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**PATENT SETTLEMENTS IN THE EU
PHARMACEUTICAL INDUSTRY
A LEGAL ANALYSIS**

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Abstract

This paper examines reverse settlement payments concluded between pharmaceutical companies that have been highlighted as potentially problematic by the European Commission's recent sector inquiry. These payments usually occur as part of settlement agreements in the framework of challenges to patent validity. A patent challenge may be settled with an undertaking not to challenge or compete against the patent in return for compensation. The concern is that these agreements may constitute violations of Article 101 TFEU in so far as payment is made in return for a delay in generic market entry beyond the scope of the patent that serves to restrict competition.

The circumstances in which such payments are concluded is explained, in addition to the motivations of parties in doing so. The findings of the sector inquiry and recent investigations launched by the Commission into restrictive settlement agreements are also considered.

Previous EU and US case law is examined in order to elaborate on the standard that may be applied to restrictive payments under European competition rules as well as the possibility of payments being exempted under Article 101(3) TFEU.

This paper finally considers the danger that cumulative use of patenting strategies and complex settlement behaviour will make the correct identification of such behaviour by the authorities more difficult.

Keywords

Patent

Patent Settlement

Reverse Payment

Pharmaceutical Company

Generic Company

Market Entry

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List of Abbreviations

ALER	American Law and Economics Review
Antitrust Bull.	Antitrust Bulletin
CJEU	Court of Justice of the European Union
Colum.L.Rev	Columbia Law Review
CPI	Competition Policy International
ECLR	European Competition Law Review
EEA	European Economic Area
EFPIA	European Federation of the Pharmaceutical Industries and Associations
EIPR	European Intellectual Property Review
EPO	European Patent Office
Fla.L.Rev.	Florida Law Review
FTC	Federal Trade Commission
IIC	International Review of Intellectual Property and Competition Law
ICCLR	International Company and Commercial Law Review
JIPLP	Journal of Intellectual Property Law & Practice
JIPR	Journal of Intellectual Property Rights
Mich.L.Rev.	Michigan Law Review
Minn.L.Rev.	Minnesota Law Review
OFT	Office of Fair Trading
TFEU	Treaty on the Functioning of the European Union
W.Comp.	World Competition

1 Introduction

This paper seeks to examine patent settlements in the pharmaceutical industry that have been highlighted as problematic by European Commission following the pharmaceutical sector inquiry undertaken in 2008. Analysis will focus on why settlement practice is problematic, how reverse settlement payments that ‘pay for delay’ might constitute a violation of competition rules and how they might be treated in the future.

Potentially anti-competitive settlement agreements are unusual in that they occur at a delicate intersection of intellectual property law and competition law, two disciplines with contrasting approaches. Intellectual property law grants temporary monopolies as a means of incentivising and rewarding innovation, whereas European competition law aims to foster and maintain a system of fair competition on the internal market, thus preventing and eliminating monopoly structures. Although they may apply contrasting methods, both aim to promote consumer welfare. Where they intersect it is usually competition law that wins the day.

As Drexl points out, “[t]he pharmaceutical industry, which has never been a major target of competition policy, at least in Europe, may well be the first to feel the pressure from more audacious control of the use of intellectual property.”¹ This may be due to the fact that the industry is atypical in many ways, which makes the task of regulatory scrutiny particularly complex. Primarily, this is because decisions regarding the access to, use of and pricing structure of pharmaceutical products are not made by the same body; rather they are split between governments, prescribing doctors, pharmacists and patients. “The pharmaceutical industry has to understand that it is not immune from antitrust and competition law. In the pharmaceutical sector, competition law is shifting from ‘abusive use’ to ‘abusive acquisition and maintenance’ of rights.”² Consequently, the sector can expect much more rigorous scrutiny of its activities in the future, beyond the traditional realm of areas such as merger control and parallel imports.

¹ J. DREXL, ‘Pay for delay and blocking patents – targeting pharmaceutical companies under European competition law’, (2009) 40(7) *IIC* 751 at p.752.

² *Ibid* p.755.

Reverse settlement payments thus provide for the type of case that seldom occurs; where it is required to “balance the interests” of both intellectual property and competition law in equal fashion as it is not a clear violation of either.³

This rest of this paper is structured as follows. Section 2 defines reverse settlement payments and assesses the motivations of parties in concluding settlements. Section 3 considers EU scrutiny of patent settlements to date, from the sector inquiry to investigations launched by the European Commission. Section 4 considers how reverse settlement payments may constitute a violation of European competition rules taking preceding US and EU case law into account. Section 5 argues that authorities must be vigilant in pursuing complex settlement behaviour and cumulative use of patenting strategies employed by companies in response to increased scrutiny. Section 6 concludes and considers possible future developments.

³ G. ROBERT, F. FALCONI, ‘Patent litigation settlement agreements in the pharmaceutical industry: marrying the innovation bride and the competition groom’, (2006) 27(9) *ECLR* 524.

2 Defining Reverse Settlement Payments

2.1 *What is a reverse settlement payment?*

A patent is a monopoly right granted in return for the disclosure of an invention for a period of 20 years. For pharmaceutical products, patents granted may be for the product (i.e. molecular composition) or for a process (the particular method of manufacturing the drug). After patent expiry, other pharmaceutical companies are free to manufacture a generic equivalent of the drug, which they sell at a lower price while still making a profit. This is possible because generic pharmaceutical companies do not have to recoup investments made in research and development as originator pharmaceutical companies do.

Reverse settlement payments form part of a settlement agreement concluded between an originator and generic pharmaceutical company as a means of bringing a specific dispute to an end. This typically occurs in the framework of a generic company's challenge to an originator company's patent.⁴ A settlement agreement may also be concluded before litigation has commenced or subsequent to the threat of litigation.

In a conventional settlement arrangement, it is usually the case that the alleged infringer compensates the patent holder. Reverse settlement payments are so-called because it is the patent holder who compensates the patent challenger in order to bring an end to the latter's challenge. The payment or value transfer may be intended to cover litigation and other costs, but the concern from a competition law perspective is that these payments are made in return for a commitment from the generic company to discontinue its patent challenge or to delay market entry of the generic drug. The generic company is thus compensated for its commitment and may sometimes still receive priority to market the drug, while the originator company is assured of its monopoly as its patent is still formally valid.

This is not to say that settlement agreements are without merit. Indeed, the Commission is careful to state that settlements are a perfectly acceptable method of bringing a dispute to an

⁴ Pharmaceutical Sector Inquiry, Final Report, 8th July 2009 (hereinafter 'Final Report'). Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf, 21st April 2011, at para. 702.

end.⁵ This seems logical, as the Commission cannot compel parties to continue to litigate a dispute which could be adequately resolved through other means. Therefore, settlements may be beneficial in so far as they avoid further litigation, delay and associated costs. The principal advantage is the removal of commercial uncertainty, which is an important consideration for both parties.

The Commission categorises settlement agreements according to those which provide for a limitation on generic entry and those that provide for a value transfer. Category A settlements do not place any limitations on generic entry. Category B settlements are those which do place limitations on generic entry. In respect of the latter category, a further distinction is made between those that do not comprise a value transfer (category B.I) and those that do (category B.II).⁶ Limitations on entry will usually take the form of a non-compete or no-challenge clause whereby the patent challenger undertakes not to challenge the patents at issue and/or to refrain from entering the market until after the patent has expired. The Commission also considers the granting of a license or distribution agreement for the drug in question to represent limitations on entry as both are controlled by the originator company to a certain extent.⁷ Transfer of value may also take various forms. A direct monetary transfer may be made in order to cover the costs of litigation or may be made in return for the purchase of an asset from the generic company. Value may also be transferred through a licensing or distribution agreement. A side deal may also be concluded for another product or another market.⁸

2.2 *Why are settlements concluded?*

In order to understand why a settlement is concluded, it is necessary to understand first, the reasons why a patent challenge is brought and second, why a company would choose to settle its dispute with the other party.

The decision of a generic company to take a patent challenge or to enter the market ‘at risk’, that is, without taking any formal challenge, will generally depend on its perception of the

⁵ *Ibid* para. 707.

⁶ *Ibid* p.270.

⁷ *Ibid* p.269.

⁸ *Ibid*.

strength of its case. If a generic company believes a patent to be weak and/or potentially invalid, it may bring an action for a declaration of invalidity of the patent before a national court or patent office, or it could enter the market at risk, thus inciting the originator company to bring an action for infringement. Alternatively, it may enter the market based on the belief that its equivalent version of the drug does not infringe any of the originator company's patents. Choosing a patent challenge over market entry or vice versa is also informed by other circumstances, such as prevailing market conditions or the jurisdiction in which the challenge is to be taken. An originator company is equally informed by these factors, and may also consider the initiation of proceedings in response to a threat of patent infringement or market entry. At present, patent cases appear to be initiated by both parties in equal proportions.⁹

Motivation to challenge a patent can also derive from a generic company's desire to benefit from what is known as 'first mover advantage'. The price of a drug generally falls as soon as the first generic producer enters the market, but the first generic drug still stands to make a profit as price competition only begins to intensify when other generic producers enter the market. This first mover advantage may accrue from winning a patent challenge, or from settling with the patent holder so as to keep other generic producers off the market.¹⁰

The moment at which a generic company will decide to mount a patent challenge is also important. Any commercially important drug will usually be covered by an intricate network of product and process patents in addition to secondary patents that have been filed throughout the lifetime of the main group of patents.¹¹ The combined effect of this plethora of patents is the creation of what is commonly known as a patent thicket. This is something which in itself may serve to deter generic entry, as determining validity for each and every patent can be a complicated exercise.¹² A patent thicket also means that generic challenges usually take place when the primary patents have expired, making victory more likely.¹³ This is because secondary patents are often perceived to be somewhat weaker, especially after the expiry of the primary patent. Generic companies prevail in 62% of patent cases

⁹ *Ibid* para. 587.

