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THE EUROPEAN PHARMACEUTICAL INDUSTRY IN A GLOBAL ECONOMY:

What drives EU exports of pharmaceuticals overseas ?

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Statutory Declaration

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Abstract

The pharmaceutical industry is one of the most competitive sectors in the European Union. With its substantial investments in Research and Development, this industry represents a key asset for the European economy and a major source of growth and employment. However, despite the importance of the pharmaceutical sector for the European Union, few researchers have attempted to assess the determinants of the EU exports of pharmaceuticals. This thesis aims at filling the aforementioned gap by addressing the following research questions: What drives EU exports of Pharmaceuticals and how to boost this trade? In order to tackle these questions, this thesis has derived hypotheses from the Gravity Model of Trade and the relevant academic literature on pharmaceuticals. Based on a methodology combining both econometric analysis and interviews, the research sheds light on the complex interaction of factors influencing the EU exports of pharmaceuticals. The thesis reveals that the protection of intellectual property in the receiving countries, their economic size, the importance of their health sector, and the quality of infrastructures constitute major drivers to the EU exports of pharmaceuticals. On the contrary, the research shows that transports costs as well as tariff barriers and non-tariff barriers tend to hinder the EU exports of pharmaceuticals. In lights of those results, the research discusses the efficiency of the current initiatives launched at the global and European levels to boost the trade of pharmaceuticals and provides some recommendations in that regard.

INTRODUCTION

The 2013 Competitiveness report of the European Commission entitled "Towards knowledge driven reindustrialisation" highlights some of global issues that the European Union needs to address, namely, the decreasing weight of the EU industry in the world, the loss of competitive advantages in many sectors and the growing EU-USA productivity gap (European Commission, 2013(a), p 13). In lights of those challenges, the report argues that the European Union should find innovative solutions to maintain its position as a major producer of knowledge in key enabling technologies and vital high-tech sectors. Being one of the top performing industries of the European Union, the pharmaceutical sector has a crucial role to play in fostering EU growth and competitiveness. With its substantial investments in Research and Development (R&D) compared to other manufacturing sectors, the pharmaceutical industry represents a key asset to the European Union in an advanced global economy. According to the 2012 EU Industrial R&D Investment Scoreboard, the pharmaceutical and biotechnology sectors represent 17.7% of business R&D expenditures in the world (European Commission, 2012(a), p 43). The pharmaceutical industry is also of crucial importance for the EU which is the major world trader in medicinal and pharmaceutical products. In 2012, the extra-EU-27 exports of pharmaceuticals accounted for 106 353 027 millions of euros (European Commission, Market access database, 2014).

However, despite the importance of this sector for the competitiveness of the EU industry, the literature on the EU Trade of pharmaceuticals is rather scarce. Most of the research on the pharmaceutical industry concerns its impact on the health sector (for few examples see Rhee, 2008; Mills, Hanson & McPake, 2002) and the respect of competition rules by pharmaceutical companies (Roberts, 2009; Danzon & Chao, 2003). Furthermore, the research on the key determinants of the EU trade of pharmaceuticals is almost non-existent in the academic literature. The aim of this thesis is therefore to address the aforementioned gap by analysing the EU pharmaceutical industry from a Trade perspective. Subsequently, this research will tackle the following questions: what drives the extra-EU exports of pharmaceuticals? What kind of policy measures should be implemented to remove the barriers affecting this trade?

Beyond its academic contribution, the ambition of this thesis is to enhance our knowledge of the factors driving the EU exports of pharmaceuticals in order to remain a major world exporter in the future. This research appears all the more necessary in a context of economic crisis and slow internal demand where trade is expected to play a crucial role in fostering EU growth and competitiveness.

Indeed, the European Commission predicts that "The contribution of external demand to economic growth is bound to increase in future, as 90 % of global economic growth by 2015 is expected to be generated outside Europe, a third of it in China alone" (European Commission, 2012(b), p. 4).

The literature on International Trade and the Gravity Model will serve as a theoretical foundation for this MA thesis. The dissertation uses a combination of quantitative and qualitative research methods to examine the determinants of the EU exports of pharmaceuticals. The econometric analysis enables to test the statistical significance of a wide range of variables on the EU exports of pharmaceuticals namely, the protection of intellectual property, the level of health care expenditure of the partner country, the existence of a Free Trade Agreement, the transport costs, the health status and the Gross Domestic Product (GDP) of the receiving country. The qualitative part of this thesis is based on interviews with representatives of the European pharmaceutical industry and a review of the literature. The rich dataset resulting from this research enables to shed light on the drivers and obstacles to the extra-EU exports of pharmaceuticals.

The remainder of this thesis is organised as follows. The first chapter depicts the main features of the EU pharmaceutical industry. The second chapter presents the theoretical framework of this research which combines insights from the Gravity Model of Trade as well as the relevant literature on the subject. The third and fourth chapters of this dissertation respectively provide a quantitative and qualitative analysis of the determinants of the EU exports of Pharmaceuticals. The fifth chapter discusses the efficiency of the different policy measures taken at the global and European levels to boost the EU exports of pharmaceuticals.

CHAPTER 1: AN OVERVIEW OF THE EUROPEAN PHARMACEUTICAL SECTOR

Since the last ten years, the European pharmaceutical industry has undertaken major changes to respond to global challenges, namely, the competition from emerging countries, the escalating cost of drug development and the expiry of the patents on blockbuster drugs. The aim of this chapter is to analyze the main economic characteristics of the pharmaceutical industry and its transformations in order to understand which factors drive the EU exports of pharmaceuticals.

SECTION 1: MARKET CHARACTERISTICS

I. MARKET STRUCTURE AND CONCENTRATION

The pharmaceutical industry is dominated by few multinational companies which share the majority of the market. Thus, in 2012, 66% of the global pharmaceutical market was divided between the top 20 pharmaceutical firms (Evaluate Pharma, 2013, p. 12). These multinational groups have their headquarters in developed countries such as the United States, Japan, Israel or Europe. The biggest pharmaceutical companies play a crucial role in medicine innovations. For instance, a study conducted by Munos (2009) reveals that 50% of the new molecular entities introduced in the market since 1950 have been discovered by 21 companies which were all belonging to the top 15 pharmaceutical firms in 2008. (Kiriyama: OCDE, 2011, p. 13). However, as the following table underlines it, the share of the top pharmaceutical groups is expected to drop by one percentage point by 2018 mostly due to the competition from emerging countries (Evaluate Pharma, 2013, p 12, also cited in Blanc, 2014, p. 2).

Table 1: the biggest 20 pharma companies and their market share

Companies	Headquarters	Worldwide Market share		Rank change
		2012	2018	
1. Novartis	Switzerland	6.4%	5.8%	+1
2. Sanofi	France	5.4%	5.5%	+2
3. Pflizer	USA	6.6%	5.2%	-2
4. Roche	Switzerland	5.3%	5.2%	+1
5. GlaxoSmithKline	UK	4.6%	4.5%	+1
6. Merck&Co	USA	5.8%	4.5%	-3
7. Johnson&Johnson	USA	3.3%	2.9%	+1
8. Novo Nordisk	Denmark	1.9%	2.4%	+9
9. Bristol-Myers Squibb	USA	1.9%	2.4%	+9
10. AbbVie	USA	3.2%	2.4%	-1
11. Gilead Sciences	USA	1.3%	2.4%	+10
12. AstraZeneca	UK	3.8%	2.3%	-5
13. Bayer	Germany	2.1%	2.2%	+2
14. Takeda	Japan	2.3%	2.0%	-
15. Amgen	USA	2.5%	1.8%	-2
16. Teva Pharmaceutical	Israel	2.5%	1.8%	-4
17. Eli Lilly	USA	2.8%	1.7%	-6
18. Boehringer Ingelheim	Germany	2.1%	1.4%	-2
19. Baxter International	USA	1.2%	1.4%	+3
20. Astellas Pharma	Japan	1.5%	1.3%	-1
Total Top 20	-	66.0%	59.1%	

Source: Evaluate Pharma, 2013, p. 12.

The European pharmaceutical industry is the 5th largest sector within the European Union accounting for 3.5% of the total EU manufacturing value (EFPIA, 2010, p. 1). The pharmaceutical sector is divided between two types of suppliers. The first one corresponds to the "originators firms" which are very active in R&D and the production of patented drugs (table 2). Most of the originators companies are big multinationals but this category also comprises Small and Medium sized Enterprises (SMEs) which are specialized in the production of certain products (European Commission, 2009, p. 23). In most of the cases, these SMEs do not have the means to develop a finished product. Therefore, they often sell their innovations to big pharmaceutical groups which can afford to conduct clinical trials and marketing activities (ibid, p24). According to the European Commission (2009, p. 24), "Currently 25% of the molecules in clinical development have been acquired from other companies, including SMEs". The second type of suppliers corresponds to generic firms which can produce and sell pharmaceuticals once the patent of these products is expired. Many of these generic companies are SMEs producing medicines sold in the domestic markets (ibid, p. 37). The market for generic products is growing faster than the

one for originators due to the expiry of many drug patents and the tightening of national health budget which push governments to promote generics (ibid, p. 38).

Table 2: Comparison between the expenditures of originators and generic companies

	Percentage of turnover spend on		
	R&D	Marketing	Manufacturing
Originators companies	18%	21%	21%
Generic companies	7%	13%	51%

Source: European Commission (2009), pp 32-40.

II. THE IMPORTANCE OF R&D IN THE PHARMACEUTICAL SECTOR

Research and Development plays a crucial role in the pharmaceutical sector. In 2010, the pharmaceutical sector employed 633 000 highly skilled people among whom 113 000 were specialized in Research and Development activities (EFPIA, 2010, p. 1). The Pharmaceutical industry is also the sector with has the biggest ratio of R&D expenditures to net sales (European Commission, 2011(a), p. 5). In 2011, R&D expenditures accounted for 15.1% of net sales in the pharmaceutical sector compared to 9.1% for the software & computer services sector (EFPIA, 2013, p. 10).

Since the 1970s, the cost of R&D has dramatically increased due to the growing regulatory requirements and the intensified research efforts on complex treatments (Ecorys, 2009, p. 85). Whereas the cost of drug development represented respectively 149 and 344 millions of euros in 1975 and 1987[1], it amounted to 868 million of euros in 2000 (ibid). Today, this cost is evaluated to more than one billion of euros (ibid, p. 85). It takes on average between 10 and 13 years to launch a new drug on the market but only a small portion of all projects is successful (EFPIA, 2013, p. 6). Indeed, according to a recent report from the European Federation of Pharmaceutical Industries and Associations (2013, p. 6): "on average, only one to two of every 10,000 substances synthesized in laboratories will successfully pass all stages of development required to become a marketable medicine".

Additionally to the rising cost of drug development, the major pharmaceutical companies are under competitive pressures due to the expiry of the patents on their best-selling pharmaceutical products. Once a drug is coming off patent, competitors can sell cheaper generics composed of the same active ingredients than the drugs sold by originator companies which considerably affect the profit of the

[1] The figures are expressed in 2000 prices.

