

A FISTFUL OF EUROS: EU COMPETITION POLICY AND REVERSE PAYMENTS IN THE PHARMACEUTICAL INDUSTRY

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A. INTRODUCTION

Patent settlement agreements (PSAs) are contracts concluded to put an end to a dispute on the validity or the scope of a patent. Reverse payments or “pay-for-delay” agreements are PSAs which stipulate a payment from the patentee to those who challenge the patent. Patent-intensive industries, such as the pharmaceutical industry, provide fertile ground for these agreements. The recent decisions of the EU Commission in *Lundbeck*, *Johnson & Johnson* and *Servier*¹ have ultimately brought the problematic relation between reverse payments and EU competition policy to the fore.

A vibrant doctrinal and academic debate surrounds reverse payments in the US. Interestingly, this debate was brought to a head by a US Supreme Court judgment issued a couple of days before the Commission’s decision in *Lundbeck*. An analysis of US antitrust practice demonstrates that the various positions in this debate primarily depend on how, and to what extent, patent law considerations come into play in the antitrust scrutiny. By contrast, the scant EU practice does not clarify how these two policies interact with each other. Bearing this in mind, we put forward an interpretation of EU competition rules—in particular, Article 101 of the Treaty on the Functioning of the European Union (TFEU)—which combines these two policies.

To do so, this article proceeds as follows. First, it enquires into the tension between patent policy and competition policy embedded in reverse payments. Secondly, while taking into consideration the applicable regulatory frameworks, it investigates how US courts have reconciled patent and competition policy when dealing with reverse payments. Thirdly, after having highlighted the

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¹ Commission Decision of 19 June 2013, *Lundbeck and others*, no public version available; Commission Decision of 10 December 2013, *Johnson & Johnson and others*, no public version available; Commission Decision of 9 July 2014, *Perindopril (Servier) and others*, no public version available.

peculiarities of the EU regulatory and economic context, it looks into the EU Commission's practice in order to identify which questions still remain open after the recent decisions on reverse payments. Bearing this in mind, it puts forward an interpretation of Article 101 capable of integrating competition policy with patent policy and consistent with the EU context. Notably, we suggest that, on the one hand, agreements providing for excessive reverse payments may be anticompetitive and can hardly be justified under Article 101(3), while, on the other hand, they may reveal that the patent on which they are based is invalid.

B. BETWEEN STATIC AND DYNAMIC EFFICIENCY: THE COMPLEX INTERACTION BETWEEN PATENT AND ANTITRUST LAW

Before delving into reverse payment agreements, it is worth analysing the economic rationale for patents as well as their interplay with competition rules. Neoclassical economics has traditionally regarded patents as an instrument to promote innovation. Innovating means nothing less than increasing scientific and technical knowledge. Seeing as knowledge is a public good,² the level of innovation would be suboptimal without government intervention.³ Patents establish property rights, thereby creating a monopoly for innovators.⁴ The prospect of future monopoly profits⁵ incentivises firms to make substantial investments in R&D,⁶ which are, in turn, conducive to innovation. The neoclassical view, however, has been seriously questioned, with some authors maintaining that patents are not conducive to innovation.⁷ Nevertheless, for the purposes of this article, we will assume that the pharmaceutical industry falls into the neoclassical framework.⁸

² See J Stiglitz, "Knowledge as a Global Public Good" in I Kaul, MA Grunberg and I Stern (eds), *Global Public Goods. International Cooperation in the 21st Century* (Oxford University Press, 1999), 308.

³ MA Lemley, "A New Balance between IP and Antitrust" (2007) 13 *Southwestern Journal of Law and Trade in the Americas* 1, 3–4.

⁴ *Ibid.*, 3–4.

⁵ See, eg SM Besen and IJ Raskind, "An Introduction to the Law and Economics of Intellectual Property" (1991) 5 *Journal of Economic Perspectives* 1, 4; EW Kitch, "The Nature and Function of the Patent System" (1977) 20 *Journal of Law and Economics* 265, 265–66.

⁶ JB Baker, "Beyond Schumpeter v Arrow: How Antitrust Fosters Innovation" (2007) 74 *Antitrust* 575, 579.

⁷ See, eg M Boldrin and DK Levine, *Against Intellectual Monopoly* (Cambridge University Press, 2008), 241; BH Hall, "Patents and Patent Policy" (2007) 23 *Oxford Review of Economic Policy* 568, 572–75; M Maggolino, "The Economics of Antitrust and IP Rights" in SD Anderman and A Ezrachi (eds), *Intellectual Property and Competition Law* (Oxford University Press, 2011), 73; M Glader, *Innovation Markets and Competition Analysis*, (Edward Elgar, 2006), 42–46.

⁸ European Commission, "Pharmaceutical Sector Inquiry, Final Report" (2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

That said, the protection and the promotion of innovation through patents comes at a price, as they constitute an interim exception to competition rules. No wonder there can be a tension between competition and patent policy, which has often been regarded as a tension between static and dynamic efficiency.⁹ Static efficiency consists in the achievement of allocative and productive efficiency.¹⁰ Dynamic efficiency, in contrast, is a quite murky concept, which has nonetheless been defined as the amount of technological progress and innovation achieved by a given economy.¹¹ Though it would seem that static and dynamic efficiency are two irreconcilable objectives, it is possible to strike a balance between them by granting patents only to truly innovative inventions. As a consequence, a high-quality patent system represents a crucial factor in balancing these apparently contrasting rules and objectives. Unfortunately, a wide range of reasons, such as heavy workload and limited resources, may lead patent offices to grant patents even when there is no valuable innovation to protect. Patent quality also varies significantly in patent systems around the world. A recent study has shown that it ranges from the high quality of the European Patent Organisation (EPO) system to the extremely low quality of the US and Canadian patent systems.¹² Be that as it may, there will always be a number of invalid patents even in the high-quality systems. For this reason, legal systems usually provide for an *ex post* judicial assessment of patent validity and scope. However, it may also be that patents are never challenged before a court.

(accessed on 2 November 2014); JR Peritz, “The Competition Question Unasked in *Actavis*: What is the Scope of the Patent Right to Exclude?” (2013) 28 *Antitrust* 45, 47.

⁹ This position does not entirely describe the role of competition and patent law. In fact, it is well established that competition rules pursue dynamic efficiency to some extent. See D Schnichels and S Sule, “The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement” (2010) 1 *Journal of European Competition Law & Practice* 93, 104; AF Abbot and S Michels, “Exclusion Payments in Patent Settlements: A Legal and Economic Perspective” (2006) 1 *Journal of Intellectual Property Law & Practice* 207, 207–8.

¹⁰ Authoritative commentators maintain that allocative and productive efficiency maximise consumer and producer welfare. See, generally Maggiolino, *supra* n 7, 76–77; D Geradin, A Layne-Farrar and N Petit, *EU Competition Law and Economics* (Oxford University Press, 2012), 66–67.

¹¹ W Kerber, “Should Competition Law Promote Efficiency? Some Reflections of an Economist on the Normative Foundations of Competition Law” in J Drexler, F Idot and J Monéger (eds), *Economic Theory and Competition Law* (Edward Elgar, 2008), 6.

