Master Thesis

How Changes in the IPR Environment in the Indian Pharmaceutical Sector Affect the Business Models of Multinational Enterprises?

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8 June 2016

Acknowledgements

This thesis is the last part of the graduation from the Master program in Innovation, Knowledge and Entrepreneurial Dynamics at Aalborg University, Denmark. The subject of the master thesis is in line with the students` personal interest in the notion of Innovation system, Intellectual Property Rights and Business Models. The students had a great learning time at the university, where new people and friendship were made. Especially, the students would like to thank their supervisor Bjørn Johnson, whose guidelines were a crucial part for the writing process of this master thesis.

Abstract

The main objective of this master thesis is to investigate how changes in the IPR environment in the Indian pharmaceutical sector affect the business models of multinational firms. The students take also into consideration the fundamental problem of social welfare versus innovator's incentives. To answer the problem formulation, a theoretical framework interlinking concepts such as Innovation System (IS) (more precisely the notion of National Innovation System (NIS) and Sectoral System of Innovation (SSI), Intellectual Property Rights (IPR), Open Innovation (OI) and Business Models (BM) is developed. Three cases that concerns MNEs` losses on patent cases in the Indian pharmaceutical sector are analysed. The master thesis uses Yin`s single embedded case study methodological approach. The main findings of the study work underpin that changes in the IPR environment in India affect differently the business model of foreign and domestic MNEs. The key implication of the thesis is that developing countries should educe their institutional environment (as the Indian case) in order to comply with the global IPR regulations, but not on the expense of their own economic and social interest. To improve the reliability of the research, there is a need for investigating more case studies from the developing countries, which concerns this master thesis. Future research could focus on developing new business models in the pharmaceutical sector which aims to solve the fundamental question: social welfare versus inventor's incentive.

Table of Contents

List of Figures

List of Tables

List of Appendix

Abbreviation

AIDS/HIV	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredients
CGPDTM	Controller General of Patents, Designs, Trademarks and Geographical Indications
CL	Compulsory Licensing
CMO	Contract Manufacturing Organisation
CPAA	Cancer Patients Aid Association
CRAMS	Contract Research and Manufacturing Services
CRP	Collaborative Research Project
DCGI	Drug Controller General of India
DPCO	Drug Price Control Order
DUI	Doing, Using and Interacting
EMR	Exclusive Marketing Right
EPO	The European Patent Office
EU	The European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
GRI	Government Research Institutes
HAL	Hindustan Antibiotics
IDPL	Indian Drugs and Pharmaceuticals
IP	Intellectual Property

IPAB	Intellectual Property Appellate Board
IPR	Intellectual Property Right
IS	Innovation System
IT	Information Technology
MNE	Multinational Enterprises
NIS/NSI	National Systems of Innovation
OECD	Organisation for Economic Co-operation and Development
OI	Open Innovation
R&D	Research and Development
RIS	Regional Systems of Innovation
SIS/SSI	Sectoral Systems of Innovation
STI	Science, Technology and Innovation
TIS	Technological Systems of Innovation
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UOI	Union of India
US	The United States
WIPO	The World Intellectual Property Organisation
WTO	World Trade Organisation

1. CHAPTER
INTRODUCTION TO THE THESIS

1. 1. Introduction to the Problem Formulation

The pharmaceutical sector is considered as one of the most important sectors worldwide for both society and economy, where innovation has a substantial impact on the health and wellness of millions of people. This highly knowledge-intensive industry relies heavily on IPR due to the fact that the patent protection virtually equals the product (Lehman, 2003, p. 7). A fundamental topic that have been discussed by national and international institutions is the relationship between IPRs, R&D incentives, pricing and access to medicines (Cockburn, 2009, p. 150). The concept of IPR has been understood differently in the developed and developing countries due to the significant economic and knowledge gap between the two contexts. An attempt to narrow down this gap is the global harmonisation of IPRs under the World Trade Organisation (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiated during the Uruguay Round (Maxwell & Ricker, 2014, p. 2). The main objective of the TRIPS Agreement is to set minimum standards for IPRs. As a consequence, developing countries were obliged to strengthen their own IPR laws in order to balance them with the ones in the developed countries.

The standardization of IPRs on a global level have increased the foreign direct investments in the developing countries and have created incentives for MNEs to pursue these new markets. However, companies face several challenges when entering developing markets due to local, economic and institutional differences (Dahan et al., 2010, p. 326). In order to conduct business successfully MNEs need to adapt their business models to the context they operate in.

In this master thesis, it has been decided to investigate the concept of IPRs in the developing countries and how it interlinks with the changes of MNEs` business model in the pharmaceutical sector. The students have chosen to analyse the context of India due to the fact that the country has one of the most advanced pharmaceutical sector from the developing countries which is the fourth largest industry in the world by volume (DIBD, 2000, p. 1). Moreover, The Indian government have used the global IPR standards in their favour by shaping the Indian Patent Act in order to serve country's own economic, social and technological conditions (Srinivasan, 2007, p. 3687). It has set high barrier for patenting in order to limit the cases of "evergreening" which is a known practice in the pharmaceutical

world that allows MNEs to extend the monopoly of an existing drug by modifying it and search new patents (Stanbrook, 2013, p. 939). This barrier is known as *Section 3(d) of the Patents (Amendment) Act of 2005,* that give protection to pharma companies only if the new medicine consists of "[...] *brand new chemical substances or enhanced the therapeutic "efficacy" of known substances*" (Bennett, 2014, p. 544). In the recent years, due to the changes in the Indian Patent Act several big MNEs (Novatris, Bayer, Roche, etc.) have lost patent cases in India. As a consequence, an international attention was brought on whether Indian IPR environment is favourable for supporting innovation.

Even though that the country is criticised to use destructive IPR policies from MNEs and other international pharmaceutical organisations, the Indian government has not break the rules of TRIPS Agreement. In this way not only India protects its domestic firms but at the same time provide affordable lifesaving medicine to the Indian people. India is the first developing country which dared to use patent laws to protect its domestic market from the MNEs` monopoly (Smedley, 2013, p. 1). These recent changes have risen some questions regarding how these MNEs can keep up with the changing environment. The traditional way of investing substantial amount of money in R&D in order to develop new medicine and focusing on evergreening will no longer work in such a dynamic set-up. Therefore, pharmaceutical companies need to implement new business models to restore profitability especially when operating in a developing context (Gilbert, et al., 2003, p. 1). After discussing all of this matters, the students have decided to investigate the following problem statement:

"How changes in the IPR environment in the Indian pharmaceutical sector affect the business models of multinational enterprises (MNEs)?"

2. CHAPTER METHODOLOGY

The research methodology chapter will provide guidelines and structure of how this thesis was conducted by a group of two master students. The students tried to frame an analysis in a critical way of the research topic. Therefore, the combination of methodology techniques, which include a research paradigm and a research method will be presented in Figure 1 in order to understand the flow of this chapter. To find an answer to the research question, the students tried to keep the analysis in a systematic way, which is based on a selected research approach. It was essential to keep in mind resources constraints, such as a limited time of the study. The design of the methodology was based on Yin (2009, 2011) research strategies.

The main objective of this study is to investigate the relationship between IPR regime and MNEs business models in the Indian pharmaceutical sector. It can be achieved by applying a case study method and presenting the analysis of outcomes in the later chapters.

Figure 1: The Methodology Flow

Source 1 : Made by the student group (2016)

2. 1. Research Approaches

To begin a research study, it requires to take few steps back and understand, which type of research approaches will be followed in order to gain knowledge of the research topic. Dewey (1933) in (Gray 2006, p. 16) outlined two ways of working on a project, (i) a deductive proof (deduction); (ii) and an inductive discovery (induction). The inductive approach can be described as a "bottom-up", and it concentrates on gathering knowledge by interviewing and observing the participant's view of the research topic. The outcomes of this approach lead to a creation of new theory, and one of the common research strategies is a grounded theory. However, this method is a time-taking, and it can not guarantee outcomes, that was expected by a researcher Creswell & Plano Clarkm (2007, p. 23). The other approach is deductive, which have been chosen by the students in order to conduct this particular master thesis. According to Creswell (2013, p. 93) "[...] *the researcher tests or verifies a theory by examining hypotheses or questions derived from it*". An understanding of it refers to "top-down", and it focuses on gathering information about a topic through a literature review, which is a fundamental element of research. Research topics conclusion may change over the period, and that is why conducting and testing already established theory can obtain new assumption and bring new concepts.

2. 2. Research Paradigm

The discussion and selection of paradigms can be seen as hidden in the research. Nevertheless, the importance of it is significant. Paradigms help to understand and explain why this specific research method and strategies were chosen (Creswell, 2013, p. 35). In general, the main research questions start with "what", "why" and "how" and they help to explain research paradigms and assist to collect necessary data for a project analysis.

According to Guba & Lincoln (1994, pp. 107-108) research paradigms can be explained through taxonomies. Taxonomies are philosophical dimensions that explain how researchers or students distinguish a research problem and how to find a solution. It is common that researchers have specific questions about certain beliefs about what knowledge is, what is knowable, and how that knowledge could be collected. There are three fundamental questions: ontological, epistemological and methodological. Ontology describes, "What is a reality?". Moreover, it can be seen as a "single reality" or "not single reality". It means that reality has one concept that can be applied to other projects or does it has different contexts and different realities. Epistemology deals with "how do you know something?". It is a theory of getting

knowledge of reality by providing an objective view and discovering "how things really are" and "how things really work" (Lincoln and Guba, 1994, p. 108). Methodology is "how do you go about finding it out" and it is how information about reality be collected. Methodology includes various strategies, for instance, qualitative, quantitative or mixed method.

According to Guba & Lincoln (1994, p. 105) a paradigm is a "basic belief", which represents "[...] the individual's place in it, and the range of possible relationships to that world and its parts". The definition from Kuhn (1970, p. 175) underpins that a paradigm is seen as a technique to research the analysis and it can "[...] act as a guide or map, dictating the kinds of problems scientists should address and the types of explanations that are acceptable to them". There are three main research paradigms: interpretivism, positivism and pragmatism.

Table 1 presents a summary of key elements of research paradigms and taxonomies.

Table 1 "Research Paradigms"

RESEARCH PARADIGMS				
PARADIGMS	**ONTOLOGY** *What is reality?*	**EPISTEMOLOGY** *How can I know reality?*	**METHODOLOGY** *How do I go about finding out?*	**RESEARCH METHOD** *What strategies do you use to find out?*
Positivism	Objective Single external reality	No influence from a researcher Reality can be measured	Experimental research Survey research	Quantitative: statistical sampling, scaling Questionnaire
Interpretivism Constructivism	No single reality, created by individuals or groups	Reality needs to be interpreted Focus on event's meaning	Case Study Grounded Theory	Qualitative: interviewing, observing, collecting and examining
Pragmatism	Reality is interpreted in humans actions	Acceptation of different viewpoints	Mixed methods	Combination of Qualitative and Quantitative

Source 2: Made by the student group (2016)

Based on Guba & Lincoln (1994, pp. 107-116) & Creswell (2013, pp. 35-40)

Interpretivism/constructivism research approach looks at reality from different perspectives, meaning that there is not a single reality that can be applied to many other cases. Ontology will tell to a researcher that there are multiple realities and the reality is socially constructed rather

than objectively determined. Through epistemology view, it can be seen that a researcher tends to rely on the "participants' views of the situation being studied" (Creswell, 2013, p.37). The gathered knowledge is positioned on their backgrounds and experiences in order to capture the meaning in human interaction and make sense of what is perceived as reality. Methodology taxonomy generally deals with case study or grounded theory, which are qualitative research strategies.

Positivism research paradigm believes that reality is stable, and it is based on objective meaning. Ontological position shows, that reality is single with a focus on laws. An analysis usually follows rational and systematic procedures. Epistemological question provides an understanding that researchers or students are independent, and interaction with participants is neutral in order to have clear distinguish between reasons and feelings. Methodology focuses on facts and value judgments. The common techniques are a creation of hypotheses research, which leads to testing and possible generalisation and replicability. This paradigm is based on statistical and mathematical research strategy methods. According to Creswell (2013, p. 36), an analysis starts with "[...] *a theory, collects data that either supports or refutes the theory, and then makes necessary revisions and conducts additional tests*".

Pragmatism research paradigm focuses on understanding all dimensions of reality. The main research topics relate to historical or political context. This paradigm is a mix and it "[...] *opens the door to multiple methods, different worldviews, and different assumptions, as well as different forms of data collection and analysis*" (Creswell, 2013, p. 40). Methodology view applies a combination of qualitative and quantitative research strategies. It is important from epistemology view to analyse different opinions in order to find out an answer to ontological question, which more interested to know "what works" and less about "truth" meaning.

2. 2. 1. Chosen Research Paradigm

In this study paper, the students used a mixture of the *Interpretivism/constructivism* and *Pragmatism* research paradigm in order to better understand and analyse how changes in the IPR environment in the Indian pharmaceutical sector affect the business models of MNEs. From the *Interpretivism/constructivism* paradigm the students is the methodology techniques which are represented by a qualitative case study research approach. However, the students are interested in understanding different worldviews and different assumptions regarding the analysed problem, hence, the reality of the p*ragmatism* paradigm is also valid in this master thesis.

2. 3. Case Study

When a researcher decides to apply a case study strategy, it is also necessary to understand what case is about. As described by Stake (2005) "[...] *a case is a framing of a particular chunk of reality, selected by a researcher, with a specific research question in mind*" (*Research Method Lecture*, 2014, slide 15). The research strategy is an appropriate tool to analyse a problem with main questions "why" or "how". Additionally, a control over events in a case study is limited of investigator's actions and it focuses on real-life situation, when boundaries of context are not clear (Yin, 2009, p. 18). The dimensions of Robson (1993) definition will be explained more in details, as it helps to connect this research strategy with the thesis's research question. Robson's definition (1993, p. 146) of a case study is a "[...] *strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence*". A *"phenomenon"* of a case study could be a person, organisation, or special event taking place in special conditions. In this thesis, there are two main phenomena- the changes in the IPR environment and the Business Models of MNEs. The aim of the students is to show that the two concepts are interlinked and affect each other. In order to show this interlinkage an analysis of the Indian pharmaceutical sector. *"Life context"* refers to that a research goes out and talk with people and the most important bringing all parts of the investigation together and clearly show the relationship between them. In this master thesis, the empirical data was collected from already published cases. The students have chosen three significant patent lost cases in India, in order to find out how the IPR changes affect the Business Model of MNEs. The cases were running in 2000s and some of them reached the investigation process for six years. "*Multiple sources of evidence"* links to data collection and in this study paper it relates to secondary data collection (market research), research papers (analysis of cases). Further information about data collection will be presented in Section 2.4.

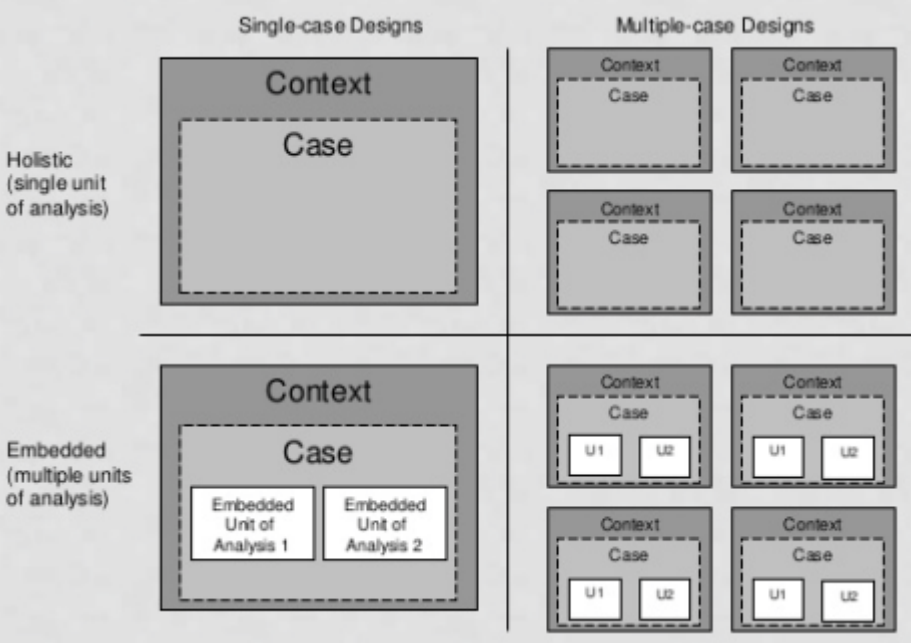
2. 3. 1. Design and Type of Cases

The type of cases directly relates to the research question and main objectives of the study paper. Yin (2009) mentioned that different types of cases assist to determine how to collect data, as a result he introduced three categories of case studies, such as exploratory, descriptive, and explanatory (p. 3). Explanatory is conducted to answer the — "how" and —"why" questions. The main attention of a study is to find a relationship between variables. This type of an approach is usually used when a researcher would like to answer a question that covers real-life interventions that are too complex for the survey or experimental strategies. The main

purpose of this study paper is to analyse the influence of IPR changes on MNEs business model in India. That is why to find out the relationship between these two contexts explanatory case study can be used. Other types of cases can not provide the needed strategies in order to answer the problem formulation. For instance, exploratory case focuses on exploring, observing and identifying variables by making hypothesis with a main question "what". A descriptive case concentrates on providing additional information of a topic, that is why it requires different types of data collection.

A case study research design can also be divided into single or multiple case study, which can also be separated to holistic or embedded. According to Figure 2, it can be seen that single case studies include only one case, while multiple can have separated cases. The difference between holistic and embedded is an amount of unit of analysis (Yin 2009, pp. 46-49).

Figure 2 "Basic Types of Designs for Case Studies"



Source 3 : Yin (2009, p. 46)

To apply holistic or embedded unit of analysis, it requires to look deeper into the selected. A holistic design can be applied, when there is only one unit of analysis and it does not have an interlinkage among other units. The main disadvantage with this is that it does not have a clear focus and it can become too broad. An embedded design examines a case study by applying several variables, which will help to make a study more focused (Yin, 2009, p. 52).

According to the thesis topic, the case study design can be defined as single embedded unit of analysis. The reason is that a case is focused only on one country India with several analysis units, such as IPR regulations and business models. The students are interested in analysing the interlinkage between these two phenomena. Using the single embedded case study design will provide for a better focus on the research topic.

2. 4. Data Collection

Data gathering is an important part of this thesis, because it helps to understand how the students researched the selected topic. In general, there are two main types of data collection: qualitative and quantitative. The decision which type of method to chose is based on research objectives, approaches and paradigms. It is also possible to combine two methods together to have a deeper understanding of a problem question.

This master thesis followed a deductive approach, that is why data collection was mainly based on a literature review. According to Cooper (2010 in Creswell, 2013, p. 61) there are four forms of a literature review: (a) integrate what previous researchers have done and how it was analysed, (b) criticise previous studies, (c) interconnect related theories together, and (d) identify central elements of a study. It is common, that a literature review is separated in subtopics (from general to narrower), and summarise the chapter by indicating interlinkage and central elements. The theoretical chapter of the thesis was based on interconnection of related theories, such as Innovation, Business, Economic, Evolutionary and Utilitarian Theories. Concepts such as Innovation Systems, Sectoral Innovation System, Intellectual Property Rights Theory, Open Innovation and Business Models were combined in order to create a theoretical framework that was used as a supporting tool to answer the investigated topic of the thesis.

The thesis's research strategy is a case study with a qualitative method. According to Yin (2011, p. 129) there are four field-based activities: interviewing, observing, collecting and examining (materials), and feeling. The students only applied one types of qualitative data collection method and it is a collecting.

Nowadays, to find relevant data can be achieved by checking web-based information. The goal of the students is to understand and apply this source of the information. According to Yin (2011, p. 149) the web-search process "[...] *should include learning about any widely recognized biases associated with the source*". However, the questions of trust and reliability can be applied to web-search. To have valid information, it is better to search through official

governmental reports, university's databases, well-known journals and organisations. Information is less valuable, if it was collected from personal postings and blogs.

This thesis includes mostly academic books and research articles from web-search processes. One of them are Google Scholar and Google Books. It helped to search by keywords, such as business models in developing countries, IPR, Indian patent regime and pharmaceutical sector, Innovation Systems and Sectoral Innovation Systems, Open Innovation, Strategy. By doing this, the students, collected the most relevant books and research papers, which were further analysed and applied to the research context. Other sources of data were collected through Aalborg University databases such as MarketLine. It provided a detailed information about Indian Pharmaceutical sector and information about selected pharmaceutical foreign and domestic MNEs. The three chosen cases are: Case 1: Novartis AG v. Union of India & Others; Case 2 "Bayer vs. Natco" and Case 3: "Roche vs. Cipla. The cases are based on the following criteria:

- The case concerns IPR in the Indian pharmaceutical sector
- The case should have attracted significant international attention
- The case should concern the fundamental problem: social welfare vs. inventor`s incentives
- The case should be between foreign and domestic MNEs
- The case should focus on lifesaving medicine

2. 4. 1. Challenges of data collection

The data collection outcomes helped the students to analyse the research topic. However, it also brought several challenges. For instance, the "collecting" data method is time-consuming, because there are a lot of research papers and articles about the topic, but it is important to select the most reliable information. It was hard to find a specific example how foreign MNEs change their business models after lawsuit procedures in India. The students assumed that it is on-going process for MNEs. In the master thesis students provide a reasonable assumption regarding how IPR changes in the Indian pharmaceutical industry affected the Business Models of MNEs. It was challenging to find the latest statistical information about number of patents in India (from domestic and foreign companies).

2. 5. Issues of Trustworthiness

To provide the reader with accurate data, the project deals with the validity and reliability of the gathered information. In order to achieve that the students tries to compare and interlink the collected data from one source to another one. This requires the availability of more than one resource which sometimes can be seen as a difficulty because of the lack of information especially when discussing IPR changes and how they affect the MNEs Business Models. Another possible solution for preventing an accurate data are peer reviewed articles and related books that students have used in this thesis.

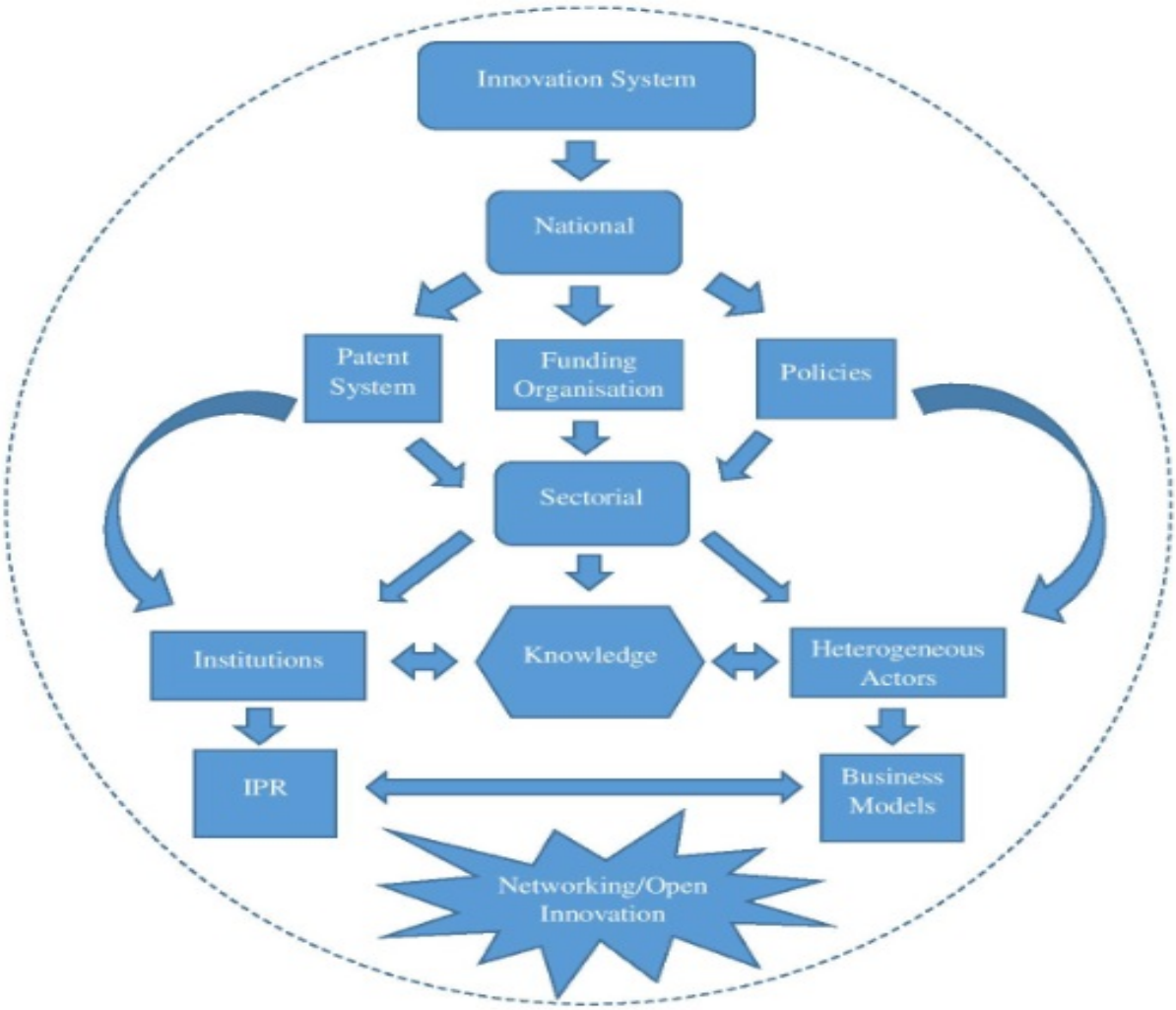
2. 6. Limitation of a Study

The time limits prescribed by the university are the most essential limitation, because it did not provide possibilities to analyse the research question by gathering primary data. In this case, the students could apply a research method as interviews with the pharmaceutical companies. By doing this, interview answers could extend the analysis part by explaining how IPR changes affect business models among different MNEs and understand more in details decision process to select new business models from first hand experience. Additionally, the discussion about profit versus patient's health care could be presented in more details. The students gathered information about the cases, when the final decision was already presented. That is why, it was not feasible to be physically involved in that process to see the discussions and detailed arguments themselves. However, it was not possible to apply other qualitative research methods, such as observation and participant observations, which could have provided a better understanding of rationales and facts of the cases.

3. CHAPTER
THEORETICAL FRAMEWORK

The main objective of the master thesis is to understand how changes in the IPR environment in the Indian pharmaceutical sector affect the business models of multinational enterprises (MNEs). In order to answer the problem formulation, a theoretical framework will be developed. The students decided to investigate how concepts such as Innovation System (IS) (more precisely the notion of National Innovation System (NIS) and Sectoral System of Innovation (SSI), Intellectual Property Rights (IPR), Open Innovation (OI) and Business Models interlink and can be used to analyse the discussed topic.

Figure 3: Theoretical Framework



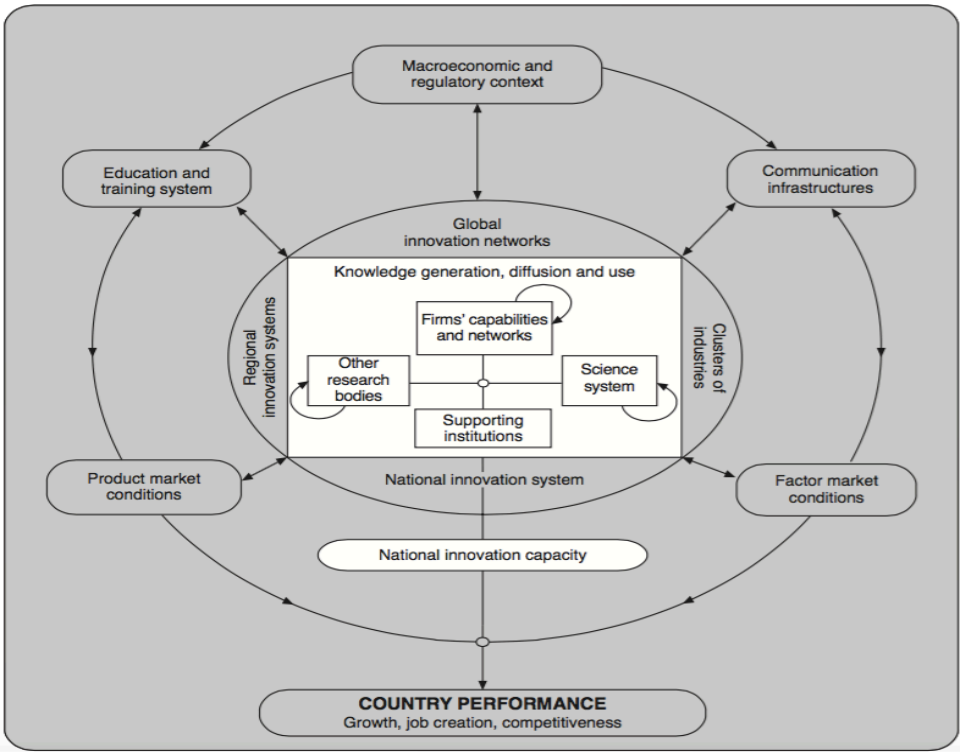
Source 4: Made by the students, 2016

In Figure 4 the theoretical framework is illustrated. One of the most essential part of the theoretical framework presented above is the notion of Innovation System which aims to explain that innovation is created by the outcome of the interaction between institutions, organisations and individuals (Lundvall & Johnson 2013, p. 1). The Innovation System is divided by sub-systems such as national, regional, sectorial and technological. All of these sub-systems co-exist and are interlinked between each other. They consist of different actors that network and collaborate in order to co-create and diffuse new knowledge in the innovation system. National Innovation System is responsible for setting Technological and Innovation policies, regulate the Patent System and provide financial incentives via various organisations. Due to the fact that the pharmaceutical sector is investigated in the thesis, the theoretical framework focuses more on the notion of Sectorial System of Innovation (SSI) which consists of three main building blocks -Institutions, Knowledge and Heterogeneous Actors. Networking is perceived as one of the main connecting activity among different parties in the system. National and Sectoral institutions are complementary to each other. Institution are crucial for the innovation system and are defined as "[...] *the laws, norms and practices which shapes patterns of behaviour and determine how firm and organizations relate and interact with each other*" (Johnson & Lundvall, 2013, p. 1). When institutions are discussed in the pharmaceutical sector, the concept of IPR should be taken into consideration. There are different institutions that are involved in the creation and regulation of the IPR laws. Heterogeneous Actors are also an important part of the SSI and are described as political (city council), economic (firms, cooperatives), social (church) and educational (universities) organisations (North, 1990, p. 5). In the case of this master thesis, there will be a focus on the economic organisations represented by MNEs. The key resource that is central for the innovation system and all the parties involved is Knowledge. An important issue that need to be discussed is why knowledge should be protected by IPRs and if this action stimulates or restrain innovation. It is also of interest to understand how changes in the IPR environment affect the business models of MNEs. In the theoretical framework the concept of OI is seen as a connecting activity between all the parties of the innovation system and it is described as the use of inflows and outflows of knowledge to improve company's internal innovation process (Chesbrough, 2006, p. 1).