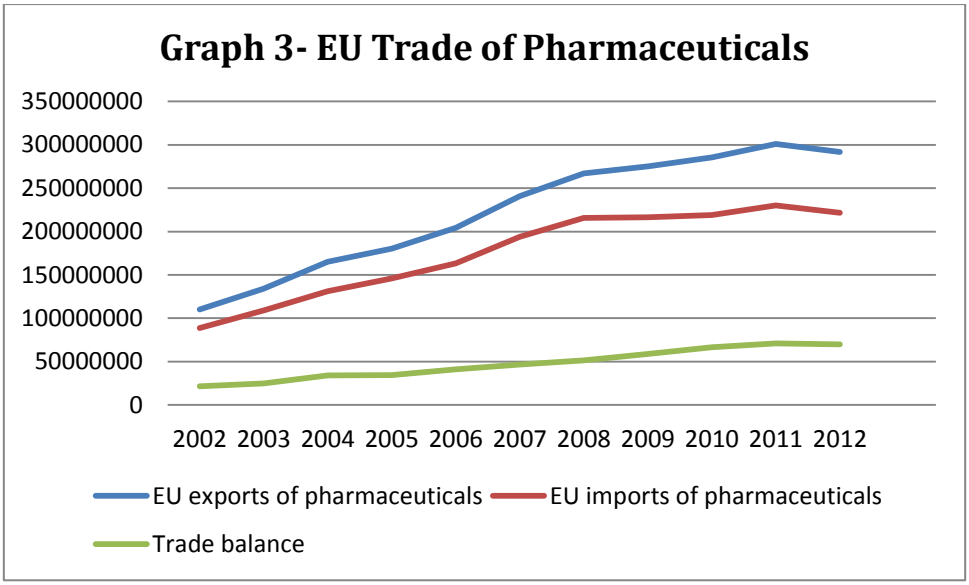
latter. For instance, in 2011, the company Pfizer was expected to lose around 10 billions of dollars of annual revenue due to the expiry of the patent on one of its top selling drug "Lipsor" (Wilson, 2011). A recent report also reveals that 230 billion of sales are threaten by patent expiries from 2013 and 2018 (Evaluate Pharma, 2013, p. 7).

As a result of these different challenges, the EU pharmaceutical industry is transforming its current business strategy in order to reduce its costs and to capture new markets overseas. Since 1990s, pharmaceutical companies been involved in Mergers and Acquisitions (M&A) and have diversified their activities in generics and biotech products (European Commission, 2009, p. 522). These M&As have enabled pharmaceutical firms to make economies of scale and to diversify their future drugs' patents portfolio (Blanc, 2014, p. 3). While pharmaceutical R&D was traditionally conducted in-house in developed countries, pharmaceutical companies increasingly carry out clinical trials in Eastern European, Asia, and Latin America in order to reduce the costs of R&D. A study from Ernest and Young (2010) estimated that pharmaceutical companies outsource between 30% to 35% of their manufacturing activities and 25% to 35% of the clinical trials overseas (cited in Kiriyama: OCDE, 2011, p. 37). Cooperation between big pharmaceutical groups in manufacturing, marketing and R&D is also rapidly developing to address the global challenges described above.

SECTION 2: EU TRADE OF PHARMACEUTICALS AND THE GLOBAL VALUE CHAIN

I. THE EUROPEAN UNION AS A MAJOR TRADE EXPORTER

The European Union represents a major manufacturer and exporter of pharmaceutical products. According to the European Commission (2011(a), p. 8): "The EU is the second global manufacturing location for pharmaceuticals behind the US and ahead of Japan, and holds a dominant position in a number of areas, including the production of vaccines where 90% of major manufacturer's global output is produced in Europe". The EU exports of pharmaceuticals in current USA dollars have continuously increased since 2002 in spite of the global economic crisis (graph 3). In 2012, the EU exports of pharmaceuticals represented 291.6 billion of dollars (Comtrade, 2014). The EU-25 pharmaceutical trade surplus has also increased from 21.5 billion of dollars in 2002 to 70 billion of dollars in 2012 (ibid).



Source: Authors' graph based on data from United Nation Comtrade extracted via the World Integrated Trade Solution (WITS) [HS2002 code 30 for pharmaceutical products].

Traditionally, the main EU trade rivals in the field of pharmaceuticals have been American, Japanese and Swiss firms (European Commission, 2011(a), p. 8). However, the EU is now confronted to the competition from Chinese and Indian generic producers which benefit from cheaper labour costs and laxer regulatory conditions (ibid, p. 8). As the table 4 illustrates it, the EU-25 export market share has declined since the beginning of the 2000s. In 2013, 60% of the world exports of pharmaceuticals originated from the EU which represents a decrease of more than 18% compared to 2002 (table 4). Meanwhile, Chinese and Indian export market shares have significantly increased. In 2012, the Indian exports of pharmaceuticals accounted for 2.9% of the world market which is more than 5 times what it represented in 2002 (Comtrade, 2014).

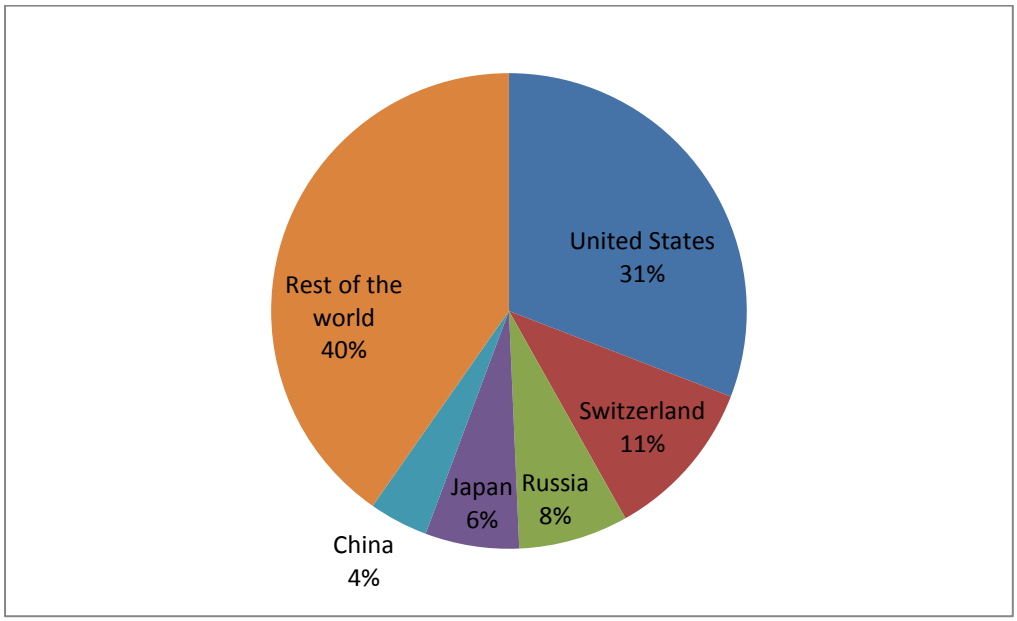
Table 4: Export market share of pharmaceutical products[2].

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
EU-25	73,8	73,5	72,2	71,8	70,1	69,7	69,1	66,6	65,4	63,9	62,0	60,0
USA	12,4	12,1	12,8	12,0	12,3	11,7	11,6	12,7	12,3	12,8	13,7	13,1
CHINA	0,4	0,4	0,5	0,6	0,6	0,6	0,7	0,8	1,0	1,0	1,0	1,1
INDIA	0,5	0,7	0,7	0,8	0,9	1,1	1,4	1,4	1,8	2,0	2,3	2,9
SWITZERLANDS	5,9	5,9	6,3	6,6	7,0	7,5	7,9	8,3	8,2	8,9	9,2	9,4
JAPAN	1,9	2,0	1,9	1,6	1,3	1,2	1,2	1,4	1,3	1,2	1,1	1,1

Source: author' own calculation based on data from United Nation Comtrade database extracted via the World Integrated Trade Solution (WITS).

The main destinations of EU-27 exports of pharmaceuticals are the United States, Switzerland's, Russia, Japan and China (see graph 5).

Graph 5- Destination of EU-27 exports of pharmaceuticals (2011)



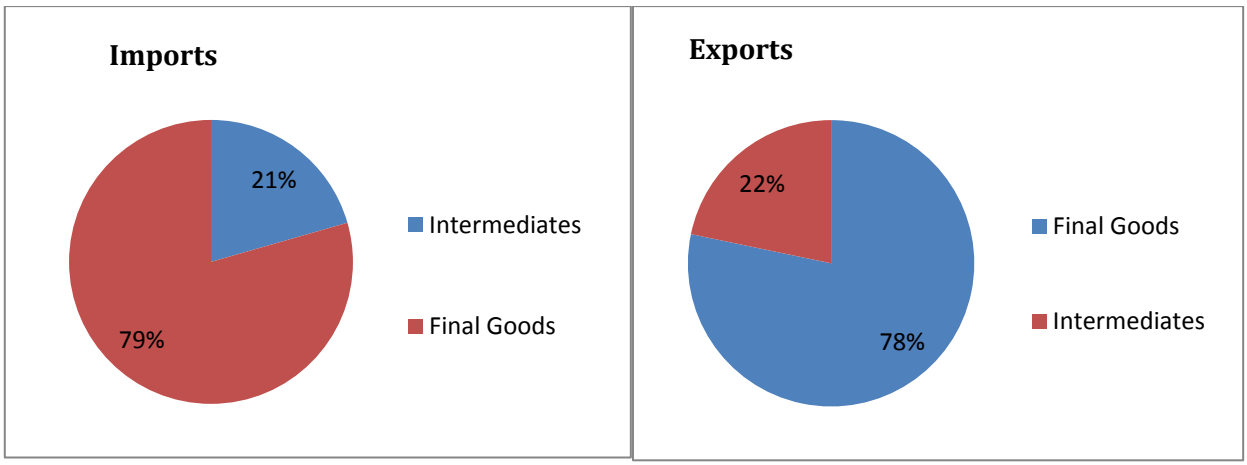
Source : European Commission, Market Access database (2014).

[2] The export market share of the pharmaceutical products was obtained by dividing the world imports of EU pharmaceutical products in US dollars by the total imports of pharmaceutical products in the world in US dollars. The result was then multiplied by 100 to express it as a percentage.

II. TRADE OF INTERMEDIATES AND FINAL GOODS IN THE PHARMACEUTICAL SECTOR

As the production of goods is becoming more and more fragmented, it is necessary to make the distinction between final goods and intermediates (OECD & WTO, 2012, p. 1). According to the OECD, three quarters of the pharmaceutical trade concern consumers' goods while the rest refers to intermediate products (Kiriyama:OECD, 2011, p. 22). In spite of the growing outsourcing of pharmaceutical production overseas, the share of consumers' goods in the world trade of pharmaceuticals has increased between 1990s and the mid-2000s (ibid). Using the classification proposed by the OECD (2011, p. 22)[3] and the database from the UN Comtrade (2014), we calculated the share of finals goods and intermediates in the EU trade of pharmaceuticals for the year 2011. The result of this analysis shows that the exports of intermediate goods represent 21% of EU-25 imports and 22% of EU-25 exports. Therefore, despite the fact that the pharmaceutical industry is very globalized, the fragmentation of the production of pharmaceuticals remains quite low.

Graph 6- Composition of EU pharmaceutical trade (2011)



Source: authors' own calculation based on the database of the World Integrated Trade Solution (UN Comtrade).

[3] Consumers goods refer to all goods identified with the number "HS 3003-3005" in the Harmonized System of the United Nations International Trade Statistics. The rest of the products under the section 30 of the Harmonized System of the United Nations International Trade Statistics correspond to intermediates.

CHAPTER 2: THEORETICAL FRAMEWORK OF THE RESEARCH

This second chapter will present the different theories of International Trade and the Gravity model which serve as a theoretical foundation for this thesis. The aim is to offer an overview of the some of the most relevant theories to analyze and explain the trade of pharmaceuticals.