¹² To measure the quality of patent systems, a recent study has developed a patent strength index. This index is composed of nine elements, such as the allotted period for examination request, the amount of resources assigned to the examiners and their workload. See M de Saint-Georges and B van Pottelsberghe de la Potterie, “A Quality Index for Patent Systems” (2013) 42 *Research Policy* 704.

C. PATENT SETTLEMENT AGREEMENTS IN THE PHARMACEUTICAL SECTOR

Reverse payments, or “pay-for-delay” agreements, represent an extrajudicial solution to disputes concerning the validity and/or scope of a patent. In the pharmaceutical sector, the parties to these agreements are a manufacturer which produces a branded drug and one or more generic companies seeking to produce a generic equivalent of the brand-name drug. The payment is “reverse” because it flows from the claimant (the patentee) to the defendant (the generic), whilst settlements usually imply a payment from the defendant to the claimant. They are also named “pay-for-delay”¹³ as the patentee, through the payment, can keep the potential competitor out of the market for a period of time agreed upon by the parties.

Parties may design those agreements in a variety of ways. Generally, the generic commits: (i) to not challenge the validity of the patent (“non-challenge” clauses); (ii) to discontinue the litigation; and (iii) to refrain from infringing or threatening to infringe the patent.¹⁴ The patentee agrees to make a payment to the generic. Reverse payments, similarly to patents, conceal a fundamental tension between dynamic and static efficiency. Patents and “pay-for-delay” agreements lie at the intersection of these two different conceptions of efficiency.

The patentee has strong economic incentives to conclude such agreements.¹⁵ Through a “pay-for-delay” agreement, the patentee circumvents judicial scrutiny, thereby perpetuating its monopoly. Interestingly enough, the generic would also be better off by entering into these agreements rather litigating. In fact, an annulment or a favourable outcome of the patent litigation more generally would let all of the generic’s competitors enter into the market, whereas the generic would obtain a share of the patentee’s monopoly profits by concluding such an agreement.¹⁶ At this juncture, two questions arise: does such an agreement genuinely favour dynamic efficiency? Is it a legitimate interim exception to competition law? The answer to these questions depends on the validity and scope of the patent. Put differently, “pay-for-delay” agreements are not problematic from a competition law viewpoint insofar as they concern a patent that is valid and in force which covers the products marketed by the patentee.¹⁷ In such circumstances, a PSA would allow the patentee to enjoy his patent rights without going through a costly litigation, and would also alleviate

¹³ In this article, we use the terms “pay-for-delay” and “reverse payments” in a completely interchangeable way.

¹⁴ P Treacy and S Lawrance, “Intellectual Property Rights and Out of Court Settlements” in Anderman and Ezrachi, *supra* n 7, 281.

¹⁵ LJ Glasgow, “Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?” (2001) 41 *IDEA: the Journal of Law and Technology* 227, 232.

¹⁶ Schnichels and Sule, *supra* n 9, 109.

¹⁷ KD McDonald, “Patent Settlement and Payments that Flow the ‘Wrong Way’: the History of a Bad Idea” (2002) 15 *Antitrust Care Chronicle* 2, 9.

the courts' workloads. Instead, when the patent is invalid or does not cover a given product, the settlement runs afoul of antitrust rules as it allows the patentee to unduly earn monopoly profits. We will now focus on how the US and EU practices reconcile this twofold nature of reverse payments.

D. "PAY-FOR-DELAY" AGREEMENTS IN THE US

1. The Regulatory Framework

In the US, "pay-for-delay" agreements have ignited a heated doctrinal and jurisprudential debate. Before considering that, however, it is worth outlining the regulatory framework in which this debate takes place. The patent system lies at the heart of this framework. Article 1, Section 8 of the US Constitution¹⁸ represents the constitutional foundation of the protection of inventions and innovation.¹⁹ On the basis of this provision, Title 35 of the United States Code sets the statutory rules governing the patent system. Although it is not possible to thoroughly analyse US patent law in this article, it is worth recalling its main provisions. New, non-obvious and useful inventions are entitled to enjoy patent protection.²⁰ Patents are presumed valid and have the character of personal property.²¹ As a consequence, patent holders may resort to injunctions to prevent (or stop) a breach of their patents²² and can sue the infringers for damages.²³ As noted above (see *supra* Section B), granting a patent establishes in principle a monopoly of the patentee. Nevertheless, the features of the demand side in the US pharmaceutical market curb the market power of the monopolist to some extent.²⁴

The Drug and Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, represents another possible restraint to the market power of the patentee. Notably, it strikes a balance between patent protection and promotion of generic entry. Under the Hatch-Waxman Act, the generic manufacturer must file an Abbreviated New Drug Application in order to seek marketing authorisation. This approval may be required before or after the expiration of the patent. The contents of pre- and post-expiration applications are similar except for one element. In pre-expiration applications, the

¹⁸ SW Halpern, CA Nard and KL Port, *Fundamentals of United States Intellectual Property Law: Copyright, Patent, Trademark* (Kluwer Law International, 2011), 191.

¹⁹ It has been noted that this provision is based on a utilitarian or economic incentive framework. See Lemley, *supra* n 3, 3.

²⁰ US Code, Title 35.

²¹ *Ibid.*

²² *Ibid.*

²³ *Ibid.*

²⁴ Drugs purchasers are generally insurance companies with a significant bargaining power. See OECD, *Pharmaceutical Pricing Policies in a Global Market* (OECD Publishing, 2008), 87–88.

generic manufacturer declares that the patent is either invalid or not infringed by its product. In response to pre-expiration applications, the patentee normally files a patent suit. If the patent is declared invalid or not infringed at the end of the proceedings, the generic may avail itself of a 180-day right to market the drug in duopoly with the branded drug producer. As a result, all other generics may enter the market only when the exclusivity period lapses. Evidently, the prospect of earning this bounty constitutes a considerable incentive to litigate for the generic.²⁵ Nevertheless, increasing numbers of parties concluded PSAs between 2004 and 2009.²⁶ Out of 218 settlement agreements in this period, 30 per cent involved a reverse payment.²⁷ As a consequence, the Federal Trade Commission (FTC) soon brought them into heightened focus.

2. Case Law on Reverse Payments

US courts took diverging views as to the consistency of these agreements with competition rules. The different approaches somehow reflect the different roles played by patent validity and scope scrutiny in assessing whether a “pay-for-delay” agreement is consistent with antitrust rules.

To begin with, part of the case law held that reverse payments are per se illegal. This is the position of the Sixth Circuit of Court of Appeals *In re Cardizem*, where the court stated that the agreement “was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade”.²⁸ In this regard, it is worth observing that the court took this view²⁹ without directly or indirectly scrutinising the validity and scope of the patent. As it clearly expressed a negative judgment towards the agreement, it did not need to analyse whether the agreement affected the relevant market or examine the applicable defences.³⁰

In contrast, the Second and Eleventh Circuits squarely rejected the per se rule and applied two different versions of scope of patent test.³¹ The Second Circuit came up with a “formal” scope of patent test according to which reverse

²⁵ SC Hemphill, “Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem” (2006) 81 *New York University Law Review* 1553, 1560.

