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Master's Thesis of Law

**Competition and Generic Pharmaceuticals:  
Reverse Payment Patent Settlements  
“Pay-for-Delay Agreements”**

경쟁과 제네릭 제약사들 : “逆支拂合意”에 관한 小考

February, 2017

Graduate School of Law  
Seoul National University  
Intellectual Property Major

May Mohamed Ahmed Hassan

**Competition and Generic Pharmaceuticals:  
Reverse Payment Patent Settlements  
“Pay-for-Delay Agreements”**

Professor Sang Jo Jong

Professor Jun-Seok Park

Submitting a master's thesis of Intellectual Property

October, 2016

Graduate School of Law

Seoul National University

Intellectual Property Major

**May Mohamed Ahmed Hassan**

**Confirming the master's thesis written by**

**May Mohamed Ahmed Hassan**

**December, 2016**

Chair \_\_\_\_\_ (Seal)

Vice Chair \_\_\_\_\_ (Seal)

Examiner \_\_\_\_\_ (Seal)

**Thesis Title: Competition and Generic Pharmaceuticals:  
Reverse Payment Patent Settlements “Pay-for-Delay Agreements”**

Category of Degree	Master’s Thesis
Department	College of Law
Student ID	2015-22166
Birth Date	May 31, 1985
E-mail	may.madly@gmail.com
Author	May Mohamed Ahmed Hassan
Date of submission	February, 2017

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I always believed that the world will be a better place if all people were able to get access to affordable medicines. Many tragedies are happening in different countries just because poor people are unable to pay for their cure. No one can deny the importance of health for every being on earth, therefore the pharmaceutical industry is a necessary part of the overall health care system. Drug innovation and access to medicine are both important factors in order to maintain the well-being, consequently any deals that may harm these two factors may lead to enormous consequences on the public health.

The purpose of this thesis is to explore effective tools that increase generic competition and decrease drug prices, while maintaining sufficient incentives that encourage continued medical innovation and balance the resulting cost savings, thus having an equilibrium between the patent holder, its competitor and the consumer welfare. However, I discovered that preparing a dissertation is a serious task in order to achieve a Master's degree. My dissertation would not have been possible without the help and support of the special people around me, therefore I wish to express my deepest gratitude to those who always supported me with their heartfelt suggestions.

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**Competition and Generic Pharmaceuticals:  
Reverse Payment Patent Settlements “Pay-for-Delay Agreements”**

**MAY MOHAMED AHMED HASSAN**

**Under the Supervision of Professor Sang Jo JONG  
and Professor Jun-Seok PARK  
at the College of Law Seoul National University**

**ABSTRACT**

Pharmaceutical competition continues to evolve every day through the entry of generic drugs, which enhance competition in the market by offering more choices to the consumer and lowering drug prices. At the same time, innovation in the pharmaceutical sector should be sustained, notably by allowing innovators to obtain exclusive rights for their advanced and original drugs, which give them enough incentives to develop and create new drugs in the long run. Originator producers seek constantly to defer the “loss of exclusivity” of their successful branded drugs and of course defer the introduction of generic replicas of their drugs in the market. Actually one of the originators’ strategies is to pay the generic producer to not enter the market in order to maintain their monopoly position, which is known as reverse payment patent settlements or pay-for-delay agreements. Unfortunately, such strategy has a negative impact on the consumer because they lose out the expected benefit of greater competition through generic entries. Some reverse payment patent settlements have been monitored in different countries. Actions have been taken against such agreements when the delay would harm consumers, because they do not only force many consumers to pay higher premiums out-of-pocket costs and oblige taxpayers to pay higher drug bills in Medicare and other programs, but also deprive others to get access to medicine. In contrast, for drug companies, pay-for-delay deals can translate to a windfall in higher profits and could generate billions of dollars in sales. This thesis explores some important issues related to intellectual property and competition in the pharmaceutical market, in addition, it highlights some effective tools that may increase eventually generic competition and decrease drug prices, while maintaining sufficient incentives to encourage continued medical innovation, with the intention to create an equilibrium between the patent holder, its competitor and the consumer welfare.

**Keywords:** Competition, Generic, Pharmaceuticals, Reverse Payment Patent Settlements, Pay-for-Delay Agreements, Consumer Welfare

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## **ACRONYM AND ABBREVIATIONS**

<b>AMA</b>	American Medical Association
<b>AMR</b>	Advanced Market Research GmbH
<b>ANDA</b>	Abbreviated New Drug Application
<b>CCI</b>	Competition Commission of India
<b>CMA</b>	Competition and Market Authority
<b>EC</b>	European Commission
<b>FDA</b>	US Food and Drug Administration
<b>FTC</b>	US Federal Trade Commission
<b>GPhA</b>	Generic Pharmaceutical Association
<b>IP</b>	Intellectual Property
<b>IPRs</b>	Intellectual Property Rights
<b>LoE</b>	Loss of Exclusivity
<b>MPP</b>	Medicines Patent Pool
<b>MSF</b>	Médecins Sans Frontières
<b>OFT</b>	Office of Fair Trading
<b>R&amp;D</b>	Research and Development
<b>SPC</b>	Supplementary Protection Certification
<b>TFEU</b>	Treaty on the Functioning of the European Union
<b>WHO</b>	World Health Organization

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## **CHAPTER ONE: INTRODUCTION**

### **1.1 The Role of Intellectual Property and Competition in the Pharmaceutical Sector**

### **1.2 Competition Issues in the Pharmaceutical Market**

1.2.1 Flaws of the Patent System

1.2.2 Ever-greening and its Intellectual Property Strategies

1.2.3 Reverse Payment Patent Settlements

### **1.3 Study Objective**

## CHAPTER ONE

### INTRODUCTION

One cannot deny the importance of the pharmaceutical industry in this era. Our health is our main priority; we strive every day to be healthier or at least maintain our level of health. Our world is actually fighting new viruses every day, ever heard about Zika virus? Zika is a new virus of 2016, and it is spread mostly by the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*). These mosquitoes are aggressive daytime biters. They can also bite at night; Zika can be passed from a pregnant woman to her fetus. Infection during pregnancy can cause certain birth defects, and there is no vaccine or medicine for Zika until this moment. (Centers for Disease Control and Prevention "CDC", 2016) In 2016, Zika virus infection was spread in Viet Nam, Peru, Saint Lucia, Chile, Papua New Guinea, Argentina, France, Netherlands', Bonaire and Aruba, Saint Maarten, Saint Vincent and the Grenadines, Trinidad and Tobago, Maldives, United States of America, Region of Americas, Dominican Republic Bolivia, Haiti... and even more countries around the world. Zika has spread through 50 countries in the past year and is believed to be responsible for nearly 2,200 cases of microcephaly where babies are born with shrunken heads and brain damage. Recently, scientists have released an army of mosquitoes infected with bacteria into Brazil and Columbia to combat the Zika outbreak. They are hoping that the millions of modified insects will mate with the local insects and spread the Wolbachia bug throughout wild populations and stop mosquitoes transmitting Zika virus. (Knapton, 2016) From the above we can conclude that virus do not affect only one country or zone, but it is easily transmitted from a country to another. Therefore, each country, even the healthiest ones, should keep in consideration that a healthier world is always a priority and certainly beneficial for everyone including its citizens whether they are infected with the virus or not.

According to the World Health Organization (WHO) archive of year 2016, there is more than 100 virus emergencies which have been detected in many countries in different continents; e.g. Chikungunya in United States of American and Kenya, Rift Valley fever and Human infection with avian influenza A(H7N9) virus in China; Enterohaemorrhagic *Escherischia coli* in United Kingdom;

Middle East respiratory syndrome coronavirus (MERS-CoV) in Bahrain, Saudi Arabia and United Arab Emirates; Yellow fever in China, Angola and Uganda; Lassa Fever in Germany, Togo and Benin; Oropouche virus disease in Peru, and the list goes on. (World Health Organization, 2016) In meanwhile, a third of the world's population lacks access to essential medicines. In many low- and medium-income countries, drug therapies are unaffordable to those who need them. (The Pharmaceutical Journal , 2014)

When we hear the word “virus”, we need to hear the word “medicine” which is the cure or drug of this virus, and the availability of such medicine is completely depended on the pharmaceutical industry which is controlled by the largest drug manufacturers around the world. The biggest drug companies are fueled by the commercialization and monetization of their patents; and patents come out of innovation; and innovation is the key of sustainable production for new and effective pharmaceutical products which cure viruses spread daily around the world, and the biggest incentive given to the innovators is of course their Intellectual Property Rights (IPRs). However, an evaluation of the various practices employed by the large companies specializing in brand-name drugs indicates that intellectual property protection is not being used to promote an incentive to create and innovate, rather, intellectual property rights are being used to gain and maintain an exclusive market share for the most profitable, not necessarily the most beneficial, drugs.

The main players of the pharmaceutical industry are: 1) The pharmaceutical companies or so-called “originators” who are active in research for new compounds. They usually produce limited number of drugs which are mostly protected by patent, whether it's a patent owned type or under a license, moreover they often invest heavily in R&D and promotion; and 2) The generic producers specialized in manufacturing non-patented drugs. They usually produce a broad range of drugs and they invest little or none on the R&D and promotion. Generic producers introduce many benefits to the market, they play an important role in promoting pharmaceutical innovation and ensuring the affordability and sustainability of healthcare care systems, which increase eventually the availability of generic medicines and foster the competition in the pharmaceutical markets, thus promote cost containment and increase access to healthcare treatments for patients. (Roos, et al., 2008)

One has to mention that the generic drugs have the same active ingredient, thus “bioequivalent” to their brand-name drug, consequently they produce the same therapeutic effect. They are actually a copy of a brand-name drug which has the same quality, same safety, same working time and strength as the branded equivalent since they are both approved by the Drug Administration of each manufacturing country and must meet its quality standards (The Swiss Pharmacy, 2012) Above all, they enhance the competition in the pharmaceutical market by offering varieties which can be translated as more choices to the consumer. However, generic drugs do not have the same formulas as the brand-name drugs, they have the same active ingredients but sometimes contain different inactive ingredients, thus a patient may have an allergic reaction to the inactive ingredients in one and not the other, still it's likely an uncommon side-effect. (Reberon, 2011)

The pharmaceutical sector dynamics usually begins with the originator which introduces a new drug protected under the patent system in the market, and after marketing authorization is granted, the new drug enters the market with a price set in accordance to the maximum reimbursable price decided by national authorities. On average, at moment in which the drug reached the market, there is around eight years of exclusivity are left out of twenty years of patent validity. At the end of the exclusive period, generic pharmaceuticals can be introduced into the market, which decrease greatly the reimbursable price of the originator's drug to meet the new market conditions, thus introduce a new competitive price. According to empirical evidence, the average price of a drug can drop up to 80% in the first two years after the generic drug enters the market. For instance, if the originator's drug costs US\$330 a month during its exclusivity period, it may be sold by generics for as little as US\$3 a month after the expiry of the exclusivity period. (Choukse, 2013) Therefore, the originator producers seek constantly to defer the loss of exclusivity (LoE) of their successful brand-name drug and of course defer the introduction of generic replicas of their drugs. Actually, one of the originator producers' strategies is to introduce new version of their drugs such as a second generation product before generic enter the market in order to maintain their monopoly position. Unfortunately, such strategy results to many consumer disadvantages because it loses out the benefit of greater competition through generic entry. (Bennett, 2013)

## **1.1 THE ROLE OF INTELLECTUAL PROPERTY AND COMPETITION IN THE PHARMACEUTICAL SECTOR**

There is a strong linkage between IPRs, competition and pharmaceutical industry. Pharmaceutical patents play a key role in the availability and affordability of drugs specially generics. Mostly the intellectual property laws translate to a situation where fewer people buy a particular good than if it were sold competitively, and these people actually pay more for each good due to the exclusive market power secured by the IPRs of big pharma companies, which give them a “lawful” monopoly over a particular drug - for a certain period of time - that can be prolonged through several strategies and tactics known in the pharmaceutical sector. IPRs are now pushed to their limits in an attempt to maximize profits on popular brand-name drugs, consequently originator companies seek constantly to increase their monopoly in the market. For instance, in the U.S., the Federal Trade Commission (FTC), Congress, and the public, voiced that large drug companies are abusing the formidable monopoly power afforded by their drug patents at the expense of competition and consumer public welfare.

Competition concerns, however, arise when originator companies use their power to delay or to prevent the generic entries which create the equivalent of the original brand-name drug. On the manufacturing side, the distinction between originator companies and generic manufacturers is often blurred, therefor many originators use potentially anti-competitive practices and other IP strategies to prolong their patents' lives, such as: 1) Using legislative provisions and loopholes to apply for a patent extension; 2) Suing generic manufacturers and producers for patent infringement; 3) Margining with direct competitors as patent rights expire in an effort to continue the monopoly; 4) Recombining drugs in slightly different ways to secure new patents and layering several patents on different aspects of the drug to secure perennial monopoly rights; 5) Using advertising and brand-name development to increase the barrier of entry to the generic drug manufacturers; (Glasgow, 2001); and 6) Engaging in pay-for-delay agreements with potential competitors that have threatened to enter the market and challenge the originators' patent validity. Such strategies create an unbalanced field where the generic manufacturers are prevented with a way or another to enter the drug market.

One has to mention that the Research and Development (R&D) is among the major factors that decides the effectiveness and magnitude of the pharmaceutical industry growth, because it focuses on the improvement of the drug whether in quantity or quality. In US, according to Forbes 2012 report, the average cost of bringing a new drug to market is between US\$1.3 to US\$4 billions. Costs could be as high as US\$11 to US\$12 billions. A single clinical trial could cost as much as US\$100 millions, and the FDA usually approves about 1 in 10 clinically tested drugs. Just as significantly, it can take up to 10 years for a drug to be approved for prescription. Even if a start-up company spent around US\$4 billions to develop and test the drug according to FDA rules, it still may not receive revenue for 10 years. (Investopedia, 2015) Thus, some major international companies, which have R&D divisions, choose to have also generics manufacturing subsidiaries producing “branded generics” since they incur fewer costs in creating the generic drug because they no longer need to make drug discovery, research or clinical trials. Moreover, they do not bear any additional costs associated with proving the safety and efficacy of the drugs through new clinical trials since these trials have already been conducted by their R&D division, in addition they get the FDA approval in a shorter period of time. As a result, they occupy more of the market share, and for some medicines, they account for a large share of the world’s market in generics.<sup>1</sup> This market is highly price competitive because buyers can choose among several sources of chemically identical medicines. (Management Sciences for Health, 2012)

However, a patent's holder monopolistic power over its patent does not necessarily mean market power, in many cases switching from a medicine to another is rarely decided by consumers who mostly buy brands because of their lack of information or their loyalty to the brand-name drug. According to the Swedish Competition Authority’s study using dataset of 897,000 observations where consumers were asked if they wanted to pay the price difference in order to get the prescribed brand-name drugs instead of the cheapest alternative in the market, most consumers are substantially more loyal toward

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<sup>1</sup> See (Bernard, 2011) e.g. Novartis develops novel agents and sells generic products through its Sandoz division, one of the world's largest generics manufacturers. Sanofi-Aventis, an innovator company, has recently acquired generics manufacturers Zentiva (Czech Republic), Laboratorios Kendrick (Mexico), Medley (Brazil), and Helvepharm (Switzerland). Many other multinational brand companies, including Abbott, Pfizer, and GlaxoSmithKline have partnered with or purchased multiple generics companies.

brand-name drugs and branded generics than toward “true” generics. (Granlund & Rudholm, 2008) Similarly, an empirical study in South Africa was conducted among 250 over-the-counter medicine consumers with different demographic profiles concluded that the brand loyalty influences are important for measuring the brand-name drug sales and that patients are indeed brand loyal and prefer branded pharmaceuticals to generic pharmaceuticals. Another study in the United States of America confirms that pharmacists, nurses and doctors, for example, bought generics 90% of the time, compared with about 70% of the time for the overall population. (Kestenbaum, 2013)

Consequently, in many western countries money equals quality, a more expensive or a brand-name drug is much better even though the manufacturing costs may be exactly the same and the only difference is in the overheads and packaging. Conversely, a cheaper drug or one manufactured by not well-known generic company is considered much less effective, thus consumer goes either for the brand-name drug or the branded generic, which increase greatly the market power of the originator company even though there is a true generic alternative in the market manufactured by another generic producer. Subsequently, the generic companies are left in confusion, taking the risk to produce generics or conduct “deals” of win-win situation with the originators. Of course, such situation differs in developing and least-developed countries who strive for affordable medicines to accommodate their poor economy. With dramatic increases in rates of both generic penetration and patent litigation, this particular industry does follow the usual market supply and demand rules, where quantities rise where prices fall, (Management Sciences for Health, 2012) accordingly, constant generic penetration is what the developing and least-developed countries are looking for.