3. 1. Innovation System

It is a well-known fact that innovation is one of the most important drivers of economic growth needed to sustain country's welfare. However, innovation activities differ from one country to another, and they depend on *"[...] industrial specialisation, specific institutional settings, policy priorities*" (OECD, 1999, p. 21). The concept that can deeply analyse these drivers and interconnect them is known as 'Systems of Innovation' or 'Innovation Systems' (IS) and it has appeared in the last decades. The concept of IS has been mentioned for the first time in a publication by Lundvall in 1985. Lundvall (1985, p. 10) stressed that *"[...] the most important innovations involve at least some elements of cooperation*". As a result, it opened new channels of information and stimulate research activities towards innovation outcomes. Edquist (1997) defined IS as "[…] *all important economic, social, political, organizational, institutional, and other factors that influence the development, diffusion and use of innovation*" (p. 182). Figure 5 from OECD report (1999, p. 23) is an outline of the relationship among elements within IS, and it can be considered as an approach to change governmental policies to improve country performance.

Figure 4: Actors and Linkage in the Innovation System



Source 5: OECD (1999, p. 23)

The first element is firm activities and capabilities and it is considered to be a centre driving act. In general, companies have a potential to implement innovation. Innovation can have different kinds of recognition, such as product or process. Referring to Edquist (2005, p. 182) "[…] *product innovations are new - or better - material goods as well as new intangible services. Process innovations are new ways of producing goods and services. They may be technological or organisational*". Product innovations mostly characterise market or customer`s needs, whereas process innovations are driven by efficiency in the life cycle of innovation. Utterback & Abernathy (in Faria & Lima (2009, p. 3) concluded that combination of both types product and process innovations will provide more benefits than applying only one of the types. Moreover, it is possible to distinguish between incremental (continuous) and radical (discontinuous) innovations. According to (Tidd & Bessant, 2009, p. 23), an incremental innovation is defined as "*do what we do but better*" and radical can be seen as "*do something different*". This type of innovation is discussed in "creative destruction" of Schumpeter's theory. An incremental innovation takes place in companies more often because it is potentially manageable, "[…] *starting from something we know about and developing improvements in it*" (Tidd & Bessant, 2009, p. 37). By contrast, firms with radical innovations take higher risks than incremental innovations. In order to support such radical innovation, there is a need of strong organisational and managerial capabilities. Lundvall (1992) stressed that innovation takes place at any part of economy and period "[…] *we expect to find on-going processes of learning, searching and exploring, which result in new products, new techniques, new forms of organisation and new markets*" (pp. 9-10). However, innovation can not always be successful, it also may have failures, for some reasons, it can be technical or incorrectly addressed to potential users (Lundvall, 1992, p. 12).

The second element of IS that help to understand innovation processes is knowledge diffusion and creation. The procedure can be explained by two modes of learning as the STI (Science, Technology and Innovation) and the DUI (Doing, Using and Interacting) (Jensen et al., 2007, p. 680). The STI mode describes innovation activities, which take place in firms and use mostly scientifically (analytical) based knowledge. Such activities can be seen in R&D divisions and universities with a focus on radical innovations (Lundvall & Johnson, 1994, p. 27). The DUI innovation mode describes innovation as incremental changes in processes or products. The initiators of changes are employees that faced any particular problems and with all the required competence can bring innovations to firms (Jensen et al., 2007, pp. 683-684). The new knowledge and knowledge exchange can come from R&D by networking and interaction with

different organisations, suppliers and users (Edquist & Johnson, 1997; Lundvall, 2007 in Johnson, 2009, p. 12). In this case, innovation activities can be seen as a collective learning considering firms as central players (Lizuka, 2013, p. 3). The creation of human capital, investment in education and support from government institutions will also accelerate a process of knowledge creation and diffusion (Nelson, 1992, Porter, 1990, Carlsson and Stankiewicz, 1991 in Johnson, 2009, pp. 12-15).

The third element relates to environmental conditions. Innovation does not take place in completely isolated surroundings. The influence of Innovation processes belongs to a supportive environment as well as to a fruitful collaboration between institutions and organisations. The role of institutions is crucial because they have *"[...] a major impact upon how economic agents behave and as well upon the conduct and performance of the system as a whole*" (Lundvall et al. 2002, p. 220). Different researchers also emphasised the role of institutions, for instance, Lundvall mentioned, that the institutional set-up is the second important dimension of the IS. Carlsson & Stankiewicz described that an "[…] *institutional infrastructure involved in the generation, diffusion, and utilisation of technology*" (in Edquist, 1997, p. 25). The other component of IS is organisations, such as firms, universities with a definition of "[…] *formal structure that is consciously created and has an explicit purpose*" (Edquist & Johnson, 1997, pp. 46-47). Institutions and organisations are not the same and play different roles in the innovation process. However, the relationship between them is essential for the economic development. According to Edquist & Johnson (1997, pp. 59-60) organisations are part of an institutional environment, for instance, the legal system of institutions has an influence on organisations, such as banks or financing firms. On the other hand, it is possible, institutions to be a part of organisations, for example, a relationship between employees. Moreover, the connection between institutions and organisations differs from one country to another which leads to different innovation performances.

The fourth element focuses on the role of policies, such as science, technology and innovation, which have an influence towards changes and innovation processes. Innovation policy focuses on building a "framework condition", that have an essential role to "[...] *review and redesign of the linkages between the parts of the system*" (Lundvall & Borras, 2005, p. 611). It is possible to achieve by building environment, where firms know "what is the best for them" and providing equal competencies so that companies can generate, absorb and use technologies. The objective of this policy to have a country's economic growth and international competitiveness. Science policy focuses on "[...] *allocating sufficient resources to science, to*

distribute them wisely between activities, to make sure that resources are used efficiently and contribute to social welfare" (Lundvall & Borras, 2005, p. 605). The main elements are educational institutions, research centres, organisations and allocation of funds. Technology policy contains more the importance of technology itself and the sector in that it should be applied (Lundvall & Borras, 2005, p. 607). The policy emphasises a strong focus on innovations, such as engineering and drugs, which are the source of economic growth. The government role is promoting the development by providing tax reductions.

From Figure 5, it can be seen that IS can exist on various levels, such as global, regional, local, national and clusters of industries (OECD, 1999, p. 23). However, every level has a knowledge base and technological capabilities, which are identified as the main source of high living standards.

3. 1. 1. Concept with roots in the economic theory

In Table 2 below, the history of IS concept will be presented.

Table 2: History of the Innovation System Concept

History of the IS concept	
Name of the researcher	Main outcomes
Classical Works	
Adam Smith (1723-1790)	Identified two different modes of innovation: - Experience-based (employees turn ideas into easier exploitation) - Science-based (employees bring new ideas based on new skills and knowledge)
Friedrich List (1789-1846)	Focused on the wealth importance for nations: - Government investments in infrastructure and training
Karl Marx (1818-1883)	Role of "science as a force of production" and "technical competition": - Joint collaboration of firms - Reduction of costs
Modern Neo-classical Economics	
Alfred Marshall (1842-1924)	Focused on a linkage of innovation to management capability - Innovation may vary across countries
Modern Innovation Theory	
Joseph Schumpeter (1883-1950)	Introduced two approaches of innovation mechanism: - Mark I (creation of "New Firms" by "New Men") - Mark II (big-business capitalism with its oligopolistic completion)
Jacob Schmookler (1917-1967)	Used empirical data to demonstrated the importance of demand-pull: - the greater and stronger the demand is, the stronger and more patentable innovations are
Kline & Rosenberg	Introduced the Chain-Linked Model: - Demand-pull and supply-push contribute to innovation processes - Identification of market needs, research, production, marketing and feedbacks
Christopher Freeman (1921-2010)	Sappho-study: - Interactions spread around all the partners of processes: suppliers, users and customers
Ludvall, Nelson and Freeman	Development of National Innovation Systems

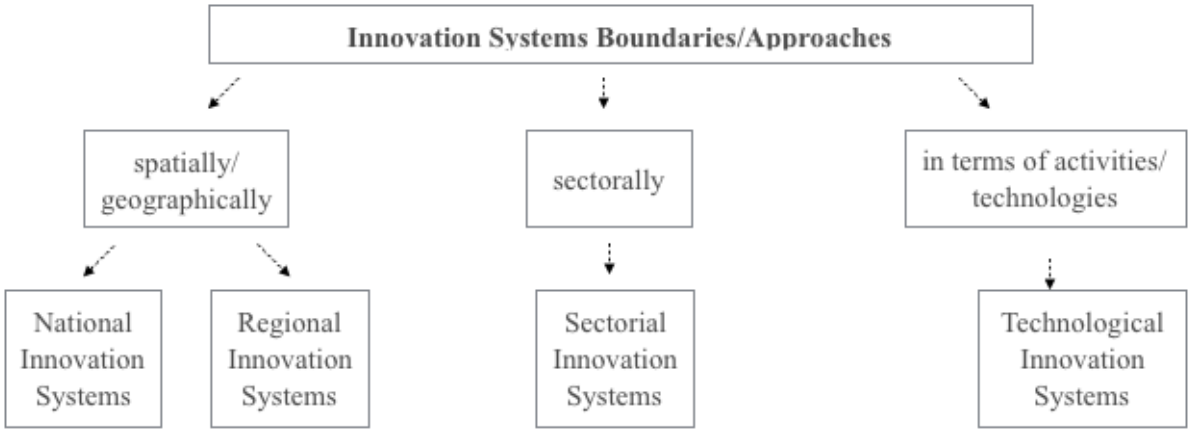
Source 6: Made by the students (2016) based on Lundvall & Johnson (2013, pp. 2-3); Lundvall (2007)

The current understanding of the IS has been influenced by many different researchers in the different period of the economy. In the work of List (1941) the concept of "National System" was already mentioned, where government interactions are necessary for leading economy (Lundvall, 2007, p. 3). However, the significance of interactions, learning processes and the role of demand side were neglected until Schmookler studies (1966). He underpinned the importance of it for stimulation innovation activities (Lundvall, 2007, p. 10 & Lundvall & Johnson, 2013, p. 3). Additionally, Lundvall (1992, 2010) focused on the interactive learning and user-producer interaction. Nelson & Rosenberg (1993) emphasised the role of organisations, which support R&D activities to promote and distribute innovations (in Lundvall, 2007, pp. 10-11).

3. 1. 2. Innovation System's Boundaries

In the last twenty years, the number of different IS have emerged. From one side, it is possible to notice, that these approaches share similarities, but from another side, they concentrate on the various aspects of IS (see Figure 6) (Johnson, 2007, p. 1; Edquist 1997, pp. 198-200).

Figure 5: Innovation Systems Boundaries/Approaches



Source 7: Made by the students based on Edquist (1997, p. 199)

The concept of National System of Innovation (NIS) can be used in various ways. A framework that helps to analyse processes of innovation (radical or incremental), actors and policy makers with a strong focus on learning and modes of innovation (STI and DUI), forms of knowledge and diffusion activities (Lundvall & Johnson, 1994, pp. 25-30). This concept is gaining recognition also among the global organisation, such as OECD and the European Union to study the production and innovation level of countries (Lundvall, 2007, p. 2). The definition of

NIS is "[...] *an open, evolving and complex system that encompasses relationship within and between organizations, institutions and social-economic structures which determine the rate and direction of innovation and competence-building emanating from processes of science-based and experience-based learning*" (Lundvall, 2009, p. 6). However, NIS faces several challenges, such as uneven distribution and access to education and knowledge, consequence, it has influence to country's welfare levels. To transfer the NIS approach from one country to another can not always be successful, because of different country's institutions and characteristics (Lundvall, 2007, pp. 21-30).

The use of Regional System of Innovation (RIS) has been growing rapidly since the middle of the 90s. Cooke (1992) and Braczyk (1998) were one of the first that emphasised the significance of the RIS concept (Cooke, 2001, p. 949). The RIS is defined as "[…] *a set of interacting private and public interests, formal institutions and other organisations that function according to organisational and institutional arrangements and relationships conducive to the generation, use and dissemination of knowledge*" (Doloreux & Parto, 2004, p. 9). To protect competitive advantage of regions, policy strategies should stimulate learning processes locally (Doloreux & Parto, 2004, p. 10). The RIS elements (institutions, universities and public organisations) have a trustful relationship between each other and have common interests. Hence, the learning interaction and innovation is induced. (Cooke 2001, p. 947)

The second innovation approach focuses on Sectorial System of Innovation (SSI), that was developed by Malerba (2002). The main building blocks are the institutions, knowledge, heterogeneous actors and networks. The detailed analysis of SSI will be presented in part 3.2. Sectoral System of Innovation.

The third innovation approach is Technological Innovation System (TIS) that was developed by Carlsson a& Stankiewicz (1991). TIS is defined as the "[…] *dynamic network of agents interacting in a specific economic/industrial area under a particular institutional infrastructure and involved in the generation, diffusion and utilization of technology* " (p. 93).

To conclude, emerged approaches (NIS, RIS, SSI, TIS) are important for the innovation process. They together are perceived as "[…] *focusing devices aiming at analysing and understanding the process of innovation (rather than allocation) where agents interact and learn (rather than engage in rational choice)*" (Lundvall, 2009, pp. 6-7).

3. 1. 3. Interlinkage between National Innovation System and Sectoral Systems of Innovation

It is important to understand that the NIS and SSI are complementary approaches. On one side, the NIS concept has a more holistic view which underpins the importance of key aspects such as "[…] *internal organisations of firms, inter-firm relationships, role of public sector, institutional set up of the financial sector, R&D intensity and R&D organisations* (Chaturvedi, 2007, p. 654). The SSI approach on another side emphasises on heterogeneous actors that have an important role in shaping their own technological and market environment without only waiting passively for market prices signs (Malerba, 2002, p. 2). According to Chaturvedi (2007) the key elements of the both concepts are discussed and presented in Figure 7 bellow.

Figure 6: Key Elements of National and Sectoral System of Innovation

National innovation system*	Sectoral innovation system**
Innovation policies	Knowledge (static and dynamic complementarities)
Research and education policies	Technological domain
Corporate activities Financial system	Actors and networks (organisations; individuals; non firm organisations; group of organisations; larger organisations)
Regulations	Institutions

Source 8:Based on the work of Lundvall (1992); Malerba (2002) in Chaturvedi, 2007, p. 654

In this master thesis, the notion of SSI and its main components are more elaborated in the following paragraphs due to the fact that the main objective is to analyse the pharmaceutical sector in India. Nevertheless, the students make the distinguish that national institutions such as the patent system have different effects on the specific Sectoral system. When discussing institutions in the SSI part, the patent system (national institution) and the changes in the IPR regulations are considered because they are complementary and influence the Sectoral institutions.

3. 2. Sectoral System of Innovation

Sectoral Systems of Innovation and Production (SSI) is a topic that turns to catch attention due to several reasons. The first key element of SSI is the combination of different factors such as learning processes, integration between firms in a specific sector, and knowledge that has an influence towards innovation and production. The second factor stressed that sectors are

different from each other (for example pharmaceutical and software), and it brings different ways for analyses and understanding (Malerba & Mani 2009, pp. 2-3).

Malerba (2005, p. 65) defined a sector as "[...] *a set of activities which are unified by some related product groups for a given or emerging demand and which share some basic knowledge*" A definition of SSI is "[...] *composed of the set of heterogeneous agents carrying out market and non-market interactions for the generation, adoption and use of (new and established) technologies and for the creation, production and use of (new and established) products that pertain to a sector ("sectoral products")"* (Malerba, 1999, p. 4). The boundaries of SSI can be measured by knowledge and technology bases. However, sectoral boundaries are not fixed, and they change over periods as well as sectoral system changes through co-evolutionary processes (Malerba, 1999, p. 5). The co-evolutionary process addresses points of transformation, and it means changes of sector's elements, knowledge, technology, actors, and institutions (Malerba, 2006, p. 396). The shifts of boundaries relate to "[...] *the transformation of knowledge, the evolution and convergence in demand, changes in competition and learning by firms"* (Malerba & Mani, 2009, p. 11).

The current understanding of SSI has a significant difference from industrial economics. According to Barthwal (2000) "[...] *industrial economics is a distinctive branch of economics which deals with the economic problems of firms and industries, and their relationship with society"* (p. 1). Industrial economic literature focuses on the "[...] the transaction cost approach, sunk cost models, game theoretic models of strategic interaction and cooperation," (Malerba, 1999, p. 29). However, these studies did not pay attention to the learning process of knowledge. The remarks were highlighted by Geroski (1998) (in Malerba, 2005, p. 248). The current understanding of SSI relates to an evolutionary theory/economics (Malerba, 1999, p. 29). Evolutionary economics is part of mainstream economics, and it transforms economy (institutions, production and growth) through agent's activities by interacting and sharing experiences). The evolutionary theory plays a major role *"[...] in knowledge, learning, and innovation among sectors and have relates sectoral differences to the technological and knowledge environment and the accumulation of competences by firms*" (Malerba, 1999, p. 2).

3. 2. 1. Building blocks

To analyse deeper, the sectoral performance of firms and competitiveness and how firm's interact and develop, it is important to investigate the building blocks of the Sectorial System

of Innovation (SSI). In the following paragraphs, the importance of Institutions, Knowledge, Heterogeneous Actors, and Networks of SSI will be presented.

3. 3. Institutions

From innovation system literature perspective, institutions are perceived as a key variable that is responsible for the success or failure of innovations (Rohracher et al., 2008, p. 1). notion of institutions has been studied by various researchers, hence, it has received variety of definitions depending on the context it is discussed. North defined institutions as a "[…] *the rules of the game in a society, or, more formally, they are the humanly devised constraints that shape human interaction*" (North, 1990 p. 3). Lundvall (1992) characterised them as "[…] *routines, guiding everyday actions in production, distribution, and consumption, but they may also be guide-posts for change*" (p. 10). Moreover, institutions are defined as informal and formal norms and rules which regulate how people interact (Johnson, 2014, p. 152). On the one hand, informal constraints are rooted in a part of culture, such as sanctions, taboos, customs, traditions, and codes of behaviour. Such institutions do not change immediately, and additionally they make interaction more structured and reduce uncertainty. On the other hand, formal rules are constitutions, laws and property rights, which can stimulate changes in economy (North, 1990, p. 47; North, 1991, p. 97). The combination of formal and informal rules provides incremental changes within every institutions and define those institutions.

According to Edquist & Johnson (1997), institutions are divided into three main categories with subcategories. The first group build on "*formal*" and "*informal*" which were already discussed in the previous paragraph. What is important to underpin is that formal and informal institutions can vary from country to country, from one sector to another. When studying institutions in one country, formal one can be researched easily, because they are more visible and codified; and informal requires observations of behaviour. The second category of institutions relates mostly to the institutional set-up and can be divided into "*basic"* and "*supporting"*. Basic institutions relate to property rights, rules of cooperation and conflict solving, and supporting institutions play a role in a specification of ground rules elements, for instance, working regulations in a certain market. The third group is "*hard*" and "*soft*" institutions, which can be described as "[…] *binding and in some way policed, and ... perceived more as rules of thumb and suggestions than as commands that have to be obeyed*" (Edquist & Johnson, 1997, p. 50).

Institutions regulate a behaviour "[…] *between people and groups of people within as well as between and outside the organisations*" (Edquist & Johnson, 1997, p. 51). Different types of institutions have certain functions. One of the main function is to "[…] "*reduce uncertainty" about the behaviour of other people or by reducing the amount of information needed*" (Edquist & Johnson, 1997, p. 52). For instance, to cope with appropriation, patents law can manage with this uncertainty. However, the knowledge exchange is needed to develop new innovation activities. An institutional function to "manage conflicts and cooperation" is important for specific levels, for example, conflicts between departments (R&D/financing/marketing) in an organisation, that will definitely result in slowing innovation development. Other example of conflict is a restructuration of economy that leads to a change of costs. The institutions can "[…] *effectively redistributes the costs of change and compensates the victims also support fast rates of innovation*" (Edquist & Johnson, 1997, p. 53). Institutions also can provide incentives in order to become a part of learning, that will give opportunities to take part in innovation operations. The incentives can be of various form, for instance, property right to knowledge (IPR), ideas or income taxes. Additionally, institutions can allocate various resources that will stimulate innovation activities, for example, funding or governmental support to R&D activities. Such institutions can also help to "[…] *channel resources to specific areas and in re-channelling them from ailing activities to new ones*" (Edquist & Johnson, 1997, p. 55). However, institutions can also be or even become obstacles to innovation and they can become "[…] *unsuitable to perform functions they previously performed or for which they were originally intended*" (Edquist, 1997, p. 26). According to North (1990) "[…] *Third World countries are poor because the institutional constraints define a set of payoffs to political/economic activity that do not encourage productive activity*" (p. 100). He also outlined that developing countries must first change their informal constraints to support new rules that will lead to a long-run growth of the development.

Institutions do change over time. One of the common force supporting this process refers to technological changes, that have an influence towards institutional barriers, replacement and even creation of new institutions. It is also possible to find reforms, for instance, in property rights, because of conflicts between economy and capital. Moreover, institutions can have influence on national and sectoral levels. In terms of national institutions, for instance, the patent system, property rights or antitrust regulations can have different outcomes depending on the sectoral specifications. However, the national institutions from different countries can behave differently towards the same sectoral area and as a result of it, the sectoral systems will

have different outcomes. The sectoral institutions relate to the specific sectoral characteristics, and it can be labour market or financial institutions. As mentioned above IPR are one of the main institutional concepts that affect the researched pharmaceutical sector. Therefore, a deeper historical and economic perspective will be further presented.

3. 3. 1. Intellectual Property Rights

Globalisation is a well-known phenomenon of the modern society, where the IPR is one of the most essential issue especially, when the economy is transiting to a learning one (Stiglitz, 2008, p. 1695). Living in a fast changing technological environment and short product life cycles has only increased the use and importance of IPR. The purpose of investing and developing new products or services is to capture value by exploiting these innovations (Tidd & Bessant, 2013, p, 59). IPR provide the inventors with exclusive rights that give the opportunity of commercial benefit and financial incentives to support the efforts in developing new products (Saha & Bhattacharya, 2011, p. 1). There are several types of IPR such as: patents, trademarks, copyrights, industrial designs, and confidentiality agreements. These different kinds of protecting the intellectual work of a person/company are industry and geographical context specific (WIPO, 2011, p. 3). For instance, in the pharmaceutical sectors, patents play an important role; whereas the copyrights law, which protect literary and artistic creations are widely used in Europe to protect software products. It is important also to understand that a patent granted in one country (India) or region (European Union) can not be applicable in other countries and regions (Singh, 2004, p. 1).

The concept of IPR is a multidimensional matter based on different ideologies, theories and geographies Shao (2011, p. 731). The theory of natural rights of the social contract is one of these models argued by John Locke (1632–1704). He claimed that the idea of a person is to be protected by the principle of natural law, where governments do not create the IPR, but seen as institutions that protect these "*natural rights*" (Andersen, 2003, p. 420). The utilitarian theorists explain the formation of IPR as suitable tools to stimulate innovation activities, whereas non-utilitarian theorists underpin the importance of the inventor`s moral rights to manage their work (Menell, 1999, p. 129). The early economic models of IPR, were very static due to the fact, that they assumed that inventors carried out research in an isolated environment and work on projects that faces no competition (Mennel, 1999, p. 136). A wave of modern literature, has taken the perspective of IPR being a part of dynamic innovation systems where network externalities play a significant role for the creation of new knowledge (Stiglitz, 2008, p. 1712).

In this fast changing environment, the importance of market and institutions is underpinned due to the fact that they can help customise the IPR laws and regulations through different types of activities such as "[...] *contracting, joint ventures, and hybrid licensing"* (Mennel, 1999, p. 134).

3. 3. 2. Real/personal Property rights versus Intellectual Property Rights

To understand the concept of IPR, there should be also a discussion regarding the difference between the real/personal intellectual rights and why the IPR are so crucial for the innovation process. In the literature real/personal property is seen as mostly a tangible asset that has physical boundaries. Even though that these types of property rights are very different they still follow similar laws. For example, an owner of any form of real or personal property, including intellectual property is entitled to " […] *sell or gift it, dispose of it upon his death by will or trust, or have it taken from him by a bankruptcy court*" (Rosen, 2004, p. 15). The main difference is that they are intangible and in order to be protected, they have to be expressed in a certain manner (Ravindran, 2008, p. 2). It is vital to understand that even though a person poses real/personal/intellectual property right, this fact does not allow the person to do whatever he/she wants due to the fact that we live in a modern society that is based on rules and regulations. When it comes to IPR regimes, companies cannot participate in abusive, anticompetitive activities (Morton & Suppiger, 1942, p. 488).

3. 3. 3. Historical Background of Intellectual Property Rights

The IPR laws and regulations has a long history which dates back to medieval Europe (Saha, & Bhattacharya, 2011, p. 1). One of the most advanced countries in that period was England, which has developed technologically faster than the rest of Europe. In the literature, the British model is widely accepted as a fundament of IPR. It dates back from the 16th century where the English Crown was entitled to grant patents in order to increase the treasury and manage the industries (Lim, 2013, p. 8). In contrast, other scholars discussed the importance of Venice, Italy as the birthplace of IP system where laws and legal system were introduced for the first time in the world and other countries followed (Saha & Bhattacharya, 2011, p. 2). The fact that the problem formulation is based on the context of India, this study paper focus on the British

model. The main role of the IPR is to protect inventor`s knowledge. Therefore, a detailed understanding of this concept will be discussed.

3. 3. 4. Knowledge

Knowledge is "[...] *the most fundamental resource in the modern economy and, accordingly, learning the most important process*" (Lundvall, 2007, p. 17). It is important to underpin that knowledge is a complex commodity which can be protected and transferred from one party to another with the use of intellectual property rights. In the following paragraph, a general discussion regarding knowledge will be first taken into consideration. Later on, there will be an emphasis on knowledge and how IPRs can protect this *impure* public good.

The significant role of knowledge was stressed by scholars of the evolutionary theory and scholars of knowledge-based economy (Malerba, 1999, pp. 7-8). From the evolutionary theory's perspective, it can be stated, that specific knowledge can differs from one sector to another in terms of domains. Dosi (1988), Nelson & Rosenberg (1993) emphasised that one domain relates to "[...] *the specific scientific and technological fields at the base of innovative activities in a sector*" (in Malerba, 1999, p. 8). The theory of knowledge-based economy also had the influence towards knowledge gathering and distribution. The changes that brought this theory relate to "[...] *redefined existing sectoral boundaries, affected relationships among actors, reshaped the innovation process, and modified the links among actors*" (Malerba & Mani, 2009, p. 9).