²⁶ FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), 4, available at <http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff> (accessed on 2 November 2014).

²⁷ *Ibid.*

²⁸ *In re Cardizem CD Antitrust Litigation*, 332 F 3d 896 (6th Cir 2003).

²⁹ This approach has also been defined as the categorical illegality approach. See E Elhauge and A Krueger, “Solving the Patent Settlement Puzzle” (2012) 91 *Texas Law Review* 283, 285.

³⁰ PE Areeda and H Hovenkamp, *Antitrust Law* (Aspen Publishers, 2006), 1509–11.

³¹ It has been observed that the “scope of patent” approach establishes a relative presumption of legality of these agreements. See, eg S Addanki and HN Butler, “Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements” (2013) 15 *Minnesota Journal of Law, Science & Technology* 1, 1.

payments are illegal insofar as they delay entry of non-infringing products.³² Instead, in *Valley Drug Co v Geneva Pharmaceuticals, Inc.*,³³ the Eleventh Circuit applied an “objective probability”³⁴ scope of patent test to a reverse payment agreement concerning a patent on an anti-hypertension drug. This test was twofold. First, it assessed whether the “pay-for-delay” agreement reflected the same “exclusionary potential” of the patent.³⁵ Secondly, it appraised the chances of success of the patentee in the patent suit.³⁶ Undoubtedly, the crucial divide between the two types of scope of patent test lies in the different relation between antitrust scrutiny and patent assessment. The Eleventh Circuit’s approach somehow linked antitrust scrutiny to patent validity, whilst the Second Circuit only assessed whether the agreement fell within the patent scope.

In *K-Dur*,³⁷ the Third Circuit added a third view to this vibrant jurisprudential debate. As a preliminary point, it found that reverse payments are presumptively illegal.³⁸ Consequently, it adopted the “quick look” or “truncated” rule of reason,³⁹ namely a simplified version of the “rule of reason”⁴⁰ applicable to agreements producing effects on competition which are akin to those of per se unlawful agreements. In remanding the case to the district court, the court also made clear that

“the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment was for a purpose other than delayed entry or offers some pro-competitive benefit”.⁴¹

Given this persisting disagreement between courts of appeals,⁴² the US Supreme Court in its recent judgment *Actavis* seized the opportunity to provide some guidance with respect to reverse payments. The court confused both the “scope of patent” test and the “quick look” approach. On the one hand, it held that

³² *In re Tamoxifen Citrate Antitrust Litigation*, 466 F 3d 211–15 (2nd Cir 2006).

³³ *Valley Drug Co v Geneva Pharms Inc* 344 F 3d 1294 (11th Cir 2003). The Eleventh Circuit confirmed the “scope of patent” approach in *Schering-Plough Corp v FTC* 402 F 3d 1056 (11th Cir 2005).

³⁴ This approach has been defined “objective probability” scope of the patent test. See Elhauge and Krueger, *supra* n 29, 286.

³⁵ *Valley Drug Co v Geneva Pharms*, *supra* n 33.

³⁶ *Ibid.*

³⁷ *In re K-Dur Antitrust Litigation*, 686 F 3d 214–18 (3rd Cir 2012).

³⁸ *Ibid.*

³⁹ *Ibid.* The Court applied the *California Dental* test. See *California Dental Association v FTC* 526 US 770 (1999).

⁴⁰ For an account of the rule of reason test see PE Areeda and H Hovenkamp, *Fundamentals of Antitrust Law* (Aspen Publishers, 2011), 15.

⁴¹ *In re K-Dur Antitrust Litigation*, *supra* n 37.

⁴² The Sixth and DC Circuits have applied the per se rule to “pay-for-delay” agreements, whilst the Second, Eleventh and Federal Circuits have opted for the “scope of patent” test. The Third seized the middle ground, by choosing the “quick look” rule of reason.

the judicial scrutiny cannot be exclusively based on patent law⁴³ owing to the potential anticompetitive effects of these agreements. On the other hand, it stated that the “quick look” approach was not suitable for assessing antitrust legality of these agreements⁴⁴ as they did not appear anticompetitive to an observer “with a rudimentary understanding of economics”.⁴⁵

The court then stated that reverse payments should be scrutinised in light of the rule of reason and remanded the case to the appellate court, which was tasked with its structuring.⁴⁶ Yet its reasoning contains an important indicator for the assessment of the anti-competitive effects of the agreement: the amount of the reverse payment.⁴⁷ In fact, not only can an extravagant amount of money signal the likely invalidity of the patent,⁴⁸ but it can also indicate the patentee’s will to share monopoly profits with the generic.⁴⁹ In this regard, the court seems to be particularly suspicious of the payments which have not been paid in consideration of services or which cannot be justified by litigation costs.⁵⁰ In doing so, the Supreme Court linked the antitrust scrutiny to an evaluation of patent validity, thereby reconciling the two dimensions which characterise “pay-for-delay” agreements. In other words, the amount of the payment is an important indicator both of the patent’s strength and of the anticompetitive effects of the “reverse payment” agreement.

E. “PAY-FOR-DELAY” AGREEMENTS IN EUROPE

1. The Regulatory Framework

Having analysed the US case law on “pay-for-delay” agreements in the pharmaceutical sector, we now turn our attention to Europe. The EU differs from the US not only in the limited number of cases on reverse payments, but also in its radically different regulatory framework.⁵¹ In this connection, the most striking difference is that there is no piece of legislation comparable to the Hacht-Waxmann Act. It is, however, possible to identify several equally relevant differences.

⁴³ *FTC v Actavis, Inc* 133 US 2223 (2013).

⁴⁴ *Ibid.*

⁴⁵ *California Dental Association*, *supra* n 39.

⁴⁶ *FTC v Actavis, Inc*, *supra* n 43.

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ P Treacy and H Hopson, “Patent Settlements: Will the European Commission Follow in the FTC’s Footsteps?” (2008) 3 *Journal of Intellectual Property Law & Practice* 622, 624.

(a) *The Role of the National Health Systems of the EU Member States*

EU Member States generally have a strong national health system (NHS), which either partially or totally bears the cost of purchase of a number of drugs.⁵² This inevitably affects the demand curve. For one thing, whoever directly pays for the drugs generally has a considerable budget.⁵³ What is more, prescription drug consumption is conditional upon the judgement of NHS agents, namely prescription doctors⁵⁴ and hospital doctors.⁵⁵ The final user (the patient) neither pays for the drug nor freely decides which drug to take.⁵⁶ In light of these features, we could conclude that the demand curve in the pharmaceutical market—especially in the prescription medicines market⁵⁷—is rather inelastic, thereby amplifying the monopoly power.⁵⁸ Nevertheless, we should add a qualification to this statement. It would appear that there is only one “substantial” buyer on the market, which will be generally as powerful as the seller.⁵⁹ The patentee can freely set the price of its patented drug, but the state can always seek to use its bargaining power or even impose an administered price regime in order to restrain the monopolist’s power. This situation seems to be akin to a bilateral monopoly,⁶⁰ where the patentee is a monopolist and the NHS is basically a monopsonist.⁶¹ In a bilateral monopoly, the power of the monopsonist generally limits that of the monopolist, and vice versa.⁶² This will not lead to a perfectly competitive market, but it will nonetheless drive the price towards marginal costs and marginal value.⁶³ Put another way, a bilateral monopoly tends to be less distortive than a monopoly or a monopsony. This is because the competition authorities should assess whether there is a bilateral monopoly

⁵² In this regard, it should be noted that medicines represents one of the main component of states’ health expenditure. European Commission, *supra* n 8, paras 42 and 125.