SECTION 1 - THEORIES OF INTERNATIONAL TRADE

I. TRADITIONAL TRADE THEORIES

Classic International Trade theories explain that the exports and imports are driven by the economic advantages of countries in some areas of production. While Adam Smith defended the idea that countries should devote all their resources to the production of goods for which they have an absolute advantage, Ricardo suggested that trade specialization should be based on the notion of comparative advantage. The latter refers to the capacity of a country to produce goods at a lower opportunity cost. However, one of the limitations of these traditional theories arises from their lack of explanations regarding the sources of economic advantage (Morgan & Katsikeas, 1997, p. 69).

The theory of factor endowment elaborated by Bertil Ohlin and Eli Heckscher in 1933 refines Ricardo's comparative advantage theory by showing that international trade is driven by the differences in factors endowment (Yingha, 2013, p. 22). Countries which possess a large population will export more labour intensive goods since this factor of production is cheaper. On the contrary, a country benefiting from abundant capitals will export capital intensive goods and import goods made from scare resources. Therefore, according to this framework, one should expect countries well-endowed with qualified labour force to have a comparative advantage in the production of research-intensive goods such as the pharmaceutical products (Wilkman, 2012, p. 7). From this perceptive, it is interesting to note that the European Union which benefit from a highly-qualified population is also a major trade exporter of pharmaceuticals. However, this comparative advantage is actually challenged by the increasing competition from emerging countries such as India, Brazil, and China. Indeed, these countries are endowed with cheap labour force and have increased their supply of skilled workers.

Although the theory of factor endowment provides interesting concepts to analyze some features of the European pharmaceutical industry, this model does not account for the emergence of multinational enterprises and the strong technological changes which took place from the 1960s (Morgan & Katsikeas, 1997, p. 69).

II. THE PRODUCT LIFE CYCLE THEORY

The product life cycle theory was elaborated at the end of the 1960s by Raymond Vernon in response to these global changes (Grimwade, 1989, p. 62). This theory provides a useful theoretical framework to analyze the pattern of international trade followed by multinationals, especially in research-intensive industries such as pharmaceuticals. The product-life cycle theory shows that the production of goods and the location of multinationals depend on different trade life cycles (ibid). In the first stage, the product is manufactured by the parent firm in innovative markets. Progressively, the product will be exported to countries with similar characteristics. As the good reached maturity, innovative firms will face an increasing competition from domestic and foreign producers (ibid, p. 63). In this phase, the patents of many products will expire which will allow foreign producers to reproduce them. The demand will become more price elastic which will push innovative firms to cut their costs to remain competitive (ibid). More and more products will be exported overseas and multinational firms will create foreign affiliates abroad to reduce their costs. In the last stage, the demand curve becomes perfectly price elastic which strengthens the competition between firms. Consequently, the product is reproduced all over the world in places where the costs of production is the cheapest. The production of the innovative country is expected to sharply decrease while the import from developing countries is likely to increase (ibid).

Several authors have applied the product life theory to analyze the peculiarities of the pharmaceutical sector. For instance, Thomas Mac Parry (1975) conducted a research in which he showed that the degree of international production of the British pharmaceutical industry is dependent on the product' life cycle**.** This means that pharmaceuticals are more likely to be produced in a large number of foreign markets as they reached maturity. More recently, some authors (Bauer & Fisher, 2000; Itkar, 2007) have used the product-life cycle to explain some of the patterns in the trade of pharmaceuticals. According to Sachrin Itkar (2007, p. 19), the life cycle of pharmaceuticals is characterized by an introduction, a growth, a maturity and a decline phase. The product-life cycle theory can explain the growing need for originator companies to find solutions to maintain market shares notably by diversifying their future patents' portfolio and by competing in other markets such as generics (ibid).

III. THEORY OF MONOPOLISTIC COMPETITION

The theory of monopolistic competition has been developed in the 1970s by Krugman and Helpman to respond to the development of intra-industry trade which could not be explained by traditional theories of Trade. These authors show that due to the economies of scale and the process of product differentiation, firms are in a situation of monopolistic competition. Economies of scale can take two forms: internal and external (Yingha, 2013, p.23). By specializing in the production of some goods, firms may realize internal economies of scales. Moreover, companies can make external economies of scale by merging or forming a cluster with a company belonging to the same industry (ibid). Krugman (1980, p. 951) also shows that the situation of monopolistic competition is driven by the willingness of producers to differentiate their products to maximize their profits. As the costs of differentiation are almost null, companies have an incentive to change the way their goods is produced, designed or packaged (ibid, p. 950). Thanks to this strategy of differentiation, companies will increase their market power, that is to say, their capacity to raise prices above marginal costs. For instance, in the pharmaceutical sector, companies may differentiate their products from their competitors by using different chemical components in their products even if the active ingredients are identical (Taylor, 1995, p. 8). Patents and brands are also an important element of the strategies of originators companies to differentiate their products from generics. Indeed, although both types of drugs can provide an efficient treatment against the same disease, they may not be perceived as completely substitutable by consumers' who are more attached to a certain brand or a label.

IV. HETEROGENEOUS FIRM THEORY

The heterogeneous firm model completes the traditional and new trade theories by showing that within an industry only a small proportion of highly productive companies will be able to export their products. Indeed, contrary to the theories presented earlier, the heterogeneous firm theory points out the difference in productivity between firms belonging to the same industry. For instance, Melitz (2003, p. 1697) shows that exports entail large sunk entry costs which can only be recouped by the most productive firms within an industry. As a consequence, only the firms with the highest productivity will be able to export their products overseas. Melitz (2008, p. 2) shows that trade and trade liberalization will provoke a reallocation of resources among firms. The less efficient firms will concentrate on the domestic market while the least efficient companies will not be able to survive in that competitive environment. Only the most productive firms will be able to exploit the opportunities of trade liberalization by exporting their goods and services abroad. According to Melizt (2008, p. 1) "these reallocations generate a new channel of productivity and welfare gains from trade".

This theoretical framework enables to shed light on the heterogeneity of the firms within the same industry. As we have seen in the first chapter of this thesis, the pharmaceutical industry comprises both multinational companies and Small and Medium Sized enterprises mostly serving the domestic market. A recent study conducted by Zhiying Ji & Jiayi Ye (2013) has applied the heterogeneous firms' theory to analyze the exports structure of pharmaceutical companies in China. This research confirms the main assumption of the heterogeneous firm theory by showing that the productivity of Chinese's Bio-Pharmaceutical firms has a significantly positive impact on their decision to export.

While the different theories presented offer some interesting insights to analyze the origins and the characteristics of the trade of pharmaceuticals, they do not contain a clear set of factors explaining why the EU exports more products to some countries than others. This is why this thesis mainly relies on the Gravity model of Trade to formulate precise hypotheses regarding the determinants of the EU exports of pharmaceuticals.

SECTION 2 - THE GRAVITY MODEL OF TRADE

The second section of this theoretical chapter presents the gravity model of trade (I) as well as the literature on pharmaceutical exports which is based on this model (II).

I. INTRODUCTION TO THE GRAVITY EQUATION

The gravity model of Trade has become more and more popular in international trade literature. Indeed, this model provides a powerful tool to analyse trade flows between countries and the trade impact of different policies. Moreover, according to Learner and and Levinsohn (1995), the Gravity model of Trade has delivered "some of the clearest and most robust findings in empirical economics" (cited in Shepherd, 2013, p. 13). The Gravity Model departs from Newton' Law of Gravity which states that the gravity between two objects is positively correlated with their masses and inversely related to the distance between them. This is translated into the following equation:

$$Fij = G * \frac{MiMj}{D^2ij} \qquad (1)$$

Where F denotes the gravitational force between two particles and M_i and M_j represent the masses of these two objects. D expresses the distance between the two objects while G is a gravitational constant.

In order to perform an usual regression analysis, Gravity models are expressed in natural logarithms (‘‘ln’’). Thus, the first equation (1) is transformed into the following linear equation (2) (Renert, 2008, p. 568).

$$\ln GFij = \ln Mi + \ln Mj - \ln Dij \qquad (2)$$

International Trade theorists depart from this equation and replace the gravitational forces by the trade flows or the exports from country i to country j (E*ij* in the third equation). While the variable Distance remains the same, Mi and Mj are measured by the Gross Domestic Product (GDP) of the countries i and j. b_1 and b_2 are expected to be positive whereas the sign of b3 should be generally negative.

$$\ln Eij\ \alpha + b1\ lnGDPi + b2\ lnGDPj + b3\ lnDij \quad (3)$$

Tinbergen (1962) and Anderson (1979) were the first scholars to apply the Newton’ Law of Gravity to analyse Trade flows between countries. Both authors consider transport costs measured by the geographical distance between two countries as a crucial factor to explain the intensity of trade volume between countries. The literature on the Gravity Model of Trade uses alternatively the variables GDP, GDP per capita or GDP and population to measure the masses of the economies of country i and j. Most of the empirical studies in this field show that these variables have a strong positive impact on the trade flows between two countries (for few examples, see Khan, Hag & Khan, 2013; Eita, 2008; Nguyen, B. X. 2010). Scholars using the Gravity Model of Trade have also looked at the potential of Free Trade Agreements in fostering Trade relations between countries. For instance, a study conducted by Baier and Bergstrang (2001) shows that the reductions in tariff rate and trade liberalisation have had a positive impact on the increase in world trade.

II. LITERATURE REVIEW ON THE GRAVITY MODEL

As mentioned in the introduction, the research about the determinants of pharmaceutical products is recent and remains quite scarce. Only three studies have tried to evaluate the determinants of the Pharmaceutical exports using of gravity model of trade, two of them concern Sweden and the other one relates to the USA trade of pharmaceuticals towards emerging countries.

In his MA thesis, Per Adolfsson used a gravity model of trade to evaluate the impact of several factors on the Swedish exports of pharmaceuticals based on the method of fixed panel data (Adofsson, 2007). The authors ran three regressions with different dependant variables for each of them. In the first

regression, Per Adolfsson measures the exports of pharmaceuticals in kilogrammes from country i to country j in Swedish krona (SEK) at time t. In the second model, the author considers the exports of pharmaceuticals in SEK from country i to country j. In the third regression, the dependent variable concerns the exports of pharmaceuticals from country i to country j in SEK per unit at time t. The independent variables used in the three regressions are the following: the logarithm of the distance between the two countries in kilometres, the GDP per capita in dollars for country j at time t, the area of the country j, the population of country j at time t, and some dummy variables concerning the religion, the language and the access to the ocean of the receiving country. However, one of the weaknesses of this research is that the author is using a dependant variable which is measured in Swedish krona (SEK) whereas some of the independent variables such as the GDP and the GDP per capita of the receiving countries are measured in dollars. Moreover, one may also question the choice of the author to measure the exports of pharmaceuticals in kilos as the range of pharmaceutical products exported is very broad. Per Adolfsson's main conclusion is that the regressors "GDP per capita" have a significant positive impact on the exports of pharmaceuticals measured in SEK, kilograms and kilograms per unit (at 5% level). He shows that landlocked and remote countries are less likely to import goods from Sweden. The result of this econometric analysis also reveals that Sweden exports more pharmaceuticals towards countries that share the same religion.

