holder is far from being straightforward. For instance, one of the issues hotly debated in the context of the SEPs encumbered technologies and products, is whether in the context of a SSO a precise agreement has been reached about the FRAND terms and conditions to which license the SEPs or whether only an agreement in principle has been reached, i.e. without defining the exact financial terms (*an* but not *quantum*). Some

company that agrees to a particular framework for licensing the relevant SEPs. The licensing framework provides for: a negotiation period of up to 12 months; and if no agreement is reached, a third party determination of FRAND terms by a court if either party chooses, or by an arbitrator if both parties agree on this. An independent monitoring trustee will advise the Commission in overseeing the proper implementation of the commitments.

[25] See Commission decision of 29 April 2014, not yet available. In the decision, the Commission has found that it was abusive for Motorola to both seek and enforce an injunction against Apple in Germany on the basis of an SEP which it had committed to license on FRAND terms and where Apple had agreed to take a licence and be bound by a determination of the FRAND royalties by the relevant German court. The Commission has also found it anticompetitive that Motorola insisted, under the threat of the enforcement of an injunction, that Apple give up its rights to challenge the validity or infringement by Apple's mobile devices of Motorola SEPs. The Commission has decided not to impose a fine on Motorola in view of the novel issues addressed by its decision.

[26] I.e. those strategies of patent ambushes put in place by patent trolls who are not active on the market and earn their life by enforcing their IP rights and attempting to extort the highest possible rents.

commentators also note that the problem of reverse hold-up should not be underestimated, i.e. the possibility that SEP implementers may themselves delay to agree to FRAND to extract better licensing terms from SEP holders. Under all these circumstances, the enforcers' intervention aimed at inhibiting the recourse to an injunction may unduly tip the contractual negotiation in favour of the candidate licensee.

Therefore, there must be a *quid pluris* justifying such an intrusive approach in this area, probably to be found in the specific features of the industry and the IPR at stake. In the ICT sector, intuitively enough, SEPs holders tend to have an extraordinary market power precisely due to the fact their patents read on an industry standard, i.e. a technology adopted by all market players. Moreover, the foreclosure effects resulting from the exercise of such rights can be accentuated by the ICT specific market features - namely direct and indirect network effects, two sided market, high R&D and fixed costs, need of interoperability relationships between market actors, etc. - which are conducive to market concentration.

In sum, while the supposedly FRAND-pledged nature of the IPR at stake should not be underestimated, these cases point nonetheless to a common trend consisting of a more aggressive antitrust enforcement in those areas where IPRs confer to their holders significant market power and market features are conducive to monopolization, thus pleading for tough antitrust intervention.

3.2 Pharmaceuticals - Branded and generic drugs

The second area in which there is growing convergence in the way the US and the EU antitrust agencies accommodate competition rules with IPR concerns the relationships between branded and generic drugs manufacturers, particularly with respect to two issues: i) the settlements between brand name and generic manufacturers designed to delay market entry of the latter in return for some profit sharing mechanism; ii) the misuse of patent rights and other regulatory procedures by branded drug manufacturers aimed at keeping generics off the market.

Reverse settlements in the pharmaceutical sector

A remarkable convergence is emerging in the treatment of the *reverse settlements* (otherwise known as *pay for delay*)in the pharmaceutical sector.[27]

In the EU, the Commission has not hesitated to challenge – although indirectly – the soundness of the patent rights standing behind these settlements.[28] The Commission has

[27] These are commercial agreements between originators and generic competitors to settle patent-related disputes (dispute/opposition procedure/litigation) concerning the manufacturing and/or marketing of a generic version of a drug which is claimed to be protected by a patent. The theory of harm pursued by the agencies on both sides of the Atlantic is the same: delay of generic entry in return for value transfer with a view to preventing direct competition is a horizontal anticompetitive agreement similar to a price-fixing or market partitioning – Sharing of monopoly profit.