⁵³ Admittedly, the “pocket” of EU Member States is not as deep as it used to be. To meet the budgetary objectives imposed by the EU Stability Pact, many EU Member States enacted restrictive fiscal policies which inevitably resulted in a substantial reduction in the NHSs’ budgets. See European Commission, *supra* n 8, paras 11–13.

⁵⁴ *Ibid.*, para 120.

⁵⁵ *Ibid.*, para 123. NHSs generally also have some degree of control over private hospitals.

⁵⁶ The relationship between a prescribing doctor and the NHS might also give rise to agency problems. For instance, the doctor may prescribe a drug even if there is a cheaper alternative or it is not strictly necessary.

⁵⁷ Prescription medicines generate the greatest portion of the pharmaceutical industry’s turnover in Europe. See European Commission, *supra* n 8, paras 43–44.

⁵⁸ S Bishop and M Walker, *The Economics of EC Competition Law* (Sweet & Maxwell, 2003), 46–47.

⁵⁹ Monopolist’s market power is more restrained in a one-purchaser system rather in a system with several purchasers, such as the US. See OECD, *supra* n 24, 88.

⁶⁰ A market where only one buyer and one seller operate. See, eg RS Pindyck and DL Rubinfeld, *Microeconomics* (Macmillan, 1989), 363.

⁶¹ OECD, *supra* n 24, 87.

⁶² *Ibid.*

⁶³ In this regard, it should be noted that the more similar the powers of the monopolist and the monopsonist, the more the price will approximate to marginal cost and marginal value. Pindyck and Rubinfeld, *supra* n 60, 364.

on a case-by-case basis, and take this element into account when conducting the antitrust scrutiny.

(b) Patents and Patents Enforcement

As is well known, there is to date no fully fledged European patent system, and intellectual property (IP) rights are still governed by national laws. The lack of political will and diverging Member States' interests have caused attempts to establish an EU patent system to fail.

Nevertheless, IP law in Europe is affected to a certain extent by supranational rules. First, the European Patent Convention (EPC) of 1973 establishes the EPO and protects IP rights in all 38 European states which are parties thereto.⁶⁴ Its protection regime does not operate as a unified patent system but, rather, as a "bundle" of national patents, which presents several pitfalls. To begin with, the application fees and costs of translation of patents make the annual renewal process rather costly.⁶⁵ In addition, as national courts have jurisdiction over patent litigation, there is an evident risk of diverging judgments in cases of litigation concerning two or more patents of the same "bundle".⁶⁶

Secondly, EU secondary legislation harmonises the enforcement of IP rights. Directive No 48 of 2004 aims at approximating legislative systems so as to ensure a high, equivalent and homogeneous level of protection in the internal market.⁶⁷ To this end, the directive imposes a general obligation on the Member States to ensure the respect of the IP rights falling within the scope of the directive (Article 3). This catch-all obligation encompasses a number of specific obligations concerning, amongst others, evidence in patent suits⁶⁸ and the right of information⁶⁹ of the claimant in a patent litigation. Of particular interest for this article is Section 4 of the directive, which contains the rules on precautionary and provisional measures. Interlocutory injunctions may be adopted to prevent or put an end to infringements of IP rights (Article 9(1)).⁷⁰ The injunctions may be subject to review upon request of the defendant. In any case, they do not have any effect if the claimant does not initiate the proceedings within a reasonable period of time (Article 9(5)). Finally, Member States are required to confer on judicial authorities the power to award damages to

⁶⁴ It is worth underlining that the EPC is not EU legislation, and nor is the EPO an EU body. See L Manderieux, "A More Unitary European IP Architecture" in A Jolly (ed), *The Handbook of European Intellectual Property Management* (Kogan Page, 2012), 8.

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

⁶⁷ Directive 48/2004/EC of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L195/16.

⁶⁸ *Ibid.*, Arts 6 and 7.

⁶⁹ *Ibid.*, Art 8.

⁷⁰ The granting of these measures may be conditioned on the lodging of an adequate security or assurance.

the defendant when the injunctions are revoked or lose effectivity, or when the subsequent judgment on the merits establishes that there was no infringement of IP rights. By ensuring both the interim protection of the patentee's rights and the generic's right to be compensated if the injunction proves to be groundless, the European Legislator seemingly aims to provide a valuable alternative to settlement for both parties.

Against this background, Council Decision No 167 of 2011⁷¹ authorised enhanced cooperation in the field of patents. In 2012, the European Parliament and the EU Member States implemented the enhanced cooperation between all Member States except Italy and Spain by enacting the "patent package",⁷² which consists of Regulation No 1260 of 2012,⁷³ Regulation No 1257 of 2012⁷⁴ and the Agreement on the Unified Patent Court. On the one hand, these regulations introduce a patent with unitary effect (or a unitary patent) and a common language regime applicable thereto. The unitary patent therefore does not replace the patents granted by the EPO but, rather, gives them unitary effects in all the Member States participating in the enhanced cooperation.⁷⁵ To obtain a unitary patent, the applicant must follow the EPC procedure. Once the European patent is granted, the patentee can request its registration in the European Patent Register within one month. The agreement also establishes the Unified Patent Court (UPC), which is a specialised court with exclusive jurisdiction on unitary patent infringements and validity disputes. The UPC is composed of a court of first instance, a court of appeals and a registry. The court will start operating as soon as the agreement enters into force, that is to say, when the conditions set out in Article 89 of the agreement are met. The Preparatory Committee of the UPC set early 2015 as the target date.

(c) *The Sector-specific Regulation*

EU secondary legislation governs the main stages of the process leading up to the commercial exploitation of new drugs.

⁷¹ Council Decision 167/2011/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection [2011] OJ L76/53.

⁷² Paradoxically, some European businesses harshly criticised the "package". J Pagenberg, "Unitary Patent and Unified Court – What Lies Ahead?" (2013) 8 *Journal of Intellectual Property Law & Practice* 480, 482.

⁷³ Regulation (EU) 1257/2012 EU of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1.

⁷⁴ Regulation (EU) 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements EU [2012] OJ L361/89.

⁷⁵ See generally KS White, "One Patent (and Court) to Rule Them All: An Unexpected European Decision?" (2013) 25 *Intellectual Property & Technology Law Journal* 24; W Tilmann, "The Compromise on the Uniform Protection for EU Patents" (2013) 8 *Journal of Intellectual Property Law & Practice* 78.

