



**Tilburg Law School**

***Reverse payment (pay-for-delay) settlement agreements  
in the Pharmaceutical industry in the USA and Europe  
Competition law analysis***

**Master Thesis**

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**Student:** Petar Rumenov Raykov

**ANR:** 956795

**Student number:** 1246934

**Supervisor:** Matteo P. Negrinotti –

Universitair docent at Tilburg Law School

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## Abbreviations

**ANDA** – Abbreviated New Drug Application, an application for an approval of a generic drug product, submitted to FDA.

**CFI** – Court of First Instance, previous name of EGC.

**CJEU** – The Court of Justice of the European Union, seated in Luxembourg.

**EGC** – The General Court, a jurisdictional instance of the CJEU.

**EPC** – The Convention on the Grant of European Patents of 5 October 1973 (a.k.a. European Patent Convention).

**EU** – The European Union.

**EPO** – The European Patent Office an organ of the European Patent Organization.

**FDA** – Food and Drug Administration (a.k.a. USFDA), an agency of the United States Department of Health and Human Services.

**FFDCA** – The Federal Food, Drug, and Cosmetic Act (1938).

**FTC** – Federal Trade Commission, an independent agency of the United States government, established in 1914 by the Federal Trade Commission Act.

**Hatch-Waxman Act** – The Drug Price Competition and Patent Term Restoration Act (1984), a federal act which amended the FFDCA.

**IP** – Intellectual property.

**Member State** – member state of the European Union, a party to treaties of the European Union.

**NDA** – New Drug Application, an application for an approval of a new medicinal product, submitted to FDA.

**PFDA** – Pure Food and Drug Act (1906), entered into force on 1st January 1907.

**R&D** – Research and development.

**SPC** – Supplementary Protection Certificate, granted under Regulation (EC) № 469/2009 of the European Parliament and of the Council of 6 May 2009.

**The Final Report** – “Pharmaceutical Sector Inquiry: Final Report”, carried out by the EU Commission and published on 8 July 2009.

**TFEU** – Treaty on the functioning of the European Union.

**TTBER** – Commission Regulation № 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements.

**USA** – The United States of America.

## Chapter One

### *Introduction*

Three main roles played by the pharmaceutical industry characterize it as a vital sector of the economy. First, the industry is innovation-driven and companies put significant research and development efforts to find better or new medicines. Second, production of safe, effective and quality drugs able to cure and prevent illness and approved by competent governmental authorities. Third, the industry is a significant factor for an economic growth, since it realizes large profits and employs thousands of people.

The amount of money spent for medicines explicitly shows the importance of the pharmaceutical. According to Kaiser Family Foundation<sup>1</sup>, in 2008 were spent 234.1 billion dollars for prescription drugs in the USA. The prognosis for the future is for an almost 200% increase and 457.8 billion dollars in drug spending in 2019<sup>2</sup>. In Europe the expenditures for drugs are also high. In its Final Report, the EU Commission announced the following data – in 2007 the European citizens spent 214 billion euros for prescription and non-prescription drugs, or each citizen spent on average 430 euros in that year<sup>3</sup>.

The lion's share of the above-mentioned sums is divided among two types of companies. Originator companies are engaged in research and development, and rely heavily on patent law to protect their inventions. They produce and sell new drugs. Generic companies produce and sell drugs which “duplicate” novel drugs made by originators. They largely free-ride on research and development carried out by brand-name companies and thus price for generic medicines is significantly lower than the price of novel drugs. However, generic companies are allowed to market their medicines only after the expiration of patent protection granted to the originator companies' drugs.

In order to cut health expenditures and grant consumers access to affordable and cheaper medicines, governments on both side of the Atlantic are trying to induce early generic entry in the market. Indeed, collected data manifests that generic entry leads to drop in price of

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<sup>1</sup> Kaiser Family Foundation, “*Prescription Drug Trends*”, May 2010, at p. 1. Available at <http://www.kff.org/rxdrugs/upload/3057-08.pdf>, accessed on 1 June 2012.

<sup>2</sup> *Ibidem*, at p. 8.

<sup>3</sup> European Commission, “*Pharmaceutical Sector Inquiry: Final Report*”, (8 July 2009), at para 1. Available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, accessed on 1 June 2012.

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pharmaceuticals – the average reduction being 35.1% in the USA<sup>4</sup> and 25% in Europe<sup>5</sup>, respectively, two years after the entry.

However, intensive competition on prices and products from generic companies may undermine innovative efforts of originator companies which could find themselves under the threat of being unable to recoup the resources spent on research and development. Since, invention is crucial for the viability of the pharmaceutical sector, authorities also try to protect the interests of the brand-name companies. Key role of this protection is played by patents which serve the purpose to safeguard the incentives for originators to innovate, as well as to reward their creative efforts.

Hence, governments try to find the delicate balance between the two conflicting policy goals and they do so by legislative initiatives. For instance, in 1984 in the USA was adopted the Hatch-Waxman Act which was (and it is) tailored to induce invention and development of new medicines and therapeutic methods, while allowing immediate entry of generic drugs at the end of the patent protection of brand-name product and even a possibility for generic companies to circumvent or attack such patents prior to their expirations. In Europe, the regulatory framework is different due, in part, to absence of EU-wide patent and common patent litigation procedures, however, intellectual property rights are seen as key element in innovation and generic medicines as a way to keep public budgets under control<sup>6</sup>.

At the same time, originator and generic companies pursue their commercial objectives by exploiting the existing regulatory regimes and use the available legitimate means to safeguard their interests. In particular, brand-name manufacturers attempt to shield their novel drugs and new formulations of existing ones with patents whereas generics challenge originator's patents for being invalid or non-infringed by the generic medicines. The confrontation between both types of companies over a patent could result in patent dispute and litigation. Since disputes and litigation proceedings create a state of uncertainty with regard to their outcome and are further associated with high costs, including litigation costs, it is not a rare occasion when an originator and a generic choose to settle the conflict between them.

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<sup>4</sup> E.R.BERNDT, M.L.AITKEN, "*Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*", (2010), at p. 21. Available at: <http://faculty.fuqua.duke.edu/~dbr1/pharma/Berndt-Aitken.pdf>, accessed on 1 June 2012. See, the same data is available at: <http://www.gabionline.net/Generics/Research/Brand-loyalty-generic-entry-and-price-competition-in-the-US>, accessed on 1 June 2012.

<sup>5</sup> Pharmaceutical Sector Inquiry – Preliminary Report, Fact Sheet "*Prices, time to generic entry and consumer savings*", at p.2.

<sup>6</sup> European Commission, "Pharmaceutical Sector Inquiry: Final Report", *supra* note 3, at para 11.

In principle, patent settlements are lawful means to put an end to disputes and like all settlements are encouraged by state authorities and policies. Both parties abandon their claims and in the case of originator-generic dispute the companies decide when the generic medicine could be put on the market. However, there is one form of patent settlements which deviates from such preferable scenario, namely reverse payment settlement agreements.

Reverse payment settlements are different in view of the fact that the brand-name company actually pays the generic competitor for delaying its market entry<sup>7</sup>. Hence, the settlement is concluded on the basis of compensation flow from the party that is presumed to have a valid right (a patent) to the party that challenges the validity of this right, rather than vice versa. Such agreement unavoidably causes doubts about the validity of the patent and significant anti-competitive concerns about the settlement itself.

Competition law is invoked since reverse payment agreements are deemed to foreclose the possibility of generic manufacturer to enter the market and compete with the brand-name company. Competition is weakened or even eliminated not on the grounds of merits of the medicines manufactured by both companies, but on value transfer between them. Thus, it is presumed that parties to the settlement are actually colluding on output and prices, and dividing the market(s). Furthermore, their behavior causes harm to consumers, since the latter are paying the social cost of high prices maintained by originator companies.

At the same time, it should be kept in mind that reverse payment settlements (as all patent settlements) save parties' expenses and time for litigation. Agreements allow both originator and generic companies to remove uncertainty over the patent validity and the outcome of the patent proceedings. They also save judicial resources and alleviate the workload for courts. It is worth noting that in many reverse payment settlements the generic company is permitted to enter the market with its own version of the brand-name drug prior to the expiration of patent protection. Such division of the patent term enhances competition between originator and generic companies, and it is actually in favor of the consumer who will be able to afford cheaper medicines earlier than the expiry of the patent whenever the latter was not challenged or attacked but held valid or non-infringed by the court.

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<sup>7</sup> Thence, their other appellation – “pay-for-delay” settlements.

Reverse payment settlements are deemed to be a consequence of the Hatch-Waxman Act<sup>8</sup>. The Act provides rather specific legal regime which in fact encourages originator and generic companies to settle through reverse payment. This type of agreements provokes serious criticism and it is heavily pursued by the FTC – one of the competition authorities in the USA – for being anti-competitive and infringing Section 1 of the Sherman Act<sup>9</sup>. However, the majority of US courts have not accepted the FTC approach. According to the predominant case-law, reverse payment settlements are almost *per se legal*, unless they exceed the scope of the patent protection or when the patent is sham. Although, the competition authorities in the USA have little success in challenging such settlements, they are determined to use all available and lawful means to attack and ban reverse payment settlements as infringing antitrust rules.

In Europe, despite the differences in legal framework, originator and generic companies also conclude patent settlements and reverse payment settlements, in particular. The Final Report carried out by the EU Commission spotted such practices and raised serious doubts that settlements could run afoul of competition rules. The continuous endeavors from part of the EU Commission to pursue such settlements if they are anti-competitive resulted in monitoring on patent agreements and opening of proceedings against companies alleged in infringing competition rules through conclusion of patent settlements which contain value transfer and block or delay generic entry. However, till now the EU Commission has never stated in a clear way how it would proceed with the issue of reverse payment settlements. Moreover, there has never been a case of reverse payment settlements brought before European courts.

With regard to all the above-mentioned it is obvious that the issue of reverse payment settlement agreements in the pharmaceutical industry is topical. The importance of health and the industry as a guarantee to the former could not be questioned. However, given the large financial interests at stake, companies in the sector sometimes engage in practices which raise significant antitrust law concerns. Amongst such practices, prominent place is occupied by reverse payment settlements. Their competition law analysis is far from being an easy task on both sides of the Atlantic for reasons of different legal regimes, case-law traditions, arguments pro and con. Nevertheless, the present master thesis will try to summarize the points of major importance for the issue and will try to present the author's view on the topic of reverse payment settlements and their examination under antitrust rules.

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<sup>8</sup> See, H.HOVENKAMP, "Antitrust and patent law analysis of pharmaceutical reverse payment settlements", (2011) at p. 3, available at: <http://ssrn.com/abstract=1741162>.

<sup>9</sup> Sherman Act, 15 USC § 1.

## Chapter Two

### *The Regulatory Regime in the USA*

#### 1. Regulation of medicines prior to the adoption of the Hatch-Waxman Act.

The United States have more than a century long legislative tradition in the regulation of drugs on federal level. The Pure Food and Drug Act (PFDA)<sup>10</sup> entered into force on 1st January 1907 and laid the beginnings of the regulatory regime on pharmaceutical products. Amongst its other provisions, the PFDA set forth a ban on manufacturing, selling and transporting of adulterated, misbranded, poisonous or deleterious drugs<sup>11</sup>.

By the 1930's the PFDA was deemed to be yet outdated, but its replacement was actually accelerated by the so-called Sulfanilamide Disaster in 1937<sup>12</sup> in which more than 100 persons lost their lives after using a medicine containing an ingredient poisonous to humans. Thus, in 1938 the PFDA was repealed and replaced by the Federal Food, Drug, and Cosmetic Act (FFDCA). The latter, as a legislative response to the previous year disaster, provided for accomplishment of tests on new drugs and federal control over their safety before being put on the market. The FFDCA, and more specifically its Chapter V, is still the statute which regulates the pharmaceutical products in the USA.

FFDCA was amended several times since 1938<sup>13</sup>. However, with regard to the topic of this master thesis, the reasons for and consequences of the 1984's amendments are of importance. Then was adopted The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) which also amended the U.S. Patent Act, 35 USC<sup>14</sup>.

Prior to the adoption of Hatch-Waxman Act, there were three procedures for applying for an approval of new drug under the 1962 regime of FFDCA. Nonetheless, the opportunity for generic companies to launch quickly inexpensive generic drugs on the market was strongly

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<sup>10</sup> Pure Food and Drug Act (1906). United States Statutes at Large (59th Cong., Sess. I, Chp. 3915, p. 768-772; cited as 34 U.S. Stats. 768), available at: <http://www.ncbi.nlm.nih.gov/books/NBK22116/>, accessed on 1 June 2012.

<sup>11</sup> *Ibidem*.

<sup>12</sup> C. BALLENTINE, "Taste of Raspberries, Taste of Death. The 1937 Elixir Sulfanilamide Incident", (1981) *FDA Consumer magazine*, available at: <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm>, accessed on 1 June 2012.

<sup>13</sup> For example, according to the amendments in 1962, any new pharmaceutical should also meet the requirement "effectiveness" in order to be marketed. See, <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm>, accessed on 1 June 2012.

<sup>14</sup> U.S. Patent Act, 35 USC, available at <http://www.uspto.gov/web/offices/pac/mpep/documents/appxl.htm>, accessed on 1 June 2012.



