

Restrictive Practices in Pharmaceutical Industry:
Reverse Payment Agreements
*Seeking for a Balance between Intellectual
Property and Competition Law*

OLGA GURGULA*

Reverse payment agreements have attracted the close attention of competition authorities as they are suspected to be the fundamental reason for encumbering competition in the pharmaceutical sector. For more than a decade the U.S. competition and judicial authorities have been scrutinising them, developing specific approaches suitable for their assessment. However, once the practice was deemed to be settled, the Third Circuit questioned this practice employing the new test. In the EU this type of agreement was not in focus until recently, therefore no relevant case law has developed whatsoever. Such uncertainty regarding the possible further developments in the assessment of reverse payment agreements is detrimental to the pharmaceutical industry, as it hinders companies' ability to adopt their business strategies without the fear of triggering antitrust liability. This article will examine the current status of the reverse payment agreements in both jurisdictions, analyse the application of article 101 TFEU and Section 1 of the Sherman Act along with other relevant legislative provisions, the applied tests and approaches, and specific examples of the agreements decided by the U.S. courts. Such a discussion pursues the practical goal of expanding understanding of what constitutes permitted behaviour for pharmaceutical companies when concluding this type of agreement with a view to avoiding antitrust liability.

I. Introduction

Intellectual property is no longer the arcane domain of intellectual property lawyers.¹ It is the most valuable corporate asset which a company may

* Attorney at law, LL.M. (Queen Mary, University of London)

possess, and a powerful weapon against its competitors. Increased understanding of the importance of intellectual property rights has advanced their protection and exploitation to a new level. As businesses have developed a greater understanding of the value of their intangible assets, they have not only pursued more rigorous enforcement policies; they have also invented more imaginative commercial strategies to gain and retain market share using their intellectual property.²

As long as such practices facilitate robust competition, they are welcomed and encouraged. However, some strategies have triggered the concern of competition authorities. Where intellectual property rights are used to restrict competition significantly and impose barriers to market entry, intervention of competition law is likely.

As one of the sectors most important to public health, the pharmaceutical industry has always warranted the close attention of competition authorities. Pharmaceutical companies rely heavily on intellectual property to protect their inventions and recoup their investment. It is also seen as the necessary incentive to advance innovation. Pharmaceutical companies therefore make great efforts to protect intellectual property rights, their main tool to ensure a large market share and to exclude competitors from the market for as long as their intellectual property allows them.

Recently, the pharmaceutical industry has undergone significant changes: various “blockbuster” medicines, which account for a substantial part of the sales and profits of large pharmaceutical companies, have lost patent protection, with more to follow in the coming years.³ This shift has forced pharmaceutical companies to develop new and reinforce current business practices using their intellectual property rights to retain their market shares.

However, not every practice is welcomed by the competition authorities. A number of new commercial practices used by pharmaceutical companies have been prohibited as exclusionary or exploitive abuses under the

¹ Carlos M Correa, Abdulqawi A. Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer Law International, The Netherlands 2008) 150.

² Steven Anderman and Ariel Ezrachi, *Intellectual Property and Competition Law: New Frontiers* (Oxford University Press 2011) 6.

³ European Commission, ‘Executive Summary of the Pharmaceutical Sector Inquiry Report’ (8 July 2009) <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry-communication_en.pdf> accessed 6 August 2012 (Executive Summary).

competition rules. The *AstraZeneca* case,⁴ for instance, raises the question of when a misuse of the patent process violates Article 102 TFEU.⁵

Other practices have attracted the attention of competition authorities for being the suspected reason for the delay or blocking of generic drug competition.⁶ Such practices include patent settlement agreements concluded between originator companies and generic companies in the context of patent disputes and opposition procedures or litigation where no final adjudication has been handed down.⁷

Certainly, not all patent settlement agreements are deemed illegal. Some are recognised as perfectly legal and even pro-competitive.⁸ Nevertheless, some of these agreements have triggered a flame debate as to their conformity within antitrust law. A main concern among competition authorities are so-called reverse payment agreements, in which the originator company pays the generic company for staying off the market. Despite mutual concerns that this type of agreement may raise competition problems, there is no agreement about which of them should be considered illegal and violative of the competition law and which may be allowed. In addition, there is no agreement as to which evaluative approach to take when considering such disputes.

This article will review the patent settlement agreements under different regimes, including those of the EU and the U.S. This review starts by considering the general background of patent settlement agreements and their types. Then, turning to the U.S. and the EU legal frameworks regarding marketing authorisation underpinning the incentive for pharmaceutical companies to conclude this type of agreement, as well as the competition law provisions of article 101 TFEU and Section 1 of the

⁴ Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-02805.

⁵ Anderman (n 2) 8.

⁶ Among such practices, the European Commission defines patent filing strategies, patent-related exchanges and litigation, oppositions and appeals, life cycle strategies for second generation products. See Executive Summary (n 3) 3.

⁷ European Commission, '3rd Report on the Monitoring of Patent Settlements (period: January-December 2011)' (25 July 2012) <http://ec.europa.eu/competition/sectors-pharmaceuticals/inquiry/patent_settlements_report3_en.pdf> accessed 6 August 2012 (3rd Monitoring Report).

⁸ European Commission, 'Pharmaceutical Sector Inquiry Final Report' (8 July 2009) <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part_1.pdf> accessed 5 August 2012 (Pharmaceutical Sector Inquiry) 255.

Sherman Act, it further examines the respective positions of the FTC and the EU Commission regarding the patent settlement agreements.

It will further detail the U.S. courts' specific approaches to evaluating this type of agreement. On the basis of relevant U.S. case law, this article will extract general rules applied by the courts in their judgements. Finally, it will consider specific examples of both lawful and unlawful reverse payment agreements as decided by the courts and will explore whether the differences between the tests applied by the U.S. courts lead to different outcomes for these agreements. It will also examine the most recent decision of the US Court of Appeal for the Third Circuit and the impact it has on the previous case law regarding the reverse payment agreements. It will further discuss the possibility to apply the US tests for the evaluation of the reverse payment agreements to the EU realia considering some differences in the legal framework of these two regimes and will suggest the possible way the reverse payment agreements evaluation under the EU legislation and applying the EU competition law doctrines.

Having discussed and analysed the legislative frameworks, competition authorities' and courts' respective positions toward the patent settlement agreements, and having examined examples of the patent settlement agreements, this article will finish with recommendations regarding the development of a coherent approach to the reverse payment agreements and possible submission of this type of disputes to the jurisdiction of the European Patent Court (EPC). This article also advises which provisions to avoid while negotiating patent settlement agreements in order not to trigger competition concerns. It is hoped that such analysis can offer a practical approach toward understanding what comprises permitted behaviour for pharmaceutical companies when concluding this type of agreement, to avoid antitrust liability.

II. Patent Settlement Agreements and Types of Reverse Payment Agreements

1. Patent Settlement Agreements: General Considerations

Parties may opt to settle a dispute in or out of court to save time and money rather than pursuing the disagreement until the final court decision, which will likely prove unsatisfactory to at least one of the parties. Patent disputes settlements are no exception, as patent litigation is typically lengthy and

extremely costly.⁹ The pharmaceutical industry in particular has recently favoured this type of agreement, where the patent is considered a primary corporate asset which the patent holder vigourously protects and which competitors target.

When a patent litigation between brand-name¹⁰ and generic pharmaceutical companies occurs, it typically involves determining whether the relevant patents are valid and have been infringed. For the brand-name drug company to prevail, it must successfully defend the validity of its patents and show that the generic's product would infringe those patents.¹¹ For the generic company to succeed, it must prove that the patent is invalid or unenforceable and/or that its generic drug does not infringe the patent.¹² Such disputes are extremely complex and demand enormous effort from both parties. Therefore, given the high costs of patent litigation and the potential uncertainty of the case outcome, brand-name and generic companies may wish to settle a dispute before a court decides on the merits. This trend is evidenced by the rapidly growing number of patent settlements during the last few years.¹³

Such settlements do not necessarily raise competition law concerns. The parties may agree that the generic company may start marketing at some point before the patent expires, but not as soon as it expects through the litigation.¹⁴ This agreement will most likely reflect the parties' beliefs on the

⁹ Pharmaceutical Sector Inquiry (n 8) (originator companies paid, on average, € 230,000 in legal fees per case in a single Member State. The highest amount of legal fees is paid in the UK, with an average of € 993,000 per litigation, followed by the Netherlands and France, approximately half that in the UK, and the lowest in Germany and Austria (€ 76,000 and € 46,000) para 659.

¹⁰ According to the Federal Food, Drug, and Cosmetic Act the term 'brand name drug company' means the party which holds the approved application (...) for a brand name drug which is a listed drug in an ANDA, or a party which owns a patent for which information is submitted for such drug (..) (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (n 41) Sec. 1111). The EU equivalent of this term is 'Originator company'.

¹¹ Federal Trade Commission Staff Study, 'Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions' (January 2010) <<http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>> accessed 6 August 2012, 3 (FTC Pay-for-Delay Study).

¹² *ibid.*

¹³ 3rd Monitoring Report (n 7) 6 (from 12 patent settlement agreements in 2000 to 120 in 2011).

¹⁴ FTC Pay-for-Delay Study (n 11) 3.

likelihood of success of their legal positions in a dispute.¹⁵ Settlements which contain no other specific provisions normally do not raise competition concerns.

However, particular types of patent settlement agreements have attracted scrutiny from competition authorities. The so-called ‘reverse payment’, ‘pay-for-delay’ or ‘exclusionary payments’ settlement, wherein some kind of consideration flows from the originator company to the generic company in exchange for the promise by the latter to refrain from entering the market, has sparked doubts about its conformity with competition law principles. The FTC launched a campaign against this type of agreements a decade ago, and the EU Commission and some other national competition authorities have made them a recent focus.

The authorities’ main concern is that the pharmaceutical brand name company uses its monopoly profits to pay the generic company to stay out of the market, thus eliminating its direct competitor. This behaviour leads to decreased competition in the pharmaceutical sector and so harms consumers, who do not receive cheaper generic version of the drug as soon as they could have done with the generic company’s entry on the market. On the other hand, the proponents of the reverse payment agreements argue that these settlement agreements benefit the public in ending the costly litigation.¹⁶ As a result, pharmaceutical companies may invest the saved resources into further research for new drugs, and save time and effort on the part of the courts, patent offices and competition authorities to decide the matter, which also has positive public interests.¹⁷

2. Specific Patent Settlement Agreements: Reverse Payment Agreements and Their Types

Although some differences exist between the types of reverse payment agreements in the U.S. and the EU, one can highlight certain common provisions used by pharmaceutical companies when settling their disputes,

¹⁵ Federal Trade Commission Report, ‘Authorized Generic Drugs: Short-Term Effects and Long-Term Impact’ (August 2011) < <http://www.ftc.gov/os/2011/08/2011-genericdrugreport.pdf> > accessed 6 August 2012, 140 (FTC Authorized Generic Drugs Report).

¹⁶ Pharmaceutical Sector Inquiry (n 8) 255.

¹⁷ 3rd Monitoring Report (n 7) 2.

based on FTC and EU Commission findings.¹⁸ The main provisions which raise competition concerns in this type of agreement are whether an agreement contains (i) limitation/restriction on market entry by the generic company and (ii) value transfer from the originator to the generic company.¹⁹

The value transfer from the originator company to the generic company may take different forms, including:

- a plain monetary transfer from originator to generic company;
- non-monetary benefits from originator to generic company, which may include, *inter alia*:
 - the originator company's granting a licence to the generic company to manufacture branded product;²⁰
 - entering into the supply/distribution agreement with the generic company;²¹
 - entering into co-marketing and co-promotion agreements;
 - a promise by the originator not to compete with the generic using its authorised generic (AGs).²²

The generic company's restrictions on market entry also vary. The parties may agree that the generic company will enter the market before, upon or after the patent expires.