¹⁰ M. VAN DER WOUDE, 'Patent Settlements and Reverse Payments Under EU Law', (2009) 5(2) *CPI* 183 at p.186.

¹¹ The Final Report found the ratio of primary to secondary patents to be 1:7. Final Report *supra* note 4 at para. 489.

¹² *Ibid* paras. 538, 722.

¹³ *Ibid* para. 478.

where final judgment is delivered,¹⁴ but this figure rises to 74% in cases concerning secondary patents. However, these figures must be read with a degree of caution as generic companies will necessarily only take the challenges they consider to have the best chance of winning.¹⁵

Ascertaining parties' motivations in settling a dispute is a more complex exercise. As noted by the Commission, the most important factors for an originator company in considering whether to settle in order of importance are the probability of winning or losing the case; the market size and revenue to be protected; litigation costs; the uncertainty involved in patent litigation; and the expected duration of litigation.¹⁶

For a generic company the most important factors in deciding to settle are litigation costs; the uncertainty involved in patent litigation; the probability of winning or losing the case; the country where the litigation takes place; and the expected duration of litigation.¹⁷ Generic companies generally have smaller resources than originator companies and it is thus to be expected that they would be more risk-averse with regard to costs in commencing or continuing patent litigation. The Commission has determined the average legal fees incurred in patent litigation in a single Member State to be €230,000; and closer to €1 million in the UK.¹⁸ While the avoidance of litigation costs may certainly be a legitimate argument, the fact that this is more important to a generic challenger than its chances of winning the case is a definite indicator of a willingness to settle.¹⁹ Thus, for a generic company, even the threat of litigation from a given company in a particular Member State may be sufficient to deter market entry for fear of incurring litigation costs or damages being awarded against it.²⁰

Interim injunctions can also be a decisive factor in deciding whether to settle a case. These were granted in 44% of cases examined by the Commission.²¹ For an interim injunction to be granted, the patent holder must demonstrate the urgency of its case, that it will suffer

¹⁴ *Ibid* para 621.

¹⁵ B. BATCHELOR, 'EC tones down its final report into the pharma sector, but ramps up enforcement activity', (2010) 31(1) *ECLR* 16 at p.18.

¹⁶ Final Report, *supra* note 4 at p.266.

¹⁷ *Ibid* p.267. The Final Report found the average duration of litigation to be 2.8 years, at para. 636.

¹⁸ *Ibid* at para. 659.

¹⁹ VAN DER WOUDE, *supra* note 10 at p.186.

²⁰ Final Report, *supra* note 4 at para. 575.

²¹ *Ibid* para. 641.

irreparable commercial harm in absence of such an injunction being granted and must show *prima facie* grounds for its main claim.²²

The grant of an interim injunction has the potential to cause substantial disruption and financial damage to a generic company where it has already entered the market with its product. Sales are prevented pending final outcome of the case, even though the generic company may ultimately prevail in its challenge. However, the latter outcome will normally result in the award of handsome damages. On the other hand, if an interim injunction is not granted, a generic company may not be particularly inclined to settle as it can remain on the market until a final decision is handed down. In such a situation, it is the originator company who has the most to lose as once generic market entry has occurred and prices have fallen, it will be very difficult to raise prices back to patent-protected levels.

Reasons for each party in mounting a challenge or deciding to settle are thus particular to each side of the dispute and influenced by factors specific to national markets or legal systems. The identification of reverse settlement payments as potentially problematic by the European Commission has set in motion a chain of regulatory scrutiny which will be discussed in the following section.

²² *Ibid* para. 640.

3 EU Scrutiny to date

3.1 Findings of the Sector Inquiry

The pharmaceutical sector inquiry was undertaken by the Commission in January 2008 as it considered that competition in this market was not functioning optimally.²³ This belief was based firstly, on an apparent decline in innovation evident in the reduction of new drugs coming to market and secondly, on perceived delays in generic market entry.

A large number of patents for commercially successful or ‘blockbuster’ drugs are said to be expiring in the coming years, thus drying up a major source of profit for originator pharmaceutical companies. Many companies depend on just a small number of blockbuster drugs for a large portion of their profits – to lose such a revenue source with no replacement blockbuster drug is a source of particular concern for pharmaceutical companies. These profits are important in that they allow the company to invest in research and development for new drugs. It has been said that it costs on average €1 billion and takes 10 years to develop and bring a new drug to market.²⁴ The failure rate for new drugs in testing is also extremely high.²⁵ Originator pharmaceutical companies are increasingly resorting to the purchase of late-stage development drugs from smaller companies and research institutes. Thus the expiry of important patents, coupled with the increasingly high cost and risky nature of research and development means that originator companies are desperate to maintain existing revenue streams until they can find the next blockbuster drug.

Concern has been expressed that the Commission did not have enough concrete evidence to mount a sector inquiry and that it was merely a “fishing expedition” for anti-competitive conduct.²⁶ It has been remarked that the decision to begin the sector inquiry with unannounced inspections was an indicator of the seriousness with which the Commission perceived its task,²⁷ although others have found the inspections to be disproportionate and arbitrary in nature, thus constituting a possible infringement of general principles of Union

²³ Commission decision of 15th January 2008, initiating an inquiry into the pharmaceutical sector. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/decision_en.pdf, 21st April 2011.

²⁴ EFPIA, ‘The Pharmaceutical Industry in Figures’, 2010 at p.7. Available at: <http://www.efpia.eu/content/default.asp?PageID=559&DocID=9158>, 1st March 2011.

²⁵ *Ibid.*

²⁶ H. ANDERSSON and E. LEGNERFALT, ‘Dawn Raids in Sector Inquiries – Fishing Expeditions in Disguise?’, (2008) 29(8) *ECLR* 439.

²⁷ C. HATTON, S. RAB, J.M. COUMES, D. CARDWELL, ‘European Commission pharmaceutical sector inquiry final report – drug problems remain but Commission backs down’, (2009) 20(11) *ICCLR* 375 at p.375.

law.²⁸ Such criticisms would seem warranted given that the inquiry has not yet produced much in the way of enforcement policy.²⁹

The main finding of the sector inquiry was that pharmaceutical companies have at their disposal a toolbox of strategies designed to prolong patent protection, delay generic market entry and block other's innovation. Of these findings, speed of generic market entry was the Commission's primary concern. It found that generic market entry occurs on average seven months after patent expiry. The Commission concluded that had generic market entry occurred immediately following patent expiry, €3 billion would have been saved over the period 2000-2007.³⁰ Accordingly, delays in generic market entry cause harm to consumers and impede effective competition in the pharmaceutical sector. Tackling reverse payments in patent settlement agreements thus forms part of Commission's objective to increase the speed of generic entry. However, it should be noted that delays to generic entry can also be caused by regulatory delays, such as the need to obtain a market authorisation or in fact, the behaviour of generic companies themselves.

While the other strategies highlighted by the sector inquiry, such as the use of secondary and defensive patenting³¹ in order to prolong patent protection are equally disconcerting, patent settlements were declared to be the Commission's main priority. It is possible that this was the case as settlements, while not as deeply problematic as other forms of conduct, are possibly easier to pursue for breach of competition rules.³² The other practices would seem much harder to act against as, on their face, they appear to constitute a legitimate use of the patent system. Criticism of such behaviour thus runs to the very heart of the patent system.

A extreme example of a settlement agreement would be one which provided for a large direct payment in return for a commitment to delay entry far beyond the scope of the patent. This allows the two companies to effectively split the continuing monopoly profits, with no benefit from generic competition passed on to the consumer. This is a clear violation of competition rules, whereas an extreme example of secondary patenting is much harder to

²⁸ ANDERSSON and LEGNERFALT, *supra* note 26.

²⁹ N. PETIT, 'Bark at the Moon?', (2009) 3 *Concurrences* 11 at pp.12-13.

³⁰ Final Report, *supra* note 4 at para. 217.

³¹ For a definition, see *infra* section 5.