Nonaka (1994) defined knowledge as "*justified true belief*" or a "*personal belief*" (p. 15). Christensen & Lundvall (2004, pp. 22-23) identified two different contexts of knowledge: (1) what kind of knowledge and how much of this information an agents have and how is possible to process it (macroeconomics standards); (2) see as an asset, meaning that it can be as an input or output in activities, additionally, such knowledge can be owned/bought and sold. Lundvall & Johnson (1994) have divided knowledge into categories as it is useful to notice different mechanisms and channels, where knowledge can take place. Know-what refers to information and basic understanding of facts; know-why important for technological development and refers to "[…] *knowledge about principles and laws of motion in nature, in the human mind and society*" (in Christensen & Lundvall, 2004, p. 34); know-how refers skills and competencies developed through own experience; know-who involves the social skills to communicate with community of different people and experts (creation of a network) (Jensen et al., 2007, p. 682). Nonaka (1994, p. 16) brought the attention to knowledge creation and how

this process can be managed by outlining two different types of knowledge: tacit and explicit. Explicit knowledge is knowledge which is codified and can be found in the written language, e.g. textbooks, manuals while tacit knowledge is knowledge which "[…] *deeply rooted in action, commitment, and involvement in a specific context*" (Polanyj, 1966, p. 4 in Nonaka, 1994, p. 16). Tacit knowledge is an important element of knowledge creation. However, an externalisation and diffusion of knowledge are essential to have a successful knowledge conversion. Knowledge creation processes start between the interaction of tacit and explicit knowledge and spreading on organisational and inter-organisational levels (Nonaka, 1994, p. 20). Knowledge spillovers are an element of knowledge sharing, Singh (2007) concluded that the knowledge flow does not only go in one direction, but an exchange and the use of knowledge goes from one country to other (p. 766). The knowledge flow possible to categorise into two flows: (1) inbound deals with accumulating of external knowledge (customers' feedbacks, publications, training and etc.), that stimulate learning and improves capabilities of employees and organisations; (2) outbound refers to the knowledge sharing by an organisation or selling of knowledge (Vallejo-Alonso et al., 2011, pp. 27-28). Knowledge flows of firms can be linked with a term of absorptive capacity, and it is a skill of giving value to relevant information to assimilate and apply it. The absorptive capacity develops in certain milieus, such as within firms, which conduct their R&D, indirect involvement with manufacturing or with direct investment, such as technical training (Cohen & Levinthal, 1990, pp. 128-129). The knowledge process that contains all the knowledge transfer, sharing and applying refers to knowledge integration, that is "[…] *the process of transferring knowledge, both tacit and explicit, across organisational boundaries, sharing it with individuals and teams at the recipient site, and applying the resultant knowledge to solve problems"*(Haddad & Bozdogan, 2009, p. 12). According to Christensen & Lundvall (2004) "[…] *a striking characteristic of knowledge production resulting in innovation is the fact that knowledge, regarding skills and competencies, is the most important input*" (p. 30).

The knowledge management that takes place at every firm is an important process. Distribution of knowledge is not equal all around the world. Therefore, organisations need to understand how to create knowledge and stay competitive, how to transfer and share that knowledge among different actors through networking activities (Nonaka, 1994, p. 15). Moreover, "[…] *the capability to learn tends to become the most important factor behind the economic success of people, organisations and regions* (Lundvall & Johnson, 1994 in Lundvall, 2007, p. 18).

The dimension of knowledge in SSI can have several measuring elements (Malerba, 1999, pp. 8-12). The first one relates to the degree of accessibility, and it is about how firms can take opportunities to gain external knowledge, which still can be divided into internal or external. The internal accessibility to a sector links with lower appropriability, meaning that competitors can quickly gain that knowledge and as a result have opportunities to imitate it to new products and processes. From the other side, external accessibility focuses on scientific and technological opportunities, for instance, through firms or non-firms organisation (universities or research centers) or human capital with the specific type of knowledge. The external source of knowledge can also be from suppliers or users. However, external knowledge cannot be easily transformed into new artefacts (Malerba, 1999, p. 9). The second dimension relates to cumulative, meaning "[...] *the degree by which the generation of new knowledge builds upon current knowledge*" (Malerba & Mani, 2009, p. 9). There are three sources of cumulativeness: (1) a cognitive and it is about how already familiar knowledge and the learning process can restrict the process of new research, but at the same time it can produce new questions and knowledge; (2) a part of organisational capabilities, that relates to firm-specific and generation of knowledge, which can define future firms learning and achievements; (3) feedbacks from market (it also can be called "success-breeds-success" process. Such innovative success will stimulate company's profit and as a result of additional investments in R&D, that will give possibilities to innovate more often. Studies of cumulative can be analysed from technological, sectoral, firms and local levels.

3. 3. 5. Intellectual Property Rights as an *impure* public good

It is essential to understand the difference between public and private goods. In economics, public goods posses two certain criteria: "*nonrival*" when the use of the good does not affect the fact that somebody else is using this good (the use of parks, streets, traffic lights); and "*nonexclusive*" means that it is not an option to exclude somebody else to consume the good (Ahlersten, 2008, p. 145). Opposite to the public good, the private one is both rival and exclusive. Knowledge in general is perceived as a public good which means that "[...] *the use of it by a certain individual does not actually reduce the amount available to be consumed by another individual*" (Samuelson, 1954, p. 387). Thomas Jefferson defined knowledge as a candle due to the fact that when one candle lights another one it does not affect the light of the the first candle (Stiglitz, 2008, p. 1700). The intellectual property consists of information that

is both nonrival and nonexclusive which are the characteristics of a public good (Boyle, 2003, p. 41). One of the main goals of the IPR law is to promote the creation and diffusion of information regarding new machines, ideas, or other novel characteristics. A conflict arises when the public goods are supplied by private companies and as a result there is a need of incentives to promote the manufacturing of public goods (Barnes, 2011, p. 534). This situation affects the free access of the information, which is restricted for a certain period of time. For the competitive markets to function effectively, there is a need for profit oriented encouragements, that are provided by the IPR rules and regulations. In that way, the production of new information is stimulated and without these incentives, the public will suffer from the lack of new knowledge. The complex nature of intellectual property information can be explained by defining it as an *"impure"* public good which can be "[...] *partially rivalrous, partially excludable, or both*" (Barnes, 2011, p. 534).

It could be concluded that there is a conflict when it comes to the economics of public goods. From one side, when intellectual property information is provided by the market and there is weak exclusive rights, this can reduce the incentives to supply information. From another side the strong exclusive rights could lead to restricted access to the knowledge that is created (Barnes, 2011, p. 563).

3. 3. 6. Monopoly, competition and Intellectual Property Right

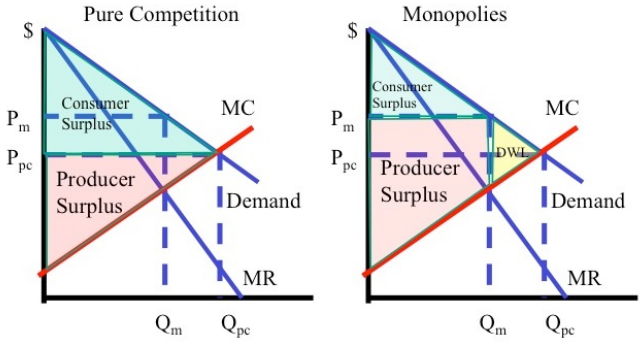
Intellectual property provides exclusive rights to the inventor for his/her intellectual work and is entitled to receive commercial benefits to return the invested time in R&D. These rights create a monopoly on the market for a limited period of time, which means that the holder of IPR restricts the competition and is able to charge higher price than the marginal cost of production (Khor, 2008, p. 1). The monopoly is an economic market structure which is identified by the following characteristics: high barriers of entry; one seller is responsible for the production of goods; profits can be maximised due to the lack of competition (Peacock & Rowley, 1972, p. 227). There are several other reasons why these practical barriers exist and restrict the market besides the Patents and exclusive rights such as: "Economies of scale" when there is only one firm that is able to recover the costs-natural monopoly; "Cost advantage" when one firm only has the access to a cheaper technology); "Strategic limitations" when the monopoly firm has set barriers to enter the market, such as putting too low prices to make it unappealing for competitors to enter; and "Political" when the government is responsible for

giving monopoly rights in a certain industry, in most cases the pharmaceutical sector (Ahlersten, 2008, pp. 89-90).

In contrast, a competitive market is characterised with a large numbers of producers which compete to satisfy the needs of large segments of customers, where the entry of barriers are low. This particular market structure in the economy is known as perfect or pure competition, where the firms are producing homogeneous products (BYUI, 2013). The fact that there is a large number of companies competing in the market, all of them are price-takers and have no market power. In a perfect competition market, all the buyers and sellers are provided with complete perfect information and it is not possible to form any type of a cartel (Ahlersten, 2008, p. 76).

In the following graphs below (8) the two different market structure are presented. The main differences between the two models are characterised by different entry barriers, numbers of company's operation in the market, as well as in the case of monopoly, the company is a price-maker rather than price-taker, which are the characteristics of pure competition. It can be seen from the graphic, that in the case of monopoly, the price is higher and the quantity lower compared to perfect competition. In regards to pure competition, the economic surplus, which equals the consumer plus producer surplus, is optimised. In this particular case the market is efficient and the goods are produced by a price equal to the marginal cost. In contrast to this situation, the monopolistic firm is responsible for restricting the quantity of the production and setting higher prices which leads to both parts of the consumer and the producer surplus to be lost (BYUI, 2013, lesson, 8). In economics, this is known as a deadweight loss which explains why monopoly is an inefficient market and has negative impact on the society (Ahlersten, 2008, p. 93).

Figure 7: Pure Competition vs. Monopolies



Source 9: BYUI (2013)

There are several economic models which, discuss the nature of competitive markets. One of the most recognised models in the economic literature regarding the efficiency of competitive markets and competitive equilibrium is the Arrow-Debreu model (Geanakoplos, 2004, p. 116). However, in a modern and dynamic economy this model is criticised due to the fact that it assumes that technology is a fixed variable and excludes the innovation aspect (Stiglitz, 2008, p. 1705). The theorist who took in consideration innovation was Joseph Schumpeter, who discussed that competition for innovation creates temporary monopolies. He assumed that only companies that have market power can provide the investments needed in regards to innovation. Every monopoly is followed by another where the creation of new firms affects the competitive environment and increase the competitive level (Laino, 2011, p. 1). In the literature, this process is known as Schumpeterian competition. In his work, he highlighted three assumptions: (1) innovations interrupt established relationships in markets through a process of "creative destruction"; (2) technological innovation provides the opportunity for temporary monopoly profit, and this linkage explains the rapid economic growth of the Western economies; and (3) large monopolistic firms are the prime source of technological innovation, because they could support the high costs of technological innovation (Merges, 1988, p. 843). Most of the theorists accepts the first two principles, but most the empirical studies reject the fact that there is interlinkage between market structure and R&D (Kamien & Schwartz, 1982, pp. 49-104; Scherer & Ross, 1990, pp. 614-660).

IPR are in the foundation of monopoly markets. They create a complex situation due to the fact that from one side they aim to stimulate innovation and keep the incentives for companies to create new knowledge, but at the same time they have a negative impact on the society (deadweight loss).

3. 3. 7. Rationale of Patents

There are several types for IPR, but patents are of a high interest to this study paper, because they are the most common, and it means to protect inventions in the pharmaceutical industry. What is of interest about the pharmaceutical industry is that, it is one of the three sectors (chemical and biotechnology), where the patent protection virtually equals the product (Lehman, 2003, p. 7). This particular industry relies heavily on scientific knowledge rather than complex manufacturing and the firm's chances to succeed are based on investments in R&D and clinical trials (Saha & Bhattacharya, 2011, p. 4). The fact that pharmaceutical products can

be easily copied by generic companies with little capital investment, patents are seen as the only effective way to return innovator's efforts on R&D (Lehman, 2003, p. 7).

The notion of patents can be found in the work of the economic philosopher John Locke, which dates back three centuries ago. He discussed that "[…] *just as people own their bodies, they also own the fruits of their labour*" (Haley & Haley, 2011, p. 610) Later on, based on his work, other scholars defined more specifically the term "fruits of labour" which refers to the invention of new technologies.

Nowadays, a patent is seen as a recognition given to the inventor for its work which meet certain criteria such as: "[…] *global novelty, non-obviousness, and industrial application*" (Saha & Bhattacharya, 2011, p. 1). It is important to know general matters such as what can be patent, novelty requirements, the process of patenting as well as the rights and responsibilities applicable in the process.

Patents can be granted for a process or product novelty and provide their owners with protection for their inventions in a certain period which is usually 20 years (WIPO, 2011, p. 5). The main rationalities for patenting an invention is to obtain monopoly over a market to return the inventor`s investment in R&D. To grant a patent companies should disclose enough information so that somebody "[…] *can replicate what is being patented* " (Stiglitz, 2008, p. 1694). Patents are regulated and granted by national patent offices or by regional bodies that are responsible for the rules and regulations of IPR (WIPO, 2011, p. 5). A usual procedure for the inventor is to file an application to the administrative bodies, where an information which include the background and a description of the invention, in proper language (Saha & Bhattacharya, 2011, p. 3).

3. 3. 8. The Role of Intellectual Property Rights in the Innovation System: Stimulate or Stumble Innovation

Everything is changing in this world, that is why creation and changing of institutions, such as regulation of production drugs or IPR laws can "[…] *influence innovating organisations and innovation processes by providing incentives or obstacles to innovation*" (Edquist & Johnson, 1997, p. 191). In the literature, there is an intense debate on the topic if IPR have positive or negative impact on the innovation process. Innovation is one of the main drivers of economic growth discussed by various researchers and policy makers in the recent years and it is protected by IPR regimes (Hudson & Minea, 2013, p. 66). As mentioned before knowledge is a non-rival

and a partially non-excludable good and therefore innovators are not able to completely prevent others from using it. This problem leads to uncertainty and risk developing new innovation and in order to prevent the market from IPR failure are implied (Papageorgiadis & Sharma, 2016, p. 70). Collaboration and sharing of innovations is a crucial for the development of new knowledge. IPR have a direct link with the benefits of knowledge spillovers. They allow the information that was protected to be known for the public and therefore further research can be conducted based on the cumulative knowledge (Mennel, 1999, p. 139). It is estimated that without IPR protection, R&D outlays in the pharmaceutical industry would be significantly reduced which will endanger future patients and the innovation process (Lim, 2013, p. 20).

In the current debate on IPR, a fundamental problem regarding the unevenness between the "*Marginal private*" and "*Social return*" exists (Stiglitz, 2008, p. 1708). In his paper Stiglitz (2008) addressed this issue and argued that by giving a patent to an individual can affect negatively the society because there will be a monopoly on the market. As a result, needed products will be very expensive for consumers and at the end, the innovation has little or even negative impact on the society. The effects of monopoly bring severe distortion of resource allocation and inefficiency (Stiglitz, 2008, p. 1708). The negative effect of patent protection is mostly visible in the pharmaceutical industry, where there is a knowledge and an economic gap between the East and the West. It is important to understand that the global legal environment create and regulate IPR regimes. Litman (1989) and Menell (1994) highlighted the importance of interested policy makers who are crucial for the development of appropriate IPR rules (Mennel,1999, p. 155). A problem arises when politicians do not understand what are the implications of a certain technology protection for the economic and social development in the long run.

There are two important views regarding the design of IPR regimes. Some of the governments (especially in the West) believe that strong IPR protection worldwide will have a positive impact on bringing new innovations to market, whereas others consider this statement as untrue and has argued that the "one model" does not fit all especially when it comes to developing context (Lim, 2013, p. 17). During the 1970s and 1980s various empirical studies were conducted by economic and industrial organisation economists, which aimed to investigate the importance of IPR in relation to technological development (Mennel, 1999, p. 139). The outcome of these studies suggested that the patents are not all the time the appropriate means to return the investment. IPR are not the only incentives for stimulating innovation. There are other ways of financing research through prizes or government and university initiatives. The

prize system is an alternative tool to the patent system, where if an individual/firm meets certain requirements will receive a prize. For instance, the individual who finds a cure for cancer will receive a big prize (Stiglitz, 2008, p. 1719). Other studies such as Qian (2007) aimed to investigate the impact strengthening of pharmaceutical patents on domestic innovation (Jagadeesh & Sasidharan, 2014, p. 193). It was found out that the implementation of patent laws alone cannot stimulate innovation activities. As an extension to that claim, other empirical research observed, that the effect of strong patent rights may complement competition-increasing product market reforms in encouraging innovative activity (Aghion et al., 2015, p. 223). In this case the policy makers were responsible for setting initiatives that can stimulate competition, innovation and economic growth.

3. 4. Heterogeneous Actors

Heterogeneous actors are an important part of the innovation system and are perceived as political, economic, social and educational organisations. According to Edquist & Johnson (1997, pp. 46-47) organisations are defined as follows: "[…] *Organisations are formal structures that are consciously created and have an explicit purpose*. They are players and actors. The behaviour of organisations is also shaped by institutions, meaning that the rules define the way that the game is played". North (1990, p. 5) defined organisations into several groups, for instance, political (city council), economic (firms, cooperatives), social (church) and educational (universities). The key actors in all sectoral systems are firms that are not only involved in the innovation and production process but also in distribution and adoption of new technologies. The firms` characteristics were pointed out from evolutionary view (Nelson & Winter, 1982; Malerba, 1992 in Malerba, 1999, p. 14). The general characteristics of firms are that they can be based on various specialisations as technological, productive or market. According to Edquist & Johnson (1997, p. 58) "[…] *firms are the main vehicles for technological change in that they carry through innovation*". Pavitt (1984, pp. 345-365) analysed technical innovation and defined four categories of firms. A company can be in the supply-dominated sector (clothing, furniture) meaning that they may develop innovation on their own and also from the competitors. Second, there are scale-intensive sectors (food, cement), where they focus on developing the most productive process of technology. The next one is specialised suppliers (engineering, software), it means that firm collaborates with proper customers and based on the feedback working and developing the product to be more efficient and innovative. The last one is science-based producers (chemical industry, biotechnology, and

electronics) that investigate the developing of the product and process in close collaboration with educational institutions (Christensen & Lundvall, 2004, p. 31). According to Edquist & Johnson (1997, p. 58) innovative firms have different roles, for instance, to search for new knowledge, to establish a process of change; to utilise the search results, apply absorptive capacity and utilise unexpected new knowledge. Moreover, from the IS, learning processes that will lead to knowledge accumulation are the essential part of actors' interaction. Agents as firms also include suppliers and users that also have an influence on the innovation process. The studies by von Hippel (1976) have emphasised that almost always the users were part of major and minor innovations (von Hippel, 1976, p. 227) rather than an instrument manufacturer (von Hippel, 1976, p. 212). In this master thesis, there will be an emphasis on the economic organisations in the face of MNEs that operate in the pharmaceutical industry. What is of interest is to understand how these organisations compete and develop their business. Therefore, in the following paragraph, there will be a discussion regarding Business Model concept and its importance for the successful development of companies.

3. 5. Business Models

Since the 'dot com era' of the mid-1990s the concept of business models has gained popularity among practitioners and researchers even though that Business models in general have been known and fundamental for economic behaviour since pre-classical time (Zott et aæ., 2011, p. 1022). A general view on the business model suggest that it is a set of assumptions regarding what type of actions a firm will consider in order to create value for all the actors, not only the customers (Magretta, 2003, p. 44). From a comprehensive quantitative perspective it can be stated that a business model deals with the following matters: "[…] *The revenues the firm expects to make in selling its products and services; the cost of external recourses needed to produce these products and services; the cost of developing and producing these costs (cost of goods sold); the investments needed to keep the business model*" (Grasl 2008, pp. 9-10).

It has been discussed that successful companies which have innovative products and processes lose at certain point their competitive advantage and shares in the market. One of the main issues that affects the mentioned situation above is the inability of firms to modify their business models to the environmental changes (Doz & Kosonen, 2010, p. 370). It is consider that business model innovation will be more essential for the firm's development rather than the product innovation itself. Therefore, it can be observed that in the recent years, more and more firms put efforts in developing strategies that can bring more value to the firm. A good business

plan is needed for both new venture and established large corporations (Magretta, 2002, p. 4). Companies face various external and internal challenges that force them to search and develop new products and process. One of the way to solve such problems is to innovate on the firms` business models. It is very difficult when it comes to change old business model with new and better ones, because in most of the cases organisations are resistant to change. It is also important to emphasize the role of a strong management and organisational culture that will be one of the main drivers for pursuing the implementation of the new business model. Companies that get through the business model transformation and innovation are the ones who break the traditional logic (Gassmann, 2014, p. 2)

The Business model concept attracts the attention of researchers from different fields and it has been used in various disciplines but it is still criticised for having a "vague" and "fuzzy" definition (Fielt, 2013, p. 85). For instance, Linder and Cantrell (2000) defined as the company's core rationale for generating value, whereas Amit and Zott (2001) discussed that "[…] *a business model is the architectural configuration ... designed to exploit business opportunities*" (in Gassmann et al., 2014, pp. 1-2). Chesbrough (2006, p. 63) has also researched the discussed concept and referred to it as "[…] *a useful framework to link ideas and technologies to economic outcomes*". The researcher determined that the business model has two essential functions which are to create and capture value (Chesbrough, 2006, p.108). Fielt (2013) aimed to increase the foundational understanding of the concept and based on his research the following definition of Business Model is given: "[…] *We define a business model as a representation of the value logic of an organization in terms of how it creates and captures customer value*" (Fielt, 2013, p. 85)

All of the definitions above, have a common trait, they all discuss the importance of value creation. It is very essential to understand what the value in the business context means. In general, the value creation process is a complex process that depends on various business activities. It is influenced by different parties such as customers, suppliers, competitors and complementary players. In order to better define value creation, it is advisable to observe a standard business situation which in this case will be the simple principle of the vertical value chain. In business, firms acquire different set of resources: raw materials, knowledge, labour, investments from suppliers to create new products and services, which afterwards are sold to the customers.

Figure 8: Brandenburger & Harborne model of value measurement

Source 10: Brandenburger & Harborne, 1996, p.8

The definition of value creation of the chain depends on two main characteristics- "willingness to pay" of the customer and the "opportunity cost "of the supplier (Brandenburger &Harborne, 1996, p. 7). A basic model for measuring the value can be seen in the following Figure 9. It shows that the value generated by the value chain equals the "willingness to pay" minus the "opportunity cost ". These two characteristics are difficult to define especially into practice. Therefore, most of the companies often perceive the value created as value-added (Müller-Stewens &Lechner, 2005, p. 370 in Grasl, 2008, p. 7) In Figure 10 is shown that value-added is calculated as the net sales of the firm minus its external costs which is also a measurement of the gross margin that a company makes.

Figure 9: Value added

Source 11: Grasl (2008, p. 7)

One of the most common definition of the Business Model is made by Osterwalder (2004). They define it as "[…] *A blueprint of how a company does business. It is a conceptual tool that contains a set of elements and their relationships and allows expressing a company's logic of earning money*". It is a description of the value a company offers to one or several segments of customers and the architecture of the firm and its network of partners for creating, marketing and delivering this value and relationship capital, in order to generate a profitable and sustainable revenue stream (Lindgren, 2010, p. 123). The authors suggested that the business model consists of four main pillars that are presented below (Fielt, 2013, p.93).

Table 3: Pillars and Building Blocks of the Business Model

Pillar	*BM (the nine building blocks)*	*Content and description*
Product	Value proposition	Gives an overall view of a company's bundle of products and services.
Customer interface	Target customer	Describes the segments of customers a company wants to offer value to.
	Distribution channel	Describes the various means the company uses to get in touch with its customers.
	Relationship	Explains the kind of links a company establishes between itself and its different customer segments.
Infrastructure management	Value configuration	Describes the arrangement of activities and resources.
	Core competency	Outlines the competencies necessary to execute the company's BM.
	Partner network	Portrays the network of cooperative agreements with other companies necessary to efficiently offer and commercialise value.
Financial aspects	Cost structure	Sums up the monetary consequences of the means employed in the BM.
	Revenue model	Describes the way a company makes money through a variety of revenue flows.

Source 12: Osterwalder et al. (2004)

The product pillar is central in the business model of every company and represents the different products and services that brings value and meet the needs of the target customers. Customers can benefit from the value propositions that offers "[…] *cost reductions, risk reduction, price and (better) performance* (Osterwalder , 2010, p. 22). The customer interface pillar consists of three blocks, which are as follows: target customers, distribution channels and the relationship that the firm establish with the target customers. It is important to understand that without paying customers, business will not exist (Coes, 2014, p. 20). The value proposition discussed in the first pillar should address and solve the needs of the target customers which are defined as "[…] *different groups of people or organizations a firm aims to reach and serve"* (Osterwalder, 2010, p. 20). Distribution channels are perceived as various communication, sales and distribution strategies, which key objective is to create a good customer awareness about the firm's value proposition. The key role of the relationship block is to determine how customers are linked to the firm, and "[…] *how a company can sell more products or services by improving customer loyalty and finding and introducing new customers*" (Coes, 2014, p. 21). The third pillow proposed by Osterwalder et.al. is the infrastructure management, which includes the value configuration, core competency and partner network building blocks. Value configuration and core competences represent the various key activities and resources that the

firm execute and use in order to make its business model works, for instance, production, problem solving and network activities (Osterwalder & Pigneur, 2010, p. 37). Partner network is an important building block, which is perceived as "[…] *the network of suppliers and partners that make the business model work*" (Osterwalder & Pigneur, 2010, p. 38) Partner network are responsible for complementing the firm's resources in order to co-create the value proposition. Financial aspects ARE the fourth pillar that describes the revenue streams and the cost structure of the company. One of the main goals for a company is to make profit which is to create more revenues than cost (Coes, 2014, p. 22). The objective of the four pillars is to give a better overview of how firms conduct business in order to serve their customers.

It is important to underpin that there is no single method to observe both the static side (such as the product structure) and dynamic side (such as value creation over time) of a business model (Grasl, 2008, p. 6).

3. 5. 1. Business Model vs. Strategy

In the literature, often the concepts of business model and firm`s strategy is considered to be similar. There are though some arguments that the particular notions can be separated and at the same time related to each other. One of the main difference between the two models is in regards to competition. Business models are more related to the firm's structure and how it optimise profits whereas business strategy deals with the fact how the company will address competition and current market situation (Noren, 2013, p. 1).

In the previous paragraph, different definitions of business model were provided. Therefore, the notion of strategy will be shortly discussed. A strategy is often seen as "[…] *a contingent plan of action designed to achieve a particular goal*" (Masanell & Ricart, 2009, p. 1). The concept is also considered as the execution of range of activities whose goal is to create unique and beneficial market position. In their paper, Masanell & Ricart (2009) concluded that a business model is perceived as a reflection of the company's accomplished strategy. Other researchers discussed that "[…] *business model refers to the logic of the firm, the way it operates and how it creates value for its stakeholders whereas strategy refers to the choice of business model through which the firm will compete in the marketplace*" (Teece, 2009, p. 180). As earlier discussed, companies will compete through their business models rather than their products. In order to sustain the competitive advantage which an innovative business model can bring, a firm's strategy should be used as a complementary factor that can help restrict competition. To conclude, strategy and business model are similar concepts but at the same

time there is one distinctive factor. "[…] *Business models explain how the different how the pieces of a business fit together. But they do not factor one critical dimension of performance: competition. Dealing with that reality is strategy's job. A competitive strategy explains how you will do better than your rivals.*" (Magretta, 2002, p.94).

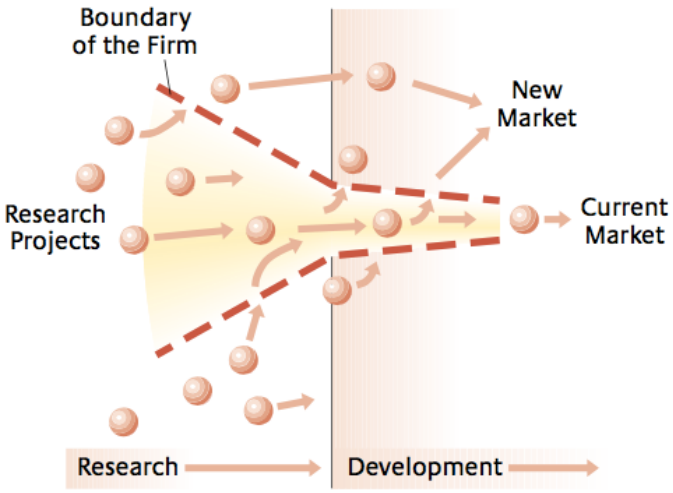
3. 6. Open Innovation

Globalization has changed the way companies conduct business both in domestic and foreign markets. Due to internationalization, the global competition has increased which leads to short product life cycles and fast changing technologies. As a consequence, companies are more conscious regarding investing in innovative projects that can be very risky and cannot return the firm's investments. In order to solve this issue, enterprises are seeking external knowledge that can improve the internal innovation process which is seen as collaboration with external partners (suppliers, customers, universities, etc.) (OECD, 2008, p. 9). In the literature, this concept is known as Open Innovation (OI) and it is discussed by various researchers and policy-makers. The model is seen as one of the main strategies to use knowledge flow across all parties to produce new innovative outcomes. Chesbrough (2003) defined OI as "[…] *a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology*" (Dahlander & Gann, 2010, p. 699). However, the idea behind OI is not a new concept. For instance, Schumpeter (1937, p. 166) already presented the need of applying accumulated knowledge for new products development. The discussions of external opportunities were also introduced by Nelson & Winter (1982, p. 101), where they pointed out the need to search new technologies outside own firms. The importance of another term, such as 'absorptive capacity' helps to capture new opportunities, because it applies to "[…] *the ability of a firm to recognise the value of new external information, assimilate it and apply it to commercial ends*" (Cohen & Levinthal, 1990, p. 128).