¹⁸ See Pharmaceutical Sector Inquiry (n 8), 3rd Monitoring Report (n 7), FTC Pay-for-Delay Study (n 11), FTC Authorized Generic Drugs Report (n 15).

¹⁹ Pharmaceutical Sector Inquiry (n 8).270.

²⁰ 3rd Monitoring Report (n 7) 3. 'A licence granted by the originator company allowing market presence of the generic company is also categorised as limiting generic entry, because the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialisation of its product freely.' (internal references are omitted) *ibid*.

²¹ *ibid*. 'The same logic applies to patent settlement agreements in which the parties agree that the generic company will be a distributor of the originator product concerned or if the generic company will source its supplies of the active pharmaceutical ingredient (API) from the originator company.' *ibid*.

²² FTC Authorized Generic Drugs Report (n 15). 'The AGs are pharmaceutical products that are approved as brand-name drugs but marketed as generic drugs. AGs do not bear the brand-name or trademark of the brand-name drug or manufacturer, but the brand-name and AG products are manufactured to the brand's specifications.' *ibid*. This form of compensation occurs when the brand-name company agrees not to launch its AG during the first-filer's 180-day exclusivity period, in exchange for the first-filer's agreement to delay its market entry.

Despite these provisions in reverse payment agreements have raised competition concerns it will be seen in section 4 of this article that not all of these agreements have been held as unlawful.

III. Legal Framework

1. Legal Framework Regarding Marketing Authorisation in the U.S. and the EU

When discussing reverse payment agreements, one must understand the legal basis which creates incentives for generic companies to challenge a patent and for originators to protect it with a claim of patent infringement. Another important factor which requires understanding of the legal framework is that, whilst significant similarities exist between settlement agreements in the EU and the U.S., there are also some differences which result partly from the different regulatory frameworks.²³

1.1. U.S. legislation

To start marketing a drug in the U.S., a pharmaceutical company must first apply for approval to the Food and Drug Administration (FDA) under the Federal Food Drug and Cosmetic Act.²⁴ A brand-name company obtains FDA approval for the new drug through a New Drug Application (NDA) and must prove that its product is safe and effective.²⁵

(a) Hatch-Waxman Act

The Hatch-Waxman Act,²⁶ enacted in 1984, and amended in 2003,²⁷ provides alternative ways for generic companies to obtain FDA approval for

²³ Pharmaceutical Sector Inquiry (n 8) 290. '(...) [i]n the USA, the first generic company to file a paragraph-IV certification is explicitly rewarded by the legislator, whilst in the EU the first to market enjoys no statutory period during which he is protected against market entry of a second, third or subsequent generic company.' *ibid*. This difference has created a specific type of value transfer – authorised generics as a bargaining asset to induce a generic company to refrain from entering the market. See FTC Authorized Generic Drugs Report (n 15) n 21. This value transfer is typical for the U.S. market, but not the EU, as the lack of exclusivity period for the first filer offers no bargaining power to the originator company.

²⁴ 21 U.S.C. § 301, 21 U.S.C. § 355(b).

²⁵ 21 U.S.C. § 355(b),(c).

²⁶ Codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271, 282.

²⁷ Amended as part of the Medicare Prescription Drug, Improvement, and Modernisation Act of 2003.

their products. The main purpose for introducing the Hatch-Waxman Amendments was to encourage generic companies to enter the market at an earlier stage, and thus facilitate competition with a brand-name drug²⁸ which would ‘make available more low cost generic drugs’²⁹ for consumers. The Act provides an accelerated process for submitting an ‘Abbreviated New Drug Application’ (ANDA) to the FDA to gain approval for a drug which is shown to be a bioequivalent to a new drug previously approved by the FDA.³⁰ Thus, in order to prove the safety and efficacy of the generic medicine a generic company now may to rely on the clinical data first submitted by the brand-name pharmaceutical company.³¹

If the generic company wants to enter the market before the patent expiration for the brand-name drug, it may apply for ‘Paragraph IV’ ANDA certifying that the ‘patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.’³² The company must also include in the application a statement that it will give notice of its certification to each owner of the patent which is the subject of certification, including a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is invalid or will not be infringed.³³

Paragraph IV certification constitutes a technical act of infringement.³⁴ It empowers the patent holder brand-name drug company to bring an action for a patent infringement within 45 days of the received notice.³⁵ The approval will be given immediately upon the expiration of 45 days if no such patent infringement action is brought within that period.³⁶ However, if the brand-name company does file a patent infringement suit within the stated period, the approval shall be made effective upon the expiration of the

²⁸ FTC Pay-for-Delay Study (n 11) 3, See also Joseph J. Jacobi, ‘Reconsidering the Antitrust Implications of Settlement in ANDA Litigation’ [2010] SRR Journal <<http://www.srr.com/article/reconsidering-antitrust-implications-settlement-anda-litigation>> accessed 6 August 2012.

²⁹ H.R. REP. NO. 98-857, at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647. (H.R. REP. NO. 98-857).

³⁰ 21 U.S.C. § 355(j). See FTC Authorized Generic Drugs Report (n 15) 3.

³¹ FTC Authorized Generic Drugs Report (n 15) 3.

³² 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

³³ 21 U.S.C. § 355(j)(2)(B).

³⁴ 35 U.S.C. § 271(e)(2)(A).

³⁵ 21 U.S.C. § 355(j)(5)(B)(iii).

³⁶ *ibid.*

30-month period beginning on the date of the receipt of the notice or upon a favourable decision of the court – whichever comes earlier.³⁷

Once the earliest event occurs, the FDA may authorise the marketing of the generic drug, and the first applicant of Paragraph IV ANDA becomes entitled to 180-day exclusivity period.³⁸ This exclusivity period means that subsequent ANDA applications will become effective only upon the expiration of this period,³⁹ which effectively protects the first to file generic company from generic competition during this period. It thereby provides an incentive to challenge patents of brand-name pharmaceutical companies seeking to enter the market prior to patent expiration.⁴⁰

(b) Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Following FTC recommendations,⁴¹ Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003⁴² to address irregularities created by the Hatch-Waxman Amendments.⁴³ The Act includes only one 30-month stay per ANDA,⁴⁴ forfeiture of the 180-day exclusivity period under certain circumstances⁴⁵ and, most important, the stipulation that agreements between ANDA applicants or between ANDA applicants and NDA holders must be filed with the Department of Justice and the FTC within 10 days of execution.⁴⁶

³⁷ *ibid.*

³⁸ 21 U.S.C. § 355(j)(5)(B)(iv)(I)–(II).

³⁹ *ibid.*

⁴⁰ FTC Authorized Generic Drugs Report (n 15) 3.

⁴¹ Federal Trade Commission, ‘Generic Drug Entry Prior to Patent Expiration: An FTC Study’ (July 2002) < <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>> accessed 6 August 2012.

⁴² Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.) (Medicare Act).

⁴³ Anne-Marie C. Yvon, ‘Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments’ (2006) 75 *Fordham Law Review* 1883, 1896.

⁴⁴ Medicare Act (n 42) Sec.1101.

⁴⁵ *ibid.* Sec.1102

⁴⁶ *ibid.* Sec. 1112,1113. See also Yvon (n 43) 1897.

1.2. EU Legislation

In the EU, as in the U.S., a pharmaceutical company must obtain marketing authorisation (MA) for a drug to be placed on the market.⁴⁷ Two types of authorisation exist: national authorisation, which is issued by the competent authorities of the EU Member States and is effective on its territory,⁴⁸ and community authorisation, which is issued by the European Commission on the basis of the centralised procedure and covers the territory of the EU.⁴⁹ Regulation (EC) No 726/2004⁵⁰ governs the centralised procedure, which offers a single application, a single evaluation, a single authorisation and the right to market medicinal product in all EU Member States.⁵¹

The generic company may receive marketing authorisation without providing its own pre-clinical tests and clinical trials if it can show that its medicine is a generic version of a previously approved drug.⁵² The authority relies on the tests and trials for the already approved drug, submitted by originator company, but only after the expiration of the data exclusivity period which protects the data relating to the approved drug.⁵³

Before 2004, the EU did not regulate product development by the generic company whilst the originator's patent was still alive; each country decided this issue at the national level.⁵⁴ The legal uncertainty about whether the research for the marketing authorisation before the patent's expiration amounted to patent infringement forced generic companies to wait for

⁴⁷ Pharmaceutical Sector Inquiry (n 8) 115.

⁴⁸ *ibid.*

⁴⁹ *ibid.*

⁵⁰ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p 1 (Regulation (EC) No 726/2004); see also Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, p 67. (Directive 2001/83/EC).

⁵¹ Pharmaceutical Sector Inquiry (n 8) 118.

⁵² Directive 2001/83/EC (n 50) Art. 10.

⁵³ *ibid.* See also Pharmaceutical Sector Inquiry (n 8) 119.

⁵⁴ Pharmaceutical Sector Inquiry (n 8) 122. See also Kristof Roox, 'The Bolar provision: a safe harbour in Europe for biosimilars', (2006) 172 *EURALex* < http://www.crowell.com/documents/DOCASSOCFKTYPE_ARTICLES_614.pdf> accessed 6 August 2012.

patent expiration to carry out their product development and related testing in countries where the basic patent had already expired or where such protection did not exist.⁵⁵

The Directive 2004/27/EC was introduced to eliminate this uncertainty.⁵⁶ The so-called '*Bolar*' provision was designed to give generic companies an exemption for pre-marketing testing, to bring EU legislation closer to the U.S.⁵⁷ This provision creates a safe harbour for certain tests and studies whilst the reference product is still patent-protected in the EU so as to enable the generic producer to apply for marketing authorisation once the period of data exclusivity granted to the holder of the original MA has elapsed.⁵⁸ After the implementation of this Directive, therefore, a generic company can obtain market authorisation for a bioequivalent drug before the patent has expired, which allows the company to start marketing its drug immediately after the patent expires.⁵⁹

2. Differences between the U.S. and EU Legal Frameworks

Despite general similarities between the U.S. and EU legal frameworks regarding drug-marketing authorisations, certain differences have led to the evolution of specific provisions of the reverse payment agreements pertaining to the particularities of the legal provisions in the respective jurisdictions.

Although, the implementation of *Bolar* provisions brought EU regulation closer to the U.S, the latter legislation has also expanded the possibilities of market entry by generic companies by introducing the so-called 'Paragraph IV' certification. This legislation enables generic companies to enter the market before a patent expires, an early entry encouraged by the 180-day

⁵⁵ Pharmaceutical Sector Inquiry (n 8) 123. See Rook (n 54). 'In the US, for example, the US Court of Appeals initially ruled in the case of *Roche v. Bolar* that the experimental use of a drug for the purposes of obtaining regulatory approval for a generic version of a patented pharmaceutical product constituted a patent infringement. Following this case, US patent law was amended to include an exemption to permit such activities'. See also Aria Joze Zomorodian, 'Settlement Agreements in Patent Litigation; American lessons for a European context' (Master thesis, Lund University 2012) 23.

⁵⁶ Directive 2004/27/EC the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use OJ L 136, 30.4.2004, p 34. (Directive 2004/27/EC).

⁵⁷ Rook (n 54) 19.

⁵⁸ Pharmaceutical Sector Inquiry (n 8) 123-124.