³² DREXL, *supra* note 1 at p.755.

prove. Although any patent application must fulfil the criteria of novelty, inventive step and industrial application, for this to constitute a violation of competition law would require evidence that the company was aware that the filing was without merit and was intended to extend patent protection in order to exclude competition. Proceeding with such a case thus comes a lot closer to criticising the merits of the patent system. Commentators have expressed grave misgivings regarding the fact that Article 102 TFEU could be used to tackle such behaviour.³³ Indeed, Hull has stated that to give the impression that such practices are problematic has risked chilling innovation across all sectors.³⁴

It is generally accepted that if the European patent system is one that allows such patents to be granted, reform should be sought at that level.³⁵ Regulatory concerns were not included in the Commission's preliminary findings and it has been said that the Commission showed a "laudable degree of institutional flexibility" in doing so for the Final Report.³⁶ This was also the cause of a notable reduction in concern from the Preliminary to the Final Report.³⁷

Criticism has also been levied at the Final Report for engendering significant legal uncertainty as a result of its failure to provide any guidance as to the standard to be applied to the behaviours identified or how it intends to proceed with regard to strategies other than settlement payments.³⁸ Indeed, the Report mentions several times that it is not the intention of the Commission to provide guidance as to what constitutes compliant behaviour according to a competition law standard.³⁹ Hull criticises this approach as taking individual cases "is likely to result in an incomplete and unbalanced legal framework erected on the basis of principles developed in a piecemeal, *ad hoc* fashion" and instead recommends a holistic set of guidelines which would evolve in line with the case law as it emerges.⁴⁰

³³ DREXL, *supra* note 1 at p.755. KJØLBYE, 'Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?', (2009) 32(2) *W.Comp.* 163 at p.163.

³⁴ D.W. HULL, 'Proceed with caution across the IP/Competition intersection', (2009) 3 *Concurrences* 14 at p.15.

³⁵ See PETIT, *supra* note 29 at p.12. This was also something addressed by the Harhoff study commissioned by DG Enterprise in 2008. Available at:

http://ec.europa.eu/internal_market/indprop/docs/patent/studies/litigation_system_en.pdf, 21st April 2011. For more on this point see KJØLBYE, *supra* note 33 at p.166.

³⁶ HULL, *supra* note 34 at, p.15.

³⁷ PETIT, *supra* note 29. See also BATCHELOR, *supra* note 15 and also C. HATTON S. RAB, J.M. COUMES, D. CARDWELL, *supra* note 27. For a consideration of the regulatory framework, see A. DAWES AND J. KILLICK, 'The Elephant Uncovered', (2009) 3 *Concurrences* 18.

³⁸ See DREXL, *supra* note 1 at p.755.

³⁹ For example, see Final Report *supra* note 4 at paras. 463, 472.

⁴⁰ HULL, *supra* note 34 at, p.16.

3.2 *Investigations Launched*

Since the conclusion of the sector inquiry, the Commission has opened three investigations into anticompetitive behaviour in the pharmaceutical industry. All of these cases concern settlement agreements and their effects on generic market entry.

Proceedings were opened against originator company Les Laboratoires Servier and also a number of generic companies including Krka, Lupin, Matrix Laboratories, Niche Generics and Teva Pharmaceutical Industries in July 2009 for possible breach of Articles 101 and Article 102 TFEU. The investigation is examining agreements concluded between each of the generic companies and Servier that may have had the object or effect of hindering market entry of a generic version of the drug Perindopril developed by Servier.⁴¹

The Commission has already issued a potentially revealing decision as part of this investigation with regard to a dispute as to documents covered by legal professional privilege as a result of a dawn raid conducted at the company's premises.⁴² The document in question is a letter from Teva's legal counsel threatening to bring Servier's conduct in breach of competition law to the attention of the Commission unless an agreement concerning the defence of Servier's patents in Belgium was reached between the two parties. The Commission ruled against Servier's claim of legal professional privilege and in any event believed that it had already obtained a copy of the same letter in the course of its inspection at Teva's premises.

The second set of proceedings was launched in January 2010 against originator pharmaceutical company Lundbeck for unilateral behaviour and agreements entered into by Lundbeck which may have had the effect of preventing or delaying market entry of the generic anti-depressant drug Citalopram in breach of Articles 101 and 102 TFEU.⁴³

⁴¹ Commission investigation, COMP/39612 [*Servier*], currently under investigation. See http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_841_6.pdf, 21st April 2011. See also, Commission Press Release, MEMO/09/322, 'Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies', 8th July 2009.

⁴² Commission decision of 23rd July 2010 relating to COMP/E-1/39.612 - Perindopril (Servier). Available at: http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_3076_9.pdf, 21st April 2011.

⁴³ Commission investigation, COMP/39226 [*Lundbeck*], currently under investigation. See http://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_319_6.pdf, 21st April 2011.

A third investigation was opened in April 2011 against originator pharmaceutical company Cephalon and generic company Teva for a settlement concluded in the US and the UK in 2005 by which Teva agreed not to sell its generic version of Modafinil, a drug used to treat sleeping disorders, on the EEA market until 2012.⁴⁴ The terms of the agreement seem to be based on side deals rather than any direct value transfer. A similar case against the parties is also pending with the Federal Trade Commission in the United States.⁴⁵ A further twist in the tale is that in May 2011, Teva announced plans to acquire Cephalon⁴⁶ pending approval of the authorities, notably the European Commission under the Merger Regulation.⁴⁷

The Commission has explicitly stated that these investigations are separate from the sector inquiry; they are merely connected in so far as knowledge acquired in the course of the sector inquiry has permitted certain conclusions to be drawn.⁴⁸

A fourth investigation into the activities of Boehringer “concern[ing] misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease drugs” had already been opened prior to the sector inquiry in February 2007.⁴⁹

The Commission states that there is no “strict deadline” in which to complete any investigation; rather that this depends on factors such as “the complexity of the case, cooperation from the undertakings concerned and the exercise of the rights of defence.”⁵⁰ On this point the timeline in the recent *AstraZeneca* case may be instructive: the first complaint was lodged with the Commission in 1999; the Commission gave its decision in 2005; and the General Court gave its decision on the appeal in July 2010.

⁴⁴ Commission investigation, COMP/39686 [*Cephalon*], currently under investigation. See Commission Press Release, IP/11/511, ‘Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva’, 28th April 2011.

⁴⁵ See *infra* section 4.1.

⁴⁶ ‘Teva to Acquire Cephalon in \$6.8 Billion Transaction’, Press Release, 2nd May 2011. Available at: http://www.tevapharm.com/pr/2011/pr_1008.asp, 2nd May 2011.

⁴⁷ Council Regulation No 139/2004 on the control of concentrations between undertakings (the EC Merger Regulation) OJ [2004] L 24/1.

⁴⁸ For example see, ‘Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck’, IP/10/8, 7th January 2010.

⁴⁹ Commission investigation, COMP/39246, [*Boehringer*], currently under investigation. See http://ec.europa.eu/competition/antitrust/cases/dec_docs/39246/39246_951_10.pdf, 21st April 2011.

⁵⁰ This is a general statement contained in almost every press release. For an example see, Commission Press Release IP/10/8, ‘Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck’, 7th January 2010.

Although it may seem strange that, as part of its settlement scrutiny, the Commission would intervene in disputes that may *prima facie* appear to be concerned with a purely internal situation, this is necessarily so by virtue of the fact that the European Union does not yet possess any unified patent system. A European patent granted by the European Patent Office is in fact a bundle of 27 different national patents. Therefore, any challenge to patent validity must take place in a given Member State. Nevertheless, the implications of patent invalidity may be felt across the internal market and any no-challenge clause in a settlement agreement is usually be pan-European in nature.

3.3 *Continued Monitoring*

In January 2010, the Commission launched a monitoring exercise into patent settlements concluded between pharmaceutical companies from July 2008 to December 2009 in order to “better understand why, by whom and under which conditions they are concluded.”⁵¹ The Commission already possessed information on settlements concluded for the duration of the sector inquiry (January 2000 to June 2008), and there is no drastic change in its analysis from the Final Report of the Sector Inquiry to the First Report on Continued Monitoring.⁵² The stated reasons do therefore seem unusual; it seems more so that the Commission wanted to confirm settlement trends in addition to sending a message to the industry as to how it intends to proceed.

The findings of the first monitoring exercise were released in July 2010 and welcomed a “decrease in potentially problematic settlements”, despite the fact that there was an increase in the overall number of patent settlements concluded.⁵³ While concerns had been expressed by the pharmaceutical sector that scrutiny would force parties to litigate their dispute to the end, the increased instance of settlement has proven such fears to be largely unfounded; pharmaceutical companies are sufficiently astute to realise that they are under scrutiny and are capable of finding less problematic terms to agree on with settling parties.

⁵¹ Commission Press Release, IP/10/12, ‘Antitrust: Commission launches monitoring of patent settlements concluded between pharmaceutical companies’, 12th January 2010.

⁵² First Report on the Monitoring of Patent Settlements, 5th July 2010. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf, 18th February 2011.

⁵³ See Commission Press Release, IP/10/887, ‘Antitrust: Commission welcomes decrease of potentially problematic patent settlements in EU pharma sector’, 5th July 2010.

The Commission has stated its intention to conduct an annual analysis of patent settlements concluded in the pharmaceutical sector until such time as it is satisfied that there is a properly functioning system of competition in place. It instigated the second monitoring exercise in January 2011.⁵⁴

3.4 Analysis of Settlement Terms

Scrutiny of settlements has shown that it is not their existence which is problematic, but the use of restrictive terms beyond the scope of the patent. Indeed, of the 207 agreements examined by the sector inquiry, only 48% restricted generic entry in various ways.⁵⁵ This figure was reduced to 43% in the first monitoring exercise.⁵⁶ Because settlements can contain such a variety of terms, and are concluded in many different circumstances, later analysis will show that it has proved difficult to find a standard of legality that is acceptable to all parties. It is thus important to examine the various possible combinations of settlement terms in greater detail.