Chesbrough et al. (2006) distinguished two separate dimension of OI: (i) inbound/outside-in, that can be described as "[…] *the practice of leveraging the discoveries of others*" (p. 229). It explains how organisation's competences can establish relationship with other firm's competences and have an access to each other knowledge; (ii) outbound/inside-out focuses on "[…] *relying entirely on internal paths to market, companies can look for external organisations with business models that are better suited to commercialise a given technology*" (p. 229). Looking at Figure 11, it can be seen that firms try to apply both ideas, from outside

and inside, the boundaries are marked with a dashed line as it enables innovations to move easier.

Figure 10: Open Innovation Model



Source 13: Chesbrough, 2003, p. 12

According to Chesbrough (2003) companies can reach new values and knowledge by applying five sources: (a) through license-in technologies; (b) establishment of co-development with partners; (c) use innocentive (an online platform to post challenges and connect with specialists) to reach a bigger amount of researchers from all around the world; (d) spin-in or find other special companies that will give an access to particular knowledge; (e) to have an 'open source', that will source external knowledge from customers or practitioners.

Additionally, Dahlander & Gann (2010, pp. 699-701) brought the discussion of OI openness. Organisations cannot innovate in isolation, because any contribution to work with the external environment provides new resources. The role of external actors will "[…] *leverage a firm's investment in internal R&D through expanding opportunities of combinations of previously disconnected silos of knowledge and capabilities*" (Dahlander & Gann, 2010, p. 699). However, the question of openness raises difficulties to protect IPR (Dahlander & Gann, 2010, p. 699). Managing carefully knowledge protection is essential and it can be done through structured collaboration agreements. The role of IPR for biotech and pharmaceutical firms plays an important role because of knowledge ownership, which is crucial to ensure R&D activities and new developments (Hall, 2010, pp. 3-4). As Chesbrough et al. (2003) stated that "[…] *OI is practiced within the context of a given set of political and economic institutions, including*

regulation, intellectual property law, capital markets, and industry structure" (p. 287). According to Wang (2012) and his studies about the impact of OI on NIS came to the conclusion, that "[…] *NIS is likely to be affected when companies change their innovation practices and the way in which they collaborate with external innovation partners*" (p. 426). It can be seen that an interaction between innovating firms with NIS to foster technological effectiveness increases. Applying OI, firms expand knowledge flows and network, have a protectable IPR system and stimulate education and training as well as mobility of skilled employees.

3. 7. Networking

Actors and institutions are connected to each via market and nonmarket relationships. Industrial economics focused on the vertical integration, meaning that it was mainly the processes of exchange, competition, which were the main relationships between the involved parties (Malerba, 1999, pp. 16-17). According to Edquist & Johnson (1997, p. 59) institutions and organisations are "embedded" to each other, meaning that "[…] *organisations are strongly influenced, colored, and shaped by institutions "and institutions are also a part of organisations, which can be seen as "concrete hosts*." However, the evolutionary theory and the IS looked into the diversity of knowledge and potential among agents as well as "[...] *the relevance of trust and the range of informal interactions and relationships among agents*" (Lundvall 1993 & Edquist 1997, Nelson 1995 (in Malerba, 1999, pp. 16-17). The interaction, for instance, between universities and public research centers is a root for innovation processes. Sectoral systems and their relationship will differ from sector to sector, because of the sectoral characteristics, knowledge base and technologies (Edquist & Johnson, 1997, p. 60).

3. 8. Summary of Theoretical Framework

The main objective of the Theoretical Framework (Figure 4) presented in the beginning of this chapter is to be used as a conceptual tool that can explain how changes in the IPR environment in the Indian pharmaceutical industry affect the business models of MNEs. The notion of Innovation System includes the rest of the discussed concepts such as Intellectual Property Rights (IPR), Business Models and Open Innovation. The innovation system represents the interaction between institutions and Heterogeneous Actors and the outcome is perceived as innovation. Institutions are the key actors because they are the "rules of the game" that shapes interactions (North, 1990 p. 3). The Theoretical Framework has focused on the Sectorial System

of Innovation, because the pharmaceutical sector is the investigated context in this master thesis. Nevertheless, the importance of National Innovation System has been taken into consideration, since the government is the one, responsible for the Patent system and setting innovation policies that affect the rest of the innovation sub systems. Crucial innovation policies that affect strongly the pharmaceutical sector are the IPR regulations. These policies aim to consider the complex nature of knowledge which cannot be observed as a "simple commodity" and it needs to be protected through IPR. The concept of IPR is seen as an ambiguous phenomenon, because it rises the dilemma whether it can stimulate innovation activities or only restrict the information flow especially in developing countries` context.

In order to keep up with the IPR policies` reforms and the fast changing business environment, MNEs need to consider new business models that can provide better value to the customer and at the same time sustain the revenue streams. For instance, companies can use different strategies by trying to employ both internal and external pathways to exploit technologies and to acquire knowledge from external sources such as suppliers, customers, universities and etc.

4. CHAPTER ANALYSIS

This chapter is divided into two main parts. *Part 1* aims to analyse the pharmaceutical industry in general, and the global institutions that are responsible for the rules and regulations of Intellectual Property Rights (IPRs) in this particular sector. Moreover, challenges in the sector will be presented as well as how multinational enterprises (MNEs) can solve these matters by implementing new Business Models. *Part 2* focuses on the case of the Indian Pharmaceutical sector. In this part, the notion of National Innovation System (NIS) and Sectorial System of Innovation (SSI) will be applied to the the Indian context. There will be an emphasis on the analysis of Indian Patent Laws, which have changed several times in the past years. Due to these changes, MNEs need to adapt their business models. Therefore, in *Part 2* possible business models which take into consideration the developing country's context will be considered. In the end of Chapter 4 a concluding remark will be presented.

4. 1. The Pharmaceutical Sector in general

Long and healthy lives are one of the few matters that are equally perceived as crucial for everyone regardless of the culture. This is one of the most important sectors where innovation has a substantial impact on the health and wellness of millions of people. The pharmaceuticals are of high interest for both society and economy. The industry is defined as companies that are involved in various activities, such as research and development (R&D), manufacturing and marketing drugs and biologicals (ITA, 2010, p. 1). The market is highly competitive and it is dominated by large multinational corporations (MNEs). In the recent years though, there is an increase in the number of small specialised ventures in the sector. One of the main reasons for having large companies in the sector is the fact that sufficient investments are needed. It is estimated that the average cost of bringing a new drug to the market is more than $800 million Boldrin & Levine (2005, p. 1). Intellectual monopoly has dominated heavily in this sector.

Lehman (2003) discussed that in some industries that are based on technological knowledge, inventors can wait until the last moment before sharing the idea to the market. This automatically gives them maximum patenting time of 20 years. It is different in the pharmaceutical industry due to the fact that the inventions should be revealed in the early stages because of government regulations. The knowledge regarding the new drug should be

communicated between scientists and clinically tested in order to fulfil the safety and efficacy regulations.

The pharmaceutical sector is R&D driven and it is strictly controlled. On the supply side, it can be stated that the sector is dominated mostly by *originator chemical drugs* and *generic drugs* (ITA, 2010, p. 3). *Originator chemical drugs (brand-name drugs)* are based on substantial research and development (R&D) and are clinically tested both on humans and animals in order to be approved by the appropriate institution. The inventors of these drugs relies heavily on patents so that they can return their investments in R&D and be able to continue the development process of new medicines. *Generic drugs (generics)* are characterised as duplicates of the *originator chemical drugs,* which poses the same dosage form, strength, quality and performance characteristics. What differs from the two products is that generics are available in the following situations: after the patent protection given to the original innovator have expired; the patent owner gives the rights to another company, or it is authorised by the United States. Food and Drug Administration (FDA) (FDA 2016, p. 8). On the demand side, the pharmaceutical industry is different from other sectors because the consumer (the patient) is not the one that makes the decision regarding the medicine that he/she needs to take due to the fact that the drugs are prescribed by the doctor (the decision maker). There is also a difference in regards to who is responsible for covering the medicine costs- it is common a national scheme to bear the costs (European Commisison*,* 2008, p. 7).

There is a high tension between generic and originator companies especially, when most of the originators` drugs' patents are about to expire and as a consequence the market can be overwhelmed by generics. This phenomenon is known as the "*patent cliff*" in the pharmaceutical industry and affects significantly all the different parties involved in the market. In order to find a solution to the issue, originator companies have started using strategies such as "*evergreening",* which is defined as "weak" patents strategies that block generics companies from entering the market (Abbott, 2010, p. 3). *Evergreening* is a widespread practice by MNEs which aims to prolong the existing monopoly by slightly modifying an existing drug and seek a new patent (Stanbrook, 2013, p. 939). Problems arise between MNEs and national governments especially in developing countries such as China, India and Brazil due to conflicts of interest. One of the most important things that divides the developed and developing country is not only the imbalance of resources but also the uneven level of knowledge, which is a crucial element for successful development (Stiglitz, 2008, p. 1694). From one side, MNEs pursue IPR protection of modified old drug in order to justify the investments spend on research and

development. From another side, national government in developing countries need to provide cheap medicine to the population which in most cases is under the average standards. In order to solve these issues, the global pharmaceutical industry is regulated by various institutions which will be discussed in the next paragraph.

4. 1. 1. Global Institutions responsible for Intellectual Property Rights

Institutions are the "*rules of the game*" that shape political, economic and social interaction (North, 1991, p. 97). The modern economies are governed by sets of institutions which structure the capital markets (Stiglitz, 2001, p. 202). From a national perspective, each government is responsible for setting national regulations in regards to IPR, but they should be also harmonised with the global authorities in order to prevent a market failure arising from international externalities (Edwin & Lai, 1998, P. 358). The coordination of IPR in a global context dates back from the 19th century which started with the Paris Convention for the Protection of Industrial Property (mostly patent protection) enforced in 1883. Afterwards, the Berne Convention for the Protection of Artistic and Literary Property (copyrights) was created in 1886. These agreements were signed by limited number of countries which were highly interested in IPR regulations. Consequently, the Madrid Agreement (trademarks), Rome Convention (performers, broadcasters, and producers of audio recordings), and the Washington Treaty (protection of computer chip designs) have emerged (Edwin & Lai, 1998, p. 358). In Chapter 5 the most relevant institutions that affect the IPR in the pharmaceutical sector in general and in the Indian context will be discussed.

National Patent Offices

In general, every country with a patent system has its own national patent office, which is responsible for solving patents issues such as setting general standards, resolving disputes over patent infringements, etc. (Lehman, 2003, p. 5). They are governmental bodies whose main duties are to grant or reject patents (European Commission, 2008, p.93). National patent offices provide also other assistance such as spreading awareness of all aspects of intellectual property as well as more specific information regarding IPR (Blackman, 1995, p. 123). Similar to the United States single patent system model, the countries of the European Union has formed the European Patent Office (EPO) which aims to simplify the patent process-one application, one

language, one procedure (Pihlajamaa, 2009, p. 5). India also has its own national patent office which is aligned with the global IPR standards and it will be discussed further in Chapter 4.

The World Intellectual Property Organisation (WIPO)

The World Intellectual Property Organisation (WIPO) was created in 1967 by United Nations (188 member states) and it aims to work for negotiations of global intellectual property treaties (Lehman, 2003, p. 6). The WIPO mission is to "[...] *lead the development of a balanced and effective international intellectual property (IP) system that enables innovation and creativity for the benefit of all*" (WIPO, 2016). It aims to keep the right balance between the interests of innovator companies and the society in order to create a suitable IPR environment where creativity and innovation can prosper.

The main activities of the organisations are to support the negotiations on IPR standards, supervise the effect of its agreements as well as mediate between international and national laws. Important agreements under its government in the late 1990s are the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Even though the organisation is involved in various activities that spread knowledge regarding the IPR standards and regulations, the WIPO could not prevent countries to apply weak IPR rules (Edwin & Lai, 1998, p. 359)

The World Trade Organisation (WTO) and TRIPS Agreement

The World Trade Organisation (WTO) is an institution that aims to liberalise trade by negotiate trade agreements and resolve trade conflicts (WTO, 2015). The organisation was officially formed in 1st January 1995 under the Marrakesh Agreement, which was signed by 123 nations on 15 April 1994, replacing the General Agreement on Tariffs and Trade (GATT) from 1948 (WTO, 2016). One of the most crucial agreement regarding the Intellectual property rights worldwide is the Trade Related Aspects of the Intellectual Property Section agreement (TRIPS) which aims to set minimum thresholds on the IPR regardless the individual members` socio-economic situation (Oguamanam, 2009, p. 137). The TRIPS agreement was signed in 1994 as a part of the Uruguay Round to harmonise intellectual property worldwide (Andersen, 2004, p. 417). It is a social policy tool which aims to stimulate innovation by setting minimum standards for IPR and ensure that these rights do not impede fair trade (Lim, 2013, p. 28). Due to the fact that this master thesis focus on patents, only the legislations in the agreement discussing this matter will be introduced. The *Article 27* of the TRIPS agreement states that "[...] patents should

be granted for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced" (WTO, 2015, p. 331). This *Article* is with a great importance and it is used as one of the main arguments in patent disputes between affected parties (detailed information will be presented in Chapter 5). Under the TRIPS agreement, many of the developing countries were obliged to accept the "product-patent" regimes.

There are some implications when trying to use "one model fits all" approach, especially when there is a big difference between developed and developing countries. Due to the fact that the agreement is based on Western European and North American property law, it does not comply with the needs of developing countries. As a result, some researchers claim that the TRIPS agreement can appoint uneven IPR regimes and can extent the knowledge gap between countries (Stiglitz, 2008, p. 1694). It has been discussed in this study work that even though companies have received IPR, they are not supposed to abuse this monopoly power especially when the society is endangered. Especially, when it comes to the pharmaceutical industry, most of the developing countries have no access to lifesaving drugs due to the fact that the prices of the patented drugs are too high for the general population (Khor, 2008, p. 17). Another factor such as global epidemics of life threatening diseases (1995-2005) increased the concerns how developing countries can access the needed medicine (Park & Jayadev 2011, p. 80). In 2001, the WTO accepted the Doha Declaration which aimed to resolve the implications regarding access to medicine. It provided rights that include "[...]identification of patentability standards that might exclude the patenting of trivial developments and grants for compulsory licenses" (Lim, 2013, p. 32). The *Article 31* (TRIPS agreement) focuses on compulsory licensing discussion. A compulsory licensing is a permission given by a national government to allow third parties to produce a patented product without the approval of the patent holder when drugs are not sufficiently supplied or are not affordable in the country (Ford, 2000, p. 949). This type of licensing has been accepted as an appropriate solution when the patent holder abuse the monopoly power. Several empirical studies (Adelman, 1977; Scherer, 1977, 1980; Tandon, 1982; Kaplow, 1984; Chang, 1995) have observed that compulsory licensing is a needed tool but opposed by the US legislation. The US legislation Article 31 of the TRIPS Agreement is criticised due to its *ambiguous terminology* and the problem of determining a clear economic value of the compulsory license (Ford, 2000, p. 949). Some of the countries which complained

against particular articles of the TRIPS Agreement have entered into several agreements which aim to promote greater IPR standards through free trade agreements (FTAs) (Frankel, 2009, p. 1024). These FTAs are known among concerned parties as TRIPS-plus agreements. The new agreements exceed the standards of minimum IPR threshold which the TRIPS Agreement requires. For instance, TRIPS plus provisions include privileges such as extending the patent period more than the standard time (20 years), or trying to limit the use of compulsory licences or restrain the generic competition. The developed countries (The US and the EU) have proposed several FTAs that are non-negotiable and are "forced" to the developing countries in exchange for other trade deals benefits (Maskus & Reichman, 2005, p. 227). In the literature there is a strong debate whether or not strengthening IPRs can be beneficial for the economic development especially when discussed the context of developing countries such as India.

U.S. Food and Drug Administration (FDA)

One of the most important regulator in the US which has a global influence on the pharmaceutical industry is the U.S. Food and Drug Administration (FDA). The organisation has started its activities in 1906 with the passage of Pure Food and Drugs Act. The FDA is responsible for "[...] *protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices*" (FDA, 2016). The institution controls activities such as testing, approval, manufacturing and marketing of drugs and biologics. The FDA creates different policy regulations regarding safety that has especially enormous impact on the new drugs development (ITA, 2010, p. 6). It is important to understand that in order for a generic drug to receive a marketing approval, it should meet FDA requirements. In the developing countries such as China and India, the FDA has opened offices in order to be able to investigate if rules are followed. In some cases, there is a conflict of interest with the local government which is the case of India that will be further discussed.

4. 1. 2. Challenges in the Pharmaceutical Sector

Pharmaceutical sector is one of the most costly but profitable business accompanied by uncertainties and risks. In order to bring a new drug to market, companies engage in extensive R&D activities, clinical trials, marketing approvals, which are very expensive and require either the company to invest part of the profits or to raise capital throughout the capital markets to cover the costs. IPR in the pharmaceutical industry is one of the most common strategy for a firm to obtain commercial benefits of the R&D efforts invested (Saha & Bhattacharya, 2011,

p. 1). Traditionally, the main goal for a company is to discover new medicine that can treat patients' diseases and at the same time bring substantial amount of revenue. In the pharmaceutical sectors, drugs that brings huge profits (where annual global turnover for that medicine exceeds $1 billion) are known as blockbuster drugs. These drugs play a crucial role in the traditional business model of Big Pharma companies (Denoon & Vollebregt, 2010, p. 687).

However, in the recent years, the pharmaceutical industry has been under endogenous and exogenous pressure. Strong regulatory controls from institutions that aim to improve the affordable access to medicine, restructuring of the global pharmaceutical value chain as well as technological changes have affected and transformed the whole industry (Capo et al., 2014, p. 1). The traditional business model of pharmaceutical firms is challenged by patent expirations of the most profitable drugs, generic threats as well as decrease in R&D productivity (Gilbert et al., 2003, p.1). The biggest wave of patent drug expirations in pharmaceutical history started in the beginning of 2010 and it is known as the "*patent cliff*" phenomenon (DeRuiter, 2012, p. 12). One of the reasons is that a large proportion of the blockbuster drugs were discovered and granted patents in a similar period of time. For instance, blockbuster drugs such as Plavix, Singulair, Diovan and Lipitor were discovered in the early 1990s, with expiration dates between 2011-2015 and another groups of drugs (Rituxan, Humira, Novolog and Avastin) found in the late 1990s will lose exclusive rights between 2014-2019 (Fernández et al., 2012, p. 1393). In 2014 the pharmaceutical sector diminished its revenue with more than $63 billion of annual income due to patent erosion by 2014 (Royal Society of Chemistry, 2009). As a consequence, generic companies can enter freely the market and start producing the off-patent drugs at very cheap costs. The *"patent cliff "* phenomenon affected strongly the whole industry as well as the way Big Pharma companies conduct their business. The lack of new drugs in the firm's pipeline and the inability to reduce R&D expenditures have forced firms to search new methods to improve the company's profitability. Firms need to find more efficient ways to manage the processes activities but at the same time to keep the righteousness of R&D (Capo et al., 2014, p. 1).

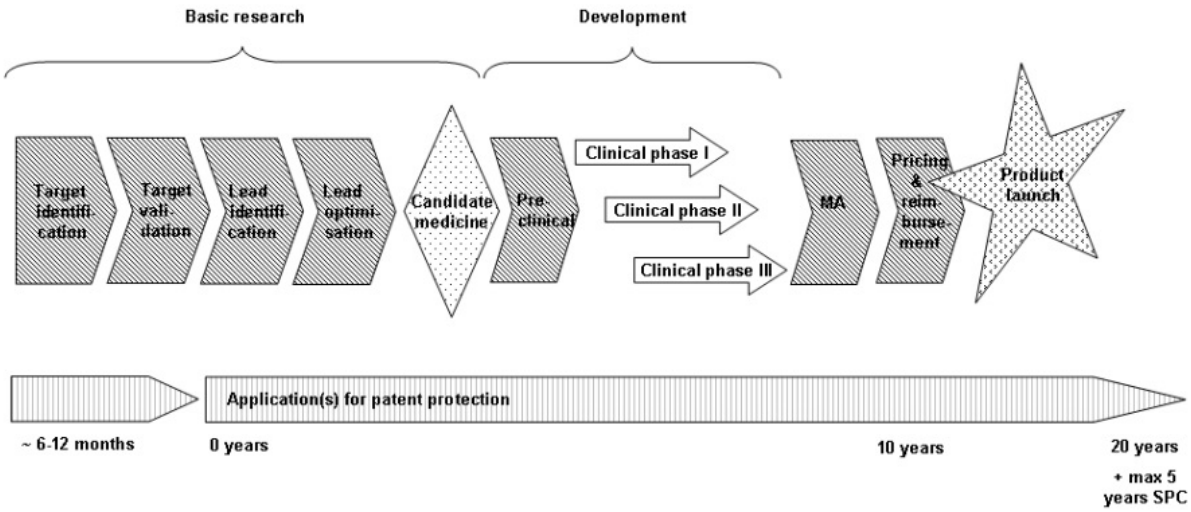
To solve some of the challenges in the industry, large pharmaceutical firms have decided to restructure their supply chains in order to reduce costs and increase productivity. For instance, some of the Big Pharma firms considered to close down some of the manufacturing facilities and reduce the number of employees in order to cut down on costs. With the money saved they could invest in more R&D with the hope to discover the new blockbuster drug. Based on a

study of 14 big pharmaceutical companies, it is estimated researched that between 2009-2015, more than 200,000 jobs have disappeared (Gilbert et al., 2003, p. 1). Litinski (2010) discussed that there is a productivity paradox in the pharmaceutical industry due to the high costs and long development time for marketing a new drug as well as external challenges such as strong regulatory environment and economic pressure (in Syrovatka, 2011, p. 33). All of these challenges lead to losses in the revenue of these large firms. One suggestion to overcome these problems is for firms to innovate the business model. For instance, companies can focus either on specific target customers or focus on development specific types of medicine. In order to reduce the uncertainties and risks related to the development of new drugs, firms can take advantage of partnership networks (PriceWaterhouseCooper, 2009). Gilbert et al. (2003) discussed that companies are advised to outsource capabilities that are not that relevant for supporting the core business (Syrovatka, 2011, p. 33).

4. 1. 3. New Business Models in the Pharmaceutical Industry

In both the developed and the developing countries the matter of solving healthcare problems has caught the attention of policymakers and multinational firms. As stated before, historical business models are not able to solve the new challenges in the pharmaceutical sector, hence, there is a need for new business models that can increase the success rates of developing new drugs and decrease the failures in the field (Hunter, 2011, p. 1817). In order to have better understanding of how new business models have developed in the pharmaceutical sector, the traditional life cycle of a new medicine (Figure 12) will be firstly discussed.

Figure 11: Life Cycle of a New Medicine



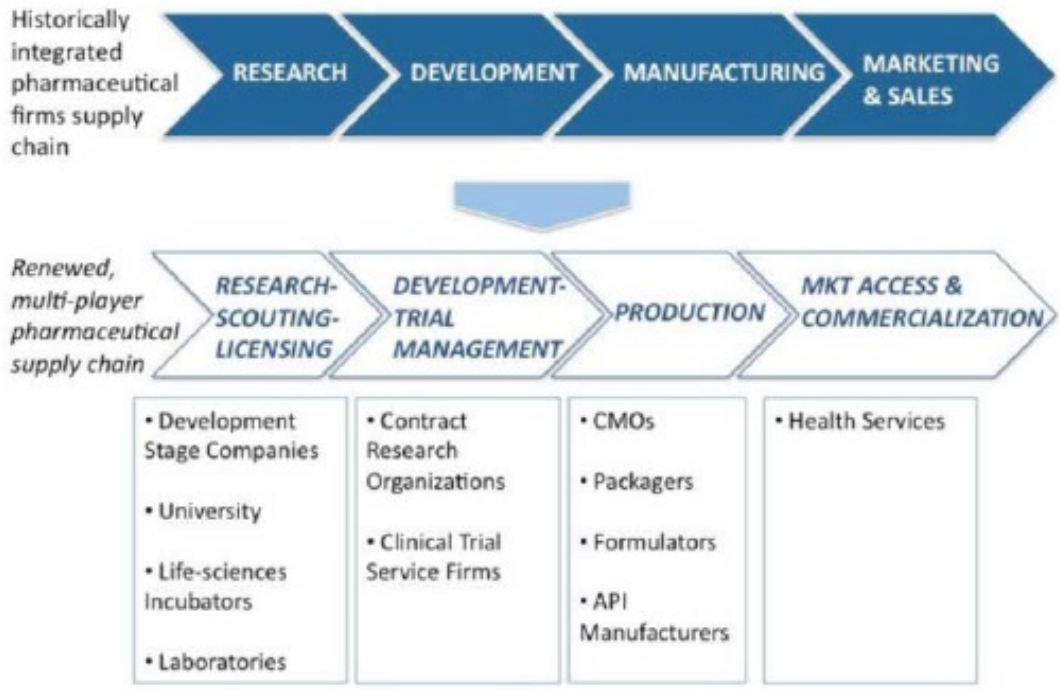
Source 14: Pharmaceutical Sector Inquiry (European Commission,2008,p.51)

The development of a new drug is a long and complex process that needs a substantial amount of investments. It usually takes between 10-12 years to develop a new medicine (Babiarz, 2008, p. 5). The life cycle of a new drug includes three main stages that are showed in the figure above. The first is the period between R&D phase and market launch. During this phase, firms are engaged in identifying new therapeutics which are put through different pre-trials and clinical trials (European Commission, 2008, p.7). The main goal of clinical trials is to ensure that the product is safe and efficacy to humans. As seen from Figure 12, typically three clinical phases are conducted in order to collect the needed information to support the licensing application. The first stage finishes when the new medicine receives a market authorisation. This procedure focuses on securing the safety and quality of new drugs. The second stage of the life cycle of new drug development is the period between launching the product and lasts until the exclusivity rights expire. During this stage, originator companies receive temporary monopoly power (patent rights) which give them the possibility to return the invested money in research and development of the new medicine. The third stage of the life cycle is the period when the patent for the new medicine expires and generic companies are allowed to reproduce copies of it at a low cost (European Commission, 2008, p. 7).

4. 1. 4. Business Models based on Renewed Multi-Player Pharmaceutical Supply Chain

From global perspectives, pharmaceutical firms are engaged in activities related to the different stages of the supply chain. One of the main problems in the sector is that pharmaceutical companies strongly relied on own capabilities aiming to follow the blockbuster business model and kept the whole value chain locked inside the firm. As a result, only few drugs reached the market and firms underutilised their resources. The major disadvantage of the blockbuster model is that it is associated with high risk and uncertainty and developing new medicine can be very costly for the firm (Syrovatka, 2011, p. 8) In order to solve, these issues Big Pharma companies have changed their supply chain by outsourcing activities from the supply chain to third parties. This action has not only reduced the costs associated with the research and development of a new drug but also risks is distributed to the different multi players in the whole global value chain (Capo et al., 2014, p. 2). In Figure 13 below the two value chains are presented.

Figure 12: Traditional and New Supply Chain in the Pharmaceutical Sector



Source 15: Capo et al., 2014, p. 2

To increase the R&D performance, outsourcing strategies are gaining popularity among various firms. Figure 13 underpins the importance of specialized actors needed for the different stages in the renewed multiplayer pharmaceutical supply chain. There are several organisations that can provide research services such as development stage companies, universities, laboratories, life science incubators etc. (Capo et al., 2014, p. 2). As it is seen in Figure 13 the development process of a new drug consists of three clinical phases that can be outsourced to third parties such as contract research organisations and clinical trials firms. Several authors suggested that the complementarity between in-house R&D and external know-how has a positive effect on the efficiency and success rates of developing new drugs (Festel et al., 2010, p. 90). An important factor for a firm is to increase its absorbing capacity in order to be able to integrated the external knowledge to its R&D activities and benefit from the outsourcing strategy. As it was earlier mentioned, companies have closed down manufacturing facilities in order to reduce the costs. Part of the production activities are outsourced to Contract Manufacturing Organisations (CMOs), Active Pharmaceutical Ingredients (API) Manufacturers, Packagers and Formulators. By making this strategic move, firms are able to succeed in increasing the flexibility in production and secure quality and supply while at the same time give the possibility for third parties to sign contracts for collaboration (Capo et al., 2014, p .3). As an overall, the strategy to outsource the production has helped traditional pharmaceutical companies to improve the efficiency of production, reduce the time to market and enhance the productive capacity. The last stage of the traditional supply chain is the marketing and sales phase. Opposite to it, the renewed multiplayer supply chain ends with a paying actor, for instance the national healthcare system or insurance schemes that are able to create value for the patient (customers) by contributing with the access to medical care (Capo et al., 2014, p. 4). Big pharma companies are able to shift the traditional business model towards new business models by outsourcing activities from the different stages of the supply chain to third parties. For instance, it is investigated that usually firms outsource R&D phases to specialised small pharma companies.