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obstructed by the statute at that time. It was only possible for limited kind of medicines (antibiotics or drugs approved before 1962) and the applicant had to prove that his drug is bioequivalent to an earlier approved medicine, thus avoiding the proof of safety and effectiveness. Whereas, while filing a New Drug Application (NDA), in fact the generic company had to repeat the lengthy and expensive application process typical for launch of a brand-name drug<sup>15</sup>, and while using the so-called "Paper" New Drug Application, he had to rely on published scientific studies which were not available for all medicines and thus ran a risk that the FDA would request additional scientific information<sup>16</sup>.

The famous *Roche Products v. Bolar Pharmaceutical* case<sup>17</sup>, a patent litigation between brand-name pharmaceutical company and generic manufacturer, played a significant role in the adoption of Hatch-Waxman Act. In its decision on 23 April 1984 the Federal Court adjudicated that "*unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention*"<sup>18</sup>. In other words, the court stipulated that generic manufacturers were not permitted to convey any research experiments with patented drugs for commercial purposes prior to the patent expiry and thus it gave the brand pharmaceutical companies additional exclusivity period over that granted by the patent itself.

## 2. Hatch-Waxman Act regime.

The difficulty of launching generic medicines according to the 1962 regime of FFDCA and the grant of additional exclusivity period for brand-name medicines by the court were the main legal reasons which led up to the adoption of Hatch-Waxman Act. The Act was introduced with the purpose to permit rapid access of inexpensive generic drugs on the market by shortening the procedure for their approval before FDA. It also tried to reconcile the interests of brand and generics companies while allowing consumers to receive the benefits from affordable and cheap generic drugs. On one hand, it brought in a simplified procedure for generic pharmaceutical companies to obtain marketing approval of their generic drugs from FDA and stipulated the so-called "Bolar" exception in the U.S. Patent Act. The

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<sup>15</sup> Th.B.LEARY, "Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II", speech delivered at the American Bar Association's Antitrust Healthcare Program on May 17, 2001, in Washington, D.C., available at: <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.shtm>, accessed on 1 June 2012.

<sup>16</sup> J.R.SANJUAN, "U.S and E.U protection of pharmaceutical test data", (2006) *CPTech Discussion Paper - № 1*, available at: <http://www.cptech.org/publications/CPTechDPNo1TestData.pdf>, accessed on 1 June 2012.

<sup>17</sup> Case *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 04/23/1984), available at: [http://biotech.law.lsu.edu/cases/ip/patent/roche\\_v\\_bolar.htm](http://biotech.law.lsu.edu/cases/ip/patent/roche_v_bolar.htm), accessed on 1 June 2012.

<sup>18</sup> *Ibidem*.

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exception in Section 35 USC § 271(e)(1) allowed testing of drugs, protected by patent, with the aim of developing and submitting the necessary information for approval by FDA of the generic version of a brand-name drug<sup>19</sup>. On the other hand, the Act set forth data exclusivity period of five years for medicines which contain new active chemical ingredient. Prior to the expiration of the data exclusivity period for such drugs, nobody is allowed to file an application for approval of a new medicine which contains the same active ingredient. Thus, the brand-name pharmaceutical companies were given the opportunity to recoup their investments in the research and development of valuable new drugs<sup>20</sup>.

The regulatory framework for obtaining a patent on and marketing approval of a new drug in the US consists of two steps. First, the pharmaceutical company has to file a patent application under 35 USC § 111<sup>21</sup> before the U.S. Patent and Trademark Office in order to obtain a patent and thus, the exclusive right to prohibit third parties to make, use, offer to sell, or sell the patented invention, within the United States, or import it into the United States during the term of the patent<sup>22</sup>. Second, the pharmaceutical company has to submit New Drug Application before FDA in order to obtain marketing approval for the medicine by demonstrating that it is safe and effective.

The Hatch-Waxman Act allowed generic pharmaceutical companies to obtain marketing approval of their version of a brand medicine from FDA through a simplified procedure by filing Abbreviated New Drug Application (ANDA) under Section 505 of FFDCA<sup>23</sup>. In essence, the ANDA procedure gives a generic manufacturer the opportunity to rely on the safety and effectiveness of an identical, previously approved drug without having to conduct the costly and time-consuming pre-clinical and clinical researches which were necessary for the approval of the brand-name drug. The generic manufacturer only has to show that his

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<sup>19</sup> "2750 Patent Term Extension for Delays at other Agencies under 35 U.S.C. - 2700 Patent Terms and Extensions", available at: [http://www.uspto.gov/web/offices/pac/mpep/documents/2700\\_2750.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/2700_2750.htm), accessed on 1 June 2012.

<sup>20</sup> D.E.TROY, "Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)", statement before the Senate Commission on Judiciary on 1 August 2003, available at: [http://www.fda.gov/NewsEvents/Testimony/ucm115033.htm?utm\\_campaign=Google2&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=hatch-waxman&utm\\_content=1](http://www.fda.gov/NewsEvents/Testimony/ucm115033.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=hatch-waxman&utm_content=1), accessed on 1 June 2012.

<sup>21</sup> 35 U.S.C. 111 Application - Patent Laws, available at: [http://www.uspto.gov/web/offices/pac/mpep/documents/appxl\\_35\\_U\\_S\\_C\\_111.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_111.htm), accessed on 2 June 2012.

<sup>22</sup> 35 U.S.C. 271 Infringement of patent. - Patent Laws, available at: [http://www.uspto.gov/web/offices/pac/mpep/documents/appxl\\_35\\_U\\_S\\_C\\_271.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_271.htm), accessed on 2 June 2012.

<sup>23</sup> SEC. 505. [21 USC §355] New Drugs, available at: <http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterDrugsandDevices/ucm108125.htm>, accessed on 2 June 2012.

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medicine is bioequivalent<sup>24</sup> of the originator drug. To establish bioequivalence is far from being a trivial matter, but it is an easier and cheaper way than carrying out all the necessary NDA researches<sup>25</sup>.

When filing an ANDA, under 21 USC § 355 (j)(2)(A)(vii) the applicant has to choose between four types of certification. The fourth certification is commonly known as “Paragraph IV” certification<sup>26</sup> or ANDA-IV<sup>27</sup> and it is used when the ANDA filer seeks pre-expiration marketing of its generic drug. In essence, the ANDA-IV filer says that the patent of the brand-name company is invalid or will not be infringed by the generic medicine, and thus he launches a patent challenge to the originator company.

Then, the filer of Paragraph IV certification, is obliged under 21 USC § 355(j)(2)(B)(i) to notify the brand-name company for the patent challenge. After receiving the notice, the originator company has 45 days at his disposal to start a court proceedings against the filer for patent infringement. If such suit is filed within the mentioned term of 45 days, FDA approval of the ANDA is automatically stayed. This stay continues until the occurrence of one of the following events: 1) the expiry of the patent; 2) final court decision in the patent infringement litigation that there was non-infringement from part of the ANDA filer; or 3) the expiry of a 30-months period which begins with the patentee's receipt of notice of the Paragraph IV certification<sup>28</sup>. The 30-month period is intended to allow time for judicial resolution on the merits of the patent. It is worth noting that the patent proprietor could bring a suit for infringement after the 45 days period, but in this case it will not benefit from the 30-months stay given by the statute<sup>29</sup>.

Generic companies are induced to file ANDA-IV, because the first generic that submits such certification is granted under 21 USC § 355 (j)(2)(B)(iv) with an 180-day exclusivity period. During this exclusivity period, the first filer (and only he) can market his drug free of competition from subsequent filers of ANDA with regard to another generic version of the

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<sup>24</sup> “Bioequivalence means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study”, FDA Code of Federal Regulation § 320.1. (e), available at: <http://law.justia.com/cfr/title21/21-5.0.1.1.7.html#21:5.0.1.1.7.1.1.1>), accessed on 2 June 2012.

<sup>25</sup> C.S.HEMPHILL, “Paying For Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem”, (2006) *81 New York University Law Review* 1553, at p. 112.

<sup>26</sup> Th.B.LEARY, “Antitrust Issues in Settlement of Pharmaceutical Patent Disputes”, speech delivered at Sixth Annual Health Care Antitrust Forum on November 3, 2000, in Chicago, Illinois, available at: <http://www.ftc.gov/speeches/leary/learypharma.shtm>, accessed on 2 June 2012.

<sup>27</sup> C.S.HEMPHILL, *supra* note 25, at p. 112.

<sup>28</sup> Th.B.LEARY, *supra* note 26.

<sup>29</sup> *Ibidem*.

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same patented medicine<sup>30</sup>. Moreover, ANDA filers are further incentivized to apply for Paragraph IV certification, since under 21 USC § 355 (j)(5)(F)(ii) the data exclusivity period is reduced to four years for ANDA-IV filers.

Although the Hatch-Waxman regime was subsequently amended<sup>31</sup>, the above-mentioned regulatory framework still represents the legal framework which gave birth to reverse payment settlements. On one hand, the generic manufacturer enjoys the simplified ANDA procedure to receive approval of his version of a brand-name medicine. Furthermore, the 180-day exclusivity period gives him sufficient time to settle himself on the market of this specific drug and obtain market share<sup>32</sup>. And finally, the exclusivity period provides him with an appreciable advantage over subsequent ANDA filers, since no other generic is entitled to such exclusivity, thus reducing the incentives for next filer to enter the market<sup>33</sup>. On the other hand, the brand-name pharmaceutical company benefits from the 30-month stay period which actually serves as an “*automatic preliminary injunction*”<sup>34</sup>. The originator does not have to prove the necessity of such injunction before court, since he is granted with it by the law. Probably, this legislative resolution is also based, besides on the search for balance in Hatch-Waxman Act between the conflicting interests on the brand-name and generic companies, on the particularly strong presumption in the USA that once granted the patent is valid<sup>35</sup> and the alleged infringer should rebut it “*by clear and convincing evidence*”<sup>36</sup>

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<sup>30</sup> W.H.ROONEY, E.KATZ, A.R.FITZPATRICK, M.LEUTZINGER,P.J.SCOOLIDGE, “Review of reverse-payment agreements: The Agencies, the Courts, Congress, and the European Commission”, (2009) *Competition Policy International, Volume 5, Number 2*, at page 123.

<sup>31</sup> In 2003, Medicare Prescription Drug, Improvement and Modernization Act introduced a mandatory notification to the US competition authorities for conclusion of certain patent settlements and it also debarred the originator company and the first generic ANDA-IV filer from the possibility to delay the approval of subsequent ANDA-IV by FDA through conclusion of a patent settlement.

<sup>32</sup> R.J.R.PERITZ, “A brief introduction to competition concerns in “pay-for-delay” settlement agreements between brand-name and generic drug companies”, (2010) Research Paper Series 10/11#10, New York Law School Legal Studies, at p. 4.

<sup>33</sup> H.HOVENKAMP, *supra* note 8, at p. 3.

<sup>34</sup> Th.B.LEARY, *supra* note 26.

<sup>35</sup> US Patent Act 35 USC § 282.

<sup>36</sup> R.J.R.PERITZ, *supra* note 32, at p. 5.

## Chapter Three

### *Reverse payment (pay-for-delay) settlement agreements in the USA*

#### 1. Rise of reverse payment settlements.

According to FTC study, a multitude of 8 019 ANDAs were filed with FDA from the adoption of Hatch-Waxman Act to 2000<sup>37</sup>. 483 of the total number of applications were ANDA-IV and their percentage was steadily increasing over the years. Filing Paragraph-IV certifications gave rise to subsequent patent litigation proceedings in which generic companies prevailed in 73 % of the cases between 1992 and June 2002<sup>38</sup>. Although, these figures substantiated the rationale behind Hatch-Waxman Act to allow generics to challenge weak patents and enter the market prior to the expiration date of such patents, the FTC report also found a problematic practice between brand-name and generic companies. Some of the patent challenges ended with a settlement agreements between the parties in litigation and nonetheless the fact that patent settlements could be procompetitive<sup>39</sup>, nine of these settlements contained payment from the patentee (or brand-name company) to the generic applicant<sup>40</sup>. The first reverse payment settlement was concluded in March 1993 between Zeneca and Barr and it is known as *Tamoxifen* settlement<sup>41</sup>.

The surveys conducted by FTC continued over the following years. The *FTC Stuff study* from January 2010 provided the following data: 218 settlement agreements were concluded from 2004 to 2009 and 66 of these settlements included payment from the originator company to the generic company, as well as a delay in the generic entry<sup>42</sup>. The number of reverse payment settlements gradually increased over the five years covered by the study. The last *FTC Stuff study* showed that for the 2010 fiscal year another 156 settlements were concluded and 28 them were described as potential reverse payment deals<sup>43</sup>.

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<sup>37</sup> FTC, "Generic Drug entry prior to patent expiration: an FTC study, July 2002", at p. vi, available at: <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>, accessed on 3 June 2012.

<sup>38</sup> *Ibidem*.

<sup>39</sup> *Ibidem*, at p. 25.

<sup>40</sup> *Ibidem*, at p. 31.

<sup>41</sup> S.C. HEMPHILL, "Drug patents settlement between rivals: a survey", (2007) Working paper, at p. 22, available at: <http://www.ssrn.com/abstract=969492>.

<sup>42</sup> FTC, "Pay-for-delay. How Drug Company Pays-Off Cost Consumers Billions" – an FTC Staff Study, January 2010, at p. 4.

<sup>43</sup> "FTC Study Finds That Pharmaceutical Industry Will Cause World To Explode", Stephen Jenei, 25 October 2011, available at: <http://www.patentbaristas.com/archives/2011/10/25/ftc-study-finds-that-pharmaceutical-industry-will-cause-world-to-explode/>, accessed on 29 May 2012.