⁵⁹ Zomorodian (n 55) 23.

exclusivity period granted to the first-to-file generic company. These provisions have no equivalent in EU law. Such provisions in U.S. legislation have triggered new kinds of reverse payment agreements which are not specific to EU law.⁶⁰ This is the case of brand-name drug companies, instead of paying the generic companies for their promise not to enter the market, agree not to launch their authorised generics in competition with the approved generic drug during the 180-day exclusivity period.⁶¹

3. U.S. and EU competition rules applicable to the reverse payment agreements

3.1. U.S. antitrust rules

Section 1 of the Sherman Act prohibits '[e]very contract, combination (...) or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations'.⁶²

3.2. EU competition rules

Historically, EU competition law treated patent settlement agreements like any other agreement.⁶³ As defined by the Court of Justice of the European Union (CJEU) in the context of 'no-challenge' clauses:

In its prohibition of certain 'agreements' between undertakings, Article [101 (1) TFEU]⁶⁴ makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.⁶⁵

The Commission scrutinises this kind of agreement under article 101 of the Treaty on the Functioning of the European Union (TFEU), which prohibits agreements and concerted practices which may affect trade and prevent or restrict competition.

⁶⁰ Pharmaceutical Sector Inquiry (n 8) 291.

⁶¹ FTC Authorized Generic Drugs Report (n 15) 141.

⁶² 15 U.S.C. §1.

⁶³ Sean-Paul Brankin, 'Patent settlements and competition law: where is the European Commission going?' (2009) 5(1) *Journal of Intellectual Property Law & Practice* 23, 23.

⁶⁴ Article 101 (1) of the Treaty on the Functioning of the European Union (TFEU).

⁶⁵ Case 65/86 *Bayer AG v Maschinenfabrik Hennecke GmbH & Heinz Sullhoftr* [1988] ECR-5249, para 15.

Unlike U.S. legislation, Section 1 of the Sherman Act, article 101 TFEU contains paragraph 3, which provides for individual exemptions to the main prohibitions set in paragraph 1, subject to specified criteria. Thus, an agreement may be exempted provided that it:

contributes 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, and which does not:

- (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
- (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.⁶⁶

In addition, several block exemption regulations give guidance to undertakings on which agreements will be exempted.⁶⁷ Of particular interest to this article is the Technology Transfer Block Exemption Regulation (TTBER), which addresses competition concerns arising, *inter alia*, due to patent licensing agreements.⁶⁸ The TTBER recognises that technology transfer agreements usually improve economic efficiency, are pro-competitive and give rise to competition concerns only when the undertakings have a high level of market power and agree to incorporate particularly damaging restrictions within the agreement.⁶⁹

In its Guidelines to the TTBER,⁷⁰ the European Commission acknowledges that the licence agreements ‘in the context of settlement agreements and non-assertion agreements is not as such restrictive of competition since it allows the parties to exploit their technologies post agreement.’⁷¹ The Commission indicates, however, that ‘the individual terms and conditions of such agreements may be caught by Article [101](1) [TFEU].’⁷² The Commission defines that ‘[w]here the parties have a significant degree of

⁶⁶ Article 101 (3) TFEU.

⁶⁷ Catherine Colston, Jonathan Galloway, *Modern Intellectual Property Law* (3rd edn, Routledge 2009) 25.

⁶⁸ Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, OJ L 123, 27.4.2004, 11 (TTBER), see also Colston (n 67) 26.

⁶⁹ TTBER (n 68) recitals para 5, see also Colston (n 67) 26.

⁷⁰ Commission Notice, ‘Guidelines on the application of Article 81 of the EC Treaty [now Art. 101 TFEU] to technology transfer agreements’ OJ [2004] C 101/02 (Technology Transfer Guidelines).

⁷¹ *ibid.*, para 204.

⁷² *ibid.*

market power and the agreement imposes restrictions that clearly go beyond what is required in order to unblock, the agreement is likely to be caught by Article [101].⁷³ The Commission does not explain what is meant by ‘beyond the unblocking’, but one may argue that, for instance, the restrictions relating to other intellectual property rights which are not in dispute may well be deemed as going beyond that needed to unblock.⁷⁴

IV. Competition Authorities’ Positions on Reverse Payment Agreements

1. FTC Position

For more than a decade, the FTC has been straggling with certain types of patent settlement agreements where the brand-name companies pay generics to delay entry.⁷⁵ The FTC contends that, although branded pharmaceutical manufacturers and their generic competitors tend to view reverse payment settlements favourably, consumers may suffer as ‘they miss out on generic prices that can be as much as 90 per cent less than brand prices.’⁷⁶ According to FTC staff analysis published in January 2010, exclusion payment settlements cost consumers \$3.5 billion per year.⁷⁷

The FTC’s main concern regarding reverse payments is that the patent holder is using part of the profits from its patent monopoly to buy off the entry of its competitor.⁷⁸ Thus, the FTC sees such agreements as a violation of antitrust law, namely Section 1 of the Sherman Act. The FTC argues that such settlements may raise serious competition concerns when they involve compensation from the brand-name company to the generic company to delay generic entry beyond the time of a simple compromise date.⁷⁹ According to the FTC position, such settlements ‘thwart the goal of the Hatch-Waxman Amendments to encourage generic companies to challenge questionable patents and promptly ‘make available more low cost generic

⁷³ *ibid*, para 207.

⁷⁴ Anderman (n 2) 283.

⁷⁵ FTC Authorized Generic Drugs Report (n 15) i.

⁷⁶ FTC Pay-for-Delay Study (n 11) 1.

⁷⁷ FTC Pay-for-Delay Study (n 11) 2.

⁷⁸ Brankin (n 63) 24.

⁷⁹ FTC Authorized Generic Drugs Report (n 15) 140. The *simple compromise date* according to the FTC is when ‘the brand and generic settle the litigation simply by agreeing on a time for generic entry that is prior to patent expiration but later than immediate entry without any compensation.’ *ibid*.

drugs', while simultaneously protecting legitimate patent claims covering innovator drugs.'⁸⁰ The FTC has challenged a number of these agreements, and is lobbying for them to be recognised as illegal at the legislative level.⁸¹

2. European Commission Position

Unlike the U.S., in Europe patent settlement agreements have neither raised significant interest by the European Commission previously⁸² nor have they been the subject of consideration before the CJEU.

However, inspired by its U.S. counterpart and following the *AstraZeneca* case,⁸³ the EU Commission has launched intensive monitoring of competition in the pharmaceutical sector.⁸⁴ Its Executive Summary of the Pharmaceutical Inquiry Report emphasises '[t]he importance of a well-functioning pharmaceutical sector and the presence of certain indications that competition in the pharmaceutical market in the European Union might not be working well.'⁸⁵ The inquiry aimed '[t]o examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline in innovation as measured by the number of new medicines coming to the market.'⁸⁶ The inquiry sought inter alia to examine practices which '[c]ompanies may use to block or delay generic competition.'⁸⁷

The inquiry identifies patent settlement agreements among such practices which delay or block generic entry.⁸⁸ The European Commission sees agreements which limit market entry of the generic and include a value

⁸⁰ FTC Authorized Generic Drugs Report (n 15) 141 citing H.R. REP. NO. 98-857 (n 29).

⁸¹ Federal Trade Commission, 'Statement by FTC Chairman Jon Leibowitz Regarding Senate Judiciary Committee Mark-up of Legislation Stopping Illegal Pay-for-Delay Drug Settlements' (07/21/2011) < <http://www.ftc.gov/opa/2011/07/pdfmarkup-.shtm> > accessed 6 December 2012;

⁸² Brankin (n 63) 23.

⁸³ *AstraZeneca* (n 4), the EU General Court agreed with the Commission's findings of the *AstraZeneca*'s abuse of a dominant market position in the pharmaceutical sector via misusing the regulatory framework to delay the market entry of competing generic products.

⁸⁴ Commission Decision of 15 January 2008 initiating an enquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).

⁸⁵ Executive Summary (n 3).

⁸⁶ *ibid.*

⁸⁷ *ibid.* 'The scope of the inquiry included companies with 80% of the relevant turnover in the EU, 43 originator and 27 generic companies, limiting products to medicines for human use within the 27 member states and the time limitation was from 2000 to 2007.' *ibid.*

⁸⁸ *ibid.*

transfer from the originator company to a generic company as potentially anticompetitive.⁸⁹ The Commission also deems potentially problematic those agreements which include restrictions beyond the exclusionary zone of the patent, meaning that they reach beyond its geographic scope, its period of protection or its exclusionary scope.⁹⁰ The Commission explains that the reason for this concern regarding this type of agreements is that such agreements do not relate directly to the IP rights granted by the patents in question.⁹¹ The Commission also indicates as problematic those agreements which include settlement agreements on a patent which the patent holder knows that it does not meet the patentability criteria.⁹² For instance, a patent may be granted following the provision of incorrect, misleading or incomplete information.⁹³ Therefore, the European Commission decided to monitor further the settlements ‘with a potential to adversely affect European consumers.’⁹⁴ Currently, three Reports in the Monitoring of Patent Settlements were concluded.⁹⁵

Following its inquiry into the pharmaceutical sector and monitoring exercises, the Commission has opened formal antitrust investigations against originator and generic companies suspected of engaging in anti-competitive practices and it has examined their patent settlement agreements. The two major cases concern the brand-name companies *Lundbeck* and *Les Laboratoires Servier*.

According to the Commission press release, the Danish company *Lundbeck* and its four generic competitors were informed of the Commission’s objections regarding their settlement agreements concerning *Citalopram*, an antidepressant.⁹⁶ The Commission has expressed its preliminary view that

⁸⁹ *ibid.*

⁹⁰ 3rd Monitoring Report (n 7).

⁹¹ *ibid.*

⁹² *ibid.*

⁹³ *ibid.*

⁹⁴ Executive Summary (n 3) 20.

⁹⁵ European Commission, ‘1st Report on the Monitoring of Patent Settlements (period: mid 2008-end 2009)’ (5 July 2010) <http://ec.europa.eu/competition/sectors/-pharmaceuticals/inquiry/patent_settlements_report1.pdf> accessed 6 August 2012; European Commission, ‘2nd Report on the Monitoring of Patent Settlements (period: January-December 2010)’ (6 July 2011) <http://ec.europa.eu/competition/sectors/-pharmaceuticals/inquiry/patent_settlements_report2.pdf> accessed 6 August 2012; 3rd Monitoring Report (n 7).

⁹⁶ European Commission Press Release, ‘Antitrust: Commission sends Statement of Objections to Lundbeck and others for preventing market entry of generic antidepressant’.

these agreements aimed to prevent the market entry of cheaper generic medicines in violation of Article 101 TFEU.⁹⁷

According to the Commission, these agreements were concluded when the generic entry became possible after certain *Lundbeck's* patents had expired.⁹⁸ The agreements contain substantial value transfers from *Lundbeck* to the generic companies, and resulted in the subsequent refrain by the latter from entering the market.⁹⁹ The value transfers occurred via direct payments from *Lundbeck* to the generic companies and via the purchase of generic Citalopram stock for destruction or guaranteed profits in a distribution agreement.¹⁰⁰ The Commission considers that these agreements may have caused substantial consumer harm, as they may have delayed the entry of generic medicine for up to two years.¹⁰¹ The price of Citalopram remained high as a result.¹⁰²

Another major investigation was launched against the French pharmaceutical company *Les Laboratoires Servier*.¹⁰³ In its press release on 30 July 2012,¹⁰⁴ the Commission stated that *Servier* and its several generic competitors were informed of the Commission's objections against their patent settlement agreements and *Servier's* acquisition of key competing technologies, which may have delayed the generic entry of the cardiovascular medicine Perindopril. The Commission alleges that *Servier* unduly protected its market exclusivity by inducing its generic challengers to conclude patent settlements, which the Commission considers a violation of EU competition rules prohibiting restrictive business practices and the abuse of a dominant market position (respectively articles 101 and 102

medicine' IP/12/834 (25 July 2012) <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/834&format=HTML&aged=0&language=EN&guiLanguage=en>> accessed 6 August 2012.