Van der Woude considers that this “relatively dispersed picture” of settlement agreements does not justify the depth of attention that they have received.⁵⁷ However, it is submitted that because each European citizen spends around €130 per year on pharmaceutical products,⁵⁸ unnecessary restrictions on generic entry are problematic even if they only occur in relatively small numbers of settlements, and are thus deserving of the Commission’s attention. This is all the more so as instances of settlements are overwhelmingly concentrated on the best-selling medicines⁵⁹ and their use appears to be limited to certain companies.⁶⁰

Category A settlements, those that do not provide for any limitation on generic entry, are generally acceptable from a competition law perspective. These are usually concluded where

⁵⁴ Commission Press Release, IP/11/40, ‘Antitrust: Commission launches second monitoring exercise of patent settlements in pharma sector’, 17th January 2011.

⁵⁵ Final Report, *supra* note 4 at para. 734.

⁵⁶ *Ibid* para. 25.

⁵⁷ VAN DER WOUDE, *supra* note 10 at p.186.

⁵⁸ The figure given is for 2007. Commission Fact Sheet, ‘Prices, times to generic entry and consumer savings’. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_1.pdf, 21st April 2011.

⁵⁹ Final Report, *supra* note 4 at para. 715.

⁶⁰ Just two companies were found to be responsible for 41% of settlements examined. *Ibid* para. 713.

patent expiry is close and/or generic market entry has already occurred (possibly where or because no interim injunction was granted).⁶¹ In such circumstances, a settlement constitutes perfectly rational behaviour, providing for certainty and the avoidance of additional legal costs.⁶² Where the patent has not yet expired, the originator may agree to allow entry in return for discontinuance of the challenge. No other generics can enter the market without taking a challenge but price competition will still occur which is beneficial to consumers. Value transfers took place in 31% of category A settlements examined, usually in the form of compensation for legal costs or damages suffered (by either party).

Category B settlements comprise those that do provide for limitations on generic entry but do not necessarily entail a value transfer. In fact, this occurred in only 45% of such settlements.⁶³ Category B.I settlements (limitation but no value transfer) usually occur where it does not appear likely that the patent challenge will prevail. Generic challengers will thus be incentivised to settle in such cases to avoid damages being awarded against them, although some of these settlements do provide for a 'traditional' settlement arrangement, whereby the generic company compensates the patent holder. The limitation in such cases usually takes the form of an undertaking not to enter the market until patent expiry.⁶⁴

Category B.II settlements are the most problematic type of settlement in that they provide for a limitation on generic entry combined with a value transfer. Although there may be legitimate reasons for providing a value transfer, the concern is that this is given in return for an undertaking not to challenge or compete with the patent at issue. In extreme circumstances, this may be tantamount to a market-sharing agreement where the challenger who suspects the patent to be invalid agrees to discontinue his challenge in return for a share of the continued monopoly profits. For an originator company, such a payment may still only represent a fraction of the profits it will continue to earn from the patented drug. Equally, for a generic company, it may be commercially logical to accept a payment that is greater than it could have won in damages or earned in sales.

⁶¹ *Ibid* para. 747.

⁶² *Ibid* para. 749.

⁶³ *Ibid* p.275.

⁶⁴ *Ibid* paras. 759-761.

Weak patents therefore lend themselves to settlement more than strong patents. The weaker the patent, the larger the amount the patent holder will be willing to pay as it has more to lose from patent nullification.⁶⁵ The inference may thus be made that a settlement is an indicator of patent invalidity. Indeed, Chairman of the US Federal Trade Commission, Jon Leibowitz has stated that “brand companies are most likely to pay-off a generic competitor when they have not innovated.”⁶⁶

If this is indeed the case, then the question which must be asked is: if a patent is clearly invalid, should the patent holder not be forced to settle with all prospective challengers?⁶⁷ Indeed, multiple settlement arrangements certainly have taken place in the past, and it is submitted that in respect of a particularly commercially successful drug, multiple settlements may still be worth the continuing monopoly profits. In any event, it is not usually the case that one can be so sure as to the outcome of the patent challenge, due to the necessarily complex nature of pharmaceutical patents. Furthermore, as the average duration of a patent challenge in the EU is 2.8 years,⁶⁸ other generic companies may be loathe to entail the risks and costs of litigation. A final point is that as settlement agreements avoid the dispute coming to court or a final judgment being handed down, their terms may often be confidential, and other generic companies may not be aware of any settlement having been concluded.

Conversely, one could also legitimately ask, why do patent holders agree to settle in cases they are relatively assured of winning? The answer is that pharmaceutical patents are so complicated in nature that one can never be completely assured of victory. Even if there is a 75% chance of victory, the patent holder may still prefer to settle by virtue of the 25% chance of losing.⁶⁹ In many cases, there may be legitimate reasons for payments being made in return for delayed entry. Hull describes a situation where, in case of loss, a generic company

⁶⁵ M. KADES, ‘Whistling past the Graveyard: The Problem with Per Se Legality Treatment of Pay-for-Delay Settlements’, (2009) 5(2) *CPI* 143 at p.150.

⁶⁶ J. LEIBOWITZ, “‘Pay-for-Delay’ Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution)”, speech delivered at the Center for American Progress 23rd June 2009. Available at: <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>, 21st April 2011.

⁶⁷ See also E. MILLER, ‘Paying it backwards’, (2006) 62 *Euro. Law.* 29.

⁶⁸ Final Report, *supra* note 4 at para. 636.

⁶⁹ H. HOVENCAMP, M. JANIS, M. LEMLEY, ‘Anticompetitive Settlements of Intellectual Property Disputes’, (2003) 87 *Minn.L.Rev.* 1719 at p. 1759.

may be incapable of paying sufficiently compensatory damages to the patent holder who may thus prefer to pay for delayed market entry.⁷⁰

In total, more than €200 million in direct payments was transferred to generic companies over the period of scrutiny of the sector inquiry.⁷¹ However, this figure fails to take account of numerous other ways in which value transfers can take place. For example, there is a risk that payment to the generic in return for its commitment may be concealed in a side deal such as a license or distribution agreement. The patent holder may also agree to buy the stock of equivalent products already manufactured.⁷² In many cases, conducting a “cost/benefit analysis” of the value transferred will not be an straightforward task.⁷³

⁷⁰ HULL, *supra* note 34 at .16.

⁷¹ Final Report, *supra* note 4 at para. 768.

⁷² *Ibid* para. 767.

⁷³ P. TREACY and S. LAWRENCE, ‘Intellectual Property Rights and Out of Court Settlements’ in *Intellectual Property and Competition Law: New Frontiers*, S. ANDERMAN and A. EZRACHI (eds.) (2011), OUP, 277 at p.290.

4 Violation of Competition Law

4.1 US case law & policy

The Final Report notes that although enforcement practice is remarkably different in the US and EU, settlement practice is nonetheless very instructive for the EU approach.⁷⁴

Important differences between the two systems must be noted at the outset. First, there is no price regulation in the US, meaning that the fall in price caused by generic entry is much more dramatic than in the EU, where the decrease is more gradual. Second, the Hatch-Waxman Act⁷⁵ encourages patent challenges, as the first successful generic challenger receives a 180-day exclusivity period in which to market the drug without competition from other generic producers. This peculiarity has led to the unforeseen consequence that the assumed common interest of the parties in price competition has been replaced by cheaper settlement payments.⁷⁶ Third, a 2003 amendment to the Hatch-Waxman Act provides for mandatory notification of a settlement to the authorities within ten days of it being concluded, with severe fines for failure to do so.⁷⁷

The current US position is that the Federal Trade Commission⁷⁸ and the Department of Justice are in favour of imposing a rule of *per se* illegality on “pay-for-delay” settlements. The FTC’s position is that settlement agreements that provide for reverse payments should be treated as presumptively illegal where the payment is substantial in amount, where generic market entry is delayed, and where there does not appear to be any motive for the payment apart from delayed generic entry.⁷⁹ However, contrary to this approach, appeal courts have largely approved reverse settlement payments and the Supreme Court has thus

⁷⁴ Final Report, *supra* note 4 at para. 790.

⁷⁵ Formally known as the Drug Price Competition and Patent Term Restoration Act 1984.

⁷⁶ R. PERITZ, ‘Reverse payments from branded to generic drug makers in the US – why they are legal, why they should not be, and what is to be done’, (2009) 40(5) *IIC* 499 at p.500.

⁷⁷ Medicare Prescription Drug, Improvement and Modernisation Act 2003. For more on fines, see DREXL, *supra* 1 note at p.754.

⁷⁸ See ‘Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions’, FTC Staff Study, January 2010. Available at: <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>, 24th February 2011.