Given these points, balancing between the patentee’s (originator) rights and the public interest was always a debate in the IP field, likewise balancing between the originator’s rights and its competitors’ welfare is a must for a healthy market. Consequently, there is a huge need to balance between the three: patent holders (originators), competitors (generic companies) and consumers’ welfare. IP and competition issues in the pharmaceutical sector are quite many, for instance, originator companies lack a unified patent enforcement system, in addition they face difficulties in many

jurisdictions to get adequate compensation for damaging patent infringements. In contrast, the generic drug manufacturers “new entrants” or “late comers” don’t have often the opportunity to deal financially with patent litigations to invalidate patents or to conduct clinical trials during the life span of a patent, which on average period require around 7.7 years, with the aim of obtaining marketing approval. In some countries, marketing generic drugs could immediately start upon expiration of a patent, however if the experiments were only possible after the expiration of a patent, the patentee could enjoy an effective monopoly for another couple of years. (Eswaran, 1994) Consequently, the pharmaceutical market is full of many harmful practices that affect its main players and its dynamics as a whole, which affect in return the market consumer.

## **1.2 COMPETITION ISSUES IN THE PHARMACEUTICAL MARKET**

The competition in the pharmaceutical sector is fierce, with the constant global and growing demand of cheaper medicines with little or no side effects, more efficacy and longer lasting potency, the pharmaceutical industry doesn’t sleep. Competition is complicated by the fact that the insurer who pays for pharmaceuticals generally has little influence over what is prescribed, the prescriber ordinarily does not bear the costs of the pharmaceuticals prescribed, and the ultimate consumer, the patient, typically has little influence on either the “brand” of the prescribed pharmaceuticals or their prices. In other words, physician may not be sensitive to price differences between a branded pioneer drug and its generic alternative, usually physicians do not have information on the drug prices charged by pharmacists. For instance, wholesalers purchase drugs from manufacturers and distribute them to pharmacies, hospitals, and other health care facilities. They may compete in the provision of a variety of services, including the repackaging of pharmaceuticals, the provision of disease management services, and the operation of drug buy-back programs. In addition, large drug wholesalers contract with generic drug manufacturers for certain retail pharmacies, particularly the smaller chains and independents that may lack the scale to negotiate effectively on their own. (Vitale, 2014)

Consequently, the success of a brand-name drug doesn't depend only on its market share during the life span of its patent, but also on other financial, economic and social factors that create a fertile environment for a certain brand-name drug to succeed in the market in the long run, even after the expiration of its patent, which has a great influence on its generic's competitive position. Generally speaking, the generic products do not only carry lower prices than brand-name drugs, but also tend to yield higher gross margins to the pharmacists, thus both the pharmacists and the consumer share interests in substituting generic products. Competition issues in the generic pharmaceuticals' market, however, arise once the physician has chosen to prescribe a brand-name drug that is available generically, at this point the pharmacist and the consumer start to play a role in deciding whether the original brand<sup>2</sup> or generic equivalent is dispensed. (Caves, et al., 1991)

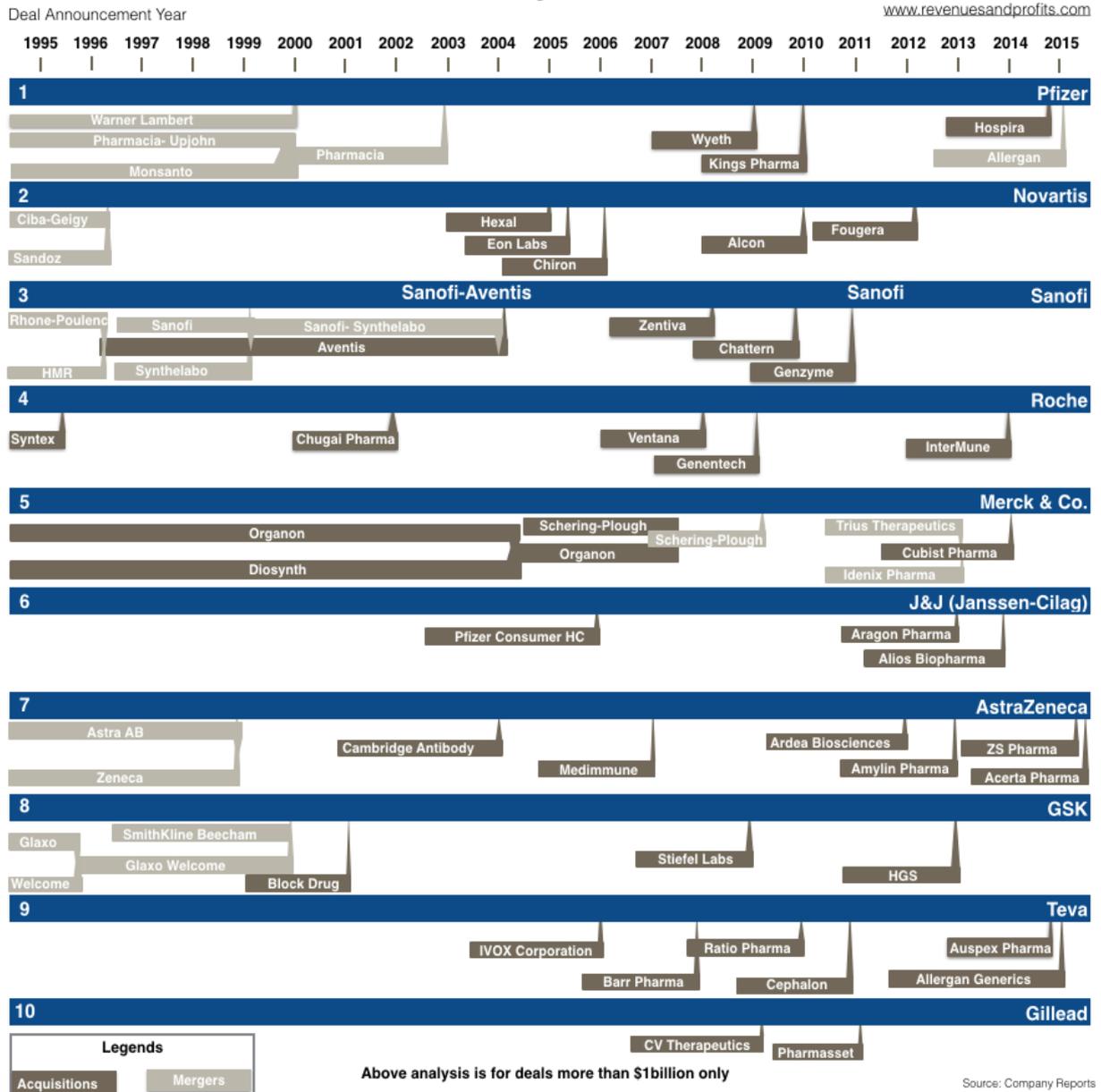
Competition is a force that all players of the industry need to contend with and overcome in order to thrive and develop, which result to many competition issues that vary from a country to another, particularly from an economy to another. In order to stay competitive in the marketplace, the players must enjoy a very resilient and financial stability, in addition they should research the market thoroughly and calculate the risk-return tradeoff before investing into a certain drug. One of the main issues in the pharmaceutical market is that a new drug experience a lengthy testing period that may last from 7 to 15 years before the approval for sales. Smaller companies generally offer greater returns by allowing for ground-floor venture capital investment, but may not be able to withstand the length of time required for approval on their own. Large companies are more likely to have multiple drugs in their product lines and therefor are able to finance the path of new drugs through FDA approval. Furthermore, mergers and acquisitions are common throughout the sector and happen largely in response to the regulatory environment experienced by creating new drugs. (Investopedia, 2015)

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<sup>2</sup> See (Wechsler, 2016) It worth to mention that there are some drugs which are developed for rare medical condition and therefore they don't attract the same type of competition that would keep prices low, such drugs are known as "orphan drugs". This term often applies only to the patented drugs. However, the FDA defines "orphan drugs" as treatment for diseases or disorders that affect less than 200,000 people in the US and are not expected to make the drug company much money.

According to a merger and acquisition analysis from 1995 to 2015, 60 pharmaceutical companies have become 10 big pharma companies, such as: Pfizer, Novartis, Sanofi, Roche, Merck & Co., Astrazeneca, and more. This consolidation has helped the big pharma companies to gain more power to influence the regulation while simultaneously diminish the competition in the pharmaceutical sector. Consequently, in 2014 only, the Department of Justice (DOJ) opened 924 new criminal health care fraud investigations that included big pharma companies like J&J and Teva, who have become like big banks which are too big to fail, therefore they continue their business as usual despite their harmful practices, such as indulging in off-label promotion, providing kickbacks, submitting false safety data and many more. (Vij, 2016) See figure (1)

# Pharma Industry M&A 1995-2015



Merger and Acquisition Analysis of Pharma Industry (1995-2015)

Figure (1)

### 1.2.1 FLAWS OF THE PATENT SYSTEM

Patents are a category of legal monopolies granted to inventions that have legally subscribed level of novelty, inventive step and industrial capacity. Monopolies in the form of patents can be the strongest in the absence of substitutes for the product and/or the presence of consumer behavior working in favor of the patented product, which is known as passive market power. It is often argued that patents generate consumer welfare by introducing new products in the market which makes creative destruction<sup>3</sup> as an on-going process. (Scherer, 1998) Even the most ardent critiques of the patent system believe that patents are of immense importance for the private pharmaceutical industry, without which many breakthrough inventions might not have occurred at all. (CENTAD, 2010)

However, according to the European Generic Medicines Association report, there are some flaws in the patent system as well as the surrounding legal and regulatory framework that allow the imbalance between the incentives of innovators and the competition in the pharmaceutical market; these flaws can be concluded but not limited to the following: 1) Failings in the system for granting quality patents; 2) Patent thickets and follow-on patents or so-called ever-greening; 3) Patent litigation procedures and its complexity; and 4) Other patent-related barriers, such as: split infringement and invalidity courts, the inability to disclose information on a confidential basis, also in some cases, nullification of the patent, local forum shopping and many more related issues.

As a result, it has been suggested from several authors that these flaws can be prevented and adjusted by elevating the standards of examination through well-trained examiners producing quality results and increasing the time of patent examination that usually takes place under a huge time pressure and productivity demands, consequently, many textbook knowledge gets misinterpreted, denied or neglected, whereas adequate examination is very important in order to prevent more failures in the patent system in the long run. Furthermore, the examination process is mainly a conversation between

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<sup>3</sup> See (Caballero, 2006) Creative destruction refers to the incessant product and process innovation mechanism by which new production units replace outdated ones.

the examiner and the applicant, therefore a third-party participation may be important in order to catch the errors and oversights in the examination process, whereas such process may provide the examiner with useful information, which would not be easily accessible otherwise, and will certainly reflect positively on the granting procedure.

Finally, there is a weakness in the opposition procedure, which is the time taken until the decision is reached. For instance, in Europe, a weak patent can go from application to grant within 18 months. Then it takes approximately four years to obtain revocation in the first instance through the EPO opposition procedure. If an appeal was lodged by the originator, this means another three years are gone to obtain the final decision. This results in nine years of uncertainty, which reflects on the market through lack of competition against the original product. Such flaw is not only in Europe but also in many other countries around the world. In addition to the burden of proof issue which may shift to opponent during the opposition procedure to demonstrate that something is not new and/or inventive, whereas the same can be more challenging and difficult to prove than the opposite. Thus, speeding the opposition proceedings would therefore be an effective and necessary mean for preventing the assertion of ultimately invalid patents aimed at hindering competition from generic medicines. (Roos, et al., 2008)

Many other flaws are common all over the world, for instance in 2008, the United States Patent and Trademark Office (USPTO) reported to have a backlog of more than 700,000 patent applications in United States alone. (Takenaka, 2008) According to the European Patent Office, the backlog of patent applications is counter-productive to legal certainty, and that has a negative effect on the innovation process. In England, the cost to the global economy of the delay in processing patent applications may be as much as £7.65 billion each year. While politicians are keen to reduce patent backlogs, those applying for patents can often prefer a lengthy “patent pending” period. The delay can benefit the applicant by 1) Deferring costs associated with examination and grant; 2) Deferring decisions regarding amendments to the application; and 3) Maintaining uncertainty for competitors as to what scope of protection may eventually be granted.

### 1.2.2 EVERGREENING AND ITS IP STRATEGIES

In order to maintain a balanced patent system, we need to ensure the quality of registered patents. In other words, there should be no doubt about the validity and the breadth of patent claims. The existence of questionable patents usually leads to more patent litigations that hinder generic competition, which consequently keeps unnecessarily high drugs' prices in the market. Patent quality is a direct reflection of the scope and quality of innovation. In the pharmaceutical sector, this standard is often stretched, resulting in inappropriate patents that should not have been ever granted. Thus, the originator companies tend to prolong unjustly the patent monopoly of their brand-name drugs which is known under the name of "ever-greening" the basic patent, which is a strategic extension of the duration of a temporary monopolistic or market dominant position by means of IP strategies, and in practice patent strategies particularly. (Roos, et al., 2008)

Such process demonstrates a slight modifications of old drugs that do not has any significant therapeutic advantage, consequently it does not improve people's health, yet the main purpose of fostering innovation and protecting public interests fades in between the ever-greening purpose to secure market monopoly. Some countries are already aware of ever-greening and are taking effective steps towards preventing it. For instance, India's Supreme Court refused to grant Swiss Pharmaceutical company "Novartis" a patent for a new version of its cancer drug "Gleevec" or "Glivec" because it doesn't include enough improvement to warrant patent protection, despite what Novartis claimed that the drug is more absorbed into the blood, and considering that it's used to fight leukemia, this is an enough improvement to grant a patent, however Anand Sharma, India's Trade and Industry minister, has confirmed that such decision is justified under the law and that India's patent law does not accept "ever-greening". There were a lot of ever-greening cases, including but not limited to Bristol-Myers Squibb and Taxolc; Pfizer and Viagra; AstraZeneca and Prilosec/Omeprazole; also AstraZeneca (Prilosec and Nexium) and Eli Lilly (Prozac and Zyprexa). In these cases, many intellectual property strategies were used in order to maintain a powerful monopoly in the market and eliminate competition. (Granstrand & Tietze, 2015)

One can illustrate some IP strategies, either by using multiple IPRs of the same type “single type protection” or multiple IPRs of different types “multi-protection”, through the practices of big pharma companies in the market, generally speaking ever-greening may include five major strategy types:

1) Using a technically minor improvement in form of a reformulation and repackaging; 2) Development of a successor product as a second product generation with an overlapping technology base; 3) Combining the patent protection with multiple trademark protection whether of the product name or color or other brand building efforts, in addition to 4) aggressive marketing of the successor product; and finally 5) Using reverse payment patent settlements. (Granstrand & Tietze, 2015)

### **1.2.3 REVERSE PAYMENT PATENT SETTLEMENTS**

Reverse payment patent settlement or pay-for-delay agreements are a form of patent dispute settlement agreement in which a generic manufacturer acknowledges the patent of the originator pharmaceutical company and agrees to refrain from marketing its generic product for a specific period of time. In return, the generic company receives a consideration in the form of a payment from the originator, such deals are known as “side deals” or “no-AG” agreements (Elfin, 2016) to prevent or restrict marketing of a generic form from a patented drug.<sup>4</sup> (Tanne, 2008) Such settlements and agreements have attracted increasing antitrust attention around the world. Action has been taken against such agreements when the delay would harm consumers, because they do not only force consumers to pay higher premiums and out-of-pocket costs, but also means that taxpayers pay higher drug bills in Medicare and other programs. (Masspirg, 2013) In contrast, for drug companies, pay-for-delay deals can translate to a windfall in higher profits, it could generate around US\$4 billion in sales that no one expected, because they allow patent holders to pay potential market entrants in order to delay their release of competing products until a later point than the one which they would have been expected to enter the market. The result also invites antitrust scrutiny, as a reverse payment patent settlement constitutes an agreement between two would-be competitors to avoid competition, resulting in higher

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<sup>4</sup> See (Tanne, 2008) The US Federal Trade Commission (FTC) reported that there were 33 final settlements in the fiscal year 2007. Fourteen included payment to the aspiring generic manufacturer and a restriction on the generic company’s ability to market the generic drug. The report did not name the companies involved.

prices for consumers and less innovation. (Lemley, 2011) In addressing pay-for-delay agreements, competition enforcers face thorny questions pertaining to the applicable legal test, and whether the nature and strength of the patent (i.e. the level of innovation) and the nature and size of the payment are relevant factors in assessing the competition harm. The main issue that the originators can adopt diverse and creative strategies to delay or prevent generic entry. Such strategies include misuses of the patent system, spreading misleading information, inducing product switching and refusal to license an essential patent...etc. Competition enforcement in this context is essential, but it also seems to be sometimes compensating for the failures of the IP and regulatory systems. One has to mention that patents confer the right to stop competitors from marketing drugs to which patents apply, meaning pay-for-delay agreements are not subject to antitrust scrutiny as long as the delay does not extend beyond the patent protected period. (Swati Shah, 2016)

Giving this introduction, we can determine some important questions that will be addressed through this thesis, which will give hopefully a clear insight about the current IP and competition environment in the pharmaceutical sector. These questions can be concluded in the following:

1. What is the possibility to achieve a balance between IP and fair competition that serves the consumer welfare in the pharmaceutical sector?
2. What is the impact of some practices such as “reverse payment patent settlements” on the consumer welfare and country’s economy?
3. What is the possibility to categorize “reverse payment patent settlements” cases by the strategy used to delay the generic entry?