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The above-mentioned figures clearly demonstrate that under Hatch-Waxman Act the reverse payment settlements are a common phenomenon. They were even called by the federal court “*a natural by-product of the Hatch-Waxman process*”<sup>44</sup>. The number of reverse payment settlements is increasing over the last eight years and they are deemed to cost the consumers about 3.5 billion dollars per year<sup>45</sup> and delay generic entry for almost 17 months<sup>46</sup>.

The increased number of ANDA-IV certifications in the late 1990s and the advent of reverse payment settlements of patent litigation in the pharmaceutical sector, compel FTC to scrutinize these agreements and express strong concerns with regard to their effect on competition<sup>47</sup>. On the grounds of Section 1 of the Sherman Act:

*“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”*<sup>48</sup>

FTC claims that such settlements are restraints of trade and put serious efforts throughout the years to attack them as violating the antitrust rules before different courts.

However, the attitude of FTC and courts towards reverse payment settlements could not be depicted as always being similar. The commission has been and is consistent in its crusade against such settlements. Yet, courts changed their approach towards reverse payment deals from deeming them *per se illegal* to adjudicating that they are almost *per se legal*. From the very outset should be noted that the Supreme Court of the USA has so far refused to tackle the problem of reverse payment settlements and the present case law is based on decisions of different Federal Courts.

## 2. Case law on reverse payment settlements.

*In re Cardizem CD Antitrust Litigation*<sup>49</sup> was the first case of reverse payment deal decided by Appellate Court of the USA<sup>50</sup>. The agreement was concluded in 1997 between the

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<sup>44</sup> Case *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003).

<sup>45</sup> J.LEIBOWITZ, “Pay-for-Delay Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers` Wallets, and Help Pay for Health Care Reform (The 35 Billion Solution)”, a speech delivered at Center for American Progress, on June 23, 2009, available at: <http://ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>, accessed on 4 June 2012.

<sup>46</sup> FTC Staff Study, *supra* note 42, at p. 2.

<sup>47</sup> W.H.ROONEY, E.KATZ, A.R.FITZPATRICK, M.LEUTZINGER,P.J.SCOOLIDGE, *supra* note 30, at p. 123.

<sup>48</sup> Sherman Act, 15 USC § 1.

<sup>49</sup> Case *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, United States Court of Appeals, Sixth Circuit.

<sup>50</sup> W.H.ROONEY, E.KATZ, A.R.FITZPATRICK, M.LEUTZINGER,P.J.SCOOLIDGE, *supra* note 30, at p. 125.

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originator company *Hoescht Marion Roussel* and the generic company *Andrx Pharmaceuticals*, which was the first to file ANDA-IV certification for the successful brand-name drug *Cardizem CD*. The settlement did not resolve the patent dispute between the parties, but actually represented an interim agreement between them. Despite the fact that FDA approved his ANDA-IV, the generic company agreed under certain conditions not to market his generic version of *Cardizem CD*, nor some other non-infringing the patent medicines. *Andrx Pharmaceuticals* also consented to retain his 180-day exclusivity period, thus creating an obstacle to subsequent ANDA-IV filers to receive approval from FDA and enter the market. In return, *Hoescht Marion Roussel* agreed to make quarterly payments of \$10 million to *Andrx Pharmaceuticals* for not marketing its generic product plus \$100 million per year, less the quarter payments already made, once the patent case was resolved<sup>51</sup>.

In its decision, the Sixth Circuit reasoned that according to Section 1 of the Sherman Act, any agreement in restraint of trade is violation of the antitrust rules. Although, the majority of the deals that restrain trade are judged by the “*rule of reason standard*”<sup>52</sup>, according to the case law of the Supreme Court agreements that lead to “*horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused*”<sup>53</sup>. Then, the Sixth Circuit noted that the agreement between *Hoescht Marion Roussel* and *Andrx Pharmaceuticals* actually was designed to eliminate competition in the *Cardizem CD* market, restrain the generic manufacturer from putting on the market other non-infringing the patent at stake drugs and to block third parties to obtain approval from FDA on their own generic version of *Cardizem CD*<sup>54</sup>, and adjudicated that:

*“There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade”*<sup>55</sup>

The decision of the Sixth Circuit is remarkable for several reasons. It was the first and, as we will see further in this chapter, the only Appellate Court’s decision which rendered that reverse payment settlement had run afoul of competition rules. Next, the court applied

<sup>51</sup> Case *In re Cardizem CD Antitrust Litigation*, *supra* note 49.

<sup>52</sup> Case 522 U.S. at 10, 118 S.Ct. 275, *State Oil Company v. U Khan*, Supreme Court of the USA.

<sup>53</sup> Case 405 U.S. 596 (92 S.Ct. 1126, 31 L.Ed.2d 515), *United States v. Topco Assocs.*, Supreme Court of the USA.

<sup>54</sup> J.R.THOMAS, “Pharmaceutical patent litigation settlements: Implication for competition and innovation”, (2010) *Congressional Research Service* 7-570, at p. 12.

<sup>55</sup> Case *In re Cardizem CD Antitrust Litigation*, *supra* note 49.

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established principles of the American antitrust law in a new area of competition litigation. Although, it was the first case of reverse payment settlement, the court reiterated that price-fixing is *per se illegal* and there is no need to evaluate the procompetitive benefits of the agreement. Finally, the Sixth Circuit advanced the notion that a patent could not be reinforced by banning competitors from entering the market through the payment to the first of them to delay its entry<sup>56</sup>. However, it is worth noting that *In re Cardizem CD Antitrust Litigation* the reverse payment settlements were also prohibiting the marketing of non-infringing or potentially non-infringing the patent at stake generic versions of the *Cardizem CD*, and thus it clearly exceeded the scope of the patent.

Three months after the *In re Cardizem CD Antitrust Litigation* judgment another Appellate Court addressed a case of reverse payment. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* case<sup>57</sup> was about two settlements concluded by *Abbott Laboratories*, manufacturer of the blockbuster brand-name drug *Hytrin*. The brand-name pharmaceutical company entered into an “interim” agreement with the first ANDA-IV filer *Geneva Pharmaceuticals* and a final settlement with other generic company *Zenith Goldline Pharmaceuticals*. In return for delayed market entry by the generics companies, *Abbott Laboratories* agreed to pay them about 146 million dollars in total<sup>58</sup>.

In light of the *Cardizem CD* decision, it was surprising that the Eleventh Circuit refused to apply *per se illegality* to reverse payment settlements. To the contrary, it overturned the district court decision that settlements at issue were *per se illegal* as a horizontal market allocation. Moreover, the Appellate Court criticized the District Court for being “premature”<sup>59</sup>, since it did not take into consideration the patent owned by the brand-name company. The reasoning of the court was that “*A patent grants its owner the lawful right to exclude others*”<sup>60</sup> and since *Abbott Laboratories* owned a patent, he was allowed to exercise his lawful exclusionary rights towards others until the expiration of the patent. The Appellate court concluded that:

*“To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate”*<sup>61</sup>

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<sup>56</sup> *Ibidem*.

<sup>57</sup> *Case Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, United States Court of Appeals, Eleventh Circuit - 350 F.3d 1181.

<sup>58</sup> S.C. HEMPHILL, *supra* note 41, at p. 33-35.

<sup>59</sup> *Case Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, *supra* note 57.

<sup>60</sup> *Ibidem*.

<sup>61</sup> *Ibidem*.



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In other words, the court adjudicated that when an agreement does not include restriction on competition greater than the “*exclusionary potential of the patent*”, it does not violate Section 1 of the Sherman Act<sup>62</sup>. Interestingly enough, the '207 patent was held invalid by a court decision rendered after the conclusion of the settlement between the parties. However, this should not undermine the value of the Eleventh Circuit judgment, since it decided the case on the basis of facts and law at the time when the settlement was concluded. Moreover, it is not for the court in an antitrust proceeding to assess the validity of a patent nor to guess the likelihood of its invalidation in a patent court litigation.

It is also worth noting that in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit adopted a method that should be applied when adjudicating over reverse payment settlements. The method consists of three steps: 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<sup>63</sup>. It could be fairly said that the method is designed to strike a balance between patent and antitrust law in cases of reverse payment settlements. It recognizes the exclusionary scope of the patent and it also declares that once the settlement went beyond that scope, it restrains competition.

The above-mentioned three-steps analysis was confirmed by the Eleventh Circuit in the *Schering-Plough Corp. v. FTC* case<sup>64</sup> in 2005. The court put some additional nuances to its stand against *per se illegality* of reverse payment settlements by stipulating that “*In the context of patent litigation ... the anticompetitive effect may be no more broad than the patent’s own exclusionary rights*”<sup>65</sup>. Moreover, since in the settlement at issue in this case, the brand-name company permitted generics to market their own version of the brand drug prior to the expiration of the patent and the generics companies granted licenses to *Schering-Plough Corp.*, this also contributed to the adjudication that the reverse payment agreements were not anti-competitive and the Eleventh Circuit overturned the FTC decision<sup>66</sup>.

The Second Circuit *In re Tamoxifen Citrate Antitrust Litigation*<sup>67</sup> and the Federal Circuit *In re Ciprofloxacin Hydrochloride Antitrust Litigation*<sup>68</sup> also refused to condemn reverse payment settlements as violating antitrust law.

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<sup>62</sup> W.H.ROONEY, E.KATZ, A.R.FITZPATRICK, M.LEUTZINGER,P.J.SCOOLIDGE, *supra* note 30, at p. 127.

<sup>63</sup> J.R.THOMAS, *supra* note 54, at p. 13.

<sup>64</sup> Case *Schering-Plough Corp. v. FTC*, United States Court of Appeals, Eleventh Circuit - 402 F.3d.

<sup>65</sup> *Ibidem*.

<sup>66</sup> J.R.THOMAS, *supra* note 54, at p. 14.

<sup>67</sup> Case *In re Tamoxifen Citrate Antitrust Litigation*, United States Court of Appeals, Second Circuit - 466 F.3d 187, 208-12 (2d Cir. 2005).

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The first case established the so-called Tamoxifen doctrine<sup>69</sup> or consensus<sup>70</sup> rule, under which:

*“Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be 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”*<sup>71</sup>

In fact, the Second Circuit decision *In re Tamoxifen Citrate Antitrust Litigation* upheld the longstanding tradition of encouraging settlements over litigation in patent disputes<sup>72</sup> and strong presumption in US law of patent validity<sup>73</sup>. And stipulated that unless there was not a sham or vexatious litigation over the patent, a settlement of such litigation which did not go outside the scope of the patent at stake is lawful.

The Federal Circuit continued the *In re Tamoxifen Citrate Antitrust Litigation* case line of reasoning *In re Ciprofloxacin Hydrochloride Antitrust Litigation*. The court held that when there was a *bona fide* patent litigation, it could be lawfully settled by the parties unless the out-of-court agreement goes beyond the exclusionary scope of that patent<sup>74</sup>. Furthermore, in conformity with the decisions in *Schering-Plough Corp.*<sup>75</sup> and *In re Tamoxifen*, the Federal Circuit rejected the FTC position that mere presence of a reverse payment in the settlement or when its size exceeds the litigation costs incurred is sufficient *“to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent protection”*<sup>76</sup>.

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<sup>68</sup> Case *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, United States Court of Appeals, Federal Circuit 544 F.3d 1323.

<sup>69</sup> “Cipro “Pay-To-Delay” Case Is Ideal Supreme Court Fodder”, *Forbes*, 10 September 2010, available at: <http://www.forbes.com/sites/danielfisher/2010/09/10/cipro-pay-to-delay-case-is-ideal-supreme-court-fodder/>, accessed on 5 June 2012.

<sup>70</sup> “Reverse Payment Terms in ANDA Settlement Agreements”, 22 June 2011, available at: <http://antitrustconnect.com/2011/06/22/reverse-payment-terms-in-anda-settlement-agreements/> accessed on 5 June 2012

<sup>71</sup> As defined *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, *supra* note 68.

<sup>72</sup> J.R.THOMAS, *supra* note 54, at p. 16.

<sup>73</sup> H.HOVENKAMP, *supra* note 8, at p. 17.

<sup>74</sup> W.H.ROONEY, E.KATZ, A.R.FITZPATRICK, M.LEUTZINGER,P.J.SCOOLIDGE, *supra* note 30, at p. 129.

<sup>75</sup> “the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy” in Case *Schering-Plough Corp. v. FTC*, United States Court of Appeals, Eleventh Circuit - 402 F.3d. “

<sup>76</sup> Case *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, *supra* note 68.

The recent decision in *FTC v. Watson Pharmaceutical* case<sup>77</sup> carried on the predominant line of the case law. The Eleventh Circuit summarized the courts' practice and thoroughly explained the rationale behind refusing to condemn reverse payment settlements. It strongly rejected the FTC argument that such settlements are running afoul of antitrust rules when there was unlikelihood for the patent holder to prevail in the patent litigation. This is because it is quite strange to base court claim on probability of the future outcome of other case. In addition, chance does not equal certainty<sup>78</sup> and the Appellate Court picturesquely stipulated that “*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*”<sup>79</sup>.