⁷⁹ For more see S.P. BRANKIN, ‘Patent settlements and competition law: where is the European Commission going?’, (2010) 5(1) *JIPLP* 23 at p.24.

far refused all requests to review the matter. Attempts to ban pay for delay payments through legislation have also failed.⁸⁰

Recent developments notwithstanding, the reasoning of the courts deserves consideration. The latest significant case is that of *Cipro*,⁸¹ in which the Federal Circuit respectfully disagreed with an earlier Sixth Circuit finding of *per se* illegality.⁸² It held that reverse payments are legal unless the agreement extends beyond the “exclusionary zone” of the patent (for example to other unpatented products); and that any anticompetitive effects are merely a necessary corollary of the nature of a patent. Furthermore, it refused to consider the probability that the patent would be found invalid had a final decision been handed down as patents enjoy a statutory presumption of validity. It would only do so where the litigation was a sham.⁸³ In light of the contradiction with the finding in the *Cardizem* case, two subsequent private actions have applied for Supreme Court review. However, these have been unsuccessful.⁸⁴

Despite the refusal of courts to outlaw reverse payments, the FTC has continued to initiate proceedings against companies for such behaviour. The latest case is that of *Cephalon*,⁸⁵ where an originator company settled with four separate generic challengers. There is also concern that the agreements concerned other products beyond the scope of the patent.⁸⁶ The case is still pending and is also the subject matter of the very recent investigation opened by the European Commission.⁸⁷ In 2010, a District Court dismissed a challenge to the case, holding that it could proceed to trial.⁸⁸

⁸⁰ A ‘Preserve Access to Affordable Generics Act’ was not passed by the 111th Congress. A similar Act (available at: <http://www.hpm.com/pdf/Preserve%20Access%20Bill-%20112th.pdf>, 2nd May 2011) was introduced to the 112th Congress in January 2011. It is currently at Committee stage but seems unlikely to pass.

⁸¹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F. 3d 1323, 1341 (Fed. Cir. 2008)

⁸² *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914-15 (6th Cir. 2003)

⁸³ R.H. STERN, ‘USA: patents – Federal Circuit upholds antitrust legality of reverse payments from patentees to accused infringers’, (2009) 31(2) *EIPR* 101 at p.102.

⁸⁴ The first was *Arkansas Carpenters Health and Welfare Fund v Bayer AG* refused in June 2009. Available at: <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/08-1194.htm>, 2nd May 2011. The second was *Louisiana Wholesale Drug Co., Inc., et al., Petitioners v. Bayer AG* refused in March 2011. See <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/10-762.htm>, 2nd May 2011.

⁸⁵ FTC File No.: 061-0182. See <http://www.ftc.gov/os/caselist/0610182/index.shtm>, 2nd May 2011.

⁸⁶ D.F. BRODER, S.J. KATZE, ‘King Drug Co of Florence Inc v Cephalon Inc: United States – anti-competitive agreements’, (2010) 31(8) *ECLR* 128 at p.129.

⁸⁷ See *infra* section 3.2.

⁸⁸ *King Drug Co of Florence Inc v Cephalon Inc*, unreported 29th March 2010 (D (US)).

US Courts have thus far decided that an individual settlement is unlikely to have a significant anti-competitive impact. The US judiciary has spent the last number of years developing a nuanced position that is in some ways similar in nature to the European position to be taken as suggested by previous European case law. However, it is submitted that a refusal to assess the strength of the underlying patent is not something that should be included in the European test. This “maximalist” position has been described by Hemphill to “produce the absurd result that an ironclad patent and a trivial patent have the same exclusionary force.”⁸⁹

Nonetheless, commentators and agencies are adamant in their belief that only a rule of *per se* illegality can prevent consumer harm as a result of delays to generic entry.⁹⁰ This may result from the US legislative framework whereby a settling challenger may still retain its 180-day exclusivity period, which only begins when it enters the market, thereby hampering the chances of other challengers. EU reverse settlement payments are potentially less restrictive in this manner as entry is only delayed for the particular challenger, not for all potential challengers. It is thus difficult to predict whether progressions in European case law will mirror those in the US or indeed run into the same difficulties.

4.2 Article 101 TFEU

Article 101 TFEU prohibits agreements between undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market. Any agreement caught by Article 101(1) is automatically void and unenforceable.⁹¹ A patent settlement is clearly an agreement within the meaning of Article 101.⁹²

Consideration will now be given to previous settlement case law of the CJEU, how reverse settlement payments could constitute a violation of Article 101(1) TFEU, how they may

⁸⁹ C.S. HEMPHILL, ‘An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition’, (2009) 109(4) *Colum.L.Rev.* 629 at p.638.

⁹⁰ See KADES, *supra* note 65 and M. CARRIER, ‘Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality’, (2009) 108(1) *Mich.L.Rev.* 37.

⁹¹ R. WHISH, *Competition Law*, 6th Ed, OUP, 2009 at p.114

⁹² *Ibid* p.97.

benefit from an exemption under Article 101(3) and finally, Article 102 as a possible alternate ground of liability.

4.2.1 Restriction by object or effect

‘Restriction of competition by object’ is a categorisation that is generally reserved for more serious types of anti-competitive behaviour, such as market-sharing, price-fixing or output limitations.⁹³ Because of their serious nature, an object offence is easier to prove as the effect on competition need not be demonstrated.⁹⁴ Such behaviour is thus presumed to be illegal.

It could be argued, taking into account the particular characteristics of the pharmaceutical sector, that reverse settlement payments, as horizontal agreements whose object is to share markets or limit output, constitute restrictions of competition by object. Drexl has argued in favour of *per se* illegality as he considers patent litigation a pre-cursor to price competition and therefore any settlement that impedes such competition as tantamount to a price cartel.⁹⁵

However, Van der Woude is sceptical as to how any settlement payments can be characterised as a restriction by object, given that there is such variety in settlement terms.⁹⁶ This is especially so in light of the statement in the Final Report that “any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.”⁹⁷ The fact that the Commission states this may provide an indication that it intends to characterise restrictive settlement agreements as effects-based offences only. However, it is submitted that at the time of compiling the Final Report, the Commission was not to know what kinds of settlements would present themselves for enforcement in the future.

⁹³ *Ibid* at p.115.

⁹⁴ TREACY and LAWRENCE, *supra* note 73 at p.292.

⁹⁵ J. DREXL, ‘Real Knowledge is to know the Extent of One’s Own Ignorance: On the Consumer Harm Approach in Innovation-related Competition Cases’, Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 09-15 *Antitrust Law Journal*, Forthcoming at p.30. Available at SSRN: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1517757, 20th February 2011.

⁹⁶ VAN DER WOUDE, *supra* note 10 at p.193.

⁹⁷ Final Report, *supra* note 4 at para. 1530.

Treacy and Lawrance take a more nuanced approach to the issue. Because a patent is designed by its very nature to block market entry, not all settlements can be characterised as object offences.⁹⁸ It is possible that only extreme instances of settlement may constitute restrictions by object, for example those concluded in the knowledge that the patent was invalid, a settlement that clearly “exceed[s] the scope of the patent”, or where the dispute is a sham.⁹⁹ This concurs with the “smoking gun” analysis applied by Batchelor.¹⁰⁰

In all likelihood, if and when a decision is taken, the Commission would surely not be so daring for such novel behaviour to argue that the settlements are a restriction of competition by object without proving any effects, or without at least arguing in that alternative that the conduct is a restriction by effect. Therefore, clarification on this point may not be provided until the General Court has the opportunity to rule on an appeal. It is also possible that demonstrating anti-competitive effects of settlements will not prove an easy task and that imposing a presumption of illegality on reverse settlement payments may be the only way for the Commission to ensure their eradication.¹⁰¹

The situation is thus one that requires a nuanced response from the Commission: settlements which do not restrict generic entry (category A) may be perfectly acceptable; others may constitute restrictions by object and others may require proof of anti-competitive effects. Brankin predicts that settlements which restrict market entry beyond the scope of the patent will be found to violate competition rules and that also that “at least some reverse payment settlements that restrict entry only within the scope of the patent” will be found to be unlawful.”¹⁰² The difficulty with this lies in that fact that it is extremely difficult to establish a “bright-line test”, that is, the exact point at which a “socially beneficial” agreement becomes a market sharing agreement.¹⁰³

⁹⁸ TREACY and LAWRENCE, *supra* note 73 at p.293.

⁹⁹ *Ibid* pp. 282, 293. As to litigation being a sham, see Case 35/83 *BAT v Commission* [1985] ECR 363.

¹⁰⁰ See BATCHELOR *supra* note 15.

¹⁰¹ *Ibid* p.294.

¹⁰² BRANKIN, *supra* note 79 at p.28.

¹⁰³ R.D. WILLIG and J.P BIGELOW, ‘Antitrust policy towards agreements that settle patent litigation’, *Antitrust Bull.* Fall 2004 655 at. p.656.