### **1.3 STUDY OBJECTIVE**

This thesis discusses the following objectives:

1. The possibility of having a balance between IP and fair competition that serves the consumer welfare in the pharmaceutical sector.
2. The impact of some practices such as “reverse payment patent settlements” on the consumer welfare and country’s economy.
3. The possibility to categorize “reverse payment patent settlements” cases by the strategy used to delay the generic entry.

## **CHAPTER TWO:**

### **AN OVERVIEW OF COMPETITION AND GENERIC PHARMACEUTICALS**

#### **2.1 A Brief History of Competition and Generic Pharmaceuticals**

#### **2.2 Pharmaceutical Pricing**

#### **2.3 Branded Competition v/s Generic Competition**

#### **2.4 Intellectual Property and Competition Strategies in the Pharmaceutical Sector**

2.4.1 IP and Competition Strategies in United States of America

2.4.2 IP and Competition Strategies in Europe

2.4.3 IP and Competition Strategies in United Kingdom

2.4.4 IP and Competition Strategies in India

2.4.5 IP and Competition Strategies in Developing and Least-Developed Countries

#### **2.5 Conclusion**

## CHAPTER TWO

### AN OVERVIEW OF COMPETITION AND GENERIC PHARMACEUTICALS

Competition issues in large scale pharmaceutical markets are not seen, either because the generic firms enter easily into the market or because there is enough competing active ingredients within the therapeutic subgroup, which makes the generic new entries have a neutral effect on the competition whether at the generic or therapeutic level. (Moreno-Torres, et al., 2007) In all situations, intellectual property and marketing will often hurdle the achievement of market authorization and market access, however a clear understanding of the real potential barriers of generic entries and developing a strategic plan to overcome these issues is of value for both companies and potential investors. (Hill, 2009)

With easier access to cutting edge knowledge, capital and other production factors, the big pharmaceutical companies are capable to produce the medicines that the market is striving for them today. In contrast, the pharmaceutical industry faces major challenges due to the ever-changing framework conditions which manifest themselves in political, economic and legal terms as well as in transition of the generics market. Most of the medium-sized pharmaceutical companies are facing a great challenge to develop innovative products and compete effectively because they often lack the strategic and economic approach in their innovation projects. Effective competition policy requires effective and efficient application of competition law and economics. Good processes are essential, thus a fair, predictable and transparent process bolsters the legitimacy of a competition authority's actions. Good economic analysis is also necessary. Any assessment of competition, whether carried out for law enforcement or wider policy purposes, will require a sound understanding of economic principles. (OECD, 2016)

There are two types of studies that have analyzed the generic entry into the pharmaceutical market, some have analyzed the competition effects on the generic take-up and others have focused on the drivers of entry. They found some key points that we have to put in consideration, and can be listed as the following: 1) The number of the generic entries depends on the market size or volume of sales

and on expected profits<sup>5</sup>; 2) Drugs that treat chronic conditions and drugs that are oral solids attract more generic entry; 3) According to a U.S. study in brand advertising, the branded-drug slightly affect the generic entry by advertising before patent expiration (Morton, 1998); 4) There are less entries in markets where there are already two or more brand-name competing companies; 5) The number of entries is affected by the number of hospital sales; 6) The number of generic incumbent firms affects negatively new entries; 7) There are more entries in markets similar to those in which the firm has experience; 8) The duration of the exclusivity period of the brand-name product affects negatively generic entry; (Moreno-Torres, et al., 2007) and 9) The chances of market entry for generic drugs the day following the expiry of the main patent in all EU markets for instance is not possible or, at best, is extremely difficult,<sup>6</sup> due to a diminishing number of newly registered products and contracting product pipelines, thus originator companies may be tempted to unjustly prolong the patent monopoly of existing pharmaceutical products. (Roos, et al., 2008)

The studies have concluded that there are four main drivers for the generic entry, the first driver is the number of generic firms in the pharmaceutical market, for instance when the number of generic firms already existing in the market is high, there are more direct competitors, thus the average number of generic entries turn lower; additionally the number of active ingredients per therapeutic subgroup decreases the average number of the generic entries, which explains why there are active ingredient markets without generics or only with few ones; moreover the market size in terms of revenues usually increases the generic entry, if the rest of variables are constant; and lastly the time trend has a significant fostering effect on the generic entry, e.g. in 1997, generics could not be introduced in Spanish pharmaceutical markets, however when the original drug turned 10 years old, many generic firms were opened gradually by regulation. (Moreno-Torres, et al., 2007)

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<sup>5</sup> See (Bernard, 2011) Generics companies are targeting not only megasellers such as Lipitor and Plavix, but also smaller-selling agents, including some with less than \$10 million in sales and 1 percent market share. According to a 2009 Thomson Reuters report, generics companies targeted as many US products with sales less than \$50 million dollars as they did blockbuster agents with sales over \$1 billion.

<sup>6</sup> See (Bernard, 2011) However, this is not the case in other countries. Teva Pharmaceuticals, the world's largest generics company, has executed over a dozen "at-risk launches" of generic products while patent litigation is pending in the US. In international markets such as Russia, India, and China, some generics companies market brand copies before the originator's brand is launched. For example, there were generic versions of the rheumatoid arthritis biologic agent Enbrel in China prior to the launch of the original brand.

## **2.1 A BRIEF HISTORY OF COMPETITION AND GENERIC PHARMACEUTICALS**

In the nineteenth century the orthodox medical profession represented by the American Medical Association (AMA) considered that it is highly unethical to prescribe drugs that were monopolized by means of patents or trade names. Drug manufacturers that complied with this way of thinking were therefore known as “ethical”. However, after World War I, doctors began to see patents and trade names from a positive perspective. Today, it is impossible, and would be unethical to try, to practice medicine without recourse to branded or patented drugs or items. (Mctavish, 2003)

The generic drug industry has been awash in controversy since the establishment of the pharmacy and medical communities in the United States of America. In 1888, the American Pharmaceutical Association (APhA) published the National Formulary to help prevent counterfeiting of branded products. (Ascione FJ, 2001) Congress came on board in 1906 with the passage of the Federal Food and Drugs Act. This law, signed by President Theodore Roosevelt, was the first to require product labeling in an effort to prevent misbranding and adulteration, and it enabled the government to take action if a product caused substantial injury or death. This was the beginning of pharmaceutical regulation by what was soon to become the FDA. (Hornecker, 2009)

Generic drugs existed vastly since 1920, the most famous example of generics competition back then was when the originator company of Bayer aspirin tried hard to keep the generic versions off the shelves. The company lost in the court which brought many variable generic aspirins in the market. Currently, the generic drugs are spread all over the world. However, 40 years ago, the requirements and testing of drugs were very flexible, the test results were shown after the drug enters the market, which had a significant danger on the health of patients specially if the drug turned out to have bad or severe reactions and side effects, e.g. the thalidomide caused thousands of birth defects in Europe, Canada, Latin America, Africa and Asia.

In 1962, the U.S. FDA revamped the Federal Food, Drug and Cosmetic Act which strengthened the drug testing laws, and for the first time, companies were required to prove that the drug is both safe and effective before it enters the market. As a result, all the new drugs had to go through a long and expensive process that included large-scale human trials. (Chris Woolston, 2016) e.g. Contrave, a diet pill which the FDA declined to approve as a treatment for obesity because the maker (Orexigen Therapeutics) need to first perform a long term study to ensure that the drug does not increase the risk of heart attacks. (Pollack, 2011) From 1960s and 1970s, there were gross violations of manufacturing practices, and the generic drug was substantially inferior to the original brand-name product. Many Congressional hearings documents confirmed that the Generic Drug Division of the FDA was a weak bureaucracy which had approved generic products on the basis of fraudulent data. (Greene, 2014) However, since the passage in 1984 of the Hatch-Waxman Act<sup>7</sup> amending the Federal Food, Drug, and Cosmetic Act, the pharmaceutical competition has evolved dramatically. (Henry Grabowski, 2013) The availability and utilization of generic alternatives to brand-name drugs have had a significant effect on cost savings for health care consumers. And in 2008, generic drugs accounted for more than 63% of total prescriptions filled in the United States. (Savage C. & Gatyas G., 2008)

## **2.2 PHARMACEUTICAL PRICING**

Pharmaceutical and biotech companies have certain hidden tactics in pharmaceutical pricing, usually they are not transparent about how they price their drugs. In general sense, pharmaceutical pricing grabs tons of factors in order to get it done, including but not limited to R&D, treatment and operating costs. Many pharmaceutical companies have explained the rise in their drugs' prices by saying that it would help to develop a better version of the drug in the future. Our current environment of high price and margin pressures push the pharmaceutical companies to work on the demand driven supply chain management by reducing the stock in inventories, in other words, practicing the demand driven

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<sup>7</sup> U.S.C. § 355(j)(2)(A)(vii)(IV) (2010) Hatch-Waxman is intended to encourage the first generic to launch a so-called "Paragraph IV" challenge to an existing drug on the ground that the patent is invalid or the new entrant does not infringe the patentee's patent.

principles in the supply chain is a key measure to achieve the top position of the AMR<sup>8</sup> list. Consequently, pharmaceutical companies are pushed to look at adopting a cost effective and an efficient process-oriented supply chain-model in order to maintain their survival in the long run. In the basic model, a higher price of the original product, relative to the average price of the generic substitutes, significantly decreases the market share, many drugs got affected by this model e.g. Atenolol, Diazepam, Furosemide, Naproxen and Propranolol. The introduction of the reference price system seems to have decreased the market shares of Furosemide, Clomipramine and Naproxen. In addition, it appears to be important to control for the introduction of the reference price system in order to identify how the change of market share of the original product is affected by the relative price. The differences in results between the substances also underline the importance of using disaggregate data. The results also suggest that the introduction of the reference price system is an important determinant of the price paths. Therefore, if we neglect the reference price system in the estimation, as in the basic model, estimated relative price effects on the changes of market shares most likely reflect a mixture of “pure” relative price effects caused by the reference price system. (Aronsson, et al., 2001)

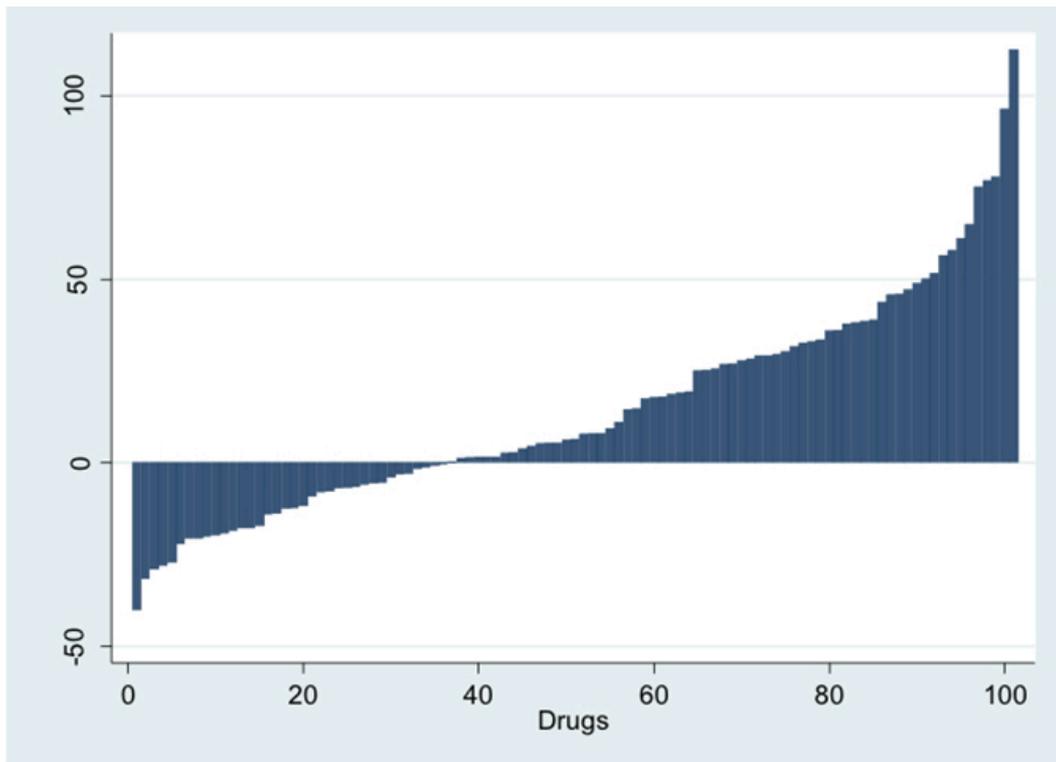
Market size is one of the main influence on the competition in the pharmaceutical market, for instance, in small markets there is a small probability of having enough entries, thus driving prices down will be literally hard to ever attain the marginal costs. In such markets, policies should focus on avoiding the abuse of market power by the originators. However, in large markets, there is no need to implement the reference price system in order to achieve generic entries. It might even have adverse effects because it deters further generic entries. It deprives the main advantage of generic drugs which is a lower price with respect to the brand-name equivalents. Implementing reference pricing when there are still few generics in the market could become a policy of short run gain at a long run loss for the third party payer (the government in most cases). Reference pricing encourages brand-name drugs to peg their prices to the reference one and make further entries of generics difficult as the market for generics squeezes. Generic take-off is constrained when price regulation gets tougher, and generics bear

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<sup>8</sup> See (AMR, 2016) AMR – Advanced Market Research GmbH is a full service market research firm catering to multi-national companies on international data collection.

the cost of becoming the reference price. Competition generated by generic firms would be more effective than the reference pricing to obtain price reductions and pharmaceutical public expenditure savings in the long run, but it is a matter that requires more research in the pharmaceutical market. As (Danzon and Chao 2000) highlighted, regulation undermines competition in off-patent markets. The potential budgetary savings from post-patent competition are not fully realized in countries with heavy regulation. According to the evidence gathered in this paper, it would be more sensible to let enough generic firms to enter drug markets before implementing mechanisms to reimburse only for the lowest price that competition has revealed. Without having enough generic entries in the market, there would be not enough competition to reveal to what extent cost may be contained for third party payers. (Moreno-Torres, et al., 2007)