First of all, Directive No 20 of 2001 regulates the clinical trials phase.⁷⁶ This directive strives to balance competing interests such as the protection of the individuals who take part in the trials and the assessment of the therapeutic effects and of safety of new drug.

After the completion of the clinic trials, the new drug can be placed on the market on condition that the producer obtains a Market Authorisation under Article 8 of Directive No 83 of 2001 from the competent national authority. For those drugs with an active ingredient that has been safely and successfully used for at least 10 years within the EU, the authorisation procedure is considerably simplified.⁷⁷ This provision clearly seems to be designed for generic producers, which can market drugs that are already present on the market more easily.

Finally, the long delay between the filing of the application and the issuance of the Market Authorisation⁷⁸ has led the European Legislator to introduce the Supplementary Protection Certificate.⁷⁹ In order to compensate for this delay, this industrial title deed allows the patentee to enjoy the patent rights for a supplementary period (up to five years) after the patent expiry.⁸⁰

2. Taking Action: The EU Commission's Inquiry into the Pharmaceutical Sector

Within this regulatory context, the pharmaceutical industry in Europe is characterised by a low rate of innovation and the delayed entry of generic producers.⁸¹ This has led the Commission to bring the pharmaceutical industry into the spotlight. At the outset, it sought to acquire the information necessary to identify the appropriate policy responses. To this end, in 2008 the Commission launched an inquiry into the pharmaceutical industry, which confirmed the existence of dangerous downward trends in entry and innovation. In response to these worrying trends, the Commission urged the Member States to speed

⁷⁶ Directive 20/2001/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L121/34. See also D Delcourt, "Public Health and the Preservation of Economic Competitiveness: the European Supplementary Protection Certificate for Medicinal Products" (2009) 4 *Journal of Intellectual Property Law & Practice* 439, 440.

⁷⁷ Art 10 of Directive 83/2001/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311.

⁷⁸ Delcourt, *supra* n 76, 442.

⁷⁹ These certificates were introduced by Regulation (EEC) 1768/1992 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L182, subsequently amended by Regulation (EC) 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1.

⁸⁰ *Ibid.*, Art 13(1).

⁸¹ N Kroes, "Commission Launches Sector Inquiry into Pharmaceuticals", SPEECH 08/18 Brussels (16 January 2008) available at http://europa.eu/rapid/press-release_SPEECH-08-18_en.htm?locale=en (accessed on 2 November 2014).

up the reimbursement procedures for generic producers and advocated the establishment of a unified EU patent system.⁸² It also committed to increasing the scrutiny of anticompetitive practices in this sector by monitoring PSAs and initiating investigations where appropriate.⁸³

Through four monitoring reports between 2008 and 2013, the Commission shed some light on the opaque universe of patent settlements in Europe. The Commission divided the PSAs into three categories:⁸⁴

- category A settlements allow a generic to freely enter the market and may or may not provide a value transfer from the branded producer to the generic;
- category B.I settlements limit the entry without providing a value transfer from the branded producer to the generic; and
- category B.II settlements combine a limitation to generic entry with a value transfer.

“Pay-for-delay” agreements correspond to the description of the agreements in category B.II. In this regard, the Commission had little difficulty in concluding that category B.II agreements have the highest anticompetitive potential.⁸⁵ By contrast, agreements providing for delayed entry without value transfer (category B.I agreements) and those not delaying entry (category A agreements) normally do not pose any particular threat to competition.

All the monitoring reports showed an overall increase of PSAs. Category B.II agreements, instead, followed a rather different pattern. In the period 2000–07, the Commission observed a constant growth in the number of category B.II agreements, which represented 22 per cent of all settlement agreements. Between 2008 and 2010, the number of these agreements dropped to 3 per cent.⁸⁶ The Third and Fourth Monitoring Reports show that, since then, the number of category B.II agreements has accounted for 10 per cent of all patent settlement agreements.⁸⁷

⁸² European Commission, “Communication on an Industrial Property Rights Strategy for Europe”, COM(2008) 465 final, available at http://ec.europa.eu/internal_market/indprop/docs/rights/2008_0465_en.pdf (accessed on 2 November 2014).

⁸³ *Ibid.*

⁸⁴ European Commission, “4th Report on the Monitoring of Patent Settlements” (2013), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf (accessed on 2 November 2014). See also European Commission, “1st Report on the Monitoring of Patent Settlements” (2010), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf (accessed on 2 November 2014).

⁸⁵ *Ibid.*

⁸⁶ *Ibid.* See also European Commission, “2nd Monitoring Report of Patent Settlement” (2011), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf (accessed on 2 November 2014).

⁸⁷ European Commission, *supra* n 84, 30.

3. Taking Action: Enforcement of EU Competition Law vis-à-vis Reverse Payments

Along with the monitoring activity, the Commission initiated several investigations on reverse payments. Between 2013 and 2014, it issued three decisions⁸⁸ imposing sanctions on the undertakings which entered into “pay-for-delay” agreements. Unfortunately, to date no public version of the decisions is available. Notwithstanding that, it is worth examining the cases relying on the scant information available. Following the pattern adopted for analysing US “pay-for-delay” practice (see *supra* Section C), our analysis will focus on the role of the assessment of patent scope and validity in the antitrust scrutiny.

(a) *Servier*⁸⁹

On 2 July 2009, the Commission opened proceedings against Servier and several generics. Despite the patent on perindopril (a blockbuster antihypertensive drug) having expired, the patentee allegedly barred generics from entering the market by acquiring the unpatented technologies which were necessary to start producing it. In response to this attempt to block entry, the generics challenged the patent held by Servier. However, they later agreed to settle the dispute in exchange for substantial payments. One of the generics even obtained a licence to sell perindopril in seven national markets. The Commission had little difficulty in concluding that the objects of these agreements were inconsistent with Article 101 TFEU. Moreover, it found that, by acquiring all of the alternative technologies, the patent holder abused its dominant position under Article 102 TFEU.

(b) *Lundbeck*⁹⁰

On 7 January 2010, the Commission initiated proceedings against Lundbeck in order to investigate actions thought to be delaying the entry into the market of citalopram, a blockbuster antidepressant. The patent covering the active ingredient of this drug had already expired. Thus, the originator could only rely on several process patents, which could not have impeded entry of generics

⁸⁸ On 28 April 2011, the Commission launched a fourth investigation on the “pay-for-delay” agreement concluded between Cephalon and Teva, which is still ongoing. See the European Commission press release, “Antitrust: Commission Opens Investigation Against Pharmaceutical Companies Cephalon and Teva”, IP/11/511, available at http://europa.eu/rapid/press-release_IP-11-511_en.htm?locale=fr (accessed on 2 November 2014).

⁸⁹ *Servier*, *supra* n 1.