Proving a restriction of competition by effect requires “extensive analysis of an agreement in its market context”¹⁰⁴ in addition to a counter-factual analysis, that is, the position which would have emerged in absence of the agreement.¹⁰⁵

Treacy and Lawrance consider that the determination as to the point where a payment transforms from being reasonable to anti-competitive requires an analysis of “likely costs of the litigation, the generic company’s exposure in terms of wasted preparations for coming to market, the expectations for generic price and market uptake in the event that it had come to market, the time that the generic would have taken to get to market, as well as the remaining term of the patent.”¹⁰⁶

For the counter-factual analysis, that is, the potential outcome in absence of settlement, it is at this point that previous case law becomes relevant. As Batchelor points out, the Commission’s biggest problem in relation to anti-competitive patent settlements is that there is no legal precedent.¹⁰⁷ The most closely related case law concerns trademark delimitation agreements and no-challenge clauses. The case law is relatively old and in some respects, conflicting in nature. It is nonetheless useful to examine this in the hope of extracting a general principle that may be applied to patent settlement agreements.

In trademark delimitation cases such as *Sirdar/Phildar*¹⁰⁸ and *Penneys*,¹⁰⁹ the Commission was concerned that agreements providing for the use of similar or confusing trademarks by each party in different parts of the common market would lead to a splitting up of the market. It thus sought to make a judgment as to outcome of the conflict in absence of settlement.¹¹⁰ The anti-competitive standard applied was that settlements which resolved a

¹⁰⁴ WHISH *supra* note 91 at p.122.

¹⁰⁵ *Ibid* at p.124.

¹⁰⁶ TREACY and LAWRENCE, *supra* note 73 at p.294. For interesting economic analysis that is beyond the scope of this paper see: A. LAYNE-FARRAR, ‘Reversing the Trend? The Possibility that Rule Changes May Lead to Fewer Reverse Payments in Pharma Settlements’, (2009) 5(2) *Competition Policy International* 165.; K. HYLTON and S. CHO, ‘The Economics of Injunctive and Reverse Settlements’, (2010) 12(1) *ALER* 181; and WILLIG and BIGELOW *supra* note 103, in which they primarily argue against any rule of *per se* illegality as money transferred does not always provide an indication as to the strength of the underlying patent. The key factor should be the effect money has on the date of generic entry. If it is earlier than would have been without payment, then the settlement is socially beneficial.

¹⁰⁷ BATCHELOR, *supra* note 15 at p.18.

¹⁰⁸ *Sirdar and Phildar Trademarks* (Commission Decision 75/297) OJ L 125.

¹⁰⁹ *Penneys* [1978] OJ L 60/19.

¹¹⁰ VAN DER WOUDE, *supra* note 10 at p.187.

real dispute and whose terms were necessary and proportionate in nature were acceptable from an [Article 101] perspective.¹¹¹

The early case law on no-challenge clauses in trade mark delimitation agreements must however be distinguished from no-challenge clauses in patent settlements as a patent is only valid for a period of 20 years whereas a trademark is granted for an indefinite duration.¹¹²

No-challenge clauses for patents were at first condemned by the the Court, as in the case of *Windsurfing*.¹¹³ However, in *Bayer v Süllhöfer*,¹¹⁴ the Commission took a prudent approach in arguing that a no-challenge clause in a licensing agreement was compatible with Article 101 TFEU

“when it is concluded in an agreement whose purpose is to put an end to proceedings pending before a court, provided that the existence of the industrial property right which is the subject-matter of the dispute is genuinely in doubt, that the agreement includes no other clauses restricting competition, and the no-challenge clause relates to the right in issue.”¹¹⁵

The Commission thus took the view that a settlement concluded in order to bring a *bona fide* dispute to an end is different from other agreements concluded under Article 101 TFEU. This interpretation was however, rejected by the Court, which stated that Article 101(1) TFEU “makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.”¹¹⁶ The Court thus did not consider that no-challenge clauses should be considered in the context in which they are concluded, that is, an agreement on a compromise to prevent further litigation. Instead, the no-challenge clause was analysed in isolation.¹¹⁷

Batchelor considers that to apply such a test to patent settlements today is “misplaced”, as it would lead to the consequence that “all patent settlements, regardless of their merits or lack

¹¹¹ *Ibid.* pp.188, 189.

¹¹² TREACY and LAWRENCE, *supra* note 73 at p.286.

¹¹³ Case 193/83 *Windsurfing International Inc v Commission* [1986] ECR 611.

¹¹⁴ Case 65/86, *Bayer AG and Maschinenfabrik Hennecke GmbH v Süllhöfer* [1988] ECR 5249.

¹¹⁵ Para. 14 of the judgment.

¹¹⁶ Para. 15 of the judgment.

¹¹⁷ VAN DER WOUDE, *supra* note 10 at pp.190, 191.

of consumer harm, would be invalid since, of themselves, they are bound to contain an agreement to cease any legal challenge.”¹¹⁸

Moreover, the Technology Transfer Guidelines now expressly approve of no-challenge clauses in settlements, stating that “it is inherent in such agreements that the parties agree not to challenge *ex post* the intellectual property rights covered by the agreement. Indeed, the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes.”¹¹⁹ These guidelines are not binding on the Court but given that they corollate with the Commission’s position in the *Bayer* case, which did seem to be a more reasonable position than that adopted by the Court, it is hoped that the Court would today follow the Commission’s approach.¹²⁰

Based on the trademark delimitation case law, the test to be applied to settlement agreements will probably be a ‘least restrictive alternative test’, whereby an agreement will not constitute a violation of Article 101 where it is less restrictive than the decision that would have given by the court had the dispute continued to its end.¹²¹ Victory for the patent holder would preclude the possibility of generic market entry before patent expiry, whereas victory for the patent challenger would allow for immediate generic entry. In addition, the terms of the agreement must be necessary and proportionate in nature. Van der Woude also adds the inference that “restrictions that have no bearing with the underlying dispute will not benefit from the presumption that they are not restrictive in nature.”¹²²

The least restrictive alternative test thus necessarily implies a judgment as to the strength of the patent at issue, something which the Commission does not seem to have the power nor ability to do.¹²³ The Final Report does not give any guidance as to how the Commission plans to proceed in this regard, although the ECJ ruled in *Windsurfing* that “although the Commission is not competent to determine the scope of a patent, it is still the case that it may not refrain from all action when the scope of the patent is relevant for the purposes of

¹¹⁸ BATCHELOR, *supra* note 15 at p.18.

¹¹⁹ Commission Notice, ‘Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements’, OJ [2004] C 101/02. (hereinafter ‘*Technology Transfer Guidelines*’), at para. 209.

¹²⁰ TREACY and LAWRENCE, *supra* note 73 at p.283.

¹²¹ VAN DER WOUDE, *supra* note 10 at pp.193, 194.

¹²² *Ibid* p.192.

¹²³ KJØLBYE, *supra* note 33 at p.186.

determining whether there has been an infringement of Article [101 or 102] of the Treaty.”¹²⁴

The Commission certainly struggled to assess the scope of a relatively straightforward patent in the *Windsurfing* case, so even if it is permitted to assess the scope of the patent in so far as is necessary to establish a breach of Article 101, one can still ask how this will be possible in the case of complex pharmaceutical patents. Treacy and Lawrance suggest the use of experts to overcome this obstacle or that the Commission “seek internal evidence of the company’s beliefs about the strength of the patent” although both options have their limitations.¹²⁵ Batchelor has suggested that proving a restriction of competition can only be achieved with proof that the patent is invalid; that “absent a ‘smoking gun’ document that shows that the patentee know the patent was invalid, how can an antitrust authority second-guess validity?”¹²⁶ Although one cannot be certain, it could be that the document at issue in the legal privilege decision for the *Servier* investigation may constitute such a smoking gun.¹²⁷

It should be noted that imposing a presumption of illegality on reverse settlement payments is an option that avoids the need for the Commission or Court to make a judgment as to patent validity – if such payments are unlawful, the parties cannot settle in this manner, thus making it more likely that the court will give a final decision as to validity.¹²⁸

One final element necessary in order to establish a violation of Article 101 is that a settlement also needs to constitute an appreciable restriction on trade. This would require an exercise in market definition so as to establish market shares of the parties.¹²⁹

4.2.2 Article 101(3) TFEU - efficiency defence

Where a settlement agreement is found to constitute a restriction on competition by object or effect, it will still be open to the parties to argue that the agreement fulfils the cumulative

¹²⁴ Case 193/83 *Windsurfing International Inc v Commission* [1986] ECR 611 at para. 26 of the judgment. See TREACY and LAWRENCE, *supra* note 73 at p.295.

¹²⁵ *Ibid* pp.296-297.

¹²⁶ BATCHELOR, *supra* note 15 at p.18.

¹²⁷ See *supra* section 3.2.

¹²⁸ DREXL, *supra* note 1 at p.753.

¹²⁹ See VAN DER WOUDE, *supra* note 10 at pp.194, 195.

conditions of the exemption provision, Article 101(3) TFEU. The agreement must contribute to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit. Furthermore, the agreement must not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives nor afford such undertakings the possibility of eliminating competition in respect of a substantial part of the markets in question.

A settlement agreement that does not place any limitation on generic entry (Category A) or that provides for some generic entry before patent expiry would appear to fulfil these conditions in that it would contribute to promoting technical or economic progress and allow consumers a fair share of the resulting benefit through price competition. However, this is based on the assumption that it would be found to constitute a restriction on competition in the first place, which is not likely considering the foregoing analysis. It may be more the case that a settlement of the B.I variety, that provides for limitations on generic entry without any value transfer would be found to come within the cumulative conditions of Article 101(3) TFEU.