The research conducted by Mats Wilkman also aims at evaluating the determinants of Swedish exports of pharmaceuticals (Wilkman, 2012). The author relies on a very similar research design than Per Adolfsson to explain the Swedish trade of pharmaceuticals. The author ran two regressions using two different dependant variables: the exports of pharmaceuticals in SEK and the exports of pharmaceuticals in kilograms per unit. Mats Wilkman tested almost the same independent variables as Per Adolfsson in his research. Therefore, he does not include any explanatory factors related to the health sector or the protection of intellectual property rights to explain the exports of pharmaceuticals from Sweden to other countries. At the end of his dissertation, Mats Wilkman concludes that the Swedish exports of pharmaceuticals are determined by the main factors as many other goods (p. 26). Indeed, this author found that like most goods, pharmaceutical exports depend positively on the variable GDP, GDP per Capita, and negatively on the distance between two countries and changes in the exchange rate.

In her paper entitled "Determinants of the United States' trade of pharmaceuticals", Anne Boring (2010) uses several econometrics models including a panel data with fixed effects to determine the most significant factors influencing the USA exports of pharmaceuticals. One of the major innovations of Anne Boring' paper is to include two dummy variables in the gravity equation to measure the effect of Intellectual Property Rights (IPR) on the USA exports towards emerging countries. The first one corresponds to the variable "TRIPS" which takes the value one when the country has implemented the

agreement on Trade-Related Aspects of Intellectual Property Rights set by the World Trade Organization. The author also uses the dummy variable "Free Trade Agreement" (FTA) which takes the value one when the country has signed an agreement with the United States. The variable FTA was expected to capture the effect of a strong IPR protection. When no information was available about the implementation of the FTA or TRIPS agreements, the author used the deadlines set in those documents (ibid, p. 8). However, one of the limits of this measurement is that the official date of the implementation of the TRIPS agreement might not necessarily reflect the real level of IPR in the country. Indeed, although some countries have adopted a legislation on Intellectual Property Rights conformingly to the TRIPS agreement, the regulation is not always properly enforced on the ground (see chapter 4, section 3 of the thesis for more details). Moreover, the variable Free Trade Agreement may not only capture the impact of Intellectual Property Protection but also the effects resulting from the elimination of other trade barriers between the USA and its partners.

The result of Anne Boring's analysis shows that the effect of Intellectual Property Rights is statistically insignificant to explain the USA exports of pharmaceuticals. Indeed, the variable "TRIPS" is almost always insignificant except in the reduced Ordinary Least Square (OLS) regression where the authors takes into account three basic elements of the gravity equation and the variable "Free Trade Agreement". The last variable mentioned is insignificant in all the regressions performed. Additionally, Anne Boring found that the following factors had a statistically significant positive impact on the USA's exports of pharmaceuticals: the natural logarithm of the GDP of the partner country j, the existence of a common language between the two countries, the presence of a major container port in the receiving country and the adhesion of the partner country to the "President's Emergency Plan for AIDS Relief" launched by George Bush in 2003. On the contrary, the natural logarithm of the distance between the countries (statistically significant at 1% level) and the incidence of tuberculosis per 100 000 people (statistically significant at 10% level) have a negative impact on the USA exports of pharmaceuticals towards emerging countries.

CHAPTER 3: ECONOMETRIC ASSESSMENT OF THE DETERMINANTS OF PHARMACEUTICAL EXPORTS

SECTION 1: METHODOLOGICAL APPROACH

I. VARIABLES SELECTED AND MEASUREMENTS

The aim of this research is to test the impact of several variables on the extra EU-25 exports of pharmaceutical products. This research is based on a list of 62 countries from different regional groups over a period of 8 years (2004-2011). The diversity of the countries selected follows a recommendation done by Jeffrey A. Frankel (1997, p. 55) in his book on "Regional Trading Blocs in the World Economic System" in which he argues that *"limiting the analysis to industrialized countries is no longer convincing, even if they once were*". The 62 countries used in this thesis represent more than 92% of extra-EU exports of pharmaceuticals (see list in appendix 1). The panel data starts in 2004 which corresponds to the enlargement of the European Union to ten Central and Eastern European countries. The period selected (2004-2011) enables to see the factors influencing the EU-25 exports of pharmaceuticals before and after the beginning of the EU crisis which started in 2008.

The variable selected stem from the classical model of Gravity and from the review of the literature on the main determinants of pharmaceutical exports. The selection of the variables has been adapted to the case of the EU exports of pharmaceuticals. The dependant variable is the natural logarithm of the EU exports of pharmaceuticals towards the partner country expressed in current USA dollars. Following the recommendation of several scholars including James E. Anderson and Eric van Wincoop (2003, p. 170) as well as Marc Bacchetta et al (2012, p. 111), this thesis uses the values of exports in nominal value rather than in real terms. The research attempts to evaluate the explanatory power of seven independent variables on the EU exports of pharmaceuticals.

- The first variable corresponds to the natural logarithm of the Gross Domestic Product (GDP) of the partner country (country j) in current dollars. The GDP is expressed in nominal terms rather than in real terms. Indeed, according to a recent report of the World Trade Organisation (2012, p. 111): "Gravity is an expenditure function allocating nominal GDP into nominal imports; therefore inappropriate deflation probably creates biases via spurious correlations". The GDP of the partner country measuring the economic size of the receiving country's market, it is expected to have a positive effect on the dependent variable.
- The second independent variable is the natural logarithm of the distance between Munich and the biggest cities in the partner country measured in kilometers. Munich has been selected as it

corresponds to one of the most important places in terms of pharmaceutical production within the European Union (Mandry & Mac Dougall, 2011, p. 4). The variable distance is used a proxy for transportation costs. It is expected to have a negative influence on the dependent variable. Indeed, it is expected that the European Union should trade more with neighboring countries.

- The third variable is the health expenditure of country j as a percentage of GDP. This is a proxy for the size of the receiving country's health care market and should therefore have a positive effect on the dependent variable (Boring, 2010, p. 14).
- The fourth explanatory variable is a dummy variable which takes the value 1 when the country possesses a major Port container and 0 when it does not. The data comes from the World shipping Council which publishes a list of the top 50 world containers. This dummy variable is used as a proxy for infrastructure quality (ibid, p. 8). Therefore, the existence of a major Port container in the country j is expected to have a positive influence on its imports of pharmaceutical products from the EU.
- The fifth independent variable corresponds to the existence of a Free Trade Agreement (FTA) between the EU and the receiving country. In general, those agreements contain provisions aiming at abolishing tariff and reducing non-tariff barriers on pharmaceutical products. Therefore, Free Trade Agreements are expected to boost the EU exports of pharmaceutical products overseas. Some authors have pointed out that the inclusion of the variable "Free Trade agreement" is likely to introduce endogeneity issues in the gravity model in the form of "reverse causality" (Baier, S. L. Bergstrand, J. H., 2003). It means that, in some cases, Free Trade Agreements might not only be a determinant of exports but also a consequence of these exports. In other terms, major trade partners with similar GDP and which are closed to each other would tend to sign more Free Trade Agreements. One of the solutions sometimes proposed to solve this problem is to use Non-Tariff Barriers as a measure of trade costs. This can be done by assessing the amount of technical regulations and standards that may affect the trade flows between some countries. However, Anderson and Wincoop (2001) argue that these two types of non-tariff barriers can be neglected as they do not affect significantly the results. Furthermore, Novy and Chen (2011) also point out that measuring the presence or the amount of standards also raises some problems of endogeneity bias. As these authors underline it (p. 407): *"Explicit measures to capture the presence or the amount of standards and regulations by using dummy or count variables, frequency or coverage ratios but their stringency remains hard to evaluate. Implicit measures suffer from similar problems. It should be added that the possible endogeneity of standards and regulations-however measured-in explaining trade flows is another concern".* Although we are aware of the potential problems of endogeneity related to the measurements of trade costs, we still decided to include this variable "Free Trade Agreement" in the Gravity model of trade for several reasons. First of all, the results of the regression are robust and do

not vary significantly with the introduction of the variable FTA. Secondly, as they are no other alternative measures of trade facilitation which would ensure better results, Free Trade Agreements have been included in the model. Moreover, since this thesis examines the EU-25 extra exports, the problem of endogeneity doesn't seem to be so important. Indeed, in our sample, many of the countries with which the European Union has signed a Free Trade Agreement (FTA) are located in Latin America and Asia. On the contrary, the European Union has still not signed a FTA with the United States which represents the biggest EU trade partner. Therefore, the variable "FTA" does not appear to be correlated with the economic importance of the receiving country or their distance.

- The variable "Tuberculosis" represents the number of people affected by tuberculosis in the country out of 100 000 inhabitants. It is as a proxy for the country's health status which is mainly used as a control variable. We expect this explanatory variable to have a negative impact on the dependent variable. Indeed, the EU should export less pharmaceutical products to countries with low health status (Boring, 2010, p. 9).
- The last regression of this empirical chapter also aims at evaluating the effect of the respect of Intellectual Property Rights on the EU exports of pharmaceuticals. In order to measure the impact of this variable on the exports of pharmaceuticals, a database has been built by using the index on "Intellectual Property Rights" developed in four annual reports conducted by the Property Right Alliance (from 2007 to 2011). The Intellectual Property Rights varies between 1 and 10 and comprises four dimensions: the protection of Intellectual Property rights, the patent strength, the copyright piracy and trademark protection (Property Right Alliance, 2007, 2008, 2009, 2010, and 2011). The higher the index, the stronger the level of Intellectual Property Rights in the country. In order to calculate the IPR index, four main sources were used by the Property Rights Alliance: the World Economic Forum's Global Competitiveness Index on Intellectual Property Rights, the Ginatre-Park Index of Patent Rights, the US Trade Representatives Watch List Report conducted by the International Intellectual Property Alliance, and the International Trademark Association' Report. In each case, the data was rescaled from 0 to 10. A weighted average of each of those four elements was calculated to obtain the ranking of the countries for the index of Intellectual Property Rights.

Table 8: variables included in the econometric model

Type of variable	Description of the variable	Expected effect on the dependent variable	Source
Dependent variable (y1)	Exports of pharmaceuticals in dollars from the EU to the country j	--	United Nation Comtrade database extracted via the World Integrated Trade Solution (WITS)
Independent variable (x2)	Natural logarithm of the GDP of the partner country in current dollars	Positive	World Bank database.
Independent variable (x3)	Natural logarithm of the distance in kilometers	Negative	Website : http://www.distance2villes.com/
Independent variable (x4)	Health expenditure as percentage of GDP	Positive	World Health Organisation database
Independent variable (x5)	Presence of a major port container in the receiving country(1) or not (0)	Positive	World Shipping Association's website
Independent variable (x6)	The country is landlocked (1) or has an access to the Ocean (0)	Negative	Mayer & Zignago (2011), Geodist. Centres d'Etudes Prospectives Internationales (CEPii)
Independent variable (x7)	Existence of a Free Trade Agreement between the EU and the country j (1) or not (0)	Positive	European Commission, website DG Enterprise and Industry.
Independent variable (x8)	The number of people affected by tuberculosis in the country (out of 100 000 inhabitants).	Negative	World Health Organisation Database
Independent variable (x9) **[latest regression]**	The protection of Intellectual Property Rights in different countries. The index is ranked between 0 and 10	Positive	Database created from the 2007, 2008, 2009, 2010, and 2011 Reports by the Property Rights Alliances on Intellectual Property Rights Index.