One of the most interesting example is Turing Pharmaceuticals which is a new company in the U.S. market that bought the U.S. marketing rights to Daraprim, which is a drug that fights parasitic infections, and almost immediately the drug price raised up by 5,000% causing public outrage and political attention on other drugs that have made similar moves like Doxycycline which an antibiotic, Isuprel and Nitropress which is a heart medication. For drugs like Daraprim, around 8,000 prescriptions are filed by year, makes the generic companies escape to enter the market or create any alternatives, because simply it is not worth it to come up with a generic alternative, yet this allows a price monopoly in which the originator manufacturer can set virtually any price it wants. (Ramsey, 2015) Surprisingly, Daraprim's patent has expired 62 years ago. The figure below shows that an increase in the number of prescriptions from the generic competition that results upon patent expiration does not always materialize. See figure (2)



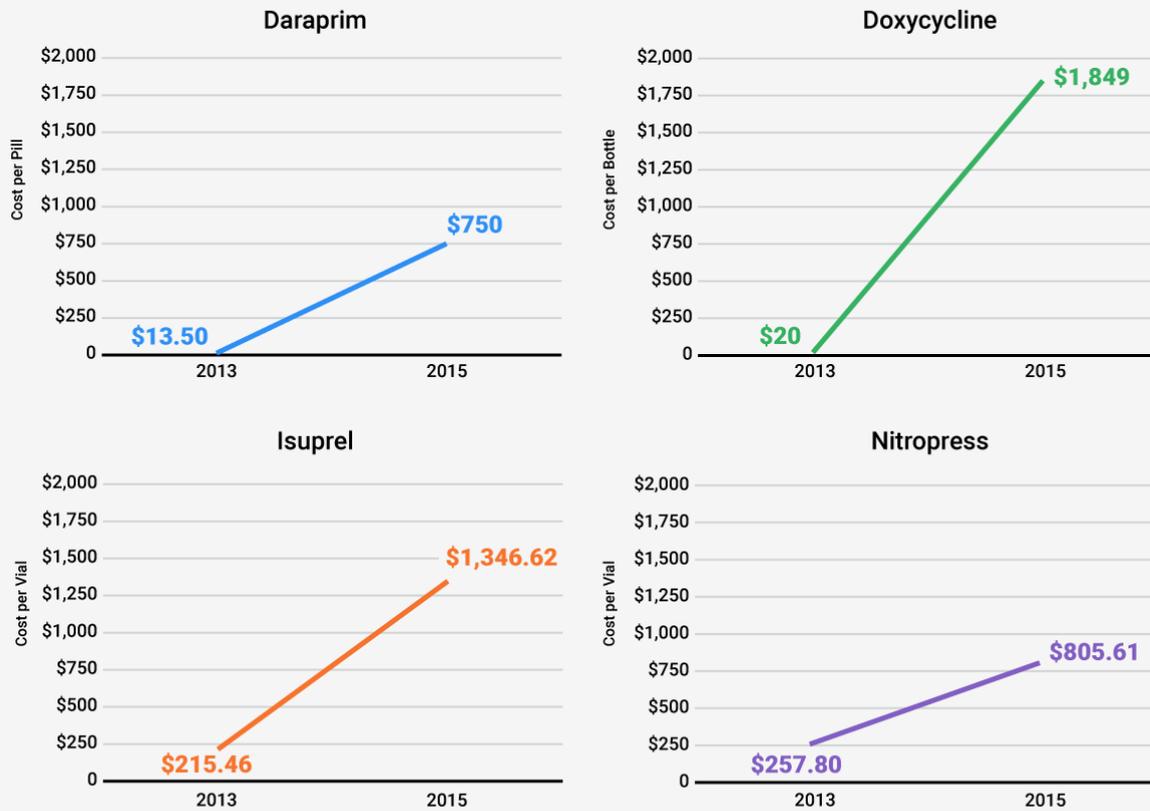
#### Before and After Patent Expiration

The volume of 40% of drugs actually declined after patent expiration

1992 – 2002 (Philipson, 2014) – Figure (2)

Price control has a direct effect on the possible profits. The degree of control depends on the regime in question and in any environment of regulation, it is the policy of the regulatory agency and the kind of the drug that decides the degree and nature of regulation. Once successful new drugs are approved, their manufacturing costs are usually a small fraction of their price, consequently it generates a profuse cash flow which can readily recover costs of past R&D ventures as well as finance fresh ones. Alternative sources of investment capital, from the bond and stock markets, are not perfect substitutes for cash-flow financing. (ProText Knowledge Services, 2010) See Figure (3)

## DRUG FLIPS: PRICES THAT HAVE INCREASED UNDER NEW OWNERSHIP, 2013–2015



SOURCES: The New York Times; The Wall Street Journal; Congress.

BUSINESS INSIDER

Price Comparison of Generic and Innovator Drugs, by number of Manufactures

Figure (3)

The costs of a drug could be reduced if government regulations could foster a more powerful competition between the original manufacturers and the manufacturers of generic substitutes. (Aronsson, et al., 2001) Thus, the potential rewards of success for generic pharmaceuticals companies are tempered by the need to overcome a country regulation. (Hill, 2009) For instance, Spain had a regulation that caps the drug prices since 1920, generic drugs were introduced in around January 1997 and in 2000, Spain created a reference pricing system where the payer (The National Health System) decides on the reference price for reimbursement of each drug. (GJ & L, 1995)

After five years of the Model Drug Product Selection Act issuing, all states had enacted laws allowing pharmacists, when filling a prescription for a specific branded drug, to dispense an equivalent generic version unless the prescribing physician instructs otherwise. According to Generic Substitution and Prescription Drug Prices: Economic Effects of Drug Product Selection Laws Report, generic substitution on eligible prescriptions rose after the passage of these laws, and that generic substitution reduced consumer expenditures. (Vitale, 2014)

A range of enforcement remedies, including court-based outcomes and court enforceable undertakings is needed in addition to a range of compliance tools to prevent breaches of the laws including business and consumer education, thus working closely with stakeholders and other agencies is a must in order to promote competition among businesses as well as promoting fair trading and providing consumer protection in the pharmaceutical market. (OECD, 2016)

### **2.3 BRANDED COMPETITION V/S GENERIC COMPETITION**

Competition policy is basically about making sure that companies compete with each other on an equal footing, on the basis of their products and prices, with no unfair advantages. As a result of corporate crossbreeding and intensifying competition, branded and generics companies have adopted many of each other's commercial approaches. For example, innovator companies are targeting and offering aggressive commercial terms to distributors and pharmacies, traditionally generic stakeholder strongholds. At the same time, generics companies in some countries are detailing physicians with sales forces that are larger than those of their innovative counterparts. Conversely, one of the most interesting outcome of branded/generic competition is commercial hybridization, which is the concept of branded generics, where a prominent innovator and generics companies both promote company-branded products, often stamped with their trusted name on product packages to convey authenticity and quality.<sup>9</sup> (Bernard, 2011)

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<sup>9</sup> See (Bernard, 2011) For example, Glaxo- SmithKline has forged relationships with generics makers in India, South Africa, and other markets to sell branded generics. Similarly, Medley and EMS Sigma Pharma, Brazil's two largest generics makers, have standard corporate brand packaging to appeal to patients. Teva named its first biosimilar agent Tevagrastim, to compete with Amgen's brand drug Neupogen (filgrastim) for severe neutropenia.

Meanwhile, the increase in generic/branded competition over some particular drugs comes at the cost of an expected reduction in competition between different branded drugs in the market that are used to treat the same condition. There are two desirable outcomes that happen once a new drug enters the market: 1) It increases the options for treatment that are available on the market today, even before a patented drug goes into its generic state, which could be years away. Thus, competition increases in the short run; and 2) The new generic entrant may prove to be more desirable for some consumers in a given class than the current originator in the market. Consequently, the new entrant increases the class of consumers who are benefited by the second entry. (Epstein, 2011)

Furthermore, the logical sequence after patent expiration is that the competition would rise. However, a study has shown that the volume of drugs prescribed declined after patent expiration, and expanded only modestly for many others. These findings suggest that there may be more to a patent expiring than a change in price competition alone because price cuts should raise volume, which suggest the possibility of certain strategies that the originator company initiate in order to keep their monopoly or position in the market. While still protected by the patent, originator companies market their products to doctors and patients to make them aware of their existence and properties. As generics have little incentive to do the same, industry-wide marketing declines dramatically upon patent expiration. Thus, when patents expire, changes in marketing and prices have opposing effects on volume. Consequently, prescriptions may decline, if the cut in marketing lowers volume more than the cut in prices raises it. (Philipson, 2014)

In meanwhile, generics many times fail to reach larger patient populations, which is especially troubling for diseases that are under-treated relative to their prevalence. Thus, many generic companies believe that entering the pharmaceutical market of a branded well known drug is full of risk, usually pharmaceutical companies build their best market capabilities mostly through two main risk assessments: Business risk assessment and Financial risk assessment.<sup>10</sup> (PEFINDO, 2014)

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<sup>10</sup> See (PEFINDO, 2014) The business risk assessment includes: 1) The Market position; 2) Product mix and development; 3) Operating Management; and 4) Marketing and Distribution Channel. The financial risk assessment includes: 1) Financial policy; 2) Capital Structure; 3) Cash flow protection and liquidity; and 4) Financial flexibility.

Consequently, entering the market needs to go through all these four steps: 1) Forecasting and planning; 2) Procurement; 3) Production; and 4) Customer Management. Therefore, not all generic companies specially the small ones are willing to take such risks or steps to enter the market, and the ones that have these capabilities are constantly tempted by the offers of the originator companies, especially if the first 180 days' period of marketing exclusivity<sup>11</sup> are done by the first generic entrant company. At this point, if a generic company took an approval of their generic drug from the FDA and decided to challenge the patent of the originator company, the 180 days' period never ends, which prevent any other generic company from entering the market, and the branded company may then make a payment to the generic company or give other incentives or benefits to not enter the market and move to settlement, which is known as reverse payment patent settlement or pay-for-delay agreements or side deals. The originator companies often offers such payments because it costs much less to prevent generic competition compared with the money it makes out of its branded drug. (Tanne, 2008)

## **2.4 INTELLECTUAL PROPERTY AND COMPETITION STRATEGIES IN THE PHARMACEUTICAL SECTOR**

Intellectual Property plays a huge role in the pharmaceutical sector, one cannot deny its importance to push originator companies to innovate new effective drugs or develop the existing ones on daily basis. However, as we mentioned before, the biggest incentive for originators is the commercialization and monetization of their IP portfolio, especially their patents. Therefor they are constantly looking forward to get the best out of their IPRs. Managing Intellectual Property Rights of branded drugs companies have become number one goal in each company to maximize their profit and get the monopoly market position they strive for. Consequently, many attempts have been born to delay and hamper the introduction of generic pharmaceuticals or new drugs that may compete with the

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<sup>11</sup> See (U.S. Department of Health and Human Services FDA, 2003) The 180-day period of generic drug exclusivity provides a very strong financial incentive for an ANDA applicant to challenge a patent that it believes it does not infringe or that it believes is invalid or unenforceable. FDA's pre-Mova interpretation limited the number of times 180-day exclusivity was granted because an ANDA applicant had to be first to challenge a patent and win the patent litigation to be eligible for 180-day exclusivity.

branded or branded generic drugs already on the market today. Such practices were monitored in different countries and economies such as Europe, United States of America, United Kingdom, India, and more.

#### **2.4.1 IP AND COMPETITION STRATEGIES IN UNITED STATES OF AMERICA**

The U.S. drug industry spent between US\$30 to 40 billion each year in the period 1999-2005 towards funding their respective research operations in the pharmaceutical sector. Since the early eighties, U.S. industries have always spent between 15-22% of their sales revenues towards R&D activities. Pfizer spends around US\$6 billion on R&D every year. Generally speaking, generic drugs may be launched upon the expiration of the originator's patent or before expiration. However, if the generic company intends to launch its product before the expiration of the patent, it must notify the FDA and certify that its product does not infringe the originator's patent or prove that such patent is invalid. The FTC concluded that the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act has increased generic drug entry, but also led to anticompetitive strategies through its two provisions governing generic drug approval prior to the originator's patent expiration that give 180 days' generic exclusivity and the 30 months stay of generic approval. (Vitale, 2014)

In July 2002, the FTC issued a report summarizing a lengthy study of allegedly anticompetitive agreements between brand and generic drug companies that took advantage of one or the other of the two provisions. The report recommended limitations and clarifications of those two provisions to mitigate the possibility of abuse that deters more generic drug availability. Consequently, the FTC has been active in bringing competition enforcement actions at the pharmaceutical manufacturer level. In the last years, the Commission has brought enforcement actions against 19 mergers in the branded and generic pharmaceutical sectors e.g. Novartis/Alcon, Merck/Schering Plough, Pfizer/Wyeth, Teva/Barr, Teva/Cephalon, Actavis/Warner Chilcott, Watson/Actavis, Mylan/Agila. The annual reports by the FTC indicate that generic versions of as many as 142 brand-name drugs have been delayed by pay-for-delay arrangements between drug manufacturers since 2005. (FTC, 2012)

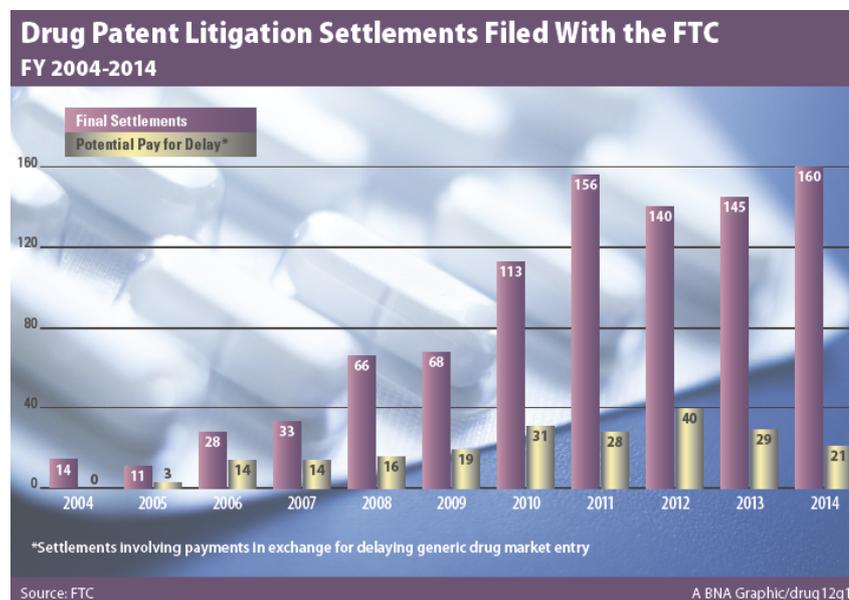
However, because the details of these deals rarely become public, consumers have largely been kept in the dark about the extent of these side deals problem. Thanks to legal challenges brought by the FTC, consumer class action lawsuits, research by legal experts, and public disclosures by drug makers, many information has been published for the public. One of the most astonishing findings was the discovering of 20 drugs affected by pay-for-delay deals that had a huge impact on the pharmaceutical market, such as holding back generic drugs used by patients with a wide range of serious or chronic conditions, ranging from cancer and heart disease, to depression and bacterial infection. In addition, these payoffs have delayed generic drug for five years, on average, and as long as nine years. Moreover, these brand-name drugs are highly expensive, as they cost 10 times more than their generic substitutes, on average, and as much as 33 times more. Finally, these brand-name drug companies have made an estimated US\$98 billion in total sales of these drugs while the generic versions were delayed. (U.S. PIRG, 2016) See figure (4)

Top 20 generics delayed by Pay-for Delay deals - Figure (4)

(U.S. PIRG, 2016)