⁹⁷ *ibid.*

⁹⁸ *ibid.*

⁹⁹ *ibid.*

¹⁰⁰ *ibid.*

¹⁰¹ *ibid.*

¹⁰² *ibid.*

¹⁰³ European Commission, Memo 'Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies' (July 2009) MEMO/09/322 <<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&language=en>> accessed 6 July 2012.

¹⁰⁴ European Commission Press Release, 'Antitrust: Commission sends Statement of Objections on perindopril to Servier and others' IP/12/835 (30 July 2012) <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/835&format=HTML&aged=0&language=EN&guiLanguage=en>> accessed 6 July 2012.

TFEU).¹⁰⁵ Additional pending investigations concern *Cephalon* and *Teva*¹⁰⁶ and *Johnson & Johnson* and *Novartis*¹⁰⁷ for potential violations of the EU competition rules.

V. U.S. Courts' Developments: Approaches, General Rules and Specific Examples of Reverse Payments Agreements

1. U.S. Courts' Approaches to Reverse Payment Agreements

Contrary to the firm position of the FTC regarding the anticompetitive nature of reverse payment agreements, U.S. courts are currently divided as to how to scrutinise such agreements. They were the subject of considerations in several appellate circuits, which have taken different approaches to their evaluations and have arrived at different conclusions. By examining the applied tests developed by the courts, the particular terms of the agreements and the outcome of the cases, we will determine which reverse payment agreements were deemed lawful and which were deemed anticompetitive.

1.1. 'Per Se Illegality' Approach

This approach was taken by the U.S. Court of Appeal for the Sixth Circuit in the case of 'first impression'. The case involved payment from a brand-name company to a generic company in exchange for the promise by the latter to refrain from entering the market even after the FDA's approval.¹⁰⁸ The Court explained that most restraints are evaluated using a 'rule of reason', other restraints, however, 'are deemed unlawful *per se*'¹⁰⁹ because they 'have such predictable and pernicious anticompetitive effect, and such

¹⁰⁵ *ibid.*

¹⁰⁶ European Commission Press Release, 'Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva' IP/11/511 (28 April 2011) <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/511&format=HTML&aged=1&language=EN&guiLanguage=en>> accessed 6 July 2012.

¹⁰⁷ European Commission Press Release, 'Antitrust: Commission opens proceedings against Johnson & Johnson and Novartis' IP/11/1228 (21 October 2011) <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/1228&format=HTML&aged=1&language=EN&guiLanguage=en>> accessed 6 July 2012.

¹⁰⁸ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert denied*, 125 S.Ct. 307 (2004) (*Cardizem* 6th Cir. 2003).

¹⁰⁹ *ibid* 906.

limited potential for pro-competitive benefit.’¹¹⁰ It referred to the Supreme Court, which ‘has identified certain types of restraints as subject to the *per se* rule. The classic examples are naked, horizontal restraints pertaining to prices or territories.’¹¹¹

The Court reiterated that ‘(...) the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviours as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or pro-competitive justifications in a particular case.’¹¹² Thus, applying this test, the Court rejected any arguments regarding the pro-competitive nature of the agreement and held that the agreement was ‘at its core, a horizontal agreement to eliminate competition (...)’ and ‘a classic example of a *per se* illegal restraint of trade.’¹¹³

1.2. ‘Rule of Reason’ Approach

The U.S. Court of Appeal for the Second Circuit used a different approach.¹¹⁴ In deciding on the lawfulness of the agreement, the Court applied the ‘*rule of reason*’ analysis, which involves a three-step process.¹¹⁵ ‘First, the plaintiff bears the initial burden of showing that the defendant’s conduct ‘had an *actual* adverse effect on competition as a whole in the relevant market’. If the plaintiff satisfies this burden, the burden then shifts to the defendant to offer evidence that its conduct had pro-competitive effects. If the defendant is able to offer such proof, the burden shifts back to the plaintiff who must prove that any legitimate competitive effects could have been achieved through a less restrictive alternative.’¹¹⁶

The Federal Circuit, agreeing with the Second Circuit regarding the application of this test, explained that the starting point is to define the

¹¹⁰ *ibid* 906 citing *Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5, 78 S.Ct. 514, 2 L.Ed.2d 545 (1958).

¹¹¹ *ibid* 907.

¹¹² *ibid* 909.

¹¹³ *ibid*.

¹¹⁴ *Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)* 604 F.3d 98 (2d Cir. 2010), cert.denied, 131 S.Ct. 1606 (2011) (*Cipro* 2d Cir. 2010).

¹¹⁵ *ibid*,104.

¹¹⁶ *Cipro* 2d Cir. 2010 (n 114) 104 citing *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537 (2d Cir. 1993).

relevant market and to determine whether the defendants possess market power therein.¹¹⁷

To analyse further whether there was ‘actual adverse effect on competition’, the first step of the ‘rule of reason’ test, the Second Circuit raised the question of whether reverse payments agreements ‘fall within the scope of the patent holder’s property rights, or whether such settlements are properly characterized as illegal marketing-sharing agreements.’¹¹⁸ Approaching this question, the Court referred to the Court’s previous decision in another case,¹¹⁹ stating that the right to enter into such an agreement falls within ‘the terms of the exclusionary grant conferred by the branded manufacture’s patent’.¹²⁰ It added that, unless the patent was obtained by fraud patent or an enforcement suit is objectively baseless, ‘there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.’¹²¹

The Federal Circuit, applying the same ‘*rule of reason*’ test, stated that there was no evidence that the settlement agreements created a bottleneck on challenges to the patent or otherwise restrained competition outside the ‘exclusionary zone’ of the patent.¹²² Therefore, ‘the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for [the drug] beyond that permitted by the patent.’¹²³ Since the plaintiffs had not provided the facts needed under the first step of this analysis, the Court found it unnecessary to consider the second or third step.¹²⁴

¹¹⁷ Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re Ciprofloxacin Hydrochloride Antitrust Litig.*), 544 F.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009) (*Cipro* Fed. Cir. 2008) 1332 citing *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 495-96 (2d Cir. 2004), and *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003).

¹¹⁸ *Cipro* 2d Cir. 2010 (n 114) 104.

¹¹⁹ *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 429 F.3d 370 (2d Cir. 2005), amended by, 466 F.3d 187 (2d Cir. 2006) (*Tamoxifen* 2d Cir. 2006).

¹²⁰ *Cipro* 2d Cir. 2010 (n 114) 105.

¹²¹ *Ibid* 106 citing *Tamoxifen* 2d Cir. 2006.

¹²² *Cipro* Fed. Cir. 2008 (n 117) 1332 citing *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) 540.

¹²³ *ibid.*

¹²⁴ *ibid.*

1.3. 'Scope of the Patent' Test

In deciding on the lawfulness of reverse payment agreements, the Eleventh Circuit preferred a more traditional analysis. It focused on the permissible exclusionary scope under the patent as compared to the exclusions and anticompetitive effects arising out of the agreement.¹²⁵ The court explained that 'neither the rule of reason nor the per se analysis is appropriate in this context,'¹²⁶ as these tests aim to determine whether the agreement had an anticompetitive effect on the market.¹²⁷ However, the Court indicated that 'by its nature patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present.'¹²⁸

The Court added, that 'the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.'¹²⁹ When discussing the first step of the test, the court held that an agreement cannot exclude more competition than the patent has the potential to exclude.¹³⁰ Otherwise, the patent holder 'has used the settlement to buy exclusionary rights that are not contained in the patent grant, and those additional rights are vulnerable to antitrust attack.'¹³¹ Thus, if the anticompetitive effects fall within the scope of the exclusionary potential of the patent, the parties are immune from antitrust liability.¹³² The Court stated that, under the patent, the originator company had the right to exclude the generic companies from the market¹³³ and to grant licenses.¹³⁴ Such rights existed until the patent expired, or until the generic manufacturers proved either that the patent was invalid or that their products did not infringe upon the originator's patent.¹³⁵

¹²⁵ Jacobi (n 28).

¹²⁶ *Schering Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005) (*Schering Plough* 11th Cir. 2005).

¹²⁷ *ibid.*

¹²⁸ *ibid.*

¹²⁹ *ibid* 1066.

¹³⁰ *FTC v. Watson Pharms, Inc.*, 677 F.3d 1298, 1308 (11th Cir. 2012) (*Watson Pharms*, 11th Cir. 2012).

¹³¹ *ibid.*

¹³² *ibid* 1309 citing *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004) 1311 (*Valley Drug* 11th Cir. 2003).

¹³³ *Schering Plough* 11th Cir. 2005 (n 126) 1066.

¹³⁴ *ibid* 1067.

¹³⁵ *ibid* 1066–67.

Under the second step of the test, the court analysed whether the settlement extended the originator's exclusionary rights beyond that scope. The court held that, as the settlements permitted generic companies to market their generic drugs several years before the patent's expiration, the competition was excluded for a shorter period than the patent allowed.¹³⁶ As a result, the Court determined that 'the reverse payment settlements did not impermissibly extend the originator's patent monopoly.'¹³⁷

The third step of this analysis requires findings about whether the reverse payment agreements were indeed an 'unfair method of competition.'¹³⁸ It referred to the Supreme Court, which requires that the effects be actually anticompetitive.¹³⁹ The Court defined that the patent claims covered the restraints at hand and defined this clause as an 'ancillary restraint.'¹⁴⁰ The Court decreed that, for a condition to be defined as an ancillary, 'an agreement limiting competition must be secondary and collateral to an independent and legitimate transaction.'¹⁴¹

The court stated that, under the agreement, the scope of the products subject to the specific entry date demonstrates an efficient narrowness and no other products were delayed by these ancillary restraints.¹⁴² Moreover, the agreement covered the identical reach of the patent.¹⁴³ Therefore, emphasising that the 'general policy of the law is to favour the settlement litigation',¹⁴⁴ the court concluded that the settlements 'fell well within the protection of the patent and were therefore not illegal'.¹⁴⁵

¹³⁶ *ibid* 1068.

¹³⁷ *Watson Pharms*, 11th Cir. 2012 (n 130) 1310.

¹³⁸ *Schering Plough* 11th Cir. 2005 (n 126) 1072.

¹³⁹ *ibid* citing *California Dental Association v. FTC*, 128 F.3d 720, (9th Cir. 1997) 775 n.12.

¹⁴⁰ *ibid* 1072.

¹⁴¹ *ibid* 1073 citing *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210 (D.C. Cir. 1986) 224.

¹⁴² *ibid*.

¹⁴³ *ibid*.

¹⁴⁴ *ibid* 1073 citing *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, (6th Cir. 1976) 1372.

¹⁴⁵ *ibid* 1076.

1.4. A Quick Look ‘Rule of Reason’ Analysis

The Third Circuit used this approach in its most recent decision regarding reverse payment agreements.¹⁴⁶ Notably, the agreements under review in this Court were already under consideration in the Eleventh Circuit.¹⁴⁷ Applying the scope of the patent test, the latter declared these agreements lawful and not violative of antitrust law as they did not exceed the scope of the patent.

The Third Circuit, considering the same agreements, disagreed with the Eleventh Circuit. The Court rejected the scope of the patent test and instead applied a quick look rule of reason analysis.¹⁴⁸ This analysis is based on the economic realities of the agreement in question.¹⁴⁹ Thus, the Court explained that the very existence of any payment from a brand-name company to a generic patent challenger who agrees to delay its market entry stands as *prima facie* evidence of an unreasonable restraint of trade.¹⁵⁰ One may rebut this presumption by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.¹⁵¹

1.5. Brief Conclusions on the U.S. Courts’ Tests

Despite the courts’ different approaches, namely the *per se* test, rule of reason and scope of the patent test, they ultimately arrived at the same conclusion: as long as the scope of the patent covers the agreement and this patent was not procured by fraud or the litigation is not baseless, the agreement is lawful and does not violate antitrust law.