II. ECONOMETRIC METHOD OF ASSESSMENT

Classical gravity models have generally used cross-section data to evaluate trade relations between several countries for a given year. However, panel data analyses which enable to observe the influence of some independent variables on the dependant variable across time provide a more useful analysis than simple cross data. Indeed, by incorporating both cross-sectional and time series dimensions, panel data enable to deliver more accurate inference of the variables tested and control for the effect of missing or unobserved variables. In lights of those advantages, this thesis will rely on the method of static panel data[4]. Using our dataset, we estimate the following gravity equation:

$$lnexptdollar_{ijt} = \beta_1 lnGDPcurrent_{jt} + \beta_2\, lndist_{ij} + \beta_3\, healthspending_{jt} + \beta_4\, landlocked_j + \beta_5\, FTA_{ijt} + \beta_6\, Tuberculosis_{jt} + \beta_7\, Portcontainer_j + \alpha_n\, Country_n + \omega_n\, Year_n + U_{ijt}$$

Where

$lnexptdollar_{ijt}$= natural logarithm of the EU exports of pharmaceuticals (country i) towards the partner country (country j),

$lnGDPcurrent_j$ = natural logarithm of the GDP of country j in current dollars,

$lndist_{ij}$ = natural logarithm of the distance between country i and country j in kilometers,

$healthspending_j$ = health expenditure of country j as percentage of its GDP,

$landlocked_j$= indicates whether the country j is landlocked (1) or has an access to the Ocean (0),

FTA_{ij} = shows the existence of a Free Trade Agreement between the country i and j (1) or not (0),

$Tuberculosis_j$ = number of people affected by tuberculosis in the country j out of 100 000 inhabitants

$Portcontainer_j$=indicates the existence of a major port container (1) in the receiving country.

$Country_n$ = dummy variable for the countries included in the model[5].

$Year_n$= dummy variable for the years contained in the model[6].

U_{ij} = error term,

t = time period

B_s = parameters.

α_n = coefficients corresponding to the binary regressors country

[4] The impact of Intellectual Property Rights on EU exports of Pharmaceuticals will be analyzed by conducting an Ordinary Least Square Regression. This is due to the fact that the data on IPR is available only from 2007 to 2011.
[5] In order not to fall into the dummy trap, we included n-1 countries in the model (that is to say 61 countries).
[6] To avoid the dummy trap, we exclude the year 2004 of our model.

ω_n = coefficients for the binary time regressors[7]

We expect the signs of β_1, β_3, β_5, β_7 to be positive while β_2, β_4, β_6 should be negative.

SECTION 2: ECONOMETRIC ANALYSIS

I. FIRST ESTIMATION OF THE MODEL

The first model was estimated by using the method of panel data with fixed and time effects. Subsequently, we regressed lnexptUSdollars on lnGDPcurrent, lndist, health, Landlocked, FTA, Tuberculosis, Portcontainer, i.years[8] and i.country[9].

Table 9: Result of the first econometric test

	(1)
	1st model
lnGDPcurrent	0.620***
	(0.000)
FTA	0.0880
	(0.119)
lndist	-0.320
	(0.133)
Tuberculosis	-0.000126
	(0.823)
Landlocked	-1.086*
	(0.036)
healthspending	0.0609***
	(0.000)
Portcontainer	0.943
	(0.066)
Constant	5.301**
	(0.006)
Observations	496
Adjusted R-squared	0.990

p-values in parentheses
* p<0.05, ** p<0.01, *** p<0.001

After running this regression, the F-test was carried out to evaluate the joint nullity of all the explanatory variables of the model. The test led to a strong rejection of the null hypothesis indicating that the fixed effects are highly significant at 1% level. The command testparm was also used to verify

[7] As we are dealing with binary variables, we have t-1 time periods in the equation.
[8] i.years is a dummy variable created for each year.
[9] i.country is a dummy variable created for each partner country j.

whether it was necessary to include the binary variables "$Country_n$" and "$Year_n$" in our analysis. Both tests test led to a strong rejection of the null hypothesis which indicates that the two aforementioned variables were statistically jointly significant. The other explanatory factors which were found to be statistically significant at 5% level were the variable "healthspending", the logarithm of the GDP of the receiving country, and the binary variable "landlocked". The variable "Portcontainer" is statistically significant at 10% level. However, the explanatory factors "FTA", "lndist" and "Tuberculosis" are not statistically different from zero even at a 10% level.

Several misspecification tests were also carried out to control for functional form misspecification and heteroskedasticity. Given the size of the sample (62 countries over 8 years), one can assume that the variables are normally distributed. However, the result of the Breush Pagan test led to a strong rejection of the assumption of homoscedasticity at 1% level (table 10). The Ramsey RESET test also led to a rejection of the null hypothesis at 5% level indicating a problem of functional form misspecification (table 10). This problem can occur when the regression is nonlinear in the parameters.

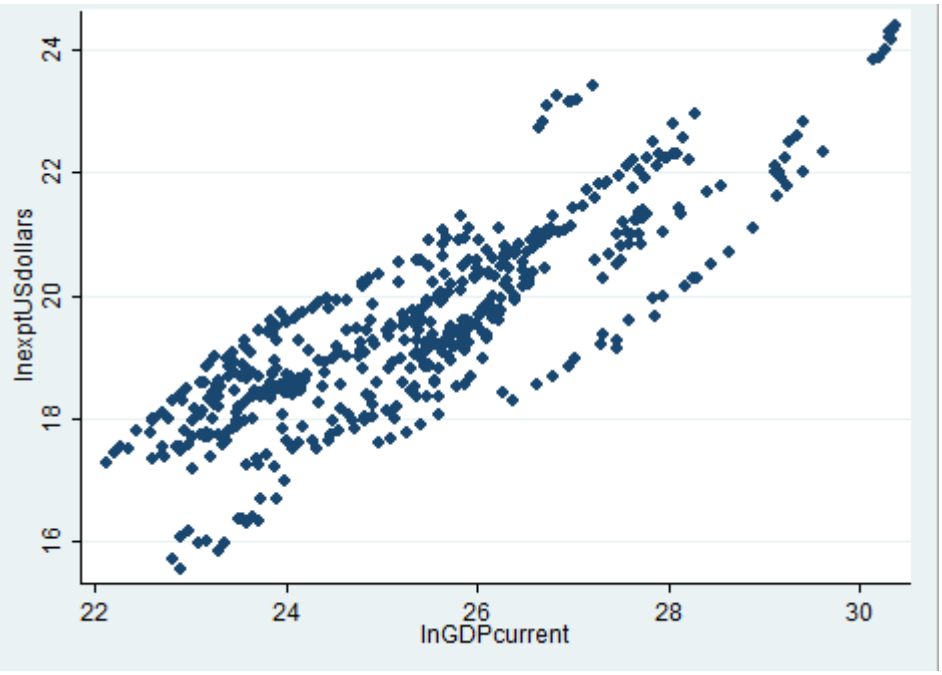
Table 10: Results of the Breush-Pagan and Ramsey reset test

```
Breusch-Pagan / Cook-Weisberg test for heteroskedasticity
         Ho: Constant variance
         Variables: fitted values of lnexptUSdollars

         chi2(1)      =    15.48
         Prob > chi2  =   0.0001

. ----- . ----

Ramsey RESET test using powers of the fitted values of lnexptUSdollars
       Ho:  model has no omitted variables
                 F(3, 419) =      5.00
                  Prob > F =      0.0020
```

II. REDEFINITION OF THE MODEL

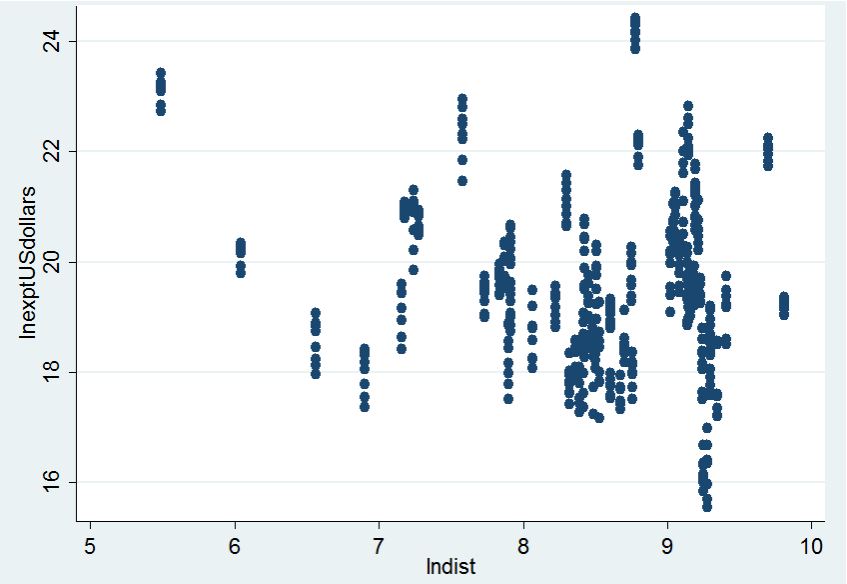
In light of the results of the Ramsey Reset test, we tried to determine which independent variables could have a non-linear relation with the dependent variable. First of all, we draw a scatterplot between the natural logarithm of the GDP of the receiving country in current dollars and the natural logarithm of the EU exports of pharmaceuticals in current dollars. The following scatterplot shows that the relation between the natural logarithm of the GDP in current dollars and the natural logarithm of the EU exports of pharmaceuticals in current dollars is quadratic rather than linear.

Graph 11: Relation between the natural logarithm of the GDP of the country j and the natural logarithm of the EU exports of pharmaceuticals in current dollars.



We also examined the relation between the natural logarithm of the distance in kilometers and the natural logarithm of the EU exports of pharmaceuticals in current dollars. The following graph shows that the relation between those two variables is not linear.

Graph 12: Relation between the natural logarithm of the distance in kilometers and the natural logarithm of the exports in current dollars.



In light of those results, we therefore introduced two new variables in the model namely the square of the natural logarithm of distance in kilometers (lndist2) and the square of the natural logarithm of GDP in current dollars (lnGDPcurrent2) in order to avoid the problem of functional form misspecification. Moreover, following the result of the Breuch Pagan test, we robustified the regression against heteroskedasticity.

Therefore, the model is now redefined as follows:

$$lnexptdollar_{ijt} = \beta_1 lnGDPcurrent_{jt} + \beta_2 (lnGDPcurrent)^2_{jt} + \beta_3\, lndist_{ij} + \beta_3\, (lndist)^2_{ij} + \beta_3\, healthspending_{jt} + \beta_4\, landlocked_j + \beta_5\, FTA_{ijt} + \beta_6\, Tuberculosis_{jt} + \beta_7\, Portcontainer_j + \alpha_n\, Country_n + \omega_n\, Year_n + U_{ijt}$$

The following table presents the result of this regression obtained in STATA[10].

[10] The table only displays the coefficient of the variables of interest in our model.

Table 13: Results of the second regression

	(1) 2nd model
lnGDPcurrent	-1.129* (0.033)
lnGDPcurrent2	0.0344*** (0.001)
FTA	0.122* (0.037)
lndist	-12.42*** (0.000)
lndist2	0.711*** (0.000)
Tuberculosis	-0.00104 (0.201)
Landlocked	0.526 (0.313)
healthspending	0.0510*** (0.000)
Portcontainer	2.812*** (0.000)
Constant	77.12*** (0.000)
Observations	496
Adjusted R-squared	0.990

p-values in parentheses
* p<0.05, ** p<0.01, *** p<0.001

The results of this regression are quite different from the former model. Indeed, all the explanatory variables of this model are statistically significant at 5% level except the variables “tuberculosis” and “landlocked”. The Ramset RESET test fails to reject the null hypothesis at 5% level. Since this model does not suffer from functional form misspecification, this regression should be preferred to the previous one on statistically ground.