Prescription Drug (and Drug Maker)	Condition the Drug is Commonly Prescribed to Treat	Annual Sales Before Generic (\$ millions) <sup>A</sup>	Year of Pay-for- Delay Deal	Length of Delay <sup>A</sup>	Price of Brand-name Drug <sup>C</sup> vs Price of Generic Drug (\$)	
					Brand-name Drug (\$)	Generic Drug (\$)
<b>Adderall XR</b> (Shire)	Attention deficit hyperactivity disorder (ADHD)	1,500 M	2006	3.0 years <sup>6</sup>	238	102
<b>Aggrenox</b> (Boehringer Ingelheim)	Stroke risk, blood clots	331 M <sup>7</sup>	2008	6.8 years <sup>8</sup>	294	73 <sup>†</sup>
<b>Altace</b> (Sanofi)	High blood pressure, heart failure	700 M <sup>9</sup>	2006	3.0 years <sup>10</sup>	115	12
<b>AndroGel</b> (Solvay Pharmaceuticals/ Abbott Laboratories)	Low testosterone in patients with AIDS, cancer and other conditions	1,332 M <sup>11</sup>	2006	8.7 years <sup>12</sup>	379	96 <sup>†</sup>
<b>BuSpar</b> (Bristol-Myers Squibb)	Anxiety	600 M <sup>13</sup>	1994	6.25 years <sup>14</sup>	not available <sup>15</sup>	12
<b>Caduet</b> (Pfizer)	High cholesterol and coronary artery disease	266 M	2008	1.7 years <sup>16</sup>	266	113
<b>Cipro</b> (Bayer)	Bacterial infection, anthrax exposure	1,300 M <sup>17</sup>	1997	7.0 years <sup>18</sup>	346	23
<b>Effexor XR</b> (Wyeth/Pfizer)	Major depressive disorder, anxiety and panic disorder	2,400 M	2005	4.7 years <sup>19</sup>	194	17
<b>K-Dur</b> (Schering-Plough/Merck)	Low blood levels of potassium (hypokalemia)	250 M <sup>20</sup>	1997	4.0 years <sup>21</sup>	not available <sup>22</sup>	21
<b>Lamictal</b> (GlaxoSmithKline)	Epilepsy, bipolar disorder, Lennox-Gastaut Syndrome	1,500 M	2005	3.0 years <sup>23</sup>	465	14
<b>Lipitor</b> (Pfizer)	High cholesterol, coronary artery disease	7,400 M	2008	1.7 years <sup>24</sup>	205	18
<b>Nexium</b> (AstraZeneca)	Gastroesophageal reflux disease (GERD), other digestive disorders	5,638 M <sup>25</sup>	2008	6.1 years <sup>26</sup>	222	56 <sup>†</sup>
<b>Niaspan</b> (Abbott Laboratories)	High cholesterol, coronary artery disease	1,037 M <sup>27</sup>	2005	8.3 years <sup>28</sup>	122	30 <sup>†</sup>
<b>Nuvigil</b> (Cephalon/Teva)	Narcolepsy, obstructive sleep apnea and hypnea syndrome	331 M <sup>29</sup>	2012	4.0 years <sup>30</sup>	450	113 <sup>†</sup>
<b>Nolvadex/Tamoxifen</b> (AstraZeneca)	Breast cancer	400 M <sup>31</sup>	1993	9.0 years <sup>32</sup>	99 <sup>33</sup>	20
<b>Propecia</b> (Merck)	Enlarged prostate, male pattern baldness	142 M <sup>34</sup>	2006	7.0 years <sup>35</sup>	89	72
<b>Provigil</b> (Cephalon/Teva)	Narcolepsy, multiple sclerosis-related fatigue	1,100 M <sup>36</sup>	2005	6.25 years <sup>37</sup>	1,213	520
<b>Sinemet CR</b> (Bristol-Myers Squibb)	Parkinson's disease	150 M <sup>38</sup>	1995	11.0 years <sup>39</sup>	39	13
<b>Wellbutrin XL -150 mg</b> (Biovail)	Major depressive disorder, seasonal affective disorder	835 M <sup>40</sup>	2006	1.0 years <sup>41</sup>	250	29
<b>Zantac</b> (GlaxoSmithKline)	GERD, digestive disorders	2,900 M <sup>42</sup>	1995	2.0 years <sup>43</sup>	278	11

In July 2010, the U.S. House of Representatives approved a bill containing a provision to curtail settlements of patent litigation between innovator drug companies and generic drug producers. Supporters of the bill call these “pay-for-delay” settlements - See figure (5) - because they delay the entry of generic drugs into pharmaceutical markets. They hope the bill will hasten generic entry and lower the price of drugs. Unfortunately, banning pay-for-delay settlements will have almost no effect on the price that patients pay for drugs, additionally it’ll reduce pharmaceutical innovation and may harm future patients.



Drug Patent Litigation Settlements filed with U.S FTC - Figure (3)

(Elfin, 2016)

In contrast, according to Médecins Sans Frontières (MSF) reports, the generic competition, for instance, has lowered the price of antiretrovirals from more than US\$10,000 per patient per year in 2000 to US\$67 today. This has helped to galvanize the fight against HIV in many of the worst affected countries. It worth to mention that MSF has developed a ‘Push, pull, pool’ project for tuberculosis drugs; it aims to have the initial costs of R&D financed through grants (push funding), further R&D achievements incentivized by milestone prizes (pull funding), and intellectual property shared to enable

collaboration and fair licensing of successful medicines (pooling). MSF believes this approach would “de-link” the costs of developing new medicines from the price of resulting therapies. Patent pooling is itself a relatively new idea. Set up in 2010, the Medicines Patent Pool (MPP) is a voluntary arrangement that has the backing of the United Nations. The MPP negotiates with key patent holders for licenses to be made available in the pool. Manufacturers can then seek a license from the MPP to produce a generic medicine and pay royalties to the patent holder. The MPP has signed agreements with Bristol Myers-Squibb, Gilead, Roche, ViiV Healthcare and the US National Institutes of Health. (The Pharmaceutical Journal , 2014)

#### **2.4.2 IP AND COMPETITION STRATEGIES IN EUROPE**

In 2009 inquiry report, the European Commission (EC) has concluded that the market of new generic entries was unnecessarily delayed and that the number of novel medicines was decreasing. According to this inquiry, it takes 7 months after patent expiry for generic medicines to arrive. This inquiry showed that the originator companies used a variety of strategies to extend the commercial life of their drugs without the generic entry for as long as possible, the main used strategies were as follows: 1) Patenting strategies such as patent clusters; 2) Disputes and litigation against potential generic competitors; 3) Patent settlements with generic companies; and 4) various interventions before regulators and launch of follow-on products. Other strategies were found that allow the novel medicines to decline in the market or get the path to the market from the first place, in particular the inquiry identified the following problems: 1) Patents aimed exclusivity against the development of a competing product; 2) Litigation against other originator companies; and 3) Opposition against, mainly, secondary patents. (Hall, 2011) According to the EC report of the pharmaceutical sector inquiry, some patent settlements in the pharmaceutical sector may prove to be problematic from a competition law perspective. Of particular interest are settlements that may restrict generic market entry in exchange for benefits transferred from the originator to the generic company sometimes referred to as "pay-for-delay" deals. Such agreements result in delayed market entry of cheaper generic medicine, to the detriment of patients and taxpayers financing the health system. Consequently, the commission had to monitor such

settlements for better understanding of the use and evolution of the patent settlements in the EU. (European Commission, 2013)

Unlike the U.S., the EU does not have a regulation similar to the Hatch-Waxman Act, which provides a single framework for resolving patent disputes between originators and generics. Instead, in the EU, patents are issued by each individual EU Member State and the originator who seek to enforce its patents and prevent generics from entering the market must bring litigation in the courts of each relevant EU Member State. In this context, it is very difficult and expensive for originator companies to effectively enforce their patents to prevent generic entry. (Clancy, et al., 2015)

According to the French Competition Authority, the development of generics is a competition factor and the sale of generic medicines represents a substantial source of savings for public accounts in France. (Taylor Wessing, 2013) In Europe, some practices of pharmaceutical companies may, in certain circumstances, lead to violations of EU competition law. These include patent clusters, patent thickets, patent settlements which aim to prolong market-exclusivity, and other anti-competitive strategies that result in high market prices. These types of behavior can also take away the incentive to innovate, as the pressure of competition from generic products encourages all pharmaceutical companies to make available the best possible drugs for EU citizens.

However, competition officials do not have as long of a history of enforcement against pharmaceutical patent settlements, but the European Commission (EC) has been very active in recent years, issuing hundreds of millions of dollars in fines. For instance, the EC issued the largest penalty to date in a reverse payment case, fining French drug manufacturer Les Laboratoires Servier and five generic companies more than €427 million for reverse payment patent settlement agreements that the EC asserts kept generic versions of blood pressure medication Perindopril off the market. (Wilson Sonsini Goodrich & Rosati, 2014) It is difficult, however, to reconcile the EC's view that reverse payment patent arrangements are likely to be anti-competitive with the decisional practice of the European Courts on settlements of litigation involving IPR.

### 2.4.3 IP AND COMPETITION STRATEGIES IN UNITED KINGDOM

In UK, a period of exclusivity is available for pharmaceutical products in the UK under the EU's 8+2+1 formula, contained in Article 10.1 of the Code for Human Medicines Directive.<sup>12</sup> For the first eight years after the issuance of the first marketing authorization for a drug, the originator company's pre-clinical and clinical data cannot be referenced in a generic marketing authorization application, for the same pharmaceutical drug (regulatory data protection). However, regulatory data protection is not a true exclusivity because it does not prevent another company or a competitor from generating its own pre-clinical and clinical data in support of a marketing authorization application for the same drug. For an additional two years, a generic company cannot market a generic version of the pharmaceutical product, although the generic company can progress its application for a marketing authorization, relying on the originator company's data, to be in a position to launch at the end of the two-year marketing protection period. An additional one year of marketing protection can be obtained where a new indication is registered for the same drug during the eight-year protection period, which brings significant clinical benefit over existing therapies. However, if the new indication is a pediatric indication which brings significant clinical benefit over existing therapies, it is not possible to also benefit from the six month SPC extension for conducting pediatric studies. The company will need to decide which of the two rewards is the most valuable. (Practical Law "A Thomson Reuters Legal Solution", 2015)

One of the most interesting patent extension in the pharmaceutical sector is the possibility to extend the protection of a substance or composition through the supplementary protection certification (SPC) system, which allow to compensate partially for the erosion of effective patent protection due to the lengthy regulatory process leading to the grant of a marketing authorization. SPC can extend the protection of a patented active ingredient, or combination of active ingredients, present in a pharmaceutical or plant protection product after the expiry of the patent. A SPC does not extend the term of the patent, but protects a product which falls within the scope of the patent and which is the

subject of a marketing authorization. A SPC expires 15 years from the date of the first marketing authorization in the EEA, or five years after expiry of the patent, whichever is earlier.<sup>13</sup> (Practical Law "A Thomson Reuters Legal Solution", 2015) which allow the originators to maximize their profit and earn the fruit of their excessive R&D investment. Despite these regulations, there are still several anti-competitive practices in the UK pharmaceutical market. According to Britain's competition watchdog, between 2001 and 2004, GlaxoSmithKline (GSK.L) has abused its position in the pharmaceutical market and has been striking deals to delay the launch of cheap generic equivalents of its former blockbuster antidepressant Seroxat and paid generic companies over 50 million pounds intentionally to delay their entrance. Therefore the Competition and Market Authority (CMA) has fined both GSK.L and other generic drug companies involved including Germany's Merck KGaA (MRCG.DE) around 45 million pounds of total penalties. (Hirschler, 2016) Mylan NV and German drugmaker Merck KGaA were also fined a total of 5.8 million pounds as part of the probe. The CMA said it also levied a 1.5 million-pound penalty on Actavis U.K. Ltd., which was Alparma Ltd. before, Xellia Pharmaceuticals ApS, formerly called Alparma ApS, and on Alparma LLC, which previously was Zoetis Products LLC, Alparma LLC and Alparma Inc. (Bodoni, 2016)

#### **2.4.4 IP AND COMPETITION STRATEGIES IN INDIA**

More than half of Indians do not have access to basic medical services and when it comes to healthcare, the estimated 1.25 billion Indians, the majority of whom live below the poverty line in rural areas, have extremely limited access to medical care in terms of money and availability. The austere disparity of available healthcare in India has shaped the current market environment and was always kept in mind when examining the industry. (Choukse, 2013)

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<sup>13</sup> See (Practical Law "A Thomson Reuters Legal Solution", 2015) SPCs are granted by the UKIPO in the UK. A further extension of six months may additionally be available if an agreed Pediatric Investigation Plan (PIP) is completed and the marketing authorization is updated with the data from the PIP. The formalities of Regulation (EC) 1901/2006 on medicinal products for pediatric use (Pediatric Medicinal Products Regulation) (for pediatric extensions) must be complied with. Like SPCs, pediatric extensions are granted in the UK by the UKIPO.

The Indian pharmaceuticals industry is one of the largest and most advanced amongst developing countries. It is the world's third largest in terms of volume and stands at fourteenth position in terms of value (US\$13 billion in 2012). (Kelly Scientific Publications, 2013) According to the Associated Chambers of Commerce and Industry in India (ASSOCHAM), the industry was expected to touch the US\$20 billion mark by 2015, making it one of the world's top ten pharmaceuticals markets. The industry was expected to grow between 11% and 13% in 2013. A report released on the industry considers that Generics will continue to dominate the market, while patent-protected products are likely to constitute 10% of the pie up to 2015 (McKinsey Report, 2007). According to ASSOCHAM, the industry could account for about 30% of the growing world generic market, up from its current 22%. (Dr. Murali Kallummal, 2012) More specifically, in 2012, 40 brand-name drugs lost their patent protection, meaning that Generics were permitted to make their own lower-priced versions (Katie Thomas, 2012).

In 2009-10, the Competition Commission of India (CCI) conducted a market study to identify the competition issues prevalent in the pharmaceuticals industry (Competition Law and Indian Pharmaceutical Industry, 2010). The study examined issues concerning the working of the pharmaceuticals sector from both the horizontal and vertical points of view. Although the report shed some light on the EU and US approach towards “Pay-for-Delay” deals, it failed to recommend or even identify its implications for the industry. In the Indian Patent Act of 1970, amended in 2005, Section 3(d) is one of the most intensely and widely discussed, though much controversial provision in the Act. Section 3 (d)<sup>14</sup> has been reintroduced as a safeguard clause to avoid broad patents in the area of pharmaceuticals. Although the main purpose of this provision is to prevent what is so-called “ever-

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<sup>14</sup> See (CENTAD, p.78-82, 2010) Section 3(d) reads as follows: ...the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy

greening”, it did not reach its ultimate expected effect out of its legal provision on the one hand. While the purpose of this provision seems to exclude certain forms of inventions by using a higher patent law threshold of inventive step, there is no prima-facie clarity on what is excluded through this exercise.