Drexl, however, does not believe that reverse settlement payments can come within Article 101(3). Although Advocate General Jacobs in the *Syfait* case¹³⁰ “made a very strong argument in favour of accepting a reduction in price competition if this enhances incentives for innovation”, to follow this argument to its logical conclusion in the context of reverse settlement payments would, according to Drexl “pervert the patent system by justifying high profit margins based on potentially invalid patents. Whoever argues otherwise argues grants a general exemption from price competition to undertakings solely based on the argument that they invest in research and development.”¹³¹

4.3 Article 102 TFEU

Article 102 TFEU prohibits the abuse of a dominant position in so far as it may affect trade between Member States.

¹³⁰ Case 53/03 *Syfait v GlaxoSmithKline* [2005] ECR I-4609.

¹³¹ DREXL, *supra* note 1 at p.754.

Although it is much more likely that reverse settlement payments will be treated under Article 101 TFEU, Article 102 TFEU may constitute an alternate base of liability where dominance can be established. Treacy and Lawrance consider that “the requirement to show only a potential effect on competition may prove ultimately less problematic than the counterfactual analysis required under Article 101 TFEU.”¹³² It is more likely that this approach would be taken where the Commission has proof of anti-competitive settlement behaviour in conjunction with other patent strategies intended to prevent or delay generic entry.¹³³

In this respect, the recent *AstraZeneca*¹³⁴ case is instructive. The first abuse of dominance case in the pharmaceutical sector, the General Court upheld the Commission’s finding that *AstraZeneca* has abused its dominant position in lying to national patent authorities in order to obtain supplementary protection certificates which provide for a further five years of patent protection in the case of pharmaceutical products.¹³⁵ The second part of the offence was the selective deregistration of the market authorisation for the capsule form of the drug in favour of a tablet form so as to prevent generics companies from obtaining market authorisation. This was found to foreclose the market although this specific type of abuse has since been prevented by legislation.¹³⁶ The fine imposed on *AstraZeneca* of €52.5 million was perceived to be much less than possible due to the novel nature of the offences.¹³⁷

For a patent settlement to violate Article 102 TFEU, it would mean that as a dominant company, a patent holder had breached its “special responsibility” in not facilitating generic entry.¹³⁸ It would perhaps settle with many challengers in the knowledge that its patent was invalid, providing for substantial direct payments. A violation of Article 102 TFEU would also require an exercise in market definition; *AstraZeneca* and other cases have shown how

¹³² TREACY and LAWRANCE, *supra* note 73, pp.300-301.

¹³³ *Ibid.*

¹³⁴ T-321/05, *AstraZeneca v Commission*. Judgment of the General Court of 1st July 2010. The case is currently on appeal to the CJEU.

¹³⁵ See J.P GUNTHER, C. BREUVART, ‘Misuse of patent and drug regulatory approval systems in the pharmaceutical industry: an analysis of US and EU converging approaches’, (2005) 26(12) *ECLR* 669 at p.678.

¹³⁶ For more on this point, see *ibid* at p.679.

¹³⁷ *Ibid.*

¹³⁸ Case 322/81 *Michelin v Commission* [1983] ECR 3461.

very narrow market definitions are becoming more common in order to allow a dominant position to be established.¹³⁹

¹³⁹ See J. WESTIN, 'Defining the relevant market in the pharmaceutical sector in light of the Losec-case – just how different is the pharmaceutical market?', (2011) 32(2) *ECLR* 57.

5 Effective Investigation and Enforcement

5.1 Complex Settlement Behaviour

The rational reaction of pharmaceutical companies to sustained regulatory attention, such as the sector inquiry, ongoing continued scrutiny and general message that the Commission perceives such settlements to be illegal is to develop more complicated settlement terms either through a willingness to comply¹⁴⁰ or a desire to avoid scrutiny. The former may be a result of the rampant uncertainty that has resulted from the Commission's failure to provide any guidelines as to the legality of such practices, while the latter possibility is disconcerting for the reason that companies will turn to more complex types of settlements. These large companies possess ample resources to employ talented lawyers and it is thus not inconceivable that they would either try to deceive the authorities, or more legitimately, try to focus settlement agreements on acceptable terms, even though the result achieved may be the same - an undertaking from a generic company not to challenge or compete against its patents.

In the US, providing for some generic entry before patent expiry may be enough to sway a court as "some entry looks better than no entry"¹⁴¹ even though the rest of the agreement may contain restrictive terms. Pre-expiration entry appears beneficial where the patent would have been upheld by a court, but if there are doubts as to patent validity (and there usually are), a final judgment would have mandated immediate generic entry. In such cases, pre-expiration entry should not be considered so beneficial as to outweigh other considerations.

Complex settlement behaviour may manifest itself in a number of other ways. The agreement may contain a side deal that either overpays or underpays for the asset transferred. The very fact of settlement may even be concealed.¹⁴²

Whether a side deal over-compensates or under-compensates depends on the direction of the transfer. Overpayment occurs where the generic company transfers an asset to the originator company, which then pays an amount superior to the value of the asset. This may be a

¹⁴⁰ See PETIT, *supra* note 29 at p.13.

¹⁴¹ HEMPHILL *supra* note 89 at p.658.

¹⁴² *Ibid* p.684.

licence for an unrelated patent, the provision of manufacturing or promotional services.¹⁴³ Underpayment occurs where the originator company transfers an asset to the generic for less than its normal value. This usually takes the form of permission to manufacture and sell an authorised generic product, be it the product at issue, a related or unrelated drug.¹⁴⁴ The concern is that compensation in return for an undertaking to delay generic entry is concealed in this transfer.

Although it is inherently difficult for authorities to determine the value of an asset transferred and whether it represents an overpayment or underpayment, Hemphill judges the fact that such deals rarely take place outside the settlement context as sufficient evidence to impose a presumption that side deals represent “disguised payment[s]” to generic companies.¹⁴⁵

Hemphill raises concerns as to the ability of authorities to keep up with “frequent [...] mutations” in settlement behaviour although Drexl points out that while tacit collusion is harder to detect, it is clearly not beyond the Commission’s capabilities as demonstrated in other areas of antitrust enforcement.¹⁴⁶

The Commission’s ability to effectively combat more complex behaviour may in large part depend on the on the outcome of the first investigations. If these prove to be straightforward violations, a clear legal principle would hopefully be established, more so than if the first case was one that required a more nuanced response. This is in line with the *adage* ‘hard cases make bad law’. Indeed, Brankin suggests that “[i]t is not unlikely that, initially at least, [the Commission] will confine itself to cases involving either only a monetary payment or a side deal that is difficult to explain as a commercial arrangement and can therefore easily be characterised as a disguised reverse payment.”¹⁴⁷ A clear principle would then hopefully prove easier to apply to more complex settlements.¹⁴⁸

¹⁴³ *Ibid* p.664.

¹⁴⁴ *Ibid* p.665.

¹⁴⁵ *Ibid.* pp.666-669.

¹⁴⁶ DREXL, *supra* note 1 at p.754.

¹⁴⁷ BRANKIN, *supra* note 79 at p.27.

¹⁴⁸ This point is echoed by Hemphill in noting the need for prompt Supreme Court review of settlements in the US, “[simpler cases] provide a much more attractive vehicle for setting a clear rule”. He later states that “if a

US settlement practice has however proven that as soon as perceived scrutiny of their behaviour decreases, either through the “waxing and waning of antitrust enforcement” or “changes in judicial interpretation”,¹⁴⁹ pharmaceutical companies will once again turn to more traditional reverse settlement payments.¹⁵⁰ This is because companies will generally not resort to a more complex or expensive type of behaviour where it is not commercially necessary to do so. In this manner, the suitability of an instrument such as continued monitoring must therefore be questioned, although this logic is somewhat circular as the monitoring exercise also permits the Commission to study a sufficiently large number of settlement terms so as to be able to understand what is really being transferred and become more adept at spotting attempts at deception.

5.2 *Cumulative Use of Strategies*

Although the cumulative use of strategies was addressed by the Commission in its Final Report, it is submitted that the examination of patent settlements as part of a wider strategy to prolong patent protection and prevent generic entry is a dimension to which the Commission has not yet given due weight. It is contended that more intense scrutiny will serve to increase the complexity of patenting strategies and settlements. This evolution in behaviour is worrying as it “makes it less likely that courts will correctly identify and condemn them.”¹⁵¹

Aside from settlements, other toolbox strategies used by pharmaceutical companies include interventions before national bodies granting market authorisation to generic companies, and the use of secondary and divisional patents to form patent clusters or thickets. The use of such patenting strategies can significantly increase the amount of time required by the EPO

court is forced to start with one of the most complex cases, without the benefit of affirmative precedent on the simpler cases, correctly identifying liability seems less likely”. HEMPHILL, *supra* note 89, at pp.662-663, 686.

¹⁴⁹ HEMPHILL, *supra* note 89 at p.657.