One may well argue that this practice was almost settled until recently. However, the Third Circuit undermined the practice with its decision¹⁵² which refused to consider the reverse payment agreements from the patent/antitrust point of view and instead concentrated on the existence of the reverse payment. As a result, there currently exist two Appellate Court

¹⁴⁶ *In re K-Dur Antitrust Litig.*, 2012 WL 2877662 (3d Cir. July 16, 2012) (*In re K-Dur* 3d Cir. 2012).

¹⁴⁷ *Schering Plough* 11th Cir. 2005 (n 126).

¹⁴⁸ *ibid* 32.

¹⁴⁹ *ibid*.

¹⁵⁰ *ibid* 33.

¹⁵¹ *ibid*.

¹⁵² *In re K-Dur* 3d Cir. 2012 (n 146).

decisions – by the Third and the Eleventh Circuits – which, through different approaches, arrived at opposite conclusions regarding the same agreements.¹⁵³

Notably, the decision of the Eleventh Circuit is often cited for triggering the increased number of reverse payment agreements.¹⁵⁴ The Third Circuit's decision regarding the same agreements may well lead to a prohibition of, or limitations imposed on, reverse payment agreements. In any case the Third Circuit's decision may mark the reason for the Supreme Court to decide this issue and finally define the coherent evaluative approach.

2. General Rules Inferred From the U.S. Case Law

As was noted above, disputes regarding reverse payment agreements are comparatively a new type of disputes in the U.S., and some circuits still need to consider them at a 'first impression'. Analysing the U.S. case law reveals a divergence in the evaluation techniques applied to these agreements, and legal society thus advocates for the harmonising the case law by implementing a coherent approach for treating and deciding on such disputes,¹⁵⁵ as some fear that these divergences may lead to opposite decisions regarding the same kind of agreements.¹⁵⁶ There are indications, however, that despite the above factors courts in general consistently segregate the specific types of reverse payment agreements. This practice derives from common rules from the previous antitrust and patent case law, and from new rules emerging from the recent case law on pay-for-delay agreements.¹⁵⁷

Analysing the courts' decisions infers the following general rules, which the courts explicitly or implicitly accept and which relate to the disputes regarding reverse payment agreements.

¹⁵³ *In re K-Dur* 3d Cir. 2012 (n 146) and *Schering Plough* 11th Cir. 2005 (n 146).

¹⁵⁴ Jon Leibowitz, Comm'r, FTC, 'Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!', Address at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust 8 (April 24, 2006) 3 <<http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>> accessed 7 August 2012; see also FTC Pay-for-Delay Study (n 11) 1.

¹⁵⁵ Yvon (n 43)1908, 1912.

¹⁵⁶ This was already proved by the recent decision of the Third Circuit. See *In re K-Dur* 3d Cir. 2012 (n 146).

¹⁵⁷ The exception to this generalisation is the Third Circuit's recent decision. See *In re K-Dur* 3d Cir. 2012 (n 146).

2.1. Presumption of Patent Validity

Some argue that reverse payment settlements fall within the exclusionary scope of the patents in question, provided those patents are valid.¹⁵⁸ Thus, in considering this type of disputes, the courts generally refer to the presumption of patent validity established in the law.¹⁵⁹ Based on this presumption, courts consider the issue of the reverse payment agreements' compatibility with the competition rules without prior revision of patent validity.

However, some authors question this legal presumption.¹⁶⁰ What if the patent is weak or obviously invalid? The proper challenge would result in the revocation or invalidity of the patent.¹⁶¹ Concluding the settlement in such a case could prevent such outcomes and thus unduly extend the period of protection enjoyed by the patent holder.¹⁶² As the Second Circuit acknowledged:

If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity.¹⁶³

Some argue that, if any of the presumptions regarding the patent validity fall, the agreement undoubtedly marks an unlawful restraint of trade.¹⁶⁴ Therefore, the question is whether the courts should consider patent validity as part of their analyses of these disputes.¹⁶⁵ Answering this question, the Federal Circuit agreeing with the Second and Eleventh Circuits stated that,

¹⁵⁸ Jacobi (n 28) 4.

¹⁵⁹ 35 U.S.C. § 282

¹⁶⁰ Markus Schmid, 'Pharmaceutical reverse payment settlements – a European perspective in the wake of the sector inquiry' [2012] E.C.L.R. 367, 373; Gregory Dolin, 'Reverse Settlements as Patent Invalidation Signals' (2011) 24 Harvard Journal of Law & Technology 281, 318; see also Anderman (n 2) 172, Jacobi (n 28) 4.

¹⁶¹ Anderman (n 2) 272.

¹⁶² *ibid.*

¹⁶³ *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 429 F.3d 370 (2d Cir. 2005), amended by, 466 F.3d 187 (2d Cir. 2006) (*Tamoxifen* 2d Cir. 2005) 211 citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) 534.

¹⁶⁴ Markus (n 160) 373, Jacobi (n 28) 4.

¹⁶⁵ Jacobi (n 28) 4.

if there is no evidence that a patent was procured by fraud or that litigation is sham, there is no need to consider patent validity in this type of dispute.¹⁶⁶

Although this presumption of patent validity is generally considered irrefutable, the Third Circuit questioned it in its recent decision. The Court stated that, rather than adopting such a presumption, it should be taken into account that ‘a patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office.’¹⁶⁷ The Court concluded that ‘the public interest supports judicial testing and elimination of weak patents.’¹⁶⁸

The Court determined that, with respect to reverse payments agreements, such logic is persuasive: as they ‘permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid’.¹⁶⁹ The Court explained that the goal of Hatch-Waxman Act is ‘to increase the availability of low cost drugs’.¹⁷⁰ Thus, in aiming to achieve this goal, it allows for the generic companies to challenge the brand-name companies’ weak or narrow patents.¹⁷¹

2.2. The Scope of the Patent

Most of the courts have accepted that, as long as agreement falls within the scope of patent protection, it should be deemed lawful and consistent with the competition law.¹⁷² Analysing the reverse payment settlement agreement, the Second Circuit admitted that the agreement in question was doubtless anticompetitive,¹⁷³ as it limited competition between a branded product and its generic version.¹⁷⁴ However, since it did not exceed the scope of the patent, it was not an unlawful anticompetitive agreement.¹⁷⁵

In this respect, it is important to define the scope of the patent, which is seen to include the claims covered by the patent, term of protection and

¹⁶⁶ *Cipro* Fed. Cir. 2008 (n 122) 1336.

¹⁶⁷ *In re K-Dur* 3d Cir. 2012 (n 146) 27 citing *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969) 670.

¹⁶⁸ *ibid* 29.

¹⁶⁹ *ibid* 30.

¹⁷⁰ *ibid* 31 citing H.R. REP. NO. 98-857 (n 29).

¹⁷¹ *ibid* 31.

¹⁷² The Third Circuit in its recent decision has rejected this approach. *ibid* 32.

¹⁷³ *Tamoxifen* 2d Cir. 2006 (n 119) 218.

¹⁷⁴ *ibid*.

¹⁷⁵ *ibid*.

geographical area.¹⁷⁶ The patent confers the right to exclude others from profiting from the patented invention.¹⁷⁷ Patents do not, however, extend the patentee's monopoly beyond its statutory right to exclude.¹⁷⁸ The Second Circuit held that the settlement agreement did not exceed the scope of the patent where: (1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; (3) the agreement did not bar other generic manufacturers from challenging the patent.¹⁷⁹

One example of exceeding the scope of the patent is when a generic company agrees to refrain from ever marketing a generic version of a patented drug.¹⁸⁰ This means that settlement agreement will block generic competition after the patent expiration, and thus will exclude competition beyond the scope of exclusion granted by the patent.¹⁸¹ Another example is when a settlement agreement allows a generic company to retain its 180-day exclusivity period even though it has no intention to market its generic drug.¹⁸² This stipulation means that the exclusivity period, which begins after the date of first commercial marketing, would never be triggered.¹⁸³ As a result, 'the exclusivity period would have acted like a cork in a bottle, blocking other generic competition from pouring into the market.'¹⁸⁴ Thus the agreement creates anticompetitive effects beyond the scope of the patent.¹⁸⁵

However, the Third Circuit did not find the scope of the patent approach persuasive.¹⁸⁶ Declining to follow it, the Court explained that it 'improperly restricts the application of antitrust law and is contrary to the policies

¹⁷⁶ 3rd Monitoring Report (n 7).

¹⁷⁷ *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

¹⁷⁸ *Mallinckrodt, Inc. v. Medipart, Inc.* 976 F.2d 700, 708 (Fed. Cir. 1992).

¹⁷⁹ *Cipro* 2d Cir. 2010 (n 114) 106 citing *Tamoxifen* 2d Cir. 2005 (n 119) 213-15.

¹⁸⁰ *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005) (*Andrx Pharmaceuticals* 11th Cir. 2005).

¹⁸¹ *Watson Pharms*, 11th Cir. 2012 (n 130) 1311 citing *Andrx Pharmaceuticals* 11th Cir. 2005, 1231 (internal citation omitted).

¹⁸² *ibid* citing *Andrx Pharmaceuticals* 11th Cir. 2005, 1231 (internal citation omitted).

¹⁸³ *ibid* citing *Andrx Pharmaceuticals* 11th Cir. 2005, 1231 (internal citation omitted).

¹⁸⁴ *ibid*.

¹⁸⁵ *ibid* citing *Andrx Pharmaceuticals* 11th Cir. 2005, 1235 (internal citation omitted).

¹⁸⁶ *In re K-Dur* 3d Cir. 2012 (n 146) 22.

underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.¹⁸⁷

2.3. Sham Litigation or Fraud in Obtaining a Patent

The Federal Circuit stated that ‘an antitrust violation could be found in the extreme situation where there was evidence of fraud on the PTO or sham litigation.’¹⁸⁸ Facing antitrust liability, a defendant may invoke the immunity under the Noerr-Pennington doctrine, which ‘allows private citizens to exercise their First Amendment rights to petition the government without fear of antitrust liability.’¹⁸⁹ However, ‘sham’ conduct falls within exceptions to the doctrine.¹⁹⁰ As the Second Circuit stated, ‘the doctrine does not extend protection to the defendants ‘where the alleged conspiracy is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor’.¹⁹¹

The situations in which the sham exception applies are defined as follows: first, where the lawsuit is objectively baseless and the defendant’s motive in bringing it was unlawful; second, where the conduct involves a series of lawsuits brought pursuant to a policy of starting legal proceedings without regard to the merits and for an unlawful purpose; third, if the allegedly unlawful conduct consists of making intentional misrepresentations to the court, litigation can be deemed a sham if a party’s knowing fraud upon, or its intentional misrepresentations to, the court deprives the litigation of its legitimacy.¹⁹² The third situation may be directed to not only a court but also the federal Patent and Trademark Office.¹⁹³ The patent obtained by fraud grants unlawful monopoly to the patent holder and thereby violates antitrust law.

¹⁸⁷ *ibid* 27.

¹⁸⁸ *Cipro* Fed. Cir. 2008 (n 117) 1335 citing *Valley Drug* 11th Cir. 2003 (n 132) 1309.

¹⁸⁹ *Kaiser Foundation Health Plan, Inc. v. Abbott Laboratories, Inc.*, 552 F.3d 1033 (9th Cir. 2009), 1044 (*Terazosin* 9th Cir. 2009) citing *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

¹⁹⁰ *ibid* 1045.