Table 14: Result of the Ramset test

```
. estat ovtest

Ramsey RESET test using powers of the fitted values of lnexptUSdollars
       Ho:  model has no omitted variables
                 F(3, 417) =      0.87
                  Prob > F =      0.4577
```

The coefficient of the variables "FTA", "Healthcare spending" and "Portcontainer" have the expected signs. Indeed, the existence of a Free Trade Agreement is expected to increase EU exports by 12.2% holding other factors constant. Moreover, a one percent point increase in health expenditure (as a percentage of GDP) will increase the exports of pharmaceuticals in dollars by 5.1%. If a country possesses a major Port container, it is expected to import 281% more pharmaceutical products from the European Union than if it doesn't.

In order to better interpret the sign of the coefficients of the variables "lndist" and "lnGDPcurrent", we used the command margin on STATA. This enables us to obtain the partial effect of the variable "lndist" and "lnGDPcurrent" on the dependent variable at its mean value[11]. Indeed, the function margin calculates the derivative of the natural logarithm of the EU exports of pharmaceuticals in current dollars with respect to the variable lnGDPcurrent at its mean value. The table 15 displayed the result obtained in STATA. From this table, one can see that the variables "lnGDPcurrent" and "lndist" are statistically significant at 1% level. A 1% increase in the GDP of the receiving country is expected to result in a 0.62% increase in the EU exports of pharmaceuticals. The table 16 indicates that a 1% in the distance between the EU and the country j measured in kilometers is expected to result in a decrease of 0.4% in the EU exports of pharmaceuticals towards this state.

Table 15: Partial effect of "lnGDPcurrent" on the dependent variable

	Delta-method				
	dy/dx	Std. Err.	z	P>|z|	[95% Conf. Interval]
lnGDPcurrent	.6194133	.0561408	11.03	0.000	.5093794 .7294472

Table 16: Partial effect of lndist on the dependent variable

	Delta-method				
	dy/dx	Std. Err.	z	P>|z|	[95% Conf. Interval]
lndist	-.4036944	.2151332	-1.88	0.061	-.8253479 .017959

[11] Subsequently, we use the following command on stata: margins, dydx(lnGDPcurrent) atmeans

III. REGRESSION WITH CLUSTERED DATA

We now consider the possibility that the observations for each country over several years are not independent but correlated. In order to control for this problem, we use the cluster option on country[12]. The following table displays the main results of this model.

Table 17: results of the third regression

	(1) 3rd model
lnGDPcurrent	-1.129 (0.213)
lnGDPcurrent2	0.0344 (0.061)
FTA	0.122 (0.100)
lndist	-12.42*** (0.000)
lndist2	0.711*** (0.000)
Tuberculosis	-0.00104 (0.457)
Landlocked	0.526 (0.396)
healthspending	0.0510* (0.014)
Portcontainer	2.812*** (0.000)
Constant	77.12*** (0.000)
Observations	496
Adjusted R-squared	0.990

p-values in parentheses
* p<0.05, ** p<0.01, *** p<0.001

The result of this regression is different from the previous one. Indeed, the variables "lnGDPcurrent" and "FTA" are not statistically significant. Moreover, the variable "lnGDPcurrent^2" is only significant at a

[12] The following command was used on stata: reg lnexptUSdollars lnGDPcurrent lnGDPcurrent2 FTA lndist lndist2 Tuberculosis Landlocked health Portcontainer i.country2 i.Years, cluster (country2)

10% level. As in the previous regression, the variables "healthspending", "Portcontainer", "lndist", "lndist^2" are statistically significant at 5% level. The command margin was performed to evaluate the marginal effect of the distance and the GDP of the country j on the dependent variable.

Table 18: Partial effects of "lnGDPcurrent" and "lndist" on the dependent variable

	Delta-method dy/dx	Std. Err.	z	P>|z|	[95% Conf.	Interval]
lnGDPcurrent	.6194133	.1014185	6.11	0.000	.4206367	.8181899

	Delta-method dy/dx	Std. Err.	z	P>|z|	[95% Conf.	Interval]
lndist	-.3683492	.1005849	-3.66	0.000	-.565492	-.1712064

The 18th table indicates that the effect of lnGDPcurrent on the dependent variable is statistically significant at 0.1% level. The coefficient indicates that the relation between the GDP of the receiving country and the EU exports of pharmaceutical products measured in dollars is positive, as we expected. The result doesn't really differ from the previous regression. Indeed, a 1% increase in the GDP of the receiving country is expected to increase the EU exports of pharmaceuticals towards this country by 0.62%. The effect of the natural logarithm of distance on the EU exports of pharmaceuticals is also statistically significant at 1% level. The negative sign of the coefficient indicates that the relation between those two variables is negative. Therefore, a 1% increase in the distance between the EU and its partner country is expected to decrease the EU exports of pharmaceuticals by 0.37 %.

IV. REGRESSION WITH INTELLECTUAL PROPERTY RIGHTS

In order to measure the impact of Intellectual Property Rights on the exports of Pharmaceuticals from the EU, we created a database using the Reports on Intellectual Property Rights Index written by the Property Right Alliance. Since these reports only started in 2007, the data on intellectual property was only available from 2007 until 2011. Given the fact that we could only test the effect of the variable Intellectual Property Rights over a period of three years, we conducted a simple regression analysis using the method of Ordinary Least Square. The result is summarised in the following table:

Table 19: results of the fourth regression with IPR

	(1)
	model4
lnGDPcurrent	0.642***
	(0.000)
FTA	-0.0287
	(0.809)
lndist	-0.610***
	(0.000)
Landlocked	-0.138
	(0.623)
healthspending	0.100***
	(0.000)
Tuberculosis	0.0000646
	(0.700)
Portcontainer	0.434***
	(0.001)
IPR	0.141***
	(0.000)
Constant	7.061***
	(0.000)
Observations	161
Adjusted R-squared	0.816

p-values in parentheses
* p<0.05, ** p<0.01, *** p<0.001

As we can see from this table the variable "Intellectual Property Right" has a statistically significant impact on the EU exports of pharmaceuticals at 1% level. This means that a one unit increase in the rating of a country on Intellectual Property Right is expected to increase the EU exports of pharmaceuticals by 14.1% holding other factors constant.

SECTION 3: DISCUSSION OF THE RESULTS

Table 19: Summary of the results of the different regressions

```
> " "3rd model" "4th model") label ar2

Comparison of different models
```

	(1) 1st model	(2) 2nd model	(3) 3rd model	(4) 4th model
lnGDPcurrent	0.6203***	-1.1294*	-1.1294	0.6417***
	(0.00)	(0.03)	(0.21)	(0.00)
FTA	0.0880	0.1220*	0.1220	-0.0287
	(0.12)	(0.04)	(0.10)	(0.81)
lndist	-0.3196	-12.4247***	-12.4247***	-0.6105***
	(0.13)	(0.00)	(0.00)	(0.00)
Tuberculosis	-0.0001	-0.0010	-0.0010	0.0001
	(0.82)	(0.20)	(0.46)	(0.70)
Landlocked	-1.0857*	0.5259	0.5259	-0.1379
	(0.04)	(0.31)	(0.40)	(0.62)
healthspending	0.0609***	0.0510***	0.0510*	0.1003***
	(0.00)	(0.00)	(0.01)	(0.00)
Portcontainer	0.9430	2.8125***	2.8125***	0.4342***
	(0.07)	(0.00)	(0.00)	(0.00)
lnGDPcurrent2		0.0344***	0.0344	
		(0.00)	(0.06)	
lndist2		0.7109***	0.7109***	
		(0.00)	(0.00)	
IPR				0.1414***
				(0.00)
Constant	5.3009**	77.1159***	77.1159***	7.0608***
	(0.01)	(0.00)	(0.00)	(0.00)
Observations	496	496	496	161
Adjusted R-squared	0.990	0.990	0.990	0.816

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p-values in parentheses
* p<0.05, ** p<0.01, *** p<0.001
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The first regression of our model indicates that the variables “healthspending”, the logarithm of the GDP, the dummy variable “landlocked” have a statistically significant impact on the EU exports of pharmaceuticals at 5% level. The variable “Portcontainer” was also statistically significant at 10% level. However, since this regression didn’t pass the test of functional form misspecification, we added the

square of the variable "lnGDPcurrent" and the square of "lndist" into our initial equation. We also robustified our model in order to avoid the problem of heteroskedasticity detected by the Breush Pagan test.

The second regression shows that all the explanatory variables of this model are statistically significant at 5% level except the variables tuberculosis and landlocked. These results are similar to a certain extent to the one obtained by Per Adolfsson, Mats Wilkman and Anne Boring. Indeed, in their respective research, those authors showed that the Swedish and USA exports of pharmaceuticals depend positively on the economic size of the receiving country, and negatively on the distance between the country i and j. Contrary to Per Adolfsson's results concerning the case of Sweden, this thesis shows that the exports of EU pharmaceutical products are not influenced by the access to the Ocean of the partner country.

However, the presence of a major container port in the receiving country has a significant positive effect on the EU exports of pharmaceuticals towards those countries. This conclusion is similar to the one reached by Anne Boring. Indeed, she showed that countries with big port container are more likely to import pharmaceutical products from the USA. However, contrary to this researcher, we found that the variable turberculosis did not have a statistically significant impact on the EU exports of pharmaceuticals even at 10% level whereas the total health expenditure as a percentage of GDP had a very strong positive effect on the dependent variable. These results can be explained by the different research designs of our respective researches. Indeed, while Anne Boring's research focuses on the USA trade with emerging countries, this thesis examines the determinants of EU exports towards the rest of the world. This could explain why the variable "Tuberculosis" is statistically significant in her research and not in ours. However, the significance of the variable "healthspending" in this thesis suggests that the bigger the size of the health sector of the partner country, the more the EU will have opportunities to export towards those countries.

A third regression was run to control for an eventual problem of correlation between the observations for each country over several years. The result of this regression does not differ so much from the previous one. The biggest difference between the second and third regression lies in the fact that the variable Free Trade Agreement is not statistically significant anymore.

Finally, the fourth regression reveals the strong positive effect of the protection of Intellectual Property Rights on the EU exports of pharmaceuticals. This result strongly differs from the one obtained by Anne Boring in 2010 for the case of the USA trade of pharmaceuticals where the dummy variables used as a proxy for Intellectual Property Protection did not appear to have a statistically significant impact on the dependent variable. The last regression performed in this chapter confirms the statistical significance at 1% level of the GDP of the receiving country, the distance, the presence of a major port container, and

the level of health spending in the receiving country on the EU exports of pharmaceuticals. However, the variable Free Trade Agreement does not appear to be statistically significant even at 10% level.

Overall, one can therefore argue that the different regressions performed confirm our main hypotheses. The protection of Intellectual Property, the GDP of the partner country, the importance of the health sector of the receiving country and the presence of a major port container in the country j have a positive impact on the EU exports of pharmaceuticals overseas. On the contrary, as we expected, the transport costs measured by the distance between the EU and the receiving country have a negative effect on the extra EU-25 exports of pharmaceuticals. It is difficult, however, to draw any definitive conclusions regarding the impact of Free Trade Agreements on the EU exports of pharmaceuticals since the last regressions of this econometric analysis yield different results. This is why, a qualitative analysis based on interviews and specific case studies may be useful to complete this econometric assessment and to discuss some key trade issues that the EU pharmaceutical industry is current facing.