Another new business model discussed in the pharmaceutical industry is the Service Model. This model can be divided into several strategies, which target different patient's needs and encourage a partnership of institutions and other pharmaceutical companies.

4. 1. 5. Business Models based on Personalized Drugs

Nowadays, an approach "*one-size-fits-all*" in the pharmaceutical sector does not provide sufficient results, because patients can respond differently to specific treatment plans. That is why need for targeted treatment or personalised drugs has been discussed among pharmaceutical companies (Bayer HealthCare, 2016, p. 28). The development of targeted medicine, which focuses mostly on cancer drugs can be achieved by biomarker diagnostics (biological indicators). This method helps to divide patients into subgroups with similar characteristics and can provide an insurance for positive treatment outcomes with almost no side-effects. According to Bayer "[...] *through personalized medicine, we want to provide each individual patient with the right medication, at the right time and in the optimum dosage"* (p. 29). By doing this, pharmaceutical companies move from *"selling pills to selling outcomes"* (Mattke et al., 2012, p. 8). Other way to work on personalised drugs can be achieved by involving patients, who require drug treatment. Patients will have an opportunity to test drugs effect before having a full treatment payment. This method is called an advanced risk-sharing model that provides a win-win situation for both patients and drug producers. However, personalised drugs can not be an ideal solution for MNEs. Reasons for that could be that patient maybe can not afford to buy drugs with such high prices. And it can work only with patients, who have a "targeted dependency" for this drug. An investment of R&D only for cancer treatment is not always a choice. The reason is that the development of drugs, which can deal with global diseases, such as diabetes, asthma and cardiovascular requires lifelong treatments compare to cancer that in the earlier stage rely on surgery and radiation rather than drugs. On one hand, the question can be raised, that treatments for those diseases are already available by generic companies, however, the efficiency and effectiveness is an open questions. For instance, in the developing economies, patient have a lack of access to medicine or do not follow prescriptions. The growing opportunity for MNEs is not the development of new drugs, but the development of new solutions for global diseases (Mattke et al., 2012, p. 4).

Part II

4. 2. Introduction to India's Pharmaceutical Industry

The demand for development of new drugs raised significantly especially after the unstable situation worldwide (World War I and II). During war times, companies were heavily investing

in resources and time to discover drugs, which will save the population and help to treat diseases. Nowadays, the worldwide pharmaceutical sector is dominated by several MNEs: Pfizer (United States), Roche and Novartis (Switzerland), Bayer (Germany) and Novo Nordisk (Denmark). Over the advancement of the foreign companies with a focus on branded drugs development, the Indian companies were mainly specialised in the production of generic version of branded drugs. The history (see Table 4) of the Indian pharmaceutical production can be divided into three phases (Mani, 2006, p. 8).

Table 4: Indian Pharmaceutical Industry

Phase	Ownership	Patent regime	Nature of drug prices	Import dependence
I (till the early 1970s)	Foreign companies	Product and process patents were recognised	High	High for essential bulk drugs
II (the late 1970s and the 1980s)	Growth of a strong indigenous production sector	Only process patents were recognized under the new patent law	Moderate due to the availability of cheaper alternatives from domestic companies Further the industry	Increased production of bulk drug and formulations has substituted imports. started exporting as well
III (since the 1990s)	Continued growth and consolidation by an indigenous production sector	For most of this, same as phase II. The patent regime made TRIPS compliant since January 1 2005.	Same as Phase II. The National Pharmaceutical Pricing Authority (NPPA) was established to monitor prices of 74 bulk drugs and to revise them periodically.	Net exports as a percent of exports increased from 37.3 in 1990-91 to 90.8 in 2002-03.

Source 16: Mani (2006, p. 8)

The pharmaceutical historical facts states that the sector was changed by several actions, such as different patent regimes (from product to process and having the TRIPS compliant), the position of domestic and foreign companies, market shares and volumes.

The pharmaceutical industry is considered to be one of the most innovative sectors in India with a domination of the United States patents. Indian pharmaceutical sector can be characterised as a combination of "[...] *cheap manufacturing facilities and world-class medicinal chemistry skills*" (Mani, 2006, p. 5). The Indian Patent Act of 1970 until 2004 provided Indian companies with the opportunity to "[...] take new drugs developed abroad, reverse-engineer the manufacturing process and begin churning out generics" (Mani, 2006, p. 10). It is also prevalent in developing countries to have a concentration of generic drugs since the realisation of radical innovation requires high costs of up-front investment. Therefore, applying already tested

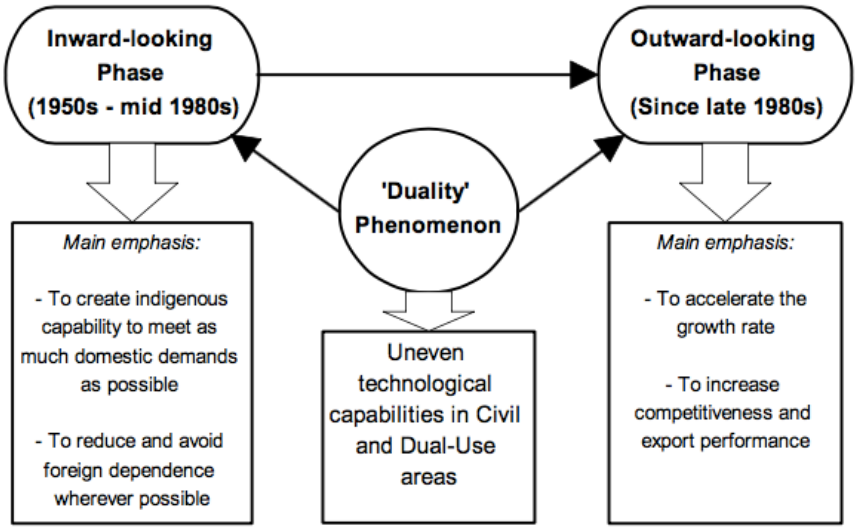
technology processes reduces the high level of uncertainty and unsuccessful diffusion of new drugs. Mani (2006) described generic manufacturers as "[...] *flexible, competitive and fast to capitalise on new opportunities*" (p. 10). Until 1988 India had a negative trade balance between import and export (see appendix 1). Nevertheless, the increase of exporting has started growing significantly, which leads to development of better technological capabilities in the country (Mani, 2006, p. 11). In the period of 2001-2006 Indian biology-based drug development increased to 69%, meaning that the generic production became a part of the pharmaceutical value chain in India. The reasons for that are "[...] *the current institutional and regulatory framework, the growth of the existing knowledge base within the pharmaceutical industry and inter-firm relationships*" (Chaturvedi, 2007, p. 644). As a consequence, Indian pharmaceutical sector has become very competitive to the global pharmaceutical value chain. The significant production of generic drugs represents a worldwide market share of 20% (Bennett, 2014, p. 538; Deloitte, 2014, p. 1). India is ranked as the fourth country for manufacturing of pharmaceutical products which represents 2% of the global market. The gained profit in 2014 was $16.0 billion compared to $8. 2 in 2010 with a growth rate of 18.2 % (Mani, 2006, p. 6; MarketLine, 2015, p. 8) (see Appendix 2). An important reason to be one of the leading manufacturing power in the world relates to the R&D outsourcing and clinical trials performed by MNCs from developed countries. Developed countries prefer to outsource activities to Indian companies because the R&D costs are one-eighth of developed countries (Mani, 2006, p. 35; PWC, 2010, p. 3). An advantage for the Indian pharmaceutical sector is the fact that India is the second largest population of English speakers who have high education. As a result, a developed human capital can perform various research activities needed to create innovation (PWC, 2010, p. 3). However, the lack of MNEs control from developed countries had an influence towards the establishment of own R&D centres, subsidiaries, and the creation of alliances with domestic firms (Mani, 2006, pp. 36-37). There are approximately 46 foreign R&D centres, but specifically pharmaceuticals are only nine (Joseph, 2011, p. 130). Indian pharmaceutical sector is expecting to growth significantly in next years. According to MarketLine (2014, p. 11), the market value forecast will reach $ 33.4 in 2019 with a growth rate of 15.8 % from 2014 (see Appendix 3) and become "[...] *a global leader in the pharmaceutical industry*" (Bennett, 2014, p. 538).

4. 3. Indian Innovation System and National System of Innovation

The Indian Innovation System (IS) is characterised by disproportionate segment's developments and income inequality. Therefore, the Indian government tries to build National Innovation System (NIS), which will not have "[...] *dualistic and lopsided feature in terms of priorities*" (Baskaran & Muchie, 2007, p. 1). The focal points relate to the establishment of science and technology innovation policies, the introduction of organisations and building knowledge and learning linkages between parties as well as diffusion of Indian R&D products abroad.

The Indian IS consists of three main elements: a proactive government policy regime with a focus on IPR, capable research institutions with the specific knowledge base and private firms, which have a potential to invest in innovation activities (Mani, 2006, p. 2). In the past 50 years, India has been through two phases: self-reliance (inward-looking), which already passed and liberalisation (outward-looking), which has the central attention to build NIS with a strong focus on science and technology policies (see Figure 14).

Figure 13: Phases of Indian National Innovation System



Source 17: Baskaran & Muchie (2007, p. 5)

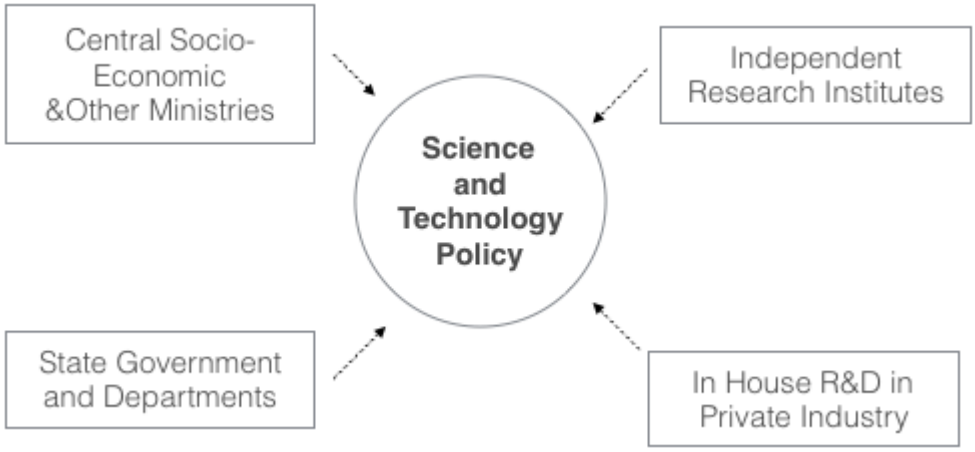
During the period between the 1950s and middle 1980s, India promoted activities to strengthen scientific and technological capabilities to get a higher level of independence from the foreign influence. India did not make a plan to become a leader and compete in different sectors

globally rather the government actions related to the creation of technological abilities to meet domestic demands. The outcomes show that India reached some degree of interdependence and accomplished "[...] *a number of measures such as industrial policy, which clearly defined the roles of private and public sectors, regulation of private investment through industrial licensing, regulation of foreign private investments, and regulation of technology imports to encourage indigenous research and development*" (Baskaran & Muchie, 2007, pp. 4-5). From one side, India increased its technological capabilities, and from another side, the major developments can not be called incremental innovations. Indian primary products development apply imported technology. However, the creation and diffusion of scientific knowledge base were the fundamental elements of Indian policy. Since the late 1980s, Indian government moved actions towards liberalisation, which aimed to stimulate economic growth through FDI flows and establishment of foreign R&D centres in the country. During the years, NIS policies helped to "[...] *create a high level of human resources in terms of qualified and skilled labour and has emerged as one of the major players in the areas of R&D services*" (Baskaran & Muchie, 2007, p. 28). However, Indian NIS still lacks strong relationships and interlinkage between R&D institutions and pharmaceutical companies.

4. 3. 1. National Innovation System's Policies

Indian government applied various policies to foster economic and technology growth. This policy is defined as "[...] the changing context of the scientific enterprise" (Herstatt et al. 2008, p. 22). The role of the Indian government is to strengthen academic infrastructure, provide total autonomy and flexibility to universities and institutions, promote and fund research activities that can lead to innovation. In Figure 15, it can be seen the main institutions and organisations, which have a contribution to the development of Indian Policies. The government contributed with more than 75% of the funding needed for supporting Science and Technology policies (Krishna, 2001, p. 182).

Figure 14: Institutions and Organisation and Indian Policy



Source 18: Made by the students, based on Herstatt (2008, p. 18)

In 1958 the "Scientific Policy Resolutions" was introduced as a main instrument for national development. Another important instrument was the "Technology Policy Statement" in 1983, which tried to involve study science activities for young population and focused on the technological development, because back then developed countries refused to invest and share technological capabilities (Singh, 2014, pp. 143-144). The development of "Science and Technology Policy" in 2003 based on public-private partnership is perceived as one of the main driving forces behind the Indian growth (Herstatt, 2008, p. 18). As a result, networking, transfer and diffusion of know-how knowledge are performed in order to improve Indian product market (Sen, 2003, p. 1).

The latest "Science, Technology and Innovation Policy" from 2013 was utilised to innovation stimulation. Knowledge is considered as a key resource that is need for the creation of national welfare, the development of infrastructure for new talented and bright minds as well as finding cost-effective innovations (Government of India, 2013; Singh, 2014, p. 146).

Indian government has prepared several important plans, which aim to stimulate the development of various sectors which can lead to increase in the country`s economic growth. One of these plans is the "Five-Years Plan" regarding the period 2013-2017 and its objective is to invest 2% of GDP on R&D by strengthening university infrastructure and inducement of R&D partnership between public and private sectors. The policy "Vision Science and Technology 2020" focuses on information technology, for instance, a creation of an online platform for ideas submission, which will increase the number of open innovation activities;

additionally, creation of Indian Innovation Centres and an establishment of science city in every state (Indian Brand Equity Foundation, 2016).

The Indian government focuses on stimulating domestic firms to innovate by investing in R&D and improving the pharmaceutical infrastructure, however, the government role is also to build efficient and comprehensive health care system in the country. The Indian healthcare system is on a lower level compared to developed countries due to that fact that the Indian nations have uneven healthcare access. For instance, in 2014, only 17% of the whole population were insured (Menha, 2014). There are two main health care programs in the country. The first one is the National Rural Health Mission, which is controlled by the Ministry of Health and Family Welfare. The focus is based on improving public health care services and preventive interventions. The second one is the insurance program (Rashtriya Swasthya Bima Yoyana), which led by the Ministry of Labour and Employment (Luthra, 2012). The main responsibility is to provide access to people, who is *"below the poverty line"* and it was 21 % in 2011 (The World Bank, 2016). The Indian government launched a long-term plan to create "Universal Health Coverage" by 2022 as a part of Twelfth Five-year plan. The key goal is to establish health care access for all nation, which could be achieved by providing insurance cover (75 % instead of the current 25%). For the population, who can not afford to have the insurance, the health care system will provide free access through government hospitals and government payments (McKinsey & Company, 2012, p. 21).

4. 3. 2. National System of Innovation - Organisations and Funds

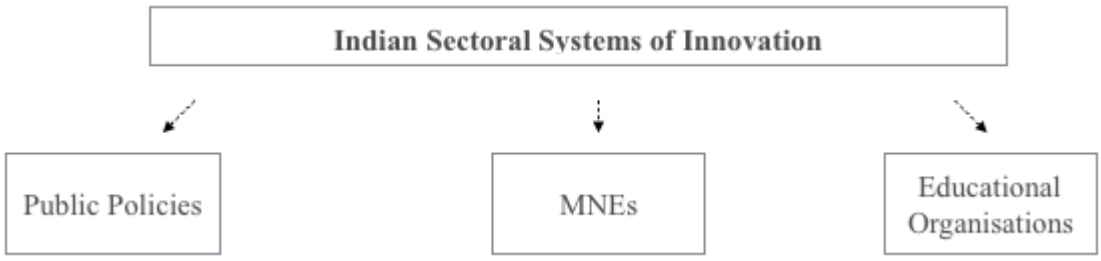
The Indian institutions and organisations have faced different challenges during the past years. Before 2004-2005, Indian sectors lacked specific funding instruments, therefore, R&D expenditure, product/process developments could not be radical. However, the situation has improved as a result of creation of new institutions and organisations that could support the innovation activities. The Pharmaceutical Research and Development Support Fund (PRDSF) was established to provide financial support for R&D project in order to increase the outcomes of this industry. The capital is estimated to be approximately $33 millions. The role of foreign investment is significant and it was changed when the government in 1995 implemented a tax exemption. Additionally, the Indian organisations (The Indian Credit and Investment Corporation of India and Small Industries Development Bank of India) also made a commitment and introduced 11 funds, which can provide the investments for start-up life

science companies with a budget of $400 millions (Chaturvedi, 2007, p. 648). The inducement of the collaboration between R&D, academic institutions and firms is stressed by Science, Technology and Innovation Policy 2013. Therefore, the Technology Development and Demonstration Programme focuses on the support for the creation innovative ideas in various collaborations. Moreover, the department of Biotechnology is an incubator for ideas generation as well as providing grants and loans for co-operations between different organisations (Chakraborty, 2014, pp. 69-71).

4. 4. Indian Sectoral System of Innovation

India is one of the developing countries, which set the pharmaceutical sector as a key industry that can increase the country's welfare. The main plan for the industry consists of several activities such as promotion and funding R&D efficiency, especially with a strong focus on communicable diseases, nutrition, maternity and child health (Chaturvedi, 2007, p. 651). The Indian SSI consists of three main elements (see Figure 16): the public policy support, the manufacturing enterprises primarily in the private sector (MNEs), and Government research institutes (Educational Organisations) (Mani, 2006, pp. 15- 29). Additionally, the pharmaceutical sector involves the interlinkage among variety of actors, such as firms, universities, R&D centres, financial institutions, Patent offices and consumers (Chaturvedi, 2007, p. 645).

Figure 15: Indian Sectoral Systems of Innovation



Source 19: Created by the students based on Mani (2006, p. 15)

4. 4. 1. Public Policy Functions

The public policy support has several key functions that aim to increase the growth of the pharmaceutical sector. One of the main functions is regulated by National Pharmaceuticals Policy 2006 (Department of Chemicals and Petrochemicals) which focuses on the promotion

of innovation by applying various activities to reach the goal. The Fiscal incentives for R&D activities help the actors involved in the pharmaceutical sector. For instance, under the Drug Price Control Order (DPCO), companies can receive price deduction for produced medicine if the firms follow specific requirements and conditions (Deloitte, 2015, p. 20). An example of these conditions are an investment of 3% of the sales on R&D; firm should employ at least 200 qualified employees, have an operation manufacture facility, or have at least 10 applications for patents based on the research that was carried in Indian context. The another policy instrument is an introduction of Pharmaceutical Research and Development Fund with a budget around $ 22 million for operations, that focuses on common diseases in developing countries, like malaria, tuberculosis, AIDS and Hepatitis-B. There is specific type of drug technologies that were previously not commercialised to the market, hence, the role of the Central Drug Research Institute is to identify and support them the entrance of these specific technologies.

The price regulations function mainly focuses on certain drugs or scheduled drugs, that are most essential for the Indian nation. The National Pharmaceutical Pricing Authority is responsible for the control of prices; and in some cases this authority can exempt price control if new or generic drugs are developed in India or manufactured by small production company.

The product and quality regulations function is based on OECD norms and principles. Before putting new produced drugs, it should be applying for Good Clinical Practices in National Compliance Monitoring Authority. The clinical trials of new drugs are regulated under the Schedule Y of the Drugs and Cosmetics Rules and monitored by the Drug Controller General of India (DCGI). If a new drug is developed in India, then a testing should be conducted from phase I also in India. From 2005, the DCGI made restrictions, which clinical trials from phase III could be only permitted in India when this phase will be completed outside India. By doing this, Indian government, stimulate foreign pharmaceutical companies to based their R&D activities in India, if they want make trials in the country (Joseph, 2011, p. 19).

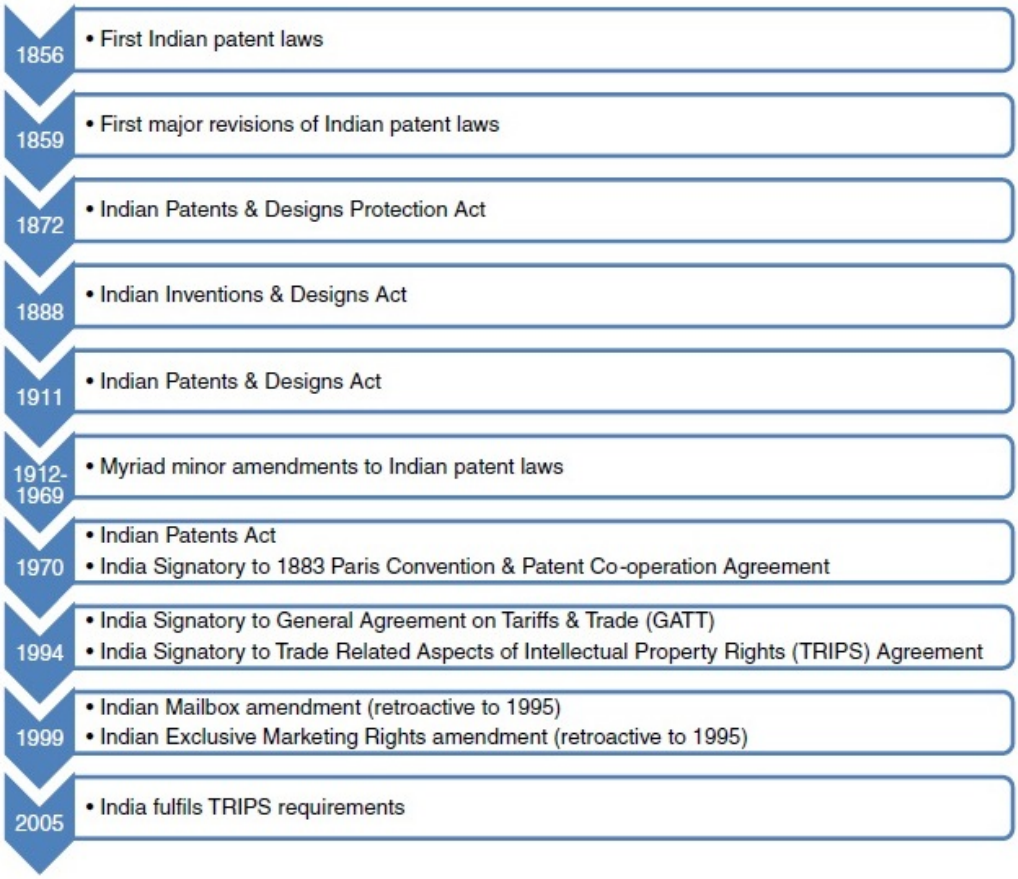
One of the main policy function is the IPR and patent regulations that will be discussed in details in the following sections.

4. 5. Analysis of Indian Patent System

An overview of the IPR changes in the Indian market in regards to patents will be discussed in this section. In order for the reader to have a better understanding and overview of the complex

changes in the Indian Patent Act, Figure 11 from Haley & Haley (2011) research paper will be presented:

Figure 16: IPR changes in regards to patents in India



Source 20: Haley & Haley (2011, p. 610)

The patent rules and regulations in India have reshaped several times in the past 150 years. Indian patent system has a long history which dates back from 1856 based on the British Patent Law of 1852 (Bennett, 2014, p. 539). The British law provided the inventor rights for a period of fourteen years. The first major modifications of the patent law came after three years. In the following years there were several revisions which led to the Patents and Designs Act (1872) and the Inventions and Designs Act of 1888 (Haley & Haley, 2011, p. 609). During that period of time, the country was starting to industrialize fast but its pharmaceutical sector was still in an early development stage. Due to the fact that India, followed the British model, the Indian patent system was affected by the changes in England in 1911. Hence, the existing act from 1888 was replaced with the Indian Patents and Design Act.32. The new legislation put the

foundation of the India's first patent administration system and lasted until 1970. (Bennett, 2014, p. 540).

One of the Acts with high contribution to the pharmaceutical sector in the country is the Patent Act of 1970 due to the fact that it replaced the "product-patent" with a "process-patent" regime. The main difference between the two regimes is that they provide different levels of protection to inventors (IndianEconomy, 2015). It is considered that developing countries prefer "process" patent regime because it provides weak IPR (the patent is granted for a certain manufacturing process, not the product itself which does not affect the production of the same product under other modified process. This change in the institutional set-up affected strongly the development of the pharmaceutical sector in India. The Act was not complied with the the international standard policies on IPR in the developed countries. The "process-patent" regime "[...] *provided seven-year process patents from application time, or five-year process patents from sealing time (the date for the official granting of the patent), whichever was shorter*" (Haley & Haley, 2011, p. 609). During this period, Indian companies were allowed to copy and produce originator drugs which had patents and were protected in the developed countries. As a result, the pharmaceutical market grew significantly based on the manufacturing of generic drugs. From the period between 1970 and 2005, the number of pharmaceutical firms grew from 2257 to over 23,000. By 1999, India was the only developing country in the world close to the state of "self-sufficiency in medicines" accounting for the production of 80% of the needed drugs for society (Park & Jayadev, 2011, p. 80). The Patent Act of 1970 had not only a positive effect from economic point of view but also had strengthened the domestic capacity for scientific and technological knowledge creation and diffusion in the Indian IS (Bennett, 2014, p. 542).

4. 5. 1. TRIPS Agreement and India

The most significant change for the Indian patent legislation is considered to be the signings of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1994 (Haley & Haley, 2011, p. 609). Officially from January, 1st 1995, the countries had to comply with the World Trade Organization (WTO)'s minimum standards for intellectual property protection (TRIPS Agreement). India was required to provide patents for *"[...] any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are able of industrial application*" (TRIPS Art.27.1) (Park & Jayadev, 2011, p. 84). By signing

the contracts, Indian pharmaceutical market was obliged to change from "process-patent regime" which gave the rights to the generic companies to "[...] freely produce medicines created by foreign drug companies at a fraction of the cost" to a "product-patent regime" (Gabble & Kohler, 2014, p. 2) The duration time of the both regimes is significantly different, the process regime provided only 7 years protection on the product while the new product regime under the TRIPS Agreement gave 20 years. This factor influenced strongly the sector by letting foreign MNEs to return again to the Indian pharmaceutical industry. The new product patent regime was very different from the current one, hence, India received a ten years-transition period (until January, 1st, 2005) to implement all the needed changes in order to comply with the TRIPS Agreement (Park & Jayadev, 2011, p. 84). During the transition period, the country was obliged to create a "mailbox" which in the Indian legislation is known as the Indian Mailbox amendment (1999). This Act gave the opportunity to companies to submit product patent applications for pharmaceuticals with a backdate from 1994. These applications were about to be examined in 2005 when the new "product-patent" regime would start (Bennett, 2014, p. 543). Another legislation that occurred in 1999 was the Exclusive Marketing Rights (EMR) system for products created after January 1, 1995. It gave the companies exclusive rights to market the products in the Indian market for a period of 5 years or until the firm was granted or rejected a patent (Haley & Haley, 2011, p. 609).

During the transition period (1995-2005) a number of issues arose in regards to patent protection and how it affects the access to lifesaving medicine. Events such as the AIDS explosion in Africa and the gap standards between developed and developing countries started the global access to medicine movement (Park & Jayadev, 2011, p. 80). The TRIPS Agreement was strongly criticized that it did not take into consideration the "[...] *country's socio-economic, developmental, technological, and public interest needs*" (Gabble & Kohler, 2014, p. 2). Therefore, the WTO member countries decided to solve this problem by providing certain flexibilities for the developing countries in the agreement known as the Doha Declaration. Several parties (The US) considered the inadequacy of The Doha Solution and how it can endanger the "credibility" of IPR in the pharmaceutical sector in developing countries (Sykes, 2002, p. 63). India took an advantage of the Doha Declaration by strengthening the patentability requirements as well as they used the compulsory licensing in 2012. These particular events will be further discussed.

The last change in the Indian Patent Act was in 2005, when India fulfilled the requirements of the TRIPS Agreement by providing full protection for the period of 20 years to pharmaceutical

products (Haley & Haley, 2011, p. 609). Patents (Amendment) Act 2005 ended the period of 36 years, in which Indian pharmaceuticals were allowed to copy brand drugs. Under the new "product patent" regime Indian companies were obliged to pay the originator drug patent holder a "reasonable" royalty for copies sold in the domestic market after January,1995. It was legal to produce only two types of generic products: "[...] off-patent generic drugs and generic versions of drugs patented before 1995" (Greene, 2007, p. 7).