[28] While in the US these cases have attracted since some time a lot of scrutiny, In the EU, these cases came for

indeed developed a test based on what appear to be "signs of weakness" of the patents involved. In particular, based on the Commission's recent practice in point, two requirements have to be met in order for such settlements to be deemed anticompetitive by object:

i) the settlement agreement somehow limits the generic company's ability to enter the market (e.g. through a no-challenge clause; non-compete clause; originator licenses the generic company/appoints the generic company as distributor);

ii) the agreements entails some value transfer from the originator to the generic company in the form of monetary transfer or in kind (e.g. distribution agreement; license); in this context the size of value transfer is an important factor to consider (i.e. the disproportion between the payment, in whatever form, and the litigation costs and risks) because it signals there may be a profit sharing mechanism.

the first time to the attention of DG Comp in the context of the pharma sector enquiry. To date, there are two pending investigations and two cases recently decided by the Commission: Lundbeck (closed with prohibition decision and fine, see Decision of 19 June 2013, not yet published), concerning direct payments, purchases of generic stock and distribution agreement when patent was expired in return for delayed generic entry; Servier (pending), which concerns alleged direct payment when patent was about to expire in return for delayed generic entry; Cephalon & Teva (pending), about alleged direct payment and side deals in return for delayed generic entry; J&J & Novartis, recently decided (see Decision of 10 December 2013, not yet published), which concerns a Co-promotion deal.

While there is ostensibly no inquiry on the validity of the patent, and the issue appears to be irrelevant for the EU assessment, nonetheless, the conclusion is that present the conditions above, there is an implicit presumption that either the settlement imposes to the generic manufacturer restrictions going well beyond the scope and duration of the patent, or the patent is weak, that is the patent holder fears its patent does not meet patentability criteria (e.g., granted based on provision of incorrect, misleading, or incomplete information) and, should its patent be challenged in court by the generic manufacturer, it would likely succumb.

Present these conditions, the Agreement will be deemed anticompetitive by object with no need to prove effects. The agreement can still be exempted under Article 101 (3) TFEU, although the burden of proof is on the parties to demonstrate that efficiencies and other redeeming virtues compensate for adverse impact on competition. In practice, this means that present these conditions (transfer value and delay of possible entry) illegality presumption is very difficult to rebut.

This approach is by and large equivalent to the US (short form) rule of reason approach recently endorsed by the US Supreme Court in the *Actavis* ruling.[29] The resemblances are strong: the test applied by the SP is whether the settlement of a patent infringement suit entails a large and unexplained payment to a generic infringer. Present this requirement, the

[29] *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013).

settlement can be held unlawful under the rule of reason analysis, i.e. without inquiry as to whether the patent is invalid or not, and even if the settlement does not go beyond the scope of the patent nominal coverage. Hence, the agencies – or a plaintiff in court - have to demonstrate i) that the payment from a branded drug manufacturer to a prospective generic exceeds the cost of avoiding litigation, ii) likelihood of market power and competitive harm. With respect to the latter requirements, though, the Supreme Court made clear that there is no need to conduct a full scale rule of reason analysis, which traditionally requires definition of a relevant market, demonstration of market power and anticompetitive effects. In this case, instead it would suffice to take the (large and unexplained) size of payment as strong indicator of market power[30] and competitive harm.[31] This is tantamount to say that, once there is evidence of a large and unexplained payment, anticompetitive effects are somehow inherent to the settlement as such - which in turn is very close to endorse an analysis by object only, like in the EU- in order to reverse the burden of proof upon the parties to the agreement.[32]

It is noteworthy that the analytical framework endorsed by the Supreme Court in *Actavis* is a midway between the agencies radical approach, suggesting an illegality per se of any reverse settlement any time a large and unexplained payment is involved, and the more deferential test devised by US Courts, which revolves around the "scope of the patent". The latter test is based on presumption of patent validity, i.e. any settlement staying within the scope of the patent (e.g. keeping the generic away from the market until the patent expires) is lawful because the patent standing alone, if valid, would have kept the generic out of the market any way. Settlement can be anticompetitive only when the patent dispute is a sham, the patent has been fraudulently obtained, restrictions clearly go beyond the exclusionary zone of the disputed patent.

