REFLECTIONS OF THE GLOBAL IMPLEMENTATION OF INTELLECTUAL PROPERTY RIGTHS ON PHARMACEUTICAL POLICIES: THE CASE OF TURKEY

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"Reflections of the Global Implementation of Intellectual Property Rights on Pharmaceutical Policies: The Case of Turkey," a thesis prepared by Nazlı Bülay Doğan in partial fulfillment of the requirements for the Master of Arts Degree at the Ataturk Institute for Modern Turkish History of Boğaziçi University.

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An abstract of the Thesis of Nazlı Bülay Doğan, for the degree of Master of Arts at the Ataturk Institute for Modern Turkish History of Boğaziçi University to be taken in May 2012

Title: Reflections of the Global Implementation of Intellectual Property Rights on Pharmaceutical Policies: The Case of Turkey

This thesis examines how the pharmaceutical policies are affected by the global implementation of intellectual property rights (IPRs) in the era of neoliberal globalization and, in return, how these policies affect the pharmaceutical sector and multinational pharmaceutical companies (MPCs), which are the main actors of this implementation process. For this objective, the study is organized in three chapters where first, the global implementation of IPRs is examined; second, the pharmaceutical policies affected by this implementation are discussed and last, their reflections in Turkey are explored. During the thesis, the literature reviews on IPRs and pharmaceutical policies are reinforced with the examination of sector reports, media scans, press releases and interviews for the aim of studying this dynamic political process. In the particular case of Turkey, the current situation is the result of a long process going back to the 1960s, since when the interests of different actors are facing each other. It is undeniable that the global implementation of IPRs creates a favorable atmosphere for MPCs, affects the domestic sector negatively, and results in increasing public pharmaceutical expenditures. For that reason, the Turkish government has conducted cost containment policies aimed especially at these drugs in question, relying on its monospony position. However, according to another result, there has not yet been a violent confrontation between MPCs and the Turkish government. Moreover, there is a tendency to loosen the tension between them. For that reason, it is believed that the current political situation will be unbalanced in the near future.

Boğaziçi Üniversitesi Atatürk İlkeleri ve İnkılap Tarihi Enstitüsü'nde Yüksek Lisans Derecesi için Nazlı Bülay Doğan tarafından Mayıs 2012'de teslim edilen tezin özeti

Başlık: Fikri Mülkiyet Haklarının Küresel Düzeyde Uygulanmasının İlaç Politikalarına Etkisi: Türkiye Örneği

Bu tezde, neoliberal küreselleşme döneminde ilaç politikalarının fikri mülkiyet haklarının küresel düzeyde uygulanmasından nasıl etkilendiklerini ve bunun karşılığında, bu politikaların ilaç sektörünü ve bu uygulamanın baş aktörü olan çok uluslu şirketleri nasıl etkilediği araştırıldı. Bu amaçla çalışmayı üç bölüme ayrıldı. İlk bölümde fikri mülkiyet haklarının küresel düzeyde uygulanması süreci, ikinci bölümde ilaç politikalarının bundan nasıl etkilendiği ve son bölümde de tüm bunların Türkiye örneğine nasıl yansıdığı incelendi. Fikri mülkiyet hakları ve ilaç politikaları üzerine olan literatürün incelenmesi; sektör raporlarının ve basın açıklamalarının incelenmesi, medya taraması yapılması ve sektörle ilişkili farklı aktörlerle gerçekleştirilen mülakatlarla sağlamlaştırıldı. Çalışmanın sonunda fikri mülkiyet haklarının küresel düzeyde uygulanmasının durağan bir durum olarak düşünülmemesi gerektiği, aksine bunun dinamik bir siyasi süreç olduğu gözlemlendi. Türkiye özelinde, güncel durum 1960'lara kadar giden bir sürecin sonucudur. Bu süreçte meydana gelen birden çok tartışma, farklı aktörlerin çıkar çatışmalarını gözler önüne sermiştir. Sonuç olarak fikri mülkiyet haklarının küresel düzeyde uygulanması çok uluslu şirketler açısından avantajlı bir atmosfer yaratırken, Türkiye'deki yerli ilaç sanayisini negatif etkilemekte ve kamunun artan ilaç harcamalarına sebep olmaktadır. Bu nedenle Türk hükümeti, özellikle son dönemde, ilaç piyasasında neredeyse tek alıcı olmasının verdiği güce dayanarak, söz konusu ilaçlara yönelik bütçe kısıtlama politikaları gütmektedir. Ama bu tez sayesinde ulaşılan başka bir sonuca göre, çok uluslu şirketler ile Türk hükümeti arasında şiddetli bir karşı karşıya geliş henüz yoktur. Hatta ikisinin arasındaki gerilim giderek azalmaktadır. Bu nedenle, mevcut siyasi durumun yakın bir gelecekte değişeceği öngörülebilir.

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CONTENTS

LIST OF ABBREVIATIONS

ACDs: Association Council Decisions
ACTA: Anti-Counterfeiting Trade Agreement
AIFD: Association of Research-based Pharmaceutical Companies
AEO: Ankara Chamber of Pharmacists
DPT: State Planning Organization
FDI: Foreign Direct Investment
FTAs: Free Trade Agreements
GATT: General Agreement on Tariffs and Trade
IEGM: General Directorate of Pharmacy and Pharmaceuticals
IEIS: Employers Union of Pharmaceutical Industry
IEO: Istanbul Chamber of Pharmacists
IPRs: Intellectual Property Rights
MPCs: Multinational Pharmaceutical Companies
PhRMA: Pharmaceutical Research and Manufacturers of America
R&D: Research and Development
SGK: Social Security Institution
TBMM: Turkish Grand National Assembly
TEB: Turkish Pharmacists' Association
TISD: Pharmaceutical Manufacturers Association of Turkey
TOBB: Union of Turkish Chambers of Commerce and Industry
TRIPS: Trade-Related Aspects of Intellectual Property Rights
TTB: Chamber of Medical Doctors
TUSIAD: Association of Turkish Industrialists and Businessmen
USTR: United States Trade Representative
WHO: World Health Organization
YISD: Local Pharmaceutical Manufacturers Association

CHAPTER I: INTRODUCTION

The main problematic of this thesis is constructed on the question of how the pharmaceutical policies are affected by the global implementation of intellectual property rights (IPRs) in the era of neoliberal globalization and, in return, how these policies affect the pharmaceutical sector and multinational pharmaceutical companies (MPCs), which are the main actors of this implementation process. To understand the global mechanisms of the political economy of our day, this subject seems more illustrative than any other subject could be. First, it is attractive because it is about a universal issue, health, which we all share without distinction. Second, it is an important subject not just because of the size of the pharmaceutical sector in the global economy, but also because of its centrality as a political project. Through the strict protection regime of IPRs on the global scale, we are all convinced that we must not "steal" others' knowledge because to protect knowledge is a "right" while producing the knowledge or using it are secondary rights.

Outline of the Chapters

The approach in which the exploiter of knowledge is favored at the expense of creators and users can be overcame by a theoretical discussion, because the implementation of this idea was realized in the theoretical realm. For that reason, the second chapter of this study, which is dedicated to theoretical discussions and to the legal structure of this implementation, is crucial. As was stated above, it is the basis on which all the study is constructed. Another importance of this chapter is related to my personal interest for theoretical debates, which became sources of radical

opposition worldwide, like in the cases of India, South Africa and Brazil. In sum, it was the departing point of this study. This chapter is also essential to understand the case of Turkey, a case that does not seem to call to mind these discussions occurring worldwide, related to the lack of such radical opposition in Turkey. It is only after a detailed analysis of what is happening worldwide about the global implementation of IPRs in the pharmaceutical sector that the hidden resemblances between the global situation and the exception like the situation in Turkey will be observable.

After the comprehension of these theoretical discussions, their reflections on the political realm had to be examined. As the subject is the health issue, the state is an important part of the study. This role attributed to the state is more precise and effective than its shadowlike presence in the second chapter. In the third chapter, the leading part belongs to the state through its pharmaceutical policies, which are more comprehensive than one might think before such an examination of the issue. The pharmaceutical policies of a country are not related just to the health issue, but also have deep relations to its commercial and industrial policies. However, a detailed analysis of these other policies is beyond the limits of this thesis. Especially, this study can be criticized for not giving sufficient attention to the role of industrial policies in terms of pharmaceutical policies. Still, it is necessary to remember that pharmaceutical policies are made within this larger framework.

The third chapter is dedicated to the pharmaceutical policies, which have been shaped with the global regulation of IPRs, and have another importance for the general structure of this thesis. The policies examined in this chapter will act as guidelines for understanding the policies in Turkey. Through them, a comparison between the pharmaceutical policy examples studied in this chapter with the ones in Turkey will be realized.

For that reason, the examples chosen in this chapter are from countries whose pharmaceutical policies are not so different from those of Turkey, even there are major differences, as is observed during the examination. For example, the United States (US) is not chosen as an example to examine in this chapter because of its exceptionality related to the quasi-absence of the state in pharmaceutical price regulations. Including Turkey, many states try to make pharmaceutical policies to regulate pharmaceutical prices as part of cost containment and cost curtailment principles. On the other hand, examples like the United Kingdom (UK) and Germany are chosen because they constitute useful instruments for the examination of Turkey. This is not because they resemble to the Turkish case closely; on the contrary, they are different from Turkey, especially in terms of the structure of the pharmaceutical sector. Both European countries are famous with their powerful domestic pharmaceutical sector from which have emerged powerful multinational pharmaceutical companies, while Turkey has a weak domestic sector dominated by these companies. For that reason, it can be argued that the selection of different European countries like Italy, Spain, Portugal or Greece would be more helpful, not just because of the resemblance of their pharmaceutical sector, but also because the pharmaceutical policies of these states will be decisive for Turkey, as will be seen in the fourth chapter about Turkey.

The selection of the UK and Germany has other reasons. The pharmaceutical policies of these two states are considered as ideal-types, which soon will become models for other countries. As the objective of the third chapter is not just to realize comparisons, but also to understand the general tendencies in pharmaceutical policies shaped with the global implementation of IPRs, the UK and Germany are better examples that realize these two objectives at the same time.

While studying other examples chosen from outside of the Europe, there are other difficulties. First, these examples are not examined in terms of all aspects of their pharmaceutical policies during the thesis. They are bunched together with a thematic concern rather than their resemblance or their difference within themselves or with the Turkish case. Even though there are resemblances through the development of their pharmaceutical sectors, like the one between Brazil and Turkey or through the public health expenditures like the one between Thailand and Turkey, there are also different examples, like India, which can be considered like an ideal type for states construct pharmaceutical policies on aggressive bargaining tools. However, as said before, these differences do not constitute an obstacle. On the contrary, they give the opportunity to see the place of Turkey within all these different examples worldwide.

Second and third chapters are instrumental in constructing an understanding of the Turkish case. The fourth chapter is exclusively about Turkey. However, it does not mean that the fourth chapter is an isolated chapter from the preceding ones. On the contrary, it has deep relations with the theoretical chapter and with the comparative chapter about pharmaceutical policies. The data from the Turkish case are processed with the examinations realized in these former chapters to constitute a comprehensive study. Different from the other chapters constructed with thematic distinctions, this chapter is divided into historical periods, which correspond also to thematic breaking points. Moreover, in this chapter, not just the period of the global regulation of IRPs, but also the previous history of this period is explained. This choice of categorization creates its own obstacles, like the necessity of examining different aspects of a period under the same section or to separate a continuing process into more than one section. However, a thematic distinction would be more

difficult to handle because all themes are so closely linked that it would be impossible to separate one from another.

The chapter on Turkey is divided in two parts. The first part is about the period before the era of neoliberal globalization and before the discussions of the global implementation of IPRs. The second part is about discussions on this implementation and their effects on pharmaceutical policies. Each discussion constitutes the heart of a specific period. However, the developments examined in these discussions are not taken as sporadic events, but studied from a larger perspective together with the reasons of the process before the discussion and with their effects on the sector and on the pharmaceutical policies after the discussion.

Objectives of the Thesis

Through these chapters, the aim is to try to observe how the process of the global implementation of IPRs in the pharmaceutical sector in Turkey is realized and how the Turkish pharmaceutical policies in the reflection of this process are affected. Another objective is to periodize the characteristics of the Turkish case and, with the aid of the second and the third chapters, to examine the resemblances and the irregularities of the Turkish case with the global political economy, departing from these characteristics. Last, there will be an attempt to define the reasons of these irregularities within the national and if related, within the international contexts.

In this framework, some of the basic questions that will be asked are: how the patent protection is emerged as a political project and how it is reflected in the pharmaceutical policies of different countries where the patent protection is accepted. Looking to the Turkish experience, it will be asked if the examination of the non-

patentability period can be an answer to the irregularity of the case, if the reaction of local actors can be read as the direct reflection of the global political project of the patent protection and if there is a confrontation between MPCs and the Turkish government, is it in the same nature as it is witnessed in other countries. All these questions will lead to the uniqueness of the Turkish case.

Research Methodology

To realize these objectives, a two-sided research methodology was implemented. There is not much to say about the theoretical data, which were found from different books and articles. However, for the empirical data used mostly for the recent periods of the fourth chapter, it can be said that the source material was plentiful. From the examination of legislatures to press releases of the different associations of the sector and to media reports, data can be found from a large range of sources.

However, I encountered some difficulties during the fieldwork that must be mentioned here. Even though the interviews could have had a much bigger place in this study, it was not possible because of the secrecy of the pharmaceutical companies. Finding useful data from interviews, if an interview could be conducted, was almost impossible. For that reason, the target group was changed to state offices, more precisely, to the General Directorate of Pharmacy and Pharmaceuticals (IEGM). This time, the obstacle was that the civil servants of IEGM did not want to go beyond the official discourse. In sum, the most helpful interviews for the study were the ones conducted with the Istanbul and Ankara Chambers of Pharmacists. The interviews conducted with pharmaceutical companies and state officers just helped to

make me familiar with the conflictual context of the end of 2011 and observe which issues are important for these different actors.

The difficulties of the fieldwork were accented with other difficulties related to the subject itself. First, there was an obstacle related to the process of pharmaceutical policies in Turkey. Similar to what Mossialos, Walley and Mrazek (2004: 9) remark in their study on European pharmaceutical policy processes at the beginning of the 2000, the quasi-experimental condition of the Turkish pharmaceutical policies in 2011-2012 creates a methodological difficulty. To be able to study a policy process, one must know the before and the after of this policy. However, in this situation, there is no such "after" from which the clear effects of these pharmaceutical policies can be observed.

Another difficulty is related to a characteristic intrinsic to the issue. Because of the many mergers and acquisitions that occur in the pharmaceutical sector, it is not easy to follow the line of a single company in different periods. An infant company could be formed of a merger of older companies while an old company can be effaced from the sector in favor of another one, which acquired the former. These changes occur not just on the global scale, but also on the national level in the Turkish pharmaceutical sector. For these reasons, one must be very careful to analyze the situation of companies in the sector.

Terminology

There are some frequently used concepts that must be explained before the beginning of the study. One of them is "neoliberal globalization", which is used to describe the present era. The qualification of "neoliberal" for the process of

globalization is necessary to distinguish it from other historical types of globalization. This globalization that has developed since the end of the 1970s can be considered in the fusion with the neoliberal ideology. This change in the global political economy deeply affects government policies, including health policies. For some thinkers, neo-liberal policies consist mainly of a decrease in the intervention of the state (Duménil and Lévy, 2005: 2) and a reduction of barriers in favor of the unconstrained movement of capital (Harvey, 2006: 11). For that reason, it is not surprising to find the welfare state and the developmentalist state as the main targets of the defenders of neoliberal policies.

The notion of "the welfare state" that is used mostly in the third chapter is a beneficial notion to compare the current period of neoliberal globalization with the former period. Together with neoliberal globalization, they serve to enlighten the reasons for the sudden increase in the pharmaceutical expenditures of different states and the change in their pharmaceutical policies in the post-1980 era. The welfare state is a post-war institution, which diverges from other institutions of state with its capacity to de-commodify the status of citizens through social rights. As Esping-Anderson (1990: 3) writes, citizens can "make their living standards independent of pure market forces".[1] Mainly, the welfare state is seen as the social protection "sheltering all income streams" from market pressures (Schwartz, 2001: 17-18). Its aim is to "protect the vulnerable from the vagaries of the market" (Polanyi, 1944 as cited in Giaimo, 2001: 334). However, there is also an approach that differentiates between the welfare state and social protection. In this approach, social protection is defined as the protection of the service sector, especially to protect the national companies of the service sector from global competition. From this perspective, its

[1] For this point, I must thank to A.Kartal Scifo, who shared her dissertation draft with me.

supporters argue that it is not the welfare state but the social protection that has been affected negatively by the deregulation and marketization of the service sector in the post-1980 globalization (Schwartz, 2001: 18). Whatever the approach, it is undeniable that the construction of recent pharmaceutical policies is deeply related, positive or negative, to the former welfare policies in terms of the health issue and pharmaceuticals.

The last notion that will be discussed in the introduction is the categorization of countries as "developed" and "developing". This categorization was a subject of uneasiness from the beginning of this study because with this categorization, it is accepted implicitly that there is a hierarchy between countries. However, as it is used in many sources profited, including legislatures like the important agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPs), and because I was not able to replace it with another categorization, it was left like this. The solution was found in the introduction of a Ph. D. (Kılıç, 2011: 19) about a similar subject. In this study, the use of this categorization is explained with the condition of pharmaceutical industries in related countries, instead of the general meaning of these concepts. Similar to the use of Kılıç, in this thesis too, the concepts of "developed" and "developing" are used to differentiate between countries having a strong pharmaceutical industry and those having a pharmaceutical industry, but not in the same degree of industrialization as the preceding ones.

After this introduction, the examination of the mechanisms of the global political economy of pharmaceuticals in the case of Turkey will begin.

CHAPTER II: INTELLECTUAL PROPERTY IN THE ERA OF NEOLIBERAL GLOBALIZATION

The aim of this theoretical chapter is to understand the background of the notion of intellectual property rights (IPRs). Although it seems like a distant and very technical notion that exists in legal documents alone, paradoxically, it is a notion that has deep impacts in our lives. Taking the example of this study, the pharmaceutical sector is one the vital areas in which the impacts of IPRs are obvious. It is a controversial subject, not just because health is a delicate issue that we are not yet accustomed to accepting within the bare framework of market relations, but also because pharmaceutical IPRs are an increasing source of burden for the governments of many countries that try to balance their health expenditures with the health care demands of their population.

Looking at other examples of IPRs, like software, music industry or seed issues, we always see that, even though they are not as striking as in the pharmaceutical industry, they all have deep impact on our everyday lives. We all use the internet, listen to music and consume seed-based foods. The excessive growth of all these industries based on information and knowledge resources shows that IPRs are becoming increasingly more central elements of capitalism. For some thinkers, it is the replacement of modern industrial society by an information society (May, 2010: 1). The reason of the centralization of IPRs-based industries is whether this change of the structure of the society or just the economical needs of the capitalism system, IPRs become more and more one of the essential elements of neoliberal globalization.

This chapter will follow the traces of IPRs from their rise in a specific economic context to their diffusion on the global scale with an extreme influence. This chapter is the foundation on which the whole study will be constructed. It is written as concentrated as possible because even in the small details that will be examined during the fourth chapter about the discussions in Turkey, there are references to this second chapter in which the theoretical background of IPRs together with the historical process of its implementation in the era of neoliberal globalization are examined.

This chapter has three main sections. It begins with the central place of these IPRs in the global political economy. After this general presentation, the pharmaceutical sector is analyzed especially through the multinational pharmaceutical companies (MPCs), which are the symbolic castles of this IPRs regime. In the last section, some of the important international agreements related to IPRs are discussed to better understand the functioning of this system.

The structure of this chapter will be like a funnel. I will set off with the large concept of property to arrive at a relatively narrow concept of intellectual property rights and then, to the concretization of this IPRs regime with the example of pharmaceutical sector. For that reason, it must be noted that when international agreements are discussed in the last section, even though they are part of a larger context related to different form of IPRs, the interest will be limited to their aspects related to health issues.

The Centrality of Intellectual Property Rights in the Global Political Economy

To understand the centrality of intellectual property rights in the global political economy, how IPRs can be a useful tool for the permanence of the capitalist system will be examined. In the first part, IPRs from the perspective of a world-system analysis will be discussed, alongside the discussions of a new imperialism or the dominance of transnational capitalist class. In this way, the aim is to understand the reasons of the commodification of knowledge and of intellectual creativity through IPRs and to observe how they are used as a response to the continuing crisis of capitalism. In the second part, the ways in which IPRs are legitimized for this process of commodification, will be examined. Because of the nature of the justifications used for the legitimization process, some of the justifications of the material property must be mentioned, along with the justifications of intellectual property.

"Constructed Scarcity": The Instrumentalization of Intellectual Property Rights

The rise of IPRs in the global economy can be traced back to the 1970s when the capitalist system underwent a deep crisis of overaccumulation. One of the solutions formulated to deal with this crisis was a process of what Harvey (2005) calls "accumulation by dispossession". According to Harvey, accumulation by dispossession releases "a set of assets at very low cost" in order that "overaccumulated capital can seize hold of such assets and immediately turn them to profitable use" (Harvey, 2005: 149). This is very similar to the process of "primitive accumulation" (Marx, 1887). As occurs in the process of primitive accumulation,

various forms of property rights, like common, collective or state property rights, are converted into exclusive private property rights for the creation of capitalist surplus (Harvey, 2005: 145).

Similar to this conversion, in neoliberal globalization, IPRs are constructed as exclusive private property rights. As May emphasizes, the protection of IPRs is based on the protection of "the rights of the owners who exploit the intellectual property which are seen as being of most importance, rather than the rights of those who might originate intellectual property in the first place or those who would use it" (May, 2010: 53). For this reason, the implementation of IPRs can be considered as a new mechanism of accumulation by dispossession (Harvey, 2005: 147; Zeller, 2008: 87). They serve to valorize the monopolistic intellectual property to be commodified in the hands of the capital (Zeller, 2008: 87). In this framework, it is not the inventors (scientists), or users (patients) who have rights; only the companies that instrumentalize these rights for economic gain are favored.

There are other theories about the commodification of knowledge. Borrowing the concept of "fictitious commodity" from Polanyi (2001), it can be said that knowledge is a fictitious commodity like labor, land and money, because even though it is a commodity that is present in the market, it is not produced for sale. But it is also true that, in some cases, knowledge can be seen as a quasicommodity or a real commodity (Jessop, 2007: 125). The degree of commodification changes according to the purpose of the production. It is not wrong to say that there is a tendency towards the real commodification of knowledge as long as IPRs continue to hold their position at the center of the global political economy.

Now, how this instrumentalization of IPRs within the neoliberal project is constructed must be asked. The main answer to this question lies in the concept of

"constructed scarcity" (May, 2010). Knowledge is not a formally scarce resource; a knowledge scarcity must be constructed through commodification (May, 2010: 64). IPRs serve this purpose of constructing scarcity. In this way, knowledge can be used to obtain a charge rent for use, a right to receive compensation for loss and an ability to transfer its rights to another actor in market relations (May: 3). It must be added that there is a close relation between constructed scarcity and rent. According to Zeller (2008: 98), "The rent is a result of a systematic shortage of supply created by the property monopoly of the supplier of a key product, which encounters no direct competition from substitution goods." For that reason, "the more inelastic the demand reacts to price increases, the larger the rent. If substitution goods exist, the demand is more elastic and thus the monopoly rent smaller" (Zeller, 2008: 98). After seeing this relation, now it is easy to see the bond between intellectual property and the idea of rent (Zeller: 106). This enclosing of knowledge is a perfect example of the penetration of capitalism into previously non-commodified social relations (Harvey, 2005 as cited in May, 2010: 11). For all these points mentioned, Zeller claims that "the current phase of imperialism corresponds to an era of political power of finance and rent-bearing capital" (Zeller: 110).

This construction of scarcity for the purpose of the commodification of knowledge is a legal construction. States are the main actors of this legal construction through international institutions. Opposed to the general belief, this situation shows that "states, rather than being the passive victims of globalization, have been its authors and enforcers" (Panitch and Gindin, 2005: 101). More clearly, as says O'Riain, globalization makes "the state more important as an effective state becomes critical to promoting competitiveness within a global economy" (O'Riain, 2000: 202). He adds that even though states are always important actors of the global

political economy, “neoliberal institutions are the dominant force shaping the relation between states and markets” in the era of neoliberal globalization (O’Riain, 2000: 187). According to Gill (2005: 128), this new process of regulation can be called as “new constitutionalism” where international institutions are used to build legal foundations for a neoliberal market order.

For some thinkers, these international institutions work for the interests of transnational capital, a class constituted of “the transnational fractions of the national capitalist class in advanced capitalist countries with the now ascendant transnational fractions in the Third World playing the role of junior partners” (Chimni, 2004: 4). For others, international institutions represent the dominance of American power (Panitch and Gindin, 2005: 112). These two opinions converge on the position of Third World states. They both agree that these states are in a disadvantageous position from which a loss of legitimacy towards relevant institutions and towards the dominant power behind these institutions can emerge (Panitch and Gindin, 2005: 123).

Another answer to the question of how the instrumentalization of IPRs is constructed for the neoliberal project can be found in the redefinition of intellectual property as a trade issue (Sell, 2003: 7). Through international institutions, Anglo-American corporate and trade law is diffused to the entire world (O’Riain, 2000: 206). In the second part about the legitimization of IPRs, different justification attempts of this relation of intellectual property with free trade will be explained in detail.

The Legitimization of Intellectual Property Rights

The legitimization of IPRs is a necessary step for the diffusion of the "neoliberal *doxa*" (Wacquant, 1999: 319). Borrowing this useful concept from Wacquant, it can be argued that the discourse based on the supremacy of IPRs is a hegemonic discourse serving the interests of the transnational capital class that was mentioned in the first part. This fact can be understood by asking the question of "whose norms are being globalized" (Halliday and Osinsky, 2006: 451). As said before, similar to the process of primitive accumulation, in the neoliberal agenda too, private rights are privileged over collective social and economic rights (Chimni, 2004: 11). The private corporate actor becomes the most powerful actor of the processes of global law making, even though states are still apparently dominant actors. However, as will be seen below in detail, most of the global legal norms that have binding elements, are constructed without taking into account the socio-economic context of the world apart from developed countries (Chimni, 2004: 18).

From this perspective, it is understandable that there must be a considerable and continuing effort to legitimize politically the protection of IPRs (May, 2010: 50). There are three main arguments for the legitimization of intellectual property rights, inspired from the history of the justification of material property rights. One is the instrumentalist theory, based on the Lockean justification that property is a natural right, which is the fruit of an individual's own labor (Locke, 1975). In this idea, property is considered the reward of the labor. Applying this idea to the domain of intellectual property, the defenders of IPRs argue that "new ideas will only be produced if the labourers of such creations are duly rewarded by receiving the benefit of such initial ownership when intellectual goods are exchanged" (May, 2010: 27).

However, they miss a point when they benefit from this justification. According to Locke, an individual can enclose a common as his/her property if there is enough good left for others, so that it will not harm the public good (Spinello and Tavani, 2005: 8-9). In the case of intellectual property, it can be argued that the scarcity constructed for the purpose of the commodification of the intellectual property and the accumulation of these rights in the hands of transnational monopolies can create a harmful situation for the rest of the world, as will be observed below, in the example of multinational pharmaceutical companies (MPCs).

Another justification found in the history of material property is the idea of Hegel. In his idea, property is the self-actualization of the individual. It is the channel through which one may express oneself and therefore, one may be free (Spinello and Tavani, 2005: 11). Once again, the use of this justification in the case of the protection of IPRs can be objected to because, as was seen in the first part, from today's global protective regulation of IPRs, what is emphasized is not the rights of the creator but especially the rights of the ones; what May describes as "who control the means of production which can take advantage of such knowledge for the accumulation and reproduction of wealth" (May, 2010: 57).

Last, according to the justification of the pragmatic argument, the construction of property rights is based on the principle of efficiency (May, 2010: 31). In this view, the knowledge of future ownership is an incentive for individuals to create more, which would be a beneficial development not just for this individual but also for the public good (Spinello and Tavani, 2005: 14). For that reason, economic development and social welfare can be realized just through the private ownership of knowledge as property (May, 2010: 87-88). The objection to this justification may come from many different industries based on IPRs. Taking the example of this

study, on the pharmaceutical industry, it can be said that it is not that easy to argue that the protection of IPRs is an effective incentive for the development of intellectual creativity, which is useful for the public good (Boldrin and Levine, 2008: 227-229).

On the other side, for the aim of legitimizing IPRs, as said before, in the global political arena, there is a huge effort to link this concept of IPRs to the trade issue. From a perspective of what Sell (2003: 17) terms a "radical free-market agenda", the protection of IPRs is represented as a central component of free trade, in a total opposition to the dominant opinion of free trade supporters a century ago (Sell, 2003: 186). According to this view, the constructed scarcity of knowledge through the protection of IPRs is a way to ensure what May (2010: 41) describes as the "availability in the public domain" by protecting private rights of owners of the knowledge. It is the way to introduce the protection of IPRs as for the general interest, instead of the interests of a certain group (May, 2010: 34). Against this view, some thinkers argue a liberal approach, according to which monopoly rights are not effective tools for the efficient performance of markets (Boldrin and Levine, 2008). However, this approach ignores whether knowledge is appropriate to market relations or not in the first place (May: 57). It must always be remembered that knowledge is a cumulative product that needs as much as freedom of diffusion possible to develop (Zeller, 2008: 106). Related to this issue, there is a well-known discussion about the inconveniences of the strong protection of IPRs for the production of knowledge. This point will be discussed in the context of IPRs in the pharmaceutical industry.