In order to comply with the world minimum IPR standards in the pharmaceutical industry, India signed the WTO`s TRIPS Agreement. As it could be seen from Figure 17 the Indian Patent Act has been modified several times due to changes in the institutional set-up. Currently, the country is under "product-patent" regime which grants patents to products that are "new chemical entities" for the period of 20 years (Haley & Haley, 2011, p. 609). The new regime brought the discussion on how the patent products will affect the domestic drug prices and if the Indian population will be able to have affordable access to medicine. All of these concerns were taken into consideration by the Indian government and therefore a modification in the Indian patent legislation was made which was in consent with the TRIPS Agreements. This change is known as Section 3(d) and it aimed to restrict the "*evergreening*" practice of MNEs and the possibility to patent variants of existing products that do not reveal enhanced effectiveness (Lim, 2013, p. 41). For a better understanding a statement of the section is provided below.

Section 3(d) of the Patents (Amendment) Act 2005 states:

"[...] [T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. —For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy" (Bennett, 2014, p. 545)

This legislation has created a conflict between the Indian government and the foreign MNEs as well as some of the global pharmaceutical institutions. Even though the section has a humanitarian aspect to provide affordable drugs, it also concerns the future business environment in the country. The Indian government was criticised to set too high barriers for patent protection in the pharmaceutical sector and not creating enough incentives for policies

that aimed to support continued R&D of new drugs (Lim, 2013, p. 41). It is important to underpin that India and the developed countries (the US and the European Western countries) have different perspective in regards to patentability standards. From developed countries` perspective, patents are given to new uses, new combinations and forms of known of existing drugs, providing incentives for both incremental and radical innovations. In this context, MNEs are able to maintain existing monopolies in order to maximise profits that are needed to return the R&D expenditures. By doing so, they restrict the generics out of the market which in a developing countries rises problems with the access to lifesaving medicine. Therefore, the Indian government decided to limit the patents to known medicine and give IPR only to radical innovationsıo Even though *Section 3(d)* is strongly criticised by foreign MNEs that it is against the TRIPS requirements, *Article 27* of the agreement enabled India to devise its own patent legislation. The country could interpret the article in favour of its domestic interest. The *Article 27* argues that "[...] *Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*." (Bennett, 2014, p. 549). This statement is opened for interpretation and it allowed India to strengthen its patent law by creating Section 3(d). For a better understanding of the conflict between foreign MNEs and India in regards to this particular section will be further presented in Chapter 5.

4. 5. 2. New Indian National IPR policy (2016)

As discussed above the IPR rules and regulations in the Indian context have changed several times and have been influenced by both exogenous and endogenous institutions. In order to promote innovation as well as to improve access to healthcare, secured food sector and environmental preservation, the government has approved a new IPR Policy (BRIC Wall, 2016). On May, 13th, 2016 the policy was released and has a main purpose to popularise the IPR as a financial asset that can be marketed. The finance minister of India, Arun Jaitley discussed that the National IPRs Policy will continue permitting the compulsory licensing with limitations to public epidemics which comply with the WTO's requirements. The policy underpinned that India has met the global IPR requirements of the TRIPS Agreement but at the same time, it utilised the flexibilities in the legislation in order to solve domestic problems (NDTV, 2016). The New Indian IPR Policy consists of seven main objectives (Government of India, 2016). One of the main objectives of the new policy is to enlighten the economic, social and cultural advantages of IPRs and how they can bring value to the public and private sector. The policy also aims to improve and increase the human resources as well as to improve

institutions` capacities for teaching, training, research and building skills in IPR environment (Government of India, 2016). It can be concluded that the new Indian IPR policy (2016) complement the already discussed Science, Technology and Innovation Policy 2013, which is beneficial for strengthening the Indian pharmaceutical industry.

4. 5. 3. Institutions responsible for IPRs in the Indian pharmaceutical sector

In this paragraph there will be focus on the institutions that directly or indirectly affect the IPRs in the Indian context. In the previous sections, the important role of the World Trade Organization's TRIPS agreement was discussed. The agreement aimed to standardise and set minimum requirements for IPRs on a global scale, hence, the Indian government had to change its Patent Act in order to comply with the international requirements. As a consequence, in 2005 the country moved from a "*process-patent*" to a "*product-patent*" regime a significant influence on the Indian pharmaceutical sector.

Another institutional entity that affects and regulates directly the IPRs is the Indian Patent Office. The patent office in India is governed by the Controller General of Patents, Designs, Trademarks and Geographical Indications (CGPDTM) which is controlled by the Ministry of Commerce and Industry (IPIndia, 2016). A detailed organisational structure can be found in the Appendix of the thesis.

There are four Patent Offices in India, which are located in Kolkata (Main Office), Mumbai, Chennai and Delhi. The Office of the CGPDTM is located in Mumbai (BRIC Wall,2016). The main activity of the patent office is the examination procedure that decides whether a patent should be granted or not. Professional examiners are considered to be an important part of the patent office procedure and they are obliged to meet certain requirements. Therefore, the Department of Industrial Policy & Promotion (DIPP) has initiated special one year training programme for newly recruited examiners in order to the ensure quality, equality and consistency in the examination and grant of patents (BRIC Wall,2016). During the past decade, India invested more than US $ 100.000 in order to modernise and create an IT system that enabled the process of IP applications (WIPO, 2016). From July, 20th, 2007 it is possible to submit the IP application online. As a consequence, the number of yearly patent application raised from 4017 (2004-2005) to 6402 (2007-2008) (CGPDTM, 2011, p. 7). The digitalization of the application system saves time of the actual application, reduces administration costs as

well as improves the security of the IP applications. Not only is the IT system a useful tool for the inventors that fill applications in order to receive a patent, but also it ease the examiners` work who have better overview of all the patent applications and can perform their job more efficiently.

From Figure 18 it can be seen that there is a growth in filing patent applications in the period of 2009-2012. The Indian patent office had experienced marginal decrease of 1.65% in 2014 when 42 951 patent applications were received. From the numbers it could be stated that only a small number of the patent applications are examined. That fact brings some issues regarding how effectively the examiners in India conduct their job. In order to solve the issue, the CGPDTM has hired more than 164 additional examiners over the past few years (Media 2015). Another important information that the figure provides is that patent granted had almost doubly decreased from 7 509 (2010-11) to only 4 227 (2013-14).

Figure 17: Trends in Patent Applications

Year	2009-10	2010-2011	2011-12	2012-13	2013-14
Filed	34,287	39,400	43,197	43,674	42,951
Examined	6,069	11,208	11,031	12,268	18,615
Granted	6,168	7,509	4,381	4,126	4,227
Disposal of requests for examination (granted+ refused+ abandoned)	11,339	12,851	8,488	9,027	11,411

Source 21: Controller General of Patents, Designs, Trademarks and Geographical Indications, India (CGPDTM)Annual report 2013-14, p.5 in Indian Government, 2014-2015

As mentioned in the beginning of this chapter, FDA is responsible for regulation and authorization of new drugs, clinical trials, marketing approvals of generic drugs and other activities that concerns the public health (FDA, 2016). One of the main reason why Indian pharmaceutical sector has attracted many foreign MNEs is due to the large number of U.S. FDA-approved factories located in India (Greene, 2007, p. 12). It is important also to note that in the last 10 years, Indian companies have moved upwards the global value chain and today they account for more than 40% of the sold generics by volume in the US pharma market (Nasdaq, 2016). In order for a generic drug to be sold in the US, it should first receive an FDA-approval. It is a crucial factor for India to comply with the FDA rules and regulations in order to sustain the market shares in the global pharmaceutical sector. In the last few years, there have

been arising conflicts between the FDA and some of the biggest MNEs. Some of the Indian firms were failing to ensure that after FDA-approvals, the drugs still meet the needed requirements (STAT, 2016). Therefore, the FDA decided to increase almost double the inspectors in 2015 (from 9 to 19) in order to secure that generics produced in India are safe and meet all the necessary criteria in order to enter the US market (RAPS, 2015). An equivalent institution to the FDA in India is the Central Drugs Standard Control Organization (CDSCO). Its main functions are to regulate the control over the import of drugs, approve new drugs and clinical trials and licensing activities. The CDSCO is responsible also for the coordination of the activities of State Drug Control Organizations. The institution governs six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories (Indian Government, 2014-2015). Both of the FDA and the CDSCO are based on countries` Drugs and Cosmetics Act but it is suggested that the FDA has stricter norms than those in the Indian context (Tiwari et al. 2011, p. 2).

4. 6. MNEs

Another element of SSI is the manufacturing enterprises or MNEs, which characterise what types of companies mainly operate in India. The Indian Pharmaceutical sector is dominated primarily by domestic private firms, such Sun Pharma, Natco, Cipla, Randoxy Laboratories and Dr. Reddy's (InvestIndia, 2012). The conditions of the sector were changed when two public enterprises the Indian Drugs and Pharmaceuticals (IDPL) and Hindustan Antibiotics (HAL) took the role and initiative to support and subsidise companies as local as foreign. These endowments gave a potential for the market growth, for instance, it can be seen in increased number of production and distribution; the inducement of innovations and the cause of industrial development (Mani, 2006, p. 26).

The pharmaceutical market can be characterised as fragmented into various medical treatment segments. Pharmaceutical companies enter into alliances with knowledge institutions and private laboratories to work on new treatment against diseases. The close collaboration links to a revenue generation, the welfare improvements and the development of economic situation. Both organisations can benefit from each other, for instance, pharmaceutical firms require testing applications, that can be managed by specific universities; and universities demand investments to generate knowledge creation, diffusion, and utilisation. The role of open innovation can take place, as it leads to improvements in development processes and knowledge networking (Chaturvedi, 2007, pp. 652-654). In the 2000s the number of merged and

acquisitions has been increased. During only one year it was made 18 international emerges in 2005 (Mani, 2006, p. 27). There are a number of reasons for such actions: entering and creating a new market, providing a diversity of products, gaining of assets (R&D centres and manufacturing locations) that will lead to bigger market shares.

The Indian patent regime provided an impulse for the development manufacturing processes and indicators for the innovation potential. The private and public R&D expenditures have significant differences. The private sector has over 85% of it, and public expenditures were dropped when two enterprises, HAL and IDPL had been financially distressed by other companies (Mani, 2006, p. 30). During 2001-2005, the leading pharmaceutical companies, such as Sun Pharma and Cipla significantly increased their R&D expenditure by reacting to TRIPS innovation regime. However, the gap between Indian and MNCs from developed countries is still visible (2% versus 18.5% in 2001). The number of pharmaceutical patents (2000-2004) report for over 20 % of Indian companies. It can be concluded, that TRIPS compliance had made companies to innovative and applied for patents more often (Mani, 2006, p. 32).

4. 7. Educational Organisations

The other element of SSI is Government Research Institutes (GRIs) or educational organisations, which have the number of nearly two-thirds contributions by the pharmaceutical industry. The main characteristics of GRIs are that it has own development infrastructure for drugs and 20 different laboratories that capture R&D activities (Mani, 2009, p. 29). By applying Science, Technology and Innovation Policy 2013 to pharmaceutical sector a contract research organisations (CROs) was funded by GRIs and it played a contribution role for stimulating collaborations between institutions and research departments (Chaturvedi, 2007, p. 646). This organisation gives opportunities to contract manufacturing and clinical research tie-ups. Additionally, CROs stimulates knowledge integration and exchange (Chaturvedi, 2007, p. 652). The collaboration activities mainly focus on developing challenging products, such as the vaccine against Hepatitis B, C, and cancer (Rajan, 2012, p. 134). An “in-house contractor” provide opportunities for MNEs from developed countries to test or build drug products based on Indian specifications (Herstatt, 2008, p. 12).

4. 8. Challenges of the Indian Innovation System

The Indian Innovation System (NIS and SSI) face several types of challenges, which have the influence on creation and diffusion of innovation. As a result, it affects the growth of the

pharmaceutical sector. According to Chaturvedi (2007) "[...] *the lack of sufficient coordination between national and Sectoral policies may lead to wastage of resources and loss of potential*" (p. 655). The central problems relate to the innovation development process (Baskaran & Muchie, 2007, p. 23).

There are several barriers when it comes to creation of innovation such as lack of screening, support from government and bureaucratic hurdles, which lead to delays and corrupt practices (Herstatt, 2008, p. 47; Chakraborty, 2014, p. 72). The innovation activities in the Indian context have not shown significant improvements because Indian SSI actors have insufficient knowledge capabilities to develop new drugs. Hence, Indian Innovation Policies should aim to solve this challenge (Mani, 2006, p. 39). The number of scientists and engineers, who are involved in R&D, is still not enough, because of imbalanced growth in different regions of India, which have an effect on the educational system (Chakraborty, 2014, p. 72). There is still a weak link between the R&D institutions and university which affect the performance of the Indian innovation system. The main reasons are the lack of in-house R&D, absorptive capacities, communication and approaches for costs savings (Baskaran & Muchie, 2007, p. 25). However, Indian private sector shows better enthusiasm for active and open business collaborations (Herstatt, 2008, p. 42). Another challenge that influences manufacturing operations relates to logistical infrastructure and lack of control. According to Herstatt (2008) India should focus on "[...] *the process of turning from a low-cost provider of routine, standardized tasks into a high-tech centre of qualified research and development work has been slow but steady and impressive, nonetheless"* (p. 47).

4. 9. MNEs Business Models in the developing countries

The collaboration between Indian pharmaceutical companies and MNEs from developed countries can improve the innovative environment, where "[...] *the foreign technology and capital have been viewed favourably in accelerating the process of competence building*" (Joseph, 2011, p. 14). In this study work, there will be focus on the four most common business models that MNEs apply in India.

The first business model is contract research and manufacturing services (CRAMS). The main activities contain "[...] *manufacturing of active pharmaceutical ingredients and formulations; chemistry and biology research for new drug compounds; preclinical trials; and clinical trials*"

(Joseph, 2011, pp. 14-15). The statistical characteristics showed that this type of business model has a growing tendency compared to the global market. In general, research contracts are made for a fixed period and focus on the therapeutical area of the investigation. A benefit for the Indian companies is an opportunity to increase the stability of their financial situation. Jubilant Organosis (Indian research company) earned $200 million in five years of contracting. However, Indian companies are not able to gain special knowledge of drug developments, because they do not have access to the whole process. As a consequence, they can not earn any future income accruing to developed products. Additionally, the technology transfer does not take place in the firm`s R&D centre, hence, it does not improve company's competencies. Clinical trial companies are responsible for administrative work, for instance: building teams from recruited researchers, finding possible suppliers, collecting data and coordinating clinical protocols (Joseph, 2011, pp. 16-21).

The second business model is collaborative research projects (CRPs). The main differences from CRAMS are that CRPs focus on selected therapeutic areas and have the joint partnership between Indian companies and MNEs. Both companies concentrate on discovering drug molecules and developing them which leads to shared risk management According to Joseph (2011, p. 22), drug's compounds are still owned by MNEs. Nevertheless, Indian companies can not receive a full income revenue, but only a fraction. However, gained experience and knowledge from this business models are higher than in the first one.

The third business model is in-licensing. It can be achieved in two ways. One of them is an acquisition of other pharmaceutical company. MNEs can benefit from a monopoly power which will restrict the competitors in the drug market. Another opportunity is licensing big pharma's products to firms, which can develop treatments on lower costs. However, relying on outsourced companies is a risk for MNEs, because they can start producing a "subgroup of targeted treatments" and decrease market sales.

The fourth business model is out-licensing, which is mostly used by the Indian pharmaceutical firms. The domestic companies develop the molecule by themselves to a certain stage and then they tried to have a partnership with MNEs, which focus on drug development on the advanced stages. According to Joseph (2011, p. 23), it is a beneficial collaboration for both partners, because on one hand Indian firms increase "[...] *the scarcity of resources in finance and research skills and on the other it gives the MNEs access to promising compounds at lower prices*".

4. 10. Summary of the chapter

In part I, the global pharmaceutical sector and global institutions were discussed. It was found out that the sector faces several challenges such as fast changing environment, patent expirations, not enough new product in the firm's` pipelines as well as stricter IPR regulations. What is of interest is to understand how these IPR regulations have an influence on business behaviour of global pharmaceutical MNEs. In order to stay competitive on the market, the MNEs have started to search for new business models that can replace the inefficient traditional business models. The New business models focus on personalised drugs development and outsourcing of R&D phases to other organisations. *Part I*, which contained the general analysis of the global pharmaceutical sector assisted the students to analyse *Part II* which deals with the Indian pharmaceutical sector. The key outcomes show that the TRIPS agreement, that is responsible for changes in the Indian patent regime, have influenced the current situation of Indian pharma sector. The role of Indian government was to apply the new global standards in order to create the regulations, which protects the Indian nation and provides the access to affordable drug treatments. As respond, foreign MNEs need to change their current business models and strategies in order to adapt to the Indian pharmaceutical business environment. Additionally, the Indian institutions and organisations applied various innovation policies, which increased the R&D activities of the domestic firms. Some of the Indian companies still rely on general research, clinical trials and manufacturing generic drugs. However, there is a tendency of more and more Indian firms to invest in new drug development activities. Nevertheless, Indian pharmaceutical sector faces several challenges, one of which is the lack of domestic investment to R&D centres. For instance, the American company Pfizer invested around $8 000 million in 2008 compared to India's top pharma companies, who combined invested only 40 % of Pfizer's investment in last ten years (Joseph, 2011, p. 13).

5. CHAPTER
CASES ANALYSIS

As discussed in Chapter 3, there are often significant differences in IPR regimes along different countries. Developed countries are in favour of strengthening the IPRs regulations which can have a negative impact on the developing countries because IPRs could restrict the affordable access to lifesaving medicine (Maxwell & Riker 2014, p. 3). The fundamental problem of how to stimulate innovation without affecting negatively the economic development of countries where a large part of the population lives in poverty has caught the attention of various policy makers, theorists and practitioners. The main objective of this chapter is to provide secondary empirical data that consider this problem (inventor's incentive vs. social welfare). Three major cases are chosen to emphasise the conflict between multinational firms (MNEs) from the developed countries who have lost patent cases in the Indian pharmaceutical sector due to regulations in the IPR environment:

Case 1: Novartis AG v. Union of India & Others

Case 2: Bayer vs. Natco

Case 3: Roche vs. Cipla

What is of interest is to analyse how changes in the IPR environment in India has affected the business models of MNEs. This matter will be further discussed in Chapter 6. The current chapter starts with description of the MNEs involved in the conflict. Then the three patent cases are described and in the end of the chapter a summary outcome is analysed and discussed in order to underpin the main issues in the conflicts.

5. 1. Description of MNEs involved in the conflicts

Novatris AG

Novatris AG, based in Basel, Switzerland, is one of the biggest pharmaceutical companies in the world. In 2015, Novartis reported a total revenue of $ 49 414 billion in 2015, which has made it the one of the largest healthcare firms by these metrics (Google Finance, 2016). Novatris was formed in 1996 by the merger of two Swiss companies, Sandoz and Ciba-Geigy (Marketline 2016, p. 6). The company operates in more than 180 countries and has around 118 700 employees. The firm is involved in three main business sectors: pharmaceuticals, eye care

products (Alcon) and generics (Sandoz). The company has a long history in the Indian pharmaceutical market in which it has operated since 1947 (NovatrisIndia, 2016). In India Novartis has worked in the following fields: pharmaceuticals, generics, Vaccines, OTC (over-the-counter medicines), eye care and Animal Health. It is important to underpin that the company has one research and development centre (R&D) in India located in Hyderabad. The R&D centre consists of "[…] Medical Scientific Communication and Documentation, Electronic Data Management, Biometrics, Technical Research and Development, Drug Regulatory Affairs, Drug Safety and Epidemiology, and Development Informatics" (Marketline 2016, pp. 5-6)

Bayer AG

Bayer AG is a global pharmaceutical company with headquarter in Leverkusen, Germany. The financial statement of the company shows a total revenue of $51 772 billion in 2015,an increase of approximately 5.5 % over 2014 (Marketline, 2016a, p. 3). The company operates in 74 countries, which include 300 consolidated companies and the total number of employees is 116 800 (MarketLine, 2016a, p. 4). The company was founded in 1863 in Germany by two scientists. Bayer called themselves a Life Science company with a combination of innovative products. In 2014 the business operations were divided into three subgroups: MaterialScience, Healthcare (pharmaceutical and consumer health segments), and CropScience (MarketLine, 2016a, p. 4). The Pharmaceutical Division products develop solutions to fight against tumours. (Bayer, 2016). In 2011, Bayer HealthCare decided to form a joint venture company with Indian Zydus Cadil and established a centre in Mumbai. Zydus Cadil is a global healthcare provider and has a high knowledge and skills in the value chain (Zydus Cadil, 2016). The new corporation named is Bayer Zydus Pharma, which has a strong R&D centre and innovative approaches, that create drugs for the developing countries. The main activities relate to oncology, cardiovascular diseases, and anti-diabetic treatments (Bayer Zydus Pharma, 2016).

La Roche

Roche is a Swiss global pharmaceutical company based in Basel, Switzerland. By 2014 the total revenue reached $ 51 913 9 million and it is 1.5 % higher than in the last year (Marketline 2015a, p. 3). The history of Roshe starts from 1896 by focusing on vitamins commercialisations. Nowadays, the company has two business divisions: pharmaceuticals and diagnostics, with a total number of 88 509 employees. Roche's pharmaceuticals division operates in over 150 countries, and its main products focus on "[...] oncology, immunology,

ophthalmology, infectious diseases and neuroscience" (MarketLine, 2015a, p. 4). Roche's diagnostic division mainly operates in Europe and in the United States by serving products for blood tests, body fluids and another diagnosis. In 1994, Roche established a subsidiary in India with a name of Roche Products India Ltd. Its main activities are based on "[...] disseminating scientific knowledge pertaining to innovative medicines to the medical fraternity" (Roche, 2016). From 2013, Roche Products India started trading by entering business activities of selling and buying.

Natco Pharma

Natco Pharma Limited has incorporated in 1981, India. The financial report from 2015 shows that Natco made an increase of total revenue by 11.7 % compared to 2014 and reached approximately $135 3 million. The company functions through several segments, which are "[...] active pharmaceuticals ingredients and finished dosage formulations" (Marketline 2015b, p. 4). Natco's operation markets are India, Canada, the United States, Mauritius, and Brazil. Natco main activities to manufacture and market affordable drugs for Indian patients. One of the strongest operations of the company is to help Indian patients to fight against oncology and tumour illnesses. Natco focuses on affordable treatments, which have processes of expanded pharmaceutical research and success marketing representation. The company tries to enter into alliances with other pharmaceutical players to manufacture and market new products. One of the examples is, when Nacto made an agreement with another Indian pharmaceutical company Dr. Reddy's Laboratories for the "[...] *development, manufacture, and supply of generic oncology drugs*" (MarketLine, 2015b, p. 5). The culture is opportunity-driven that gives possibilities to respond to new ideas and have competencies to be strategically flexible; and to integrate to value chain regarding quality, costs, and logistics (Natco, 2016).

Cipla Limited

Cipla is a multinational India-based manufacturer and has its headquarter in Mumbai. The company recorded in 2014 $ 1 676 7 million to compare with 2013; it is an increase of 22% (Marketline 2015a, p. 3). The company's diversity shows that Cipla is involved in development, manufacture and sales of products. Cipla exports "[...] *to 150 countries and manufactures more than 2000 products in 65 therapeutic categories in its 34 facilities located across India*" (MarketLine, 2015a, p. 4). All products can be divided into three categories: active pharmaceutical ingredients (APIs), formulations and veterinary. Cipla operates in the following product areas: antimalarial, diabetology, HIV/AIDS, oncology, and anti-infectives. The firm

also practices partnership with other organisations and institutions, for instance: domestic collaboration with the Indian Institute of Chemical Technology for the development of drugs for cancer chemotherapy; foreign collaboration with a Japanese bio-venture firm to develop nano steroids in 2006. Cipla has been granted around 100 patents, which include the development of drug products, medical devices and technologies (Cipla, 2016).

5. 2. Case 1: Novartis AG v. Union of India & Others

5. 2. 1. Introduction to the case

One of the most intense cases in the history of the pharmaceutical industry is the Case of Novatris AG versus Union of India (UOI) and others (Natco Pharma Ltd. and M/S Cancer Patients Aid Association). The Supreme Court rejected in April 2013 the plea of the multinational firm for patent protection for its anti-cancer drug sold in the name of Glivec or Gleevec (imatinib mesylate) (Chaudhuri, 2014, p. 14). This outcome was the final decision of the court and drew a significant international attention and affected strongly the market. The Novartis case is very important due to the fact that it illustrates major problems regarding IPR and the affordable access to medicine. This issue has affected not only how MNEs conduct business in India but also it underpins the role of India as "Pharmacy of the Developing World" (Gabble & Kohler, 2014, p. 3). The fight between Novatris and Union of India & Others had lasted for more than a decade.

5. 2. 2. The Conflict

To understand the conflict between the affected parties in the Novatris case, the anti-cancer drug Glivec should be first discussed since it is the core problem. According to Lee the drug is "[…] *almost ten times more effective than traditional interferon therapy, due to its ability to target specific cancer proteins., however, the drug does not give a permanent cure from cancer … [it] only stalls its progress*" (Lee, 2008, p. 281).What is important to be taken in consideration in this case, is that there is a significant price gap between the patented version of Glivec and its generic copy. It is estimated that a monthly treatment of the originator drug can cost over $5 000 in the United States., whereas a monthly dose of the generic drug can cost less than $200 in the Indian Market (Gabble & Kohler, 2014, p. 3) There is also a huge income

gap between the Developed and Developing countries which only leads to the paradox of IPR incentives vs affordable medicine. This issue will be further discussed in Chapter 6.

The patent history of Glivec with its main compound imatinib started in April,1992 when a Swiss patent application was filed by the company originator-Novatris. As following events, patent applications were filed in 1993 concerning the EU and US (excluding India) and in 1996 Novatris received patents in these particular markets. As discussed in Chapter 4, the Indian Patent law was changing during that time due to the fact that India has signed the WTO`s TRIPS agreement in 1995 which gave the country 10 years period to comply with the global intellectual property rights threshold. Back then India was under "process regime" and patents were not granted on product innovation (Lim, 2013, p. 26). In 1997, Novatris developed the beta crystalline form of imatinib which is called imatinib mesylate and then applied for second round of patents which included India (Ecks, 2008, p. 168). At that time as mentioned above India did not grant product patents but had a "mailbox" (1994-2004) which was used from companies to request patents during the Indian patent transition. Initially, the Indian government granted Exclusive Marketing Rights (EMR) to Novatris until its application was processing in 2003. This decision was strongly criticised by generic firms as well as non-profit organisations such as the Cancer Patients Aid Association (CPAA). The firm was accused of restricting the affordable medicine to the Indian population (Gabble & Kohler, 2014, p. 3). It must be noted that Novatris has initiated the "Glivec International Patient Assistance Program" which provides the lifesaving medicine free of charge to 16,000 patients in India, around 95% of those who need the treatment (Forbes, 2002). This was one of the company's attempts to solve the problem regarding affordable access to the needed medicine. In almost all of the countries that Novatris applied for patent on the second version of their product Glivec, they were granted one. In India though, the company was rejected a patent first in June, 2006 by the Indian Patent Office and then second time by the Intellectual Property Appellate Board (IPAB) in June, 2009. The case ended in 2013 when the Indian Supreme Court refused to grant a patent on Novatris`s drug.

The reason for the rejection was based on the fact that the modified versions of Glivec was not complied with the *Section 3(d)* of the Indian Patent Act. The section is one of the most discussed topic among foreign and domestic institutions and it aims to provide a tougher standard for limiting "evergreening" activities. In order to comply with the section and receive a patent, a firm has to introduce new versions of its products that are "[…] *therapeutically more beneficial than earlier versions on which patents had expired"* (Bennett, 2014, p. 544). Even though the

Section 3(d) was criticised strongly by the US, it does not infringe the TRIPS agreement. Novatris AG also complained about *Section 3(d)* of the Indian Patent Act (2005). The company claimed that the section is vague and it did not comply with the TRIPS Agreement bringing into consideration Article 27 of TRIPS (Mudur, 2012, p. 1). The *Article 27* of the TRIPS Agreement states: "[…] *Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application"* (Bennett, 2014, p. 549). It explained that patents are granted to inventions that are new and involve "innovative" step which in the Novatris case was the imatinib mesylate in Glivec (Gabble & Kohler, 2014, p. 4). The Indian government had another interpretation of the same article which actually helped them strengthen their Patent Act by the creation of the exact criticised the *Section 3(d)*. It is interesting to observe that the two parties in the conflicts have used the same Article from the TRIPS Agreement as their main argument.

5. 2. 3. The outcome

The Novartis v. Union of India & Others case ended in 2013 when the Indian Supreme Court denied patent for Novatris`s medicine Glivec. As a consequence, any generic company in India can legally produce a copy of the version on substantially lower price and profit from all of the R&D efforts that Novatris has put in the development of the drug (Forbes, 2002). Indian Pharmaceutical Department has emphasised the importance of ensuring that expensive lifesaving medicine is available at affordable price to the poor. In this case, Novartis is not able to appeal further due to the bad publicity but the firm can share its experience regarding "unfavourable" IPR atmosphere in India. This action can affect the Foreign Direct Investments (FDI) in the pharmaceutical sector in India negatively (Srinivasan, 2007, p. 3687). The firm's vice-chairman and managing director in India stated that the company "[…] *will be cautious about investing in India, especially over introducing new drugs, and seek patent protection before launching any new products "* (The Guardian, 2013).