⁹⁰ *Lundbeck*, *supra* n 1. See generally W Choi, B Den Uyl and M Hughes, “Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and Others” (2014) 5 *Journal of European Competition Law & Practice* 44; MJ Clancy, D Geradin and A Lazerow, “Reverse-Payment Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law” (2014) 59 *Antitrust Bulletin* 153.

into the market. In this context, Lundbeck and the generics⁹¹ entered into several “pay-for-delay” agreements whereby Lundbeck committed to: (i) pay lump sums; (ii) buy the generics’ stock only to destroy it; and (iii) guarantee profits in a distribution agreement. The generics, in return, committed to refrain from entering the market before the expiry date of the agreements. The Commission found that the agreements’ objects violated Article 101 TFEU.

(c) *Johnson & Johnson*

On 18 October 2011, the Commission opened proceedings on a “pay-for-delay” agreement concluded between Johnson & Johnson’s⁹² Dutch subsidiary, Janssen-Cilag, and Novartis’s Dutch subsidiary, Sandoz. Janssen-Cilag held a patent on a powerful painkiller (fentanyl), whilst Sandoz was on the brink of marketing a generic version of the drug. To stop or at least delay the generic’s imminent entry, the patentee committed to pay a substantial amount of money, which exceeded the expected profits of the generic in case of entry. The delayed entry resulted in an unprecedented increase in the drug’s price. Following its previous decisions, the Commission held that the object of the agreement violated Article 101 TFEU.

F. THE COMMISSION’S REASONING IN THE REVERSE PAYMENT CASES

Given the current dearth of information on the above cases, it is difficult to have a clear picture of the reasoning which led the Commission to find restrictions by object under Article 101 TFEU. Nevertheless, with his speech at the 40th Annual Conference on International Antitrust Law and Policy in New York,⁹³ Mr Alexander Italianer, Director General of the DG Competition of the EU Commission, shed some light on the line of reasoning of the Commission in *Lundbeck* and indirectly on the subsequent cases.

Notably, his speech reveals that the Commission followed a two-step approach. First, it assessed whether generics were potential competitors of Lundbeck. Secondly, it sought to identify the obstacle which prevented the generics from actually competing with Lundbeck. In relation to the first question, the Commission found that the generics which were seeking to enter

⁹¹ The generic companies involved are Alparma, Merck KGaA/Generics UK, Arrow and Ranbaxy.

⁹² *Johnson & Johnson*, *supra* n 1.

⁹³ A Italianer, “Competitor Agreements under EU Competition Law”, speech given at the 40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute, New York, 26 September 2013, available at http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf (accessed on 2 November 2014).

into the market of the patentee were its potential competitors. With regard to the second question, it observed that the product patents had already expired and the process patents could not represent an obstacle to market entry. In other words, had the reverse payment agreement not been concluded, the generics could have circumvented the process patents, thereby entering the market. Arguably, the same reasoning applies also to *Johnson & Johnson* and *Servier*,⁹⁴ owing to the evident commonalities between these cases.

It is debatable whether the approach set out in *Lundbeck* should apply, on the one hand, to cases where the product patent has expired but the generics cannot circumvent the process patent and, on the other hand, to cases where the product patent has not expired. Although, at first glance, these situations may look extremely different, they actually share significant similarities. Indeed, if the patented process is the only viable route to the market, the patentee can still legitimately exclude its competitors from the product market by enforcing the process patent. Put differently, holding a process patent in such circumstances is tantamount to holding a product patent. It follows that the approach adopted in *Lundbeck* is not appropriate for such cases. This contention evidently raises several questions. How should the antitrust scrutiny be structured? Should antitrust and patent scrutiny be addressed separately? Should they be integrated following the US Supreme Court's approach?

G. ANTITRUST SCRUTINY OF REVERSE PAYMENTS NOT FALLING WITHIN THE SCOPE OF *LUNDBECK*

The answers to the above questions lie in the Commission Guidelines on the application of Article 101 TFEU to technology transfer agreements⁹⁵ and in the European Court of Justice (ECJ) case law on PSAs.

To begin with, the Guidelines address a clause commonly included in “pay-for-delay” agreements and PSAs more generally,⁹⁶ namely the “non-challenge” clause. This clause prevents the generic from challenging the validity and scope of the patent. In this regard, the Guidelines preliminarily make clear that such clauses are not part of the patentee's right.⁹⁷ Moreover, as they may stifle competition if included in a PSA,⁹⁸ they are not exempted from antitrust scrutiny.

⁹⁴ The reasoning is all the more true with respect to *Servier*, where neither a process nor a product patent was in force.

⁹⁵ European Commission, “Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Technology Transfer Agreements (2014/C 89/03)” [2014] OJ C89/3.

⁹⁶ Treacy and Lawrance, *supra* n 14, 287.

⁹⁷ European Commission, *supra* n 95, para 243.

⁹⁸ *Ibid.*

The Guidelines are in line with the ECJ case law on the subject matter.⁹⁹ By the same token, under the Guidelines, “pay-for-delay” agreements concluded between competitors should be attentively scrutinised vis-à-vis Article 101 TFEU.¹⁰⁰

With this in mind, we must consider how patent validity and scope can affect antitrust scrutiny of PSAs and, consequently, reverse payments. It has been held that, when scrutinising PSAs, the Commission “may not refrain from all action when the scope of the patent is relevant for the purposes of determining whether there has been an infringement of Article [101 or 102] of the Treaty”.¹⁰¹ The assessment includes, on the one hand, the analysis of the “wording of the patent claim” accepted by the competent Patent Office according to the “interpretative rulings” of the relevant national system¹⁰² and, on the other hand, the “geographical scope of the patent”.¹⁰³ Put differently, the court integrated antitrust scrutiny under Article 101(1) with the patent scope assessment. Although the court only referred to patent scope scrutiny, we believe that this holding should also apply to the scrutiny of the validity of the patent, because patent scope and patent validity are equally relevant in the antitrust scrutiny of reverse payments. However, assessing the validity of a patent is not a simple exercise, and is far more complicated than ascertaining whether the patent is in force and covers a given product.¹⁰⁴

In this context, the Commission and the ECJ face two alternatives: they can either confine themselves to a formal assessment (Is the patent in force? Does it cover the product?) or they can embark on a substantial assessment (Is the patent valid?). Were they to take the first route, they would probably leave unaddressed a number of anticompetitive agreements, whereas the second route would be fraught with pitfalls owing to the level of difficulty of such an assessment for the Commission and the ECJ.¹⁰⁵ However, in facing this seemingly impossible dilemma, they should not overlook that the generics have

⁹⁹ Case C-193/83 *Windsurfing v International Inc v Commission of the European Communities* [1986] ECR-00611, para 92; Case C-65/86 *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Sülhöfer* [1988] ECR-05249, para 16.

¹⁰⁰ European Commission, *supra* n 95, para 239.

¹⁰¹ *Windsurfing*, *supra* n 99, para 26.

¹⁰² *Ibid.*, para 30.

¹⁰³ The geographical scope of the agreement under scrutiny must not exceed the scope of the patent.