¹⁹¹ *Tamoxifen* 2d Cir. 2006 (n 119) 217 citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972) (quoting *Noerr*, 365 U.S. at 144).

¹⁹² *Terazosin* 9th Cir. 2009 (n 189) 1045 citing *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991).

¹⁹³ *Terazosin* 9th Cir. 2009 (n 189) 1045 citing *Sosa v. DIRECTV, Inc.*, 437 F.3d 923, 938 (9th Cir. 2006).

2.4. The Agreement Must Settle the Dispute Finally

The settlement must fully resolve litigation between the generic company and the originator company to enable the other generic manufacturers to enter the market. Interim settlements which aim to withdraw generic entry whilst the litigation is pending are viewed as unlawful.¹⁹⁴ The Second Circuit stated that ‘rather than resolve the litigation, the settlements in those cases prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly.’¹⁹⁵ The alleged purpose of this kind of agreement is to create a bottleneck: delaying the triggering of the 180-day exclusivity period in turn delays the entry of both the first filer and any other potential generic company.¹⁹⁶

2.5. Likelihood to Prevail in the Dispute

Although courts have rejected the ‘*likelihood to prevail in the dispute*’ approach, it is one worth noting as the FTC firmly stands by this position. In one case involving the invalidation of the patent after the settlement agreement, the Eleventh Circuit held that in case the decision about the patent invalidity was held after the settlement agreement this decision should not be taken into account.¹⁹⁷ All that matters is the patent’s ‘potential exclusionary power as it appeared at the time of settlement.’¹⁹⁸

The FTC has developed a ‘not likely to prevail’ test, arguing that ‘a patent has no exclusionary potential if its holder was not likely to win the underlying infringement suit.’¹⁹⁹ It also argues that ‘if the patent has no exclusionary potential then any reverse payment settlement that excludes any competition from the market necessarily exceeds the potential exclusionary scope of the patent and must be seen as the patent holder’s illegal ‘buying off’ of a serious threat to competition.’²⁰⁰ The FTC advocates adopting a rule according to which ‘an exclusion payment is unlawful if, viewing the situation objectively as of the time of the

¹⁹⁴ *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002) (*Andrx* D.C. Cir. 2001).

¹⁹⁵ *Tamoxifen* 2d Cir. 2006 (n 119) 215.

¹⁹⁶ *In re K-Dur* 3d Cir. 2012 (n 146) 20 citing *Andrx* D.C. Cir. 2001, 804.

¹⁹⁷ *Watson Pharms*, 11th Cir. 2012 (n 130) 1308.

¹⁹⁸ *ibid* citing *Valley Drug* 11th Cir. 2003 (n 132) 1311.

¹⁹⁹ *ibid*, 1312.

²⁰⁰ *ibid*.

settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.²⁰¹

The Eleventh Circuit rejected this proposed test firmly, holding that:

Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not only for the side that is likely to lose but also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.²⁰²

3. Examples of Reverse Payment Agreements as Decided by U.S. Courts

The following are examples of terms and conditions of the reverse payment agreements which violate antitrust law, as decided by U.S. courts:

3.1. Examples of Unlawful Reverse Payment Agreements

(a) Agreement Recognised As Per Se Illegal

Agreement contained payments from the originator company to the generic company beginning on the date of FDA approval obtained by the generic company and ending on the date when the generic company started selling its generic version of the patented drug or when the court considering the patent infringement dispute recognised the infringement. In return, the generic company promised not to market its generic version of a patented drug even after the FDA approval. The agreement included generics which did not infringe the patent and promise by the generic company not to relinquish the 180-day period of market exclusivity.²⁰³

The Sixth Circuit held that such restrictions on market entry coupled with payments, non-infringing product and abuse of the 180-day market exclusivity precluding subsequent generic companies from entering the

²⁰¹ *ibid.*

²⁰² *ibid* 1313.

²⁰³ *Cardizem* 6th Cir. 2003 (n 108).

market are per se unlawful and violate antitrust law. Therefore, the court recognised this agreement ‘at its core, a horizontal agreement to eliminate competition in the market for a [patented drug] (...) a classic example of a per se illegal restraint of trade.’²⁰⁴

(b) Agreement Recognised As Illegal under the ‘Scope of the Patent’ Test

Agreement contained recognition of the patent infringement by the generic company and promise to refrain from ever entering the market with its generic version of the drug in exchange for a license from brand-name company to manufacture a generic controlled version of the drug.²⁰⁵

The Eleventh Circuit held that the promise to refrain from ever marketing a generic version of patented drug would block generic competition after the patent expired, and thus excluded competition beyond the scope of exclusion granted by the relevant patent.²⁰⁶ The agreement also allowed the generic company to retain its 180-day exclusivity period even though that company had no intention to market its generic drug.²⁰⁷ This agreement would have acted ‘like a cork in a bottle, blocking other generic competition’. Therefore, the Court determined that the settlement yielded anticompetitive effects beyond the scope of the patent and was unlawful.²⁰⁸

(c) Common Features of Agreements Which Were Held Unlawful

When evaluating the provisions of the above reverse payment agreements, the courts used different tests for their evaluations, yet the outcome was the same: these agreements were held unlawful. Comparing the provisions of these two agreements indicates that they have a common feature: their provisions, such as non-infringing product, refraining from ever marketing generic version and abuse of market exclusivity, go beyond the scope of the patent protection. Therefore, despite applying different tests, the courts reached the same conclusion that these agreements violate antitrust law.

3.2. Examples of Lawful Reverse Payment Agreements

The following reverse payment agreements were found lawful:

²⁰⁴ *ibid* 908.

²⁰⁵ *Andrx Pharmaceuticals* 11th Cir. 2005 (n 180).

²⁰⁶ *Watson Pharms*, 11th Cir. 2012 (n 130) 1311.

²⁰⁷ *ibid* citing *Andrx Pharmaceuticals* 11th Cir. 2005 (n 180) 1231.

²⁰⁸ *ibid* 1311.

(a) *Agreement Held Lawful Under the ‘Rule of Reason’ Approach*

According to the agreement, the originator company agreed to pay a lump sum immediately and make quarterly payments for the duration of the patent, except for the last six months before the patent’s expiration. The originator also agreed to provide the generic manufacturers a guaranteed licence to sell brand-name drug at a reduced rate for the six months before the patent’s expiration. In exchange, generic company recognised the patent validity and agreed not to market its generic version of a drug before the patent’s expiration.²⁰⁹

The Second Circuit found that the agreement is lawful as it falls within the scope of the patent.²¹⁰

(b) *Agreement Held As Lawful under the ‘Scope of the Patent’ Test*

Generic companies agreed not to market generic versions of a drug until five years before patent expiration unless another manufacturer launched its generic drug beforehand. They also agreed to promote branded drug to doctors and to serve as a backup manufacturer for branded drug. Originator company, in return, agreed to make yearly payments and additional annual payments for the backup manufacturing assistance.²¹¹

The court agreed with the district court that the agreement did not exceed the scope of the patent.²¹²

(c) *Common Features of the Agreements That Were Held Lawful*

Notably, these agreements contain restrictions on both generic market entry and value transfer from the originator company to the generic company. They also were evaluated under different approaches. Nevertheless, courts declared them lawful because they fell within the scope of the patent.

As stated by the Federal Circuit: ‘wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive

²⁰⁹ *Cipro* 2d Cir. 2010 (n 114).

²¹⁰ *ibid*, 103, 110.

²¹¹ *Watson Pharms*, 11th Cir. 2012 (n 130).

²¹² *ibid*, 1306, 1315.

effects, or under patent law by analysing the right to exclude afforded by the patent.²¹³

3.3. Conflicting Decisions of the Eleventh and the Third Circuits

Currently, there exist two conflicting decisions regarding the same agreement. The reverse payment agreements decided by both Circuits restricted the generic entry date to one earlier than patent expiration, the licence from the generic company to the originator company and payments from the originator company to the generic company which included legal fees and royalty for the licence.²¹⁴

On 8 March 2005 the Eleventh Circuit considering the dispute held this agreement lawful as it fell within the scope of patent protection.²¹⁵ It took into account that the settlement excluded competition for a shorter period before the patent expiration.²¹⁶ It also held that payments from originator to generic company were a ‘fair price’ for the product under the licence granted by the generic company to originator, and therefore the aim of these payments was not to delay the market entry.²¹⁷ Therefore, the Court rejected ‘a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic’s entry date, and, in an ancillary transaction, pays for other products licences by the generic’.²¹⁸

On 16 July 2012, the Third Circuit considering the same agreements disagreed with the Eleventh Circuit and rejected the scope of the patent test. Instead, the court applied a quick look rule of reason analysis. It declared that any payment from patent holder to a generic company which promises to refrain from entering the market should be treated as *prima facie* evidence of unreasonable restraint of trade, unless it is proved that the payment did not seek to delay the generic market entry or offers a pro-competitive effect.²¹⁹

²¹³ *Cipro* Fed. Cir. 2008 (n 117) 1336.

²¹⁴ *Schering Plough* 11th Cir. 2005 (n 126), *In re K-Dur* 3d Cir. 2012 (n 146)

²¹⁵ *ibid*, 1076.

²¹⁶ *ibid*, 1068.

²¹⁷ *ibid*, 1071.

²¹⁸ *ibid*, 1076.

²¹⁹ *In re K-Dur* 3d Cir. 2012 (n 146), 33. See analysis to n 146-151.

As stated above, these two decisions sharply divided the circuits that prior to the latter decision despite the diverse approaches applied to the reverse payment agreements had ultimately arrived at a similar conclusions. Considering the importance of the issue, which concerns both public and private interests and which may distort the fragile balance between intellectual property protection and competition rules, this disagreement between circuits must be resolved. It is up to the Supreme Court or the legislative authorities to upend this discrepancy in the case law and to settle the coherent practice within the U.S. courts.

VI. EU Developments: Approaches and General Rules in Disputes Regarding Patent Settlement Agreements

Although the EU lacks relevant case law regarding reverse payment agreements, it may prove helpful to explore the evolving pattern in the U.S. jurisprudence and modify it for the EU, and to infer approaches and general principles from the previous EU case law which might apply to reverse payment agreements.

1. Incorporating the U.S. Approaches and Tests for Reverse Payment Agreements into the European Legal Framework

It is generally viewed that the EU competition authorities' position would likely follow the U.S. courts' approaches to assessing reverse payment agreements based on the exclusionary scope of a patent.²²⁰ In this respect, and considering the lack of relevant case law in the EU, it is interesting to analyse whether European courts may use the US courts' current approaches and tests in disputes regarding reverse payment agreements. To understand whether the U.S. judicial approaches would suit the European competition environment, one must grasp the peculiarities of the European competition legal framework compared to that of the U.S. At the very basic level, the difference between these regimes is that the EU promotes a single market under the main principle of free movement of goods among its Member States, which does not occur in U.S. competition law.

Section 1 of the Sherman Act and its sister provision (albeit not identical) article 101 (1) TFEU aim to tackle practices which restrict competition in

²²⁰ William H. Rooney and Elai Katz, 'Review of Reverse-Payment Agreements: The Agencies, the Courts, Congress, and the European Commission' (2009) 5 *Competition Policy International* 120, 136.

these two regimes.²²¹ However, as discussed above, article 101 goes further and offers in its paragraph 3 exceptions to the prohibitions set forth in paragraph 1. Therefore, the EU analysis of possible anticompetitive effect found within the scope of paragraph 1 will ultimately evaluate whether the agreement may be exempt under paragraph 3. These particularities cause certain difficulties in applying the U.S. tests and approaches to the EU realia.