In concluding this section about the centrality of intellectual property rights in the global political economy, a point that I have neglected until this moment is that

the enforcement of global regulation of IPRs is a neoliberal project born especially thanks to the efforts of the private sector of the US. Once again, it must be said that details of this subject will be discussed in the following section. However, at least it must be mentioned that, for some thinkers, this trade linkage concept between intellectual property and trade is a concept found by some of the powerful agents of the US private sector as a solution to the problems of the US government, like the burgeoning trade deficit and its inability to effectively compete in the international arena (Sell 2003: 99). Now, in the section about pharmaceutical industry, there will be the chance to examine all these subjects with more concrete details.

A Perfect Example of "Knowledge Cartels": Multinational Pharmaceutical Companies

As many other "knowledge cartels" (Maskus and Reichman, 2004: 295 as cited in May, 2010: 108) of the neoliberal period, multinational pharmaceutical companies (MPCs) are powerful actors of the global political economy of IPRs. This power is the outcome of the search for solution to some of the structural needs of the sector. In the first section about the structure of the global pharmaceutical sector, these different needs and different solutions found against these needs will be observed after examining the general condition of the sector after the 1980s. The second section will examine why the strong protection of IPRs is a vital political act for the survival of MPCs.

The Structure of the Global Pharmaceutical Sector

The pharmaceutical sector is a large-scale one, known to be one of the most profitable sectors for a very long time. For example, in the economy of the US, it has been the leading sector for almost twenty years (Boldrin and Levine, 2008: 226). In 2003, the profits of the pharmaceutical companies of the US were approximately three times that of other industries (Semin and Güldal, 2008: 390). However, these figures must not convince us to think that this is a monolithic sector. There are different types of companies at the local and global levels with specializations in the main categories of research and development (R&D), generic drugs or over-the-counter (OTC) drugs. For some cases, a pharmaceutical company can have different branches specialized in more than one of these categories. Many thinkers adopt a careful approach and avoid using the term of "monopoly" to characterize the structure of the global pharmaceutical sector for the reason of that multitude and diversity. However, it must not be forgotten that multinational pharmaceutical companies (MPCs) that are mostly "proprietary pharmaceutical companies" (Muzaka, 2009) are the main actors, which rank at the first place within the sector. It also must be added that most of these powerful actors of the global political arena exist in the pharmaceutical sector since the second half of the 19th century. Pfizer, Merck, Eli Lilly, Squibb of now Bristol-Myers Squibb, Ciba and Sandoz of now Novartis, Bayer, Hoescht of now Aventis are some of the companies, which were established in the 19th and which are the leading companies of the 2000s (Hira, 2009: 86-87).

As can be seen in the figures below, global pharmaceutical sector is not just a profitable sector of the past, but it is also a fast developing giant sector. The sales of

prescribed drugs (patented and generic drugs) have increased from US$188 billion in 1992 (Vickery and Tarabusi, 1999: 14) to US$364 billion in 2001 (Busfield 2003: 581), and to US$712 billion in 2007 (Abacıoğlu, 2010: 200). In just one year, from 2008 to 2009, the pharmaceutical market grew from US$781 billion to US$808 billion with an annual growth of 3.5% (IMAP, 2011: 3). In 2010, global sales reached to US$850 billion (Pharma.about.com, 2012). Compared with the modest figures of the Turkish pharmaceutical market, these global figures seem enormous. In Turkey, the pharmaceutical market size was 13.8 billion TL (IEIS.org.tr, 2012), approximately US$7.84 billion, in the same year (2010). It is smaller than 1% of the global market.

Even though there is a multitude and diversity, one of the most striking features of the pharmaceutical sector is its concentration tendency, which exists not just in the case of production, but also in consumption. In 1990, more than 70% of the worldwide production and also consumption were realized in OECD countries (Vickery and Tarabusi, 1999: 14). In 2001, the tendency continued with growing numbers; pharmaceutical sales in North America, Europe and Japan added up to 87% of world pharmaceutical sales (Busfield, 2003: 601). This situation has had a dramatic outcome; most drug companies, especially the top ones, tend to produce drugs against chronic but not fatal health problems commonly seen in the developed world instead of drugs against diseases seen in developing countries (Busfield : 598-599). Cancer and so-called lifestyle drugs like the ones against obesity, balding, and erectile dysfunction are popular research areas of the sector (Sell, 2007: 51).

On the other side, on the side of the production, the tendency towards concentration is also quite visible. Muzaka states that the share of global sales of ten leading companies, all proprietary MPCs, increased from 12% to around 50%

between late 1980s and the early 2000s (Muzaka, 2009: 291). In detail, it can be seen that in 1995, ten leading companies constituted approximately 36% of worldwide sales (Vickery and Tarabusi, 1999: 24) whereas in 2000, the figure increases to 45.7% (Busfield, 2003: 586), and to 47.8% in 2003 (Hira, 2009: 86). In 2008, their total share decreased to 39.5% with US$308.5 billion (Deloitte, 2009: 6) of US$781 billion.

The concentration tendency until the beginning of the 2000s can be explained by many different factors. One of them is linked directly to the nature of the pharmaceutical sector. The high risk level, which takes its source from the long and expensive testing processes and the long-term returns because of the period before a drug can enter the market are important reasons for the elimination of small companies for the benefit of MPCs (Hira, 2009: 87).

Another reason for this concentration in the pharmaceutical sector is related to the global patent regime. The enforcement of IPRs is surely a condition preferred by MPCs. However, it must be remembered once again that the pharmaceutical sector is not a monolithic one. For that reason, it is true that there are actors who take important advantages from this patent regime, but there are also disadvantaged inside the pharmaceutical sector. MPCs and their licensee companies can be counted among the advantageous ones. On the other side, generic pharmaceutical companies and small research-based companies are definitely among the disadvantaged of the patent regime. The reason is quite simple. The strong protection of IPRs creates a global pharmaceutical sector in which the research-based manufacturers are favored.

As will be observed in the following part about the importance of IPRs for the pharmaceutical sector, actors from MPCs are the dominant powers behind the construction of this patent regime. However, this huge opportunity to make immense

gains based on royalty rents, which mean rents based on patent returns, creates problems not just for generic manufacturers but also for research-based manufacturers. In this regime of IPRs, acquiring a patent, defending it from other competitors and asserting it in courts are so expensive that only large companies, obviously MPCs, are capable of using this opportunity (Dutfield, 2009: 45). For that reason, together with relaxed anti-trust enforcement policies and expanded property rights, the life sciences industries has become one of the most concentrated sectors of the world in the aim of overcoming difficulties and obtaining immense gains (Sell, 2007: 50).

However, as it is shown in the ratio about the sales of ten leading companies in 2008, during the 2000s, there has been a declining tendency of concentration in the sales figures of leading companies. This is the result of the growth of the generic market, which emerged due to many patent expirations, so-called "patent cliff" (IMAP, 2011: 3-4), and thanks to the interest of several governments from different countries in containing health care expenditures through generic drugs (Muzaka, 2009: 293). The result of this growth was the interest of the MPCs in the generic market.

It also must be remarked that the concentration in the pharmaceutical sector is a process that has had different characteristics during different periods. For example, in the first wave of concentration, most of the mergers and acquisitions were between the research-based companies of developed countries. These methods have been dominant in all periods of the history of the pharmaceutical sector; however, since the late 1980s, there has been an increase in the dimension of these mergers and acquisitions. Between 1988 and 1992, there were a total of 226 mergers and acquisitions, worth a total of US$13.1 billion. These movements were between

companies of Europe and the US (Vickery and Tarabusi, 1999: 47). Since the beginning of the 1990s, alongside many acquisitions realized by the leading companies, also mergers begin to be realized between the leading companies of the sector (Busfield, 2003: 585). From the late 1980s to the early 2000s, there are many examples of important mergers and acquisitions realized between leading companies like the mergers between Bristol Myers and Squibb in 1989, Glaxo and Burroughs Wellcome in 1995, Pharmacia and Upjohn in 1995, Zeneca and Astra in 1999, Hoescst and Rhône Poulenc in 1999, Glaxo and SmithKline Beecham in 2000, and Pfizer and Warner-Lambert in 2000. There were also important acquisitions like the acquisition of DuPont Pharmaceuticals by Bristol-Myers Squibb in 2001 and the acquisition of Pharmacia by Pfizer in 2003 (Busfield, 2003: 587). In 2004, the trend of mergers continued with the merger of Sanofi and Aventis, while the biggest acquisitions are those of Wyeth by Pfizer and Scherring Plough by Merck in 2009 (Deloitte, 2009: 16). These examples are worth mentioning because, in this way, the concentration tendency in the pharmaceutical sector can be observed clearly.

Always in this first wave of concentration, licensee agreements were traditional for the pharmaceutical sector. The MPCs used this method to enter smaller markets. Licensee agreements can be seen as a prologue to foreign direct investments (FDIs) (Vickery and Tarabusi, 1999: 55-56). FDIs became more common after the global enforcement of IPRs on different states through binding international agreements.

However, especially with the 2000s, the concentration of the pharmaceutical sector took a different shape. Instead of intra-movements, proprietary MPCs turned towards the generic manufacturers. This change has had important political consequences. After this tendency of MPCs towards generic market, the MPCs have

begun to be dominant in this market, too. Therefore, there has been a renouncement of their ideological aggression towards generic drugs. In this second wave, the distinction between research-based and generic drug manufacturers has become more and more blurred with the acquisitions of and joint ventures with generic companies by proprietary MPCs with concerns about patent expirations.

In some other cases, MPCs prefer to develop their own department of generic drugs (Muzaka, 2009: 290-291). In this way, the generic department can develop the generic version of an original drug of the same company without any conflict of interest that other generic companies confront frequently. The example of the merger between Ciba and Sandoz in 1996 is a good one for the case where a research-based company merges with a generic drugs manufacturer to form another powerful MPC, Novartis in this case (Busfield, 2003: 587). Before this tendency, the MPCs mostly chose the strategy to delay the introduction of generic companies to the market to impede the price-reducing competition caused by them (Dutfield, 2009: 46-47). After their dominance in the generic market, it can be claimed that they have been more tolerant of the generic drug campaigns of different governments.

After seeing this concentrated situation in the pharmaceutical sector, it can be said easily that there is an oligopolistic structure in this sector. However, many thinkers object to that view. One argument says that even though there is a visible concentration in the hands of dominant MPCs, as it was observed above, the combined worldwide market share of the top thirty MPCs is just over 50% and, for example in 2004, the sales of the two largest companies were just 15% of the global market. For that reason, a monopoly in the industry cannot be remarked (Boldrin and Levine, 2008: 225). Other thinkers prefer to make analytical distinctions to analyze this concentration. For example, Busfield (2003: 602) abstains from qualifying this

concentration as globalization and prefer using the term of internationalization. Her argument about this reservation in using the term "globalization" is that in the pharmaceutical sector, "the spread of pharmaceutical manufacturing, R&D activity, and consumption is primarily focused in advanced industrial societies" (Busfield, 2003: 604).

Even though these reservations about the terms "monopoly" and "globalization" must be taken into consideration, it also must be seen that the MPCs are the dominant actors of the political economy and they have a neoliberal agenda to become monopolies by regulating not just the markets of developed countries, but also those of developing countries. In the following part, why and how IPRs are instrumentalized by the MPCs to achieve these goals will be discussed.

The Importance of Intellectual Property Rights for the Pharmaceutical Sector

There is a deep relation between intellectual property rights (IPRs) and the pharmaceutical sector because of the nature of the sector itself. Contrary to the contemporary claims of the sector, the modern pharmaceutical industry owes its development to weak patent regimes (Boldrin and Levine, 2008: 215). In this part, the reasons and the consequences of this relationship in the present will be discussed, without examining in detail their relationship in past decades.

The pharmaceutical sector is based primarily on innovation. For Boldrin and Levine, it is like the textbook description of a "traditional Schumpeterian industry" with "large fixed cost, small and constant marginal cost, innovation as the main competitive tool, and the market concentrated in rich countries where pirating is practically absent" (Boldrin and Levine, 2008: 213). The centrality of the large fixed

cost that is constituted of massive research and development (R&D) expenditures is the basis on which the pharmaceutical industry grounds its argument about the vitality of a patent protection. However, even though defenders of the industry claim that patent protection is necessary to provide incentives to make researches in this sector where R&D expenditures and risk factors are so high (Busfield, 2003: 590), there are many ambiguities about the nature of this relationship between R&D expenditures, research and cures.

From one side, even though prices of drugs are very high thanks to the strong protection of IPRs and the growing sales, R&D expenditures are not growing as fast as these prices. When sales were growing 12% a year in the 1990s and 8% in the early 2000s, R&D expenditures grew just 6% (Boldrin and Levine, 2008: 225). Between 1992 and 1993, the R&D expenditures of the ten leading companies were approximately 16% of pharmaceutical sales (Vickery and Tarabusi, 1999: 20). In 2006, the average of R&D expenditures in the industry was 19% whereas promotion expenditures were almost twice, as can be observed in the example of Novartis (Boldrin and Levine, 2008: 226). Numbers change from example to example and from one period to another, but there is an unchanging fact that expenditures on marketing and promotion are bigger than the expenditures on R&D in all the pharmaceutical industry (Muzaka, 2009: 292).

There is little proof, however, that R&D expenditures are productive. For example, in the US, R&D expenditures on pharmaceuticals doubled between 1995 and 2002, while it is argued that pharmaceutical innovation declined both in quality and in quantity. These facts generate questions about "the correlation that industry asserts between strong patent protection and innovation" (Sell, 2007: 63). Therefore, even though it is accepted that a strong patent regime is beneficial because it assists

to cover R&D expenditures, it does not mean that it would be beneficial in terms of cures.

Today, the actors of the pharmaceutical sector show themselves like the victims of piracy in many markets throughout the world (Barton, 2004: 147). However, taking the issue of R&D expenditures as a landmark, it can be observed easily that it is a successful distortion of facts, a *doxa*, as said before. In reality, not only R&D expenditures occupy a place as large as the sector declares, but also, these expenditures can be socially inefficient for two reasons. One is that these expenditures are utilized to secure patents that create monopolies, which prevent competitors from developing generic drugs (Sell, 2003: 16). The other is the tendency to conduct research on drugs that are already in the market in order to develop a similar patented drug that can share its privileged position without falling into the position of a generic drug. Busfield writes that these drugs, called "me-too drugs", are "similar to others already on the market, though sufficiently different in chemical formulation that they can be patented in their own right" (Busfield, 2003: 590). Moreover, these me-too drugs, the social benefits of which are questionable, constitute approximately 75% of the general R&D expenditures on pharmaceuticals (Boldrin and Levine, 2008: 226).

After examining all these points, it is seen that even though increasing expenditures of R&D are not a challengeable fact, it cannot be a satisfactory reason for MPCs to be so enthusiastically dedicated to the global enforcement of IPRs, as was demonstrated. Different reasons for this dedication must be sought.

It can be argued that the real reason is the crisis of the pharmaceutical sector, more clearly, the reduced rate of growth of pharmaceuticals in the 1990s (Muzaka, 2009: 291). This situation originated in the early 1970s, when advanced technologies

became the dominant determinant for global competition and the source of an incessant and increasing pressure for this competition (Dutfield, 2009: 34). In the 1980s, this pressure for competition took on the shape of what Dutfield describes as a "feeling of declinism" for the political elites of the US against Japan in high-technology sectors and against South Korea and Taiwan in manufacturing sectors (Dutfield: 241-242). It is in this context that the pharmaceutical sector makes its move towards the international protection of IPRs in an alliance with copyright and trademark industries (Dutfield: 236). This move, which is realized through different representatives of sectors based on IPRs like Pharmaceutical Research and Manufacturers of America (PhRMA), results in what Harvey describes as "a flow of technological rents from the rest of the world into the US economy," and the US has become a rentier state through this global regulation of IPRs (Harvey, 2005: 221). In other words, developed countries, especially the US, export not only intellectual property-protected products, technologies and services, but also the rights themselves in the form of licenses (Dutfield, 2009: 237). Patents become one of the most valuable economic resources of this era (Sell, 2003: 74).

One of the many results of this new tendency is inevitably a quest for markets to collect this rent. "Pharmerging markets," markets of developing countries where there is a rapid growth in the share of global pharmaceutical sales, are a response to this quest (Muzaka, 2009: 291). These pharmerging markets are potential large gain sources based on the relatively small but growing middle classes of the emerging giants of the developing world. Global enforcement of IPRs can be read as a tool of this agenda (Hira, 2009: 85). It can even be argued that this situation is closely related to the overaccumulation crisis of capitalism where the solution is founded on the search for or the creation of new markets. As said before, however, it must not be

forgotten that developed countries' markets, especially the market of the US, are the main places where the sale of pharmaceutical products is realized. Therefore, there must be some reservations using this argument, according to which the pharmaceutical sector is creating the category of pharmerging markets as a solution to the overaccumulation crisis.

In the end, it can be said that the relationship between patents and the pharmaceutical sector is not a direct dependence relation, but a relation of instrumentalization. For some thinkers, the reason for the exclusion of pharmaceuticals from patentability is not moral concerns but rather pragmatic reasons to protect domestic infant industries as is seen in many examples from Europe (Dutfield, 2009: 7) and also in the US (Sell, 2003: 65). Today, this instrumentalization takes another shape. Now, the global enforcement of IPRs is a serious problem not just for generic manufacturers and research-based small companies, but also for MPCs because of the high costs of developing new medicines and concerns about the patent expiration of key drugs (Muzaka, 2009: 291).

The MPCs have developed many new strategies in this new global patent regime. As said before, economic concentration is one of the results of the new global patent regime. The reliance on key drugs is another important strategy. In this strategy, especially MPCs rely on specific products with sales of more than $1 billion dollars in some cases. These drugs are called "megabrands" or "blockbusters" in the pharmaceutical sector (Busfield, 2003: 596). Me-too drugs can be seen as a backup strategy against the patent expiration of blockbuster drugs. According to Dutfield, other possible strategies are "clustering," which means "building a patent wall around a product" and "bracketing," which means "surrounding a competitor's key

patent with so many of one's own that it cannot be commercialized" (Dutfied, 2009: 46). For example with the strategy of clustering a drug, alongside the product patent, the drug can be protected by formulation patents, process patents and method-of-treatment patents (Drahos, 2007: 16). All these strategies of competition can have negative impacts for the public interest, because they aim to block new research by competing inventors and companies (Dutfield, 2009: 46) and therefore, they can be seen as an example of the notion of the constructed scarcity discussed in the first section.

In the case of me-too drugs, there is an optimistic approach according to which these drugs can decrease the prices of patented drugs. However, it also must be remembered that the large R&D expenditures made for these drugs remain a tool for the legitimization of a regime of strong patent protection. For that reason, it is considerably difficult to see this decrease of price realized through me-too drugs as a meaningful compensation against the establishment of global regulation of IPRs.

In the following part, different international agreements to concretize the role of actors from the pharmaceutical industry in the mechanisms of global enforcement of IPRs will be examined.

The Global Enforcement of Intellectual Property Rights

The global enforcement of IPRs must be thought of the context of all of the issues discussed in terms of international institutions so far. It was said that international institutions can be seen as a means of building legal foundations for a neoliberal market order. In this view, the law is considered an instrument in the hands of transnational capital. Without totally falling in this reductionist approach, its

effectiveness in understanding the complex issue of IPRs must be admitted. In this section, this approach to understand the global patent regime will be used, while bearing in mind the approach of Koskeniemmi, for whom international law is an arena that oscillates between creating a utopia and serving interests of strong states (Koskenniemi, 2005).

This section discusses the methods of the mechanism of this enforcement in three different stages, the construction of the global patent regime, an attempt to make a breach in this regime, and the consolidation of the regime. Before analyzing these stages, the globalization of law will be discussed generally by means of the specific example of the global regulation of IPRs.

As Sell writes, it must not be forgotten that "the public law is ultimately constructed" and "(it) does not exist "out there" or come down from on high" (Sell, 2003: 176). When talking about the construction on a global scale, international law comes into play. In the global arena of political economy, global actors, transnational capital in our example, act to constitute structures of "normmaking" and "lawmaking" through which they can legitimize and also expand their power with transnational quasilegislatures, global regulatory bodies and global dispute resolution bodies (Halliday and Osinsky, 2006: 452). In the global regulation of IPRs, the aim of international institutions is to link intellectual property and trade, as it was already mentioned in the previous sections. However, the power of such institutions to create norms and enforce them is not shaped in determined and stable conditions. The tension between the private interests of intellectual property owners and public interest, the respected balance between creation and diffusion, and more importantly the strategic powers of different actors change global structures. For that reason, the

characteristics of global regulation are changeable by many different variables. They can be constructed, breached and consolidated again.

One changing characteristic of the global regulation is that, by definition, as Halliday and Osinsky write "most (of the international legal norms) are not (binding) and only obtain legal force when implemented by states" (Halliday and Osinsky, 2006: 449). However, when the process of the expansion of intellectual property rights is observed, it can be seen that there is a tendency to constitute these norms as binding supranational norms. Before the constitution of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPs), there were some attempts to regulate IPRs on a global scale with the aid of international institutions. The World International Property Organization (WIPO) is an important example of these attempts. Sell writes that during the 1970s, the WIPO is seen as a "fairly balanced agency" between the OECD and developing countries to regulate IPRs-related trade issues (Sell, 2003: 20). However, the WIPO did not have any enforcement power and for that reason, it failed to resolve disputes about IPRs (May 2010: 72). It was one of the most important reasons for the quest of actors from MPCs for a new global mechanism to protect IPRs. The following section examines this new mechanism.

The Construction of the Global Patent Regime: The Trade-Related Aspects of Intellectual Property Rights Agreement

When talking about the construction of the global patent regime, a concrete expression other than the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement cannot be thought of. It is the legal structure from which most of the controversies about intellectual property rights (IPRs) take their sources. The

TRIPs agreement can be seen as a complete victory for the actors of the transnational capitalist class (Muzaka, 2009: 295). From this perspective, as Muzaka writes, the TRIPs agreement is "the 'solution' to a 'problem' framed by business actors whose private IPRs the agreement ultimately protects" (Muzaka: 293). The diversity of the actors of which transnational capitalist class constituted deep relations to pursue their interests through the implementation of the TRIPs agreement must be noted. Sell lists these actors as "domestic interindustry counterparts, domestic governments, foreign governments, foreign private sector counterparts, domestic and foreign industry associations, and international organizations" (Sell, 2003: 7). This diversity of actors is one of the reasons for the expansion of the political audience of the issue of IPRs. Even though the aim of the TRIPs agreements is to remove this debate from the political realm to the legal realm (May, 2010: 74) and to redefine it as what May calls a pure "technical legal debate" (May: 91), contrarily, the consequence of this agreement has been the expansion of the debate (May: 88).

Another reason for its expansion can be found in the vitality of the areas that the TRIPs agreement affects. As said before, this commodification of knowledge through IPRs causes the expansion of market relations to areas that have not been under these relations. Even though patents were long seen as the source of problems for the access to medicines issue in developing countries for many years (Gereffi, 1983 as cited in Drahos, 2007: 12), the TRIPs agreement crystallized many sharp changes in the area of health care, an area that once considered inaccessible to market relations. As Gill writes, the TRIPs agreement demonstrated that even "issues of bare survival are determined by market forces, in particular by private corporations" (Gill, 2005: 127). As a result, it provoked a widespread political reaction related to the strong social impact of the agreement (May, 2010: 92).

The TRIPs agreement is so controversial because even though all participants wishing to be part of the World Trade Organization (WTO) signed it in 1994 as the final act of the Uruguay Round of General Agreement on Tariffs and Trade (GATT), the agreement is not seen in the same way by the countries that gave their consent. Sell notes that the TRIPs agreement is considered "as a floor –a minimum baseline for intellectual property" by negotiators from developed countries and "as a ceiling – a maximum standard of protection beyond which they were unwilling and/or unable to go" for negotiators from developing countries (Sell, 2007: 58-59). When the TRIPS agreement was brought onto the political agenda in Turkey in 1995, it was considered as a ceiling especially for the issue of transitional periods. However, in Turkey, this issue was not shaped simply in the framework of the WTO, but also, and more importantly, as a bargaining instrument in the process of membership to the European Union (EU). For that reason, Turkey was more willing to accept this agreement than other countries in the same disadvantageous position. The discussions of 1995 about patent protection in Turkey will be examined in more detail in the fourth chapter.

Returning once again to the global picture, it can be said that a natural consequence of this difference in approaches to the TRIPs agreement is the continuous attempts to bend the agreement in other opposite directions. In the following parts, there will be attempts to examine these two opposite attempts. However, before passing to these parts, some of the general characteristics of the TRIPs agreement will be studied through articles related to the debate of pharmaceutical patents. The points that will be discussed are the expansion of the patentability, the rights and the obligations of different countries, and the reinforcement mechanisms constituted at the first time by the TRIPs agreement. In

this examination, the text of the agreement will be used, accompanied by the commentary of different thinkers.

In Article 27(1), it is clearly stated 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." By this article, pharmaceutical goods, which until then had benefitted from exceptions to patentability, lost most certainly their privileged status. It is true that this sentence is completed by Article 27(2) where the agreement accepts a possibility to the exception of patents by "the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment." However, as will be observed in other articles, there is a huge ambiguity to define this *ordre public* through which exceptions can take place.

Another ambiguity appears about the rights and the obligations of member countries. The structure of the agreement is constructed upon the rights of developed countries to protect the IPRs of their national companies and the obligations of developing countries to renew their national legislation for the same purpose, more clearly, to protect the IPRs of these companies based on the developed countries (May, 2010: 89). Even though Article 67 predicts vaguely a "technical cooperation," and says that "in order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members," it is not a realistic thought.

As can be seen from the history of the world pharmaceutical sector, May writes that "the protection of IPRs only makes policy sense once a certain level of

technological momentum has been achieved" (May, 2010: 90). As said before, the modern pharmaceutical industry owes its development to weak patent regimes. Especially in European countries like France, Germany, Switzerland, Italy and Spain, it is observed that a pro-patent tendency exists if the domestic industry is grown enough to compete with other countries' pharmaceutical sectors (Boldrin and Levine, 2008: 215-217).

Now, to understand the motive behind the acceptance of the TRIPs agreement by developing countries, the discussion must digress. As was argued in the last paragraph, developing countries do not make direct gains from this agreement. Nevertheless, it cannot be argued that they accept it without measuring its costs and its benefits. Before the global regulation of IPRs through the TRIPs agreement, developing countries were face to face to economic pressures, especially from the US through the US Trade Representative Office (USTR) and its sanction mechanisms, such as Section 301 and Special 301 (Muzaka, 2009: 295). For that reason, the TRIPs agreement is considered by most developing states as a solution to these bilateral pressures (Sell, 2003: 109). These bilateral agreements will be studied in greater detail in the last part of this chapter.

Returning to the subject of the rights of developing countries in the TRIPs agreement, even though the right to technology transfer is not a proper right for developing countries, it can be said that there are other options in the agreement that are considered in the category of rights. These are rights to exceptions. There are two exceptional rights in the agreement. The first one is the right to have transition periods aimed at facilitating the implementation of the agreement, and the second one is the right to flexibilities, like compulsory licensing, parallel imports and Bolar

exceptions. All these rights to exceptions can be considered as the fruits of many lengthy negotiations between developing countries and developed ones.

On the subject of transitional arrangements, Article 65 and 66 of the TRIPs agreement are dedicated to this issue. These articles give grace periods of five to fifteen years for developing and least-developed countries (Sell, 2003: 117). However, it must not be forgotten that the TRIPs agreement is the product of the success of the transnational capital in accordance with the developed countries' governments. For that reason, there is an asymmetry of power between TRIPs defenders and opponents (Sell, 2007: 58), which means that the grace periods are not exploited effectively in many developing countries. The same argument could be made for the use of compulsory licensing, too. It must be remembered that grace periods or flexibilities of the TRIPs agreement are exploited mostly by relatively powerful countries with the production and/or consumption capacities to compete with developed countries. Examples of some of these rights will be presented in the third chapter of this work. Now, the discussion will continue with an examination of compulsory licensing, which is an important category of TRIPs flexibilities.

The right to compulsory licensing is the subject of Article 31 of the TRIPs agreement. Compulsory licensing is "authorizing a third party to work an invention and excluding the property owner from exploiting the resource" (Sell, 2003: 115-116). However, it must be remarked that this right is surrounded by carefully drawn limits. According to Article 31, a compulsory license can no longer cover a whole field of technology (31.a) and there must be a situation of national emergency for its application (31.b). Moreover, it must be limited to a specific purpose (31.c). It must be non-transferable, non-assignable (31.e), and must only be used to supply a

domestic market (31.f) with including “adequate remuneration” to the right holder (31.h), and must be subject to the prospect of juridical review (31.i) (May, 2010: 83).

The usability of this right in many aspects can be criticized. First, the exclusion of the whole pharmaceutical patents as a need of public health can no longer be mentioned. Second, according to Article 31.f, countries that do not have the capacity to produce generic drugs via compulsory licensing have no other option than to use the patented drugs. This situation remained unsolved until the Doha Declaration in 2001 because of the intense ambiguity around the right of parallel importing of drugs related to the doctrine of exhaustion of IPRs (Article 6). For that reason, whether a drug is patented, generic or produced with compulsory licensing, attempts at parallel importing encountered many obstacles and ambiguities until the Doha Declaration, a subject that will be studied in the following part.

Putting aside rights that are ambiguously mentioned in the agreement like parallel imports, even explicitly written rights like compulsory licensing are not frequently used rights. However, the importance of compulsory licensing lays in its use as a bargaining tool by developing and also by developed countries’ governments (May: 82). Once again, examples of the political use of compulsory licensing will be presented in the third chapter dedicated to the pharmaceutical policies of different governments.