¹⁰⁴ The Eleventh Circuit in *Watson Pharmaceuticals* used the expression “turducken task” to emphasise the difficulty of reconciling a patent case with an antitrust case. See *FTC v Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir 2012). The turducken is a dish consisting of a deboned chicken stuffed into a deboned duck, which is in turn stuffed into a deboned turkey. By contrast, Justice Scalia has observed that considering “every other factor other than the strength of the patent is . . . to leave the elephant out of the room”. See JJ O’Connell, “Editor’s Note: the Elephant Remains” (2013) 28 *Antitrust* 6.

¹⁰⁵ See, eg Treacy and Lawrance, *supra* n 14, 296; J Chiou and R Schmidtke, “Revisiting Antitrust Limits to Probabilistic Patent Disputes: Strategic Entry and Asymmetric Information” (2012) 14 *American Law and Economics Review*, 425.

prevailed over the branded manufacturers in 62 per cent of patent suits.¹⁰⁶ Thus, abstaining from a substantial assessment would certainly warrant monopolies created by invalid patents.

Therefore, we believe that the Commission and the ECJ should conduct both a formal and a substantial patent assessment by integrating them into the framework of Article 101 TFEU.¹⁰⁷ Indeed, not only should they directly assess the patent's scope and whether it is in force when applying Article 101(1) TFEU, but they should also (at least) indirectly assess the patent's validity when deciding whether to apply the justification under Article 101(3) TFEU.

To sum up, if a reverse payment is based on a patent which does not cover the branded drug,¹⁰⁸ it is *prima facie* anticompetitive and cannot be justified under Article 101(3) TFEU. In other words, the lack of a patent immediately rules out the possibility of justifying the agreement. In contrast, when only the validity of the patent is at stake, the agreement should be found in breach of Article 101(1), because it restricts or may restrict competition. Nevertheless, this restriction can be justified under Article 101(3) TFEU on condition that the patent is valid. The next section illustrates how an indirect assessment of patent validity may be integrated into the framework of Article 101(3).

H. RECONCILING PATENT AND COMPETITION LAW: THE INDIRECT SCRUTINY OF PATENT VALIDITY IN THE FRAMEWORK OF ARTICLE 101(3) OF TFEU

When an agreement breaches Article 101(1) TFEU, it may be nonetheless justified under Article 101(3) TFEU. In such circumstances, the efficiencies offset the anticompetitive effects of the agreements. According to the Commission Guidelines on the application of Article 101(3),¹⁰⁹ efficiency claims must specify: (i) the nature of the efficiencies; (ii) the link between the agreement and the efficiency; (iii) the likelihood and the magnitude of the efficiency; and (iv) when and how it will be achieved. Efficiencies include both “an improvement in the production and distribution of goods or in technical and economic progress”.¹¹⁰ The Guidelines clarify that the concept of “efficiency”

¹⁰⁶ European Commission, *supra* n 8, para 620.

¹⁰⁷ This position seems to be consistent with the European Commission's approach according to which “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”. *Ibid*, para 763.

¹⁰⁸ This is certainly the case of the product patent, which can be circumvented by the generics.

¹⁰⁹ European Commission, “Notice: Guidelines on the Application of Article 81(3) of the Treaty (2004/C 101/08)” [2004] OJ C101/97, para 51.

¹¹⁰ This clause has often been interpreted extensively so to include a wide range of policies, such as environment, industry, employment and territorial cohesion. See R Whish, *Competition Law*

encompasses cost efficiency and qualitative efficiency. The former may stem from the development of new production technologies or methods,¹¹¹ synergies between undertakings,¹¹² economies of scale or scope¹¹³ and better planning.¹¹⁴ The latter consists in the improvement of quality or in the introduction of products with novel characteristics.¹¹⁵

However, the mere achievement of dynamic or static efficiencies is not sufficient to justify an anticompetitive agreement. In fact, three further conditions should be cumulatively met. First, a fair share of the benefits resulting from the efficiencies must be passed on to the consumers. This means that the consumers must receive a share of the—either cost or quality—efficiencies sufficient at least to compensate the negative effects of the agreements.¹¹⁶ For instance, if the agreement brings about an increase in price, it can nonetheless be justified if consumers benefit from considerably higher quality.¹¹⁷ Secondly, the restriction must be necessary to achieve greater efficiency. In this regard, the Guidelines specify that this requirement applies both to the agreement as a whole and to the individual restriction contained therein.¹¹⁸ Lastly, the agreement must not result in an elimination of competition in a substantial part of the market. Pursuant to the Guidelines, the assessment of the elimination of competition consists in a comparison between the degree of competition before and after the agreement.¹¹⁹ In so doing, the competition authority must take into account, amongst others, the sources of competition in the market,¹²⁰ the market share¹²¹ and the past competitive interactions between the parties.¹²²

Whether the justification under Article 101(3) TFEU applies to reverse payments depends primarily on the amount of dynamic efficiency that an agreement can generate. As noted above, a tension between static and dynamic efficiency is embedded in patents and reverse payments. They forgo static efficiency in order to stimulate innovation. The game is worth the candle only if the gain in terms of dynamic efficiency outweighs the loss

(Oxford University Press, 2012), 157; G Monti, “Article 81 EC and Public Policy” (2012) 39 *Common Market Law Review* 1057, 1069–79.

¹¹¹ European Commission, *supra* n 109, para 64.

¹¹² *Ibid.*, para 65.

¹¹³ ¹¹⁰ *Ibid.*, para 66.

¹¹⁴ *Ibid.*, para 67.

¹¹⁵ *Ibid.*, para 71.

¹¹⁶ *Ibid.*, paras 85–86.

¹¹⁷ Commission Decision of 19 December 2007, *MasterCard, Eurocommerce and Commercial Cards* (COMP/34.579, COMP/36.518, COMP/38580) [2007] OJ C264/8, para 734.

¹¹⁸ European Commission, *supra* n 108, para 73.

¹¹⁹ *Ibid.*, para 107.

¹²⁰ *Ibid.*, para 109.

¹²¹ *Ibid.*, para 111.

¹²² *Ibid.*, para 112.

of static efficiency. Generally, this condition is met insofar as the patent is valid. This is because it is crucial to graft the assessment of patent validity into the antitrust scrutiny.