On the other hand, the Indian Patent Office rejected 46 cases where a pharmaceutical patent application was opposed by generic companies and/or public health groups. In these 46 rejections, around 60% were based on failure to comply with section 3(d). This briefly illustrates the importance of section 3(d) in preventing “ever-greening” of pharmaceutical inventions. (CENTAD, 2010) In addition, it ensures that India has taken a step in the right direction to encourage domestic pharmaceutical innovation. (Basheer, 2009) Section 3(d) excludes mere discovery of new forms (derivatives) of known substances from patentability unless they result in the enhancement of known efficacy of the substance. This “efficacy” provision is further explained to mean differing “significantly in properties with regard to efficacy”. This restriction is aimed at circumventing ever-greening of patents. However, there is distinction between what amounts to ever-greening and what are generally called as incrementally modified drugs which is often tricky. (EU Competition Commission, 2009) therefor the Competition Commission of India (CCI), has begun scrutinizing and investigating pharmaceutical patent settlement agreements between brand and generic firms for potential anticompetitive effects. It has been reported that the CCI is examining two sets of settlements resolving patent litigation in India. These investigations involve U.S. and Indian companies engaged in litigation in India. (CENTAD, 2010)

The Competition Act 2002 recognizes the importance of IPR, including patents. While section 3 of the Competition Act prohibits anti-competitive agreements, sub-section (5) thereof states that this prohibition shall not restrict "the right of any person to restrain any infringement of or to impose reasonable conditions, as may be necessary for protecting any of his rights". Therefore, by implication, unreasonable conditions such as “pay-for-delay” imposed by Originator in order to protect his patent may appear to be anti-competitive under the Act. Such an unfair/unreasonable condition when imposed

by a dominant player i.e. the Originator in this case, may also amount to abuse of dominant position under section 4 of the Competition Act. (Choukse, 2013)

The CCI analysis of patent settlement agreements is likely to parallel the enforcement policies that the FTC has pursued in the United States. The competition authorities from the two countries have had a strong working relationship over many years. FTC competition staff has visited and served as advisors to the CCI in an effort to assist the country in developing competition policy and enforcement procedure. In 2012, the CCI and the United States competition agencies (FTC and DOJ) codified this relationship by signing a Memorandum of Understanding in order to promote increased cooperation and communication between the agencies. The memorandum provides, among other things, that 1) the agencies will cooperate as agreed and work to keep each other informed of significant competition policy and enforcement developments, and 2) that the agencies will consult on competition matters and communicate through regular meetings to exchange information on policy and enforcement priorities. (Wilson Sonsini Goodrich & Rosati, 2014)

Some pay-for-delay agreements has been detected in India, according to several reports, the CCI has examined patent settlements made between foreign brand-name pharmaceutical companies and their generic counterparts in India which may lead to the unavailability of cheaper drugs in the market. The anti-trust agency has reportedly noticed two deals. One involved the Tarceva lung cancer drug made by Roche and a deal with Cipla. The other was a settlement between Glenmark Pharmaceuticals, one of India's largest generic drug makers, and Merck concerning the Januvia diabetes pill. (Silverman, 2014)

#### **2.4.5 IP AND COMPETITION STRATEGIES IN DEVELOPING AND LEAST-DEVELOPED COUNTRIES**

The impact of Intellectual Property regime on public health in developing and least-developed countries is enormous, thus many of these countries especially the African Group were constantly in need of clear clarification for many international regulations and flexibilities that rule access to

medicine such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Consequently, the Doha Declaration on TRIPS and Public Health was conducted in order to give the full right to the World Trade Organization (WTO) countries members to protect public health and, in particular, to promote access to medicines for all.

Additionally, detecting side deals in some countries may be hard to monitor, however, one has to observe how they actually get their medicines. Do they have the pharmaceutical industry required to enter the pharmaceutical market? Do they have generic manufacturers or able to provide generic drugs for their domestic market? Do they have the awareness, regulations and enforcement methods that may help to detect and stop such agreements that will certainly decrease their access to medicine? Of course, the answer for these questions vary greatly from a country to another and certainly needs a separate research. Access to medicine is a global struggle and this struggle is incomparable in some of these countries, where the availability of generic drugs has a massive importance since it has a major influence on the drug prices, therefore a fair pharmaceutical competition is a must in order to maintain a sustainable access to medicine.

One has to mention that some pharmaceutical companies are making some efforts to improve access for affordable medicines in developing countries, for instance in September 2014, U.S. pharmaceutical company Gilead Sciences agreed to license “voluntary license” hepatitis C antivirals sofosbuvir and ledipasvir to seven India-based manufacturers, which will be able to produce and sell more affordable versions in 91 developing countries. (The Pharmaceutical Journal , 2014) Moreover, the World Trade Organization (WTO) agreements allow for member countries to compulsorily license medicines in certain circumstances if they believe the health of the nation requires such license. This has happened recently in Indonesia; the government issued compulsory licenses for seven HIV medicines with the owner companies to receive 0.5% in royalties. (The Pharmaceutical Journal , 2014)

## 2.5 CONCLUSION

Generic drugs or bio-similar fill the role of lowering the price of health further when patents expire. However, the introduction of these copies is contingent on the prior existence of a branded drug. Thus, the benefits of generic drugs are made possible only through the brand – the average cost of a new drug can be \$800 million to \$2.6 billion. (Grabowski, 2002 ) In other words, a generic drug cannot lower the price of health further unless its branded parent drug lowered the price to start with. Thus, the larger affordability of health that occurs when generic alternatives are introduced is mostly attributable to the branded drug, as without the branded drug, the further price cuts would be infeasible. Additionally, generics often do not expand the reach of medicines to a broader patient population. Patent expirations lead to increased generic competition that, in turn, results in lower prices and thus more patients can afford cheaper medicines. This is indeed the classic economic argument for competition lowering prices and raising volume upon which much of intellectual property law is based. However, according to some economists this may not directly apply to biopharmaceuticals. (Philipson, 2014) As we have seen, reverse payment patent settlements or pay-for-delay agreements have been detected in many countries. Many authorities have taken concrete steps towards banning such deals, however the question remains if banning these agreements will have any effect on the drugs' prices or affect negatively the pharmaceutical innovation in the future.

## **CHAPTER THREE: REVERSE PAYMENT PATENT SETTLEMENTS**

### **3.1 The Notion of Reverse Payment Patent Settlements “Pay-for-Delay Agreements”**

### **3.2 The Economics of Reverse Payment Patent Settlements**

3.2.1 Strategies of Patent Litigations

3.2.2 The Incentives for Reverse Payment Patent Settlements

3.2.3 Risks of the Originators’ Monopoly

### **3.3 The Impact of Reverse Payment Patent Settlements**

3.3.1 The Impact on the Domestic Market

3.3.1.1 The Impact on Patent Holders

3.3.1.2 The Impact on Consumers

3.3.2 The Impact on the National Level

3.3.3 The Impact on the International Level

### **3.4 Conclusion**

## **CHAPTER THREE**

### **REVERSE PAYMENT PATENT SETTLEMENTS**

#### **3.1 THE NOTION OF REVERSE PAYMENT PATENT SETTLEMENTS**

Reverse payment patent settlements, also known as "pay-for-delay" agreements or "pay-to-delay" deals, are a kind of an agreement that settles patent infringement litigations, in which the patent holder agree to make a payment for a potential generic competitor that has threatened to enter the market. In other words, a pay-to-delay deal is where the branded-drug firm settles with the generic firm by paying it to acknowledge the validity of the patent and to stay out of the market for a number of years. In some cases, the generic firm may gain an authorized entry under license from the branded firm into the market at a later date but before the expiration of the patent. (Bokhari, 2016) The term "reverse payment" refers to the fact that the payment moves in the opposite direction compared to what would ordinarily be expected in patent law in which a potential infringer often pays the patent holder for the right to enter the market. Such settlements have been criticized and categorized in some cases as anti-competitive practices, thus contrary to the public interest and violate competition regulations in many countries, since they frustrate the principle of fostering competition and the incentive of generic firms to enter the market. (Wikipedia, 2015)

#### **3.2 THE ECONOMICS OF PAY-FOR-DELAY SETTLEMENTS**

Generic manufacturers mostly wish either to challenge the validity of a patent or arguing that their generic version is not violating the patent for the main purpose of entering the market. In such context, a patent holder may sue a generic manufacturer even when the patent is weak, which will allow him to sidestep competition by offering patent settlements that pay the generic firm and prevent lower-cost alternatives to enter the market, which effectively block all other generic drug competition for a growing number of branded drugs.

### 3.2.1 STRATEGIES OF PATENT LITIGATIONS

Patent litigations often arise because the patents are not a full-proof property right, in another word, there is always some uncertainty in both the validity and the scope of the patent. Thus, determining the patent scope and validity is very important in many antitrust suits challenging pharmaceutical patent settlements. For instance in U.S., the prospect of earning higher profits as the only firm marketing a generic version of a drug for 6 months (180-day) forms an incentive to defend against the patent infringement claims brought by the branded drug firm. (U.S. Food & Drug Administration, 2003) Over the past years, generics firms have initiated 65% more U.S. patent lawsuits against branded pharmaceuticals and won 70% of cases, often resulting in generic copies coming to market years before scheduled patent expirations. In addition, innovator companies are realizing that generic competition in emerging markets can be even more formidable, often with dozens of generic copies for a single brand. (Bernard, 2011)

Accordingly, Generic Pharmaceutical Association (“GPhA”) vigorously opposes restricting the right of parties in drug patent litigation to settle their disputes out of court. Settling patent cases cuts short lengthy court trials with potential appeals and may or may not guarantee that lower cost generic versions of brand-name drugs come to market before patents expire. Banning settlements would force companies to continue drawn-out litigation until a court handed down its decision and then allow generic market entry only if the generic company wins the case. Over the past years, generics have won less than 50 percent of the patent cases. (Generic Pharmaceutical Association, 2013) The bottom line is clear and convincing: settlements guarantee savings for consumers, the government and healthcare providers. In contrast, limiting settlements may result to losing these savings by betting that the generic company will always win the patent suit. So far, GPhA is committed to preserving current law, which allows companies to settle patent litigations out of court. (Wright, 2015)

### 3.2.2 INCENTIVES FOR PAY-FOR-DELAY SETTLEMENTS

The counteracting incentives of the originator and generic companies close to loss of exclusivity lead generally to patent litigation and both of them have an important incentive to prevail in the patent infringement lawsuit. The originator tends to preserve its patent monopoly in the market by proving that its patent is valid, in contrast the generic knows that it may enter the market with an advantage of a period of exclusivity if it proves that the patent is invalid. Both parties in general have strong incentives to settle, because paying the generic company is certainly easier than competing in the market, even though it is highly likely that the originator will win the patent litigation. Mostly, both parties tend to avoid the cost of prolonged litigation, in addition, settlement will prevent the patent to be invalid, thus generate monopoly profits that the originator and the generic can divide between them. The generic often agrees to dismiss the suit, even though the patent is vulnerable, mostly because the originator pay the generic more than the generic would have earned by invalidating the patent. (Geradin, et al., 2015) The main issue here is that the generic maker does not internalize the consumer benefit coming out of contesting the patented drug.

In the U.S., Generic manufacturers are incentivized via a clause in the Hatch-Waxman Act of 1984, known as the “para 4 challenge”, which states that the first generic which successfully challenge a patent will get a 6 months’ exclusivity period. For instance, if a generic challenges a patent and win, no other generic will be allowed to enter the market for another 6 months from the entry date of the winning generic manufacturer. Therefor the branded-drug firms started to prevent this entry through pay-to-delay deals, so that the generic firm drop the patent challenge and stay out of the market. Consequently, these deals prevent the validity of the patent from being fully scrutinized by the court because if the patent turn to be invalidated, this will encourage generics to enter the market and cause prices to drop. In this sense, pay-to-delay deals represent a form of anti-competitive practices and are subject to increase scrutiny by competition authorities. Practically speaking, branded-drug firms need to pay off just one or a handful of generic challenges so that the remaining generic firms choose to stay out of the market. In other words, if there is a large first mover advantage in the generic segment of the

market, then the branded-drug firm can credibly threaten to launch an authorized generic via one of the firms it has already reached a pay-for-delay deal with. In this case, the remain generic firms will choose to not challenge the validity of the patent and the original pay-for-delay deal will be profitable for both involved parties, because if the branded-drug firm can launch an authorized generic, it will deprive the potential entrant of the large profit associated with first entry, consequently the expected profit will turn smaller than the litigation costs which push the remaining generic firms to stay out of the market. (Bokhari, 2016)

### **3.2.3 RISKS OF THE ORIGINATORS' MONOPOLY**

A market dominant position is generally determined by considering various factors combined, which include the IP holder's influence in the relevant market, the existence of competitors and their competitiveness, the possibility of substitute products or technologies to enter the market, the effects from neighboring markets, and so on. (Chang & Kim, 2016) Monopolies usually maintain super-normal profits in the long run. Once the originator maintains its monopoly over its brand-name drug through a pay-for-delay agreement, it automatically maintains a price monopoly over such drug in which the originator can set virtually any price it wants, since the Brand-name manufacturers rely on monopolistic pricing to recoup the high cost of bringing a new drug to market and to realize a profit on the drug. (Fialkof, 2014) The risks that evolve around such situation are enormous. First of all, many generic companies stay out of the market, thus only the originator continues to sell its branded-drug with no other alternative for consumers, which maintain the same high price of the drug or even increase the prices sometimes despite the fact that the patent is weak or its protection period has expired.

### **3.3 THE IMPACT OF PAY-FOR-DELAY AGREEMENTS**

The impact of pay-for delay agreements between brand-name pharmaceutical companies and generic makers has been labeled under anti-competitive practice in so many cases where they illegally stifle competition and preserve monopolies, which violate competition laws in most countries.

Although Generic makers may win about 75 percent of the patent suits that have been litigated to final judgement, reverse payment patent settlements are made to delay the entry of generic drugs to the market. The annual cost to consumers may reach \$3.5 billion in artificially higher prices. (Sullivan, 2013) The impact to the originator companies by the entry of generic drug is decreased revenues to lower drug prices and a significant decrease in the sales of the brand-name drug due to the existence of other similar and cheaper drugs in the market. (McClerkin-Small, et al., 2016)

### **3.3.1 THE IMPACT OF PAY-FOR-DELAY AGREEMENTS ON THE DOMESTIC MARKET**

When the drug makers settle patent litigations by making large payments to potential rivals, the possibility of competition entry is often affected negatively, which harm generic suppliers and prevent them from access to domestic market greatly. In contrast, if the generic firm win the litigation, either by establishing that the patent is invalid or that the generic firms' competing product is not infringing, the generic firms can get access to market prior to scheduled expiration. Successful pre-expiration challenges reallocate billions of dollars from drug producers to consumers. (Hemphill, 2006)

#### **3.3.1.1 THE IMPACT OF PAY-FOR-DELAY AGREEMENTS ON PATENT HOLDERS**

The most beneficial player in the pharmaceutical industry is typically the patent holder (the originator) since its patent has the longest exclusivity period of protection. Usually, the impact of pay-for-delay agreements on patent holders is highly positive. They gain million and sometimes billions of dollars in return of such agreements. Taking this position therefore has two advantages: 1) it simplifies what is now a complex and inconclusive inquiry as to which of these arrangements pass the rule of reason test and which of them do not; and 2) it probably corrects the current imbalance in the system, stemming from the short period of exclusivity left under the current regime. At worst, therefore, this maneuver looks like an extra six months on the patent life, which is welcome in its own right.