Interestingly, although it is clear that in assessing the antitrust legality of reverse settlements there is no need to evaluate the validity of the patent at stake, it is equally clear that, like in the EU, under the analytical framework endorsed by the Supreme Court in *Actavis*, antitrust concerns prevail over those of patent law in those cases where the patent is (presumed to be) unworthy of protection– e.g. in those cases where the delay in entering the market agreed in the settlement does not extend beyond the patent coverage and yet the

[30] The reasoning behind is that in patent dispute a patent holder would pay no more than the anticipated monopoly rents generated by the branded drug over the remaining period. This is why a large payment is indicative of market power.

[31] The reason being that a large payment would be irrational unless the branded drug manufacturer believes the generic drug would significantly reduce its monopoly profits.

[32] Moreover, in pharma cases, existence of market power and effects tend to be easy to demonstrate given that it is very common that a branded drug manufacturer holds a significant share - if not monopoly of the relevant market -, and the selling price of brand name drug is significantly higher than a generic drug, hence the effect of preventing a generic producer from entering the market on prices are significant by definition.

large payment made by branded drug producer to the generic manufacturer to stay away will be taken as indirect evidence of the weakness of the patent.[33]

Misuse of patent and other regulatory procedures against generics

Although in this area there are no cases having been recently assessed in parallel in the EU and the US, the state of the art on both sides of the Atlantic is similar.

In the US, the issue of patent frauds has since long been tackled from an antitrust angle,[34] i.e. patents obtained as a result of inaccurate or misleading representations to the competent patent authorities may be deemed to constitute illegal monopolizations contrary to S. 2 of the Sherman Act, to the extent it can be demonstrated that misrepresentation has been deliberately carried out (i.e. intent), such patents confer market power to the patent holder and have indeed been enforced – e.g. by claiming royalties or warning rivals to stay out of the market.

Also other types of misuse of regulatory procedures involving IP rights with the aim of keeping generics off the market may result in a violation of S. 2 the Sherman Act. In particular, the US agencies and courts have found that strategies put in place by the branded drug manufacturer to artificially manipulate the pharmaceutical regulatory framework - such as for instance an artificial change of the formulation of the brand name drug from capsule to tablets or from a dosage to another - with the specific aim of blocking the generic entry without bringing any tangible product improvement, can violate antitrust rules.[35]

In the EU, the leading case *Astra Zeneca*[36] deals with both the issue of patent frauds and other forms of manipulation of the regulatory system aimed at keeping competitors out of the market. With respect to patent fraud, based on the Astra Zeneca ruling, it appears that a misleading representation to a patent office[37] made by a dominant firm to obtain an exclusive right (in this case supplementary patent protection) with a view to keeping competitors away from the market constitutes an abuse of dominant position.[38] Therefore, under the EU case-law the main requirement in order for this type of abuse to materialize is that the exclusive right enabling the dominant firm to exclude

[33] For a comment on Actavis, see H. Hovenkamp "*Anticompetitive patent settlements and the Supreme Court's Actavis decision*", Minnesota Journal of Law 15. 1 (20014), p. 3.

[34] See *Walker process v. Food Machinery and Chem. Corp.* 382 US 172 (1965).

[35] *Abbott v. Teva*,432 F Supp 2d 408 (D Del 2006).

[36] Case C-457/10 P, *Astra Zeneca v Commission.*

[37] The Commission found that Astrazeneca had made misleading representations to the patent offices of a number of EU member states with respect to the issuance date of the first marketing authorization for its drug Losec. This led some patent offices to grant Astra Zeneca a longer patent protection period than it should have been entitled.