Another point that causes the inefficiency of compulsory licenses is related to the juridical issue. According to Article 32, when a patent holder is threatened with compulsory licensing, it can process a case countless times against the one who tries to use a compulsory license (May: 83). This article reflects the research-based industry supporter nature of the TRIPs agreement. As can be seen in Article 34, Dhar and Rao write that not just in the case of compulsory licensing, but also in the case of

ordinary generic drugs, "the burden of proof has been switched from the plaintiff to the defendant" (Dhar and Rao, 1996: 315-317, as cited in May: 84). The defendant, the manufacturer of the generic drug in this example, must prove that the process used is a new one, different from the patented process (May, 2010: 84). This change in favor of research-based industry, more clearly in favor of multinational pharmaceutical companies (MPCs), can be read as another strategy of the industry to impede competition by complicating the market approval of generic drugs.

The last characteristic of the TRIPs agreement is about the constitution of reinforcement mechanisms (Article 64). It can be said that this point is the most significant characteristic of the agreement because the TRIPs agreement has been distinguished from other international agreements so far, with this new regulation. Through the dispute settlement mechanisms of the WTO, the norms of the TRIPs agreement have become binding norms. According to May, it gives "teeth" to the global patent regime (May, 2010: 87).

At the end of all these discussions, even though just the articles related to pharmaceutical patents have been cited, it is easily seen that the TRIPs agreement creates a much less flexible regime for IPRs than earlier periods (Sell, 2003: 12). Boldrin and Levine define this new regime as "a steady process of worldwide harmonization of patent rules in the pharmaceutical and other industries" (Boldrin and Levine, 2008: 217). However, this "one-size-fits-all" approach is not compatible with the diversity of different members signing the agreement (May 2010: 107). The TRIPs agreement promotes universality (Sell, 2003: 12), but actually, this universality does not exist. According to Drahos, the TRIPs agreement is legitimized by MPCs as "the protection of private property rights versus piracy by developing countries" (Drahos, 2007: 18). As Lanoszka notes, the agreement just "helps to

create powerful monopolies that control the market for often essential knowledge-based products" (Lanoszka, 2003: 182). It is similar to the general situation of IPRs in the era of neoliberal globalization, as was seen above. In this case, the problem is that if "patents are winner-take-all systems" (Dutfield, 2009: 43), what do the losers of this system do? The answer is the Doha Declaration as an attempt to make a breach in the system.

An Attempt to Make a Breach: The Doha Declaration

The Declaration on The TRIPs Agreement and Public Health was discussed and signed in November 2001 during the fourth session of the ministerial conference of the World Trade Organization (WTO). It was an important step, giving "teeth" at this time to developing countries against the multinational pharmaceutical companies (MPCs). This declaration was the fruit of a coalition between the Africa group who had inspired the declaration with a proposal in April 2001, different non-governmental organizations (NGOs) related to the access to medicines issue such as Oxfam and *Médecins sans Frontières* (Doctors without Borders), and developing countries that had economic and/or social interests in this issue like Brazil and India, along with the quiet support of some European states to this coalition against the pressures of multinational pharmaceutical companies (MPCs) (Drahos, 2007: 18-19).

The Doha Declaration was not written outside the framework of intellectual property rights (Paragraph 3), or the TRIPs agreement (Paragraph 2). For the declaration, the TRIPs agreement is not a part of the problem, but a part of the solution (Drahos, 2007: 23). Even though it does not constitute a radical opposition, its emphasis on the TRIPs flexibilities (Paragraphs 4 and 5) is significant to modify

the power balance in the global regulation of intellectual property rights (IPRs) for the pharmaceutical sector and health issues.

The Doha Declaration is important because, even though, as Sell argues "it did nothing but restate what was already in TRIPs" (Sell, 2003: 161), as Drahos adds, the declaration was successful to "clear the air of the uncertainty (…) surrounding the use of TRIP flexibilities because of a lack of experience and administrative know how in these countries in the regulation of patents" (Drahos, 2007: 17). However, its importance for India, Brazil and South Africa, which were deeply involved participants in the global TRIPs agreement discussions and also, of the Doha Declaration discussions, was not reflected in the policy agenda, nor in the media of other countries, which were more passive actors. Turkey is one of these passive actors on the global level. As will examined more in detail in the fourth chapter, even though the TRIPs agreement did create some echoes in the national arena, the Doha Declaration passed without significant effects.

Returning once again to the examination of the Doha Declaration, it is noticed that another characteristic of the Doha Declaration completely changed one of the central *doxa*s of the TRIPs agreement. The Doha Declaration speaks quite often of the rights of member states instead of the private rights of corporate actors. Paragraphs 4, 5, 6 and 7 are all about the rights of member states to use efficiently the flexibilities offered by the TRIPs agreement for "taking measures to protect public health" (Paragraph 4). As an example, on the issue of compulsory licensing, the declaration explicitly argues that the right to compulsory licensing and the determination of situations to grant this right must be left to each member's option (Paragraph 5). The problem of the use of compulsory licensing by least developed countries is solved by Paragraph 6, according to which, the "ability to export generic

drugs produced under compulsory license to countries lacking pharmaceutical manufacturing capacity" is acknowledged (Sell, 2007: 48). In this way, the rights of parallel importing became clearer than they had been in the framework of the TRIPs agreement.

There are many criticisms of the Doha Declaration. Questions about its necessity and its success are common. Actually, the Doha Declaration cannot be thought separately from the Access to Essential Medicines Campaign. For the advocates of the MPCs, the protection of patents is unrelated to the access issue. According to them, poverty and limited spending on health care are the most important barriers to access to medicines (Sell, 2003: 159). From this perspective, the compulsory licensing that the declaration supports with so much effort is a negative strategy that can weaken the incentives to develop drugs for the markets of developing and least developed countries because of the possibility of lower prices, a possible negative impact on manufacturing incentives. However, it must not be forgotten that incentives of the MPCs to develop drugs for these markets are already very low (Barton, 2004: 150). Moreover, as Barton writes, the MPCs argue that "patients in developing countries do not receive adequate access to even those drugs that have long since been off patent and are available in much of the world at relatively low prices" (Barton, 2004: 150). Still, it cannot be a legitimate argument to create royalties through the IPRs of drugs of which consumers in developing and least developed countries are in the need.

For some thinkers, the Doha Declaration and the Access to Essential Medicines Campaign have rebutted the formula of the MPCs, according to which the cure is considered equal to research and all of them seem to be equal to profits (Sell, 2003: 174). Alongside the HIV/AIDS crisis in many countries, patent rights began to

be seen "as a public health issue rather than a trade issue," as Sell (2003: 27) writes. Moreover, as Drahos states, the declaration managed to break the legitimization of the TRIPs agreement as the protection of IPRs against the piracy of developing countries and developed an approach based on "the rights of states to protect public health versus the extension of patent monopoly power" (Drahos, 2007: 18-19). For all these reasons, Barton holds that the Doha Declaration can be seen "as a victory by the developing world and as a defeat by the research-based drug industry" (Barton, 2004: 149), although all it did was to reassert the TRIPs agreement's "invocation of health emergencies as legitimate reasons for the compulsory licensing of pharmaceuticals," as May (2010: 88) points out.

The last part of this chapter focuses the counterattack of the MPCs against the relative victory of developing countries. This part is the consolidation of the regime by the pressures of the MPCs through bilateral and multilateral free trade agreements.

The Consolidation of the Regime: Free Trade Agreements

The consolidation of the patent regime is crucial in the eyes of the MPCs to avoid what Muzaka describes as the "*de facto* erosion of global patent protection mandated by the TRIPs agreement" and encouraged by the Doha Declaration (Muzaka, 2009: 297). Even though the Doha Declaration created a positive atmosphere in favor of developing countries, these countries did not implement the necessary strategies to realize the gains of this declaration (Drahos, 2007: 24). This situation, which can be criticized as a failure of the Doha Declaration, created an

ambiguity from which the MPCs profited for the implementation of free trade agreements (FTAs).

The use of bilateral and regional FTAs as a policy mechanism for the protection of intellectual property rights (IPRs) is not unique to the US. There are many examples of these agreements between the EU and developing countries via the European Free Trade Association (EFTA) (Correa, 2006: 399). In fact, this strategy has been used by the US since the 1980s. One of the most significant changes in the nature of these new FTAs used by the US after the Doha Declaration is that in the 2000s, they mostly have been regional agreements (Drahos, 2007: 13). Another change is the sudden increase in the number of these agreements. Between 2001 and 2005, the US realized 11 bilateral and regional FTAs with 23 countries (Correa, 2006: 399). Correa writes that other important characteristics of these new agreements are that they are "negotiated outside the World Trade Organization (WTO)" and "require even higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement, and in some cases go beyond what is required in the developed countries that are promoting them" (Correa, 2006: 399). In summary, FTAs go beyond the requirements of the TRIPs agreement alongside creating new obligations (Drahos, 2007: 13). Until this time, there has not been a FTA between Turkey and the US or with any other country. However, it is a recommended strategy as was observed in a wikileaks cable dating from May 2009 (Wikileaks.org, 2009).

Another controversial issue is that FTA negotiations are not realized in the same globally visible and transparent ways in which WTO negotiations are realized (Drahos, 2007: 20). It is quite understandable when the example of US FTAs is observed. It is observed that the purpose of these bilateral agreements is not the

promotion of free trade; on the contrary, it is to advance the US intellectual property protection. It can be seen as the renunciation of the legitimization of IPRs as an indispensable element of free trade as it was in the context of the TRIPs agreement. However, similar to the period before the TRIPs agreement, many developing countries accept these FTAs "to gain access to large, affluent markets." Sell describes this situation as "[offering] countries WTO-Plus market access in exchange for TRIPs-Plus policies" (Sell, 2007: 59).

Now, some characteristics of these bilateral agreements will be examined. FTAs are mostly realized with the purpose of blocking the competition of generic drugs. For example, with data exclusivity provisions, generic drug manufacturers are enforced to generate their own clinical trial test data, rather than rely on the safety and efficacy findings of the brand name drugs in the generic drug approval process. According to Semin and Güldal, different from data protection, which means the "protection of data against illegal commercial use" and which is present in the text of the TRIPs agreement, data exclusivity requires the prohibition of "generic pharmaceutical manufacturers to use original product data as reference when they apply for a license after expiration of the patent period and is another means of market protection for an additional period" (Semin and Güldal, 2008: 384). They describe data exclusivity as related directly to generic companies. Another researcher, Kılıç, describes it through its relation with state authorities. In her approach, "data exclusivity rules prevent the regulatory authority from being able to rely on the originator's data when registering a generic version of the same product" (Kılıç, 2011: 128). As will be discussed in the chapter dedicated to the Turkish case, data exclusivity has been one of the important issues in the period after-TRIPs.

Moreover, through FTAs, MPCs try to link drug registration to patent protection. With this linkage, generic drug manufacturers are forced to have the patent holder's approval to enter the market. This makes practically impossible any use of compulsory licensing, let alone parallel imports of drugs produced by compulsory license. To highlight all these points, many FTAs explicitly emphasize restrictions about the use of compulsory licenses alongside the prohibition of parallel importation (Sell, 2007: 60-62).

Patent term extensions constitute another important aspect of FTAs. Through FTAs, developed countries try to constitute automatic patent term extensions beyond the TRIPs agreement, like 20-year terms of patent protection. Sell writes that these are "not only TRIPs-Plus but are in fact, US-*Plus* provisions" (Sell, 2007: 63). Clearly, FTAs reflect the approach of the MPCs in considering the TRIPs agreement as a minimum baseline for intellectual property. There is no maximum period for patent term extension (Correa, 2006: 400). The legitimacy of these TRIPs-plus provisions lies in the pretext that current levels of protection are not enough to recover increasing research and development (R&D) expenditures (Correa, 2006: 400). This legitimization bring to mind once again all the arguments and the counter-arguments about the relation of IPRs with R&D expenditures and efficiency. These arguments will not be discussed again; however, it must be said that, in the post-Doha Declaration context, they are not convincing arguments. For that reason, FTAs can be considered as crude political tools of the coercive protection of IPRs in favor of the MPCs.

The consolidation through bilateral and regional FTAs has had injurious effects on the hopes arisen with the Doha Declaration (Velasquez, 2004 as cited by Sell 2007: 50). Many developing countries are on the verge of accepting those

agreements, which strengthen the hand of the MPCs. On the other side, there is also a continuing opposition directed by some developing countries. The Declaration on Intellectual Property, Access to Medicines and Public Health signed by South American countries in 2006 was an important step to emphasize the protection of TRIPs flexibilities like compulsory licensing, parallel imports and Bolar exceptions and the refusal of TRIPs-plus provisions, like the linkage of patent grants with marketing approval and the extension of the scope of patentability (Sell, 2007: 65). Another concretization of the criticisms of TRIPs-plus provisions is the report of the WHO's Commission on Intellectual Property Rights, Innovation and Public Health in April 2006, according to which innovation must be defined not only with discovery and development but also with delivery of the discovered results to people who need them. From this perspective, the protection of IPRs is not an end but a means (Sell, 2007: 64).

In the end, it cannot be said that the political conflicts of IPRs on the subject of pharmaceuticals are finished. Even though just these three steps in the global regulation of IPRs are analyzed in this chapter, there are other up-to-date processes on this issue. The Anti-Counterfeiting Trade Agreement (ACTA) was a recently formed step. This multilateral TRIPs-plus agreement was signed by Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the US in October 2011 and accepted by all members of the EU in January 2012 (USTR.gov, 2012). Even though there has not been any research on this agreement because of its newness, it can be argued that this agreement is the most recent move toward the global regulation of strong IPRs. The secret nature of the negotiations of the ACTA proves the influence of transnational capital in the process of this agreement (Infojustice.org, 2012). As was seen in bilateral and regional FTAs and in the TRIPs

agreement, transnational capital in general and the MPCs in particular, cannot be part of World Trade Organization (WTO) mechanisms directly. They need governmental actors to be involved in these agreements (Muzaka, 2009: 296). In the ACTA, the role conferred to governmental actors is much more minimized against the maximized influence of actors from the private sectors of developed countries. Related to the IPRs of pharmaceuticals, the ACTA brought provisions not just against TRIPs flexibilities that became clearer with the Doha Declaration, it even criminalized all generic drugs as counterfeited drugs. Turkey did not sign the agreement and so far, there is a cautious but critical approach in the dominant media (Blog.milliyet.com.tr, 2012).

Even though it is not within the scope of analysis of this work, it must be said that certainly, this agreement will have to be examined in detail at future studies.

The following chapter of this thesis concretizes the pressures of this global regulation of pharmaceutical IPRs towards health policies of different countries. Referring to Gill, it can be said that the reason of this linkage between the global political economy of pharmaceutical IPRs and health policies is that "(the) redefinition of property rights under new constitutionalism partly determines the very nature of public health systems, and the conditions under which they operate" (Gill, 2005: 131). It was already said that the global regulation of IPRs has important consequences in our everyday lives. However, looking at the scheme drawn until now in the second chapter, there is not a direct link that comes through to our lives. The third chapter, which is dedicated to pharmaceutical policies shaped under this global regulation, will help us to understand the interaction between governmental policies and global political economy of IPRs.

CHAPTER III: PHARMACEUTICAL POLICIES UNDER THE PRESSURE OF INTELLECTUAL PROPERTY RIGHTS

The aim of the theoretical chapter was to understand the background of the notion of intellectual property rights (IPRs). During this chapter, there was an attempt to follow the traces of IPRs from its rise in a specific political economic context to its diffusion in the global scale with an extreme influence. This third chapter seeks to concretize the pressures of the global regulation of pharmaceutical IPRs towards pharmaceutical policies to understand the interaction between governmental policies and global political economy of IPRs.

The choice of the pharmaceutical sector as the subject of this thesis is not limited to the fact that pharmaceutical companies constitute a perfect example to understand the global regulation of IPRs. As was discussed in the first and the second chapters, the subject was chosen also because of the delicacy of the health issue. Health is considered a universal right through the Universal Declaration of Human Rights. According to Article 25 (1), "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control" (UN.org). In terms of theoretical matters, by most people, health is seen as an issue of "bare survival" as it is discussed in the second chapter, referencing Gill. For that reason, as will be seen in the part dedicated to the effects of neoliberal globalization in health policies, this change accented through the global regulation of IPRs is not just a shift in health policies, but also a shift or a fear of shift in the meaning of health itself.

To better explain this change, the arguments of Block can be used and it can be defended that the determination of the health issue by pure market forces creates a confusion in the theory of blocked and unblocked exchanges. According to Block, "a market economy needs a complex mixture of blocked and unblocked exchanges" (Block, 2002: 225). The expansion of market rules to all aspects of society is controversial for many people. The health issue debates show that we are not ready to accept that human health is an unblocked exchange, a real commodity more specifically. In this way, it is seen that pharmaceutical IPRs trigger not just the discussion of the commodification of knowledge, but also the discussion of the commodification of health.

This chapter is made up of two sections in which pharmaceutical policies under the pressure of IPRs in the era of neoliberal globalization will be studied. First, health care and pharmaceutical policies will be observed from an overall perspective, and in the second section, different examples of pharmaceutical policies worldwide will be studied to understand the global situation and to be able to make some comparisons. The examination of these issues will help us in the fourth chapter, to categorize the characteristics of the Turkish pharmaceutical policies and to comprehend that the choices of Turkish policy makers are deeply related to the examples from around the world, especially from Europe, as will be observed during the discussion of examples from Europe. Many of the pharmaceutical policy mechanisms that will be examined in this chapter will appear in the fourth chapter once again.

General Information on Pharmaceutical Policies

In this section, the change in pharmaceutical policies, and more generally the change in health policies under neoliberal globalization will be analyzed. For this aim, the increasing health expenditures and especially pharmaceutical expenditures from a global perspective will be examined, without scrutinizing the local characteristics of different states. After these, different control mechanisms implemented against these increasing expenditures will be studied in the categories of supply-side and demand-side regulatories. The section will conclude with the role of states in the shaping of the global regulation of IPRs, as it applies to the pharmaceutical policies.

Before passing to these specific topics, some of the general characteristics of pharmaceutical policies will be observed and the question of why "medicines are clearly a politically charged sector" (Permanand and Altenstetter, 2004: 40) will be answered.

The pharmaceutical market is different from other markets, on both the supply and the demand sides. Some of the differences of this market are related to the supply-side, like lengthy periods of regulatory approvals and late-coming gains. For the demand side, the four-tiered structure with prescribers (physicians), distributors (pharmacists), consumers (patients) and payers (state or private insurers) is the main reason of this difference. For some thinkers, this characteristic of the market can be read as "market imperfections" (Mossialos, Walley and Mrazek, 2004: 2). Even though these characteristics show that the pharmaceutical market is not an ordinary market, it does not mean it is unique. However, it can be used to argue that pharmaceuticals and more generally, health is not an issue that can easily be solved

in pure market relations. One approach argues that this is the reason why the pharmaceutical market needs constant state regulation. This approach will be discussed in the last part of this section. Another approach says that this is one of the reasons why health care must not be transformed into a commodity.

It is possible to elaborate this four-tiered structure of the pharmaceutical sector to explain the plurality of actors related to pharmaceutical policies. There are many national and supranational actors with different policy objectives in the pharmaceutical sector. Among these actors, there are actors from the state, actors from the industry, health professionals and consumers. There are three types of governmental actors. These are the ministries of trade and industry, which aim for economic rewards and generally have objectives encouraging local industry to improve rates of employment and exports; the ministries of finance and service, which look after the optimization of health expenditures with maximum access to care; and the ministry of health, which targets the efficiency, access, equity and quality of pharmaceuticals (Permanand and Altenstetter, 2004: 41). Here, it also must be added that the structure of state actors varies on whether it is a single-payer system with a national health service or it is a multi-payer system payroll-tax financing with a national health insurance (Hacker, 2004: 695). If this is a payroll-tax financing system, the ministry of labor and social security can be added to these state actors, next to the ministries of finance and service.

Another category of actors is from the pharmaceutical sector. Some examples are research and development (R&D) based companies, which aim for the maximization of profits alongside the protection of research resources; generic companies, which defend the competition in the market; wholesalers, which target to improve their profits; private insurance companies, which segment the market for the

maximization of their own advantage, and lastly, there are consumers, who desire access to safe and effective drugs. There are also other actors like pharmaceutical importers, hospitals or scientific communities related to the pharmaceutical issue (Permanand and Altenstetter, 2004: 41). However, they are not included in the scheme because they do not occupy a central place in the examination at hand.

In the last point, to be able to understand pharmaceutical policies and their related actors, they must be analyzed within the larger context of the "competing pharmaceutical policy interests," which can be categorized as health care policies, industrial policies and public health policies. Public health policies, mostly of the ministry of health, aim for patient access of high quality, efficacious and safe medicines with innovative cures (Permanand and Altenstetter, 2004: 39). To realize a successful public health policy, the health care policies executed by the ministries of finance or labor and the social security and industrial policies executed by the ministries of trade or industry must be balanced delicately (Mossialos, Walley and Mrazek, 2004: 2). From one side, policy makers must regulate the pharmaceutical industry in favor of its actors because of the economic rewards (Permanand and Altenstetter, 2004: 43) and on the other side, they must not just look after cost containment objectives in the search for cost-effective medications against increasing costs of health policies but also, "intervene to prevent the emergence of monopolies" (Permanand and Altenstetter, 2004: 39-40).

Another issue that must not be ignored is the tension between national and supranational policy makers, which can be seen mostly in the shape of a tension between policies of cost containment and the policies of market liberalization, as is seen in the examples of European states against the rules of the EU (Permanand and Altenstetter, 2004: 41). In some specific examples, it is witnessed that states can

encounter the free market regulations of the European Agency for the Evaluation of Medical Products (Mossialos, Walley and Mrazek, 2004: 5).

After this short study on general characteristics of pharmaceutical policies, the ideological change related to the health issue in the 1980s will be examined.

The Change in Health and Pharmaceutical Policies with Neoliberal Globalization

The effects of the decline of the welfare state on health care policies will be the basic point of departure of this section. From the beginning of this thesis, it has been argued that the subject is closely related to the spirit of the era, the era of neoliberal globalization. In this chapter, it is observed that along with the internal tensions of the health issue itself, all national health policies are affected negatively by neoliberal globalization (Hacker, 2004: 698).

For some thinkers, the negative impact of the post-1980 globalization on health policies has two reasons. One is the market decline in rates of economic growth in the 1970s and the other one is what Hacker calls "the anti-welfare state political movements" of the neoliberal ideology in the 1980s (Hacker, 2004: 697-698). Increased with the new fiscal order and the rapid inflation of health expenditures as an important budgetary problem, this ideology has resulted in cost containment policies in health care in the 1980s for many states (Hacker, 2004: 699). In the former era, health policies were regulated in many developed countries under the rules of the welfare state. However, with the era of neoliberal globalization, these rules had to change. In the new era, public health policies are considered no longer in the interface of other public policies related to the physical environment or to the social environment, but as an area reliant more and more to market signals (Leys,

2009: 9-10). On a political atmosphere in which the welfare state was seen as equal to high costs and deteriorating economic performance, it is not surprising to see that the health care systems of the welfare state was considered a "cost explosion" and the welfare reform, and related to the former, the health reform, was considered obligatory. In this new picture, the actors who finance the welfare state (for our subject, it can be replaced with health policies) have become more influential than those who provide and receive social benefits (once again, it can be said health care) (Giaimo, 2001: 334-336). As a result, "stewards of public and private benefits increasingly conceived of themselves as 'payers' rather than guarantors; and, as payers, their goal was to control what was paid," as Hacker (2004: 701) writes. Similar to the neoliberal *doxa* of the protection of intellectual property rights, another *doxa* has been created around the debate of health care. Even though the aim was to control health expenditures without cutting the former benefits of the population (Hacker, 2004: 721), in the new era, health care policies are shaped especially with the terms of "cost containment" and "economic competitiveness" (Giaimo, 2001: 339).

It can be argued that health is still a right to be protected and to be diffused by contemporary health care policies. However, even though states continue to expend important amounts for health policies, as will be explained in the following parts, there has been an ideological change in the nature of the execution of these policies that has resulted in structural changes. This change is concretized in what Klein terms a "global epidemic" of health care reforms (Klein, 1993 as cited in Agartan, 2011: 37). For all these reasons, it is clearly demonstrated that in health and especially pharmaceutical policies, states are still important actors. First and more generally, because they have immense powers as the buyers of this market and

second, because they can have the role of enforcers and authors of global norms to promote competitiveness in a global economy. As it is said in the world-systems theory, core states compete to organize the global economy in shaping the globalization project (Arrighi, 1994 as cited in O'Riain, 2000: 189). There will be the chance to examine some examples of this situation in the last part of this section. In this way, it will be seen whether this global regulation of IPRs can be seen as an arena in which actors of pharmaceutical sector and governmental agents encounter each other or this arena can be considered as an option for creating new alliances.

Increasing Health Expenditures

If the change in the health issue is examined more in detail, it is observed that there was an important increase in health expenditures between 1960 and 1980 in many developed countries. The percentage change in the share of gross domestic product (GDP) devoted to health expenditures increases 94.4%. There was a general decline in the increase of health expenditures between 1980 and 2000 at just 23.3% (Hacker, 2004: 699-700). According to the OECD approximate figures, health expenditure as a share of GDP increases from 4% in 1960 to 7% in 1980 and to 9% in 2010 for the average of OECD countries. And between 2000 and 2009, health expenditure grew by 4% per capita for the OECD average (OECD, 2011: 149).

Increasing health expenditures cannot be analyzed easily under the effects of the decline of the welfare state, because as is seen, health expenditures continue to grow under neoliberal globalization even if it is with modest figures. What is different, as is explained in the former part, is the ideological change, which gave birth to the idea of health reforms. Closely related to increasing health expenditures,

the need for health reforms has important reasons peculiar to the health care, different from the global change in social policies. Some of the internal reasons are the development of expensive technological innovations, the ageing of Western countries along with low birth rates and the structure of the health sector as a huge generator of service sector employment with low productivity (Giaimo, 2001: 336-338). All these factors can be cited as additional sources of the increasing health expenditures apart general reasons of the transformation of social policies.

Two of these factors cited above, the expensive technological innovations and the ageing of Western countries, are directly related to the increase in pharmaceutical expenditures. Looking more in detail, it can be said that pharmaceutical expenditures have become a serious problem since the 1980s, not just because of the increase in health expenditures, but also because of its own increase. The replacement of older, cheaper drugs by newer and more expensive ones, the increase in the drug usage, the introduction of new drugs for which hitherto no treatment has been available and the price increase of existing drugs can be added as other reasons of the increase in pharmaceutical expenditures (de Joncheere et al., 2002: 9). Excluding the increase in drug usage and the ageing of Western countries, it can be commented that all other factors cited above are directly related to the global regulation of pharmaceutical IPRs, which causes a necessary increase of drug prices. More clearly, the monopoly constructed by IPRs is an important reason for the increase of pharmaceutical policies. The constructed scarcity that was mentioned in the second chapter is concretized in this context.

The figures about pharmaceutical expenditures are demonstrative of this fact. Pharmaceutical spending as a share of GDP has fairly been stable in most European countries since the 1980s (Permanand and Altenstetter, 2004: 40). For example, in

one of the examples with the lowest figures, in Denmark, the ratio of pharmaceutical spending as a share of GDP is increased just from 0.6% to 0.8% between 1980 and 2000 (Mossialos, Walley and Mrazek, 2004: 4). In 2009, they still constitute 0.8% of GDP (OECD, 2011: 155). In another example, in the UK, the ratio is 0.7% in 1980 to 1.1% in 1997 (Mossialos, Walley and Mrazek, 2004: 4), and it is 1% in 2009 (OECD, 2011: 155). In Greece, an example with one of the highest ratios, the ratio increased from 1.2% to 1.5% between 1980 and 2000 (Mossialos, Walley and Mrazek, 2004: 4) while it increased to 2.4% in 2009 (OECD, 2011: 155). It can be added that the average of OECD countries increased from 0.9% in 1980 to 1.2% in 1996 (Jacobzone, 2000: 63), and reached 1.5% in 2009 (OECD, 2011: 155).

Besides these figures, the percentage of pharmaceutical expenditure in total health expenditure has risen sharply from the early 1990s (Permanand and Altenstetter, 2004: 40). It shows that health care containment policies have not covered pharmaceutical expenditures properly in this period, even though there were some attempts. An example is the condition of EU member states (excluding Austria), where the average of per capita pharmaceutical expenditure is increased by 79.9% between 1990 and 2000 (Mossialos, Walley and Mrazek, 2004: 3). The OECD average is also significant, with an increase of 41.6% between 1980 and 1990 and 31.3% between 1990 and 1996 (Jacobzone, 2000: 65). From 1990 to 1996, the ratio of pharmaceutical expenditures in total health expenditures increased from 6.7% to 8.5% in Denmark, from 13.7% to 16.1% in the UK and from 16.9% to 23.8% in Greece. In Turkey, ratios are high, with 25% in 1990 and 28.9% in 1996. However, the OECD average remained stable between the same years with 15.4% (Jacobzone, 2000: 64). It must be added that in these years, in parallel with total pharmaceutical expenditures, also public pharmaceutical expenditures increased

considerably. The increase of the OECD average of public pharmaceutical expenditure per capita between 1980 and 1990 was 54.9% while the one between 1990 and 1996 was 33.4% (Jacobzone, 2000: 65). These increase ratios show that pharmaceutical expenditures became important elements of expenditures increases and for that reason, became important targets for cost containment policies during the 1990s.

Control Mechanisms for Pharmaceutical Expenditures

The control mechanisms of pharmaceutical policies can be divided in to two main categories, price control mechanisms and volume control mechanisms. Price control mechanisms are supply-side regulatory directed at pharmaceutical companies. On the other hand, volume control mechanisms are demand-side regulatory directed at prescribers, distributers and consumers like inducements for generic or lower cost drugs, co-payment regulations and reimbursement policies (Mossialos and Oliver, 2005: 292).