The gains from additional stimulation today could easily offset the monopolization effects down the road. Put otherwise, this approach makes best in the second best world by addressing the more fundamental flaw in the patent system: too-short initial terms. (Epstein, 2011)

### **3.3.1.2 THE IMPACT OF PAY-FOR-DELAY AGREEMENTS ON CONSUMERS**

The impact of pay-for-delay agreements on consumer welfare is huge. Consumer is the main player affected negatively by such practices, since they don't only decrease the amount of the alternative pharmaceuticals in the market, but also maintain high prices which cannot be affordable for many individuals specially in developed and under-developed countries. According to FTC study, these anti-competitive deals cost consumers and taxpayers \$3.5 billion in higher drug costs ever year. (Federal Trade Commission, 2016) Settlements between branded-drug firms and generic firms may harm consumers twice – first by delaying entry of generic drugs and then by preventing additional generic competition in the market following the generic entry. Such deals may inflate the prices of prescription drugs and harm competition, regardless of the form they take. (Federal Trade Commission, 2016)

In 2005, the European Commission imposed a fine of EUR60 million on an originator, AstraZeneca, for abusing the patent system in order to thwart generic competition from the market, for the blockbuster ulcer drug named Losec (see AstraZeneca/Losec and AstraZeneca appeal). This marked one of the first steps taken by the European Commission towards reforming the pharmaceuticals sector, which intensified with the launch of the pharmaceuticals sector inquiry launched in early 2008. This sector inquiry targeted the Originators and the Generics, and was coupled with unannounced inspections. The inquiry indicated a number of structural issues and problems in companies' practices that could delay entry of cheaper medicines into the European Economic Area (EEA). It radically contributed to the debate on EU policies for pharmaceuticals, especially for generic medicines. Following the sector inquiry, the European Commission conducted two monitoring exercises of patent settlements in 2010 and 2011. Pharmaceuticals companies were issued a request to file copies of patent

settlements. The sector inquiry concluded that the unfair practices in the sector have cost consumers more than EUR3 billion. (European Commission, 2008)

### **3.3.2 THE IMPACT OF PAY-FOR-DELAY AGREEMENTS ON THE NATIONAL LEVEL**

In 2011, the nonpartisan Congressional Budget Office (CBO) said a U.S. Senate bill to ban reverse payments would save the government \$4.79 billion and lower U.S. spending on prescription drugs by \$11 billion over a decade. (Sullivan, 2013) Such number may lead other governments into debt. It worth to mention that FTC has launched a campaign to stop deals in which brand-name drug producers pay generic-drug competitors to drop patent lawsuits that could lead to the earliest possible market entry of lower-cost generic medicines. The Federal Trade Commission unveiled the settlement, marking the first time the U.S. agency has obtained monetary remedies for drug purchasers in a "pay-for-delay" case. The U.S. agency alleged Cephalon collectively compensated several generic drug producers, including Teva, about \$300 million in exchange for abandoning challenges to the patent for Provigil and to refrain from selling generic versions of the drug until 2012. The FTC will hold the settlement money in an escrow account that will be available to compensate drug purchasers, including wholesalers, pharmacies and insurers that overpaid for the drug. In another portion of the settlement, Teva agreed not to enter into similar types of drug industry accords in the future that can postpone the introduction of generic drugs. The settlement comes ahead of trial proceedings that were scheduled to begin in a Philadelphia federal court. (Kendall, 2015)

### **3.3.3 THE IMPACT OF PAY-FOR-DELAY AGREEMENTS ON THE INTERNATIONAL LEVEL**

Following its sector inquiry in 2008-09, the European Commission, in 2009, started an investigation into the Indian generics Unichem Laboratories, Matrix Laboratories and Lupin along with the originator French firm Les Laboratoires Servier for potentially delaying the generic entry of

perindopril by entering into various patent settlement agreement (see Servier and generic companies). The recent fine on Ranbaxy and the ongoing European Commission investigation into Indian Generics will pose major challenges for the CCI in times to come. Although executed outside India, these deals can cause, or are likely to cause, an appreciable adverse effect on competition (AAEC) within India. The CCI has extra-territorial jurisdiction to undertake an inquiry into an agreement or an abuse of dominance that has taken place outside of India so long as there is an AAEC within India (see section 32, Competition Act 2002).

### **3.4 CONCLUSION**

Reverse payment patent settlements have pros and cons, on the one hand they may guarantee savings for consumers, the government and healthcare providers if the generic company do not win the patent suit. On the other hand, such settlements may harm the consumer welfare, first by delaying entry of generic drugs and then by preventing additional generic competition in the market following the generic entry. Such deals may inflate the prices of prescription drugs and harm competition, regardless of the form they take.

## **CHAPTER FOUR:**

### **STRATEGIES TO DELAY GENERIC ENTRY (CASE STUDIES)**

#### **4.1 Paying to Not Compete**

4.1.1 Federal Trade Commission v. Endo Pharmaceuticals Inc., Endo International Plc., Teikoku Pharma USA, Inc., Teikoku Seiyaku Co., Ltd., Watson Laboratories, Inc., Allergan Plc., Impax Laboratories, Inc.

4.1.2 Lundbeck v. Merck Kgaa/Generics UK (“Guk”), Alpharma, Arrow and Ranbaxy

4.1.3 Federal Trade Commission v. Actavis Inc.

4.1.4 Merck & Co. Inc. v. La Wholesale Drug Co. Et Al

4.1.5 Glaxosmithkline (Gsk) v. Merck Kgaa (Mrcg.De)

4.1.6 Secretary of State for Health and Others v. Servier Laboratories Ltd. and Others

4.1.7 Glaxosmithkline v. Korea Fair Trade Commission

#### **4.2 Reformulations of Drug**

4.2.1 Mylan Pharmaceuticals Inc., Et Al v. Warner Chilcott Public Limited, Et Al

4.2.2 Astrazeneca and its Blockbuster Drug Losec

#### **4.3 “No-AG” Agreements**

4.3.1 Smithkline Beecham Cooperation D/B/A Glaxosmithkline v. Teva Pharmaceuticals USA

4.3.2 Wyeth Llc v. Teva Pharmaceuticals USA, Inc.

#### **4.4 Conclusion**

## **CHAPTER FOUR: STRATEGIES TO DELAY GENERIC ENTRIES**

### **(CASE STUDIES)**

Pay-for-Delay agreements started to become a serious issue spread among countries which deprived potentially the public consumer of the significant price falls that generally result from generic competition. These deals were detected in Europe, United States of America, United Kingdom, India and more, they may harm the consumers and may lead the country's economy in vain. Pharmaceutical companies and governments must work together to ensure that the protection of intellectual property is not placed above public health. On the one hand, delaying the entry of cheaper drugs certainly has a negative impact on the well-being of consumers in the short run. Yet, on the other hand, shortening the exclusivity period during which pharmaceutical firms enjoy monopoly profits is likely to reduce their incentives to produce new drugs, which may harm the consumers' well-being in the long run. (Belleflamme, 2010)

According to a FTC staff report in the U.S., pharmaceutical companies filed a total of 145 final patent dispute settlements in fiscal year 2013, of which 29 created potential "pay-for-delay" agreements between branded and generic drug firms. Although the number of potential pay-for-delay settlements is down from FY 2012, it is similar to FY 2010 and 2011. Those 29 settlements potentially involve pay-for-delay because the brand manufacturer compensated the generic manufacturer, and the generic manufacturer was restricted from marketing its product in competition with the branded product for some period of time. The 29 settlements involved 21 different branded pharmaceutical products, with combined annual U.S. sales of approximately \$4.3 billion. Of the 29 potential pay-for-delay settlements, 13 involved generics that were so-called "first filers" meaning the companies were the first to seek FDA approval to market a generic version of the branded drug and at the time of the settlement were eligible to market the generic product for 180 days without competition from other non-first filing generics. Under FDA regulations, when first filers delay entering the market, other generic manufacturers cannot

enter, which makes these patent settlement deals particularly harmful to consumers. (Federal Trade Commission, 2014)

#### **4.1 PAYING TO NOT COMPETE**

##### **4.1.1 FEDERAL TRADE COMMISSION V. ENDO PHARMACEUTICALS INC., ENDO INTERNATIONAL PLC, TEIKOKU PHARMA USA, INC., TEIKOKU SEIYAKU CO., LTD., WATSON LABORATORIES, INC., ALLERGAN PLC, IMPAX LABORATORIES, INC.**

The FTC filed a complaint in federal district court alleging that Endo Pharmaceuticals Inc. and several other drug companies violated antitrust laws by using pay-for-delay settlements to block consumers' access to lower-cost generic versions of Opana ER and Lidoderm comprising approximately 64% of Endo's total annual revenues. In 2010, Endo and Impax illegally agreed that until January 2013, Endo would not compete by marketing an authorized generic version of Endo's Opana ER. In exchange, Endo paid Impax more than US\$112 million, including US\$10 million under a development and co-promotion agreement signed during the same time period. Endo used this period of delay to transition patients to a new formulation of Opana ER, thereby maintaining its monopoly power even after Impax's generic entry. In 2010, Opana ER sales in the United States exceeded US\$250 million. In May 2012, Endo and its partners, Teikoku Seiyaku Co. Ltd. and Teikoku Pharma USA, Inc., illegally agreed with Watson Laboratories, Inc. that until September 2013, Watson would not compete with Endo and Teikoku by marketing a generic version of Endo's Lidoderm patch. In exchange, Endo paid Watson hundreds of millions of dollars, including US\$96 millions of free branded Lidoderm product that Endo and Teikoku gave to Watson. As a result, Endo illegally maintained its monopoly over Lidoderm. In 2012, Lidoderm sales in the United States approached US\$1 billion. (United States District Court For The Eastern District Of Pennsylvania , 2016)

Endo and Watson illegally agreed that, for 7½ months after September 2013 (including the 180-day first-filer exclusivity period for which Watson was eligible), Endo would not compete by marketing an authorized generic version of Lidoderm. This agreement left Watson as the only generic version of

Lidoderm on the market, substantially reducing competition and increasing prices for generic lidocaine patches. As a result, Watson made hundreds of millions of dollars more in generic Lidoderm sales. With the complaint, the Commission also filed a stipulated order for permanent injunction against Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA, Inc., settling charges for those two defendants. Under the stipulated order, the Teikoku entities are prohibited for 20 years from engaging in certain types of reverse payment agreements, including settlements containing no-AG commitments like those alleged in the complaint. The agreed-upon order preserves Teikoku's ability to enter other types of settlement agreements in which the value transferred is unlikely to present antitrust concerns, such as those providing payment for saved future litigation expenses. The Commission vote to file the complaint was 3-1, with Commissioner Maureen K. Ohlhausen voting no and issuing a dissenting statement in connection with this vote. The Commission vote to accept the Teikoku settlement was 4-0. The complaint was filed under seal in the U.S. District Court for the Eastern District of Pennsylvania on March 30, 2016. (Federal Trade Commission, 2016)

#### **4.1.2 LUNDBECK V. MERCK KGAA/GENERICS UK (“GUK”), ALPHARMA, ARROW AND RANBAXY**

The European Commission has opened four formal proceedings in relation to patent settlements, involving Laboratoires Servier, Lundbeck, Teva & Cephalon, Johnson & Johnson and Novartis. The Commission fined nine drug makers for blocking the supply of a cheaper anti-depressant Cipramil (citalopram) to the market. The fines announced in 2013 totaled €146 million, and also targeted Merck KGaA, Ranbaxy, Arrow Group and Alpharma. (Anon., 2016) Several of these companies also filed appeals. Based on the Commission press release, when Generics were close to entering the market, Lundbeck agreed with each of them that they would stay out of the market in return for payment. Lundbeck did not prevent market entry by successfully enforcing its patent rights; rather, it simply paid Generics so that they would not compete, giving them the equivalent of what they would have earned if they had entered the market. Apart from making substantial payments, Lundbeck purchased generics stock for the sole purpose of destroying it, and offered guaranteed profits under a distribution

agreement. Lundbeck bought for itself the certainty that Generics would not enter the market for the duration of the agreements without giving the Generics any guarantee for entering the market thereafter. This is the first decision adopted by European Commission on “Pay-for-Delay” cases. (Choukse, 2013)

However, Lundbeck appealed against the “Pay-for-Delay” decision and lost it, in its judgment, the GC confirms the European Commission’s decision namely that the agreements between Lundbeck and the generic producers (Merck KGaA/Generics UK (GUK), Alpharma, Arrow and Ranbaxy) restricted competition ‘by object’ in violation of Art. 101(1) of the Treaty on the Functioning of the European Union (TFEU). (Cole & Robert, 2016)

#### **4.1.3 FEDERAL TRADE COMMISSION V. ACTAVIS INC.**

In 2003, Watson Pharmaceuticals known now as Actavis, Inc. filed an Abbreviated New Drug Application (ANDA), seeking approval to market a generic drug, AndroGel. The Originator, Solvay Pharmaceuticals, filed a suit against Actavis for patent infringement. The drug generated nearly US\$875 million in sales in 2012. The case soon settled by way of a settlement agreement, under which Solvay, the Originator, agreed to pay Actavis US\$19-30 million a year for nine years, while Actavis, Inc. agreed to promote Originator's AndroGel along with delaying entry of its own generic drug until 2015. (Sullivan, 2013) On 17 June 2013, arguably, the most significant patent antitrust decision in decades was delivered by the US Supreme Court, in *Federal Trade Commission v. Actavis, Inc.* reversing the order of Eleventh Circuit Court and holding that reverse payment patent settlements are subject to antitrust scrutiny under the “rule of reason” analysis<sup>15</sup> instead of being analyzed under the “scope of the patent” test. (Kim, 2015)

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<sup>15</sup> See (Supreme Court of United States, 2013) The Court did not agree with FTC's assertion that these settlements are per se illegal. It, rather, provided for the examination of these agreements under the “rule of reason”, as these settlements may only at times infringe antitrust laws.

#### **4.1.4 MERCK & CO. INC. V. LA WHOLESALE DRUG CO. ET AL.**

Merck & Co., an originator firm, filed a supplemental brief in the Supreme Court pleading that the Third Circuit had held in a suit against Merck and Generics in July 2012 that a pay-for-delay settlement should be presumed to be anti-competitive, which did not square with the recent ruling of the Supreme Court. On 24 June 2013, the Supreme Court vacated the ruling of Third Circuit and remanded the case back to the Third Circuit to evaluate these alleged anti-competitive agreements using the rule of reason.<sup>16</sup>

#### **4.1.5 GLAXOSMITHKLINE (GSK) V. MERCK KGAA (MRCG.DE)**

In April 2013, the Office of Fair Trading (OFT) issued a Statement of Objections to GlaxoSmithKline (GSK) for abusing its dominant position for striking deals with three generic drug makers by paying them to delay launching a generic version of paroxetine. GSK paid generic drug companies over 50 million pounds with the intention of delaying the potential entry of independent competitors, thereby depriving the National Health Service (NHS) of cheaper supplies. (Hirschler, 2016) The move by the OFT is the latest example of regulators trying to curb "pay-for-delay" deals, following a series of investigations against drug companies by the EU and US.

#### **4.1.6 SECRETARY OF STATE FOR HEALTH AND OTHERS V. SERVIER LABORATORIES LTD AND OTHERS**

In 2011, the UK Secretary of State for Health launched a lawsuit claiming £220 million damages from Servier Laboratories for abusing its dominant position in order to delay the entry of Generics.

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<sup>16</sup> See (Khurram Aziz, 2009), (Robert Pear, 2009) and (Choukse, 2013) Interestingly, President Barak Obama was elected after promising to bring down healthcare costs and specifically targeted anti-competitive behavior of pharmaceutical companies in his campaign.

The UK High Court suspended damages action against Servier due to the ongoing European Commission investigation. (Practical Law, 2016) It is certain that the OFT will gain momentum on the issue gradually against the backdrop of the OFT's recent investigation into GSK and the recent decision of the European Commission against Lundbeck. (Choukse, 2013)

#### **4.1.7 GLAXOSMITHKLINE V. KOREA FAIR TRADE COMMISSION**

The Supreme Court decision on GlaxoSmithKline's appeal to seek revocation of the KFTC decision which found that GSK and a domestic generic producer had engaged in unfair collaborative acts, thus violating the MRFTA in entering into a patent settlement agreement where the generic producer had agreed to withdraw its generic drugs from the market in exchange of, among others, the right to distribute GSK's original drugs for certain limited channels. (Chang & Kim, 2016)

## **4.2 REFORMULATIONS OF DRUG**

### **4.2.1 MYLAN PHARMACEUTICALS INC, ET AL V. WARNER CHILCOTT PUBLIC LIMITED, ET AL**

The FTC filed its amicus brief in a private antitrust action in which Mylan Pharmaceuticals Inc. alleges that Warner Chilcott PLC/Mayne Pharm Group maintained a monopoly in the market for its antibiotic Doryx by suppressing generic competition through three successive insignificant reformulations of the drug, combined with various efforts to curtail the availability of the original formulations. The district court granted the defendants' motion for summary judgment, and the plaintiffs appealed that ruling to the U.S. Court of Appeals for the Third Circuit. The FTC filed an amicus brief before the U.S. Court of Appeals for the Third Circuit explaining that the district court made significant analytical errors in ruling for defendants in a dispute involving allegations of pharmaceutical "product hopping." The brief explains that, in examining whether such conduct is unlawful, courts should account for the unique aspects of the pharmaceutical marketplace, including the nature of competition between branded pharmaceutical products and their generic counterparts.