Despite the Sixth Circuit decision in *Cardizem CD* case, it could be inferred from all above-said that the American case law on reverse payment settlements is consistent and sensible. Courts refuse to ban such settlements as infringing antitrust rules unless these go beyond certain stated criteria. Thus, a legal certainty is provided for private parties. And a very delicate balance between interests of brand-name companies, generic companies and consumers, as well as between patent law and competition rules, is struck. It should be admitted that the judicial approach is correct in that the exclusionary scope of the patent at stake makes reverse payment settlements rather specific and different from settlements where no patents rights are involved. In addition, courts' refusal to judge on or make predictions about patent validity in antitrust litigation and hold settlements to be anti-competitive because of the mere presence of reverse payment therein, as well as allowing pharmaceutical companies the freedom to choose which patents to challenge, which cases to settle and under what conditions, provided that the scope of the patent is not exceeded, further contribute to the merits of the Appellate Courts' stand.

### 3. US Supreme Court and reverse payment settlements.

Under Rule 10(a) of the Rules of the United States Supreme Court when “*a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter*”<sup>80</sup> and there are “*compelling reasons*”, the Supreme Court could grant a writ of certiorari or in other words to review the case law over the important matter. As explained above, there is a circuit split between The Sixth Circuit, on

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<sup>77</sup> Case *FTC v. Watson Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc.*, United States Courts of Appeals. Eleventh Circuit, No. 10-12729. Decision rendered on 25 April 2012.

<sup>78</sup> *Ibidem.*

<sup>79</sup> *Ibidem.*

<sup>80</sup> Rules of the United States Supreme Court, Rule 10 (a), available at: [http://www.law.cornell.edu/rules/supct/rule\\_10](http://www.law.cornell.edu/rules/supct/rule_10), accessed on 5 June 2012.

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one hand, and the Eleventh, the Second and the Federal Circuits, on the other hand, with regard to the reverse payment settlements issue. Although, petitions for writ of certiorari were brought throughout the years to the Supreme Court, the latter refused so far to grant certiorari. It did so with the petitions of writ of certiorari in the *Schering-Plough Corp.* case, *Tamoxifen* case and *Ciprofloxacin* cases<sup>81</sup>.

The Supreme Court consistent position to refuse to review the reverse settlement issue seems strange. It is so, in particular, when we take into account the healthcare and economic importance of the pharmaceutical sector<sup>82</sup>, the 3.5 billion dollars loss caused to consumers by these settlements per year<sup>83</sup>, the now common position of the FTC and the Department of Justice<sup>84</sup>, and the briefs as *amicus curiae* which were filed to the court from 54 law, economic and business scholars and from 34 State Attorneys General to reject the predominant view of the Appellate courts that reverse payment settlements are almost *per se legal*. However, we should bear in mind that the Supreme Court grants writ of certiorari in a very low rate in comparison with the total number of petitions brought<sup>85</sup>. Furthermore, in essence the questions raised in the petitions were nearly the same and asked the Supreme Court to reverse the almost *per se legality* approach. Since the Court has denied to deal with them from the very first petition for a certiorari in the *Schering-Plough Corp.* case, it is sensible that it continued to do so when approached with similar questions. Although, the exact reasons for the Supreme Court's refusals are not known, since the petitions as common rule are denied without any comment, it is predictable that a new petition to be filed is very unlikely.

#### 4. Proposals for legislative changes.

However, there is one more level on which the issue of *legality* or *illegality* of reverse payment settlements in the pharmaceutical industry is debated and this is the legislative level.

There are certain propositions in the law literature how and what to be amended in the Hatch-Waxman Act. For instance, Rudolph J.R. Peritz suggests that in the case of settlement

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<sup>81</sup> Case *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. Oct. 15, 2008), cert. denied, 129 S.Ct. 2828 (2009); Case *Arkansas Carpenters Health and Welfare v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), cert. denied, 2011.

<sup>82</sup> "Reverse payment settlements: the time for change has arrived", *Bloomberg law reports*, 2010, available at: [http://www.labaton.com/cs\\_upload/en/about/published/23791\\_1.pdf](http://www.labaton.com/cs_upload/en/about/published/23791_1.pdf), accessed on 5 June 2012.

<sup>83</sup> J.LEIBOWITZ, *supra* note 45.

<sup>84</sup> In this sense, See W.H.ROONEY, E.KATZ, A.R.FITZPATRICK, M.LEUTZINGER,P.J.SCOOLIDGE, *supra* note 30, at p. 132-133.

<sup>85</sup> "the Court accepts between 100-150 of the more than 7,000 cases that it is asked to review each year" – available at: <http://www.uscourts.gov/EducationalResources/ConstitutionResources/SeparationOfPowers/>, accessed on 5 June 2012.

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between the brand name company and the first ANDA-IV filer, the 180-day exclusivity should be granted to the next Paragraph IV filer<sup>86</sup>. With regard to the exclusivity period, C. Scott Hemphill and Mark A. Lemley propose that this period should be actually deserved by the first filer by either winning the patent dispute, settling the dispute with a clause that grants immediate market access or receiving FDA approval without being sued<sup>87</sup>. Rudolph J.R. Peritz also suggests that the brand-name company should not be granted with the automatic 30-months stay, stating that such preliminary injunction should only be available on the same strict merits as in all patent cases<sup>88</sup>.

There are two bills proposed to the US Senate which forbid the reverse payment settlements between brand-name and generic company. The first one is the Kohl bill<sup>89</sup> introduced on 3rd February 2009 and reintroduced on 25th January 2011. Under its Section 28, the bill establishes a presumption that *“any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product”*<sup>90</sup> is anticompetitive and illegal, when the ANDA filer *“receives anything of value”*<sup>91</sup> and *“agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time”*<sup>92</sup>. The presumption is rebuttable *“by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement”*<sup>93</sup>. On 22nd July 2011 the bill was placed on Senate Legislative Calendar under General Orders. The second bill is the Rush bill<sup>94</sup> introduced on 25th March 2009 and reintroduced on 9th February 2012. According to it, *“any agreement resolving or settling a patent infringement claim”*<sup>95</sup> is illegal when the ANDA filer *“receives anything of value”*<sup>96</sup> and *“agrees not to research, develop, manufacture, market, or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim”*<sup>97</sup>.

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<sup>86</sup> R.J.R.PERITZ, *supra* note 32, at p. 5.

<sup>87</sup> C.S.HEMPHILL, M.A.LEMLEY, “Earning exclusivity: generic drug incentives and the Hatch-Waxman Act”, (2011) 77 *Antitrust Law Journal* № 3, 947-989, at p. 969.

<sup>88</sup> R.J.R.PERITZ, *supra* note 32 at p. 5-6.

<sup>89</sup> S.369 Preserve Access to Affordable Generics Act (Kohl bill). Available at: <http://thomas.loc.gov/>, accessed on 5 June 2012.

<sup>90</sup> *Ibidem*, Sec. 28 (a)(1).

<sup>91</sup> *Ibidem*, Sec. 28 (a)(2)(A)(i).

<sup>92</sup> *Ibidem*, Sec. 28 (a)(2)(A)(ii).

<sup>93</sup> *Ibidem*, Sec. 28 (a)(2)(A).

<sup>94</sup> H.R. 3995 Protecting Consumer Access to Generic Drugs Act (Rush bill). Available at: <http://thomas.loc.gov/>, accessed on 5 June 2012.

<sup>95</sup> *Ibidem*, Sec. 2(a).

<sup>96</sup> *Ibidem*, Sec. 2(a)(1).

<sup>97</sup> *Ibidem*, Sec. 2(a)(2).

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Whether one of these two bills will be passed by the Congress and the Senate is a political matter. However, the President Obama administration has shown its supportive stand towards the ban of reverse payment settlements<sup>98</sup>. Meanwhile, the FTC continues to consider the reverse payment settlements as its top antitrust priority and declares its will to “*aggressively pursue*” them through investigations and enforcement actions, along with its efforts in relation to the final legislative solution to the issue<sup>99</sup>. Thus, it seems that legislative change is about to be adopted. Till that moment, it is unlikely that courts will change their position towards reverse payment settlements and given the regulatory regime, they have no reason to do so.

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<sup>98</sup> R.J.R.PERITZ, *supra* note 32, at p. 1.

<sup>99</sup> J.LEIBOWITZ, “How the Federal Trade Commission works to promote competition and benefit consumers in a dynamic economy”, a prepared statement delivered before United States Senate, on June 9, 2010, available at: <http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf>, accessed on 5 June 2012.

## Chapter Four

### *The Pharmaceutical sector in Europe*

Understanding the topic of reverse payment settlements in Europe is impossible without knowledge of the characteristics of the Pharmaceutical sector on the continent. Thus, the present chapter of this master thesis provides information on the specific features of the industry.

The Pharmaceutical sector in Europe is disparate from any other sector of the economy. Its supply side is formed by two types of companies which conduct their commercial policies by opposite means, whereas on the demand side is the consumer whose choices are intermediated by state, health insurers, doctors and pharmacists with regard to medicines and prices. States intervene in the sector not only in relation to the consumers and their protection, but also to reconcile two conflicting objectives: a) to promote research and development; and b) to reduce and keep prices of drugs at affordable level for maximum number of consumers by incentivizing the price competition on the supply side. Since innovation is crucial for the sector, important role is played by the intellectual property law and patent law, in particular. However, grant of intellectual property protection for pharmaceuticals and its enforcement are not harmonized in Europe (as distinct from the homogenous regime in the USA), which further contributes to the specificity of the sector.

#### **1. Features of the supply side.**

The supply side of the pharmaceutical sector is characterized by the presence of two kinds of undertakings. Their business models are diametrically opposed and this is reflected heavily in the incentives they are driven by, the strategies they pursue and their price policies.

On one hand, there are the originator (brand-name) companies. They are involved in research and development of new drugs with the aim to obtain patent protection and market authorization for their products and put them on the market<sup>100</sup>. Thus, innovation is deemed to be core activity of the originator companies. Their incentive is to create new medicines or improved version of the existing ones through research and development (R&D) processes. Indeed, for the period 2000-2007, they spent on innovation 17% of their global turnover<sup>101</sup>. In

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<sup>100</sup> European Commission, "Pharmaceutical Sector Inquiry: Final Report", *supra* note 3, at para 47.

<sup>101</sup> *Ibidem*, at para 72.

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particular, this expenditure ranks amongst the highest investment on research and development in Europe<sup>102</sup>.

On the other hand, there are the generic companies. They piggyback on the R&D done by the originators and then produce and market their own versions of patented medicines, after the expiration of the patent protection of the latter<sup>103</sup>. As noted in the EU Commission Pharmaceutical Sector Inquiry Final Report (the Final Report), generics are also involved in innovation by creating different formulation and dosage of existing brand-name drugs<sup>104</sup>. However, their main strategy is to take advantage of the loss of exclusivity of successful and lucrative originators' drugs and put on the market their own inexpensive identical versions<sup>105</sup>. Marketing cheaper generic drugs is possible because generic companies could simply rely on the data of pre-clinical and clinical trials for originators' medicines, and prove that their version is equivalent of the brand-name medicine and fulfills the requirements of quality, safety and efficacy.

When a generic drug enters the market, its price is typically 25 % lower than that of the originator's product<sup>106</sup>. Generic entry also causes price decrease of the drug and thus brings benefits and savings to health system and consumer. The decrease also means reduction in profits for the originator companies, which facing the generic competition cannot sell the same amount of their brand-name drug nor can do it for the same price prior to the generic entry. Moreover, since generics frequently bring their version of the medicine with new formulation and/or dosage, both types of companies have to compete on improvement of the quality of the drug. In other words, generic entry brings pro-competitive effects on the market and the final beneficiary of the price (and quality of the products) competition between originator and generic pharmaceutical companies is the society.

Several factors have significant impact on the originator-generic competition and the achievement of its desirable outcome depicted above.

First, the European pharmaceutical market is fragmented into the pharmaceutical markets of the Member States, since each of them exercises different policy in the sector. With regard to the pricing policy, Member States are using free pricing system, price-regulated system, or a

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<sup>102</sup> Communication from the Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, (8 July 2009), at p. 2. Available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>, accessed on 6 June 2012.

<sup>103</sup> European Commission, "Pharmaceutical Sector Inquiry: Final Report", *supra* note 3, at para 48.

<sup>104</sup> European Commission, "Pharmaceutical Sector Inquiry: Final Report", *supra* note 3, at para 93-94.

<sup>105</sup> *Ibidem*, at para 89-90.

<sup>106</sup> *Ibidem*, at para 222.



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combination of both<sup>107</sup>. The price regime chosen by a Member State strongly influences the decision of generic companies which national market to enter, when and at what price. For example, price open markets are very attractive to generic companies because of their lucrativeness and the opportunity to share the profits with originators, whereas the pre-conditioned price levels and low profitability margins make generic's entry in price-regulated systems not so likely nor quickly<sup>108</sup>.

Second, Member States intervene and regulate the pharmaceutical market in order to secure that only qualitative, safe and efficient medicines are put on the market<sup>109</sup>. They also support generic entry on the market<sup>110</sup>, since the latter contributes to the price competition between pharmaceutical companies and use of generic drugs reduces public health expenditure<sup>111</sup>.

Third, generic manufacturers not always await the loss of exclusivity by originator companies, especially with regard to the best selling brand-name products. They challenge originator drugs' patents by being invalid or not infringed by their generic version of the medicines. If successful, the generics are able to market their drugs even before the expiry of the originators products' protection.