As price control (supply-side) mechanisms, some pharmaceutical policy instruments are fixed price controls, profit controls or rate-of-return regulations and reference pricing systems. First, fixed price control policies aim to have a "reasonable" price for health service. They can be realized through many different ways, for example, through negotiations between a company and a state or through price comparisons with the prices of another country or with other products within the same country. Second, profit control or rate-of-return regulations aim to prevent excessive profits of pharmaceutical companies, especially in the case of patented drugs. With these policies, the government tries to balance cost containment with the

rewarding of the innovation. Last, reference pricing is closely related to reimbursement policies, which are considered as one of the most effective pharmaceutical policies. They determine the amount to be paid by the government. If a drug is more expensive than a reference prices, the difference is to be paid by the consumer (Mossialos, Walley and Mrazek, 2004: 10-12).

These reimbursement policies are the fruit of negotiations between the payer, the government (or the health insurance funds) and the pharmaceutical sector. They function with positive or negative lists to define drugs that will be covered by or be excluded from the coverage of the health care systems (Mossialos and Oliver, 2005: 297). They are also useful tools for executing institutional discounts, which influence indirectly but effectively the pricing of drugs. Some researchers categorize reimbursement policies not in the price control mechanisms, but in the volume-side mechanisms. However, their direct effect on drug prices, especially in countries where the state is powerful due to its monospony position, it is useful to examine them in the category of price control. When I pass to the examination of the Turkish case, this situation will be observed more closely.

It must not be forgotten that these policies cannot yield anticipated results if they are not supported by demand-side mechanisms. For example, reference pricing systems can cause an artificial price floor if they are not used together with incentives to pharmacists or to physicians for the selection of least-cost generic equivalent by patients. Another example, profit control mechanisms, which are already difficult political tools, can be a failure if there is an increase in the volume of prescribing or an introduction of new products against strict direct price regulation. The political instruments cited in this category are generally open to the

manipulation of pharmaceutical companies, especially in the case of the attempts of fixed pricing policies (Mossialos, Walley and Mrazek, 2004: 10-12).

Within the volume control (demand-side) mechanisms, which target mostly the behavior of physicians, pharmacists and patients, the use of generic drugs, more specifically the use of the least expensive drugs, is the main solution to increasing pharmaceutical expenditures (Mossialos, Walley and Mrazek, 2004: 25). These policies include basically good prescribing incentives with the medical appropriateness index, the use of medical records, financial incentives and punitive disincentives to physicians; the freedom to engage in generic and therapeutic substitution to pharmacists with financial incentives like fixed fee per item instead of fixed percentage of a product's price; and co-payments of patients through co-insurance, flat-rate payments or deductibles (Mossialos, Walley and Mrazek, 2004: 15-25).

Beside these health policies, there are also other types of indirect trade and industry policies, which are implemented for pharmaceutical policy aims. The use of compulsory licensing as a bargaining tool to decrease drug prices of MPCs was already mentioned. Parallel imports can be added to these political tools. In the section dedicated to pharmaceutical policy examples around the world, some of these situations where the flexibilities of international patent protection agreements are used as aggressive political tools will be examined.

Returning once again to compromise-based pharmaceutical policies, it is witnessed that in most European countries, volume control mechanisms are more implemented than price control mechanisms (Mossialos and Oliver, 2005: 292). One reason for this shift can be the industrial and commercial concerns of European countries. Another reason, related to the former, is surely the increasing political

power of the MPCs through the global regulation of IPRs. As will be analyzed in the following part, industrial or foreign trade policies can become much more accented than health care policies in some specific conditions. However, for some thinkers, this shift is risky for pharmaceutical cost containment policies because the demand for health care is determined mostly by the suppliers of this health care and for that reason, demand-side mechanisms are not as effective as supply-side mechanisms. Another criticism of these pharmaceutical policies is about the co-payment of patients. In this view, co-payment policies are harmful to the equity objective of general health policies because it can hinder the access to health care of low-incomers. For that reason, it is arguable that financial disincentives are placed not on prescribers but on patients in the actual condition (Mossialos, Walley and Mrazek, 2004: 25).

To better understand this shift in pharmaceutical policies, the relation of states with national pharmaceutical sectors and also their relations with MPCs must be examined.

The Role of States in the Global Regulation of IPRs about Pharmaceutical Policies

The role of states in the global regulation of IPRs about pharmaceutical policies is an issue directly related to the industrial and foreign trade policies of the subject state. More specifically, as Giaimo writes, the policy preferences of public payers change whether the existing health care systems is beneficial for "broader strategies of economic competitiveness" (Giaimo, 2001: 339). In other words, the regulation about pharmaceutical policies is deeply related to a government choice of industrial, trade or health policy approaches (Mossialos, Walley and Mrazek, 2004:

6). There are different political approaches that emerge from the relationship between governmental authorities and actors from the pharmaceutical sector. For example, policy makers can choose between negotiating directly with actors from the pharmaceutical industry, establish regulations on company profits with maximum reimbursement prices or make price-volume agreements with pharmaceutical companies (Mossialos, Walley and Mrazek, 2004: 5).

As was observed in the second chapter of this thesis, encounters and alliances between states and actors from the industry are crystallized in many bilateral and multilateral agreements between states. The agreements discussed in the second chapter, the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement, The Doha Declaration on the TRIPs Agreement and Public Health, Anti-Counterfeiting Trade Agreement (ACTA), and many free trade agreements (FTAs) are all outcomes of the relation between states and the MPCs.

The US and some of the European states under the umbrella of the EU are the most important state actors of the global regulation of IPRs. In the second chapter, it was observed that actors from MPCs need state actors to be part of the multilateral and bilateral agreements between states. The US is actively involved in global pressures against other states to protect its national pharmaceutical sector with many trade sanctions. Alongside the US, also states from the EU have concerns about the innovation and the competition capacities of European pharmaceutical industries. In the overall picture, it can be claimed that many European states try to protect their national pharmaceutical industries, MPCs in most of the cases, against the rise of the pharmaceutical industries not just of the US, but also of China, India and Singapore, without renouncing their national pricing and profit control policies aimed at public health objectives (Hancher, 2010: 635-637). Even though the EU has important

regulative rules to promote a single market in pharmaceuticals with rules related to EU product licensing, wholesale distribution and patent protection, it has no ability to affect directly pricing and reimbursement policies of national governments.

This explains the impotence of the European Agency for the Evaluation of Medical Products, the institution responsible for EU market approval for pharmaceutical products, which is only capable of recommending to European states without sanction powers against them (Permanand and Altenstetter, 2004: 40). Regardless of its impotence, the European Agency for the Evaluation of Medical Products is a pro-industry institution that works more like a licensing office than a patient protection agency (Permanand and Altenstetter, 2004: 45). It is the perfect example of a supranational pharmaceutical institution that protects the interests of MPCs in accord with the commercial policies of different European countries. Besides such specific institutions, even the European Commission acts in favor of MPCs to improve the competitiveness of the EU pharmaceutical industry (Permanand and Altenstetter, 2004: 46-47). It can be argued that this tendency is similar to the feeling of declinism that American political elites felt in the 1980s, as was mentioned in the second chapter. Similarly, they respond to this feeling with a pro-MPCs political attitude strengthened with industry lobbying (Permanand and Altenstetter, 2004: 47). The close relation of the pharmaceutical industry with the European Commission and European Agency for the Evaluation of Medical Products is accented by the assistance of the European Federation of Pharmaceutical Industries and Associations (Permanand and Altenstetter, 2004: 49). How the effects of this lobbying change from case to case will be examined in the following section through the examples of the UK and Germany.

In some cases, the national interests of a state can be harmful to other states even though they are just health care policies not related to commercial or industrial objectives. More clearly, it can be witnessed that the national cost containment optimization realized according to the political choices of a specific government can be harmful to the optimization of cost containment of other countries. To defend this argument, the situation can be explained with a possible strategy of the pharmaceutical sector. Pharmaceutical companies can agree to cost containment policies of a government through strict volume control mechanisms with free pricing policies. According to this strategy, they can use the pricing of this country where they have high prices for their products as a reference price for other countries where volume control mechanisms do not exist (Mossialos, Walley and Mrazek, 2004: 12-13). As a result, compensations in one country return to the sector as important gains on the global level. An example of this situation will be examined below.

The result of this situation is that in countries where MPCs can bring industrial and commercial gains, there are strong alliances between actors from the industrial sector and state actors to construct and to protect the global regulation of IPRs. Apart these countries, there are two different situations in pharmaceutical sectors in worldwide. On one side, in countries where the pharmaceutical industry is not developed, states do not have strong incentives to protect national pharmaceutical sector from MPCs and from the global regulation that they have constructed. On the other side, in countries where the national pharmaceutical sector is developed with generic manufacturing, states oppose this global regulation to protect their own industry. The global regulation of TRIPs is an act that damages all countries seen like the pharmerging markets by MPCs, especially it is against if these are opposing countries with developed pharmaceutical industries relatively independent from

MPCs. There will be some important examples of these countries in the following section.

Examples of Pharmaceutical Policies

This section is divided in two parts; in the first one, compromise-based responses from European countries will be studied and in the second one, examples of governments that use the TRIPs flexibilities as a compulsory license and parallel importing as aggressive bargaining tools against MPCs will be discussed. In the first part, the pharmaceutical policies of the UK and Germany will be examined. As was explained in the first chapter, the selection of these countries is based on more than one reason. From one hand, they are important examples for observing different pharmaceutical policies. On the other hand, they are not good examples, if these examples are just to make comparisons with the pharmaceutical policies in Turkey because they are different from the Turkish case. The main reason for this difference is the condition of their pharmaceutical industries. Both in the UK and in Germany, there are strong pharmaceutical companies that are mostly active players around the world, as being MPCs. As will be observed during this part about compromise-based responses, governments act not just under the pressure of public health concerns, or under commercial pressures of foreign pharmaceutical companies, but their own domestic pharmaceutical industry. For that reason, the examination of these examples will provide a different perspective that could not be obtained with similar examples to the Turkish pharmaceutical policies.

It can be argued that in this case, the pharmaceutical policies in the US also must be examined because they constitute an uncommon model where the

government does not use power in the health issue against powerful US-based MPCs. It was decided not to examine this example because the US represents a totally different example where any similar pharmaceutical policy to the ones observed in Turkey cannot be observed. Many characteristics of the UK and German pharmaceutical policies will be benefitted from in the fourth chapter while Turkish pharmaceutical policies will be observed. More specifically, the UK is selected because the pharmaceutical policies of this country constitute an ideal-type while the selection of Germany is related to its resemblance to the situation in Turkey.

In the second part, the examples mainly will be from India, Brazil and Thailand, as these countries are important examples through their use of the mechanisms of compulsory license and parallel importing, which are uncommon pharmaceutical policy tools. However, I must warn that none of these examples will be discussed in detail. Only a brief examination will be given to understand the global situation about pharmaceutical policies under the pressure of IPRs, and to position the Turkish case in the global picture.

Compromise-based Responses

Before examining the specific political tools used by these two countries against increasing pharmaceutical expenditures, the general characteristics of their health care systems must be discussed.

The model of the UK health care is one that is predominantly public with a single-payer that is the state itself (Hacker, 2004: 696). For that reason, it can be said that there is an obvious monospony in the UK pharmaceutical sector. Moreover, most elements of health and pharmaceutical policies are controlled by the

Department of Health (Permanand and Altenstetter, 2004: 44) and this state-administrated universal model is financed by general revenues (Giaimo, 2001: 335). Health care services are conducted by the National Health Service (Hacker, 2004: 696).

Even though UK state actors appear to be autonomous because of the status of single-payer, in reality, because of the financial system of health care, the state is directly responsible to its taxpayers, who finance the healthcare budget. In summary, this status of single-player does not bring total freedom to the state (Giaimo, 2001: 340). On the contrary, state can be considered caught between the expectations of the taxpayers and the demands of the pharmaceutical sector.

Looking at the other example, Germany, it is observed that the health care system is a mixed one of public and private with diverse coverage models. In the Corporatist Health Insurance system financed by payrolls, there is not just a single-payer as is the case in the UK (Hacker, 2004: 696). The German health insurance system covers approximately 90% of the population (Giaimo, 2001: 350) with a structure in which employers and employees have equal responsibility in the finance of this insurance system (Giaimo, 2001: 335). The diffuse structure of health care is more accented with policy sharing between the federal government, the federated states of Germany, sickness funds and physicians' and dentists' associations (Permanand and Altenstetter, 2004: 44). There are many results of this structure of the German health care system. One of them is that the increase in health expenditures has a direct impact on labor costs. According to another one closely related to our subject, even though the state is not the direct payer of health expenditures, it has a critical role in regulating the sector especially in cases of disaccord between payers and providers (Giaimo, 2001: 350-351).

Comparing the two examples, the UK with the National Health Service and Germany with the Corporatist Health Insurance System, it is clear that the health care budgets are more easily controlled in systems where the single-payer is also the regulator of the system than in systems where the decision making and control of budgets are in the hands of several different political bodies (Permanand and Altenstetter, 2004: 44). This is an important point that must be remembered in other examples of countries. It will provide some clues about the relation between the concentration of power and the success of pharmaceutical policies.

Another reason for the relative failure of Germany in the health care related cost containment policies is that, different from the UK, which aims for cost containment policies in the first place, Germany tries also to improve the efficiency of its health system in addition to cost containment (Permanand and Altenstetter, 2004: 40).

Now, I can begin to examine compromise-based responses of the UK and of Germany in the face of increasing pharmaceutical expenditures.

The most important feature of these examples is that both are countries with strong pharmaceutical industries, a fact that deeply affects the nature of pharmaceutical policies. First of all, beside all other differences, governments tend to have freer pricing mechanisms for industry (Permanand and Altenstetter, 2004: 43). Similar but softer than the situation in the US, in these two examples, the objective of fixing drug prices at a reasonable and affordable price can be ignored sometimes in favor of the profit of the pharmaceutical industry to the national economy (Mrazek and Mossialos, 2004: 118). In these examples, even though there is a monospony or a multi-payer system, actors from the local pharmaceutical sector are more powerful than their colleagues in other countries, and for that reason, they are more capable of

pressuring the government. It is a situation that cannot be observed in Turkey, where the situation is more like the examples of the second part of this section. The pressure comes not from the domestic pharmaceutical industry, but from the outside, from the MPCs.

For example, in the UK, prices are not regulated at drug launch. They are regulated later, in an indirect way, through the Pharmaceutical Price Regulation Scheme, which is a non-statutory profit control regulation (Mossialos, Walley and Mrazek, 2004: 11). Even though this institution is managed by the Department of Health, its main policy is to support the local pharmaceutical sector by creating a business atmosphere in which it is possible to increase the investment in pharmaceuticals (Permanand and Altenstetter, 2004: 43-44). It can be said that in the balance between industrial/trade policies and health policies, the Pharmaceutical Price Regulation Scheme is definitely a pro-industry policy institution. Through the supply-control mechanisms of the health care policies, industry in the UK is limited to a 21% return on capital employed as permissible profit. Even though this profit regulation can be considered as a pressure on the industry, in fact, this percentage is higher than other UK industries and much higher than the 12% average in other examples worldwide (Mossialos, Walley and Mrazek, 2004: 11). Beside the Pharmaceutical Price Regulation Scheme, the National Institute of Clinical Excellence is another institution that affects the pricing of drugs even though it does not set prices directly. For some thinkers, the recommendations of this institution constitute one of the important reasons for the increase in drug costs of the UK health care system in recent years (Mossialos, Walley and Mrazek, 2004: 13-14). The UK pharmaceutical industry was opposed strongly to the creation of National Institute of Clinical Excellence in the fear out of the restriction of new and expensive drugs.

However, different from these concerns, National Institute of Clinical Excellence has become an institution that does not consider issues of affordability, and for that reason, it has created such new problems for cost containment policies (Mossialos and Oliver, 2005: 297).

Other institutions in the construction of pharmaceutical policies of the UK are the Health's Medicines Division, which is responsible for drug licenses and the Committee on Safety of Medicines, which gives advices to the Medicines Division that is composed of members with financial interests in the industry. There is "a 'revolving-door' syndrome with industry officials moving to the Medicines Division for a period and then back to industry," as Abraham and Lewis (2000, as cited in Permanand and Altenstetter, 2004: 48) describe. For others, this relation between health policy institutions ant the pharmaceutical industry creates a case of "clientele pluralism" where the state is quite powerful with little autonomy and with a relationship of mutual dependence between the state and actors from the pharmaceutical sector (Permanand and Altenstetter, 2004: 47-48).

It was already mentioned in the first section of this chapter that the pharmaceutical sector of a country can accept the volume control mechanisms of a government if it provides relative pricing freedom that can be used in the markets of other countries. The UK is the perfect example to understand this strategy emerged from the close relationship between the state and the pharmaceutical sector. Many MPCs prefer to launch their products in the UK market to benefit from high prices. In this way, against attempts of reference price policies of other governments, MPCs present the prices in the UK. As a result, a reference pricing based on the prices in the UK does not achieve a meaningful cost containment policy that can harm the profits of MPCs.

This close relationship has other consequences on pharmaceutical policies. A significant example is about the use of parallel imports. Not just in the UK but also in Germany, although importing of drugs that are sold cheaper in other countries have an important market share, this policy is not encouraged by governments because of its possible damage to local R&D based pharmaceutical industries (Permanand and Altenstetter, 2004: 46).

Another issue is about generic drugs. Generic drugs are used both in the UK and in Germany thanks to volume-side policies directed at the use of generic drugs. Physician incentives are regularly used to promote the use of generic drugs. Generic name prescribing is encouraged or required in both countries. In the UK, there is a prescription support system named PRODIGY that lists drugs by their generic names. Moreover, generic prescribing is encouraged with face to face consultation and monitoring. Another common policy is to create prescribing budgets with financial disincentives towards physicians like penalties for exceeding this prescribing budget (Mrazek and Frank, 2004: 248).

As the result of all these volume-side policies, the use of generic drugs is quite high in the UK and in Germany. The ratio of the volume of generic drugs in prescriptions is significant with 52% in the UK and with 36% in Germany at the beginning of the 2000. However, the ratio of value is different from these figures. In the UK, generic drugs constitute only 18% of the total value of the prescription market, while in Germany, the figure is 21%. In both countries, the ratio of volume to value is very small, with 2.9 for the UK and lower than 2 for Germany (Mrazek and Frank, 2004: 245-246). These differences illustrate that even though generic drugs are in the market thanks to different incentives towards physicians, patented drugs still constitute a central place in pharmaceutical expenditures.

After examining the situation at the prescription stage, the situation in the distribution stage must be analyzed. In the UK, there are policies to encourage pharmacists to sell generic drugs. Instead of margins based on a fixed percentage of product's price, as in Germany, pharmacists receive a fixed reimbursement price on generics in the UK. In this way, they can save the difference between the purchase price and the reimbursement price if the product sold is cheaper than the reimbursement price. This is another successful volume-side policy directed to pharmacists to make them sell cheaper generic drugs instead of patented drugs (Mossialos, Walley and Mrazek, 2004: 22). On the other hand, in Germany, even since 2002, pharmacists have been allowed to substitute branded drugs with generic drugs if physicians do not disallow it explicitly in prescriptions, they have not much incentives to effectuate it because of the low margins in generic drugs (Mossialos and Oliver, 2005: 300).

Even though the German health care system is not as successful as the system in the UK in terms of volume-side policies, there are tools used for cost containment. One of these tools is the reference pricing system. Mentioned briefly in the case of the UK as a wanted reference market for MPCs, reference pricing can be considered a successful policy in some points. However, as seen in the German case, this policy cannot be used efficiently for patented drugs that are mostly the most expensive drugs (Mossialos, Walley and Mrazek, 2004: 11). Similar to the situation in the UK, th price of patented drugs is set by the industry itself (Mossialos and Oliver, 2005: 303). On the other hand, drug prices can be influenced indirectly through the reference price system even it is outside of the system. Companies can choose to effectuate such decreases to attract patients that incline toward drugs in the reference price system (Vogelbruch, 2000 as cited in Mrazek and Mossialos, 2004: 124) after a

period of high price for drugs outside of the system at the beginning of the reference price system. Before this decrease, the price of such drugs left outside increased by 20% in Germany (Statistiches Bundesamt, 1998 as cited in Mrazek and Mossialos, 2004: 125).

In this case, once again, it can be argued that patented drugs avoid regulation under the national pharmaceutical policies of cost containment. At least, it must be admitted that it is very difficult to regulate them in countries with powerful domestic pharmaceutical industries. However, it must also be remarked that the UK and Germany are the only European countries where no kind of direct regulation for pharmaceutical prices of patented drugs exists (Mrazek and Mossialos, 2004: 115). In 2003, France also began to regulate free pricing for drugs. However, this free pricing system has been limited with innovative drugs defined by a governmental commission responsible to the ministries of health and social security (Mrazej and Mossialos, 2004: 117-118).

Another volume-side policy used both by the UK and by Germany is the co-payment system. In the UK, the co-payment is about 10 euros per prescription for all drugs while in Germany it is 10% of the cost of all prescribed drugs with limits between 5 to 10 euros. However, in both countries, there are people excluded from this system, like children, the unemployed, low-income earners and the chronically ill (Mossialos and Oliver, 2005: 295).

In the overall picture, the UK is seen as a successful example where public health principles and health care attempts continue to exist without excluding the most vulnerable members of society from the system, as it is seen in other examples around the world. Germany is also a quite successful example of public health principles with a relative failure in terms of cost containment policies (Giaimo, 2001:

335). However, it must always be remembered that, even though it is a consistently used pretext by the pharmaceutical sector; it is true that cost containment policies can cause a decrease of efficiency leading to more hospital admissions as happened in Germany in the 1990s (Mossialos and Oliver, 2005: 304).

It must also be added that MPCs have many strategies that cause socially inefficient situations for health policies. Neither the UK nor Germany has been able to find solutions to some of the strategies of the pharmaceutical sector that harm the public health. For example, in many studies conducted on pharmaceutical policies, I came across to the issue of "me-too drugs," which were discussed in the second chapter. For example, in the UK, because the cost containment system is based on the rate-of-returns, the pharmaceutical sector chooses to over-invest in me-too drugs without focusing on innovative drugs (Mossialos and Oliver, 2005: 302). In all countries, but especially in Germany and in the UK where MPCs are strong actors in pharmaceutical policies, it is observed that even there is a decrease in the cost of existing drugs, new drugs continue to be a burden for cost containment policies. This situation is accented by the move from older drugs to newer and more expensive patented drugs, sometimes me-too drugs, with similar therapeutic effects to older ones (Mossialos and Oliver, 2005: 293-294 and de Joncheere, 2001: 222). Even though there are many supranational and national institutions that are responsible for the control of such drugs, it is difficult to identify and to exclude them totally from the insurance or health care scopes because of the complexity of the issue of technological innovation in drugs.

Now, I will begin to examine a totally different context and try to examine same objectives of public health, cost containment and industry/trade policies with different political tools.

Aggressive Bargaining Tools: The Use of Compulsory License and Parallel Importing

In this part, another type of pharmaceutical policy will be analyzed. Before beginning to this part, a remark about the method of this section in general and particularly about this part is needed. Even though there are huge differences between cited examples like the differences in their pharmaceutical sectors, health expenditures and government types, all of my examples are from developing countries. I must state once again that in the examination of these examples, not all characteristics of pharmaceutical policies of subject countries will be analyzed. Similar to the former part of compromise-based pharmaceutical policies, I will focus on the use of specific tools to understand these different approaches. This method can be criticized for creating ideal-types instead of showing an integrated analyze. It is important to note that my aim is not to claim that compromise-based examples are peculiar to developed countries or bargaining tools are peculiar to developing countries. In the countries cited in this part, it is possible to witness many other pharmaceutical policies that can be categorized as compromise-based policies. However, these aspects will not be analyzed.

My examples are mostly from developing countries because, contrary to the situation in the United Kingdom and in Germany, the global regulation of IPRs creates a negative impact on pharmaceutical policies of these countries, which cannot take any industrial or commercial benefits from this regulation through their local pharmaceutical sectors. On the contrary, it is harmful for our examples not just for public health issues and cost containment policies, but also for industrial policies

related to their own local pharmaceutical sectors. This is similar to the situation in Turkey where the global regulation of IPRs is a requirement of international relations, which does not create a favorable atmosphere in terms of health, or in terms of local industry.

As all these sides of the issue are undeniable, the current debates are shaped basically on trade policies, which is the arena of coercions, incentives and bargains related to our subject. For that reason, the relation of trade policies with pharmaceutical policies will be emphasized in the discussion through the issues of parallel imports and compulsory licensing. Even though Turkey is in a similar position as these examples, it is interesting that Turkey has never used these aggressive pharmaceutical policies. The fourth chapter will discuss this issue of the non-use of these policies.

The issue of parallel imports and compulsory licensing are important bargaining tools used against MPCs. In many drug crises around the world, it is observed that governments target to import generic drugs manufactured in India and in Brazil against the branded and expensive drugs of MPCs. The reason for the selection of India and Brazil was related closely to the structure of the domestic pharmaceutical sectors, alongside industrial and commercial policies implemented in these two countries related to the pharmaceutical sector. In the case of India, it is observed that the Indian pharmaceutical sector chose to be united against the pressures of MPCs to exploit all flexibilities allowed under the TRIPs agreement (Eren-Vural, 2007a: 127). The policies of the Indian government back to the 1960s and to the 1970s has created an atmosphere in favor of the development of a local pharmaceutical industry relatively independent of MPCs. Chaudhuri writes that in the period before TRIPs, “the commercial freedom allowed by the abolition of

patents was complemented by self-sufficiency in pharma-chemical production, and accumulation of research and development capabilities by local manufacturers on process technologies" (Chaudhuri, 1999 as cited in Eren-Vural, 2007a: 114-115). The government is not just a regulator to facilitate the development of the industry, but an active actor to create this industry through public investments and public support institutions.

Eren-Vural categorizes this industrial policy of the Indian government as the part of "a state guided capitalist development." The advantages of this policy, like the large pharmaceutical market, investment incentives and trade protection resulted firstly in the pharma-chemical production and secondly in the export power of Indian pharmaceutical sector since the mid-1980s (Eren-Vural, 2007a: 115-116). In the period after TRIPs, it is witnessed that these characteristics of the Indian pharmaceutical companies have revealed themselves not just in issues related to its domestic market but also in many controversial issues related to the access to medicines in developing countries. In the period right before the implementation of the TRIPs agreement in India, it was the producer of one-fifth of the world's generic drugs (Stokes, 2005 as cited in Klug, 2008: 233).

The best-known example of such crises is the case of antiretroviral (ARV) drugs in South Africa. In the Medicines Amendment Act of 1997, compulsory licensing and parallel imports were allowed by the South African government. The aimed export countries of this policy of parallel imports were especially India and Brazil. Even though the United States and many MPCs objected to this attempt with legal procedures, because of the pressure coming from international non-governmental organizations (NGOs), they could not pursue their coercive approaches. In result, South Africa succeeded at decreasing drug prices by means of

this aggressive pharmaceutical policy (Correa, 2002: 271; Lanoszka, 2003: 191-192; Klug, 2008: 219-221).

Even though India implemented the TRIPs agreement in 2005, the Indian government was very successful in benefitting from the flexibilities of this agreement not just with using transitional periods but also in interpreting the rights of parallel imports and compulsory licensing. It is true that India is one of the countries that implemented the TRIPs agreement at the latest date. Even after implementing the TRIPs, it has significantly different interpretations of "parallel imports" from many other countries where the global regulation of IPRs is implemented strictly. In a more flexible approach, the Indian government introduced a patent bill in 2005 where the right to parallel imports is interpreted together with compulsory licenses. Eren-Vural conceptualizes it as "an export oriented compulsory licensing mechanism" (Eren-Vural, 2007a: 126).

This concept can be explained first with the interpretation of compulsory licensing. Based on the TRIPs agreement, the right to compulsory licensing can be used in situations of national emergencies and public health matters where there are problems related to the availability and to the adequate supply as was explained in the second chapter. However, in the Indian case, the price of the patented subject is included in the list of causes. Moreover, with this patent bill, Indian manufacturers are free to export a product that has been produced under compulsory licensing even if the compulsory license was given just for the supply of the domestic market (Eren-Vural, 2007a: 126).

A recent example of the use of compulsory license by India itself is the case of Sorafenib, an anti-cancer drug patented by Bayer (Ipkitten.blogspot.com). The cost of the drug is around Rs.280,000 ($5,138.07) per month. However, the Indian

generic company Cipla has been selling this drug at around Rs. 30,000 ($550.51) per month and has an ongoing patent infringement action because of this drug. Now, another company, Natco, requested a compulsory license to sell it at around Rs. 8880 ($162.95) per month from the Indian government. And in 2011, the Indian government accepted this request. Even though India was the subject of many TRIPs-related issues in past years, it is the first official implementation of the compulsory license in India.[2]

Brazil that is another country referenced regularly as a potential export of cheap generic ARV drugs. Different from India, Brazil is a regular user of compulsory licensing as an aggressive tool to reduce pharmaceutical prices. Once again, differently from India, Brazil did not know to use flexibility of transitional periods of the TRIPs agreement. The Brazilian Patent Law in 1996 implemented the patenting of pharmaceutical products and processes with twenty years of exclusive rights and with the prohibition of parallel imports. All these points are in accord with the TRIPs agreement. However, Article 71 of this law about compulsory licensing is significantly different. According to this article, all patented pharmaceuticals can become the subject of a compulsory license in the case of national emergency or public interest (Thach and Marsnik, 2009: 247).