¹⁵⁰ See M. CARRIER, ‘2025: Reverse-Payments Settlements Unleashed’, *CPI Antitrust Journal*, December 2010 for an overview of this phenomenon. The FTC recently found that the instance of ‘pay-for-delay’ settlements increased by 63% in 2010. This is a direct result of successive favourable court decisions and failures to legislate. FTC, ‘Overview of Agreements Filed in FY 2010’. Available at: <http://www.ftc.gov/os/2011/05/2010mmastaffreport.pdf>, 4th May 2011.

¹⁵¹ HEMPHILL, *supra* note 89 at p.688.

to examine a patent¹⁵² and creates uncertainty for other innovators and potential generic challengers.¹⁵³

The Final Report found that “intensity of use [of secondary and/or divisional patenting] increases with the commercial importance of the product”¹⁵⁴ although establishing causality over such a long period would appear a difficult task.¹⁵⁵ The point is that it is very hard to draw the line as to where such practices are legitimate and where they constitute an exclusion of competition as it is perfectly legitimate for a company to protect its innovation in every manner permitted by the patent system.

The practice of secondary patenting in order to prolong patent protection is known as ‘evergreening’. Incremental innovation may be beneficial in many ways – a new formulation of a drug may increase its effectiveness, reduce side effects, facilitate administration or reduce the required dosage.¹⁵⁶ It should be noted that a secondary patent must fulfil the criteria for patentability like any other patent.¹⁵⁷ However, when viewed as part of a larger strategy to keep generics off the market, this behaviour may pose problems, particularly under Article 102 TFEU.

As part of this practice of filing secondary patents, a company may also release a second-generation version of their drug which may be covered by existing primary or secondary patents. All promotional activities will then be aimed at informing prescribing doctors of the benefits of the new drug, coupled with withdrawal of the first-generation drug from the market or an increase in its price.¹⁵⁸ These actions are intended to switch enough consumers before patent expiry of the first drug so that when generic equivalents reach the market, doctors and consumers will already be focussed on the new drug. The timing of such a

¹⁵² See Final Report, *supra* note 4 at p.201.

¹⁵³ *Ibid* para. 1068.

¹⁵⁴ *Ibid* para. 1065.

¹⁵⁵ *Ibid* para. 1058.

¹⁵⁶ *Ibid* para. 1323.

¹⁵⁷ HATTON et al., *supra* note 37 at p.377.

¹⁵⁸ M. CARRIER, ‘A real-world analysis of pharmaceutical settlements: the missing dimension of product hopping’, (2010) 62 *Fla.L.Rev.* 1032 at p.1024.

switch is considered critical, as a launch after generic entry would not achieve the same effect.¹⁵⁹

This practice of ‘brand migration’ is something for which the Office of Fair Trading in the UK has recently fined Reckitt Benckiser £10 million.¹⁶⁰ Reckitt Benckiser admitted to having removed its product Gaviscon Original Liquid from the NHS prescription channel before patent expiry in order to switch patients to the second-generation product Gaviscon Advance Liquid, before any generic product could enter the market. Furthermore, in removing the product from the system, doctors were prevented from prescribing any generic equivalent to Gaviscon Original Liquid and could instead only prescribe Gaviscon Advance Liquid. This is also similar to the second offence in the *AstraZeneca* case.¹⁶¹

Carrier argues that considering the practice of ‘product hopping’ in combination with settlements offers a new perspective that shows settlements to be more damaging than previously thought.¹⁶² A non-compete clause in a settlement agreement provides an originator company with a predefined period of time in which to continue profiting from its drug. It also provides an assured period of time in which to switch patients to a second-generation drug before the agreed date of generic entry. This can provide for a more effective exercise in patient-switching, as the second-generation drug will have captured more of the market than would have been possible in a shorter timeframe. Generic entry is then further delayed by the need to develop and obtain market authorisation for the improved version, which may be more difficult where an *AstraZeneca*-type offence has been employed. According to this model, accrued benefit to consumers is far more delayed than previously thought. Carrier thus submits that in considering settlements as potential violations of competition law, courts should pay heed to the “silent, but brutally effective dimension of product hopping.”¹⁶³

Although companies may merge for many reasons, the timing of the announcement of the planned Cephalon/Teva merger one week after the Commission announced it was opening

¹⁵⁹ *Ibid* pp.1035-1036.

¹⁶⁰ OFT Press Release, ‘Reckitt Benckiser agrees to pay £10.2 million penalty for abuse of dominance’, 15th October 2010. Available at: <http://www.of.gov.uk/news-and-updates/press/2010/106-10>, 12th February 2011.

¹⁶¹ See *supra* section 4.2.

¹⁶² CARRIER, *supra* note 158 at p.1033.

¹⁶³ *Ibid*.

an investigation into settlement behaviour is demonstrative of another strategy that companies may use in order to avoid scrutiny of their settlement practices.¹⁶⁴ The planned merger is unusual in that it is a generic company, albeit one with a brand drug division, acquiring an originator company. Nonetheless, their patent portfolios, once combined should provide considerable opportunities to innovate. The launch of ‘authorised generic’ products by originator is another method of controlling generic presence of a market through pricing and other strategies.

¹⁶⁴ See *supra* section 3.2.

6 Conclusion: Possible Future Developments

Patent settlements concluded in order to delay generic market entry are very much an emerging area of competition law, that look set to provide for much controversy in the future. It is thus submitted that the European response is one that must be nuanced in nature. Patent settlements can be concluded in so many different circumstances and with so many other considerations in mind that it is not an area that lends itself to making generalisations. Patent settlement agreements providing for reverse payments should be found to breach competition rules, though perhaps not in all circumstances.

As for developments in the near future, the Commission will proceed with its initial investigations: Boehringer, Lundbeck, Servier and Cephalon. The outcome of the proposed Cephalon/Teva merger may also be of interest.

Taking *AstraZeneca* and the sector inquiry also into account, DG Competition has now spent some years analysing the pharmaceutical sector. The modernisation process means that many cases are now taken by national competition authorities and the Commission can increasingly limit itself to more significant cases such as *Microsoft*¹⁶⁵ and *AstraZeneca*. It thus has the luxury of increased resources which means it can take its time in building a careful case that will have important precedential value. This is also important because rejection by the General Court on appeal for any reason would be disastrous for the Commission's cause and would have wider implications for possible future cases tackling different strategies used by pharmaceutical companies.

The Commission has also stated its intention to continue an annual analysis of settlements until it is satisfied that competition is functioning in the market. This may continue for some years. Alternatively, the outcome of the forthcoming investigations may be clear enough so as to remove any need for continued monitoring. The Commission will, in any case, have learned enough about settlements to know when to pursue individual infringements.

¹⁶⁵ T-201/04 *Microsoft Corp v Commission* [2007] ECR II-3601.

There is also the possibility that the Commission will issue guidelines to the pharmaceutical sector as to what constitutes acceptable behaviour.¹⁶⁶ There was some disappointment that this was not done at the conclusion of the sector inquiry. Some have argued that a “consolidated statement of the legal framework” would be preferable to *ad hoc* development of the law, which may take a considerable period of time. The issuance of guidelines would serve to remove the uncertainty that companies, authorities and national courts are now faced with.¹⁶⁷

A further possibility is that of mandatory notification of settlements, something which occurs in the US. Batchelor says that an earlier such proposal within the European Union was dropped¹⁶⁸ and in any event, notification of settlements would be contrary to the ethos of the modernisation process which provides for more self-regulation. Hemphill makes the interesting suggestion that a court could be required to approve the settlement between the parties although it is unclear how this would operate in a European context.¹⁶⁹ Something that is more likely would be an instrument akin to a block exemption for settlements, which would be more in line with modernisation. However, success would largely depend on the level at which the standard of compliance was set. If it was relatively easy, then parties would be incentivised to do so. Yet if the standard was set too high, parties may continue with complex settlement behaviour. Such an instrument would probably achieve much the same result as guidelines but would be more legally binding in nature.

It is also important to consider how settlement practice and enforcement would develop if a European Patent and Court were ever to become reality. A streamlined litigation system would certainly incentivise generic challenge as one would only need to take a single case and victory opens up the entire market as opposed to that of one Member State. Translation and legal costs would also be greatly reduced. A European Patent would also do much to remove uncertainty as to patent validity arising from conflicting national judgments.¹⁷⁰

¹⁶⁶ P. TREACY, S. LAWRANCE, H. HOPSON, ‘Competition Law in Pharmaceuticals: a moving target?’, Oxera Agenda, December 2008, p.3.

¹⁶⁷ HATTON et al. *supra* note 37 at pp.377-378.

¹⁶⁸ BATCHELOR, *supra* note 15 at p.18.

¹⁶⁹ HEMPHILL, *supra* note 89, at pp.640-641.

¹⁷⁰ See Final Report, *supra* note 4 at p.461.

However, in March 2011 these plans were dealt a major blow when the CJEU ruled that a Patent Court would not be compatible with the provisions of European Union law.¹⁷¹

Reform of the patent system as it stands also seems necessary in many respects. It would seem hypocritical of the Commission were it to pursue the other strategies outlined by the sector inquiry as a violation of competition law without simultaneously seeking deeper reforms.¹⁷²

¹⁷¹ *Opinion I/09* (Re: European and Community Patents Court) [2011] ECR 000.

¹⁷² See D. HARHOFF, 'Patent system design – an economic perspective', (2010) 4(2) *IIC* 121.

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