[38] The Court has set the standards of proof very low, requiring only demonstration of the misleading nature of the representation based on which IPR protection has been obtained. Instead, neither proof of deliberate anticompetitive intent nor of actual enforcement of the patent rights wrongfully obtained is required.

rivals from the market has been granted on grounds which prove to be false or inaccurate.

As to other forms of misuse of regulatory procedures, In *Astra Zeneca* the Commission found that Astra Zeneca had committed an abuse of dominance for having deregistered the marketing authorization of one of the formulations of its drug Losac (capsules) in some EU member states precisely with a view to preventing competitors from marketing the generic versions based on the abridged marketing procedure – which was available to the generic manufacturer only in presence of a regular market authorization of the brand name drug. The Court then upheld the Commission's view, holding that a strategy designed by an originator to take undue advantage of the existing regulatory framework – even if consisting of conducts which are otherwise lawful - in order to create artificial barriers to the generic entry, can be deemed abusive if it has no objective justifications but the very aim of keeping generic manufacturers off the market.

In sum, in both US and EU jurisdictions manipulation of IPR rules with a view to obtaining monopoly power and keep competitors off the market can give rise to two distinct unilateral anticompetitive conducts: i) under the first category (the patent fraud) competition rules directly clash with and override IPRs, for the latter are deemed to be flawed, i.e. they have been granted based on inaccurate or misleading representations. Under the second category, which rather concerns the misuse of ancillary regulatory procedures with a view to excluding rivals, IPRs are not directly questioned.

3.3 The view of NCAs - Pfizer

While EU and US head towards convergence in the areas highlighted above, some recent decisions taken by National Competition Authorities of the EU in the Antitrust/IP intersection area remind us that convergence is also an issue to consider within the EU.

The most exemplary case in this respect is the recent decision for abuse of dominance taken in Italy by the Italian Competition Authority, where Pfizer was heavily fined for having misused administrative procedures and litigation in the context of a complex strategy designed to artificially delay the entry of new generic drug competing with Pfizer product Xalatan.[39]

Although the ICA decision explicitly refers to the abuse of regulatory procedure theory applied by the EU Commission in *Astra Zeneca* and endorsed by the ECJ, the facts appear somehow different. In *Astra Zeneca*, as mentioned earlier, the foundation of the Commission's theory of harm was the fact that Astra Zeneca had obtained patent protection by submitting misleading information to the competent patent agency; in this case, conversely, it is undisputed that Pfizer employed lawful means provided by the patent system to extend the duration of the protection (a divisional patent). Nonetheless the ICA considered that the fact to file an application

[39] See ICA Decision of 11 January 2012, n. 23194.

for a divisional patent – which as such was a perfectly legitimate conduct under Italian Patent Law[40] – in combination with other conducts (such as launching judicial proceeding against the generic suppliers in order to prevent the sale of the generic and putting in place other strategies designed to block the entry), was not "competition on the merits" and constituted an abusive strategy solely designed to artificially delay a generic competitor from entering the market. The ICA reasoning was ultimately upheld by the Administrative Supreme Court.[41] The Judge held that a dominant company could not engage in conducts that, although legitimate pursuant to patent laws, has the sole purpose of foreclosing rivals. In particular, the Judge held that such abuse of dominant position belongs to the broader category of "*abuse of rights,*" i.e. a legitimate right is instrumentally exercised for a purpose other than that for which it was granted. In the case at stake, the State Council noted in line with the ICA's reasoning, a divisional patent was requested not to obtain a protection for an additional therapeutic use, rather with the sole aim of extending the duration of the original patent protection and thus hinder the entrance of competitors in the market. The problem with this reading is that, to the extent an originator has obtained a valid (divisional) patent right without filing inaccurate or misleading submissions with the patent agency, he is entitled to exclude competitors in order to reap the reward of exclusivity without violating antitrust rules, for this is the very essence of a patent right.[42]