Brazil used this right to compulsory license as a threat in many cases of ARV drugs. It served as a negotiation tool in 2001 with Roche for a price reduction of 40% and in 2005 with Abbott Laboratories for a reduction of 50%. In 2007, Brazil issued a compulsory license for an ARV drug of Merck. And more recently, in 2008, it attempted the parallel import of the generic version of another patented ARV drug. For some thinkers, this is the result of pressures from NGOs and the Brazilian

[2] The amounts in USD are calculated in terms of the current exchange rate in 16 Mai 2012 (http://themoneyconverter.com/USD/INR.aspx).

pharmaceutical sector (Thach and Marsnik, 2009: 247). However, from another perspective, it can be thought that the MPCs accepted these lower prices because of the opportunities of the size of the market (Barton, 2004: 152). The example of Brazil fits in with this picture because it is the largest country market and the second largest market for medicines in Latin America (Thach and Marsnik, 2009: 248). For MPCs, the threat of their products being pulled from the Brazilian market is greater than being pulled from countries with smaller markets.

The last example that will be discussed in this part is the case of Thailand. After many unsuccessful attempts to use compulsory licensing at the end of the 1990s and at the beginning of the 2000s, Thailand managed to issue three compulsory licenses between November 2006 and January 2007, in the midst of the signature of a bilateral free trade agreement (FTA) with the US. One major reason of the use of this tool is the increasing burden of health expenditures, especially because of the expenditures related to the access to ARV drugs, generated with the National Security Act of 2001 that implemented a universal health coverage system. In just one year (2003-2004), the number of patients who had access to medicines under this universal coverage increased from 27000 to 52500. According to Krikorian (2009: 40), another reason for this use was the massive mobilization in Thailand against the negotiations of FTA, which was seen as "the emblematic example of neoliberal politics" of Prime Minister of the period.

Another important factor from which this policy emerged, was the military coup of September 2006. It created a greater autonomy to health policy makers than a stable civilian government, which could be affected easily by the pressures of MPCs. And the last factor is that this policy is used after the Doha Declaration, in an

atmosphere rather hostile to “IP extremists” who are seen against the Access to Essential Medicines Campaign of poor countries (Krikorian, 2009: 29-49).

The Thai example shows clearly that the success of the use of these tools as pharmaceutical policies are not stable outcomes. They can change with many factors related to the subject country and to the conditions of the period. Even though it was not discussed in detail, all of these attempts of aggressive bargaining tools are to encounter the threats of MPCs and economic coercions coming from the US. As explained before, the US is a perfect example for the examination of the close relation of the state with the pharmaceutical sector. Through the Generalized System of Preferences, Section 301, and many other mechanisms, the US coerces to countries that attempt to use these pharmaceutical policies.

In this part, I presented just a few successful cases to prove that even it is not an easy method to implement; it is still a type of policy that can be successful if realized in suitable conditions.

In the fourth chapter, which is dedicated to the case in Turkey, I will benefit from all these examples of pharmaceutical policies not just to explain the current situation but also to give meaning to the past of the Turkish pharmaceutical sector and to examine the pharmaceutical policies realized in relation with the global regulation of intellectual property rights.

CHAPTER IV: THE EFFECTS OF THE GLOBAL IMPLEMENTATION OF INTELLECTUAL PROPERTY RIGHTS ON THE TURKISH EXPERIENCE

After the second and the third chapters where the examination was on a global perspective, the fourth chapter is focused on the Turkish experience. As mentioned before in the introduction of this thesis, discussions in Turkey are quite difficult to observe not just because of many difficulties of the fieldwork, but also because of the hidden character of the conflict itself. On one hand, there is no obvious conflict between pharmaceutical companies and state actors apart from sporadic cases of short duration. On the other hand, the low prices of pharmaceuticals verify that there is not just a pressure coming from the pharmaceutical sector, but also a resistance coming from the government. For that reason, the aim of this chapter is to understand the mechanisms of the pharmaceutical sector, together with pharmaceutical policies affected by the global regulation of IPRs, which is realized through the structural power of MPCs. At the end of the chapter, I will be able to comment about the nature of the confrontation between MPCs and the Turkish government.

Differently from the former chapters, this chapter is constructed using a historical approach. First, the historical background of the Turkish pharmaceutical sector up to 1984 will be discussed. In the second section, historical periods will be examined in terms of specific issues. The first attempt of the implementation of the global regulation of IPRs around the discussions of 1984 will be discussed firstly in this section. The second historical division will be dedicated to the process of the implementation of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPs) in 1995. After the examination of the TRIPs issue, I will

pass to the issue of data exclusivity, which is still an important matter of discussion in 2012. The last issue to be discussed will be the intensive pharmaceutical policies of the recent period. In the end of the each part of the second section, there will be an overview with figures from the pharmaceutical sector.

The Historical Background of the Turkish Pharmaceutical Sector

This first section is about the structure of the Turkish pharmaceutical sector before the discussions of the implementation of the TRIPs agreement. In this section, the examination will be realized in two parts, with a brief history of the sector and a discussion of pharmaceutical policies before the global implementation of intellectual property rights. The first part of this section is dedicated to the emergence of the Turkish pharmaceutical sector, while the second one will be about the non-patentability period between 1961 and 1984. This examination will be useful to understand the reasons for some characteristics of the pharmaceutical sector in recent periods.

The Emergence of the Turkish Pharmaceutical Sector

The pharmaceutical sector in Turkey is regulated under the Act on Medical Products for Human Use of 1928. It is still in effect with many amendments (Çelik and Seiter, 2008: 5). The first pharmaceutical factory was set up in 1951 by E.R. Squibb and Sons. The first factory with local capital belonged to Eczacıbaşı, which was an important actor in the Turkish pharmaceutical sector up to the early 2000s. This one was set up in 1952 (Acar and Yeğenoğlu, 2004: 271).

One of the main characteristics of the Turkish pharmaceutical sector in this period is that even though pharmaceutical production was encouraged by government policies, the sector was largely dependent on imports (Semin and Güldal, 2008: 381). Imported foreign technology and imported pharma-chemicals were essential to local production (Eren-Vural, 2007a: 114). This characteristic has been important for the Turkish pharmaceutical sector throughout its history. Another important characteristic of this period is that the Turkish pharmaceutical industry was united against the direct intervention of the state. For that reason, the state acted just as a regulator that protected the industry from trade competition through the restriction of the activities of MPCs and investments incentives for local companies. It did not intervene in the technology development, nor in the production of pharma-chemicals. The political choice to exclude the state from any kind of investment resulted in an inability to product pharma-chemicals, the production of which is too expensive to be overcome by infant pharmaceutical companies. In sum, against the reaction of the sector, the state confined itself to proposing joint ventures between local manufacturers instead of public investment in the pharmaceutical sector (Eren-Vural, 2007a: 116).

In 1954, the Turkish government made a policy shift and offered incentives to encourage foreign capital and investments through the Law No. 6224 (Atay, 1992: 7). This resulted in rapid growth in pharmaceutical sector. MPCs entered the Turkish pharmaceutical sector in three different ways, by direct investments, by providing capital to local pharmaceutical companies and through licensing agreements (Semin and Güldal, 2008: 381). Some examples of these MPCs are Hoechst in 1954 (Pharmavision.com.tr), BIFA (constituted from Schering, Merck, Knoll and Bayer) in 1954 (Bayer.com.tr), Pfizer in 1957 (Pfizer.com.tr) and Hoffman-La Roche in

1958 (Roche.com.tr). However, with the 1960s, even though the pace of the foreign presence continued to increase in the sector, it would be limited to strict policies of import substitution, as will be explained in the following part.

The Long Experience of Non-patentability

After the military coup of 1960, the Constitutional Assembly of the period made an important decision about the Turkish pharmaceutical sector. Through this decision of 1961, all pharmaceuticals were excluded from any kind of patent protection (Atay, 1992: 7). This decision initiated a non-patent period that lasted more than thirty years. Patent protection, intellectual property rights for pharmaceuticals would not be accepted in Turkey until the 1990s. In 1985, Kırım described this period as "the longest experience of non-patentability" among developing countries. The justification of this act is based on the monopoly position of patent holders, high prices and the importance of vital drugs (Kırım, 1985: 220). It can be argued that all these factors are valid arguments for contemporary debates. However, as it was explained in the first chapter, these arguments cannot be thought of independently from the principles of the political economy. In the 1960s and the 1970s, like many other countries, Turkey chose non-patentability for pharmaceuticals as a political choice in accordance with import substitution policies (Eren-Vural, 2007a: 112).

Looking at other pharmaceutical policies of the period, it can be seen that there was an attempt by the government to contain public pharmaceutical expenditures. They were mostly supply-side mechanisms towards pharmaceutical companies via cost control, direct price control and profit control regulations. I have

already examined all of these policies in the third chapter. In Turkey, an example of the implementation of these policies was the regulation of 1972 named the "Pharmaceutical Price Regulation." With this regulation, an increase in prices was permitted to pharmaceutical companies, only if the cost of the product exceeded 20% of the first price of the drug (Semin, 1998 as cited in Semin and Güldal, 2008: 388). Until the regulation of 1984, all pharmaceutical regulations anticipated the control of the General Directorate of Pharmacy and Pharmaceuticals (IEGM) for cost data of pharmaceutical companies. In 1984, it was changed in favor of companies and from this date on, these pharmaceutical regulations would be based on the cost declarations of pharmaceutical companies. I will explain this issue more in detail in the section dedicated to the discussions of 1984.

Returning once again to the issue of patent protection, it can be seen that the Turkish experience of non-patentability constitutes an exception in many aspects. For some thinkers, weak patent protection can be a driver of technological development for developing countries, similar to the earlier period of industrialization in developed countries. However, the example of Turkey shows that the absence of patent protection does not always bring such a domestic technological infrastructure, or innovational capabilities, as argued by those who object to the patent protection (Kırım, 1985: 220). The lack of domestic technological infrastructure is observed with the dependency on imported raw materials, which was more than 70% of total raw material consumption (75,5% in 1981, according to Kırım, 1985: 231) and with the fact that just 16 of 81 companies were producing raw materials at the end of this period (Semin and Güldal, 2008: 385).

It is also observed that non-patentability did not decrease the flow of foreign direct investment (FDI) or the transfer of technology into the country, as was argued

by the defenders of the strong patent protection (Kırım, 1985: 220). Some figures providing these facts are that 77% of the drugs in the market in 1982 were introduced in the market in the period of the non-patentability of pharmaceuticals. Moreover, no delay of drugs was observed during this period. This means that even though there was no patent protection for innovative drugs, pharmaceutical companies still chose to launch immediately their products in the Turkish pharmaceutical market after their first launch in another country. The presence of local drug manufacturers and most importantly, the largeness of the growing Turkish market were significant factors that prevented such a negative consequence of non-patentability policies (Kırım, 1985: 229-230). In sum, foreign pharmaceutical companies still wanted to be in the Turkish market because of its earning potential and for that reason, they entered the market with license agreements, as will be discussed below.

In the post-1961 period, because of import substitution policies, there were strict limits on the entry of foreign companies into the pharmaceutical sector. They could not enter the sector to sell finished products, or to the formulation sector if they did not invest in pharma-chemicals production. This was an effective way of keeping away powerful foreign companies and to assist to the development of the local capital in the pharmaceutical sector. Foreign companies did not want to invest in pharma-chemical production in Turkey because of the high costs. Instead, they developed license agreements with local companies to exist in the formulation sector. The formulation sector is a relatively easy step in the process of producing a drug. In this step, the manufacturer does not produce costly pharma-chemicals, but just combines chemical substances to form the finished drug. Local pharmaceutical companies in Turkey could be developed in this sector, not just because of the

absence of foreign companies, but also this sector was relatively more accessible to an infant industry.

On the other hand, even though no "new" foreign manufacturing subsidiary was present in the pharmaceutical market because of the prohibition on foreign investment by the government to prevent the entry of foreign capital into the formulation industry, important MPCs like Hoffman-La Roche, Pfizer and Hoechst continued to increase the amount of their capital investments in the Turkish pharmaceutical sector (Kırım, 1985: 226). In this period, licensing agreements were more common than technology transfer agreements. However, one point to be remarked is that these licensing agreements often included restrictive clauses about export rights and the production of similar products like within a patent protection system. This fact shows that even though patents were forbidden by government policies, in practice they were quasi-present through trade agreements (Kırım, 1985: 228-229).

According to the figures from the Ministry of Health, in 1984, before the consolidation of the economic liberalization in Turkey, the sales share of MPCs was 37% (Eren-Vural, 2007b: 350). In 1979, 23% of total foreign capital stock in the manufacturing sector in Turkey was in the pharmaceutical industry (Kırım, 1985: 227). In sum, in the early 1980s, at the end of this period of non-patentability, the market share of foreign companies was quite low compared to other developing countries with important pharmaceutical sectors (Semin and Güldal, 2008: 383). They are not percentages to be underestimated, considering that it was right after a long period of non-patentability.

All these foreign investments resulted in a significant increase in domestic production. Turkey moved up into countries with reproductive capabilities in the

pharmaceutical sector, which means the capacity to produce active ingredients and finished products. Between 1973 and 1983, the production by boxes of pharmaceuticals increased by 80%, from 286 million to 515 million. Even though there was always a high dependency on imported raw materials, 95% of pharmaceutical needs were met by domestic production at the end of the non-patentability period (Semin and Güldal, 2008: 384-385).

Another important consequence of these restrictions of FDI on finished drug production is that MPCs had to collaborate with local companies to enter the market. This gave important power to the local capital. Different from other developing countries with significant pharmaceutical industries, Turkey was distinctive with the structure of its pharmaceutical sector where local companies were dominant over MPCs subsidiaries. In 1981, the market leader of the sector was a local company (Turgut Holding) and there were four local companies among the ten largest pharmaceutical companies list (Kırım, 1985: 231). These figures are significant in considering that there was a high concentration in the market during this period. For example, between 1970 and 1983, the market share of the twenty leading firms was 85% (Semin and Güldal, 2008: 383). However, local companies later lost this opportunity because of the economic liberalization policies of the period of neoliberal globalization right after the military coup of 1980.

This section will be ended with discussions on patent protection in 1984, not because the non-patentability period came to an end with this date, but because the patent issue appeared on the policy agenda with the new global context of neoliberalism.

Reflections of the Global Regulation of Intellectual Property Rights in the Turkish Pharmaceutical Sector (1980-2011)

The discussions that will be conducted in this section are important because they combine many points examined in former parts of the thesis. In this part, the reflections of the global regulation of intellectual property rights (IPRs) in the Turkish pharmaceutical sector around four important episodes will be discussed. Through these discussions, It will be witnessed that the sector and other related actors reacted to similar issues differently, according to different political conjunctures and different economical relations. For that reason, it is arguable that there is no such a definite and constant response against the global regulation of IPRs.

In the first attempt of the 1980s, I will discuss the reaction to the global implementation of intellectual property rights via the discussions on patent protection, the 1990s will be discussed as the years of a quasi-acquiescing of patent protection, and the 2000s will be the subject of discussion of an another reactionary current around the issue of data exclusivity. Last, in the 2010s, it will be observed that an indirect protest against patented drugs through pharmaceutical cost containment policies aimed especially at original (patented and off-patent) drugs.

Discussions of 1984: The First Attempt at the Implementation of Intellectual Property Rights

As in many sectors in Turkey, the economic liberalization of the 1980s was crucial for the pharmaceutical sector. The radical shift from import substitution

policies toward the export-oriented model affected local pharmaceutical companies profoundly. The first attempt at patent protection occurred at the beginning of the structural change in the sector. In 1984, the Ministry of Trade and Industry tried to include pharmaceuticals in the scope of patentability. However, this attempt was prevented by the reaction of local pharmaceutical companies, which succeeded in acting united against the MPCs (Eren-Vural, 2007b: 365). This united reaction owed its presence to the relative power of licensee companies against MPCs. As mentioned in the former section, local companies had been powerful against MPCs during the non-patentability period because MPCs had to use them as bridges to enter the sector. The discussions of 1984 constitute the last episode in which this power of licensee companies can be seen. After this issue, the balance of power was quickly changed in favor of the MPCs.

The process, which began with the liberalization of foreign capital stock increases in 1980, worked to the advantage of the MPCs, which increased their capital stocks after this date (Kırım, 1985: 227). The foreign investment policy of the government was to treat domestic and foreign capital equally during the 1980s (Koseoglu, 1994 cited in Eren-Vural, 2007b: 365). On the other hand, cost containment policies of pharmaceutical expenditures were little or nonexistent at the beginning of the 1980s. The regulation of 1984 was an example of these ineffective cost containment policies of the period. Similar to the 1972 Regulation, this one was also a supply-side mechanism, which aimed to control profits of pharmaceutical companies. It restricted profits to below 15% of the company's annual sales (Semin and Güldal, 2008: 387). However, different from the 1972 Regulation, the 1984 Regulation did not seek any state control for the cost data of pharmaceutical companies, but relied on declarations coming from the companies. Some thinkers

interpret this inefficiency as the absence of any drug price regulation and say that from this date to the 2000s, pharmaceutical prices were set in a discretionary way by pharmaceutical companies, which resulted in an uncontrollable increase in drug prices (Semin and Güldal, 2008: 387). One obvious manifestation of this fact is that during the 1980s and the 1990s, even though pharmaceutical companies were consistent with this regulation in appearance, they kept growing at such a high rate that from 1979 to 2003, the number of pharmaceutical companies in the 500 largest companies increased from 3 to 16 (Semin and Güldal, 2008: 390).

As was mentioned in the third chapter, the pharmaceutical policies of profit control can be manipulated easily by pharmaceutical companies. What happened in this period was similar. The liberalization of the cost control mechanisms of the state created a manipulative atmosphere in favor of pharmaceutical companies. In the example of Turkey, this manipulative atmosphere was reflected in a lack of transparency where the drug prices of companies with which the state could bargain were lower than the drug prices of companies with which state could not bargain.

It should be added that other cost containment policies were made at the beginning of the 1980s. One of them was co-payment in pharmaceuticals. According to these policies, 20% of drug costs was charged to employed workers and 10% of them was charged to retired workers (Semin and Güldal, 2008: 389). This regulation is still in force with added co-payments.

The process of the opening of the sector to foreign capital continued with the liberalization of foreign direct investment (FDI) in 1986. This year is especially important for the shift of power between MPCs and local licensee companies. The ratio of local capital to foreign capital was 62% to 38% at the beginning of the 1980s. In 1995, it was balanced between 50% local capital and 50% foreign capital (Acar

and Yeğenoğlu, 2004: 272). According to Eren-Vural, between 1986 and 1999, 30 MPCs entered the Turkish market by profiting from these policies. Related to all these developments, licensee companies, or what Eren-Vural describes as "the internationalized fractions of the local pharmaceutical sector" had to face increasing pressures from MPCs, to which they were bound with license agreements. Without restrictive policies on FDI, MPCs even had the possibility to threaten their licensees with canceling license agreements and entering the market directly. As a result, "the antipatent alliance between the domestic and internationalized fractions of the local pharmaceutical capital gradually dissolved" according to Eren-Vural (2007b: 366-367).

Another important development that influenced the pharmaceutical sector in this period was the hegemonic project of the integration with the European Union (Eren-Vural, 2007b: 371). This project was realized through Turkish conglomerate capital, which chose this project as a political strategy in their articulation with transnational capital. The conglomerate capital owes its presence to import substitution policies in the 1960s and in the 1970s and it is in the 1980s that most of them chose to rearticulate with the transnational capital (Ercan, 2002 as cited in Eren-Vural, 2007b: 365). In the end, conglomerate capital was in a defensive position in the case of patent protection not just because of its articulation with transnational capital, which was concretized in MPCs but also, and more importantly, because of the principles of the EU related to the pharmaceutical patents. For that reason, in the following parts where it is seen that in Turkey the patentability of pharmaceuticals is discussed not within the framework of the famous TRIPs agreement as is the case in many other developing countries, but related mostly to the EU membership of Turkey, this must be remembered.

Discussions of 1995: The implementation of the Patent Protection

Even though discussions of 1995 were shaped with approaches of different actors in the Turkish pharmaceutical sector, external pressures play an undeniable role in the issue. The first one of these pressures was the General Agreement on Tariffs and Trade (GATT) Uruguay negotiations, which began in 1988 and resulted in the signature of the Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPs) in 1994. Another one was the inclusion of Turkey in the Special 301 priority watch list by the United States Trade Representative (USTR) in 1994 (USTR, 1994: 12) as a means of economic pressure, as was discussed in the first and the second chapters. This threat of the watch lists of USTR has been used repeatedly in the years since against Turkey, as has been the case for many other developing countries. The last external pressure is the process of the Customs Union between the European Union (EU) and Turkey.

In the result of these factors, it can easily be argued that the implementation of the patent protection in 1995 was the result of external pressures that emerged from international agreements like the TRIPs agreement and Association Council Decisions (ACDs) between the EU and Turkey (Semin and Güldal, 2008: 383). The global regulation of IPRs was implemented in Turkey through what Yalçıner describes as "a mere external imposition on the Turkish state by the advanced capitalist countries or EU" (Yalçıner, 1999 as cited in Eren-Vural, 2007b: 340) cannot be accepted as the sole reason. The fact that different local actors, like conglomerate capital, internationalized fractions of the local pharmaceutical capital and governmental actors from the Ministry of Trade and Industry, used these global

mechanisms as political strategies and for that reason, the patent issue in 1995 was also shaped by internal discussions must be taken in consideration.

The draft code of the patent issue came to the Turkish Grand National Assembly (TBMM) in 1992. First, discussions were realized in the Trade and Industry Committee, where MPCs and licensee companies were quite influential. After many efforts on the part of the Turkish Pharmacists' Association (TEB) and the Ministry of Health, the discussions were carried to the Health Committee. The main discussions of this episode of 1995 were not the acceptance of the patentability of pharmaceuticals, which was considered as an inevitable fact, nor the many flexibilities of the TRIPs agreement, like compulsory licensing or parallel imports. It was just the length of the transitional periods to the patent protection of pharmaceuticals that was discussed between 1992 and 1995 (Eren-Vural, 2007b: 368-369).

During the discussions in the parliament, the Ministry of Trade and Industry, multinational pharmaceutical companies (MPCs), and their licensee companies, which are large local pharmaceutical companies (internationalized fractions of the local pharmaceutical capital) defended this patent draft, while the Ministry of Health, medium and small-sized local companies (domestic fractions of the local pharmaceutical companies) were more willing to discuss the length of transitional periods (Acar and Yeğenoğlu, 2004: 279).

The Approaches of Different Actors

More in detail, the MPCs wanted immediate protection without transitional periods. Moreover, they asked for retroactive protection for pharmaceutical products,

which had been patented during the 1990s, a phenomenon termed "pipeline protection" (Eren-Vural, 2007b: 369). Even though licensee companies, the interests of which were represented in the Employers Union of Pharmaceutical Industry (IEIS) and which were supported by the Association of Turkish Industrialists and Businessmen (TUSIAD) supported the patent draft because of the power loss during the 1980s, they had some reservations about the immediate implementation of patent protection. Rather than such an aggressive approach, they chose a transitional period that "would not create problems for Turkey in its relations with the EU, the European Free Trade Association (EFTA) countries, and the US," as Eren-Vural (2007b: 369) writes. Another motivated supporter of the patent draft, the Ministry of Trade and Industry, which had proposed the draft in the first place, was very close to the view of licensee companies with same concerns about the relations with the EU, EFTA countries and the US (TBMM, 1993 as cited in Eren-Vural, 2007b: 369). The discussions held in the Trade and Industry Committee reflected these approaches and for that reason, they ended up with the proposal on the reduction of the transition period to four year with a retroactive protection for pharmaceutical products that had been patented during the 1990s (TBMM, 1995 as cited in Eren-Vural, 2007b: 370).

Medium and small-sized local companies, the interests of which were represented in the Pharmaceutical Manufacturers Association of Turkey (TISD) and the Local Pharmaceutical Manufacturers Association (YISD), could not oppose the implementation of the patent protection even though it was against their interests. The entire objection they could realize, once again, was about the length of the transitional period. Their attitude was supported by the Chamber of Medical Doctors (TTB), the Association of Consumer Rights, and the Union of Turkish Chambers of Commerce and Industry (TOBB). On the other hand, the Ministry of Health

defended that Turkey must profit from the flexibilities of the TRIPs agreement and seek the longest possible transition period in the framework of the agreement (Eren-Vural, 2007b: 368-370). When the issue was carried to the Health Committee, the arisen decision to lengthen the transitional period to ten years without the pipeline protection, the retroactive protection, was parallel to the approach of these actors (TBMM, 1995 as cited in Eren-Vural, 2007b: 370).

Even though the patent issue had been on the political agenda since 1992, the date of the draft, it changed its guise at the beginning of 1995 with an external factor. Discussions in TBMM did not last longer because of the pressure of the process of the negotiations between the EU and Turkey about the Customs Union. ACD No. 1/95 signed in March 1995 projected the Customs Union between the EU and Turkey, and it settled 1 January 1996 as the final date for the completion of this process. The government instrumentalized this international agreement and used especially the Association meeting of the EU in October to shift the issue away from the parliament, where different actors could find the chance to get involved and to have a voice, towards a centered power where the interests of the conglomerate capital was strongly represented. Through a mandate from the parliament under the pretext of making many changes within a short period, the government had the power to use decree-laws for many important subjects related to the Customs Union, including the patent issue (Eren-Vural, 2007b: 372).

In the end, the patent protection for pharmaceuticals was implemented in Turkey in 24 June 1995 through Decree-Law No. 551 on the Protection of Patent Rights. This decree-law stipulated that the transitional period for the patent protection for pharmaceutical processes would be five years and the protection would start on 1 January 2000 while the one for pharmaceutical products would be ten years

and the protection would start on 1 January 2005. However, Turkey did not use this granted transition period and started the patent protection in processes and products starting 1 January 1999 (Gökovalı, 2009: 70-71).

This change was realized through another decree-law on 19 September 1995, which reduced the length of transitional period to three years (Eren-Vural, 2007b: 373). With this latest regulation, the patent term was determined as twenty years, R&D period included (Acar and Yeğenoğlu, 2004: 277). It is interesting to note that one of the interviewees described this change as "a change realized in one night". The meaning of this qualification becomes clear when I pay attention to the date. As Eren-Vural specifies in her work, it was the day before the collapse of the coalition between the True Path Party and Republican People's Party (Eren-Vural, 2007b: 373). Some researchers like Eren-Vural claim that even though the apparent pressure factor was the European Commission, the main actors of this sudden change in the patent legislation was the EU-based and the US-based pharmaceutical companies operating in Turkey. Even though I do not have documents about the background of this change and its relation with pressures coming from MPCs, as was witnessed in some cases and as I will try to demonstrate concretely during the part dedicated to the discussions about data exclusivity, there is an undeniable fact that some actors related to the patent issue see this change as having been the result of some negotiations realized behind closed doors because it was not subject to public discussions.

Returning once again to the apparent actors of the patent discussions of 1995, I have one point to stress especially. It is that in these discussions, the most dedicated protester against the patent draft was TEB, which discussed the issue not in terms of the limits of the length of transitional periods as other related actors, but in the

complete exclusion of the patentability of pharmaceutical products and processes (Eren-Vural, 2007b: 369). After their defeat by the acceptance of the patent protection in 1995, they continued their contest with the campaign of "the implementation of the patent protection must be postponed."[3] They had one main and three supportive arguments on the subject. The main argument was that the delay was crucial to having an affordable supply of drugs. They argued that an early implementation of the patent protection could demolish the local pharmaceutical industry, cause an external dependency in pharmaceuticals and result in the dysfunction of social security institutions (TEB, March-April 1998 as cited in Acar and Yeğenoğlu, 2004: 279). In May 1998, TEB supported the draft code of the Ministry of Health, which was prepared in line with the comment of the General Directorate of Pharmacy and Pharmaceuticals (IEGM) about the negative effects of the transition to the patent protection in 1999 on the local pharmaceutical sector and implicitly, on the public health. In this draft, it was proposed to postpone the implementation of the patent protection in pharmaceuticals to 2005 (TEB, May-June 1998).

TEB had two reasons for its objections to patent protection. The first reason was political. During the 1990s, a leftist group named the Association of Modern Pharmacists (ÇEB) was quite dominant within TEB. Their political view about the patent protection of pharmaceuticals was supported by the economic concerns of larger groups of pharmacists. For many pharmacies, commercial discounts realized by pharmaceutical companies and wholesalers were crucial to survive. However, these discounts could be realized if pharmaceutical companies needed to negotiate with pharmacies; in other words, there had to be a power balance between

[3] *Patente Geçiş Ertelenmelidir.*

pharmaceutical companies and pharmacies. The patent protection of pharmaceuticals posed a danger of the concentration of the sector in the hands of powerful oligopolies. In such a case, pharmaceutical companies would not need to realize these discounts and it would create a worse disparity between companies and pharmacies and it would damage the independence of pharmacists as individual merchants. This was the economic reason for the protest of TEB against patent protection.

However, during the interviews conducted in December 2011 with the Ankara Chamber of Pharmacists (AEO), it was observed that this radicalism has melted in the past decade. They are no longer against the patentability of pharmaceuticals. On the other hand, the interviews conducted in the same time with Istanbul Chamber of Pharmacists (IEO) demonstrated that they somewhat maintained their protester approach in the patent issue.

Overview of the Sector after the Discussions of 1995

After all these legal changes related to the Turkish pharmaceutical sector, some structural changes took place in the sector. The most important change was the pace of the increase of foreign capital into the pharmaceutical sector. As was discussed in the first chapter, about the gains of developing countries, the central argument of the defenders of the protection of IPRs is the technology transfer from developed countries to developing countries. In this way, they argue that it is possible for local pharmaceutical sectors to develop with the new knowledge and technology. However, as I observe in the Turkish example, it does not reflect the situation. The Turkish pharmaceutical sector has become increasingly dominated by

MPCs, while there also has been a sharp increase in the ratio of pharmaceutical imports. Even though the placement of local capital with MPCs does not affect negatively the public health necessarily or directly, it still constitutes an important change for the sector itself.