Finally, the originator companies use variety of strategies to strengthen and prolong the protection granted by law to innovative medicines. Among these strategies are: 1) strategic patenting; 2) patent litigation; 3) patent settlements; 4) intervention before national regulatory authorities; 5) life cycle strategies for follow-on products<sup>112</sup>. These and other strategies are used in different combinations with one another and it is stated that they are amongst the reasons why generic entry is delayed<sup>113</sup>.

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<sup>107</sup> S. SIMOENS, "A review of generic medicine pricing in Europe", *Generics and Biosimilars Initiative Journal (GaBI Journal)*. 2012;1(1):8-12. Available at: <http://gabi-journal.net/a-review-of-generic-medicine-pricing-in-europe.html>, accessed 7 June 2012.

<sup>108</sup> P. DYLST, S. SIMOENS, "Generic medicine pricing policies in Europe: Current status and impact", (5 March 2010) *Pharmaceuticals* 2010, 3, 471-481.

<sup>109</sup> S. ANDERMAN, A. EZRACHI, "Intellectual Property and Competition Law. New Frontiers", Oxford University Press, Oxford 2011. Chapter 11, at p. 248.

<sup>110</sup> European Commission, "Pharmaceutical Sector Inquiry: Final Report", *supra* note 3, at para 92.

<sup>111</sup> S. ANDERMAN, A. EZRACHI, *supra* note 109, at p. 248.

<sup>112</sup> European Commission, "Pharmaceutical Sector Inquiry: Final Report", *supra* note 3, at para 466.

<sup>113</sup> *Ibidem*, at para 1067.

## 2. Features of the demand side.

The demand side of the sector is characterized by the Final Report as “rather unique”<sup>114</sup>. On one hand, typical and mass consumers are not in a position to evaluate properly the pharmaceutical products because of lack of medical and pharmacological knowledge. Their “decisions” what drug to buy largely depend on the doctors’ prescriptions and pharmacists, especially when the latter are allowed to substitute the prescription medicine. On the other hand, the price for prescription drugs is not always borne by the end consumers themselves. The price, or part of it, is paid by state or private health insurers, which actually negotiate it with the manufacturers (originator and generic companies)<sup>115</sup>, in accordance with the price system implemented by the government.

Therefore, the beneficiary of the medicinal products – the patient – is not actually the typical end user who chooses what and at what price to buy. Patients cannot substitute drugs and suppliers of drugs, or they cannot do it with the same ease as in other sectors. Thus, the demand side of the pharmaceutical sector differs significantly from the normal standard of demand in other sectors of economy where consumers evaluate, buy and substitute goods. The demand substitutability as a competitive constraint is not the same “most immediate and effective disciplinary force on the suppliers”<sup>116</sup>. Hence, prices for medicine products are more determined by the interaction between intermediaries like the state and health insurer, on one side, and pharmaceutical companies, on the other, as well as by the competition on the supply side between originators themselves and between them and generic manufacturers.

Originator companies are heavily involved in research and development. However, investing time and money in innovation of new pharmaceuticals is reasonable for companies only when their new products will be shielded by intellectual property law and patent law, in particular. This is because the costs of development of a new drug are enormous, really successful medicines are few and there is a long time between obtaining a patent and market the patented product<sup>117</sup>.

## 3. Intellectual property protection of medicines.

Patent is an intellectual property right which is granted in order to incentivize innovation by permitting the patentee to use its invention and prevent third parties not having his consent to

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<sup>114</sup> *Ibidem*, at para 119.

<sup>115</sup> *Ibidem*, at para 126-127.

<sup>116</sup> Commission notice on the definition of the relevant market for the purposes of Community competition law [1997] OJ C 372 of 9.12.1997, at para 13.

<sup>117</sup> S. ANDERMAN, A. EZRACHI, *supra* note 109, at p. 247.

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use it<sup>118</sup>. Although, material rules with regard to patents are very similar in different Member States of the EU, it could be fairly said that patent system in Europe is not homogeneous and significantly differs from that in the USA, either in its substantive law elements and in the enforcement of patents.

Currently, there is no opportunity for a patent applicant to obtain patent protection that covers all countries in Europe or at least the Member States of the EU. Applicants may proceed in one of the two ways: 1) file applications before national patent authorities for national patents in each or in certain chosen Member States, or 2) file application before the European Patent Office (EPO) for a European Patent<sup>119</sup>. In fact, once granted with European Patent, the patentee has to validate it in each or in certain chosen Member States of the European Patent Convention (EPC). The validation is deemed to be quite costly and time-consuming process<sup>120</sup>.

Patent also grants its holder the right to oppose infringements. Under Art. 22 (4) of Council Regulation (EC) № 44/2001<sup>121</sup> courts of the Member State where patent protection was applied for, have the exclusive jurisdiction over matters concerned with registration and validity of patents. Hence, enforcements of the patent right has to be sought individually for any particular infringement in each particular state where the patent was validated. For instance, in *Roche v. Primus and Goldbenberg* case<sup>122</sup>, the CJEU held that when defendants were different and the infringements were committed in different Member States, and since patents were (and are) governed by national laws<sup>123</sup>, a European patent could be enforced in one proceeding for all infringements committed. In addition, in *GAT* case<sup>124</sup> the CJEU ruled out that courts of one Member State cannot adjudicate upon whether a patent granted by the

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<sup>118</sup> The scope of the patent as recognized by the CJEU: “the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by grant of licenses to third parties, as well as to impose infringements”, Case 15/74, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc.*, [1974] ECR 01147, at para 9.

<sup>119</sup> European Commission, Proposal for a Regulation of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection, COM (2011) 215/3, at p. 1.

<sup>120</sup> *Ibidem*.

<sup>121</sup> Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 012 , 16/01/2001 P. 0001 – 0023.

<sup>122</sup> Case C-539/03, *Roche Nederland BV and Others v Frederick Primus and Milton Goldenberg*, [2006] ECR I-06535.

<sup>123</sup> *Ibidem*, at para 29.

<sup>124</sup> Case C-4/03, *Gesellschaft für Antriebstechnik mbH & Co. KG v Lamellen und Kupplungsbau Beteiligungs KG*, [2006] ECR I-06509.

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patent authority of another Member State is valid or not, since “jurisdiction rests with courts closely linked to the proceedings in fact and law”<sup>125</sup>.

In conclusion, by contrast with the regime in the USA, in Europe common patent that covers all Member States of the EU or those of the EPC does not exist. The European Patent granted by the EPO is a bundle of different national patents. What is more, the European Patent cannot be enforced through the entire EU or the territories of the EPC Member States, but only in states where it has been validated by its proprietor and on a case by case basis. All of this causes significant drawbacks in terms of time and costs of patent litigation, and uncertainty with regard to the outcome of different patent proceedings.

Potential generic entry is not only related with expiration of patent protection. In fact, generic entry is only allowed when the originator medicine loses all of its protections or its exclusivity status. Loss of exclusivity, as defined in the Final Report, consists of patent expiration potentially extended by the Supplementary Protection Certificate (SPC), on one hand, and data and market exclusivity, on the other<sup>126</sup>.

In order to compensate the innovation efforts of pharmaceutical companies, the legislator grants additional period of exclusivity through the SPC. Art. 3 of the Regulation (EC) № 469/2009<sup>127</sup> sets forth cumulative conditions for obtaining SPC. For the certificate are eligible products which at the date of application are protected by patent in force, possess valid market authorization and have not already been subject of the certificate. If granted, the SPC serves as an additional protection for the patent holder after the expiration of the patent itself. This additional exclusivity is for maximum of five years<sup>128</sup>.

A patent proprietor also benefits from data and market exclusivity. Directive 2004/27/EC<sup>129</sup> introduced the so-called 8+2(+1) formula<sup>130</sup>. The formula means the following: patented pharmaceutical product enjoys eight years of data exclusivity plus two additional years of market exclusivity plus one more year given when a new therapeutic indication for (use of) the product was authorized and the indication is with significant clinical benefit<sup>131</sup>. Data exclusivity stays for the period when data obtained by the originator company during clinical

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<sup>125</sup> *Ibidem*, at para 21.

<sup>126</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 49.

<sup>127</sup> Regulation (EC) № 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, [2009] OJ L 152/1.

<sup>128</sup> *Ibidem*, at Art. 13.

<sup>129</sup> Directive 2004/27/EC of 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, [2004] OJ L 136.

<sup>130</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 326.

<sup>131</sup> *Ibidem*, at para 328.

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tests of the medicine is protected. The market exclusivity starts with the market authorization but lasts two years more than data exclusivity. During these two years, generic companies may rely on the data but cannot market its own version of the brand-name product. Hence, generics can enter the market only when ten or eleven years passed after the market authorization of the medicine<sup>132</sup>.

However, generic companies are not in so bad position as it could seem from the above-mentioned. First and with regard to market exclusivity of the brand-name product, they can use the abridged procedure under Art. 10 of Directive 2001/83/EC. According to this provision, when applying for market authorization of generic medicine, generic companies are not required to provide the results of tests or clinical trials but may rely on the results submitted for the brand-name drug. To do so, generics have to demonstrate that their product is essentially similar to the brand-name product, the data exclusivity of the brand-name product has expired and the originator drug is authorized and marketed in the Member State where the generic company applies for market authorization. Second and with regard to patent protection of the originator company's product, Art. 10 (6) of Directive 2001/83/EC as amended by Directive 2004/27/EC introduced a rule which is similar to the American "Bolar" exception. According to this provision, generic companies do not infringe the patent rights or SPC protection granted to the brand-name product when they conduct the necessary research works on this medicine in order to apply for the abridge procedure<sup>133</sup>.

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<sup>132</sup> J.R.SANJUAN, *supra* note 16, at p. 13.

<sup>133</sup> L.HANCHER, "The EU pharmaceuticals market: parameters and pathway", at p. 652. Available at: [http://www.euro.who.int/\\_data/assets/pdf\\_file/0004/138190/E94886\\_ch15.pdf](http://www.euro.who.int/_data/assets/pdf_file/0004/138190/E94886_ch15.pdf), accessed on 11 June 2012.

## Chapter Five

### *Reverse payment (pay-for-delay) settlement agreements in Europe*

Patent settlements were detected by the EU Commission as one of the tools used by originator companies to block or delay generic entry in the market<sup>134</sup>. During the period covered by the Final Report, both types of companies entered into 207 patent settlements as a way to resolve patent disputes, opposition proceedings and mostly patent cases between them<sup>135</sup>. From all settlements concluded, 45 agreements caused delay of generic entry and contained value transfer from the originator to the generic company, at the same time. Namely, these are the reverse payment (pay-for-delay) settlement agreements. The EU Commission did a thorough job to scrutinize and classify them.

Patent settlements are capable to delay generic entry in several ways. A generic company could assume the obligation not to challenge the validity of the brand-name drug's patent and/or not to enter the market prior to the expiry of the patent. The generic could also become a licensee or a distributor of the originator medicine, and even tie his supplies for production of his generic drug with the originator company. Although, license and distributor agreements are deemed to be pro-competitive, they could be used in such a way as to obstruct or at least to make generic opportunities to market their drug dependent on the originator<sup>136</sup>.

There are three main ways in which value is transferred from originator to generic company. It could be done through direct transfer of money, conclusion of side-deals or license agreements. In any of these cases, the brand-name company actually “pays” the generic for delay its entry on the market. However, the originator could allow generic entry prior to the expiration of the patent or in different territory or with different medicinal products<sup>137</sup>.

The first kind of patent settlements is called A-type<sup>138</sup>. Agreements falling into this category do not limit generic entry. They permit the generic company to enter the market after the conclusion of the settlement. Thus, this type of agreements generally does not raise any anti-

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<sup>134</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 466.

<sup>135</sup> Executive Summary of the Pharmaceutical Sector Inquiry Report, *supra* note 102, at p. 12-13.

<sup>136</sup> 1<sup>st</sup> Report on the Monitoring of Patent Settlements, 5 July 2010, at para 8; and 2<sup>nd</sup> Report on the Monitoring of Patent Settlements, 6 July 2011, at para 8.

<sup>137</sup> *Ibidem*, at para 9.

<sup>138</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 741.

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competitive concerns. According to the Final Report, 108 out of 207 patent settlements were A-type<sup>139</sup>.

The second kind of patent settlements is called B-type<sup>140</sup>. Agreements falling into this category limit generic entry. Depending on whether there is a value transfer in B-type agreements, they are further subdivided. B.I. settlements do not contain value transfer and, save in exceptional circumstances<sup>141</sup>, they do not run afoul of competition rules. According to the Final Report, 54 out of 207 patent settlements were B.I<sup>142</sup>. Settlements classified into B.II. category contain a value transfer from the originator to the generic company and this makes them subject to competition law scrutiny without claiming that they are *a priori* anti-competitive<sup>143</sup>.

The EU Commission expressed strong concerns that reverse payment settlements might be anti-competitive and cause harm to consumers and health insurance schemes<sup>144</sup>. The EU Commission acknowledged that due to lack of sufficient experience with such settlements, it was unable to manifest how it would treat them under competition rules<sup>145</sup>. However, the EU Commission explicitly showed that it would further monitor patent settlements and that it was ready to undertake enforcement actions against alleged infringements<sup>146</sup>.