The Novatris case presents how developing country such as India can use the international laws in order to protect its domestic public health sector. This case brought more attention regarding the effect of IPR in the context of the developing countries if they really support innovation activities or they only restrict the generic companies to provide affordable drugs to the population. By ruling against Novatris, India has saved many lives and helped its domestic MNEs to flourish by being able to copycat the Glivec product. From another side, foreign

MNEs as Novartis, will not feel secure to invest in a market such as India. This will lead to limited innovative solutions to drug development and will affect the global patients in the long run.

5. 3. Case 2: Bayer vs. Natco

5. 3. 1. Introduction to the case

The first Indian compulsory licence (CL) was filled between German pharmaceutical company Bayer and the Indian generic drug manufacturer Natco in March 2012. The CL was based on Bayer's patent drug with a brand name Nexavar, which is a kidney cancer treatment that can increase life expectancy of patients. Natco claimed that the branded drug did not fulfil the requirements of the Indian Patent Act 84. The drug was not available to the majority of patients and the price was significantly higher than patients could afford. The medicine was firstly patented in 2000 in the United States, and in 2008 Bayer received the patent by the Indian Patent Office. Natco made an achievement to develop a generic version of Nexavar and as a result received a licence for marketing and manufacturing in July, 2011.

5. 3. 2. The conflict

According to the Indian Patent Act of 2005, Natco had obtained the CL according to Section 84 from the Controller of Patents. Following the *Section 84 (1),* which gives permission to any interested person to send a request to the Controller for a CL grant, but only after the expiration of the period of three years from the date of grant/patent. It should also follow special conditions: (a) the reasonable requirements of the public have not been satisfied; (b) the patented product is not available to the public at a reasonable price; (c) the patent is not manufactured in India (Bakhru, 2012, p. 46).

Based on the above conditions, Natco claimed that Bayer did not comply with these requirements. One of the main reason was that requirements of this drug were not succeeded due to a lower purchase of buying. Only 2% of the cancer patients could afford to use Nexavar drug against their disease. However, according to GLOBOCAN data, which evaluated some patients with cancer, for instance, they are 20 000 liver cancer patients and 8 900 kidney cancer patients (Bakhru, 2012 p. 46). According to the international agreement on IPR (including TRIPS, Paris Convention and the *Indian Patent Act 84(6*), drugs producers should be "worked in the territory of India", nevertheless, Bayer had failed to do it, even after four years from the

patent grant date. Another argument from Bayer`s side was related to the process of manufacturing. The company outlined that supplying the drug to India already means a process of the production. Despite, Bayer had manufacturing facilities in India, and Natco argued that there were no reasons to import drugs. Nevertheless, Bayer also emphasised that the small demand of their product will not be a rational decision to manufacture in India as Bayer by this time knew about the generic version from Natco.

Bayer's sales of Nexavar did not reach the needed amount, not because of low purchasing rates, but also because of the small amount of bottles` supply. In 2008, it reached only 200 bottles and in 2009 and 2010 there were no imports of Nexavar from Bayer's side. Even through, Indian population requires approximately 23 000 bottles per month. Additionally, the drug was only available in main metropolitan cities like Mumbai and Delhi.

Another argument in this case was that the price of the drug which was essentially higher than a generic drug of company Cipla with a price per bottle of $420 and consequently could not reach for the most of the patients. Additionally, there was a huge price difference between Natco's and Bayer's drug, for instance, the price for a month's treatment was around $130 instead of $4 200 in Bayer's case (Bakhru, 2012 p. 46). However, Bayer claimed that the drug is based on a "reasonably affordable price". The foreign MNE did not lower the price by arguing that they need to return the investment in R&D in order to be able to develop and improve demanded medicines for Indian patients. A solution proposed by the Indian government was to offer Bayer 50% orphan drug tax that could give the possibilities to lower the price for the Indian market. An issue arose when Bayer did not disclose the cost of R&D expenditures of the drug development. Furthermore, Bayer did not agree with the calculation of affordable price because in that way the firm would lose its monopolistic rights. When Natco received the compulsory licence, Cipla decreased the price until 100 and Bayer argued if it is necessary to have two manufacturers of the same drug at the affordable price. The case against Cipla and Bayer is still ongoing, and it can not have any effect on the compulsory licences decision from the Indian Patent Act.

Additionally, India's Intellectual Property Applied Board (IPAB) made an effort to acquire a voluntary licence for Natco. However, it did not achieve executive actions, because of Bayer's statement that Natco did not put any negotiable efforts, and the voluntary licence was denied by the German company (Sood, 2013, p. 106).

5. 3. 3. The outcome

The outcome of this case, is that the generic company Natco was granted a CL on Bayer`s medicine Nexavar. Indian Patent Act, Section 90 have several conditions, which should be followed by the licensee when the CL is granted. Natco was permitted to manufacture and market the generic version of Nexavar based on the amount and price of a production. The produced number per month should not exceed 120 tables and the price should not exceed $180 per one month's treatment. Another requirement is that Natco is obliged to pay 6% of the net sales to German pharmaceutical company and supply the Nexavar drug to 600 needy patients per year for free. Manufacturing and marketing of the drug should possibly happen only on the territory of Indian country and only for the treatment of liver and kidney cancer. Any sub-licence of Nexavar drug to another manufacture is not feasible for Natco as the compulsory licence is a non-assignable and non-exclusive licence. Another obligation for Natco is a public/private presentation that the generic drug is the same product as Bayer's Nexavar. From Bayer's side, the company has no liability to manufacture the drug at Natco fabric as it will increase the number of produced drugs for Natco (Bakhru, 2012 p. 46).

The general discussion about a compulsory licence affects strongly the pharmaceutical industry. On one side, MNEs` business models need to adapt to this environment. Foreign drug companies stress that due to CL they would be more reluctant to launch new medicines and development innovation solutions in the Indian market (Bakhru, 2012 p. 47). However, foreign companies should not only argue against Indian Patent Act but also consider other business model strategies that can work together with compulsory licences. In some situations, MNEs can enter into a licensing agreement (e.g. a voluntary licence) with a domestic pharmaceutical company. As a result, it will provide some insurance of a drug distribution. By doing so, patentees can not only negotiate a drug market price but also establish various pricing strategies for specific sectors of a population rather than be forced by Patent Controller. Decreasing the price of drugs is a big decision for MNEs as it can have an effect on the profit margins and the market share in developing countries. A solution, in this case, can be to take a credit, which can lower the costs of research investment.

5. 4. Case 3: Roche vs. Cipla

5. 4. 1. Introduction to the case

The battle between Roche and Cipla started in 2008 and it is based on the Roche's patent for the anticancer drug with the brand name Tarceva which is one of the main blockbuster drugs of the MNE. On one side, Roche requested a patent infringement, which restrained Indian company Cipla from manufacturing and selling the generic version of the drug. On the other side, Cipla counterclaimed for Roche's patent validity. This case related to the first Patent Litigation because it included pricing elements and public interests together with India's *Sector 3 (d)* that prevents evergreening (Khurana, 2012, p.1). The case of Roche vs. Cipla has taken 7 long years of litigation.

5. 4. 2. The conflict

The conflict started, when in 2008 Cipla announced a production of the generic version of Tarceva which is Roche's brand drug introduced to the Indian market in 2006. Tarceva was granted a patent and commercialized in India based on "Erlotinib Hydrochloride"- without being limited to any of its polymorphs. As a response to the Roche`s claim, the generic manufacturer Cipla questioned the patent validity of Tarceva. It was argued that the branded drug was invalid, because components of it has derivative "Erlotinib Hydrochloride" molecule and according to *Indian Patents Act 3 (d)* this component known as not patentable. Roche counterclaim that the derivative is a novel compound and it is not "[...] salts, esters, polymorphs, particle size, mixture of isomers" (Generics Industry Rejoices, 2012, p. 2; Bennett, 2014, p. 545). According to Cipla's allegations, Roche's patented drug in the United Stated only applied for a combination of Polymorph B form. However, the generic version contained elements not only Polymorph A, but also Polymorph B to produce "Erlotinib Hydrochloride" compound. An Argument from Roche's side was that the preparation of Polymorph B requires an involvement of Polymorph A (Srivastava, 2012).

There were three court decisions. The first one from the single judge declined a temporary injunction on the ground of "public interest" and allowed Cipla to produce the drug on an affordable price. Cipla claimed that the price between the branded and generic drug should be taken into account. The price difference for Cipla's drug is three times cheaper than Roche's drug ($ 33 vs $ 100 per tablet) Generics Industry Rejoices, 2012, p. 1). Therefore, The Single Judge stated, that "[...] *the injunction might not be granted because the public interest in great*

public access to a life saving drug would outweigh the public interest in granting an injunction to the Appellants Roche" (IP India, 2010). Additionally, the branded drug was imported to India and the Court mentioned that "[...] *the right to access to lifesaving drugs, and the need for secure long term suppliers, is a serious issue in India*" (Generics Industry Rejoices, 2012, p. 2). The second court decision was taken by Division Bench and it was more in favour of Roche by claiming that Tarceva`s patent was under a serious validity attack by the generic firm Cipla (Lexology, 2016). The last court decision was from the Delhi High Court which cancelled the claim form Roche's side due to the fact that the company failed to disclose the information regarding "Erlotinib Hydrochloride" compound a manufacturing process. This matter is against the Indian Patents Act (IP India, 2010).

5. 4. 3. The outcome

The result of the case showed the court's final decision rejected Roche's claim for an injunction on Cipla's product, as taking into consideration that the patent was due to expire in March 2016 (Lexology, 2013) Another important argument for that decision was that Tarceva is a lifesaving drug and the government needed to ensure that this expensive drug can be accessible for the majority. According to *Indian Constitution Article 21*, which states the "right to life" refers to patient rights. However, foreign R&D centers argue that Indian Drug authorities should better control drug's price and patentee's monopoly. A rejection of foreign claims can have an effect on Indian attractiveness for MNEs and patentee's rights will have an opposite side of the desired effect in the long run. International pharmaceutical companies bring a discussion that "[...] *the purpose of the Patents Act is to grant a statutory monopoly that will enable the patentee to exploit research in which it has invested considerable time and money*" (Generics Industry Rejoices, 2012, p. 3). While Roche was focusing on making the case stronger and bigger, Cipla was lowering the price of their generic drug and as a result, Cipla was in favour (Generics Industry Rejoices, 2012, p. 2). There is a high tension between foreign and domestic companies. Most of the foreign MNEs are concerned that even though they complied with all the domestic rules and regulations they would be still denied a patent due to price differential in comparison to the local firms.

5. 5. The Cases outcomes` summary

From the three cases presented in this chapter, it can be concluded that the affordable access to lifesaving medicine has been a crucial problem especially for developing countries. Unlike most

developed countries, India lacks a proper health care system and large part of the population is not able to pay for the needed treatment. Establishing a strong health care system might help people in need to have a better access to medicine.

The aim of standardizing and strengthening the IPR worldwide is supposed to have a positive effect on developing new innovative medicine that can fulfil patients` needs. Unfortunately, in fact in the collected three cases it was observed that MNEs` monopoly on lifesaving drugs restricted the access to the needed treatment in India. Therefore, firms market power only hurted the common man (Bennett, 2014, p. 557). In order to protect the Indian society and to secure affordable access to medicine which in general is a basic human right, the Indian government has decided to act by changing the Patent Act. As mentioned before the TRIPS agreement has given developing countries some flexibilities. By using wisely, the global standards, in particular *Article 27* and *Article 31* (TRIPS), India was able to shape rules and regulations that can prevent MNEs from evergreening (*Section 3(d) of Indian Patent Act*) and to provide affordable access to lifesaving drugs to the population (compulsory licensing) (Park & Jayadev, 2011, p. 80). In Case 1, Novatris was not granted a patent due to the fact that the Glivec did not show enough efficacy and novelty in order to comply with *Section 3(d)* of Indian Patent Act. In Case 2, Indian government was allowed to give to a third party (Natco) a compulsory licensing to produce Bayer`s brand drug Nexavar. It is important to emphasise that all of the conditions needed (Article 31 from the TRIPS Agreement) for issuing a compulsory licensing were met before starting this action. Case 3 is considered as very contradictory due to the different and ambiguous court decisions. Nevertheless, Roche was granted a patent on the brand drug Tarceva in 2006, the generic company Cipla was allowed temporary to produce the medicine (first judge decision) because the price of the brand drug was too high and was not affordable to the common man (IP India, 2010). The second court decision ruled in favour of Roche by admitting that the Indian generic company has infringed the foreign MNE`s patent. In the end, even though it was decided that Rouch`s patent was violated, Cipla was not restricted to produce the medicine taking into consideration the fact that the patent would expire in March, 2016 (IndianExpress 2015).

As a consequence, all of these lost patent cases have discouraged foreign MNEs to invest and introduce new innovative solution to the Indian market. The firms argued that without having protection on the IPR, there would be no incentive for a firm to invest and manufacture new drugs that could be easily copied by generic firms (Bennett, 2014, p. 557). Novatris has strongly criticised *Section 3 (d)* of the Indian Patent Act because it does not support incremental

innovation which is also a very important aspect when developing and discovering new products and processes. Other international companies have started claiming that the Indian government sets the prices not only for the expensive patent drugs. It is estimated that there are around 348 drugs that have price caps. It is observed that innovative drugs developed by Indian researchers are *immune* to the price control of the government for the period of five years. It is a good initiative from the government to stimulate the domestic R&D activities but simultaneously discriminates in a way the foreign R&D efforts (Forbes, 2013).

6. CHAPTER
Discussion and Concluding Remarks

The main objective of the chapter is to provide an answer to the problem formulation of the master`s thesis. The theoretical framework created in Chapter 3 was applied in the Analysis of the thesis which consists of Chapter 4 and Chapter 5 in order to find out how changes in the IPR environment in India affected the business models of MNEs. Finally, the concluding remarks of the thesis will be presented.

It is a well-known fact that innovation is one of the key drivers for economic growth. When discussing the context of developing countries, innovation is often found to be less evolved due to not sufficiently advanced innovation system (Chaturvedi, 2007, p. 654). What is of interest about the pharmaceutical industry is that the patent protection virtually equals the product, hence, the sector is unusually sensitive to changes in IPRs regulations (Lehman, 2003, p. 7). There is a need to understand that developed and developing countries have different views on the concept of IPRs. It is often debated whether the concept of IPR stimulates or restrict innovation activities due to the unevenness between the "Marginal private" and "Social return" matters (Stiglitz, 2008, p. 1708). The harmonization of global IPR standards has risen the question if developed countries benefit on the expense of the developing one. It is underpinned that the significant difference in the welfare systems as well as the knowledge gap between the two economies are not taken into consideration when designing the global IPR standards proposed by the TRIPS Agreement (Maxwell & Ricker, 2014, p. 3). It should not be forgotten that developing countries are in a disadvantaged position because they are "[...] *the "second comers" in a world that has been shaped by "first comers"* (Srinivasan, 2007, p. 3688). As a consequence, the developing countries cannot see the benefit of strengthening the IPRs, since a large part of the population will be restricted to have affordable access to medicine. The TRIPS agreement is responsible for changing the National and Sector System of Innovation in India. When discussing the concept of IPRs and their effect on the innovation process, other ways of stimulating innovation activities should be considered. For instance, financing research through prizes or government and university initiatives. The prize system is an alternative tool to the patent system, where if an individual/firm meets certain requirements will receive a prize. For instance, the individual who finds a cure for cancer will receive a big prize (Stiglitz, 2008, p. 1719).

The Indian government have used the global IPR standards in their favour by shaping the Indian Patent Act in order to serve country's own economic, social and technological conditions (Srinivasan, 2007, p. 3687). As discussed before *Section 3(d)* and *Section 84* of Indian Patent Act are responsible for protecting the Indian population from the abusive monopolistic power of foreign MNEs. Even though the country is highly criticized by MNEs and the US, the Indian IPR rules are complying with the global IPRs standards (TRIPS Agreement). India is perceived as the first mover from the developing countries that has taken a stand in order to support its own interest. Other developing countries such as Brazil and China which have similar health care problems can take an example from the changes in Indian Patent Act.

During the past decades, globalisation has played a key role for the world economy and influenced firms to engage in international trade activities which have affected the global, national and sectoral context (Crescenzi et al., 2012, p. 1). The role of foreign MNEs in India has influenced the technological development of domestic firms capabilities. The government has been involved in stimulating collaboration between foreign and domestic companies in order to improve local learning capabilities. It is considered that stronger IPR regulations will ease the transfer of better technology. However, foreign companies are often accused of transferring only old technology to the Indian market. What should be taken into consideration is that in the context of weak IPR regulations, foreign firms have no other incentives of doing otherwise (Zambad & Londhe, 2014, p. 826).

6. 1. Intellectual Property Right changes and the effect on Business Models of MNEs

From the three cases presented in Chapter 5 it was found out that the main problem of why Novatris, Bayer and Roche lost patent cases in India is due to the fundamental problem: welfare vs. inventor's incentives. By complying with the global IPR standards discussed in the TRIPS agreement, the Indian government shaped its Patent Act in order to provide a better access to lifesaving drugs as well as support for the local MNEs. What is of interest is to investigate how business models of MNEs have been affected by the changing IPR environment in India. The four pillars of Business Model by Osterwalder et al. (2004) that were presented in Chapter 3 will be used as a supporting tool in order to discuss how the foreign and domestic MNEs business model have been influenced by the IPR reforms in India.

Table 5: Affected business models of foreign and domestic MNEs by IPR changes in India

Pillars of the Business Model	Foreign MNEs	Domestic MNEs
Product	✓ Need for more radical innovation	✓ Start to invest more in new drug development
Customer Interface	✓ National Health Care/cancer patients (users)	✓ National Health Care/ cancer patients (users)
Infrastructure management	✓ Need for more R&D performed in India ✓ Focus not only on imports ✓ Collaboration with domestic MNEs, universities, research centres	✓ Export activities ✓ Focus more on R&D activities ✓ Collaboration with foreign MNEs, universities, research centres
Financial aspects	✓ Lost revenues ✓ Government price regulations	✓ Earn revenues ✓ Immune for 5 years from Government price regulations

Source 22: Adapted to the analysis. Based on Osterwalder et al. (2004)

Product

In regards to the product pillar, there is a difference between foreign and domestic MNEs. The Indian Government did not grant patent to Novatris because the company was accused of not bringing a novel medicine to the market. A solution for the firm can be to focus on more radical innovation activities which can be a patentable matter in India. However, Novatris has strongly criticised the changes in the Indian Patent Act due to the fact that it does not stimulate incremental innovation and can discourage FDI in the Indian pharmaceutical sector. In the case of Bayer and Roche, the Indian government decided to grant compulsory licensing to domestic MNEs (Natco and Cipla) because a large part of the population was not able to afford the needed treatment. The foreign firms are concerned about the unfavourable IPR atmosphere in India, hence, they will not be willing to introduce new solutions to the market. That will endanger the health of the patients. Therefore, domestic MNEs should also consider new drug development instead of only focusing on generics.

Customer Interface

In the case of pharmaceutical sector, the customers are represented by national health care systems or insurance funds, whereas the patients are only the users of the medicine (especially when cancer drugs are discussed). The users are not able to switch to another product due to the fact that doctors are the ones with the purchasing power and are responsible for prescribing the drugs. In the case of both domestic and foreign MNEs in the investigated context of India, there is a need for closer collaboration with the national health care system as well as with the patients in order to find better solutions.

Infrastructure management

One of the main arguments why foreign MNEs were not granted patents or their monopoly power was restricted was due to the fact that companies were focused on importing the drugs and not developing and manufacturing in the Indian market. Therefore, the Indian government granted compulsory licenses to domestic firms (Natco and Cipla). This action not only provided access to affordable drugs but also improved the local firm`s technological and research capabilities. Moreover, domestic firms are able to increase the drug export to US and EU market because they have improved their capabilities of producing better quality generic products. It is advisable for both foreign and domestic MNEs to engage in collaborative activities between each other, as well as with universities and research organizations. As a result, all of the parties involved in the innovation process can improve their capabilities which depends on the actor`s absorptive capacity. By collaborating, firms also share the risks when discovering new drugs. As discussed in Chapter 4, there are possible collaborative strategies, especially suitable for developing countries such as India. Firms can engage in contract research and manufacturing services, collaborative research projects as well as in-licensing and out-licensing activities.

Financial Aspect

The pillar that was significantly affected by the changes in the IPR regulations in India is the financial one. Foreign MNEs have lost market shares in the country because their exclusivities power was restricted and generic competition was allowed to enter the market. As a consequence, the revenue streams of foreign MNEs decline drastically. Opposite to that, local companies improved their financial situation from selling generic versions of the branded drugs. Another matter in this pillar, is the government price regulations on drugs which was supposed to be only on very expensive lifesaving drugs but has spread out to more common

medicine as well. Domestic MNEs are immune for five years from these regulation, hence, they are able to return the invested money in R&D of new drugs. Unfortunately, foreign MNEs can not benefit from this privilege. A recommendation could be to collaborate with an Indian partner so that the foreign firm can receive this price incentive.

6. 2. Concluding remarks

The use of IPR in the pharmaceutical sector in both developed and developing countries is a complex matter. It is challenging to balance between the *static* benefits to patients from low drug prices and competitive supply with the dynamic benefits from innovative new medicine (Cockburn, 2009, p. 150). The pharmaceutical industry is pressured by increasing R&D costs and inefficiency of the blockbuster business model. Even though, innovation is important for the sector, the high prices of on-patent drugs raise questions in regards to the affordable access to medicine for low income or disadvantaged groups even in relatively wealthy countries' context. In order to solve this issue policy makers have insisted on increasing the public healthcare budgets.

Global IPRs standards need to evolve but not on the expense of the development process and poor people. In the researched Indian context, it was found out that foreign MNEs tended to abuse their monopoly power and affect negatively the Indian population which was not able to afford lifesaving drugs. Drug monopoly is considered to be harmful to the majority but beneficial for the firm responsible for the development of the new drug. A suggestion that can solve the fundamental problem of welfare vs. inventor's incentive is the idea of not having patents on drugs important for the public healthcare or automatic compulsory licensing (Srinivasan, 2007, p. 3688). From the three cases presented in the thesis it was found out that changes in the Indian IPR environment affected differently the business models of foreign and domestic MNEs. The Indian government has set policies that are in favour of local firm and influenced negatively the foreign MNEs. A recommendation can be for both foreign and domestic firms to engage in contract research and manufacturing services, collaborative research projects as well as in-licensing and out-licensing activities. To conclude, policymakers should focus on reduction of poverty in developing countries by stimulating innovation and technological transfer that are applicable to their context while also making available the medicine at the most competitive price.

7. CHAPTER

Bibliography and Appendix

7. 1. Bibliography

Abbott, Frederick M. 2010. *Access to Medicines and Intellectual Property Rights*.

Aghion, Philippe, Peter Howitt, and Susanne Prantl. 2015. "Patent Rights, Product Market Reforms, and Innovation." *Journal Economic Growth* 20: 223–62.

Ahlersten, Krister. 2008. "Public Goods." In *Essentials of Microeconomics*, Ventus Publishning ApS, 145–47.

Andersen, Birgitte. 2004. "If 'intellectual Property Rights' Is the Answer, What Is the Question? Revisiting the Patent Controversies." *Economics of Innovation and New Technology* 13(5): 417–42.

Babiarz, J.C. 2008. "Overview of FDA and Drug Development." In *FDA Regulatory Affairs. A Guide for Prescription Drugs, Medical Devices, and Biologics*, eds. D.J Pisano and D.S Mantus. New York: Informa Healthcare.

Bakhru, Rachna. 2012. "India Grants First Compulsory Licence under Patents Act." *Intellectual Property Magazine*: 46–47.

Barnes, D. 2011. "Congestible Intellectual Property and Impure Public Goods." *Northwestern Journal of Technology and Intellectual Property* 9(8).

Barthwal, R.R. 2000. "The Scope of Industrial Economics and Its History." In *Industrial Economics An Introductory Textbook*, New Delhi: New Age International (P) Ltd, 1–12.

Baskaran, Angathevar, and Mammo Muchie. 2007. Development, Innovation and International Political Economy Research (DIIPER) *The Making of the Indian National Innovation Systems: Lessons on the Specific Characteristics of the Domestic and the External Co-Evolutions of Technologies, Institutions and Incentives*. Aalborg.

Bayer. 2016. "Bayer Focuses on Life Sciences." http://www.bayer.com/en/focus-life-sciences-article.aspx (May 14, 2016).

———. "Personalized Medicine against Cancer." *Bayer HealthCare Research*: 22–37. http://www.research.bayer.com/en/23-personalized-medicine.pdfx (June 1, 2016).

Bayer Zydus Pharma. 2016. "Bayer Zydus Pharma." http://bayerzyduspharma.com/bayer_zydus_pharma.php (May 14, 2016).

Bennett, William J. 2014. "Indian Pharmaceutical Patent Law and the Effects of Novartis AG v. Union of India." *Washington University Global Studies Law Review VO - 13* 13(3): 535.

Blackman, Michael. 1995. "Provision of Patent Information: A National Patent Office Perspective." *Elsevier Science Ltd* 17(2): 115–23.

Boldrin, Michele, and David K Levine. 2005. *The Pharmaceutical Industry*.

Boyle, James. 2003. "The Second Enclosure Movement and the Construction of the Public Domain." *LAW & CONTEMP. PROBS*: 41–42.

Brandenburger, Adam, and Stuart Harborne. 1996. "Value-Based Business Strategy." *Journal of Economics & Management Strategy* 5: 5–24.

BRIC. 2016. "The Much Awaited Indian National IPR Policy Has Arrived!" *BRIC Wall*. https://bricwallblog.wordpress.com/category/indian-patent-office/ (June 1, 2016).

BYUI. 2013. "Monopolies." https://courses.byui.edu/econ_150/econ_150_old_site/lesson_08.htm (April 15, 2016).

Capo, Francesca, Federica Brunetta, and Paolo Boccardelli. 2014. "Innovative Business Models in the Pharmaceutical Industry: A Case on Exploiting Value Networks to Stay Competitive." *International Journal of Engineering Business Management* 6(1): 1–11.

Carlsson, B, and R Stankiewicz. 1991. "On the Nature, Function and Composition of Technological Systems." *Journal of Evolutionary Economics* 1: 93–118.

Chakraborty, Shyamal Kumar. 2014. *National Innovation Systems : India's Perspective*.

Chaturvedi, Sachin. 2007. "Exploring Interlinkages between National and Sectoral Innovation Systems for Rapid Technological Catch-up: Case of Indian Biopharmaceutical Industry." *Technology Analysis & Strategic Management* 19(5): 643–57.

Chaudhuri, Sudip. 2014. *MNCs in Pharmaceutical Industry in India after TRIPS*. New Delhi.

Chesbrough, H. 2003. *Open Innovation: The New Imperative for Creating and Profiting from Technology*. Boston: Harvard Business School Press.

Chesbrough, H, and A.K. Crowther. 2006. "Beyond High-Tech: Early Adopters of Open Innovation in Other Industries." *R&D Management* 36(3): 229–36.

Christensen, Jesper, and Bengt-Åke Lundvall. 2004. "Product Innovation, Interactive Learning and Economic Performance." *Research and Technological Innovation and Management Policy* 8: 21–42.

Cipla. 2016. "Leader in Drug Delivery." http://www.cipla.com/en/r-d/leader-in-drug-delivery.html (May 24, 2016).

Cockburn, I. 2009. *INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICALS: CHALLENGES AND OPPORTUNITIES FOR ECONOMIC RESEARCH*. THE ECONOMICS OF INTELLECTUAL PROPERTY.

Coes, Bastian. 2014. *CRITICALLY ASSESSING THE STRENGTHS AND LIMITATIONS OF THE BUSINESS MODEL CANVAS*.

Cohen, W.M, and Daniel A Levinthal. 1990. "Absorptive Capacity : A New Perspective on and Innovation Learning." *Administrative Science Quarterly* 35(1): 128–52.

Cooke, Philip. 2001. "Regional Innovation Systems, Clusters, and the Knowledge Economy." *Oxford University Press* 10(4): 945–74.

Crescenzi, R, A Rodriguerz-Pose, and M Storper. 2012. "The Territorial Dynamics of Innovation in China and India." *Journal Economic Growth* 12(6): 1125–1085.

Creswell, J, and V Plano Clarkm. 2007. *Designing and Conducting Mixed Methods Research*. Thousand Oaks: Sage Publications.

Creswell, John W. 2013. 1 Statewide Agricultural Land Use Baseline 2015 *Qualitative, Quantitative and Mixed Methods Approaches*. 4th ed. Los Angeles: Sage Publications.

Dahan, Nicolas M., Jonathan P. Doh, Jennifer Oetzel, and Michael Yaziji. 2010. "Corporate-NGO Collaboration: Co-Creating New Business Models for Developing Markets." *Long Range Planning* 43(2-3): 326–42.