As was discussed below, MPCs were eager to enter the Turkish pharmaceutical market from the 1980s. With the 1990s, Turkey became a much more attractive market. One reason was certainly the implementation of the patent protection, which was welcomed by the MPCs. Looking at the patents taken between 1995 and 2006, the ratio of local companies in total patent applications and grants did not surpass 1% while important MPCs like Sanofi-Aventis (10.3%), GlaxoSmithKline (9.3%), AstraZeneca (7.8%), Roche (7.0%), Pfizer (6.9%) and Eli Lilly (6.0%) were important demanders of patent protection (Gökovalı, 2009: 71-72). However, it was not just with the patent protection legislation, but also and maybe more importantly, it was the increase in the pharmaceutical consumption, which attracted foreign capital to the Turkish pharmaceutical market.

Pharmaceutical consumption per capita increased from $8 to $85 by consumer prices and the expenditure on health by person increased from $55 to $153 between 1980 and 2003. The first one is an increase of 850% and the second one is an increase of 270%. Both ratios are important, taking into account that pharmaceutical expenditures constitute an increasing part of health expenditures. From 1990 to 2003, pharmaceutical expenditures constituted 22% to 55% of total health expenditures, while the world average was just 15.2% in 2000. By volume, the consumption increased from seven boxes per person in 1989 to 16 boxes in 2003 (Semin and Güldal, 2008: 391-392). In another source, the figures for 2003 are $52.7 with 11.6 units for per capita consumption (Çelik and Seiter, 2008: 14).

Another important development of this period was the increasing share of public expenditures in pharmaceuticals from the end of the 1980s to the beginning to the 2000s. The ratio, which was 35.9% in 1988 became 71% in 1995 and reached 78% in 2001 (Semin and Güldal, 2008: 391-392). This increase resulted in an undeniable problem of finance with the 2000s and for that reason, it would be one the reasons of the government's activity in pharmaceutical policies to regulate drug prices more strictly than in the 1980s and the 1990s, when pharmaceutical policies covered just profit controls and free pricing policies (Semin and Güldal, 2008: 388).

Actors from MPCs see the increase in the consumption of pharmaceuticals as a positive development and they argue that such an increase positively affect the health indicators in a country. During my fieldwork, I attended a seminar course in which an experienced manager working at a MPC cited figures about expectancy at birth and infant mortality in Turkey and connected them with the consumption of pharmaceuticals. However, according to researchers, there is no such correlation between life expectancy at birth or infant mortality and the consumption of pharmaceuticals (Semin and Güldal, 2008: 392).

Putting aside all the potential effects of the increase in pharmaceutical consumption, it is an undeniable fact that such an increase caused a rapid growth in the market. In 2003, the Turkish pharmaceutical market was the second fastest growing market in the world (Semin and Güldal, 2008: 391-392). For that reason, it is not surprising to hear that Turkey is cited as one of the "pharmerging markets."

MPCs enter the Turkish pharmaceutical sector mostly by acquisitions, as was the case in the acquisition of İlsan İlaç by Hexal in 1999 (Hexal was later acquired by Sandoz in 2005, a global generic producing company working under Novartis), the acquisition of Fako İlaç by Actavis in 2003, and the acquisition of the generic

production department of Eczacıbaşı by Zentiva in 2007 (Zentiva is the generic company working under Sanofi-Aventis since 2009) (Deloitte, 2009: 18). In 2007, EastPharma purchased the majority of shares of Deva (Deva.com.tr, 2012). Another recent acquisition is the acquisition of Mustafa Nevzat by Amgen, a US-based MPC in 2012 (Hurriyet.com.tr, 2012).

Joint ventures or mergers are not common in the Turkish pharmaceutical sector. For that reason, the entry of MPCs is not a fruitful situation for local companies; either for internationalized fractions, or for domestic fractions. In the sector, the ratio of foreign to local capital was 50% in 1995. This ratio increased to 51% in 1998 and it increased to 65% after the beginning of the patent protection in 1999 (Semin and Güldal, 2008: 383). This growth trend continues in the 2000s, as will be examined in the following part.

The increase in the ratio of pharmaceutical imports to pharmaceutical consumption was another characteristic of the 1990s. Actually, this increase began in the 1980s, however, it continued with accelerating speed in the 1990s. The ratio, which was 27.3% in 1982, increased to 41.8% in 1992 and to 53.1% in 1998. When 2003 arrived, this ratio was 59.8% (Semin and Güldal, 2008: 386). To say that this increase in imports was just a consequence of the increase in pharmaceutical consumption would be an optimistic view because they are ratios of imports to consumption. This increase in imports occured at the same time as the decrease in domestic production. According to an executive working in a domestic pharmaceutical producer company, even pharmaceuticals, which had been produced in Turkey for 20, 25 years, began to be imported. In former periods, the dependency in pharmaceuticals had been shaped in the form of the import of raw materials. In the 1990, the external dependency on raw material continued with the rising import ratio

of finished products. In 2005, the sales ratio of domestic production in pharmaceutical consumption declined to 58%, a ratio that had been 95% in the beginning of the period of neoliberal globalization, while the ratio of imported raw material remained approximately 70% as it had been in the beginning of the 1980s (IEIS, 2006 as cited in Semin and Güldal, 2008: 385). The ratio of imported pharmaceuticals continues to be examined in the following part about the discussions of 2005.

The number of companies producing pharma-chemicals in the sector declined between these years. Just 13 of 96 companies produced pharma-chemicals in 2005 (Semin and Güldal, 2008: 385). Between 1998 and 2003, the sharpness of the decline can be observed. It decreased from 7,076 tons to 3,324 tons (Semin and Güldal, 2008: 324) while it had been 8,860 tons in 1997. As for the production of finished products, the figures float with an increase between 1997 and 2000 of approximately 885 million boxes to 1.094 billion boxes, then a decrease with approximately 952 million boxes in 2001 (Acar and Yeğenoğlu, 2004: 272). The production once again increased in 2003 with 1.130 million boxes (Semin and Güldal, 2008: 386).

The decline in the domestic production of raw materials and the fixed import ratio of them are meaningful, when the entry of the MPCs to the market is considered. Many MPCs do not prefer to produce their products in Turkey. It is true that some MPCs like Novartis and Pfizer have factories in Turkey. Moreover, Pfizer has a R&D office in Istanbul (Pfizer.com.tr, 2012). However, these do not affirm that the products that they represent in the Turkish pharmaceutical market are produced in Turkey. During the interviews realized at the IEGM, it was learned that there have been some attempts to break this custom and to attract foreign investment in the pharmaceutical industry. However, such attempts to create new pharmaceutical

policies would be the subject of the 2000s, together with another strategic move of MPCs about intellectual property rights in pharmaceuticals.

Discussions of 2005: The implementation of Data Exclusivity

The discussions in 2005 about data protection and data exclusivity can be read as the continuation of the discussions of the patent protection or as a completely new set of discussions. From one side, it can be considered as a continuation in the framework of the global regulation of intellectual property rights in pharmaceuticals. The actors demanding these legal changes are the same ones, MPCs. However, the context is largely different from the one in the 1990s. The 2000s can be seen as the beginning of cost containment policies that affected the pharmaceutical sector considerably. For that reason, this part is dedicated to the first effective policy attempts at cost containment and the issue of data exclusivity will be the concretization of the power struggle between different actors related to the pharmaceutical sector.

Data exclusivity, which was discussed in detail in the second chapter was an important issue in the pharmaceutical sector at the beginning of the 2000s. This issue divided the sector between generic and original drug producers because different from data protection, this notion of data exclusivity had the purpose of favoring patented drugs through the postponement of the launch of generic drugs. Almost every local pharmaceutical company was located in the bloc of generic producers, while original drug producers, mostly MPCs, which were producing original off-patent drugs or importing patented drugs were in the other bloc. This division will be examined more in detail soon.

Data exclusivity was accepted in Turkey with the Association Council Decision (ACD) No: 2/97 signed in May 1997. According to this decision, Turkey had the obligation to implement data exclusivity in pharmaceuticals dating from 1 January 2001 (DPT, 2005: 47). In the Decree-Law of 1995, too, there were specific clauses about the protection of test data in patented drugs. However, in this legislation, data protection was considered related to the patent protection, not related to the registration process, as it is in the EU. This regulation was under the competency of the Ministry of Health and had no power of enforcement. These were the reasons of the weakness of the data protection, according to the State Planning Organization (DPT). The institution also argued that the exclusion of off-patent drugs from the framework of data exclusivity ruined the integrity of the system (DPT, 2005: 49). From these comments, it is clearly that the DPT defended data exclusivity instead of the production of generic drugs. It must be remembered once again that data exclusivity is one of the strategies of MPCs to extend the monopolistic power that they have during the patent period to the post-patent period. In this approach, DPT did not care about the concerns of the Ministry of Health and social security institutions about the increasing pharmaceutical expenditures, which were accented with the crises of the beginning of the 2000s. One reason for this approach of DPT can be the specific department that prepared this report. The author of this report was the General Directorate of Economic Sectors and Coordination (İSKGM). For that reason, it can be argued that this approach was not the view of DPT in general, but of İSKGM, a department that is more sensible to the interests of transnational capital.

Cost Containment Policies

For the Ministry of Health and social security institutions, generic drugs became an important opportunity to contain pharmaceutical expenditures. In the beginning of the 2000s, the Turkish economy was deeply influenced by recurrent crises. One of the solutions found to these crises was to contain and curtail public drug expenditures, similar to what happened in European countries in the 1990s, as was examined in the second chapter. The decision to contain costs was confirmed with the implementation of data exclusivity, which was an added burden to public expenditures because of its retarding effect on the market entry of generic drugs. The new regulations about the inclusion of most people as beneficiaries of public pharmaceutical expenditures exacerbated the problem. An example of this increase was the rule change of Social Insurance Organization for Workers in 2004, by which its beneficiaries were allowed to use other service providers than their own (Çelik and Seiter, 2008: 24). It was in February 2005 that they were allowed to benefit from other pharmacies than their own ones (Deloitte, 2009: 2). Another example was the inclusion of the pharmaceutical expenditures of green cards holders in 2005, with a co-payment of 20% (Liu et al., 2005: 20). At the same time, there was a general increase in the population secured by the state. Between 2002 and 2007, the number of beneficiaries of social security institutions increased from 46,318,627 to 56,423,907 (SGK, 2010). This increase is more than 20% and this was an added burden to public expenditures.

The first policy realized in the objective of cost containment was the reimbursement of only the cheapest generic version of original drugs (Eren-Vural, 2007b: 374). Even though there were many earlier regulations about the issue, I will

reference the regulation of 2004. In this regulation, it is stipulated that only drugs the prices of which do not exceed the price of the cheapest generic plus 30% of this price would be reimbursed. This regulation is important because it is implemented together with the legislation about the reference price system, in which the creation of a reimbursement commission was projected.

Another advantage of this regulation on the cheapest generic drug was that it gave incentives to pharmacists to promote cheaper generic drugs because it stipulated decreasing profit margins related to drug prices. Moreover, pharmacists could take initiatives to substitute a generic for an original drug prescribed by the physician (Çelik and Seiter, 2008: 22). As was observed in the second chapter, it is a volume-side pharmaceutical policy. Pharmacist-directed incentives are crucial in generic drug policies because, otherwise, these policies can be easily neutralized if there are important commercial discounts coming from wholesalers (Kanavos et al., 2005: 103). A pharmacist can choose to sell a drug for which there is an important commercial discount even it is disadvantageous for the public budget. Such incentives must be powerful enough to prevent such conditions.

The second cost containment policy was the reference price system, which was implemented in Turkey through Cabinet Decree No. 2004/6781 signed on 14 February 2004. According to this decree, five countries from the EU would be selected to realize price comparisons. The reference price was determined looking to the two countries in which the price is the lowest for the selected drug. For original drugs, the price in Turkey would be 90% of the lowest price, while for generic drugs, it would be 70% of the lowest price with an exception of 80% for generic drugs produced with local pharma-chemicals. For 2004, the chosen countries were France, Italy, Spain, Portugal and Greece.

Here, a point must be remarked. In the Turkish legislation, the price of drugs is defined whether it is an original or a generic drug. However, this differentiation does not reflect the differentiation of patented and non-patented drugs, as it is the case in other examples. Many original drugs in this period are under the category of off-patent drugs due to the newness of the acceptance of the patentability of drugs. This situation leads to many miscomprehensions about the price reduction done to patented drugs. In further legal regulations, there will be another differentiation between original drugs with generics (off-patent drugs) and original drugs without generics (patented drugs). After this differentiation, there is no price reduction by reference pricing system for original drugs that are accepted as patented drugs in Turkey.

Returning once again to the subject, some argue that selecting European countries for reference pricing is not fair, taking into consideration the difference of per capita national incomes between European countries and Turkey (Semin and Güldal, 2008: 388). On the other hand, during the interviews, many actors related to the issue defended that the number of selected countries must be increased. Actors from the state defended that reference countries must be selected including the former Soviet republics, while actors from the industry were for the inclusion of countries like the UK where drug prices are higher than other countries in the EU. It is the concretization of the hypothesis discussed in the second chapter. For the pharmaceutical companies of the Turkish market, the free pricing policies of the UK are an advantage while the pharmaceutical policies of the UK constitute a disadvantage for the Turkish government, which tries to curtail its pharmaceutical expenditures in conformity with the system in the EU.

The pharmaceutical policies of the period did not cover effectively physician-directed incentive mechanisms. Unlike in many European countries, in Turkey there were no volume-side mechanisms for physicians like positive or negative incentives, nor an efficient good prescribing monitoring system. As observed from what was said during the interviews, physicians were more open to bribery than pharmacists were. It was an important lack that the government tried to fulfill in the period of intensive policies at the end of the 2000s.

Moreover, with this decree about the reference price system, the state began to distinguish between generic drugs and original drugs. Another reform of this decree was the creation of a reimbursement commission constituted of the representatives of the Ministry of Health, DPT, the Undersecretariat of Treasury, social security institutions (Social Insurance Organization for Workers, Social Security Organization for the Self-Employed, Government Employees), in the coordination of the Ministry of Finance. In the text, it is mentioned that this commission takes into consideration the views of non-governmental organizations. Other researchers assert that two representatives of the pharmaceutical sector, one from R&D based companies (MPCs), other one from domestic companies, were included in the commission (Çelik and Seiter, 2008: 6).

International Pressures

Actually, MPCs were more interested in the subject of pharmaceutical reforms than they appear to be. They saw these regulations as an important threat that they must immediately overcome (Eren-Vural, 2007b: 374). With the efforts of MPCs, Turkey was elevated once again on the Priority Watch List of the United

States Trade Representative (USTR) in 2004 (USTR, 2004: 21 as cited in Semin and Güldal, 2008: 384). This is one of the categories of the USTR to punish countries that do not implement the protection of intellectual property rights (IPRs). Turkey was on the Watch List of the USTR since 1994. The Priority Watch List is a more disadvantageous position than the Watch List.

Another attempt to overcome this situation was direct pressure on the government. In January 2003, an interesting article appeared in the newspapers,[4] according to which, Pfizer had forced the Minister of Labor and Social Security of the period to cancel the regulation that had taken place in the Social Insurance Organization for Workers and in the Social Security Organization for the Self-Employed about the reimbursement of only the cheapest generic version, because it had caused a great loss of profits for the company. In 2002, these two social security institutions had saved expenses of approximately 550 million TL. In the article, it was asserted that Pfizer had been affected gravely by this regulation. Just with one drug, which was a hypertension drug called Norvasc, Pfizer had lost more than 10 million TL because the active material of Norvasc, a pharma-chemical called amplodipine, was excluded from the reimbursement list of these two social security institutions with this regulation. In February 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA) prepared a report on the subject, argued that their loss of gains would be $100 million because of the reimbursement system of the cheapest generic version of original drugs and asked that the US government pressures the Turkish government on the issue. In May 2002, a committee constituted of the executives of Pfizer came to Turkey to meet with the Minister of

[4] I am thankful to Nurdan Demirkan for talking about this issue with me.

Labor and Social Security. In the end, the pharma-chemical in question was once again included on the reimbursement list (Haber.gazetevatan.com, 2003).

Pressures coming from MPCs continued with the complaint of the European Federation of Pharmaceutical Industries and Associations to the European Commission in October 2003 (Semin and Güldal, 2008: 384). In this complaint, the EU-based MPCs argued that there were "discriminatory pricing and discriminatory margins, local production requirements, discriminatory distribution policies, lack of data protection/data exclusivity as well as overall lack of transparency in the pricing system" in Turkey. An examination procedure began in December 2003 according to this complaint (European Commission, 2004).

The European Union was largely involved with the implementation of data exclusivity in Turkey even without the direct action of MPCs. In December 2004, the European Commission gave a diplomatic note to the Turkish government about the data exclusivity of pharmaceuticals. This was a worrying development for the Turkish government and for that reason, it can be argued that it became an important catalysis for the concretization of data exclusivity in the legislation related to pharmaceuticals. This note received a great deal of attention in the newspapers during January 2005. Different journalists adopted a discourse, in which they aggressively blamed generic producers with "stealing drug ingredients" of original drugs (Radikal.com.tr, 2005). In other news, statements like "pirate drug production" and "copying without doing research" were commonly used, while talking about generic drug manufacturing (Artan, 2005). During this period, the internationalized fractions of the local pharmaceutical sector acted together with domestic fractions against this attack in the public opinion coming from MPCs. Different from the 1990s, when the big companies of the sector like Eczacıbaşı acted against the small

generic manufacturers and reviled against them, this time Eczacıbaşı itself led the opposition against the MPCs, as can be observed in the process of the splitting of the Employers Union of Pharmaceutical Industry (IEIS) that I will examine soon.

Wikileaks documents offer us much information about the attention of MPCs on the subject of new pharmaceutical regulations (Subjectif.org, 2011).[5] For the period between 2002 and 2010, there exist 240 cables related to pharmaceuticals and data exclusivity. Turkey is in the first place with 76 cables. Most of these cables reflect concerns of the US-based MPCs about data protection and new pricing regulations (Keionline.org, 2011). In these cables, it is clearly observable that the US ambassador to Turkey is closely interested in discussions on these subjects. Through the ambassador, the US-based MPCs ask the US government to pressure the Turkish government on the subjects in question. The ambassador held many meetings with MPCs, the minister of health, the minister of industry, the minister of finance, the minister of economy and the state minister of foreign trade. These meetings prove what I said in the second chapter about the diversity of pharmaceutical policies. In this case, I must repeat that pharmaceutical policies cannot be thought of just within the framework of health policies, but in a larger picture where financial, economic and industrial policies together with trade policies are taken into consideration.

In one of the cables, the importance of the meetings with the Ministry of Health and with the Foreign Trade Undersecretariat is clearly declared:

> Frequent meetings with the MOH [Ministry of Health], who has ultimate control over data protection and pricing and reimbursement decisions, I also discuss the issue periodically with officials from the Foreign Trade Undersecretariat (FTU), who is responsible for ensuring that Turkey meets its international, including WTO and TRIPS, obligations (Wikileaks.org, 2006).

[5] This is a useful site to examine many wikileaks documents related to our subject.

This quotation shows that the US ambassador and MPCs acted to persuade or to obligate the Turkish government mostly in terms of its international obligations. During these meetings, Special 301 lists of the USTR (Keionline.org, 2012) and the process of the membership of Turkey to the EU (Wikileaks.org, 2006a) were frequently used coercion instruments.

The Approaches of Different Actors

While these coercion mechanisms were operating in the international arena, there were some important developments about the political alliance between MPCs and their licensee companies in the Turkish pharmaceutical sector. The issue of data exclusivity became a litmus test for new alliances in the sector. The domestic and internationalized fractions of the local pharmaceutical capital united against the implementation of data exclusivity. In the result of these discussions, the MPCs parted ways with internationalized fractions of the sector, separated from the Employers Union of Pharmaceutical Industry (IEIS) and founded the Association of Research-Based Pharmaceutical Companies (AIFD) (Eren-Vural, 2007b: 374-375). AIFD became quickly a center of interests of the MPCs. Thereby, just like the Pharmaceutical Manufacturers Association of Turkey (TISD), IEIS became also a center of interests of generic manufacturers of Turkey.

After several meetings realized in December 2004 between the ministry of finance, undersecretariat of foreign trade, the ministry of industry, DPT and the ministry of foreign affairs, the Ministry of Health prepared a regulation for data exclusivity (Eren-Vural, 2007b: 376). It is meaningful that almost all these actors

were addressed by the US ambassador in closed-door meetings, as was observed in the Wikileaks documents.

As the result, data exclusivity was concretized in Turkey through Article 9 of Regulation No. 25705 on the Registration of Pharmaceutical Products, which was implemented in January 2005. According to this regulation, the data exclusivity for pharmaceuticals was for six years starting from the first market approval in the Customs Union area (DPT, 2005: 51-52). The Ministry of Health had two aims while it set that the first market approval was not in Turkey, but in the Customs Union area. In this way, it intended to prevent "unnecessary extensions in the duration of market exclusivity" and to encourage "the earlier introduction of the product in the national market" as Eren-Vural (2007b: 377) writes. During the interviews, it was quickly observed that the actors from the sector were not content with this principle and defended that the period of six years was insufficient to benefit from the market exclusivity. They asserted that in practice, they had entered the market in the same time that their generics enter. It was one of the main discussion points for the actors from the pharmaceutical sector even in 2011.

From this point, it can be estimated that MPCs were more worried about their off-patent branded drugs, the patents of which had expired, than their patented ones. Patented drugs are under protection and therefore, they are immune to generic competition for 20 years. However, the MPCs wanted similar protection for their original off-patent drugs, when they wanted to launch them into the Turkish market.

In the process of the preparation of this regulation, local pharmaceutical companies were aware of the obligations of Turkey about the implementation of data exclusivity. For that reason, they first tried to postpone the implementation to the date of the full membership of Turkey in the EU, as a bargaining tool. In addition,

they tried to restrict the period of exclusivity to the shortest period in the EU member states. Last, they wanted to bind the period of data exclusivity with that of the patents. Even though they failed in two of these objectives, they were successful in restricting the period of data exclusivity to the shortest one in the EU.

On the other hand, the MPCs achieved most of their objectives. It was accepted to introduce immediately data exclusivity (1 January 2005) with a limited retroactive clause to cover licensed drugs since 2001, the date Turkey had projected in its signature of the relevant ACD in 1997 (Eren-Vural, 2007b: 375-376). A small victory for the generic companies was the clause about the exclusion of drugs whose registration request had been realized between 2001 and 2005 (DPT, 2005: 51).

After the discussions of 2005, the MPCs appeared to be satisfied with the governmental policies. In a press release of AIFD dated January 2007, the reference price system of 2004 was praised for bringing transparency to the pricing system and because it provided the access to "modern drugs" with the lowest European prices (Aifd.org.tr, 2007). However, the MPCs were always anxious to remind everyone of their importance. In another press release of the same time, in January 2007, the MPCs declared that Turkey remained in Generalized System of Preferences of the USTR thanks to the efforts of PhRMA and AIFD (Aifd.org.tr, 2007a). This press release can be read in a different way, as intimidation on the part of the political power of MPCs.

Overview of the Sector after the Discussions of 2005

Now, the situation in the Turkish pharmaceutical market during all these changes and power struggles must be observed. In 2001, there were 120

pharmaceutical companies in the sector with 84 local and 36 foreign companies in a market of $2.553 billion (TÜBİTAK, 2003: 4). The pharmaceutical market grew from 4.8 billion TL in 2002 to 12.1 billion TL in 2008 (Deloitte, 2009: 9). From 1999 to 2004, the increase in the volume of pharmaceuticals was just 20%, while the increase in the sales of them was 700% (IMS, 2004 as cited in Liu et al., 2005: 63).

In 2008, among the ten largest pharmaceutical companies, there were three local companies, Abdi Ibrahim, with $623 million in sales; Bilim İlaç, with $420 million in sales; and Sanovel, with $318 million in sales. The leading company was Novartis with $624 million sales and together with other six MPCs, they constituted total sales of $2.975 billion (Deloitte, 2009: 8). However, as Acar and Yeğenoğlu remark, from the 2000s, it is more correct to categorize pharmaceutical companies depending on whether they produce generic drugs or original drugs instead of their source of capital (Acar and Yeğenoğlu, 2004: 280).

With the new regulations, which promoted the production of generic drugs, generic drugs began to have a significant market share. In 2005, they constituted 55% of the 5,338 drugs on the market and had a market sale of 38%, while originals had a sale of 62% (Semin and Güldal, 2008: 389). Within prescribed drugs, the box number of generic drugs increased from 345 to 678, while the box number of original drugs increased from 390 to 634, between 2001 and 2007. The value of generic drugs increased from 0.7 billion euros to 2.1 billion euros, while the value of original drugs increased from 1.8 billion euros to 4.1 billion euros in the same period (Çelik and Seiter, 2008: 16). It was relative progress toward the increase in the consumption of generic drugs. However, even if it was not as striking as it was in the European examples that were observed in the second chapter, the ratio of volume to value (1.4) was relatively small in generic products vis-à-vis the condition in original drugs.

On the other hand, there was a constant decline in the ratio of locally produced drugs against the ratio of imported drugs in the market. In 2001, the domestic production answered 88% of the pharmaceutical needs in number of boxes (IEIS, 2002 as cited in Acar and Yeğenoğlu, 2004: 272). The ratio of local production in boxes, which was 89.6% in 2002, declined to 80.1% in 2008. Related to the former, a more striking decline occurred in the ratio of sales of locally produced drugs, with a decline from 66.5% to 50.2% between 2002 and 2008. As a result, in the year of 2007, imported drugs constituted 17.9% of drug boxes with a sale ratio of 49.8% (Deloitte, 2009: 10).

In many resources, it is clearly indicated that one the major issues of the pharmaceutical expenditures was the unplanned importation of pharmaceuticals (Semin and Güldal, 2008: 386). Unplanned importation means the import realized for an individual patient or for a group of patients who need a specific drug that does not exist in the Turkish market. In these conditions, the state does not have bargaining power over the drug price even though it pays the price if patients are secured by SGK. This issue is brought on during the interviews with Ankara Chamber of Pharmacists (AEO). It is argued that such kind of unplanned importation cases result in important expenditures because there are many cases like this in the recent period. This issue is added to the larger picture of the increasing ratio of the public share in the total pharmaceutical expenditures. The public share, which had increased to 78% in 2001, decreased to 63% in 2004 (Liu et al., 2005: 57). From 2000 to 2007, public pharmaceutical expenditures increased from $2.227 billion to $6.809 billion, while an increase in total public health expenditures was occurred from $4.223 billion to $15.360 billion (Çelik and Seiter, 2008: 23). In another source in which the figures are in TL, it corresponds to an increase from 7.912 billion TL to 13.006 billion TL

for pharmaceutical expenditures and an increase from 15.677 billion TL to 31.068 billion TL for total health expenditures between 2000 and 2007. In 2009, expenditures reached 15.585 billion TL for pharmaceutical expenditures and 36.368 billion TL for total health expenditures (Deloitte, 2011: 9).

These figures show that in 2009, 42.85% of public health expenditures were realized for pharmaceutical expenditures. This ratio is greatly different from the European examples that were studied in the third chapter, the United Kingdom with 11.6% in 2008 and Germany with 15% in the same year (OECD Health Data, 2011).

Some actors from the pharmaceutical sector tried to justify the high ratio of pharmaceutical expenditures in total expenditures with the high cost of labor in Turkey (Liu et al.: xi). However, it must be remarked that this is a weak justification pro-MPCs. In the context, where the global regulation of intellectual property rights in pharmaceuticals is discussed so widely, to explain the rise of the drug prices as a simple fact of high labor costs in just one country is not meaningful. Moreover, even World Bank reports declare that one of the main reasons for the increase of pharmaceutical expenditures in Turkey is due to the introduction of new drugs, which are mostly expensive innovative drugs (Semin and Güldal, 2008: 389).

Related to this period of 2005, the MPCs argued that the pharmaceutical policies of this period were not realized with a concern of cost-effectiveness, but within a narrow framework of the curtailment of pharmaceutical expenditures, and for that reason, these policies were not sensitive to innovative drugs. Instead, they were favoring either ex-patent original drugs with high costs, or generic drugs with linked prices to original drugs (Kanavos et al., 2005: xi-xiv). However, at the end of the examination of these discussions through the figures from the sector, it is observed that on the one hand, a favorable atmosphere was created for MPCs in the

Turkish market and from the other hand, pharmaceutical expenditures continued to grow at undeniable rates despite all the regulations realized in the opposite direction.

In the end, beginning from 2007, the government decided to realize more intensive methods to curtail pharmaceutical expenditures. The last part of this chapter is dedicated to the discussion of these policies, which reached their peak in November 2011.

Discussions of 2011: Intensive Pharmaceutical Policies as a Response to the Implementation of Intellectual Property Rights

Even though the title of the part highlights the year 2011, the discussion of November 2011 must be thought of in a larger period, as was in earlier parts. I must also take into consideration that this part has deep relations with the former part and it can be read as the continuation of the reforms of 2004-2005. However, it must be admitted that the reforms of this period are more intensive. For that reason, reactions coming from the sector too are more violent than the ones of the former period. The examination begins with giving some examples of these reforms.