The survey of patent settlements in the pharmaceutical sector continues after the Final Report. The EU Commission issued its 1st and 2nd reports on the monitoring of patent settlements in 2010 and 2011, and the third report is about to be published in the upcoming days. Meanwhile, the EU Commission opened proceedings against *Les Laboratoires Servier*, *Lundbeck*, *Johnson&Johnson* and *Novartis*, *Cephalon* and *Teva*, *AstraZeneca*, and *GlaxoSmithKline*. Both types of action are in the line with the statements of the EU Commission that it would keep on tackling the problem of patent settlements which are used to delay generic entry and raise anti-competitive concerns<sup>147</sup>.

However, in the last two years we observe some surprising outcomes.

Firstly, the total number of patent settlements in the pharmaceutical industry is increasing – 73 and 89 agreements were concluded between originator and generic companies in 2009 and

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<sup>139</sup> *Ibidem*, at para 743.

<sup>140</sup> *Ibidem*, at para 741.

<sup>141</sup> See, Reports on the Monitoring of Patent Settlements, *supra* note 136, at para 13.

<sup>142</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 743.

<sup>143</sup> *Ibidem*, at para 763.

<sup>144</sup> *Ibidem*, at para 1572-1573.

<sup>145</sup> *Ibidem*, at para 1351.

<sup>146</sup> *Ibidem*, at para 1574-1575.

<sup>147</sup> *Ibidem*, at para 1608.

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2010, respectively. Meanwhile, out of the total percentage of patent settlements the percentage of concluded B.II. settlements is decreasing sharply from 22% in the Final Report to 3% in 2010<sup>148</sup>. Although the exact reasons for both trends are not stated<sup>149</sup>, it could be said that despite the increased inclination of companies to settle, the number of type B.II. settlements diminished and only 3 such agreements were concluded in 2010<sup>150</sup>.

Such figures could be misleading, though. The overall percentage of B.II. settlements is decreasing, but if we take a look at the number of such settlements concluded through the years the picture is slightly different. From 2000 to 2010 there were concluded in total 57 type B.II. settlements, or 5.18 such settlements were concluded per year, on average. Hence, it could be inferred that the number of type B.II settlements is relatively steady and actually the drop is found only for the last period surveyed. It would be too audacious to conclude that such settlements are about to disappear only on the basis of data from 2010 or by playing with statistics and percentages, and in the eve of the upcoming 3rd Report.

Secondly, while the majority of the proceedings opened by the EU Commission are still pending, investigations into *AstraZeneca* and *GlaxoSmithKline* were ceased in the beginning of March 2012. There is still no information available about the reasons which led to discontinuance of both proceedings. Perhaps, difficulties to bring agreements that delay or block generic entry under Art. 101 and Art. 102 TFEU could be amongst the causes.

However, the claimed diminishing number of type B.II. settlements and closure of proceedings could serve as a forerunner of changed position by the EU Commission with regard to reverse payment settlement agreements. The upcoming 3<sup>rd</sup> Report will provide us with more accuracy towards this point.

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<sup>148</sup> 2<sup>nd</sup> Report on the Monitoring of Patent Settlements, 6 July 2011, at para 35.

<sup>149</sup> *Ibidem*, at para 20.

<sup>150</sup> *Ibidem*, at para 31.



## Chapter Six

### *Reverse payment settlement agreements and Art. 101 TFEU*

In principle, patent settlements are recognized by the EU Commission as an acceptable mean to put an end to a disagreement between originator and generic company<sup>151</sup>. However, they are by their nature commercial agreements between private parties and their provisions are intended to preserve the parties' own private interests. Such decisions are far from being always socially efficient<sup>152</sup> and, even worse, settlements could have severe anti-competitive effects as being tailored to harm competitors and consumers. As already pointed out, the EU Commission is concerned with type B.II. settlements or reverse payment settlements, as well as with agreements that go outside the scope of the exclusive rights granted by a patent or are concluded as a means to resolve vexatious litigation or dispute<sup>153</sup>.

Patent settlements which put an end of a dispute are agreements between undertakings and on an equal footing could be caught by Art. 101. Indeed, in *Bayer v. Süllhöfer* case<sup>154</sup> the CJEU held that there is “no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind”<sup>155</sup>. However, Art. 101 TFEU could be applied to patent settlements, and type B.II. settlements in particular, only when the conditions stipulated in the provision are met by such agreements.

Thus, the analysis will be tailored to whether reverse payment settlements restrict competition by object or by effect when examined under Art. 101. From the outset it should be pointed out that “by object” and by “effect” are used as alternatives in the provision and once is proved that an agreement restrict competition by object, it is not necessary to examine whether the agreement restricts competition by effect. Also, reverse payment settlements are concluded between manufacturers of medicine which are both on the supply side of the pharmaceutical market and are competitors, hence the agreements between them are of horizontal cooperation and could affect inter-brand competition.

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<sup>151</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 707.

<sup>152</sup> M.A.LEMLEY, “A new balance between IP and Antitrust”, (2007) John M. Olin Program in Law and Economics, Stanford Law School, *Working Paper No 340*, at. p. 19.

<sup>153</sup> See, Reports on the Monitoring of Patent Settlements, *supra* note 136, at para 13.

<sup>154</sup> Case 65/86, *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer*, [1988] ECR 05249.

<sup>155</sup> *Ibidem*, at para 15.

## 1. Reverse payment settlements and restriction of competition by object.

Agreements that restrict competition by object are those which are considered “*by their very nature, as being injurious to the proper functioning of normal competition*”<sup>156</sup>. Horizontal agreements that contain provisions as price fixing, output limitations or sharing of markets or consumers are deemed to fall into that category<sup>157</sup>. However, this is not an exhaustive list and agreements that do not contain such hardcore restrictions, when investigated on an individual basis and with regard to the specific legal and economic context in which they were concluded and performed, could also result in restriction of competition by object<sup>158</sup>. It is worth noting that, as distinct from the USA regime, where under Section 1 of Sherman Act price fixing and market division are per se “*illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use*”<sup>159</sup>, in Europe it is possible to justify an infringement by object under Art. 101(3) TFEU, although it is difficult to do so.

Reverse payment settlements seem to restrict completion by object, since the delay of the generic company to entry allows the originator to preserve market(s) for commercialization of its own patented medicine (sharing of markets) or to maintain prices for that medicine (price-fixing). The significant difference in the case of reverse payment agreements is that the brand-name company possesses a patent and by entering into an agreement resolving patent dispute with the generic, the originator actually does nothing more than exercise the exclusionary rights conferred on it by the patent. Once granted, the patent is presumed to be valid, and its proprietor could block or delay market entry by competitors which are trying to enter with products infringing the patent.

It is worth noting that, as distinct from the USA, in Europe a patent settlement blocks the entry of the generic, but it cannot serve as a deterrent to subsequent candidates to enter into the market. Other generic companies could challenge the originator’s patent, despite a previous patent settlement, and could do so in different Member States. Hence, a reverse payment settlement concluded in Europe does not give the originator a free hand to use its patent rights without being threatened with subsequent attack by other generic companies in one or more different Member States’ markets.

However, a patent grants determinate scope and period of protection to its holder. The patentee is not allowed to go any further in exercising its rights and opposing infringements

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<sup>156</sup> Case C-8/08, *T-Mobile Netherlands BV and Others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit*, [2009], at para 29.

<sup>157</sup> Commission notice – Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements; OJ 2001/C 3/02.

<sup>158</sup> See, *T-Mobile case*, *supra* note 156, at para 31.

<sup>159</sup> Case *Northern Pacific Railroad Co. v. United States*, 356 U.S. 1, 5 (1957), Supreme Court of the USA.

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than within the protection granted. Thus, a patent settlement will restrict competition by object when it delays the generic entry even after the period of protection of the patent or when limits output and sales of non-infringing the patent generic medicines<sup>160</sup>. However, given the increased scrutiny of the EU Commission over patent settlements in the pharmaceutical sector, it would be very unlikely that originator and generic companies would enter into such agreement.

Another restriction of competition by object could be found in the case when the originator company would not have been granted with the patent at all. Such issue could arise when the “patent” was not new and/or did not involve inventive step and the brand-name company knew about it at the time of filing the application. This means that the patent was granted in error by the patent office due for example to patentee misleading actions to conceal that the novelty is destroyed<sup>161</sup>. It should be recalled that under the case law of CJEU “*it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error*”<sup>162</sup>. Therefore, taking advantage of patent protection to which it is not entitled and restricting competitor(s) on this ground, will bring originator company under the responsibility for infringing Art. 101 TFEU and competition by object. The significant impediment in finding such an infringement is that patentee’s prior knowledge of the invalidity of its own patent should be revealed and proved by the competition authorities.

Thus, given the inherent exclusionary rights to a patent and significant difficulties to prove that a patent was granted in error, it would be a rare occasion for the EU Commission catch patent settlement(s) as restricting competition by object.

## **2. Reverse payment settlements and restriction of competition by effect.**

An agreement is restrictive by effect when it affects actual or potential competition to such an extent that on the relevant market negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability<sup>163</sup>. However, there is no presumption of restrictive effects and the latter must be proved to be appreciable in order to catch the agreement under Art. 101 TFEU. Thus, the agreement has to

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<sup>160</sup> S. ANDERMAN, A. EZRACHI, “*Intellectual Property and Competition Law. New Frontiers*”, Oxford University Press, Oxford 2011. Chapter 12, at p. 293.

<sup>161</sup> *Ibidem*.

<sup>162</sup> Case 193/83, *Windsurfing International Inc. v Commission of the European Communities*, [1986] ECR 00611, at para 92.

<sup>163</sup> Communication from the Commission — Notice — Guidelines on the application of Article 81(3) of the Treaty; OJ C 101, 27.4.2004, p. 97–118; at para 24.

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be examined in its market context, the market power of the parties which concluded it and the agreement itself and its clauses.

The relevant market comprises the relevant product and the relevant geographic market. Since, pharmaceutical markets in different Member States vary significantly one from another due to state intervention and price policies, amongst other factors, it would be fair to conclude that each Member State's market will be separate relevant geographic market as distinct from “*neighboring areas* (other Member States' markets) *because the conditions of competition are appreciably different in those areas*”<sup>164</sup>. To determine the relevant product market, the specificity of the product – medicines – should be considered, as well as the fact that the consumer is usually not able to assess the substitutability of different drugs. However, guided by the decision of EGC in *AstraZeneca* case<sup>165</sup>, it is sensible to conclude that the product market for a drug is determined by the therapeutic effects of the medicine and how it is used in medicinal practice. Thus, a single medicine could form a single market if it is distinct from other medicines with regard to its matchless therapeutic effects or could form part of the market of drugs used to treat particular (form of) disease.

The assessment of market power of the companies entering into a patent settlement is necessary in order to examine its significance and potential to affect trade between Member States. According to the *De Minimis Notice*<sup>166</sup>, agreements that are not capable to appreciably affect trade between Member States do not fall under Art. 101 TFEU<sup>167</sup>. Given the definitions of small and medium-sized undertakings and the threshold of 10% of the aggregate market shares in the *De Minimis notice*<sup>168</sup>, as well as the trends of concentration between pharmaceutical companies<sup>169</sup> and the annual turnover they realize, it is quite unlikely that the *De Minimis Notice* could be applied in this case.

Therefore, the narrow definition of pharmaceutical product market and the market power of undertaking concerns, as well as the likelihood that such an agreement will deal with patent disputes which take place in different Member States with regard to the same European patent (validated in these Member States), give stable grounds to tackle the issue as affecting trade between Member States to an appreciable extent. Moreover, the EU Commission itself

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<sup>164</sup> Commission Notice on the definition of relevant market, OJ C 372, 9.12.1997, at para 8.

<sup>165</sup> Case T-321/05, *AstraZeneca AB and AstraZeneca plc v European Commission*, [2010] ECR II-02805.

<sup>166</sup> Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81, OJ C 368, 22.12.2001.

<sup>167</sup> *Ibidem*, at para 3.

<sup>168</sup> *Ibidem*, at para 3 and 7a.

<sup>169</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 87 and 105, respectively.

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considers that it is more appropriate to deal with patent settlements as restricting competition by effect<sup>170</sup>.

However, the problem to catch reverse payment agreement under Art. 101 as restrictive of competition by effect is the more or less the same as with restriction of competition by object. The originator company has a valid patent. The question is why does it choose to pay the generic competitor(s) to stay out of the market, then?

The presumably valid patent rights should be examined in the light of the value transfer, its amount and form.

First, the EU Commission itself seems prone to criticize and attack reverse payment agreements on the basis of weak patents<sup>171</sup>. As it shows in Table 21 of the Final Report the probability of winning or losing a patent case, in other words the strength of the patent, is considered to be the major factor inducing originator company to enter into an agreement. The difficulty is how the patent at stake will be assessed. Apparently, the burden will rest on the EU Commission. It will have to appraise the scope of the patent and prove that the IP holder did something that it is beyond that scope. However, according to the case law “*the Commission is not competent to determine the scope of a patent*”<sup>172</sup>, but it could carry out such analysis in order to assess whether there is infringement of competition rules. The problem is that pharmaceutical patents are rather complex and have nothing to do with evaluation of mechanical patents as in *Windsurfing* case. With regard to pharmaceuticals, a vast chemical knowledge in the specific area of the patent is needed<sup>173</sup>. Hence, even a non-determinative assessment of the patent from part of the EU Commission is unlikely to be rendered. Which is more, in patent law there are no weak and strong patents, but just patents. Therefore, such division of patents is artificial and is not backed up with any legal grounds to be carried out.