Generic competition through state automatic substitution laws saves American consumers billions of dollars each year. Brand-name pharmaceutical companies can avoid this competition and preserve monopoly profits by combining minor product reformulations with efforts to damage or destroy the market for the original formulation. This tactic, commonly called “product hopping” can harm consumers. (Federal Trade Commission, 2015)

#### **4.2.2 ASTRAZENECA AND ITS BLOCKBUSTER DRUG LOSEC**

The tragic 9/11 events in 2001 implied a delay in the court proceedings in Boston that dealt with a case involving AstraZeneca and its blockbuster drug Losec (Prilosec in the US, with generic name omeprazol, with its key basic patent received by the Swedish company Astra in the US in 1981, later merged with Zeneca in 1998-9. This delay implied in turn that competitive entry into the Losec market was delayed. At this time media circulated an estimate of \$200 millions as the monthly profits reaped by AZ from this drug, profits that were to be heavily reduced by competitive entry which was sure to take place as soon as possible as the key patent expired as generic drug manufacturers had prepared their springboards for entry into this lucrative market. The sales, profits and profit margin of a blockbuster drug towards the end of its effective patent protection usually is very large, which incentivizes pharma firms to employ a myriad of means and tactics to delay entries by competitors, i.e. means to maintain a competitive position and sustain any temporary competitive advantages, such as patent protection. In the case of AZ and its pre-merger constituent Astra, the expiration of this key patent, i.e. the patent cliff, together with Astra’s anticipated overdependence upon Losec had early on been perceived in Astra to have such dramatic consequences on its financial performance that it became an argument in favor of Astra’s merger with Zeneca in 1998-1999. Astra had then since the 1980s tried to generate more radical innovations in its R&D pipeline but essentially without enough successes to be perceived as providing a business portfolio sufficiently diversified to pick up the company’s expected financial drop from the patent cliff, perceived by some as suicidal while disputed by others. Thus all in all, extending the effective patent protection of Losec and its successor Nexium in a second

product generation, i.e. what is referred to as ever-greening, bridging the patent cliff had become a strategic issue for AZ with powerful incentives to invent various strategies to that effect. (Granstrand & Tietze, 2015) Consequently, the originator and the first generic maker divide the market between them in whatever way they see fit. In the end, they usually seek to maximize their joint product by choosing the same prices and quantities as the single incumbent had done before the patent was invalidated. (Epstein, 2011)

### **4.3 “NO-AG” AGREEMENTS**

#### **4.3.1 SMITHKLINE BEECHAM COOPERATION D/B/A GLAXOSMITHKLINE V. TEVA PHARMACEUTICALS USA**

A New Jersey case was brought against GlaxoSmithKline (GSK) and Teva Pharmaceuticals (Teva) by direct purchasers of certain anti-epileptic drug products containing the active ingredient lamotrigine and marketed by GSK as LAMICTAL<sup>17</sup>. Although they entered into an agreement providing that GSK would not market an authorized generic version of Lamictal Tablets and Lamictal Chewables, and this agreement was well beyond the exclusionary scope of a now-expired patent listed in the Orange Book for GSK’s lamotrigine drug products and constitutes a naked market allocation agreement, the New Jersey court ruled that such patent settlements that involves authorized generic (AG)<sup>18</sup> agreements are not illegal. The Third Circuit’s K-Dur opinion is directed towards settlements when a generic manufacturer is paid off with money, which is not the case here. the Third Circuit contemplates a cash payment when it uses the term “reverse payment”, the lack of any case in which a drug patent settlement without a cash payment was subject to antitrust scrutiny, and that the lamotrigine agreement actually created generic competition sooner than otherwise would have occurred had Teva not challenged GSK’s patent. (Sullivan, 2013)

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<sup>17</sup> GSK’s Lamictal is indicated for the treatment of bipolar disorder and epilepsy, and had U.S. sales of approximately \$47 million in 2004 for the chewable tablets, and approximately \$825 million in 2004 for the tablets, according to IMS.

<sup>18</sup> An AG is a drug that is chemically identical to the branded drug but sold as a generic product.

#### **4.3.2 WYETH LLC V. TEVA PHARMACEUTICALS USA, INC.**

Professional Drug Company, Inc., Rochester Drug Co-Operative, Inc., Stephen L. LaFrance Holdings, Inc., Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors, and Uniondale Chemists, Inc. alleged that Wyeth prevented and delayed the approval and marketing of generic versions of its drug Effexor XR in violation of the Sherman Act. Specifically, the direct purchasers alleged that Wyeth engaged in sham litigation to block and delay multiple generic companies from entering the generic Effexor XR market; entered into an illegal horizontal market-allocation and price-fixing reverse settlement agreement with Teva Pharmaceuticals; and negotiated settlements with subsequent generic applicants for the sole purpose of preserving and protecting its alleged monopoly and market-division agreement with Teva. After Teva filed an Abbreviated New Drug Application (ANDA), seeking approval of a generic version of Effexor XR, Wyeth brought suit against Teva for infringement. The parties settled the suit, with Wyeth allowing Teva to sell a generic version of Effexor IR before the original compound patent for venlafaxine expired in June 2008 and agreeing that it would not compete with Teva's marketing of a generic version of Effexor IR by launching its own authorized generic during that period. Wyeth brought infringement suits against 16 additional generic companies that sought to market a generic version of Effexor XR, and eventually settled each suit. The direct purchaser failed to support its Sherman Act claims, according to the court. The rule of reason analysis requires a large "reverse" payment that is "unexplained." In cases where a non-monetary payment are alleged, the pleading must demonstrate the reliable foundation showing a reliable cash value of the non-monetary payment through the use of more facts upon which the plaintiff depends. The direct purchasers alleged that the reverse payment was an agreement between Wyeth and Teva that Wyeth would not launch an authorized generic version of Effexor XR during the 180-day exclusivity period, which would benefit Teva. The direct purchasers estimated the benefit of not having to compete with a generic would be over \$500 million. The total payment in this case was the value of the no authorized generic promise for Effexor XR for eleven months, added to the value of the allowing Teva to release a generic of Effexor IR before the expiration of the Husbands patent, subtracted by the value of the avoided litigation costs and the royalties Teva would pay to Wyeth during those eleven months.

Although the direct purchasers provided some background on the effect of generic competition and provided estimates of the expected market sales of a generic, it did not provide any explanation as to how those estimations were used to formulate the approximate value of the no-authorized generic agreement. Because the direct purchasers failed to provide sufficient evidence on which to determine the value of the payment, the complaint did not meet the required pleading standards. Because the direct purchasers failed to provide sufficient evidence for the court to determine the value of the non-monetary payment, the court also could not determine the direction of the payment. The court also could not determine whether the payment was large. A large payment is one that is large from the perspective of the brand company making the payment. (Coultas, 2014)

The FTC sought leave to file an amicus brief in private antitrust litigation in the U.S. District Court for the District of New Jersey concerning Wyeth Pharmaceuticals Inc.'s anti-depressant drug Effexor XR (venlafaxine HCl) Extended-release Tablets. The judge denied the FTC's motion for leave to file its amicus brief. The FTC has moved for leave to file an amicus brief in US District Court in New Jersey in another AG case, arguing that a branded company's commitment not to launch an AG in competition with a generic company (a "no-AG commitment") as part of a patent settlement constitutes a "payment" for delayed generic entry under the Third Circuit's decision in *In re K-Dur Antitrust Litigation* adopting the FTC's position on the standard for antitrust review of pharmaceutical patent settlements.

#### 4.4 CONCLUSION

After analyzing the case studies of reverse payment patent settlements, we have found certain tactics and strategies that the branded-name pharmaceutical companies and generic makers use to delay the generic entry: 1) The originator pay the generic makers so that they would not compete, giving them the equivalent of what they would have earned if they had entered the market. Apart from making substantial payments, the originator may purchase generics stock for the sole purpose of destroying it, and offer guaranteed profits under a distribution agreement; 2) They may illegally agree to not compete in addition to agree on marketing an authorized generic version owned by the originator company. In exchange, the originator may pay millions of dollars under two types of agreements, pay-for-delay and development and co-promotion agreement signed during the same time period. In the same time, the originator simply use this period of delay to transition patients to a new formulation of the generic, thereby maintaining its monopoly power even after the generic entry; 3) The Originator may agree to pay the generic maker millions, in return the generic may also agree to promote the Originator's drug along with delaying entry of its own generic drug for certain period of time; 4) The originator may maintain a monopoly in the market for his branded-name drug by suppressing generic competition through several successive insignificant reformulations of the drug, combined with various efforts to curtail the availability of the original formulations; and 5) If the generic maker is the "first filer," meaning the company was the first to seek FDA approval to market a generic version of the branded drug, and, at the time of the settlement, was eligible to market the generic product for 180 days without competition from other non-first filing generics. Then the generic manufacturers cannot enter the market under the FDA regulations, which makes these patent settlement deals particularly harmful to consumers.

## **CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS**

### **5.1 Analysis of Deficiencies**

### **5.2 Conclusion**

### **5.3 Recommendations**

## **CHAPTER FIVE**

### **CONCLUSION AND RECOMMENDATIONS**

#### **5.1 ANALYSIS OF DEFICIENCIES**

The originator usually needs to pay off just one or a handful of generic challengers so that the remaining choose to stay out of the market. In fact, when a large first mover advantage in the generic segment of the market exists, the originator can threaten to launch an authorized generic through one of the firms which agreed to settle for pay to delay deal. In this case, the remaining generic firms will choose not to challenge the patent validity and the initial pay to delay deal will be profitable for the parties involved. This is because if the originator can launch an authorized generic, it deprives the potential entrant of the large profit associated with first entry, and so if the expected profit becomes smaller than the litigation costs, the later challengers will choose to stay out. (Bokhari, 2016)

The EC considers that the main concerns areas are the following settlements: 1) Settlements relating to patent of which the company knew that it does not meet the patentability criteria; 2) Settlements containing restrictions beyond the exclusionary zone of the contested patent, whether in time or scope; 3) Settlements that prohibit unlimited and immediate generic entry, which are accompanied by a significant value transfer from the originator to the generic company whether it is in form of payment or any other value transfer and/or side deals. (Murphy & Mcfalls, 2010)

## 5.2 CONCLUSION

The pharmaceutical industry has argued that patent settlements are good for competition because they allow generic drugs on the market before the patent expires on a branded drug, while removing the uncertainty of litigation for both sides. (Kendall, 2012) Moreover, banning settlements would force companies to continue drawn-out litigation until a court handed down its decision and then allow generic market entry only if the generic company wins the case. Over the past 12 years, generics have won less than 50 to 70 percent of the patent cases. The bottom line is clear and convincing: settlements guarantee savings for consumers, the government and healthcare providers, thus limiting settlements risks these savings by betting that the generic company will always win the patent suit.

In contrast, some authors have argued that pay-for-delay agreements should carry a presumption of per se anti-competitive behavior. Others have argued that as long as the settlement does not exceed the original period or scope of the patent, then such reverse payment should not be per se illegal, in fact, many even can be seen as pro-competitive given the nature of such deals. In addition, changing the law where a generic is no longer awarded a period of exclusivity is not necessarily going to solve the problem of pay-to-delay deals. In fact, this reform may make things worse, since it takes away the incentives to challenge weak patents. Instead, other policy options – particularly those targeting a patent holder’s ability to launch an authorized or pseudo generic against a winning challenger – are much more promising for both the US and EU in terms of removing the possibility of pay-for-delay deals when the underlying patent is weak.

### 5.3 RECOMMENDATIONS

1. Each government should take a deep look to its competition regulations in order to make sure that they foster a more powerful competition between the original manufacturers and the manufacturers of generic substitutes.
2. Introduce in the national system a notification of any settlements between an original drug patent holder and the generic producer. The notification is required to provide details of the settlement such as the parties, terms and conditions, timing of settlement, and other related information to the settlement. Such notification will allow the national authority to act towards each deal properly and prevent any harmful deals that may cause disadvantages to consumers.<sup>19</sup>
3. Introduce particular provisions in the national intellectual property law that work as a safeguard clause to avoid broad patents in the area of pharmaceuticals and prevent “ever-greening”.
4. Introduce particular provisions in the country’s regulations that allow pharmacists, when filling a prescription for a specific brand-name drug, to dispense an equivalent generic version unless the prescribing physician instructs otherwise.
5. Prevent breaches of the laws through other means such as: 1) business and consumer education, 2) working closely with stakeholders and other agencies in order to promote competition among businesses as well as promoting fair trading and providing consumer protection in the pharmaceutical market.

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<sup>19</sup> See (Chang & Kim, 2016) In March 2015, a drug approval-patent linkage system for pharmaceutical products was fully implemented in Korea which mandates notification of any settlements of legal proceedings contested between an original drug patent holder and the generic producer who intends to market generic drugs to the KFTC and the Ministry of Food and Drug Safety.

6. A “no-AG” commitment, where a branded company’s commit not to launch an authorized generic (AG) in competition with a generic company as a part of a patent settlement, should be foreseen as a “payment” for delayed generic entry on the standard for antitrust review of pharmaceutical patent settlements, since it has the same negative impact on the consumer welfare.
7. Pay-for-delay agreements should carry a presumption of per se anti-competitive behavior, while examining the position of the originator and the generic producer in the pharmaceutical market, in addition to the number of current competitors in the market.
8. Pay-for-Delay deals should be one of the top priorities in each country in order to oppose such settlements that are believed to have stifled the competition from releasing lower-cost generic medicines to consumers. Restricting such arrangements would also reduce government debt by billions of dollars over years.
9. Elevating the standards of patent examination through well-trained examiners producing quality results and increasing the time of patent examination that usually takes place under a huge time pressure and productivity demands.
10. Speeding the opposition proceedings which are effective and necessary means of preventing the assertion of ultimately invalid patents aimed at hindering competition from generic medicines.
11. Create more entities like Medicines Patent Pool (MPP) that negotiate with key patent holders for licenses to be made available in the pool. Manufacturers can then seek a license from the responsible entity to produce a generic medicine and pay royalties to the patent holder.

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## 국문 초록

제약 분야의 경쟁은 제네릭 의약품의 시장진입을 통해 소비자들에게 좀 더 많은 선택지를 제공하고 약가를 인하하는 방식으로 계속적으로 진전되고 있다. 동시에, 제약 분야의 혁신은 신약개발자에게 신약 개발을 위한 유인을 제공해줄 수 있는 오리지널 의약품에 대한 배타적 권리를 보장해줌으로써 유지된다. 오리지널 제약사는 그들의 성공적인 브랜드 의약품에 대한 배타적 권리의 상실과 제네릭 의약품의 시장진입을 미루기 위하여 끊임없이 노력한다. 오리지널 제약사의 전략 중 하나는 제네릭 제약사에게 시장 진입을 하지 않는 대가로 일정 금액을 지급하는 것인데 이러한 방식은 “역지불합의” 라고 알려져 있다. 불행하게도, 이러한 전략은 소비자들에게 부정적인 영향을 미치는데 왜냐하면 소비자로서는 제네릭 제약사의 진입을 통해 이루어지는 경쟁에 따른 기대 이득을 상실할 수밖에 없기 때문이다. 일부 역지불합의는 각 국에서 감시되어 왔다. 역지불합의를 통한 시장진입이 소비자에게 피해를 주는 경우에는 그러한 역지불합의에 대한 대응이 이루어졌는데, 왜냐하면 역지불합의는 많은 소비자들에게 의약품에 대한 추가적인 비용을 지불하게 하고 납세자들에게 의료보험과 관련된 더욱 많은 세금을 부담하게 할뿐만 아니라, 의약품에 대한 접근권까지 박탈시키기 때문이다. 반면에, 제약사들의 입장에서 역지불합의는 높은 이윤을 보장해주고 수 조원의 매출을 발생시킬 수 있다. 본고는 제약 분야에서 지식재산권 및 경쟁과 관련된 중요한 쟁점들을 다루어 본다. 추가적으로, 본고는 특허권자와 경쟁자, 그리고 소비자 후생 사이의 균형을 달성하기 위한 의도 하에, 의약품의 지속적인 혁신을 위한 충분한 인센티브를 유지하는 동시에 제네릭 의약품의 경쟁을 증가시키고 약가를 인하할 수 있는 효과적인 수단을 중점적으로 살펴본다.