Main Cost Containment Policies

Pharmaceutical pricing policies continued to be regulated in the period after 2005 with several cabinet decrees. In 2007, in 2009 and in 2011, the regulation of drug prices was conducted with apparently little differences that created large reflections in the pharmaceutical sector. In the cabinet decree of 2007, the price of original drugs (both patented and off-patent patent drugs) was limited to the price of

the reference price, while the price of generic drugs was limited with 80% of the reference price (Cabinet Decree No. 2007/12325 signed in 30 June 2007). In 2009, all non-patented drugs, original or generic were limited to a price of 60% of the reference price (Cabinet Decree No. 2009/15434 signed in 18 September 2009). In this way, the pricing of original and generic drugs were balanced for the first time. The same year, because of the reactions coming from the pharmaceutical sector, this price was increased to 66% of the reference price (Cabinet Decree No. 2009/15631 signed in 3 December 2009). However in 2011, the price of original (off-patent) and generic drugs were once again decreased to 60% of the reference price (Cabinet Decree No. 2011/2368 signed in 10 December 2011). All of these policies regulated the price of patented drugs at 100% of the reference price because they were protected with international agreements like the TRIPs agreement and association council decisions between the European Union and Turkey. However, the Turkish government tried to regulate the price of patented drugs through institutional discounts of the Social Security Institution (SGK).

Besides the supply-side mechanisms realized through cabinet decrees, cost containment policies were also realized with other pharmaceutical policies towards volume-side. One example is the use of SGK, which was established in 2006 through the unification of three different profession-based social security institutions of Turkey (Social Security Institution Law No. 5502). Institutional discounts were an important instrument of the government for many years because there was always a situation of quasi-monopsony in Turkey and the state could use this power to regulate indirectly drug prices. The pricing system in Turkey is described in the report of IMS (2010: 40) as a “two-stage pricing system” with the maximum pricing and the reimbursement pricing. As it is mentioned in the third chapter about

pharmaceutical policies, even though the institutional discounts of social security institutions can be cited as a volume-side mechanism of cost containment, in reality, its indirect effects on drug prices make it deserve to be cited as a price-side mechanism. Through this dual system, in 2009, the pharmaceutical expenditures of SGK reached 15.585 billion TL (Deloitte, 2011: 9) while the size of the pharmaceutical market was accepted as 14 billion TL (IEIS.org.tr, 2012).

When the development process of this public pharmaceutical expenditure in 2009 is observed, it is seen that at the end of the first decade of the 2000s, the tendency to use this power of bargain became sharper with the global economic crisis of 2009. This tendency was strengthened with the sharp increase in pharmaceutical expenditures of SGK between 2008 and 2009. According to another source, it reached 15.9 billion TL in 2009 with a ratio increase of 14.4% and, in this way, it surpassed the original budget of 14.6 billion TL for 2009. After a series of meetings with the pharmaceutical sector in July 2009, the government decided to implement the policy of the global budget for the reimbursement of pharmaceuticals (IMS, 2010: 25). A change in the Social Insurances and General Health Security Law No. 5510 was realized through a decree signed in September 2009 and according to this degree/protocol, SGK began to stipulate the budget dedicated to pharmaceutical expenditures for next years. It predicted a budget of 14.6 billion TL, 8.9% lower than the expenditure in 2009, for 2010; a budget of 15.56 billion TL for 2011; and a budget of 16.67 billion TL for 2012. The pharmaceutical industry acknowledged these budgets and agreed to repay the government with further price decreases if these budgets would be exceeded (IMS, 2010: 25).

The Approaches of Different Actors

Even though the pharmaceutical industry agreed to this policy, it soon began to react against institutional discounts realized in accordance with it because of another clause of the same protocol signed in September 2009. According to this clause, next to the right to implement compulsory discounts, the government had the responsibility to increase drug prices in a condition of a constant exchange difference of three months. From 2009 to 2011, in many press releases of the Association of Research-Based Pharmaceutical Companies (AIFD), these additional discounts were interpreted as an injustice towards research-based pharmaceutical companies (AIFD.org.tr, 2009). In November 2011, another institutional discount was implemented through the Statement on the Health Implementation. According to this statement, patented original drugs had to be sold with an institutional discount of 41% and off-patented original ones had to be sold with a discount of 28% together with the rule of 66% of the reference price (Article 28[5]). The discount was implemented especially in patented and off-patent original drugs because, as was declared clearly during the interview with AEO, the main reason for the exceeding of the global budget was the price of the famous patented drugs, and especially the price of the so-called “me-too” drugs that were discussed in the first chapter.

This time, the reactions of the pharmaceutical sector were larger with the contribution of other associations of the sector through joint press statements (AIFD.org.tr, 2011a). The MPCs argued that despite this decrease in drug prices, there must be a price increase because of the exchange difference that caused a loss of 25% in prices. As a result, AIFD opposed clearly one clause of this protocol, which was about the reimbursement of stock damages of wholesalers and pharmacies

by pharmaceutical companies, with the pretext of defending this other clause, which stipulates the concurrency of exchange differences (AIFD.org.tr, 2011). This opposition started a discussion in which the state, through different ministries, MPCs, through AIFD, and pharmacists, through TEB, were included. After the press release of AIFD, the Minister of Labor and Social Security declared that they would not accept this attitude and he threatened the MPCs with the exclusion of 341 drugs, for which companies had rejected to implement the regulation, from the positive list of SGK. There were important insulin and antiretroviral drugs within these debated drugs (Ntvmsnbc.com, 2011a).

During these discussions, pharmacies began not to purchase or not to sell these drugs because it caused a huge burden for them (DHA.com.tr, 2011). With the monitoring system MEDULA, prices were reflected to the pharmacies in the instant. As a result, they had to sell a drug, moreover an expensive drugs, at a lower price than its arrival price. Many pharmacists refused to sell these drugs until the issue was solved or they asked patients to compensate the difference in accordance with directives coming from pharmaceutical companies (Ntvmsnbc.com, 2011). During an interview with a pharmacist, he confessed that he had not purchased such drugs from wholesalers in this period. He added that many patients had imported individually those needed drugs from Greece during these discussions. In the end, the issue was solved with the retreat of the government. In the first step, an agreement on a discount about the value-added-tax of pharmaceuticals was realized (Stargazete.com, 2011). After that, the prices of the 125 crucial drugs were changed to the former prices, before additional discounts. Also for other drugs, the government decided to change prices (Hurriyet.com.tr, 2011).

Even though the discussions of 2011 were solved with the victory of the MPCs, this issue of "constructed scarcity" brought to minds radical possibilities. One of them is a situation in which a MPC decides to withdraw one of its products or not to enter into the Turkish pharmaceutical market with this product. During the interviews, it was learnt that in 2002, Pfizer said that it would pull out of the Turkish market because of the pharmaceutical policies. However, as the interviewee declared, it was a bluff that most people saw through. However, the same interviewee claimed that in 2011, when Novartis said the same things, it was not a bluff and the company really was thinking of withdrawing. According to some pharmacists, such a situation could happen in the near future if the government continues with these pharmaceutical policies.

State agents think that even the strong MPCs cannot take such a risk because of the size of the Turkish pharmaceutical market. Turkey has not used any of the TRIPs flexibilities so far. However, it is uncertain if it will be an attempt to use a compulsory license in the case of need of a specific drug. During the interviews, actors either were not aware of such a right or thought that the Turkish government had never used and would not use this right in the future.

Meanwhile, actors from the sector continue to argue that the pharmaceutical policies are implemented within a narrow framework of the curtailment of pharmaceutical expenditures and for that reason, they are not sustainable policies. During the interviews, it was observed that many different actors are of the same opinion. Even actors working in the General Directorate of Pharmacy and Pharmaceuticals (IEGM) think that implementing additional institutional discounts to imported drugs in a context where there are increasing exchange differences is not meaningful. Other actors think that the government chooses its policies related to the

reactions coming from the sector. It proceeds with trying. If there are too many reactions, it withdraws its policy. If there are not, it takes another step. It is already seen that in the international arena, the implementation of the global regulation of intellectual property rights and their reflections on pharmaceutical policies were shaped by countless negotiations between the MPCs and different governments. The Turkish example shows us that these negotiations continue to exist also in national arenas with a high intensity.

Other Minor Cost Containment Policies

Besides the global budget system, reference pricing and compulsory institutional discounts, the government tries to implement minor pharmaceutical policies. One of them is the Good Manufacturing Practices regulated in March 2010 by the Regulation No. 27516. According to this regulation, the Ministry of Health has the authority to control the production place of all drugs in the market, including imported drugs. This regulation is not considered as a serious policy by the actors from the pharmaceutical sector. Interviews with some of these actors showed that for them, US control mechanisms like the one conducted by Food and Drug Administration are more valid controls than national controls. Even interviewees from IEGM see this regulation of the Good Manufacturing Practices not as a system in itself but as an instrument to extend the period of registration of imported drugs in favor of locally produced drugs. The negative impact of this approach to imported drugs was observable from the news (Sagliginsesi.com, 2010).

Other recent attempts of pharmaceutical policy are the implementation of control mechanisms on the demand-side. The government tries to control the

prescription behavior of physicians through monitoring and negative incentives to prevent the consumption of expensive or unnecessary drugs. In November 2011, there was news about a regulation of negative performance towards physicians who write unnecessary drug prescriptions (Sabah.com.tr, 2011). Such a regulation can be effective to contain pharmaceutical expenditures because, as it is remarked by AEO, physicians turn easily towards new and expensive drugs instead of old and cheap drugs, even these new ones are just "me-too" drugs. This behavior prevents any pharmaceutical policy conducted against such expensive "me-too" drugs. Moreover, there is some illegal behavior on the part of physicians to lead their patients to ask for a specific drug instead of the generic one reimbursed by the SGK. This behavior can be the consequence of a bribery, as well as an ethical act if the physician believes that the reimbursed drug is not as efficient as the original one.

A worker from an international generic company declared that not all of the generics on the market are of the same quality. Some of the interviewed pharmacists verified this declaration. They think that there is a lack of state control and for that reason, even within the generic market, there is no equivalence. This declaration can be true to a limited extent. This extent is the fact that as it is the case in other countries, in Turkey, the MPCs entered aggressively to the generic market and acquired many local generic companies. As the result, they left their hostile criticism of generic drugs and adopted a smoother approach for these drugs. Now, they argue that there is a differentiation between international generic companies, which work mostly under MPCs, and other local generic companies. Exceptions like Abdi İbrahim and Bilim İlaç are the only remaining strong local generic companies that can exist within the leading ten pharmaceutical companies in 2009 (IMS, 2010: 57).

The government tries also to control the registration behavior of physicians by controlling the visits of company representatives by an instruction of 2009 (Instruction No. 2009/25 of the Ministry of Health). Another attempt is to change directly the number of drugs within a box. Inspired by some European examples, it seems that the government will try this policy of reducing the volume of drugs in boxes in the near future (Haberturk.com, 2011). In addition, there are new policies about co-payments for drugs to prevent the unnecessary use of drugs with 3TL for each prescription up to three drugs and 1TL for each added drug (Ntvmsnbc.com.tr, 2011b). Even though there is a strong tendency to curtail and contain pharmaceutical expenditures with all these regulations, the policies implemented in favor of the interests of the MPCs must not be overlooked.

The mention of an independent institution to regulate pharmaceuticals with authority over registration, pricing and control mechanisms was present even in reports dating from 2005. For a long time, the MPCs criticized that IEGM was in an integrated structure with the Ministry of Health and they gave examples of the US, France, the UK, Canada and Japan where these mechanisms were conducted through independent institutions (Kanavos et al., 2005: 94-95). Clearly, through the impact of these requests, IEGM is transformed into an independent institution that functions still under the Ministry of Health. More importantly, Article 58 of the Decree-Law No. 663, signed in 11 October 2011 (as a change made to Articles 2 and 3(j) of the Law No. 209) stipulates that all donations made by third parties are accepted as incomes of the institution.[6] This regulation was commented on by the media as an instrument of lobbying and bribery between pharmaceutical companies and the government (Muhalifgazete.com, 2011).

[6] Once again, I am thankful to Nurdan Demirkan.

Another tendency in favor of the MPCs is the discussions about a new patent code. Data about this issue cannot be found, neither in press releases, nor in the media. Referencing the patent code draft of TPE, it can be observed that in this new code, international discussions like parallel imports and exhaustion of patent rights would be included (TPE, 2009). The highlighting of these issues can be a clue about the increasing export ratios of generic drugs in Turkey. However, it is not clear yet if these discussions will result in a patent code favoring solely the MPCs or a mixture of interests of different groups.

During the interviews, some actors mentioned meetings organized between the sector and the government in the beginning of the 2012 about the increasing pharmaceutical expenditures and the decreasing profit margins of the MPCs because of the cost containment policies. One solution found in these meetings is that the government must be saved from the burden of the pharmaceutical expenditures by the transfer of this burden to consumers and the enlargement of a less-controlled market that would be out of the reimbursement list of SGK. If such developments will occur, there would be an immense increase in drug prices. Even such claims cannot be confirmed because of the lack of data, it is highly possible when the tendency to loosen the tension between the MPCs and the government is considered.

Overview of the Sector after the Discussions of 2011

At the end of all these intensive pharmaceutical policies, I will look at how the sector is affected by them. In the examination of the sector, the retail sector, which involves 94% of the total market, will be examined (IMS, 2010: 63). I will begin with comparing the figures from the retail market, beginning with 2005, the

date in which beneficiaries of the Social Insurance Organization for Workers began to purchase drugs from community pharmacists.

The sales of pharmaceuticals increased from 789 million boxes to 1.379 billion boxes between 2002 and 2008, while the sales in price increased from 4.8 billion TL to 12.1 billion TL in the same period. The ratio for the volume increase is 74.77% and the ratio for the price increase is 152%. This difference in ratios is meaningful. These figures verify a claim of AEO, according to which the growth of the pharmaceutical market is not growth in terms of consumption, but growth related to the price increase of drugs, especially of patented drugs. The figures reached 1.39 billion boxes with a sale of 14 billion TL. The increase was not enormous for the drug volume (approximately 2.7%), but the increase in sales was spectacular with a rise of 16.2%. As said before, it is after this increase that the government implemented the global budget system. Due to this policy, sales figures in TL remained relatively stable between 2009 and 2011. With a small decline in 2010 (-1.5%) and small increase in 2011 (1.4%), it remained 14 billion TL both in 2009 and in 2011. On the other hand, the drug volume continued to its constant rise. Respectively, it increased to 1.39 billion, to 1.43 billion and to 1.56 billion in 2009, 2010 and 2011. The increase in last year was significant with a ratio of 9.1% (IEIS.org.tr, 2012).

In the meantime, the increasing ratio of beneficiaries in this period must also be considered. The ratio of beneficiaries of SGK within the total population continued to increase at the end of the first decade of the 2000s. From 80% in 2008 to 83% in 2010 with a number of 57,338,454 to 61,506,194 between same years (SGK, 2010). For that reason, it can be argued that the pharmaceutical policies of this period were certainly intensive altogether with this increase in the population of

secured people. However, one must be careful to comment on these policies. It is easy to think that these policies had negative effects on the sector and, as it is argued by the MPCs, many companies are on the edge to lose. The situation is not quite like this when the pharmaceutical sector is examined.

The lists of leading pharmaceutical companies in Turkey have been dominated by the MPCs in recent years. In the top ten list of 2008, there were just three fully local capitals, while the leader of the list was Novartis (Deloitte, 2009: 8). In 2009, the number of local capital decreased to two, without counting the tenth company, Deva, whose majority shares were purchased by EasyPharma in 2007. Novartis was once again the leading company with 1.209 billion TL sales and with an annual growth of 17.7%.

There is an important point to stress in this list. Even though Abdi İbrahim is just the third company with 970.2 million TL sales, its annual growth is greater than most of the other companies with a rate of 21.2% (IMS, 2010: 57). In 2010, this growth rate became more influential and causes a change in the sector. Abdi İbrahim became the leading company with 1.118 billion TL sales, while the sales of Novartis decreased to 959 million TL (Deloitte, 2011: 24). This situation cannot be explained simply by the success of a company and the failure of another because there was a decrease of sales in all MPCs and an increase not just in Abdi İbrahim, but also in Bilim İlaç, which is the other local company in the list. Moreover, Sanovel entered once again to the leading ten companies list.

At the end of the first decade of the 2000s, generic companies had important shares in the Turkish pharmaceutical sector. Not just local capital, but also foreign capital was attracted through policies favoring generic production. One of the reasons for this attraction was the relatively high prices of generic drugs. As was

observed earlier, the ratio of volume to value of generic drugs is not as small as it is in Europe. For that reason, it can be argued that producing and selling generic drugs in Turkey is more profitable than in Europe. When MPCs are observed, it is seen that they want to be active in the generic market and choose to produce generic drugs in Turkey.

Sandoz is a good example of this case. As already discussed, Sandoz is a global generic company working under Novartis. It has been the export leader of Turkey since 2005. In 2010, its drug exports reached $51 million towards 46 different countries (Sandoz.com.tr). Even though their separate sales from Novartis or their ratio of sales and production in Turkey are not known, one interviewee said that Sandoz has not been influenced by the pharmaceutical cost containment policies of the recent period because they work mostly for exports. According to import and export data of Turkey between 2001 and 2011, it is observed that drug exports in sales increased even though there was a modest increase beside the important increase in imports. Exports increased from $149 to $576 million, while imports increased from $1.534 billion to $4.697 billion (IEIS.org.tr). It can be estimated that a large part of these exports were exports of generic drugs. In sum, exports are slowly becoming an important subject for the generic production in Turkey.

Referencing a report from the beginning of the 2000, I said above that companies must not be categorized any longer as local and foreign capitals, but with their production as generic or original (reference) drugs. However, with the changes in these years, there is the illusion that once again the source of the capital becomes important. Yet, the situation is different. In the light of all that has been examined in this part, it is seen that it is not local capital that is favored and thus, which grows, but it is the local production and the production of generic drugs that are encouraged

and remunerated. This argument can be proven with figures about the ratios about generic-original production and imported-locally produced drugs in recent years.

When the ratio of generic and original drugs in the pharmaceutical market is observed, it is seen that there has been an increase in the market share of generic drugs, not a significant increase in volume, as one can guess, but an increase in sales ratio. From 2009 to 2011, the volume ratio of generic drugs increased from 52% to 52.4%, while its ratio in sales increased from 35.3% to 38.4%. There was a similar increase in the ratios of volume and sales of imported and locally produced drugs. The volume of locally produced drugs decreased from 79.8% to 78.1%, while the sales ratio increased from 48.7% to 50.5% (IEIS.org.tr, 2012). All these figures show that the pharmaceutical policies of the end of the first decade of the 2000s were aimed at original and imported drugs, which are the main products of the MPCs.

However, after these examinations, it must not be supposed that the MPCs are the victims of these policies as they try to represent themselves. On the one hand, it is true that the MPCs do not earn as much as they did at the beginning of the 2000s and the number of dismissals increased importantly in the recent period. On the other hand, the MPCs make the pharmacists, who are as a buffer zone between MPCs and the government, pay some of the damages caused by these policies. This fact can be observed in the example of institutional discounts. SGK realizes this discount officially to pharmaceutical companies. However, by cutting commercial discounts made for wholesalers and indirectly to pharmacists, pharmaceutical companies neutralize some of these discounts. As a result, the pharmacist often has to sell a product without returns, sometimes at a loss. It is certain that such strategies against pharmacies cannot recompense all the damages and the MPCs are receiving the consequences of the discounts too. However, as is discussed in the IMS Report on

Turkey, the pharmacists are affected negatively, especially by the cost containment policies of 2009. In 2009, TEB had foreseen that many pharmacies were likely to go bankrupt. Another development is happened related directly to the number of pharmacies. With the change in the Law No. 6197 on Pharmacists and Pharmacies, it is decided that the number of pharmacies would be limited with one pharmacy for 3,500 persons (TEB.org.tr, 2012). For now, there is no such a dramatic decrease in the number of pharmacies but, the number, which was 24,703 in 2009 (IMS, 2010: 61) will quite likely decrease to approximately 21,500 according to this law.

In 2009, pharmacists still had some negotiation power against the pharmaceutical companies. They acted united against the cancellation of commercial discounts of Pfizer and Servier and they succeeded to retake these discounts (IMS, 2010: 47). However, in a concentrated pharmaceutical market, dominated by powerful MPCs, the negotiation power of pharmacists would diminish certainly. This power loss of the pharmacists is intensified with the new governmental projects about the sale of drugs at supermarkets (Sabah.com.tr, 2009). In this picture, news about the greed of the pharmacies face to the victimhood of the pharmaceutical companies (Haber.gazetevatan.com, 2009) must be discussed very carefully.

For that reason, it can be argued that the government and the MPCs are not face to face as is in other examples observed in former chapters. The MPCs consent to these policies, first, because of the opportunities of the size of the Turkish market and second, because of the governmental policies done in favor of them. Another reason is the absorption of some of the damages of the MPCs by the pharmacies. In the end, even though speculations about the new era are not in the framework of this study, it can be said that many recent developments in the pharmaceutical sector give clues about the negative future of public health under the domination of MPCs.

CHAPTER V: CONCLUSION

The study concludes with the observation that the process of the global implementation of intellectual property rights (IPRs) in Turkey was realized as part of an interrelation between the local pharmaceutical sector and the Turkish pharmaceutical policies. However, it was also demonstrated during the study that this process could not be thought of as limited to the national framework and is part of a larger picture where the most powerful actors are multinational pharmaceutical companies (MPCs) and the developed countries in which these MPCs are based. The comparisons realized in the fourth chapter on Turkey through the second and the third chapters verified that there are not just resemblances, but also divergences between the global situation and the Turkish case.

In accordance with the global context, IPRs in pharmaceuticals were implemented in Turkey during the era of neoliberal globalization, as the extension of the global political project according to which the cure is considered equal to research, both seem to be equal to profits and therefore, the patent protection is accepted as vital. Differently from the general tendency, this process diffused by powerful MPCs was firstly objected to by the united reaction of the Turkish local pharmaceutical industry. The main reason for this unity was the relative power of licensee companies, which acted like bridges to the MPCs to enter into the Turkish market during the period of non-patentability. This unity was demolished at the end of the 1980s because of the decline of the licensee companies, which became more dependent on the MPCs after the permission of foreign direct investments in the pharmaceutical sector. The 1990s witnessed a quasi-unquestioned acceptance of the global implementation of IPRs in pharmaceuticals, not just because of the dissolution

of local companies against MPCs but also because of the approach of the Turkish conglomerate capital, which supported strongly the settlement of the IPRs of pharmaceuticals into the process of the membership to the European Union (EU). The non-patentability period was useful just for the temporary power of licensee companies until the end of the 1980s. As it is discussed in detail during the work, it did not result in a powerful local pharmaceutical sector and in sum, except for some discussions about transitional periods, the implementation was realized in Turkey without serious discussions. Even today, this implementation is not discussed, but accepted as a fact that should be done, more clearly as part of the neoliberal *doxa*, as I argued.

One of the origins of this weak reaction in the 1990s from the pharmaceutical sector can be traced back to the period of the emergence of the sector in the 1950 when actors from the sector refused all kind of state intervention. This resulted in an external-dependant industry even in the non-patentability period, which differentiates the Turkish pharmaceutical sector from other countries' where the local sector is powerful enough to react against the MPCs in the global implementation of IPRs, as was examined in the third chapter in the cases of India and Brazil.

Today, the discussions about the patentability of pharmaceuticals are shaped mostly around the issue of the data exclusivity. On the global scale, this issue continues to be discussed related to the mechanism of international agreements like the agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPs). However, in Turkey, this issue too is considered as a step in the process of the membership to the EU and not in the larger global picture, as an issue that concerns many countries that are not related to the EU. One reason for this situation is the absence of free trade agreements with Turkey. Turkey is not in a radical position

because it is not threatened directly by developed countries. Another reason for this docile position is that Turkey is not in the position of countries like Brazil, India or South Africa, where expensive pharmaceuticals are crucial issues for the treatment of cancer. In Turkey, there is not such a situation of national emergency related to a disease. For that reason, the economic dimension of the issue is more emphasized than the health dimension, similar to developed countries with powerful local pharmaceutical sectors, even such a sector is missing in the Turkish case.

As was observed from recent data, the pharmaceutical policies of the end of the first decade of the 2000s aimed at original (patented and off-patent) drugs rather than generic drugs because of the cost of innovative drugs and its burden on public expenditures. Relying on its monospony position, the Turkish government negotiates with the MPCs in the national arena with a high intensity. From the negotiation aspect, it is observed that Turkey resembles much more to the examples that use aggressive bargaining tools, even though there are no similar health emergencies.

More precisely, the Turkish government reacts to the patent protection not with the compromise-based policies of developed countries exactly, nor with the aggressive bargaining tools of developing countries. All the examples from the Turkish experience show that this is a case between them.

In Turkey, the cost containment policies of the government can be criticized for not being mindful about the cost-effectiveness of pharmaceuticals, as is argued by the MPCs. On the other hand, as was argued during the study, contrary to the common belief on innovative drugs, most of these pharmaceuticals are developed not for effectiveness criteria, but as a solution to the decreasing profit margins of pharmaceutical companies, as it is seen in the examples of me-too drugs. For that reason, even there is always a danger of increasing health expenditures while trying

to contain pharmaceutical expenditures, governments must be judged carefully in their attempts to curtail and contain pharmaceutical expenditures through price decreases on innovative drugs. The price of a drug is not always an indicator of its effectiveness, especially in the context of the global pharmaceutical market, in which prices are kept high through a constructed scarcity realized by IPRs, more precisely by patent rights.

The case of Turkey is different from other examples on another point, too. As was shown in the last chapter, there is not a situation in which the government and MPCs are in an open conflictual position except some sporadic cases. While these sporadic cases happen, they are solved mostly through incentives for one part of the pharmaceutical sector (like incentives done on behalf of generic or local companies) or through the pressure on pharmacies. Such incentives create fractures within the sector and sometimes, it strengthens the hands of less powerful parts, like local companies, against powerful MPCs. For that reason, to read the reaction of local actors as the direct reflection of the global implementation process is not quite true. For many cases, it is seen that if the local industry is relatively powerful, it tries to have a moderate opposing position against the MPCs and indirectly, against many aspects of the patent protection because of their conflict of interests with MPCs and with the global implementation of patent protection. The pressure on pharmacies can be read also as a pharmaceutical policy, which loosens the tension between MPCs and the government. It can be argued that the government aims to reduce the number of pharmacies in the aim of reducing the distributors' profit margins in total.

Another estimation about cost containment policies is related to unofficial meetings between the sector and the government in the aim to channel the pharmaceutical expenditures to the citizens instead of the government itself. Even

these objectives are not cited as official tendencies of pharmaceutical policies, such possible objectives can always be thought of. In a context where the new structure of General Directorate of Pharmacy and Pharmaceuticals creates an "industry-friendly" atmosphere, it is not that wrong to estimate that the implicit confrontation between MPCs and the government will be loosen in the near future with new solutions that would not be positive for public health.

The lack of consumers' reaction can be questioned in such a context. This is mostly due to the role of the state as the biggest buyer, the monospony condition. Most consumers are not affected by increases or decreases in drug prices. They are only affected when the state ceases to pay for a drug that previously has been reimbursed by the social security institution. In these cases, consumers react against the government, which they hold responsible and the pharmacist, who is in front of them. Pharmaceutical companies are not the subjects of reaction, even though in the common belief, they are seen as big earners. From the data found during the interviews, even some pharmacists see the government as the only party responsible for their situation and do not blame the pharmaceutical companies. Needless to say, my proposal is not to accuse pharmaceutical companies, or discredit the MPCs, but to analyze the pharmaceutical policies of the recent period from a larger perspective where historic developments and global structure must not be ignored.

As for the position of the state, I did not argue that pharmaceutical policies are realized for the pure interest-seeking of the citizens. On the contrary, I tried to demonstrate that the same issues could be interpreted differently according to governmental choices shaped by economic requirements and political relations. However, for Turkey, on the issue of pharmaceuticals, at least as long as the state continues to pay for the pharmaceutical expenditures of the citizens, the government

will pursue policies of cost containment and will target drug prices. The reason is that as a nation-state, the Turkish state in this study, cannot protect, at least openly, the interests of the MPCs, which are not directly related to the state with relations of economic gain, as is the case for the states of developed countries with powerful pharmaceutical sectors. Moreover, as Turkey is not yet the subject of a bilateral free trade agreement, its radius of action is larger than many other developing countries. In sum, it can avoid the global implementation of IPRs to a certain degree for economic concerns. For us, it can be a good opportunity to discuss at length why IPRs in pharmaceuticals must not be thought of just as market rights, but also within the larger context of health rights.

Actually, it can be argued that not just the health issue, but also other issues related to intellectual creativity must be taught outside market relations, as was discussed in the second chapter. The issue of IPRs in health can help us to move forward on other issues that are less vital in comparison to the health issue, but important as well because of their place in our lives for example, discussions on the IPRs of software.

On the other hand, the health issue also can help us question the commodification of many different things in the era of neoliberal globalization through intellectual or material property rights. In this perspective, even the commodification of water cannot be thought of separately from the commodification of health that is examined through the global implementation of IPRs in pharmaceuticals.

In the end, similar to a conclusion reached in another study, I look at pharmaceutical issues in the framework of what Semin and Güldal describe as “the idea of health as a basic human right rather than a field for profit” (Semin and

Güldal, 2008: 393), and I defend not being limited to the concepts of the market freedom and market rights on an issue that concerns all people without exception. Moreover, I hope to utilize this new perspective to criticize other issues related to the global implementation of IPRs, inspired by the commodification of knowledge and the commodification of health issues that were benefitted from in this study.