Moreover, as there are no provisions in the EU equivalent to the Hatch-Waxman Act which provides an exclusivity period to the first to file generic company, a reverse payment in the EU would only delay entry of the generic company which is a party to the agreement and would not delay generic entry in the market to any other generic company.²²² Therefore, it may be argued, that the potential effects of a reverse payment are likely to be less restrictive of competition in the EU than in the U.S.

In further discussing possible applications of the U.S. approaches and tests analysed in section 4 of this article, the following will suggest relevant modifications subject to the EU law peculiarities in general, and to the specific nature of reverse payments agreements in particular.

1.1. Modified *Per Se* Test

As shown above,²²³ the U.S. case law addresses certain types of trade practices which are considered plainly anticompetitive.²²⁴ These practices include agreements which fix purchase or selling prices, share markets or limit production.²²⁵ It was recognised that, where the agreement is plainly anticompetitive, the *per se* approach will be used. It was explained that the chances that these practices will not prove anti-competitive are so limited that, for reasons of judicial economy and certainty of law, they should be

²²¹ Pietro Manzini, 'The European rule of reason-crossing the sea of doubt' (2002) 23(8) European Competition Law Review 392, 384.

²²² Gavin Robert and Fabio Falconi, 'Patent litigation settlement agreements in the pharmaceutical industry: marrying the innovation bride and competition groom' (2006) 27(9) European Competition Law Review 524, 532.

²²³ See section 4.

²²⁴ See text to n 108-113.

²²⁵ *Cardizem* 6th Cir. 2003 (n108) 907 citing *National College Athletic Ass'n v. Board of Regents*, 468 U.S. 85, 100 (1984), Manzini (n 221) 394.

considered prohibited *ex ante*, without having to evaluate their actual competitive value.²²⁶

The General Court²²⁷ acknowledged such an approach in the *European Night Services & Co. v. Commission*, which stated that:

in assessing an agreement under Article [101] (1) of the Treaty, account should be taken of the actual conditions in which it functions (...) unless it is an agreement containing obvious restrictions of competition such as price-fixing, market-sharing or the control of outlets.²²⁸

However, article 101 TFEU excludes the possibility of such *ex ante* analysis.²²⁹ Paragraph 3 states that ‘any’ practice restricting competition and prohibited under paragraph 1 may be exempt from the prohibition if it satisfies all conditions set forth in paragraph 3.²³⁰

In the *Matra Hachette v. Commission* the General Court stated that:

in principle, no anti-competitive practice can exist which, whatever the extent of its effects on a given market, cannot be exempted, provided that all the conditions laid down in Article [101](3) of the Treaty are satisfied.²³¹

Thus, contrary to the U.S. legal doctrine, the EU legal framework requests an evaluation of the pro and anti-competitive effects of practices, not immediately under article 101 (1) TFEU, but further under article 101 (3) TFEU.²³²

1.2. Modified ‘Rule of Reason’ Test

The rule of reason doctrine has evolved in the U.S. jurisprudence and evaluates the pro- and anti-competitive aspects of a given agreement.²³³ As

²²⁶ *Cardizem* 6th Cir. 2003 (n 108) 907, Manzini (n 221) 392.

²²⁷ The then Court of First Instance.

²²⁸ Cases T-374/94, T-375/94, T-384/94 and T-388/94, *ENS & Co v. Commission*, [1998] E.C.R. II-3141, para 136.

²²⁹ Manzini (n 221) 398.

²³⁰ Manzini (n 221) 398.

²³¹ Case T-17/93, *Matra Hachette v. Commission* [1994] E.C.R. II-595, para. 85.

²³² Manzini (n 221) 398.

²³³ *ibid* 393.

the Supreme Court has stated, there are certain types of ‘agreements whose anti-competitive effect can only be evaluated by analysing the facts peculiar to the business, the history of the restraint and the reason why it was imposed’.²³⁴ Before 2001, there was no defined position of whether the rule of reason exists in the EU competition law.²³⁵ Some suggestions for implementing this test date back to the late-1960s.²³⁶ However, despite this doctrinal support, the CJEU was not convinced of the possibility to apply the rule of reason under article 101 (1) TFEU.²³⁷

The *Métropole Télévision* decision resolved all doubts regarding the rule of reason test.²³⁸ In this case, the applicants argued that the Commission should have applied the then equivalent of article 101 (1) TFEU in light of a rule of reason, under which an anti-competitive practice falls outside the scope of its prohibition if it has more positive than negative effect on competition in a given market.²³⁹ However, the General Court held that such an interpretation of article 101 (1) TFEU was difficult to reconcile with the rules prescribed by that provision.²⁴⁰ Firmly rejecting this suggestion, the Court held that article [101 (3) TFEU] expressly allows for the possibility of exempting agreements which restrict competition if they fulfil the conditions prescribed by this paragraph.²⁴¹ The Court emphasised that, only within this provision, one could apply the pro- and anti-competitive analysis of a restriction. It added that:

Article [101 (3) TFEU] would lose much of its effectiveness if such an examination had to be carried out already under article [101 (1) TFEU].²⁴²

Thus, this decision implies that one cannot incorporate the rule of reason in its initial form from the U.S. case law into article 101 (1) TFEU. Rather, the

²³⁴ *National Society of Professional Engineers v. U.S.* 435 U.S. 679 (1978).

²³⁵ Manzini (n 221) 396.

²³⁶ *ibid* 394, referencing to René Joliet, *The Rule of Reason in Antitrust Law, American, German and Common Market Law in Comparative Perspective*, (1967) Le Haye.

²³⁷ Manzini (n 221) 395, Cases C-56 and 58/64 *Consten-Grundig v. Commission* [1966] E.C.R. 341; [1966] *Common Market Law Review* 48.

²³⁸ Manzini (n 221) 398. Case T-112/99 *Métropole Télévision (M6) & Co v. Commission* [2001] E.C.R. 2001.

²³⁹ *Métropole Télévision* (n 238), para 68.

²⁴⁰ *ibid*, para 73.

²⁴¹ *ibid*, para 74.

²⁴² *ibid*.

balance of pro- and anti-competitive effects must be drawn on the basis of Article 101(1) in conjunction with article 101(3) TFEU.²⁴³

1.3. Ancillary Restraints Doctrine in European Case Law

Ancillary restraints are restraints which are needed to conclude a lawful contract, and their importance is subordinate to the latter.²⁴⁴ The CJEU stipulated that the ancillary restraints to competition which are necessary to conduct a lawful practice do not fall within the scope of Article 101(1) TFEU.²⁴⁵ Thus, in the *Remia v. Commission* case, the Court recognised that such restraints were necessary for the non-competition agreements included in sale of business contracts which ‘have the merit of ensuring that the transfer has the effect intended’,²⁴⁶ as long as their duration and scope are strictly limited to this purpose.²⁴⁷

In *Métropole Télévision*, the General Court had discussed the ancillary restraints doctrine when considering the applicant’s claim that the exclusivity clause and the clause relating to the special-interest channels were ancillary to their joint venture. The applicant argued that, since the Commission had found that the joint venture did not infringe article 101(1) TFEU, the ancillary clauses should also have been cleared.²⁴⁸

In its findings, the General Court stated that ‘the concept of an “ancillary restriction” covers any restriction which is directly related and necessary to the implementation of a main operation.’²⁴⁹ The Court held that ‘a restriction “directly related” to implementation of a main operation must be understood to be any restriction which is subordinate to the implementation of that operation and which has an evident link with it’.²⁵⁰ The Court defined two conditions for satisfying the necessity test: it must establish,

²⁴³ Manzini (n 221) 398.

²⁴⁴ *ibid* 399.

²⁴⁵ Case C-42/84, *Remia v. Commission* [1985] E.C.R. 2545; [1987] 1 Common Market Law Review 1; Case C-161/84, *Pronuptia de Paris* [1986] E.C.R. 353 [1986] 1 Common Market Law Review 414; Case C-250/92, *Goettrup-Klim & Co.* [1994] E.C.R. I-5641 [1996] 4 Common Market Law Review 191, see also Manzini (n 221) 397.

²⁴⁶ *Remia v. Commission* (n 245), para. 19.

²⁴⁷ *ibid*, para. 20

²⁴⁸ *Métropole Télévision* (n 238), para 80-91, See also Alison Jones and Brenda Sufrin, *EU Competition Law; Text, Cases and Materials* (4th edn, Oxford University Press 2011) 231.

²⁴⁹ *Métropole Télévision* (n 238), para 104.

²⁵⁰ *ibid*, para 105.

first, whether the restriction is objectively necessary to implement the main operation and, second, whether the restriction is proportional to it.²⁵¹

For the finding of the objective necessity, the court determined that ‘[i]f, without the restriction, the main operation is difficult or even impossible to implement, the restriction may be regarded as objectively necessary for its implementation.’²⁵² The Court referred to the Commission’s findings that a number of restrictions were objectively needed to implement certain operations if, failing such restrictions, the operation in question ‘could not be implemented or could only be implemented under more uncertain conditions, at substantially higher cost, over an appreciably longer period or with considerably less probability of success’.²⁵³ When the restriction was found objectively necessary to implement a main operation, ‘it is still necessary to verify whether its duration and its material and geographic scope do not exceed what is necessary to implement that operation.’²⁵⁴ The Court explained that ‘[i]f the duration or the scope of the restriction exceed what is necessary in order to implement the operation, it must be assessed separately under article [101(3) TFEU].’²⁵⁵

If the direct relation and the necessity conditions to achieve a main operation are established, one may examine the compatibility of that restriction with the competition rules together with that of the main operation.²⁵⁶ Therefore, if the main operation is found not to infringe article 101(1) TFEU, the same result must be found for the restrictions directly related to and necessary for that operation.²⁵⁷ Alternately, if the main operation found to infringe article 101 (1) TFEU may be exempted under article 101(3) TFEU as it satisfies its conditions, the exemption also extends to the ancillary restrictions.²⁵⁸

²⁵¹ *ibid.*, para 106.

²⁵² *ibid.*, para 109.

²⁵³ *ibid.*, para 111.

²⁵⁴ *ibid.*, para 113.

²⁵⁵ *ibid.*

²⁵⁶ *ibid.*, para 115.

²⁵⁷ *ibid.*, para 116.

²⁵⁸ *ibid.*

1.4. Possible Way to Assess the Reverse Payment Agreements under EU Competition Law

Applying the aforementioned approaches of the EU case law, one may suggest the following assessment of reverse payments agreements. Article 101(1) TFEU defines that an agreement falls within its prohibition when it has as its object or effect the prevention, restriction or distortion of competition. One may argue that the main purpose of the reverse payment agreements is to settle a patent dispute, thus ending the high-cost litigation which would last a considerable period. Settling the dispute therefore marks a main operation. The European Commission in its Guidelines has acknowledged in terms of the ‘non-challenge clauses’ that ‘the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes’.²⁵⁹ Therefore, it is possible to conclude that such an agreement falls outside the scope of article 101 (1) TFEU.

The provisions of the settlement agreement which limit generic competition (such as licence agreement) and contain the value transfer from the originator company to the generic company may be deemed ancillary restraints to the main operation. To conclude that limitation on generic competition and reverse payment are ancillary restraints, parties must prove that such restraints are directly related and necessary to implementing the main agreement, namely settling the dispute.

The restraints relate directly to the main transaction if they are subordinate to the implementation of that transaction.²⁶⁰ As defined above, the settlement of the patent dispute is the main transaction. Thus, all provisions in the settlement which aim to resolve the dispute among the parties may be deemed subordinate, and thereby directly related, to implementing the transaction. Such settlement may include restrictions on the generic competition and certain value transfer from one party to another.

The necessity test is satisfied if it establishes the following two conditions: (a) it is objectively necessary for the implementing the main operation; (b) it is proportional to the main operation.²⁶¹

²⁵⁹Technology Transfer Guidelines (n 70), para 209.