CHAPTER 4: ANALYSIS OF THE MAJOR TRADE ISSUES FOR THE EUROPEAN PHARMACEUTICAL INDUSTRY

The aim of this chapter is to provide an in-depth analysis of the factors representing a serious obstacle to the trade of pharmaceuticals. The findings of this part are based on interviews conducted with representatives of the EU pharmaceutical industry and the review of official reports.

SECTION 1: TARIFF BARRIERS

Most of the OECD members have zero tariffs for pharmaceutical products as a result of the Uruguay round (1986-1994) (Kiriyama: OECD, 2011, p. 43). However, emerging countries such as China, India, Russia, MERCOSUR and ASEAN countries still impose high tariff on pharmaceutical imports from the European Union (European Commission, 2011(a), p. 9). For instance, the report from the European Commission cited above indicates that a tariff of 10% is applied to EU generics containing penicillin and their derivatives in India (p. 9). These high tariffs imposed by some emerging countries are a source of concern for the EU pharmaceutical industry as it increases the price of their products overseas and limits the access to medicines (interview EFPIA, February 2014). According to the OECD, 66.8% of the revenues gained from tariff on pharmaceuticals are earned by the 10 non-OECD members in 2008 (Kiriyama, op. cit, p. 44). According to the same source, the weighted average tariff in these countries was 7.58% in 2008 (p. 44). The following table illustrates more in detail the difference of tariff on active pharmaceutical ingredients and finished products applied by lower, upper-middle income and high income countries.

Table 7: Distribution of tariff rates by country groups for active pharmaceutical ingredients and finished products containing other antibiotics.

a) Active pharmaceutical ingredients containing other antibiotics (300320)						
Tariffs rate (%)	Number of countries (n=140)	Percentage of all countries	Low-income countries	Lower-middle-income countries	Upper-middle-income countries	high-income countries
0	70	50%	22	18	13	17
0-5	28	20%	9	11	6	2
5.1-10	29	21%	8	9	10	2
10.1-20	10	7%	3[21]	4[22]	3[23]	0
> 20	3	2%	1[24]	2[25]	0	0
*MEAN- 4.46%; MEDIAN- 0.50%						
b) Finished products containing other antibiotics (300420)						
Tariffs rate (%)	Number of countries (n=148)	Percentage of countries	Low-income countries	Lower-middle-income countries	Upper-middle-income countries	High-income countries
0	64	43%	21	14	12	17
0-5	35	24%	11	14	7	3
5.1-10	34	23%	10	10	10	4
10.1-20	13	9%	3[26]	7[27]	3[28]	0
> 20	2	1%	1[29]	1[30]	0	0
*MEAN- 5.14%; MEDIAN- 3.5%						

Source: Olcay & Laing (2005, p. 27)

The report conducted that Müge Olcay and Richard Laing (2005, p. 38) show that even though the revenues generated from the levies on medicines are quite small, these tariffs may limit the access of the poor and the sickest to affordable medicines. This is why the removal of tariff barriers should be considered as a priority for policy makers in order to guarantee an access to essential drugs for the most vulnerable people.

SECTION 2: NON-TARIFF BARRIERS

Due to their impact on the health sector, pharmaceutical products are highly regulated. Although most of the regulations and standards are justified, they may significantly affect the trade of pharmaceuticals. It is therefore essential to ensure that the measures are strictly necessary and that do not represent discriminatory or disproportionate regulations or standards. According to the representatives of the pharmaceutical industry, non-tariff barriers (NTBs) are one of the most important sources of concern for this sector (Interview EFPIA, February 2014). These NTBs can take several forms ranging from registration, certification, or government policies concerning the price and the reimbursement of medications (European Commission, 2011(a), p. 10).

Registration barriers can represent a serious obstacle to the trade of pharmaceuticals. Indeed, additionally to the standards set by European Medicine Agency, EU producers have to comply with many requirements to obtain an authorization to export their products (ibid, p. 11). These certificates

can differ from one country to another which increases the administrative burden on pharmaceutical companies. In emerging economies such as China, India, Russia, and Brazil, the EU has to comply with different requirements and market authorizations which are often very long to obtain (ibid, p. 11). An important form of non-tariff barriers concerns the obligation for the pharmaceutical industry to conduct local clinical trials before registering their product in the country. This is notably the case in India and China where clinical trials have to be conducted locally for new medicines to be authorized in the country (ibid, p. 12).

Pharmaceutical companies are also affected by non-tariff measures (NTM) in developed countries such as Japan and the United States. For instance, the regulatory differences between the United States and Europe induce an additional cost of 9.5% for EU exporters (Berden, François, Thelle, Wymerga, Tamminen, 2009, p. 30). Pharmaceutical companies exporting their products to Japan are also seriously affected the complexity of the regulatory environment of this country (Sunesen, Francois and Thelle, 2009, p. 10). Indeed, Japan doesn't recognize foreign clinical trials which forces companies to duplicate these tests to be able to sell their products in this country. Pharmaceutical companies have to go through very lengthy and burdensome procedures to obtain a marketing authorization for their new drugs (ibid, p. 10). This often delays the introduction of EU pharmaceuticals in Japan and may give a competitive advantage to the domestic firms. Finally, EU pharmaceutical products are not very well reimbursed in Japan which tends to discourage customers from buying them (ibid). These non-tariff barriers are estimated to increase the cost of EU pharmaceutical exports to Japan by 22 percent (ibid).

Custom control and procedures can also represent barriers to the trade of pharmaceuticals. Indeed, the process by which custom authorities will examine, test products and store pharmaceuticals may delay their distribution in the country (European Commission, 2011(a), p. 11).

SECTION 3: THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

As the econometric model of this thesis revealed it, the protection of Intellectual Property Right is a key determinant of extra EU-25 exports. Since the Pharmaceutical industry is very research intensive, the protection of Intellectual Property is crucial to preserve the competitiveness of this industry. Indeed, the lack of enforcement of IPR creates disincentive for innovation and prevent pharmaceutical companies to recoup their investments in R&D. A study conducted by Lanjouw in 2005 also confirms that stronger patent protection will encourage companies to launch more rapidly new drugs in the market (cited in Kiriyama: OECD, p 52).

Counterfeiting medicines and Piracy are also considered a crucial issue by the EU pharmaceutical industry. Indeed, counterfeit medicines create a disincentive for originators companies to invest in R&D to develop new drugs and threaten the competitiveness of this industry (interview EFPIA, February 2014). According to the European Alliance for Access to safe medicines (2008): "A medicine is counterfeit when it is deliberately and fraudulently mislabeled with respect to its identity, history and/or source" (p. 8). A recent report from this organization shows that the volume of counterfeiting seized in Europe has considerably increased in the latest years. For instance, in 2006, 2.7 million of counterfeit products were found which represents more than 8 times the volume discovered in 2004 (p. 10). Since then, the development of counterfeit medicines has continuously increased.

Three countries can be considered as problematic regarding the respect of Intellectual Property Rights namely China, India and Canada (EFPIA interview, February 2014; European Commission, 2011, p.15). In China, concerns related to the protection of Intellectual Property Rights do not arise from the lack of regulation and rules on IPR. Indeed, the Chinese law on intellectual property right complies with the Trade-Related Aspects of Intellectual Property Rights agreement which guarantees a 20 years patent terms and 6 years data exclusivity to new drugs after the date of the marketing approval (Festel, Kreimeyer, Zedtwitz, 2005, p. 94). The problem comes mainly from the inadequate enforcement of the regulation on IPR which facilitates the production and selling of counterfeiting. The cost of counterfeiting drugs for pharmaceutical groups in China represents 10% to 25% of their annual sales (ibid, p. 94).

The EU pharmaceutical industry is also concerned with the weak enforcement of Intellectual Property Rights in India. Indeed, before 2005, this country only applied patent protection to processes and not products (European Commission, 2011(a), p. 8). It was therefore, very easy for Indian generic producers to copy medicines developed by foreign companies. Since January 2005, the Indian legislation has evolved to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Abbott, Nelson & Dukes, 2009, p. 25). However, despite this evolution, EU companies are significantly affected by the insufficient enforcement of IP regulation in the country (UK Intellectual Property Office, 2013, p. 9). Indeed, once pharmaceutical companies have applied for a patent, they often have to wait two years for the patent to be examined and approved (Kiriyama, 2011, p. 53). The protection of Intellectual Property Rights in India is a very sensitive issue as 70 per cent of medical costs are directly paid by private households (Ward & Kazmin, 2014). The government and the Supreme Court are applying a restricted interpretation of Intellectual Property Rights to facilitate the replacement of more expensive life-saving medicines by cheaper generic drug. For instance, in 2013, the Supreme Court in India has rejected a plea from Novartis to patent the cancer treatment drug "Glivec". However, this situation could hamper the competitiveness of drug manufacturers who have to

bear the high costs of R&D to develop of new drugs but may not be able to fully recoup their investments due to the lack of Intellectual Property Protection.

Compared to many developed countries, Canada is lagging behind in the protection of Intellectual Property Rights (European Commission, 2013(c), p. 1). Indeed, the Canadian law on data protection only applies to a small subset of new medicines. Thus, only drug ingredients that are contained within a medication for the first time will receive benefit from data protection (Kierans, Wagner, Thill-Tayara, 2011, p. 3). This means that a medicine combining several drug ingredients will not be subject to Intellectual Property Protection unless it contains at least one innovative component (ibid). What is more, as a recent report from Norton Rose states it "new drug uses, formulations and dosage forms are also not eligible for data protection"(ibid, p. 3). The weak protection of intellectual property rights in Canada compared to other developed countries is an important source of concern for the EU pharmaceutical industry. It seems therefore essential to implement some measures to ensure a better protection of Intellectual Property Rights in the different countries mentioned as this variable affects the profitability of pharmaceutical companies, and their capacity to innovate and to sell their products abroad.

CHAPTER 5: POLICY MEASURES TO BOOST THE EU EXPORTS OF PHARMACEUTICALS

The two last chapters of this thesis have revealed that the EU exports of pharmaceuticals depend on several characteristics of the receiving country: its economic size, its distance from the EU, the importance of the health sector, the presence of a major port container, the protection of intellectual property rights and the existence of trade barriers. In light of those results, the objective of this chapter is to draw some recommendations regarding the measures that should be implemented to boost the EU exports of Pharmaceuticals. As many initiatives have already been adopted both at the global and European levels, the objective of this chapter is to provide a critical analysis of the existing measures so as to formulate recommendations regarding the future trade policy developments.

SECTION 1: PROMOTING MULTILATERAL COOPERATION TO TACKLE TRADE BARRIERS

Multilateral cooperation within the World Trade Organization (WTO) represents an essential tool to remove both tariff and non-tariff barriers that can affect the pharmaceutical industry. Indeed, the advantage of this type of framework is that it includes all countries member of this organization and may facilitate a better enforcement of the agreement than bilateral negotiations (Maggi, 1999, p.208)[13]. As the tariffs in the world are already quite low, the priority is now to dismantle non-tariff barriers which significantly affect trade flows between countries. Since 1994, several initiatives have been implemented within the WTO to tackle non-tariff barriers and to improve the protection of intellectual property rights. For instance, the Technical Barriers to Trade (TBT) committee enables WTO members to raise some concerns and to discuss regulatory issues affecting trade flows. Several meetings of this committee have already focused on the technical barriers hindering the trade of pharmaceuticals[14]. By providing a forum for multilateral discussions, the TBT can improve the awareness of Member States on the negative impact of a regulation. The European Union being an important member of the WTO, it should use this opportunity to discuss some of the key regulatory issues and technical standards that affect the EU exports of pharmaceuticals. However, the success of these negotiations will be probably highly dependent on the cost of the requested modifications (Gruszczynski, 2013, p. 21). Indeed, if the

[13] Indeed, the violation of a bilateral agreement will only be punished by one embargo from the partner country. However, if a country breaks a multilateral agreement it will be sanctioned by the interruption of trade with several countries.