No doubt combining competition and patent law assessments is a complex task. Nevertheless, it is submitted that the Commission and the ECJ could carry out an indirect scrutiny of patent validity when assessing whether reverse payments are consistent with EU competition law. In this regard, the legal and economic literature puts forward several indicators which can indirectly appraise whether a patent is valid or not. For instance, it has been suggested that the Commission should look for documents proving that the patent holder is not confident in the validity of the patent. As it is not always possible to find the “smoking gun”, this indicator might prove to be ineffective.¹²³ To infer the validity of the agreement, the competition authority could also look at the number of PSAs stipulated in relation to a given patent. However, this indicator could also be misleading, as a patent holder may decide to settle or not on the basis of a wealth of considerations which have little to do with the strength of the patent. For example, a patent holder may decide to settle with a generic because of their previous relations.¹²⁴ Unfortunately, these indicators are neither completely reliable nor easily accessible. Thus, as suggested by the US Supreme Court in *Actavis*,¹²⁵ the amount of the reverse payment constitutes a valuable indicator not only for indirectly assessing patent validity, but also for appraising the anti-competitiveness of reverse payments.¹²⁶ As to patent validity, it is possible to establish an inverse correlation between the size of the payment and the likelihood that the patent is valid:¹²⁷ the weaker the patent, the more the patent holder will be willing to pay. This is all the more true in the European system, where the generally high quality of the patent system makes the position of the patentee generally stronger. Therefore, the patentee’s willingness to pay a substantial amount of money clearly indicates that in all likelihood the patent is invalid. Such a patent creates a monopolistic market for a non-innovative good. As a consequence, a reverse payment which perpetuates this situation can hardly be justified under Article 101(3) TFEU. Indeed, it is extremely unlikely that a large reverse payment would generate qualitative efficiencies, let alone cost efficiencies, that can be passed on to consumers. In relation to qualitative efficiency, suffice it to say that, as explained above,

¹²³ Treacy and Lawrance, *supra* n 14, 297; S Brankin, “Patent Settlement and Competition Law: Where is the European Commission Going?” (2010) 5 *Journal of Intellectual Property Law & Practice* 23, 28.

¹²⁴ *Ibid.*

¹²⁵ See, generally, Areeda and Hovenkamp, *supra* n 30, 2046; C Shapiro, “Antitrust Analysis of Patent Settlements Between Rivals” (2003) 17 *Antitrust* 70, 72.

¹²⁶ *Ibid.*

¹²⁷ *Ibid.* See also *Actavis*, *supra* n 43.

large payments are usually made when the patent is weak and has little or no innovative effect. Similarly, no cost efficiencies are possible if the patentee and the generics share the monopoly profits by agreeing on a large payment. In this regard, some authors have argued that in some cases a large payment can be justified by the risk aversion of the parties. Although this argument may sound convincing at first sight, it has no apparent legal basis.¹²⁸

However, identifying “large payments” is not an easy task, but there is a criterion to identifying “suspect” payments. All reverse payments which exceed the avoided litigation costs should be considered presumptively anticompetitive.¹²⁹ This presumption can be rebutted by demonstrating, for example, that the payment was made in exchange for other goods or services received by the patentee.¹³⁰

At this juncture, one could argue that this approach would probably entail the risk of false positives. Be that as it may, it cannot be denied that refusing this indirect assessment of patent validity would considerably increase the number of false negatives. Neither choice is costless and riskless.¹³¹ Still, an indirect scrutiny of patent invalidity in the framework of Article 101(3) TFEU would enable the Commission and EU courts to shape EU competition policy vis-à-vis reverse payments in accordance with the regulatory and economic context in which they are placed.

Despite the harmonisation of national legislations on patent enforcement, there remains a tremendous difference in terms of length and cost of patent suits between Member States. Indeed, the duration of patent suits ranges from seven months in France to more than six years in Italy and Portugal. Moreover, although, on average, legal fees per case amount to €230,000, they can vary considerably from Member State to Member State.¹³² The situation is further complicated if one considers that a patentee often has to initiate several parallel patent suits in different Member States to protect its patent. In this context, reverse payments may also represent a legitimate choice for a firm. Instead of embarking on several proceedings characterised by relatively high costs as well as the risk of different lengths and outcomes, they may decide to enter

¹²⁸ Compare the arguments offered against this claim in AS Edlin, CS Hemphill, H Hovenkamp and C Shapiro, “Activating Actavis” (2013) 28 *Antitrust* 16, 18; BC Harris, KM Murphy, RD Willig and MB Wright, “Activating Actavis: A More Complete Story” (2014) 28 *Antitrust* 83, 85.

¹²⁹ C Shapiro, “Antitrust Limits to Patent Settlements” (2003) 34 *RAND Journal of Economics* 391, 408; M Lemley and C Shapiro, “Probabilistic Patents” (2004) 19 *Journal of Economic Perspectives* 75, 93.

¹³⁰ Shapiro, *supra* n 124, 72. This test, however, raises delicate measurement issues. See generally W Kerr and CB Tyler, “Measuring Reverse Payments in the Wake of *Actavis*” (2013) 28 *Antitrust* 29, 30–34.

¹³¹ See generally MK Friedland, “Antitrust Implications of Patent Settlements: Balancing Patent Policy, Antitrust Law, and the Practical Limits of Litigation” (2008) 9 *Engage* 89.

¹³² For instance, litigation costs are 20 times higher in the UK than in Austria. European Commission, *supra* n 8, paras 636–37.

into such agreements. Hopefully, the new UPC will probably reduce these disparities, but it will not eliminate reverse payments or the need for an indirect scrutiny of patent validity and scope in the course of antitrust litigation.¹³³ In addition, due to the role of the NHSs on the demand side, the pharmaceutical market in Europe loosely resembles a bilateral monopoly (see *supra* Section E). EU competition policy cannot overlook these crucial features of the European pharmaceutical market. In this setting, distinguishing between “good” and “bad” reverse payments is of paramount importance, as it would allow EU courts and the Commission to uphold reverse payments which are not anticompetitive. The amount of the payment is an appropriate and reliable tool for evaluating whether the agreement seeks a legitimate objective or aims at restricting competition.

I. CONCLUSION

The antitrust scrutiny of reverse payments inevitably entails a difficult balancing between antitrust and patent policy, which ultimately results in a balancing between static and dynamic efficiency.

An analysis of the US practice reveals that the kaleidoscope of positions in the US case law is primarily based on the different role of patent scrutiny in antitrust assessment. To put an end to this long-lasting disagreement, the US Supreme Court held that reverse payments are subject to the rule of reason test. In providing some guidance to the Court of Appeals on how the test should be structured, the Supreme Court seems to combine antitrust scrutiny and an indirect assessment of patent validity. Notably, it has adopted the amount of the reverse payment as an indirect indicator of its anticompetitive effects as well as of patent strength.

By contrast, EU practice is far less developed. The Commission’s recent decisions on reverse payments only clarify its approach with respect to agreements based on patents covering processes which can be circumvented by the generics. They are of little help in elucidating what the approach of the Commission would be if the product patent and the patent covering the only viable drug production process were still in force. The Commission Guidelines on technology transfer agreements and the ECJ case law on PSAs, however, shed some light on this issue. In particular, they seem to integrate the antitrust assessment under Article 101(1) TFEU with a scrutiny of patent scope. We believe that this approach could be extended to the assessment of patent

¹³³ It is worth noting that the US Court of Appeals for Federal Circuit has exclusive jurisdiction of appeals from final decisions on patent suits, but this did not prevent the enforcement of competition law with respect to reverse payments. This is because reverse payments are indeed an alternative to litigation.

validity. In our view, it is possible to integrate an indirect assessment of patent validity into the framework of Article 101(3) TFEU. The *trait d'union* between these two elements is the amount of the reverse payment. An excessive reverse payment not only generally signals a weak patent, but also can hardly meet the conditions under Article 101(3) TFEU. This approach would also be consistent with the peculiar European economic and legal context.