Second argument against attacking reverse payment settlements on the basis of patent strength is that the EU Commission would actually have to predict the outcome of patent dispute if it was not settled by the parties. Such approach seems reasonable given the high percentage of patent cases won by generic companies against originators. However, pharmaceutical patents are sophisticated and patent litigation as specific is dealt with in specialized courts (in most of the Member States). Thus any prediction by the EU Commission is likely to be at least not well-founded. Moreover, patents are still national rights and the EU Commission will have to

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<sup>170</sup> *Ibidem*, at para 1530.

<sup>171</sup> *Ibidem*, at para 720.

<sup>172</sup> *Windsurfing* case, *supra* note 162, at para 26.

<sup>173</sup> *See*, S. ANDERMAN, A. EZRACHI, *supra* note 160, at p. 296.

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examine the specific rules, procedures and case law in the Member States where patent was challenged, which make its task even more cumbersome. Also, relying on statistics of cases won or lost is far from sensible, since statistics could change in the future<sup>174</sup> and involves high risks that competition intervention would not take into account the percentage of cases won by the patent holders and that the particular patent could be upheld valid by the court. Lastly, if the patent validity is confirmed by the court, the generic would enter the market only after the regular expiration of patent or related (SPC) protection<sup>175</sup>. Since many reverse payment settlements allow earlier entry for the generic, it could be fairly said that they, in absence of prior invalidity known by the patentee, are preferable to litigation till the final decision is rendered.

Therefore, decision on whether reverse payment settlement is anti-competitive by effect should not be made by assessment of patent validity. EU Commission, as well as EGC and CJEU, are not well-equipped to judge on pharmaceutical patents. Moreover, if delivered such decision would bear the mark of “guesswork”. This would undermine the legal certainty while dealing with reverse payment cases, as well as the value of the decision itself.

The other main aspect of reverse payment settlements is the value transfer. Actually, the payment brings completion law scrutiny over these agreements and their probable illegality. That is why originator preserves its position on the market of a certain drug, the generic is paid to stay off and consumers (and health insurers) are bearing the negatives of both parties` agreement as continuing to pay high prices for the medicine.

Judging the effects on competition of reverse payment settlements in the light of the value transfer is fairer since it encompasses the behavior of both undertakings. Moreover, the value transfer is the meeting point of the firms` mutual interests and indication of possible collusive behavior.

First, it is hinted that when the value transfer exceeds the likely generic`s profits, the settlement would be anti-competitive<sup>176</sup>. This is not a solid ground to tackle reverse payment settlements, since the likelihood of profits is dependent on number of variables. At least, in Europe there is no 180-days of bounty period as in the USA and the price of the drug is also contingent on subsequent generic entries. Moreover, if the payment is lower than the expected returns for the generic, it does not mean that the settlement is not running afoul of competition

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<sup>174</sup> In view of the fact of “*raise the bar*” policy of the EPO (See, <http://www.epo.org/about-us/office/annual-report/2008/focus.html>) and/or adoption of common EU patent and litigation rules.

<sup>175</sup> J.DREXL, “Real knowledge is to know the extent of one`s own ignorance: On the consumer harm approach in innovation related competition cases”, Max Planck Institute for Intellectual Property, Competition and Tax Law, at p. 28, available at: <http://www.ssrn.com/abstract=1517757>.

<sup>176</sup> See, ANDERMAN, A. EZRACHI, *supra* note 160, at p. 299.

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rules, as the payment is made on the basis of companies' own predictions of what is appropriate and their position in the negotiations. Hence, such an approach must not be adopted since it would be based on speculations.

Second, an adoption of the approach, sustained by the FTC and proposed as a legislation in the Kohl bill, that when payment exceeds certain amount of money it is indicative of the anti-competitive effects of the settlement, it is also not very suitable. It does not take into account the market power of the undertakings concerned and, which is more, the value of the patent and protected medicine. Thus, such threshold could be too low or too high depending on the profitability of the drug at stake. In addition, binding the threshold with estimated costs of litigation is also not correct. The agreement could be used to settle different cases in different Member States and litigation costs also vary from one state to another making the proper fixing of such sum quite difficult.

Third, settlement of patent dispute with one generic does not prevent subsequent challenges and generic entries. The originator could find himself involved in a number of litigation proceedings in different markets with different generic companies. Despite how sure is he in the strength of his patent, there are always risks associated with litigation and in particular with decisions invalidating its patent in certain Member States and confirming its validity in others. Thus, the originator must be allowed to use patent settlements to remove the uncertainty in the outcome of the proceedings and pay to generics in order to induce them to enter into agreements. Further, such an approach is consistent with the notion that each company needs freedom to deal with each case on its own individual merits<sup>177</sup>.

In essence, tying certain amount of or just value transfer with anti-competitive effects seems risky and not well-grounded in Europe. Besides, not all reverse payment settlements contain a pure value transfer. Agreements could be more complicated, since they could be accompanied by side deals, license or distributor agreements, which must be further evaluated. Pharmaceutical companies also need certainty and freedom when settle patent without doubting whether the EU Commission would second-guess the fair value transfer for their agreement<sup>178</sup>.

### **3. Non-challenge clauses and license agreements as part of reverse payment deals.**

Specific provisions in patent settlements could also raise anti-competitive concerns. The obvious example is the non-challenge clause which is typical for agreements that dispose of

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<sup>177</sup> *Ibidem*, at p. 297.

<sup>178</sup> *Ibidem*, at p. 300.

attacks on the validity of a patent. The stand of the EU Commission on this point is that such clauses do not fall in Art. 101, since they are inherent for such agreements which very purpose is to “*settle existing conflicts and/or to avoid future disputes*”<sup>179</sup>. In *Bayer v. Süllhöfer* case the EU Commission made a proposal that a non-challenge clause is compatible with Art. 101 provided that the aim of the agreement is to put an end of litigation, the IP right at stake is valid and the non-challenge clause relates to it, and there are no other provisions that restrict competition<sup>180</sup>. However, the case law differs. First, the stand of CJEU is that a non-challenge clause “*clearly does not fall within the specific subject-matter of the patent, which cannot be interpreted as also affording protection against actions brought in order challenge the patent’s validity*”<sup>181</sup>. Second, in *Bayer v. Süllhöfer* case the CJEU refused the EU Commission’s approach as unacceptable. It further stated that “*a no-challenge clause included in a patent licensing agreement may, in the light of the legal and economic context, restrict competition*”<sup>182</sup>, unless the license is free or for outdated technology. Hence, there is not a firm rule how a non-challenge clause would be treated in the future. It is likely that the EU Commission will follow its previous practice and guidelines. These could serve to undertakings as instructions how to design such clauses in their agreements in order to avoid EU Commission’s interventions. Yet, EU Commission methods and guidelines are not binding for EGC and CJEU, and its plausible to believe that they will decide a future case in a manner consistent with the previous case law.

License agreements, as part of patent settlements, also raise competition law concerns, since originators could them to delay generic entry, as well as a form of value transfer. This seems to contradict the fundamental position that licensing itself is enhancing economic efficiency and is pro-competitive<sup>183</sup>. Indeed, licensing is generally compatible with Art. 101 TFEU, unless an exclusive license agreement prohibits passive sales or a license agreement contains hardcore restrictions on competition. Certain conditions are provided in TTBER – market-share thresholds and no hardcore nor excluded restrictions in the agreements – which once met, exempt the license agreement from the application of Art. 101. Although, it is unlikely in the context of a reverse payment settlement that the concomitant license agreement fulfills the market-share conditions, it must be assessed individually and TTBER and its Guidelines

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<sup>179</sup> Commission Notice. Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements; [2004] OJ C 101/02, at para 209.

<sup>180</sup> *Bayer v. Süllhöfer* case, *supra* note 154, at para 14.

<sup>181</sup> *Windsurfing* case, *supra* note 162, at para 92.

<sup>182</sup> *Bayer v. Süllhöfer* case, *supra* note 154, at para 16.

<sup>183</sup> Commission Regulation № 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (TTBER), OJ L 123, 27.4.2004, p. 11–17, at para 5 (recitals). See, Commission Notice, *supra* note 179, at para 9.



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should be applied to it by analogy<sup>184</sup>. Thus, private parties must use TTBER and the Guidelines in order to design license clauses/agreements in a way compatible with competition law. This would not be the case when the originator imposes an obligation on his licensee (the generic) not to use competing technology<sup>185</sup>. In *BAT* case<sup>186</sup> the CJEU held that when an agreement serves no other purpose than that of enabling one undertaking to control and prevent the marketing of goods produced by the other contracting party on certain market, it runs afoul of Art. 101<sup>187</sup>. Hence, any prohibition on the generic, which is beyond the scope of the IP licensed, in the context of reverse payment settlements would block the generic entry and prevent generic company from determining freely its behavior on the market. The situation would be all but not changed when the license is free or for outdated technology as stated in the *Bayer v. Sülhölfer* case. It is almost unlikely that the originator would grant free license to other generics and the obsolescence of the technology is speculative when, for example, it is related to the old formulation of de facto the same drug. Thus, the licensing would constitute a pure value transfer and provoke serious competition law issues<sup>188</sup>.

#### **4. Possible approaches towards reverse payment settlements when examined under Art. 101 TFEU.**

Dealing with reverse payment settlements under Art. 101 is far from being an easy task. The lack of common EU-patent and fragmentation of the pharmaceutical market in Europe constitute additional burdens to implement one decision or another. Thus, it is not surprising the fact that the EU Commission has not so far elaborated clear position on the issue of reverse payment agreements. Although, this is a matter of future decision, the possible variants could be summarized in three groups. First, declare all reverse payment settlements *per se illegal*. Second, declare them *per se legal*, except when they exceed the scope of the patent or the patent is sham. And third, tackle them on a case-by-case basis.

Complete ban on reverse payment settlements would significantly alleviate the workload for EU Commission and courts. They would not have to make decisions after considering burdensome questions of patent validity, form and amount of value transfers, nor after conveying counterfactual analysis what would be the situation without the settlement. They would only need to detect the reverse payment and declare the entire settlement void<sup>189</sup>. At

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<sup>184</sup> Commission Notice, *supra* note 179, at para 37,40 and 130.

<sup>185</sup> See, Commission Notice, *supra* note 179, at para 12(a).

<sup>186</sup> Case 35/83, *BAT Cigaretten-Fabriken GmbH v Commission of the European Communities*, [1985] ECR 00363.

<sup>187</sup> *Ibidem*, para 37-38.

<sup>188</sup> See, ANDERMAN, A. EZRACHI, *supra* note 160, at p. 285.

<sup>189</sup> J.DREXL, *supra* note 175, at p. 29-30.

the same time, to prohibit reverse payment agreements seems a radical measure. Such an approach does not take into account the specificity of different settlements and the rationale behind them. Moreover, there are serious arguments that reverse payment settlements are not anti-competitive like not each settlement is concluded because of “weak” patent and an agreement could allow generic entry prior to expiry of the protection enjoyed by the originator product.

The second approach resembles the stand taken by the majority of USA Appellate Courts. To summarize it, when the settlement is within the scope of the patent at stake, it is valid. There is serious rationale behind this position – it leaves the question of patent validity to experts and let parties free to decide which patents are worth challenging and which cases are worth settling. Furthermore, settlements are deemed to have no bigger competitive effects than the patent has<sup>190</sup>, which ground is further strengthened when the agreement allows generic entry prior to the expiration of the patent. However, such an approach is subject to heavy criticism from part of competition authorities and scholars, and it is likely that forthcoming changes in legislation would put an end to the reverse payment settlements in the USA, the way we know it now. Moreover, pure adoption of the almost *per se legality* approach does not seem very suitable for Europe where the presumption of patent validity is weaker than in the USA and the legal framework is completely different.

Finally, a case-by-case dealing with reverse payment settlements is in conformity with the manifested stand of the EU Commission that not every settlement is presumed to be anti-competitive<sup>191</sup>, as well as with the case law. In addition, the characteristics of each settlement would be carefully considered before a final judgment on it is rendered. However, the serious drawback of this approach is that it deprives private entities of legal certainty. Their agreements would be exposed on the second-guessing of the EU Commission and eventually courts, without any predictability of the outcome of such investigations and court proceedings.

A combination of case-by-case analysis plus a list of certain criteria what would be considered as anti-competitive could greatly reconcile the strengths and weaknesses of the three approaches. In addition, undertakings would know what they could and what could not include in their settlements without being under the threat of competition proceedings. Moreover, in the area where IP law and competition law interact, establishing a set of criteria

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<sup>190</sup> S. ANDERMAN, A. EZRACHI, *supra* note 109, at p. 273.

<sup>191</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 1530. *See*, Reports on the Monitoring of Patent Settlements, *supra* note 136, at para 14.

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in order to assess the behavior of the private entities would not be anything new (e.g. in the *IMS* case<sup>192</sup>).

A future reverse payment settlements' set of criteria could be based on the following grounds:

Reverse payment settlements are lawful, unless they: a) exceed the scope of the patent at stake; and/or b) are concluded in sham litigation; and/or c) contain large value transfer from the originator to the generic which transfer constitutes the only plausible justification for the delay of generic entry<sup>193</sup>. When one of the above-mentioned criteria is fulfilled, the settlement would be caught under Art. 101. Thus, the EU Commission would have firm grounds to attack them, leaving the burden to prove the contrary to the parties of the agreement. Since, the contracting parties are in the best position to rebut the presence of condition(s) that make(s) the agreement anti-competitive and also to claim that Art. 101 (3) should be applied in the case. Such an approach gives certainty to both EU Commission and private undertakings, and also fairly distributes between them the onus of proving their allegations and arguments.