Dahlander, Linus, and David Gann. 2010. "How Open Is Innovation?" *Reseach Policy* 39: 699–709.

Deloitte. 2014. "2015 Life Sciences: India." : 1–3.

Denoon, A, and E Vollebregt. 2010. "Can Regenerative Medicine Save Big Pharma's Business Model from the Patent Cliff?" *Editorial Regen. Medicine* 5(5): 687–90.

DeRuiter, Jack. 2012. "Drug Patent Expirations and the 'Patent Cliff.'" https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff.

DIBD. 2000. *The Indian Pharma Industry*.

Doloreux, David, and Saeed Parto. 2004. "Regional Innovation Systems : A Critical Review." *Maastricht MERIT* 190(1): 1–26.

Doz, Yves L., and Mikko Kosonen. 2010. "Embedding Strategic Agility: A Leadership Agenda for Accelerating Business Model Renewal." *Long Range Planning* 43(2-3): 370–82.

Ecks, S. 2008. "Global Pharmaceutical Markets and Corporate Citizenship: The Case of Novartis' Anti-Cancer Drug Glivec." *BioSocieties* 3: 165–81.

Edquist, Charles. 1997. 53 Journal of Chemical Information and Modeling *Systems of Innovation: Technologies, Institutions and Organizations*. London: Pinter Publishers/Cassell Academic.

———. 2005. "Systems of Innovation: Perspectives and Challenges." In *Oxford Handbook of Innovation*, eds. Jan Fagerberg, D Mowevry, and R Nelson. Oxford: Oxford University Press, 181–208.

Edquist, Charles, and Björn Johnson. 1997. "Institutions and Organizations in Systems of Innovation." In *Systems of Innovation: Technologies, Institutions and Organizations*, ed. Charles Edquist. Pinter Publishers/Cassell Academic, 41–63.

Edwin, L, and C Lai. 1998. "International Intellectual Property Rights Protection and the Rate of Product Innovation." *Journal of Development Economics* 55: 133–39.

Faria, Pedro, and F Lima. 2009. Druid Summer Conference *Firm Decision on Innovation Types: Evidence on Product, Process and Organizational Innovation*.

FDA. 2016. Office of Pharmaceutical Sciences, CDER, USFDA. *Generic Drugs*.

"FDA Slams Another Indian Drug Maker for Serius Quality Problems." 2016. *STAT*. https://www.statnews.com/pharmalot/2016/01/06/fda-warning-letter-cadila/ (May 30, 2016).

Fernández, Bruno, Martinez Hurtado, and Juan Leonardo. 2012. "'Biosimilars: Company Strategies to Capture Value from the Biologics Market.'" *Pharmaceuticals* 5(12): 1393–1408.

Festel, Gunter, Alexander Schicker, and Roman Boutellier. 2010. "Performance Improvement in Pharmaceutical R&D through New Outsourcing Models." *Journal of Business Chemistry* 7: 89–96.

Fielt, E. 2013. "Conceptualising Business Models: Definitions, Frameworks and Classifications." *Journal of Business Models* 1(1): 85–105.

Ford, Sara M. 2000. "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents." *American University Journal of International Law & Policy* 15(4): 941–74.

Frankel, S. 2009. "Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes." *Journal of International Economic Law* 12(4): 1023–2065.

Gabble, R, and J Kohler. 2014. 10 *"To Patent or Not to Patent? The Case of Novartis' Cancer Drug Glivec in India."*

Gassmann. 2014. *The Business Model Navigator*. Financial Times Publishing.

Geanakoplos, John. 2004. *The Arrow-Debreu Model of General Equilibrium*.

Gilbert, J, P Henske, and A Singh. 2003. "Rebuilding Big Pharma's Business Model." *WINDHOVER INFORMATION INC* 21(10).

Grasl, Oliver. 2008. transentis management consulting GmbH *Business Model Analysis: A Multi-Method Approach*.

Gray, Davis. 2006. "Doing Research in the Real World." In *Doing Research in the Real World*, Los Angeles: Sage Publications, 16–38.

Greene, W. 2007. "The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market." *OFFICE OF ECONOMICS WORKING PAPER U.S. INTERNATIONAL TRADE COMMISSION*.

Guba, Egon, and Yvonna S. Lincoln. 1994. "Competing Paradigms in Qualitative Research." In *Handbook of Qualitative Research*, Thousand Oaks: Sage Publications, 105–17.

Gudwani, Ayushi, Palash Mitra, Ankur Puri, and Mandar Vaidya. 2012. *India Healthcare: Inspiring Possibilities, Challenging Journey*.

Haddad, M, and K Bozdogan. 2009. *Knowledge Integration in Large-Scale Organizations. Massach*.

Haley, T.G, and U.V Haley. 2011. "The Effects of Patent-Law Changes on Innovation: The Case of India's Pharmaceutical Industry, Technological Forecasting & Social Change." : 607–19.

Hall, Bronwyn H. 2010. The two-edged sword *Open Innovation and Intellectual Property Rights – The Two-Edged Sword*.

Herstatt, Cornelius, Rajnish Tiwari, Dieter Ernst, and Stephan Buse. 2008. E A S T - W E S T C E N T E R W O R K I N G P A P E R S *India's National Innovation System: Key Elements and Corporate Perspectives*.

Hippel, Von E. 1976. "The Dominant Role of Users in the Scientific Instrument Innovation Process." *Reseach Policy* 5(3): 212–39.

Hudson, John, and Alexandru Minea. 2013. "Innovation, Intellectual Property Rights, and Economic Development: A Unified Empirical Investigation." *World Development* 46: 66–78.

Hunter, Jckie. 2011. "Challenges for Pharmaceutical Industy: New Partnership for Sustainable Human Health." *Philosophical Transactions: Mathematical, Physical and Engineering Sciences* 369(1942): 1817–25.

"India's Generic Drug Manufacturers: Poised for Continued Growth." 2016. *Nasdaq*. http://www.nasdaq.com/article/indias-generic-drug-manufacturers-poised-for-continued-growth-cm586029#ixzz49NFoQeFI (May 30, 2016).

Indian Government. *Controller General of Patents, Designs, Trademarks and Geographical Indications*.

IndianEconomy. 2015. "What Is the Difference between Product Patent and Process Patent?" http://www.indianeconomy.net/splclassroom/98/what-is-the-difference-between-product-patent-and-process-patent/ (April 27, 2016).

IndianExpress. 2015. "Cipla Infringing Roche's Patent in Lung Cancer Drug, Says Delhi HC." http://indianexpress.com/article/business/companies/cipla-infringing-roches-patent-in-lung-cancer-drug-says-delhi-hc/4/ (May 10, 2016).

International Trade Administration (ITA). 2010. Pharmaceutical Research *Pharmaceutical Industry Profile*.

IP India. 2010. *Patent : Temporary Injunction – F . Ho Ff Mann-LA Roche Vs . Cipla – Case 8*.

IPIndia. 2016. "Intellectual Property India." *Government of India*. http://www.ipindia.nic.in (June 2, 2016).

Jagadeesh, Harishankar, and Subash Sasidharan. 2014. "Do Stronger IPR Regimes Influence R&D Efforts? Evidence from the Indian Pharmaceutical Industry." *Global Business Review* 15(2): 189–204.

Jensen, Morten Berg, B. Johnson, Edward Lorenz, and Bengt-Åke Lundvall. 2007. "Forms of Knowledge and Modes of Innovation." *Research Policy* 36(5): 680–93.

Johnson, Anna. 2009. Electronic paper at the Nelson and Winter Conference *Functions in Innovation System Approaches*. Aalborg.

Joseph, Reji K. 2011. "The R&D Scenario in the Indian Pharmaceutical Industry." *Research and Information System for Developing Countries*.

Kamien, M., and N Schwartz. 1982. *Market Structure and Innovation*. Cambridge: Cambridge University Press.

Khor, Martin. 2008. *Intellectual Property, Competition and Development*.

Khurana, Meenakshi. 2012. *Cipla Won the Landmark Roche v Cipla Litigation*.

Krishna, V.V. 2001. "Changing Policy Cultures, Phases and Trends in Science and Technology in India." *Science and Public Policy* 28(3): 179–94.

Laino, Antonella. 2011. MPRA Paper No. 35321 *Innovation and Monopoly: The Position of Schumpeter*.

Lee, L. 2008. "Trials and TRIPS-Ulations: Indian Patent Law and Novartis AG v. Union of India." *Berkeley Technol Law Journal* 28(298): 281–90.

Lehman, Bruce. 2003. *The Pharmaceutical Industry and the Patent System*. Cambridge: Cambridge University Press.

Lexology. 2016. *Roche Vs Cipla : Final Leg of Battle over Tarceva Patent*.

Lim, Clarissa. 2013. "INTELLECTUAL PROPERTY ARMY: FIGHTING WARS AND HEALING THE WORLD." *MURDOCH RESEARCH REPOSITORY*: 1–69.

Lindgren. 2010. "From Single Firm to Network-Based Business Model Innovation." *International Journal of Entrepreneurship and Innovation Management* 12(2).

Lizuka, Michiko. 2013. *Innovation Systems Framework: Still Useful in the New Global Context?* Maastricht.

Lundvall, B. Å. 1985. *Product Innovation and User-Producer Interaction*. Aalborg.

Lundvall, B.Å, Björn Johnson, Esben Sloth Andersen, and Bent Dalum. 2002. "National Systems of Production, Innovation and Competence Building." *Reseach Policy*: 213–31.

Lundvall, B.Å. 1992. *National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning*. London: Pinter.

Lundvall, Bengt-Åke. 2007. *Innovation System Research Where It Came from and Where It Might Go*.

Lundvall, Bengt-Åke, and S Borras. 2005. "'Science, Technology and Innovation Policy - Old Issues and New Challenges.'" In *Handbook of Innovation*, eds. Jan Fagerberg, D Mowery, and R Nelson. Oxford: Oxford University Press, 599–629.

Lundvall, Bengt-Åke, and Björn Johnson. 1994. "The Learning Economy." *Journal of Industry Studies* 1(2): 23–42.

———. 2013. "National Innovation Systems." In *Encyclopedia of Creativity, Invention, Innovation, and Entrepreneurship*, ed. Elias Garayannis. London: Springer Reference, 1–7.

Lundvall, Bengt-Åke, K. Joseph, Cristina Chaminade, and Jan Vang. 2009. Handbook of Innovation Systems and Developing Countries – Building Domestic Capabilities in a Global Setting *Handbook of Innovation Systems and Developing Countries*. Glos:

Edward Elgar Publishing.

Luthra, Sonia. 2012. “Healthcare in India: A Call for Innovative Reform.” *The National Bureau of Asian Research*. http://www.nbr.org/research/activity.aspx?id=298 (June 1, 2016).

Magretta, J. 2003. “Why Business Models Matter?” *Harvard Business Review* 80(5): 86–92.

Malerba, Franco. 1999. *SECTORAL SYSTEMS OF INNOVATION AND PRODUCTION DRUID Conference on : National Innovation Systems , Industrial Dynamics and Innovation Policy*.

———. 2002. “Sectoral Systems of Innovation and Production.” *Research Policy* 31(2): 247–64.

———. 2005. “Sectoral Systems of Innovation: A Framework for Linking Innovation to the Knowledge Base, Structure and Dynamics of Sectors.” *Economics of Innovation and New Technology* 14(1-2): 63–82.

———. 2006. “Sectoral Systems: How and Why Innovation Differs Across Sectors.” In *The Oxford Handbook of Innovation*, ed. Jan Fagerberg. Oxford: Oxford University Press, 379–406.

Malerba, Franco, and Sunil Mani. 2009. *Sectoral Systems of Innovation and Production in Developing Countries*. Edward Elgar Publishing Limited.

Mani, Sunil. 2006. “The Sectoral System of Innovation of Indian Pharmaceutical Industry.” *CDS working papers* (September): 1–59.

Marketline. 2015a. *Cipla Limited*.

———. 2015b. *Hoffmann-La Roche*.

———. 2015c. *Natco Pharma Limited*.

———. 2015d. “Pharmaceuticals in India.” : 1–40.

———. 2016a. *Bayer AG*.

———. 2016b. *Novartis*.

Masanell, R, and J Ricart. 2009. “From Strategy to Business Models and to Tactics.” *Harvard Business School*: 10–36.

Maskus, K, and J Reichman. 2005. Cambridge University Press *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*. Chambridge.

Mattke, Soeren, Lisa Klautzer, and Tewodaj Mengistu. 2012. “Medicines as a Service. A New Coomercial Model for Big Pharma in the Postblockbuster World.” *RAND Health. Occasional paper.* Occasional: 1–12.

Maxwell, Alexi, and David Riker. 2014. “The Economic Implications of Strengthening Intellectual Property Rights in Developing Countries.” *Journal of International Commerce and Economics* (62): 1–9.

Media, IAM. 2015. “Indian Companies Remain Worryingly Indifferent about Filing Patents at Home.” http://www.iam-media.com/blog/detail.aspx?g=be7365e8-701c-4c35-9691-382bc9b68ac3 (May 15, 2015).

Menell, Peter S. 1999. *INTELLECTUAL PROPERTY: GENERAL THEORIES*.

Menha, Puja. 2014. “Only 17% Have Health Insurance Cover.” *The Hindu*. http://www.thehindu.com/news/national/only-17-have-health-insurance-cover/article6713952.ece (June 1, 2016).

Merges, Robert. 1988. “Commercial Success and Patent Standards: Economic Perspectives on Innovation.” *California Law Review* 76: 803–76.

Morton, Salt, and G Suppiger. 1942. *U.S. Supreme Court*.

Mudur, G. 2012. “Final Hearings Begin in Epic Legal Battle over Novartis Drug in India.” *BMJ*: 1–2.

N.d. 2012. *Generics Industry Rejoices*.

Natco. 2016. “Our Strengths.” http://natcopharma.co.in/about/our-strengths/ (May 14, 2016).

NDTV. 2016. “India’s New Trademark, Patennt, IPR Policy Explained in 10 Points.” http://www.ndtv.com/india-news/indias-new-trademark-patent-ipr-policy-explained-in-10-points-1405985 (May 25, 2016).

Nelson, Richard, and Sidney Winter. 1982. *An Evolutionary Theory of Economic Change*. The Belknap Press.

Nonaka, Ikujiro. 1994. “A Dynamic Theory of Organizational Knowledge Creation.” *Organization Science* 5(1): 14–37.

Noren, E. 2013. “Difference Between Business Models and Business Strategy.” http://www.digitalbusinessmodelguru.com/2013/02/difference-between-business-models-and.html (April 8, 2016).

North, C. Douglass. 1990. *Institutions, Institutional Change, and Economic Performance*. Cambridge University Press.

———. 1991. “Institutions.” *Journal of Economic Pespectives* 5(1): 97–112.

“Novartis.” 2016. *Google Finance*. https://www.google.com/finance?q=novartis&ei=WONVV8mRHNLisAG53rToBQ (May 6, 2016).

“Novartis Denied Cancer Drug Patent in Landmark Indian Case.” 2013. *The Guardian*. http://www.theguardian.com/world/2013/apr/01/novartis-denied-cancer-drug-patent-india (May 12, 2016).

“NovatrisIndia.” 2016. http://www.novartis.in (May 15, 2016).

OECD. 1999. *Managing National Innovation Systems*. Paris.

———. 2008. *Open Innovation in Global Networks*.

Oguamanam, Chidi. 2009. “BEYOND THEORIES: INTELLECTUAL PROPERTY DYNAMICS IN THE GLOBAL KNOWLEDGE ECONOMY.” *Intellectual Property Law Journal* 9: 105–45.

Osterwalder, A. 2004. *The Business Model Ontology- A Proposition in a Design Science Approach*. Switzerland: University Of Lausanne.

Papageorgiadis, Nikolaos, and Abhijit Sharma. 2016. “Intellectual Property Rights and Innovation: A Panel Analysis.” *Economics Letters* 141: 70–72.

Park, Chan, and Arjun Jayadev. 2011. “Access to Medicines in India Introduction and Background – Patents, Medicines and Access in India.” In *Access to Knowledge in India New Research on Intellectual Property, Innovation & Development*, eds. Ramesh Subramanian and Lea Shaver. Bloomsbury Academic, 78–108.

Pavitt, Keith. 1984. “Sectoral Patterns of Technical Change: Towards a Taxonomy and a Theory.” *Research Policy* 13(6): 343–73.

Peacock, Alan, and Charles Rowley. 1972. “Welfare Economics and the Pulic Regulation of Natural Monopoly.” *Journal of Public Economics* 1(2): 227–44.

Pharmaceutical Sector Inquiry Preliminary Report. 2008. European Commission.

“Pharmaceuticals.” 2012. *Invest India*. http://www.investindia.gov.in/pharmaceuticals-sector/.

Pihlajamaa, H. 2009. *The European Patent Office and the Patent Granting Procedure*.

Policy, Industrial. 2016. *NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY*.

“Poverty & Equity India.” 2016. *The World Bank*. http://povertydata.worldbank.org/poverty/country/IND (May 28, 2016).

PriceWaterhouseCooper. 2009. “Pharma 2020: Challenging Business Models.” http://www.pwc.com/nl/nl/publicaties/pharma-2020-challenging-business-models.jhtml (May 25, 2016).

PWC. 2010. “Global Pharma Looks to India : Prospects for Growth.” *PWC*: 40.

Rajan, Y S. 2012. The Global Innovation Index *Shaping the National Innovation System: The Indian Perspective*.

Ravindran, Sudhir. 2008. *REAL PROPERTY vs INTELLECTUAL PROPERTY*.

Research Method Lecture. 2014.

Robson, Colin. 1993. *Real World Research A Resourcre for Social Scientists and Practitioner- Researchers*. Blackwell Publishing.

“Roche.” 2016. http://www.roche.com/about.htm (May 7, 2016).

Rohracher, Harald, Bernhard Truffer, and Jochen Markard. 2008. DIME Conference 2008 *Doing Institutional Analysis of Innovation Systems: A Conceptual Framework*.

Rosen. 2004. *Intellectual Property*.

Royal Society of Chemistry. 2009. “Pharma Refocuses on the Patent Cliff.”

http://www.rsc.org/chemistryworld/Issues/2009/January/PharmaRefocusesOnThePatentCliff.asp (April 6, 2016).

Saha, Chandra Nath, and Sanjib Bhattacharya. 2011. "Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry." *Journal of advanced pharmaceutical technology & research* 2(2): 88–93.

Samuelson, Paul. 1954. "The Pure Theory of Public Expenditure." *Review of Economics and Statistics*: 387–89.

Scherer, Frederic, and David Ross. 1990. *Industrial Market Structure and Economic Performance*. 3rd ed. Boston: Houghton Mifflin.

Schumpeter, J.A. 1937. *Preface to Japanese Edition of 'Theorie Der Wirtschaftlichen Entwicklung*.

"Science And Technology in India." 2016. *India Brand Equity Foundation*. http://www.ibef.org/industry/science-and-technology.aspx (June 1, 2016).

Science, Technology and Innovation Policies 2013. 2013.

Sen, Nirupa. 2003. "Science and Technology Policy – 2003." *CURRENT SCIENCE* 84(1): 13.

Shao, Ken. 2011. "'Monopoly or Reward? The Origin of Copyright and Authorship in England, France and China and a New Criticism of Intellectual Property.'" *Hong Kong Law Journal* 41: 731–32.

Singh, J. 2007. "Asymmetry of Knowledge Spillovers between MNCs and Host Country Firms." *Journal of International Business Studies* 38(5): 764–86.

Singh, Pratap Bhanu. 2014. "Science Communication in India : Policy Framework." *Journal of Scientific Temper* 2(1&2): 141–51.

Singh, R. 2004. *Law Relating to Intellectual Property (A Complete Comprehensive Material on Intellectual Property Covering Acts, Rules, Conventions, Treaties, Agreements, Case Law and Much More)*. New Delhi: Universal Law Publishing Co. Pvt. Ltd.

Smedley, Tim. 2013. "Patent Wars: Has India Taken on Big Pharma and Won?" *The Guardian*. http://www.theguardian.com/sustainable-business/patent-wars-india-takes-on-big-pharma (May 7, 2016).

"Solving The Drug Patent Problem." 2002. *Forbes*. http://www.forbes.com/2002/05/02/0502patents.html (May 17, 2016).

Sood, Mansi. 2013. *NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA*. Bangalore.

Srinivasan, S. 2007. "Patent Laws : Battling The Glivec Case." *Economic and Political Weekly* 42(37): 3686–90.

Srivastava, Kamakhya. 2012. "India: The 'Tarceva' Patent Case." http://www.mondaq.com/content/author.asp?article_id=207290&author_id=776338 (May 15, 2016).

Stanbrook, M.B. 2013. *Limiting "evergreening" for a Better Balance of Drug Innovation*

Incentives.

Stiglitz, Joseph E. 2008. 57 Duke Law Journal *Economic Foundations of Intellectual Property Rights*.

Sykes, Alan. 2002. "'TRIPS, Pharmaceuticals, Developing Countries and the Doha 'Solution.'" *Chicago Journal of International Law* 3(1).

Syrovatka, Tetyana. 2011. "Shift in Business Models in Pharmaceutical Industry." *Lund University* (June 2011).

Teece, D. 2009. "Business Models, Business Strategy and Innovation Long Range Planning." *Elsevier*.

"The Concept of Intellectual Property." 2016. In *WIPO Intellectual Property Handbook. Policy, Law and Use*, WIPO PUBLICATION, 3–12.

"The GATT Years: From Havana to Marrakesh." 2015. *WTO*. https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (April 27, 2016).

Tidd, Joe, and John Bessant. 2009. 1 Statewide Agricultural Land Use Baseline 2015 *Managing Innovation: Integrating Technological, Market and Organizational Change*. 4th ed. West Sussex: John Wiley & Sons, Ltd.

Tiwari, Rajnish, G Tiwari, A Rai, and B Srivastawa. 2011. "Management of Intellectual Property Rights in India: An Updated Review." *Journal National Science Biology Medicine* 2(1): 2–12.

Vallejo-Alonso, Belen, Arturo Rodriguez-Castellanos, and Gerardo Arregui-Ayastuy. 2011. "Knowledge Flow Audit: Identifying, Measuring and Managing Knowledge Asset Dynamics." In *Identifying, Measuring, and Valuing Knowledge-Based Intangible Assets: New Perspectives*, New York, 22–43.

Wang, Yuandi, Wim Vanhaverbeke, and Nadine Roijakkers. 2012. "Exploring the Impact of Open Innovation on National Systems of Innovation - A Theoretical Analysis." *Technological Forecasting and Social Change* 79(3): 419–28.

Yin, Robert. 2009. *Case Study Research Design and Methods*. 4th ed. ed. Sage Publisher.

———. 2011. 53 Journal of Chemical Information and Modeling *QUALITATIVE RESEARCH FROM START TO FINISH*. New York: The Guilford Press.

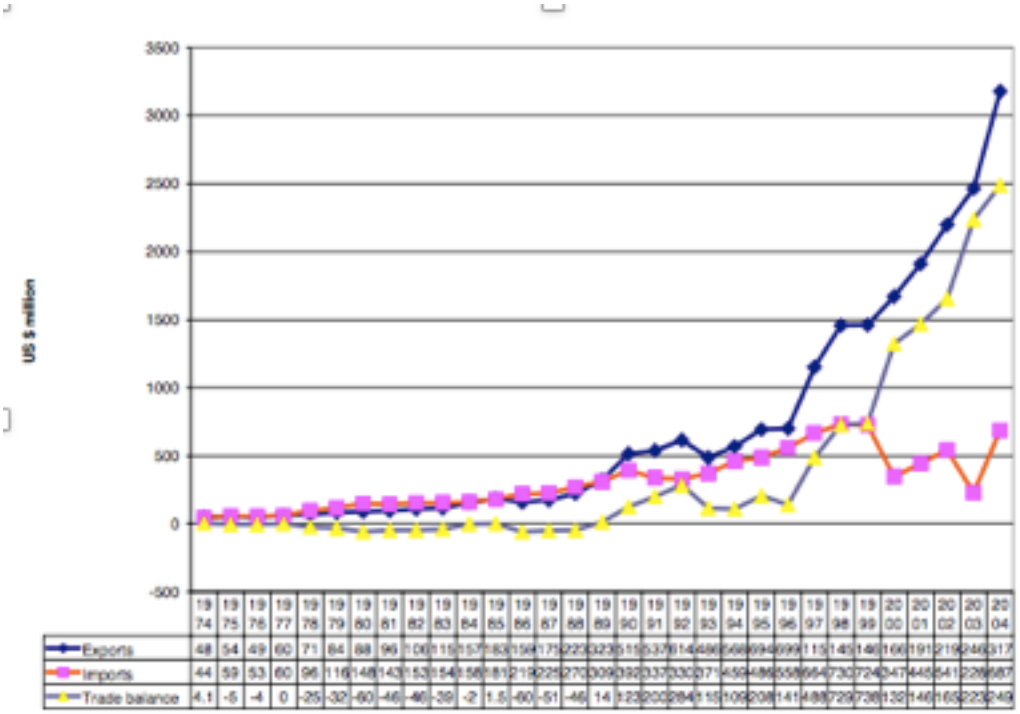
Zambad, Sarika, and B R Londhe. 2014. "To Study The Scope & Importance Of Amended Patent Act On Indian Pharmaceutical Company With Respect To Innovation." *Procedia Economics and Finance* 11(14): 819–28.

Zott, Christoph, Raphael Amit, and L. Massa. 2011. "The Business Model: Recent Developments and Future Research." *Journal of Management* 37(4): 1019–42.

ZydusCadil. 2016. "The Company About Us." http://zyduscadila.com (May 14, 2016).

7. 2. Appendix

Appendix 1: Trends in Trade Balance of Pharmaceutical Products 1974-2004



Source 23: Mani (2006, p. 7)

Appendix 2: India Pharmaceuticals Market value: $ billion, 2010-2014

Year	$ billion	Rs. billion	€ billion	% Growth
2010	8.2	500.0	6.2	
2011	9.5	576.5	7.1	15.3%
2012	10.6	647.8	8.0	12.4%
2013	12.0	731.5	9.0	12.9%
2014	16.0	975.4	12.1	33.3%
CAGR: 2010–14				18.2%

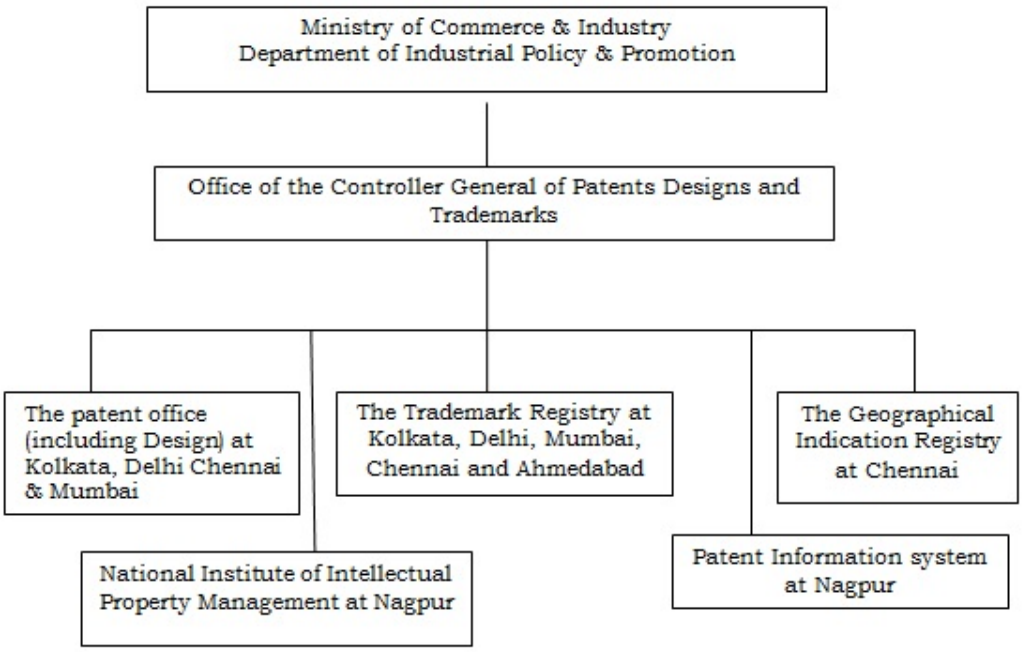
Source 24: Marketline (2015, p. 8)

Appendix 3: India Pharmaceuticals Market Value Forecasts: $ billion, 2014-2019

Year	$ billion	Rs. billion	€ billion	% Growth
2014	16.0	975.4	12.1	33.3%
2015	20.0	1,219.2	15.1	25%
2016	22.7	1,383.0	17.1	13.4%
2017	26.7	1,626.9	20.1	17.6%
2018	30.0	1,830.7	22.6	12.5%
2019	33.4	2,034.6	25.2	11.1%
CAGR: 2014–19				15.8%

Source 25: Marketline (2015, p. 11)

Appendix 4: Organisational Structure of the Indian IPRs Office



Source 26: BRIC (2016)