APPENDIXES

Appendix A: Global Pharmaceutical Market

Table 1: Leading Pharmaceutical Companies in 1992

		1992			1989	1981
	Milliyeti	Sıra	Satış (milyon dolar)	Toplama göre %satış	Sıra	Sıra
Merck	A.B.D.	1	8,214.5	85.0%	1	3
Gloxo	İngiltere	2	7,986.4	100.0	2	20
Bristol-Myers Squibb	İngiltere	3	6,313.0	56.6	3	10/14
Hoechst	Almanya	4	6,042.1	20.6	4	1
Ciba-Geigy	İsviçre	5	5,192.0	32.9	5	4
SmithKline Beecham	İng./ABD	6	5,100.5	55.4	6	13/22
Hoffman La Roche	İsviçre	7	4,896.9	53.2	7	7
Sandoz	İsviçre	8	4,885.5	47.7	8	8
Bayer	İngiltere	9	4,669.9	17.7	9	2
American Home Products	ABD	10	4,589.3	58.3	106	
Pfizer	ABD	11	4,557.9	63.0	11	5
Eli Lilly	ABD	12	4,536.5	73.6	12	9
Johnson and Johnson	ABD	13	4,340.0	31.6	13	19
Rhone-Phoulec Rorer	Fransa/ABD	14	4,095.0	100.0	14	16
Abbott	ABD	15	4,025.0	51.3	15	17

Source: OECD, 1996

Table 2: Leading Pharmaceutical Companies in 2000

Company	Head office	Rank	Sales value, £ millions	Share of world market, %
Pfizer	U.S.	1	15,266	7.3
GlaxoSmithKline	U.K.	2	14,533	6.9
Merck & Co.	U.S.	3	10,875	5.2
AstraZeneca	U.K.	4	9,423	4.5
Novartis	Switzerland	5	8,758	4.2
Bristol-Myers Squibb	U.S.	6	8,187	3.9
Johnson & Johnson	U.S.	7	8,152	3.9
Pharmacia	U.S.	8	7,457	3.6
Aventis	France	9	6,758	3.2
American Home Products[a]	U.S.	10	6,310	3.0
Total			95,721	45.7

Source: ABPI (2).
[a]Renamed Wyeth in March 2002.

Table 3: Leading Pharmaceutical Companies in 2003

Company	Country	Sales £	Growth[a] (%)	Share of world market[b] (%)
Pfizer	USA	28,836	14	10.1
GlaxoSmithKline	UK	18,868	9	6.6
Merck & Co	USA	13,798	11	4.8
Johnson & Johnson	USA	13,610	16	4.8
Novartis	SWI	12,421	24	4.3
Astrazeneca	UK	11,773	5	4.1
Aventis	FRA	10,487	18	3.7
Bristol-Myers SQB.	USA	9,631	9	3.4
Roche	SWI	9,377	20	3.3
Abbott	USA	8,124	15	2.8
Leading 10		*136,925*	*13*	*47.8*
Wyeth	USA	7,840	11	2.7
Lilly	USA	7,162	17	2.5
Amgen	USA	5,131	40	1.8
Sanofi-Synthelabo	FRA	4,989	32	1.7
Takeda	JAP	4,903	15	1.7
Schering-Plough	USA	4,605	− 20	1.6
Boehringer Ingelheim	GER	4,242	20	1.5
Bayer	GER	3,719	9	1.3
Schering AG	GER	2,687	16	0.9
Eisai	JAP	2,547	18	0.9
Leading 20		*184,749*	*14*	*64.5*

Notes: [a]Calculated in US$; [b]IMS audited markets; by worldwide sales value
Sources: IMS; Association of the British Pharmaceutical Industry (ABPI) web site (accessed February 2005)

Table 4: Leading Pharmaceutical Companies in 2010

Sıra No		"Temmuz 2010 İtibariyle Son 12 Aylık Ciro (USD)"	Ülkesi
1	PFIZER	55.192.000	ABD
2	NOVARTIS	39.802.820	İsviçre
3	MERCK & CO	38.797.840	ABD
4	ASTRAZENECA	34.456.980	İngiltere/İsveç
5	SANOFI-AVENTIS	33.516.880	Fransa
6	GLAXOSMITHKLINE	33.211.740	İngiltere
7	ROCHE	30.488.060	İsviçre
8	JOHNSON & JOHNSON	23.295.570	ABD
9	LILLY	20.915.940	ABD
10	ABBOTT	19.767.340	ABD
11	TEVA	16.841.790	İsrail
12	AMGEN	15.355.270	ABD
13	BOEHRINGER INGEL	14.704.530	Almanya
14	BRISTOL-MYERS SQUIBB	14.435.250	İngiltere
15	TAKEDA	13.071.060	Japonya
16	BAYER	12.266.530	Almanya
17	DAIICHI SANKYO	8.885.853	Japonya
18	NOVO NORDISK	8.554.261	Danimarka
19	EISAI	8.295.906	Japonya
20	OTSUKA	7.262.112	Japonya

Kaynak: IMS

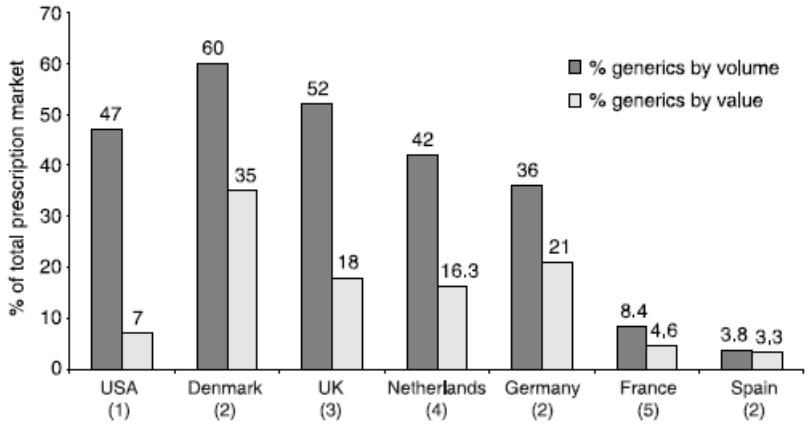


Figure 14.1 Sales of generics in selected EU countries and the USA by value and volume, 2001. Volume to value ratios: USA, 6.7; Denmark, 1.7; UK, 2.9; Netherlands, 2.6; Germany, 1.7; France, 1.8; Spain, 1.2. *Sources and notes*: (1) Pharmaceutical Research and Manufacturers of America (2002) (note: US data are for 2000); (2) European Generic Medicines Association (2003); (3) Department of Health (2002a); (4) Foundation for Pharmaceutical Statistics (2002); (5) CNAMTS (2003a) (note: French data are for 2002 and include reimbursed medicines only).

Figure 1: Generic drugs in Europe

Appendix B: The Turkish Pharmaceutical Market

Table 5: Leading Pharmaceutical Companies in 2008

Türkiye ilaç pazarında firmalar (Ciro - 2008 – Milyon USD)		
1	Novartis	624
2	Abdi ibrahim	623
3	Sanofi-Aventis	492
4	Pfizer	435
5	Bilim İlaç	420
6	GSK	413
7	AstraZeneca	351
8	EastPharma	345
9	Sanovel	318
10	Bayer	315
Kaynak: IMS		

Table 6: Leading Pharmaceutical Companies in 2009

Sales of Leading Corporations (MAT Qtr III 2009)
Retail and Hospital Market at Ex-Manufacturer Prices

Company	TL (million)	Market Share	Annual Growth
Novartis	1209.5	7.9%	17.7%
Sanofi-Aventis	1160.1	7.6%	6.9%
Ibrahim	970.2	6.3%	21.2%
Pfizer	687.1	4.5%	12.0%
GlaxoSmithKline	666.4	4.3%	19.4%
Bilim	648.7	4.2%	12.3%
Bayer	641.3	4.2%	12.6%
AstraZeneca	545.3	3.6%	8.9%
Roche	484.8	3.2%	21.7%
Deva	465.5	3.0%	-2.9%

Note: This table does not reflect Pfizer's acquisition of Wyeth and the merger of Merck & Co with Schering Plough; these changes will be implemented in the Qtr IV 2009 MIDAS updates.
Source: IMS Health

Table 7: Leading Pharmaceutical Companies in 2010

Sıra No		"Kasım 2010 itibariyle Son 12 Aylık Satış (TL)"
1	ABDİ İBRAHİM	1.118.773.622
2	NOVARTIS	959.112.320
3	BİLİM İLAÇ	756.327.022
4	PFIZER	722.952.232
5	GLAXOSMITHKLINE	634.561.193
6	EASTPHARMA	588.968.796
7	SANOFI-AVENTIS (*)	587.063.224
8	BAYER	503.970.156
9	ASTRAZENECA	488.635.736
10	SANOVEL	462.570.767
11	MSD	444.192.330
12	ROCHE	429.616.767
13	MENARINI	392.639.591
14	ZENTIVA (*)	299.065.887
15	SANTA FARMA	279.434.208
16	ALI RAİF	277.357.818
17	ABBOTT	267.950.933
18	BOEHRINGER ING	263.660.064
19	NOBEL	259.653.528
20	MUSTAFA NEVZAT	247.042.111

Kaynak: IMS

(*) Sanofi-Aventis 2010 itibariyle Zentiva'yı bünyesine almıştır. Bu satınalma neticesinde ciro itibariyle Sanofi-Aventis, Türkiye'de üçüncü büyük firma konumuna yükselmiştir.

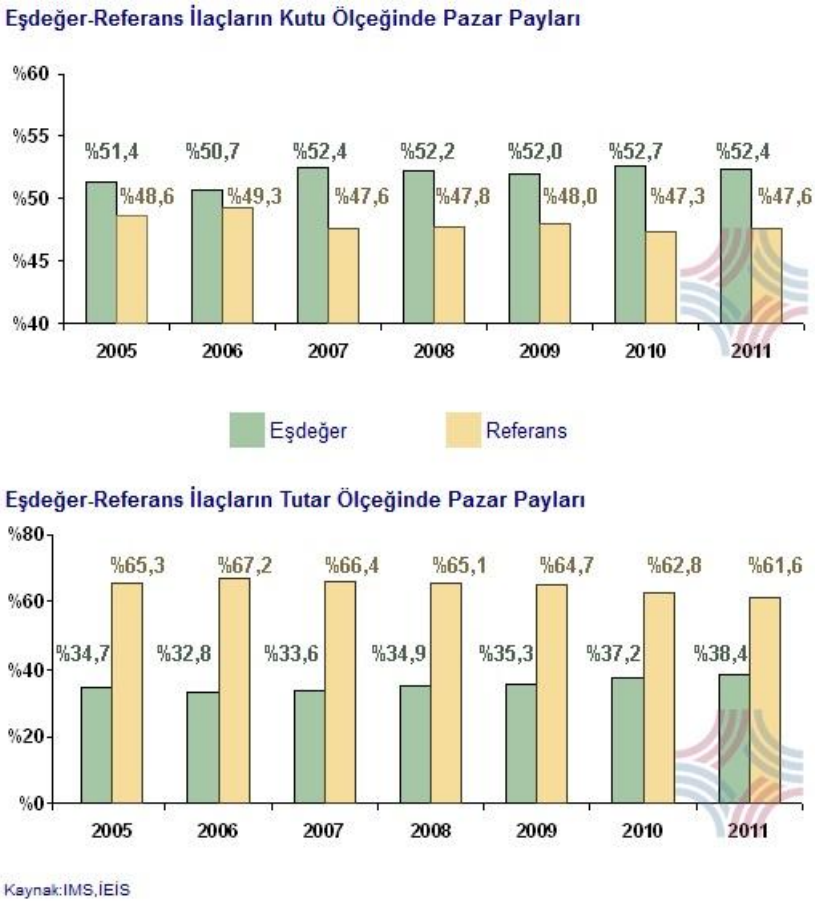


Figure 2: Generic drugs in Turkey

Table 8: The Ratio of Imported Drugs in Turkey in Boxes (2002-2009)

% - kutu	2002	2003	2004	2005	2006	2007	2008	2009
İthal	10,4	11,6	12,7	14,1	15,8	17,9	19,9	21,7
Yerli	89,6	88,4	87,3	85,9	84,2	82,1	80,1	78,3

Kaynak: IEIS

Table 9: The Ratio of Imported Drugs in Turkey in Sales (2002-2009)

% - TL	2002	2003	2004	2005	2006	2007	2008	2009
İthal	33,5	37,3	37,1	41	45,2	47,9	49,8	48,1
Yerli	66,5	62,7	62,9	59	54,8	52,1	50,2	51,9

Kaynak: IEIS

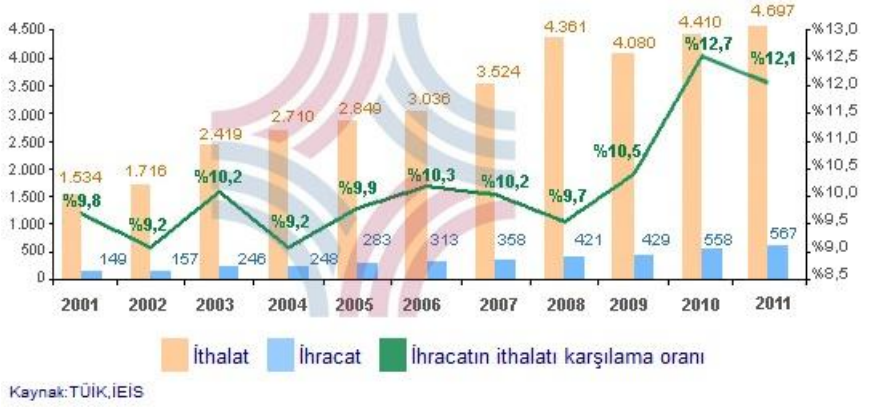


Figure 3: Imports and exports in Turkey (2001-2011)

Table 10: Pharmaceutical Imports in Turkey by Percentage (1982-2003)

Year	Pharmaceutical import/ pharmaceutical consumption	Finished product import/ total pharmaceutical import	Pharmaceutical export/ pharmaceutical import
1982	27.3	1.7	15.8
1992	41.8	18.3	14.9
1998	53.1	34.8	10.9
2003	59.8	48.9	10.1

Source: Pharmaceutical Manufacturer Association of Turkey.

Figure 4: The Turkish pharmaceutical market in boxes (2002-2008)

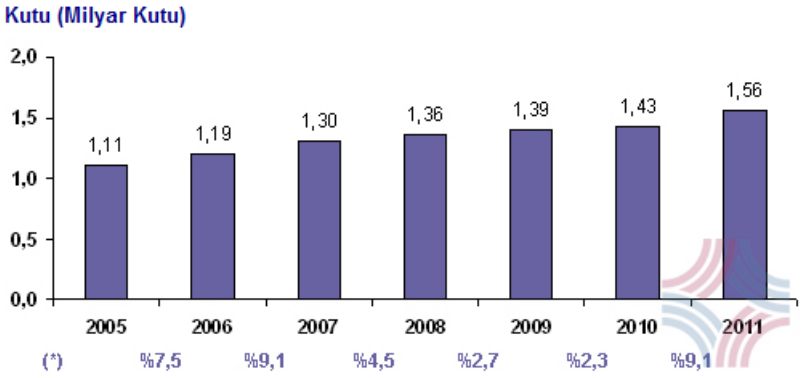


Figure 5: The Turkish pharmaceutical market in boxes (2005-2011)

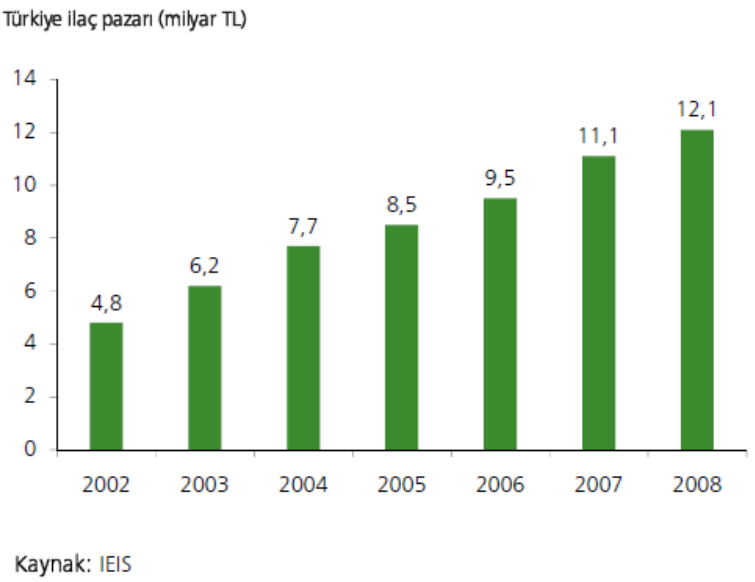


Figure 6: The Turkish pharmaceutical market in sales (2002-2008)

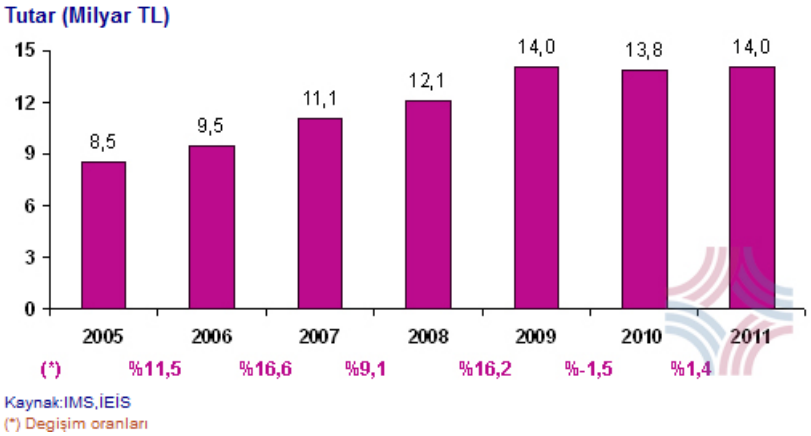


Figure 7: The Turkish pharmaceutical market in sales (2005-2011)

Appendix C: Global Health and Pharmaceutical Expenditures

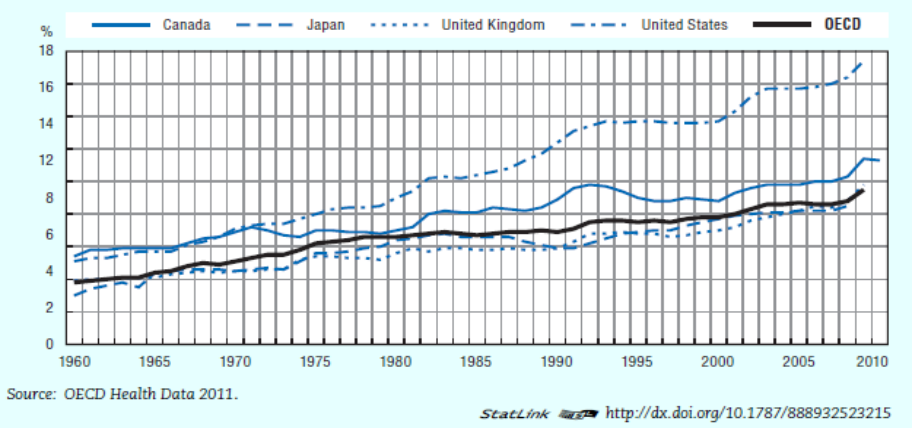
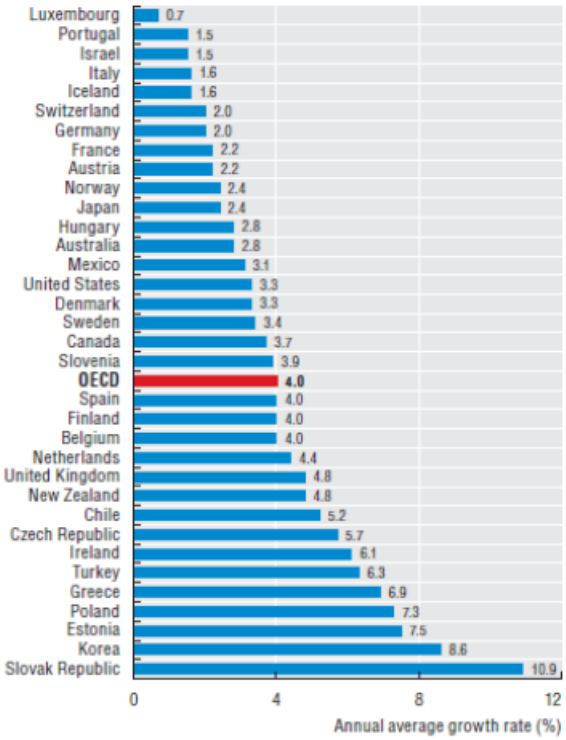
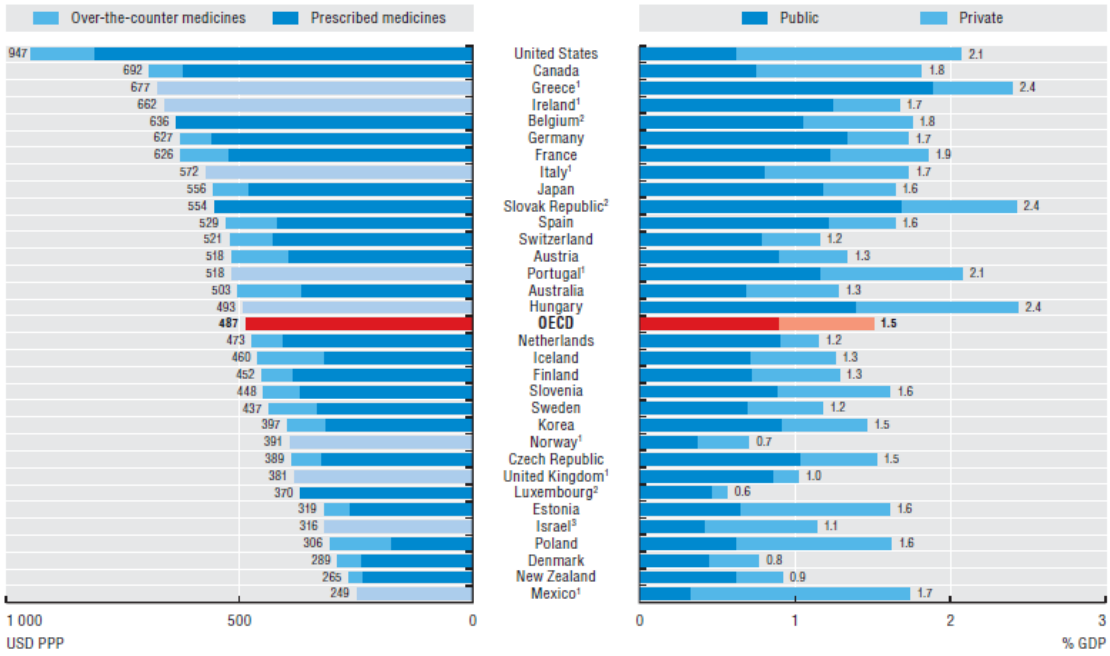


Figure 8: Health expendiure as a share of GDP in selected OECD Countries (1960-2009)



Source: OECD Health Data 2011

Figure 9: Annual average growth rate in health expenditure for selected OECD Countries (2000-2009)



1. Cannot be separated and includes medical non-durables. 2. Prescribed medicines only. 3. Total medical goods.

Source: OECD Health Data 2011.

StatLink http://dx.doi.org/10.1787/888932526217

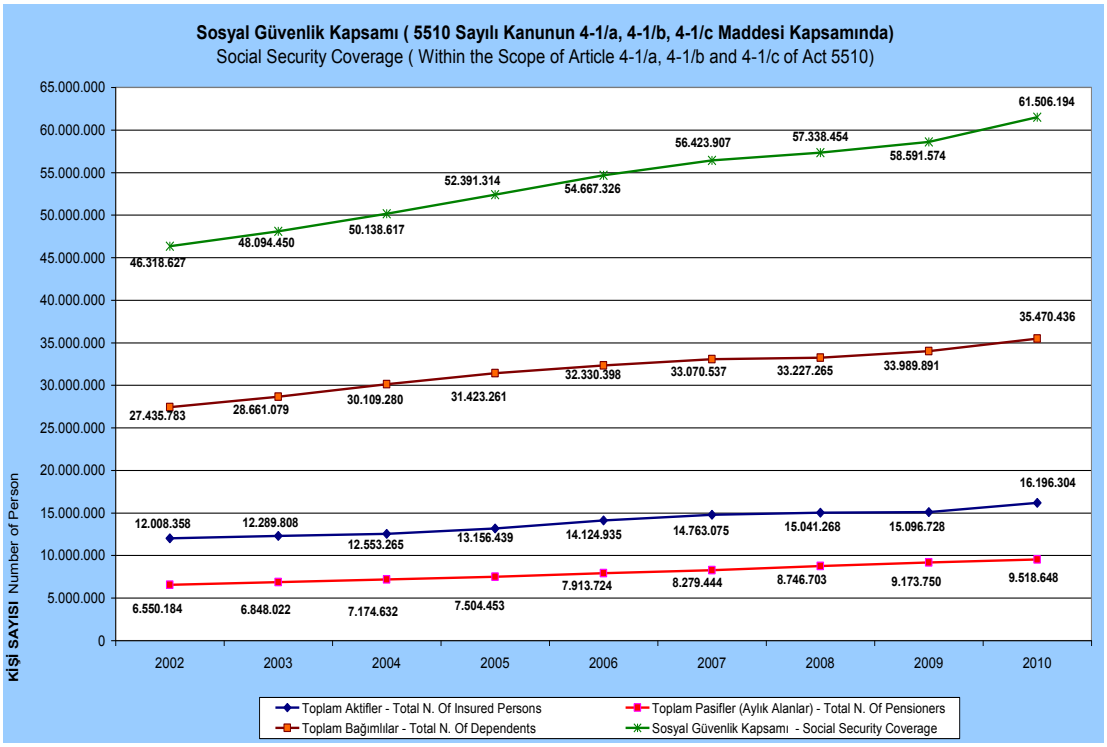
Figure 10: Pharmaceutical expenditure per capita and as a share of GDP in 2009

Table 11: Pharmaceutical Expenditures of EU Member States (1980-2000)

	Total expenditure on pharmaceuticals (% GDP)					*Total expenditure on pharmaceuticals (% of total health expenditure)*					*Public expenditure on pharmaceuticals (% of total pharmaceutical expenditure)*					*Total per capita expenditure on pharmaceuticals (US$ PPPs)*				
	1980	*1985*	*1990*	*1995*	*2000**	*1980*	*1985*	*1990*	*1995*	*2000**	*1980*	*1985*	*1990*	*1995*	*2000**	*1980*	*1985*	*1990*	*1995*	*2000**
Austria[c]	—	—	—	—	1.1[a]	—	—	13.2	10.4	14.1[a]	—	—	—	—	65.4[a]	—	—	—	—	270[a]
Belgium	1.1	1.1	1.1	1.4	1.4[c]	17.4	15.7	15.5	16.3	16.3[c]	57.3	51.0	46.8	43.0	44.7[c]	100	139	193	309	328[c]
Denmark	0.6	0.6	0.6	0.7	0.8	6.0	6.6	7.5	9.1	9.2	49.9	45.5	34.2	48.6	46.1	50	77	109	171	223
Finland	0.7	0.7	0.7	1.1	1.0	10.7	9.7	9.4	14.0	15.5	46.7	44.5	47.4	45.3	50.1	54	82	122	199	259
France	—	—	1.4	1.7	1.9	—	—	16.8	17.5	20.1	—	—	61.9	61.4	65.1	—	—	254	346	473
Germany	1.2	1.3	1.2	1.3	1.3[b]	13.4	13.8	14.3	12.3	12.7[b]	73.7	71.9	73.1	72.3	69.2[b]	110	172	228	269	312[b]
Greece	1.2	1.1	1.1	1.5	1.5	18.8	—	14.5	17.3	18.4	60.0	—	70.3	70.0	61.6	65	83	104	195	258
Ireland	0.9	0.8	0.7	0.7	0.6	10.9	9.9	11.3	9.7	9.6	52.7	60.7	65.0	78.3	83.9	50	58	88	126	187
Italy	—	—	1.7	1.5	1.9[d]	—	—	21.2	20.9	23.7[d]	—	—	62.8	38.3	53.3[d]	—	—	280	311	459[d]
Luxembourg	0.9	0.9	0.9	0.8	0.7[a]	14.5	14.7	14.9	12.0	11.7[a]	86.4	86.0	84.6	81.7	80.8[a]	88	132	223	255	307[a]
Netherlands	0.6	0.7	0.8	0.9	1.0	8.0	9.3	9.6	11.0	11.8	66.7	63.3	66.6	88.8	63.7	53	83	128	196	264
Portugal	1.1	1.5	1.5	1.9	2.0[b]	19.9	25.4	24.9	23.2	23.5[b]	68.6	64.7	62.3	63.3	66.1[c]	53	97	152	266	316[b]
Spain	1.1	1.1	1.2	1.4	1.4[c]	21.0	20.3	17.8	17.7	19.0[c]	64.0	62.5	71.7	75.8	78.1[c]	69	93	145	210	246[c]
Sweden	0.6	0.6	0.7	1.0	1.0[c]	6.5	7.0	8.0	12.5	12.8[c]	71.8	70.1	71.7	71.4	71.2[c]	55	82	120	202	227[c]
United Kingdom	0.7	0.8	0.8	1.1	1.1[c]	12.8	14.1	13.5	15.3	15.9[c]	67.6	64.1	66.6	63.5	64.2[c]	57	94	131	201	236[c]

Notes: *Or latest available year. Data from [a]1999, [b]1998, [c]1997, [d]2001. [c]Data for Austria from ÖBIG (Rosian *et al.* 2001).
Source: OECD (2002).

Appendix D: Health and Pharmaceutical Expenditures in Turkey



Source: SGK, 2010

Figure 11: Social security coverage in Turkey (2002-2010)

Table 12: Public Health Expenditures in Turkey
(million TL)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
İlaç	7.912	9.118	10.720	11.186	12.152	12.089	12.831	13.006	13.727	15.586
Tedavi	6.922	7.669	8.619	9.962	11.686	11.060	15.385	17.059	19.560	20.200
Toplam	15.677	17.807	20.360	22.268	25.111	24.514	29.239	31.068	34.003	36.368

Kaynak: TEPAV - SGK

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