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<sup>192</sup> Case C-418/01, *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG*, [2004] ECR I-05039.

<sup>193</sup> ANDERMAN, A. EZRACHI, *supra* note 160, at p. 300.

## Chapter Seven

### *Reverse payment settlement agreements and Art. 101 TFEU*

Besides Art. 101, EU Commission could tackle reverse payment settlements in Europe under Art. 102 for abuse of dominant position. In order to do so, it would have to prove three things – dominant position, abuse and that the abuse affects trade between Member States.

As shown above, it is quite likely that a reverse payment settlement, as putting an end to patent disputes in different Member States with regard to the same European patent, affects trade between Member States.

#### **1. Dominant position in case of reverse payment settlement.**

Since in reverse payment settlement a patent is involved, it should be noted from the very outset that although the patent gives its proprietor exclusive rights, it does not confer dominance to its holder<sup>194</sup>. Hence, other factors should be taken into account, along with the IPR at stake, in order to infer dominant position. The decision of EGC in *AstraZeneca* case, as concerning patent and SPC, gives us valuable guidelines on how the EU Commission and courts will proceed. First, they will look at the market shares as evidence of market power. It was already shown that an originator company with a successful medicine is likely to enjoy large market power. In *AstraZeneca* case was further stipulated that an undertaking with high market shares which were higher than those of its competitors was a relevant indicator of its market power<sup>195</sup>. Second, price levels of the medicine at stake would be considered. Prices for pharmaceuticals in Europe are “*not the result of normal market forces*”<sup>196</sup>, however in the *AstraZeneca* case it was found that an undertaking with large market share is able to maintain high market prices independently of its competitors, health insurers and patients<sup>197</sup>. In addition, in *Syfait II* case<sup>198</sup> the CJEU explicitly stipulated that “*the control exercised by Member States over the selling prices or the reimbursement of medicinal products does not*

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<sup>194</sup> Case 24-67, *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm*, [1968], “*the exercise of the rights under a patent... does not, of itself, constitute an infringement of the rules of competition...*”. Joined cases C-241/91 P and C-242/91 P, *RTE and ITP v Commission of the European Communities*, [1995] ECR I-00743, at para 46 “*mere ownership of an intellectual property right cannot confer such a position*”.

<sup>195</sup> *AstraZeneca* case, *supra* note 165, at para 253.

<sup>196</sup> *Ibidem*, at para 265.

<sup>197</sup> *Ibidem*, at para 266.

<sup>198</sup> Joined Cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proionton, formerly Glaxowellcome AEVE*, [2008] ECR I-07139.

entirely remove the prices of those products from the law of supply and demand<sup>199</sup>. Thus, according to the case law, whatever the pricing policies are adopted by different Member States, pharmaceutical companies have influence in the pricing. Third, although holding a patent does not mean dominant position, the patent protection of the medicine allowed *AstraZeneca* to exert significant pressure on its competitors<sup>200</sup>. Fourth, the first-mover status by an undertaking entering the market with a new, innovative drug, gives it an appreciable competitive advantage over its competitors<sup>201</sup> and thus, further strengthens its dominant position as an originator company. Last, the financial power and superior resources also contributed to the assessment that *AstraZeneca* was in a dominant position.

It is easy to foresee that in a case of reverse payment settlement, similar analysis would be conveyed and the same conclusions would be drawn. Hence, it is plausible to believe that an originator company, party to such agreement, would be found to enjoy dominant position on the market.

## 2. Abuse of dominant position in case of reverse payment settlement.

In *Parke, Davis and Co.* case the CJEU held that although a patent confers on its holder a special protection, its exercise could imply abuse of a dominant position when and only if such exercise of the patent were to degenerate into an abuse, thus leaving opened the possibility to find infringement of Art. 102 when the IP holder does not use its rights properly. The subsequent case law developed this general stand and delineated when use of IP rights could lead to abuse of the dominant position. However, the issue of reverse payment settlements does not seem in line with the previous practice and the EU Commission would have to establish a new type of abuse<sup>202</sup>. It would be facilitated by the fact that behavior of the dominant undertaking which has the potential to affect competition on the market is sufficient to prove abuse without showing actual harm. Judgment in *AstraZeneca* case, as well as other strategies used by originator companies to block or delay generic entry, could lend a hand to the EU Commission in applying Art. 102.

First, as specified in the Final Report, patent settlements are one of the instruments used by originators in their competition with generics. A reverse payment settlement used in combination with some other strategies – strategic patenting, patent disputes, interventions before national regulatory authorities or life cycle strategies – could uncover a line of conduct

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<sup>199</sup> *Ibidem*, at para 61.

<sup>200</sup> *AstraZeneca* case, *supra* note 165, at para 272.

<sup>201</sup> *Ibidem*, at para 278 and 280.

<sup>202</sup> ANDERMAN, A. EZRACHI, *supra* note 160, at p. 300.

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which is contrary to methods used in normal competition on the merits. Such approach could be grounded on the second abuse in *AstraZeneca* case where was found that the follow-on strategy of selective deregistration and removal from market of one drug formulation and simultaneous introduction of a new formulation of the same product is an abuse of dominance, since it permitted the originator to restrict the market for generic products<sup>203</sup>. Since it is possible to find abuse by the originator company for using one strategy against generic competitors, it would be even more reasonable to expect that the brand-name company abuses its position when it is using more instruments to block or delay entry. Moreover, an originator company in a dominant position “*has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market*”<sup>204</sup>. The likelihood that a combination of different strategies used against generics (and against other originators) is in line with such special responsibility is more than doubtful. Further, since abuse is an objective concept, the EU Commission does not have to prove intention from part of the originator company to abuse its dominance.

Second, in *AstraZeneca* case the first abuse consisted of submission of misleading information to patent authorities to obtain SPC protection to which the firm was not allowed or was allowed for a shorter time. In other words, the additional protection was granted in error and it was deemed as “*falling outside the scope of competition on the merits*”<sup>205</sup>. Thus, any behavior from part of an originator that is tailored to fraud public procedures and institutions could be catch under Art. 102 as leading to serious anticompetitive effects. For example, brand-name company, party to a reverse payment settlement, which is shielding its successful medicine with a number of secondary and not so strong patents, and/or engages in many litigation proceedings, could be found to abuse public procedures and try to “*maintain its exclusivity beyond the period envisaged by the legislator*”<sup>206</sup>. Thus, a combination of dominant originator firm’s actions could lead to the conclusion that the undertaking abused its dominant position.

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<sup>203</sup> European Commission, “Pharmaceutical Sector Inquiry: Final Report”, *supra* note 3, at para 864.

<sup>204</sup> Case 322/81, *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 03461, at para 57.

<sup>205</sup> *AstraZeneca* case, *supra* note 165, at para 355.

<sup>206</sup> *Ibidem*, at para 367.

### 3. Vexatious litigation and reverse payment settlement.

Vexatious litigation is other example how a reverse payment settlement in combination with other factors could be caught under Art. 102. A case of sham litigation decided by European court is the *ITT Promedia* case<sup>207</sup>.

In principle, private parties can legitimately assert their rights before courts. Then, it seems rather problematic that initiating a legal proceeding by dominant undertaking constitutes an abuse, unless there are some exceptional circumstances<sup>208</sup>. In *ITT Promedia* case, the CFI upheld the two-steps test invented by the EU Commission when a litigation could constitute an abuse of dominant position. The test is strict, since it constitute an exception to a general rule, and it could be applied only when the claim fulfills two cumulative conditions: 1) it cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and can therefore only serve to harass the opposite party; and 2) it is conceived in the framework of a plan whose goal is to eliminate competition<sup>209</sup>. In other words, the claim must be unfounded and aimed at eliminating competition when considering the whole situation at the moment of its lodgement<sup>210</sup>. In addition the application of the test is not bound by the existence of the right at stake, but it is enough to find that the claim was intended to assert what that undertaking could, at that moment of bringing the action before court, reasonably consider to be its rights<sup>211</sup>.

The *ITT Promedia* case is a precedent of sham litigation in Europe, but it case provides valuable insights how will be proceeded with vexatious litigation in case of reverse payment settlement. First, EU Commission and courts will consider the agreement in its relation to the litigation itself and both as instruments to delay generic entry. Second, speculations about the validity of the patent at stake and what the patent holder considers about the patent would be avoided, simplifying the burden of proof. Hence, the analysis of the situation would be done on objective grounds by use of facts and evidences. Furthermore, it is a settled case law that, in specific circumstances, the dominant firm is deprived to undertake actions or measures which generally would not be subject to competition law objections, but precisely the special responsibility of the dominant firm gives them the brand of abuse<sup>212</sup>. Even a conclusion of contract (e.g. reverse payment settlement) could be an abuse under Art. 102 TFEU when the agreement is concluded by a dominant company<sup>213</sup>. Although, a supplementary element,

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<sup>207</sup> Case T-111/96, *ITT Promedia NV v Commission of the European Communities*, [1998] ECR II-02937.

<sup>208</sup> *Ibidem*, at para 60.

<sup>209</sup> *Ibidem*, at para 55

<sup>210</sup> *Ibidem*, at para 72.

<sup>211</sup> *Ibidem*, at para 73

<sup>212</sup> *Ibidem*, at para 139.

<sup>213</sup> *Ibidem*.

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external to the agreement, is not necessary for finding abuse<sup>214</sup>, a sham litigation and other strategies used by the originator could significantly contribute to the assessment that the brand-name company, party to a reverse payment settlement, abused its dominant position.

#### **4. Justification of the conduct of the originator company.**

Once a brand-name company has found to abuse his dominant position, he will have at his disposal three lines of defense. However, none of them seems to be of use in this case. First, objective justification is determined on external factors, like public health and safety, which are decided by public authorities. Thus, it is quite unlikely that the dominant firm's exclusionary conduct of delaying generic entrants could be objectively necessary and proportionate<sup>215</sup>. Second, under meeting competition defense the dominant firm is allowed to protect its commercial interests when the latter are attacked. Yet, the originator could hardly prove that engaging in a number of strategies to block or delay generic entry is reasonable and not specifically designed to strengthen its dominant position nor to abuse it<sup>216</sup>. Finally, under efficiency defense the brand-name company has to show that his actions are preventing generic entry is justified on the grounds of future efficiency gains (e.g. improved quality of medicines or lower prices). However, it is far from conceivable that such gains could be achieved with preventing generic entry on the market and that the originator's conduct was indispensable<sup>217</sup>.

#### **5. Conclusion.**

Art. 102 offers several advantages of tackling reverse payment settlements in Europe. The EU Commission and courts do not have to make judgments on the validity and strength of the patent at stake, nor to second-guess the appropriate size of the value transfer. Thus, their decisions would not be based on speculations nor would undermine the integrity of the patent system in Europe and the right of undertakings to carry out freely their business and settle disputes between them. In addition, a reverse payment settlement would not be examined alone but in its relation to other practices and methods to block or delay generic entry, which

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<sup>214</sup> Case T-51/89, *Tetra Pak Rausing SA v Commission of the European Communities*, [1990] ECR II-00309, at para 24.

<sup>215</sup> See, Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings; OJ C 045, 24/02/2009, P. 0007 – 0020, para 28

<sup>216</sup> *Syfait II* case, *supra* note 198, at para 50. Case C-52/07, *Kanal 5 Ltd and TV 4 AB v Föreningen Svenska Tonsättares Internationella Musikbyrå (STIM) upa*, [2008] ECR I-09275, at para 26.

<sup>217</sup> Communication from the Commission, *supra* note 215.



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strategies have (a potential for) harmful effect on competition. Hence, the whole situation surrounding the conclusion of such agreement would be taken into consideration. This would give greater objectivity to any decision rendered in the future and would send an explicit message to pharmaceutical companies that their overall behavior on the market is under scrutiny and not some isolated practices.

## **Chapter Eight**

### ***Concluding remarks***

Reverse payment settlements are an area where intellectual property and antitrust rules interact. Since, the two law branches stimulate competition on the merits but use different means, their interaction leads to more questions than to firm answers.

Thus, it is not surprising the fact that the issue of reverse payment settlements in the pharmaceutical sector is a hot topic on both sides of the Atlantic. In the USA, the competition authorities fiercely try to prove the anti-competitive nature of such agreements, whereas the courts take the opposite stand, save in some exceptional circumstances. In Europe, the EU Commission has not declared a clear position how it will deal with reverse payment agreements, but it continues the intense monitoring of patent settlements.

This situation seems to alter with regard to proposed legislative changes in the USA, as well as to the future outcome of EU Commission monitoring exercise and opened proceedings against pharmaceutical companies. Whatever these changes will be, a delicate balance must be found. Giving primacy of intellectual property over competition law, or vice versa, is equally inappropriate, since not only innovation and pharmaceutical patents are at stake in this case, but also health and welfare of the society.

In addition, the topic of reverse payment settlements should be carefully examined and because it is not correct to narrowly limit it only to the pharmaceutical sector. Given the suitable conditions, it is conceivable that the issue of settling a patent dispute through payment for the patent challenger to delay his market entry could also arise in other industries. Thus, a successful solution to the problem of reverse payment settlements could prevent its appearance and hectic disputes over it in other sectors of the economy which are innovation-driven.

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