[14] For instance, in 2010, the EU, Switzerland and the United States raised concerns regarding the fact that Turkey stopped recognizing the Good Manufacturing Certificates produced by Foreign Regulatory Authorities (United States Trade Representative, 2013, p. 87).

change in the regulation entails strong costs for the partner country, the latter will be less willing to accept a compromise with the EU.

Since 1994, the question of Intellectual Property also has been included in the multilateral negotiations on trade mainly due to the request of more developed countries (Golderg, 2009, p. 2). The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was negotiated at the end of the Uruguay Round in 1994. According to this agreement, all states must recognize and apply patents for products and processes in all field of technology including pharmaceuticals for a period of 20 years (WTO, 1994, article 27 and 33). This agreement is important to ensure that innovation is protected in key emerging markets and that pharmaceutical industries can recoup their investment in R&D. However, as we underlined it in the previous chapter, there are still some problems regarding the protection of Intellectual Property Rights in emerging markets such as China or India. Indeed, although these countries have adopted some legislation on Intellectual Property Rights conformingly to the TRIPS agreement, the regulation is not always properly enforced on the ground. Therefore, it is not sufficient that Member States adopt a legislation conform to the TRIPS agreement as they also have to enforce it correctly in order to foster the world trade of pharmaceuticals. This is why, in complement to the negotiation at multilateral level, several plurilateral and bilateral dialogues should be promoted in order to tackle the insufficient enforcement of Intellectual Property Rights in some countries.

SECTION 2. STRENGTHENING PLURILATERAL DIALOGUE ON REGULATORY ISSUES

In a context of growing outsourcing of R&D and manufacturing activities, the recognition and harmonization of standards is becoming an important issue to foster the trade of pharmaceuticals. Indeed, the lack of common of standards and procedure may induce additional costs for the pharmaceutical industry and deter their exports and investment overseas. This is why it is essential to strengthen plurilateral dialogues to tackle these regulatory issues. Outside the WTO framework, three main organizations have provided a platform for discussion on regulatory standards and guidelines, namely the Organisation for Economic Co-operation and Development (OECD), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human and the Pharmaceutical Inspection Co-operation Scheme.

However, one of the major weaknesses of these initiatives on regulatory cooperation is that they do not include many emerging countries which are now representing key markets for the pharmaceutical industry (Kiriyama: OECD, 2011, p. 57). For instance, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human (ICH) only includes the regulatory authorities and pharmaceutical companies from Europe, Japan and the USA. While the high quality of the norms and standards fixed by the ICH is widely recognized, many developing countries do

not have the means and resources to adopt all ICH regulation (WHO, 2001, p. 21). Since ICH standards were only elaborated by three regions of the world, they do not necessarily responds to the need and particularities of all developing countries. Due to these limitations, many low and middle income countries have adopted their own standards and the problem of regulatory discrepancies in the field of pharmaceutical regulation persists. In order to be really effective the ICH should therefore involve more emerging countries in the discussion and make sure that they have the capacity to adopt the standards adopted within this organization.

Another limit related to the current initiatives on regulatory standards is that they are not constraining. For instance, the members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) are not obliged to recognize the inspection results conducted by other adherents (Kiriyama: OECD, 2011, p. 48). This is a major weakness as the duplication of inspection procedures represents substantial costs for pharmaceutical companies.

As the pharmaceutical industry is highly regulated due to its impact on the heath sector, it is extremely important to develop initiatives to facilitate the adoption of common standards and to avoid the duplication of procedures. However, when it comes to the cooperation between States on regulatory issues, two aspects should be improved. First of all, emerging countries should be better included in these initiatives in order to encourage a wider adoption of common regulations and to diminish the costs resulting from duplicated procedures. Secondly, more constraining mechanisms should be implemented to facilitate the mutual recognition of data and thus reduce the costs for the pharmaceutical industry. This would ultimately be beneficial to the trade of pharmaceuticals.

SECTION 3. PURSUING COMPREHENSIVE FREE TRADE POLICY AGREEMENTS WITH KEY PARTNERS

In addition to the initiatives launched at the global level, the European Union has started many bilateral negotiations with countries to eliminate trade barriers and open up markets with key partners. Many of the Free Trade Agreements currently negotiated concern key markets for the pharmaceutical industry notably Japan, India, the USA, ASEAN countries, and Canada (European Commission, 2011(a), p 9). These agreements can provide opportunity to eliminate both tariff and non-tariff barriers while reinforcing Intellectual Property Rights in the partner country. For instance, a Free Trade Agreement with Canada could enable this country to increase its standards on Intellectual Property to a level similar to the EU (European Commission, 2013(c), p. 2). This would in turn ensure a better protection of the rights of originator companies and encourage them to invest more in this country.

The benefits from a free trade agreement with Japan are also expected to be quite high for the pharmaceutical sector. Thus, a recent report states it: "the largest trade gains from NTM [non-tariff barriers] reduction occur in the chemicals (incl. pharmaceuticals) sector, followed by motor vehicles and medical equipment" (Sunesen, Francois & Thelle, 2009, p. 10). According to the same source, a reduction of 2% of non-tariff barriers could boost EU exports of pharmaceuticals by 60% (p. 10).

The future EU-US Transatlantic Trade and Investment Partnership (TTIP) could also improve the regulatory convergence between these countries and address issues concerning the pricing and reimbursement of medicines. According to a recent report, the annual income gain from an EU-US Transatlantic Trade and Investment Partnership for the EU chemical cosmetic & pharmaceutical sector is expected to vary between 7.1 and 9.2 billion of dollars (Koen et al, 2007, p. 26). By reducing regulatory discrepancies between the USA and the EU, the TTIP could also reduce trade and investment costs for the EU Pharmaceutical companies by 9.5% (ibid, p. 106). Thus, the bilateral negotiations between the European Union and its partners represent major tools to remove non-tariff barriers affecting the trade of pharmaceuticals. These negotiations are all the more important in a context of economic crisis and staggering internal demand where trade is expected to represent a major source growth (European Commission, 2012(b), p. 4).

To put it in a nutshell, two major elements should be improved to increase the trade of pharmaceuticals. First of all, the improvement of Intellectual Property Right represents an important element to boost the EU exports of pharmaceuticals. Indeed, strong patent protection provides an incentive for pharmaceuticals to innovate and enables them to recoup their investments in Research and Innovation. Greater harmonisation of standards and elimination of technical barriers also represent a crucial challenge to strengthen the EU trade of pharmaceuticals. Indeed, in a context of growing outsourcing of clinical trials and manufacturing activities of pharmaceuticals, it has become urgent to facilitate the adoption of common guidelines and the recognition of data among countries. These technical barriers may represent substantial costs for the pharmaceutical industry and hinder the trade of these products. Multilateral and regional dialogues as well Free Trade Agreements should be used to achieve these goals. However, it is necessary to include better emerging countries in these types of initiatives as they now represent key emerging markets for the pharmaceutical sector.

CONCLUSION

The EU pharmaceutical industry is an important source of growth and competitiveness for the European Economy. However, despite the importance of this sector for the future of the European Union, few academics have analyzed the European pharmaceutical industry from a trade-related perceptive. Most of the research on the European pharmaceutical industry generally focuses on its impact on the health sector or on the rules to maintain competition in the industry. This lack of research on the EU exports of pharmaceuticals is all the more surprising in a context of economic crisis where trade has a major role to play to boost EU competitiveness and growth. The aim of this thesis was to fill this literature gap by enhancing our knowledge of the drivers and obstacles to the extra-EU exports of pharmaceuticals. Subsequently this dissertation addressed the following research questions: What are the key drivers of the extra-EU exports of pharmaceuticals? What kind of policy measures should be implemented to remove the barriers to the trade of pharmaceuticals?

After reviewing the main characteristics of the Pharmaceutical industry, this thesis presented the theoretical framework of this research which combines insights from the International Trade theories as well as the Gravity Model. Based on this review of the literature, the thesis formulated various hypotheses concerning the determinants of the EU exports of pharmaceuticals. The different regressions conducted in the econometric part of this thesis confirm that the respect of intellectual property rights, the existence of a major container port, the economic size of the partner country and the level of health care expenditure of the partner country have a positive impact on the extra-EU exports of pharmaceuticals. On the contrary, as it was expected, the distance between the EU and the receiving country used a proxy for transport costs have a negative effect on the extra EU-25 exports of pharmaceuticals. However, the access to the Ocean of the receiving Countries did not have a statistically significant impact on the dependent variable. Moreover, it was difficult also to draw any definitive conclusions regarding the impact of Free Trade Agreements on the EU exports of pharmaceuticals since our regressions yield different results. In order to complete this analysis, this thesis relied on interviews with representatives of the European Pharmaceutical industry and on official reports on the topic. This qualitative analysis sheds light on the importance of tariff and non-tariff barriers and on the level of intellectual Property Rights on the EU exports of pharmaceuticals.

Based on this analysis, the last chapter of this thesis discusses the relevance of the main policies developed at the global and European levels to foster the trade of pharmaceuticals. While many of the determinants of the EU exports of pharmaceuticals can be difficult to address through common policies such as the costs of transports, the economic size of the countries, the level of health expenditure of the partner country, initiatives launched at the global and European levels can play a crucial role in

removing trade barriers and improving the protection of Intellectual Property Rights. The last chapter of this thesis has revealed the diversity of the measures already implemented to address these different issues. Whilst some important efforts have been undertaken by countries to reduce their trade barriers and harmonize their regulations, a lot of progresses still remain to be done to improve the mutual recognition of standards, the enforcement of intellectual propriety rights and the elimination of non-tariff barriers. In that context, multilateral cooperation, plurilateral dialogue and Free Trade Agreements between the EU and its key trade partners represent important tools to remove the main trade barriers affecting the trade of pharmaceuticals. However, given the growing importance of emerging countries in this sector, it has become more than necessary to strengthen the dialogue with these states to design international standards, harmonize regulations and ensure a better enforcement of Intellectual Property Rights.

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Interviews

Interview with three members of EFPIA, the European Federation of Pharmaceutical Industries and Associations, the 21st of February 2014.

APPENDIX

Appendix 1: List of countries included in the sample

Russia	Cameroon
Switzerland	Pakistan
Australia	Colombia
Ukraine	Albania
Algeria	Panama
Saudi Arabia	Benin
South Africa	Georgia
Norway	Congo
United Arab Emirates	Kenya
Croatia	Gabon
Vietnam	Japan
Israel	Indonesia
Mexico	South Korea
Kazakhstan	Malaysia
Egypt	Philippine
Morocco	Thailand
Jordan	China
Côte d'Ivoire	Canada
Lebanon	United states
Nigeria	Brasil
Belarus	Chile
Senegal	Colombia
Bosnia and Herzegovina	Ecuador
Singapore	Peru
Iraq	Venezuela
New Zealand	Bolivia
Uzbekistan	Paraguay
Kuwait	Uruguay
Ghana	India
Angola	Ethiopia
Sudan	Qatar