The novel – and alarming – development of this case is that it marks a further – and more substantial invasion of antitrust rules over the sovereign sphere of IP rights. Under the *Astra Zeneca* doctrine, abusive behavior by a dominant firm could materialize in case of either patent fraud or misuse of regulatory procedures aimed at excluding rivals. Following the *Pfizer* ruling, there is a new category of abuse, namely instrumental use of legitimate patent rights with a view to foreclosing rivals. Accordingly, not only can antitrust rules prevail and nullify IP rights' typical features (i.e. *ius excludendi omnes alios*) in those limited cases where it can be presumed there is something wrong with the patent in the first place (e.g. an inaccurate representation to the Patent Office); but also can antitrust rules challenge perfectly lawful patent rights in those situations where such rights are exercised – possibly in combination with other conducts – with an exclusionary intent, i.e. with a view to preventing competitors' entry; which is tantamount to say that the existence as such a lawful patent right may now be exposed to antitrust scrutiny, for attempting to protect exclusivity and keep competitors out of the

[40] It is noteworthy that Pfizer application for a divisional patent was first annulled and then ultimately upheld by the EPO (following an appeal procedure).

[41] See Consiglio di Stato, Judgement of 12 February 2014, *Autorità garante c. Pfizer*, n. 09181.

[42] For a comment of the decision, see D. Geradin "W*hen competition law analysis goes wrong, the Italian Pfizer/Pharmacia case*" 2014.

market is the most typical way of exerting a patent right.

4 CONCLUSIONS

In reconciling antitrust rules and IPR the US and the EU have been traditionally regarded as two worlds apart. Under the EU *Microsoft* doctrine - the argument goes – an IPR holder has an exorbitant duty to deal with competitors as long as it can be demonstrated that the refusal results in significant elimination of competition from the market. The reality is that, despite *Microsoft*, US and EU approaches are increasingly consistent.

In light of the recent developments in the area of judicial injunctions and SEPs, and following the Supreme Court ruling in Actavis with respect to reverse settlements, it is now clear that the US is departing from the traditional symmetry principle under which antitrust rules are applied to IPR exactly the same way as other property rights.[43] There is in particular an increasing recognition that IPR cannot be wholesale antitrust exempted and may deserve special attention due to their specific features (probabilistic nature) and their strength, i.e. their potential to cause significant market foreclosure, depending also on the relevant economic sector. Hence antitrust enforcement is becoming increasingly strong when IPRs are (implicitly) judged unworthy of protection (e.g. a weak patent protecting a branded drug which, but for the settlement, would have been otherwise successfully challenged by a generic manufacturer); and is also strong when IPR are strong[44] – e.g. SEPs in sectors prone to monopolization due to the specific market features (network effects, two sided markets, switching costs, etc.).

As to the EU, although the duty to deal principle set forth by the *Microsoft* doctrine is still good law and may potentially have far-reaching implications, as a matter of fact, since *Microsoft*, no cases yet have been decided based on this doctrine. In the meantime, in other important areas of intersection of antitrust rules and IPR, such as SEPs in the ITC sector and patent rights in the pharma sector, the Commission cases show a significant level of consistency relative to the US twin investigations.[45]

What is left as a potential source of inconsistency is the practice of some NCAs across the EU, which in an attempt to emulate the Commission's bold stance, may take sometimes decisions having disruptive effects over the very essence of IP rights.[46]

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[43] On the symmetry principle in the US, see J. Wright, D. Ginsburg "*Whither symmetry? Antitrust analysis of intellectual property rights at the FTC and DOJ*", CPI, 2013 (9) 2, 41.

[44] On the topic, see M. Lemley, *New balance between IP and antitrust*, Sw. J L & Trade Am., 2007, 237.

[45] Although, admittedly, in some of the latest investigations the Commission's attitude remains bolder than the US, the difference is more to with the EU administrative enforcement model enabling the Commission to be more assertive in its enforcement action.

[46] Todino M., *Antitrust rules and Intellectual Property Rights in the EU and the US – Towards convergence?*
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