²⁶⁰ European Commission, ‘Communication from the Commission Notice Guidelines on the application of the Article 81 (3) of the Treaty’ OJ [2004] 101/08, para 29.

²⁶¹*Métropole Télévision* (n 238) para 106.

Regarding the objective necessity, one may argue that, failing such restrictions, the parties would not agree to settle the dispute. For settlements to succeed, the generic company must acknowledge patent validity and promise not to infringe it in the future, that is not to enter the market whilst it is pending. Likewise, signing the licencing agreement could prove objectively necessary, as continuing litigation would lead to uncertain outcome 'at substantially higher cost, over an appreciably longer period or with considerably less probability of success.'²⁶² Regarding proportionality, here one may incorporate the theory of the scope of the patent. If such limitations fall within the scope of the patent (ie concern the product covered by the patent, within its term of protection and geographical area), the restrictions may be considered proportionate.

Thus, when such limitations on generic competition and reverse payment are found to be ancillary restraints, they must be further evaluated together with the main agreement. Therefore, as the settlement agreements fall outside Article 101 (1) TFEU so do the said ancillary restraints.

2. General Rules Inferred from the EU Case Law

Deciding on the patent settlement agreements, specifically in the form of licence agreements, the CJEU adhered to the following principles.

2.1. The Scope of Intellectual Property Rights

In its 3rd Report on the Monitoring of Patent Settlements, the Commission defined as potentially troublesome patent settlement agreements those with restrictions beyond the exclusionary zone of the patent, as they would not appear directly related to the intellectual property rights granted by the patents in question.²⁶³ According to the Commission, this position means that they would reach beyond its geographic scope, its period of protection or its exclusionary scope.²⁶⁴

The CJEU jurisprudence may support such a position. In one of its decisions relating to the licence agreement, the CJEU stated that the clauses contained in the licencing agreements, in so far as they relate to parts of the invention not covered by the patent, may find no justification on grounds of protecting

²⁶² *ibid*, para 111.

²⁶³ 3rd Monitoring Report (n 7) 2.

²⁶⁴ *ibid*.

an industrial property right.²⁶⁵ Deciding further on the compatibility of the above clause, the Court concluded that it cannot accept that the obligation of the licensee only to sell the patented product in conjunction with a product outside the scope of the patent is indispensable to exploiting the patent.²⁶⁶

The Court took the same position regarding the provisions which try to gain the protection granted by the patent in a country which lacks patent protection.²⁶⁷ The Court stated that it ‘limited freedom of competition by means of a clause which had nothing to do with the patent.’²⁶⁸ Moreover, in one of its decisions, the CJEU declared that the other party’s abandoning of its right to advertise its product in the settlement agreement ‘does not bear even the semblance of a connection with the question of the use of the [right concerned]’.²⁶⁹

Applying this case law to the reverse payment agreements, one may conclude that, in cases where the agreements contain provisions which include products not covered by the patent, extend to the territory beyond that defined in the patent or contain obligations of the party which have no connection to the patent, such agreement will go beyond the scope of the patent and thus will likely trigger competition concerns.

2.2. ‘No-Challenge’ Clause

In its Technology Transfer Guidelines, the European Commission acknowledges the ‘no-challenge’ clause in the settlement agreement. It states 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.²⁷⁰

²⁶⁵ Case 193/83 *Windsurfing International Inc v Commission* [1986] ECR 611, para 36.

²⁶⁶ *ibid* para 57.

²⁶⁷ *ibid*, para 85.

²⁶⁸ *ibid*.

²⁶⁹ Case 35/83 *BAT Cigaretten-Fabriken GmbH v Commission* [1985] ECR 363, para 34.

²⁷⁰ Technology Transfer Guidelines (n 70), para 209.

Thus, the Guidelines generally consider non-challenge clauses to fall outside Article 101 (1) TFEU.²⁷¹

However, this position of the European Commission does not align with the previous CJEU case law.²⁷² The Court considers such clauses to fall outside ‘the specific subject matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent’s validity’.²⁷³ The Court emphasised: ‘it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error’.²⁷⁴ Thus, such provisions were held as ‘an unlawful restriction on competition’.²⁷⁵

2.3. ‘Sham’ Conduct

As stated above, licence agreements which settle a dispute are generally accepted.²⁷⁶ However, this tendency may be true only in case of a genuine dispute about a valid right.²⁷⁷ When ‘the dispute is sham, or if the right is itself invalid any “settlement” agreement involving restrictions of competition’²⁷⁸ will fall under Article 101 (1) TFEU.²⁷⁹

In *BAT Cigaretten-Fabriken GmbH v Commission*, the CJEU considered the compatibility of a settlement agreement known as ‘delimitation agreement’ with the competition law.²⁸⁰ The agreement concerned the settlement of a trademark dispute related to one party’s application for trademark registration and the other party’s opposition, though the trademark proved to be dormant.

The Court stated that the opposition by ‘the proprietor of an unused, dormant, trade mark which is liable to be removed from the register upon application by any interested party (...) as part of its efforts to control the distribution of the [other party’s] products, constitute an abuse of the rights

²⁷¹ *ibid*, para 209.

²⁷² *Anderman* (n 2) 283.

²⁷³ *Windsurfing* (n 265) para 92.

²⁷⁴ *ibid*.

²⁷⁵ *ibid*, para 93.

²⁷⁶ Technology Transfer Guidelines (n 70) para 204.

²⁷⁷ *Anderman* (n 2) 282.

²⁷⁸ *ibid*.

²⁷⁹ *ibid*.

²⁸⁰ *BAT Cigaretten* (n 269).

conferred upon it by its trade mark ownership.²⁸¹ Thus, the Court found that this agreement fell within the prohibition of Article 101 (1) TFEU.

Therefore, in applying the CJEU's conclusions to reverse payment agreements, one may contend that settling a patent dispute is lawful unless the originator's enforcement of a patent is a sham due to patent invalidity. These actions will likely qualify as abuse of the rights conferred upon by the patent and will fall within the prohibition laid down by Article 101 (1) TFEU.

VII. Conclusions

A classic tension between the intellectual property legal system and competition law recently has gained a sharp and tangible essence in moving from academic discussion to our everyday life. It has transformed into a fierce battle between competition authorities and pharmaceutical companies. The aim of the former is to protect competition to benefit consumers, using every possible tool (administrative, judicial, and political). The latter, meanwhile, claims the right to settle disputes with their competitors to protect their main corporate asset, by which they retain market share and secure their profits.

Both the FTC and the European Commission have defined a separate group of patent settlement agreements which combine certain provisions, such as restrictions on generic market entry and value transfer from a brand-name company to a generic company as a cause of their main concern treating such agreements as a violation of article 101 TFEU and Section 1 of the Sherman Act. Such concern was fuelled by certain indications that generic competition in the pharmaceutical industry is not working well. The competition authorities defined reverse payment agreements as one of the reasons for the delay of generic drugs' entry. Armed with provisions prohibiting restrictions on competition, the competition authorities have launched a campaign against these agreements. They claim violation of antitrust law if they find evidence of restriction on generic market entry along with value transfer from a brand-name to a generic company.

The U.S. courts facing this new type of patent-antitrust disputes have proven more cautious in their judgments. They carefully separate from the bundle

²⁸¹ *ibid*, para 35.

of reverse payment agreements only truly anticompetitive agreements as per their view, based on the already settled patent and antitrust case law and new rules and approaches. However, the Third Court's maverick decision²⁸² on 16 July 2012 undermined the comparatively settled case law since 2005, which relies mainly on the scope of patent doctrine. Firmly rejected previous practice, the Court declared all settlement agreements containing reverse payments to be presumably unlawful. This stance has led to two conflicting decisions by the two different circuits concerning the same agreements. Before the Third Circuit decision, the Supreme Court had never agreed to consider the matter. Thus, one may assume that this tension will probably serve as a sound ground for the Supreme Court to address this tension and construe the guidance to the courts as to how approach such agreements.

As the Court of Justice of the European Union has never considered this type of dispute, a U.S. Supreme Court decision on this matter may play a crucial role in establishing the relevant EU case law. As discussed above, however, the EU case law contains certain tests and approaches which may apply to the context of reverse payment agreements disputes.

These judicial, administrative and political developments in the U.S. and the EU regarding the assessment of reverse payment agreements matter as the agreements are comparatively new: the overwhelming majority of jurisdictions have never considered them. As soon as the practice settles in these jurisdictions, competition authorities in other jurisdictions are likely to follow that approach.

This article aimed to analyse current developments in these two jurisdictions and to define the current status of reverse payment agreements. It also aimed to extract provisions which most likely will raise the interest of competition authorities and which may lead to the recognition of an agreement as illegal and violative of antitrust law. Since pharmaceutical companies may risk being the target of competition authorities' investigations and subsequently litigation, such analysis pursued the practical goal of deepening understanding of what constitutes permitted behaviour for pharmaceutical companies when concluding this type of agreement to avoid antitrust liability.

²⁸² *In re K-Dur* 3d Cir. 2012 (n 146).

Therefore, despite some difficulties in deducing the coherent line regarding reverse payment agreements after the Third Circuit's recent decision the following precautions would still seem sensible for those involved in negotiating settlements of patent disputes between pharmaceutical companies.²⁸³ First, it is advisable to avoid settlements which restrict generic entry in relation to products, periods or geographical areas outside the scope of the patents in question.²⁸⁴ It is likewise reasonable to avoid settlements which include direct payments from originator to generic company or agreements such as royalty-free licences, as they might be seen as equivalent to a direct payment.²⁸⁵

As a general recommendation, I would suggest the following. It could be cumbersome and complicated to produce one set of rules for such a complex issue, as each agreement may contain various provisions which distinguish it from a seemingly similar one. This variety forces competition authorities and courts to evaluate each agreement on a case-by-case basis. However, it may be useful to develop a specific set of guidelines based on the general principles which already exist in the U.S. case law, as well as in the EU. This consistency will help orientate the pharmaceutical industry and help both competition authorities and pharmaceutical companies conserve resources.

Another proposal relates to the recent decision to establish European Patent Court. As future patent settlement agreements will undoubtedly concern the European patents and disputes held by the EPC, to avoid the divergent approaches observed in the U.S. courts it may be reasonable to submit these disputes to the EPC jurisdiction. It would be worth considering the possibility of evaluation by the EPC of the patent validity on a *prima facie* basis. In refusing to decide this issue whilst reviewing the conformity of the reverse payment agreements, the U.S. courts appeal partially to the presumption of patent validity and partially to the lack of the necessary knowledge in reviewing it.²⁸⁶ As the EPC is a specialised patent court, it has the ability to decide on patent validity on a *prima facie* basis. This approach would eliminate all doubts as to the strength of the patent and would

²⁸³ Brankin (n 63) 28.

²⁸⁴ *ibid.*

²⁸⁵ *ibid.*

²⁸⁶ *Watson Pharms*, 11th Cir. 2012 (n 130) 1315.

exclude all allegations of undeserved monopoly gained by the weak or invalid patent.

To conclude, though it may sound striking, however, in order to reconcile two legal systems (competition and patent) the result will be unavoidable: whilst patent is pending, the patent holder may exclude its competitors and settle the dispute, however anticompetitive it would not seem, unless this settlement exceeds the scope of the patent. Otherwise, the fragile balance could be injured, pushing the measures in one or another direction may damage or even destroy one of the systems. Overly strong patent protection will distort competition and ultimately harm consumers, who will suffer from the patent monopoly. The opposing situation, favouring competition over patent protection and expanding the boundaries of antitrust liability, will hamper industry innovation, also to the detriment of consumers.