8 PATENT RIGHTS AND THEIR ECONOMIC IMPACTS: THE CASE OF THE TURKISH PHARMACEUTICAL INDUSTRY

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ABSTRACT

The impact of patent protection on pharmaceutical innovation has been a controversial issue. The TRIPS Agreement entered into force in 1995 as a multilateral trade agreement, and has been the subject of an incessant debate on the extension of intellectual property rights in pharmaceutical innovation, particularly in developing countries. This study investigates the evolution of the pharmaceutical sector in Turkey, with special reference to developments after the TRIPS Agreement entered into force. To this end, it explores several performance criteria, along with patenting behaviour in the pharmaceutical sector in Turkey. An analysis of the data reveals that the country distribution as well as firm distribution of patents in Turkey is in line with the global distribution of pharmaceutical production, trade and ranking of the firms. This analysis also indicates that the domestic pharmaceutical sector has declined over the years and this trend became more visible post-TRIPS.

Keywords: *pharmaceutical sector, TRIPS Agreement, pharmaceutical patents, pharmaceutical firms*

I. INTRODUCTION

Firms are reliant on a variety of protection mechanisms for their innovations such as secrecy, first mover advantages and patents. The use of these mechanisms differs according to the sectors. In the pharmaceutical sector, patents are frequently used for the protection of innovations. In this way, firms intend to offset their expenditures, which may include not only expenses related to research and development (R&D) of pharmaceutical products, but also expenditures related to safety requirements and fees for the registration of medicinal products by the national drug authorities.[1] Hence, firms enjoy exclusive rights in terms of production, supply, distribution and to some extent control over price for the duration of the patent term.

In 1994, the Uruguay Round negotiations led to the adoption of the Agreement establishing the World Trade Organization (WTO), which came into force on 1 January 1995. As part of the multilateral package, Members each accept all the Agreements as a single package, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement sets out universal rules for the protection of inventions in all technological fields, including the pharmaceutical sector. Since the TRIPS Agreement entered into force, there has been continuous debate over the implications of applying the intellectual property standards established by the Agreement to developing countries. The debate largely

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[1] Kukrus and Kartus, 'Patent Protection of Pharmaceutical Products in the Globalizing World Economy' (2005) TUTWPE, (n 136).

focuses on the effects such extensions have on pricing and accessibility of drugs, and the structure of the pharmaceutical sector and public health, especially in developing countries. It is argued that without patent protection, there is no incentive for investment in the discovery and development of pharmaceuticals, not only in developed countries but also in developing countries.

There are three claims opposing this argument. Firstly, an efficient patent protection system for pharmaceutical products leads to higher returns for companies as pharmaceutical prices rise beyond research, development and production costs combined[2] [3] [4], and pharmaceutical prices in developing countries are often higher than production costs.[3] [4] [5] [6] Carey et al.[7] reports that the return on equity of the five biggest US-based pharmaceutical firms has averaged 30 per cent a year, which is far higher than that of the top 500 companies since 1998.

Secondly, patent protection, at least up to the present, has failed to facilitate access to new medicines, where the market is estimated to be small[8], or to medicines for diseases in the developing world.[9] Pharmaceutical firms have failed to invest in the discovery of new medicines, where this has not been profitable. Only 16 out of 1393 new chemical entities marketed between 1975 and 1999 were targeted at diseases in poor countries.[10] Instead of investing in the development of pharmaceuticals for diseases commonly found in poor countries, firms invest in higher priced medicines and similar versions of existing medicines or monopoly extensions for new uses of old medicines.[11] Moreover, the number of marketing authorizations granted, which may be taken as an indicator of pharmaceutical innovation, has fallen both in the European Union and in the United States.[12] Further, applications for marketing authorization for new active substances have fallen in the European Union as well.[13]

[2] Carey et al., 'Drug Prices: What is Fair?' (2001) *Business Week*, December 10:60-68.

[3] WHO, 'Access to Medicines' (2005) WHO Drug Information, 19 (3), 236-241.

[4] Malpani and Kamal-Yanni, 'Patents Versus Patients: Five years after the Doha Declaration' (2006) Oxfam Briefing Paper, November.

[5] Mintzberg, 'Patent Nonsense: Evidence Tells of an Industry Out of Social Control' (2006) Canadian Medical Association Journal 175 (4), available online at: <http://wwwcmaj.ca/cgi/content/full/175/4/374>

[6] For example, the cost of patent-protected antiretroviral treatments was over US$10.000 per patient per year when it was first introduced (WHO, 2005). At the time, this was far above the reach of the vast majority of HIV patients in developing countries. When the generic version was introduced into the market in 2001 and more competition was allowed with the other entrance of generic manufacturers, the price dropped to US$350 per patient per year (WHO, 2005). This price dropped even further to US$136 per patient per year on account of the competition from Indian generic producers (Malpani and Kamal-Yanni, 2006).

[7] Carey et al., 'Drug Prices: What is Fair?' (2001) Business Week, 60-68.

[8] WHO 'Access to Medicines' (2005) WHO Drug Information, 19 (3), 236-241.

[9] Malpani and Kamal-Yanni, 'Patents Versus Patients: Five Years after the Doha Declaration' (2006) Oxfam Briefing Paper, November.

[10] Trouiller et al., 'Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure' (2002) Lancet, 359:2188-2194.

[11] Mintzberg 'Patent Nonsense: Evidence Tells of an Industry Out of Social Control' (2006) Canadian Medical Association Journal 175 (4), available online at: <http://wwwcmaj.ca/cgi/content/full/175/4/374>

[12] CRA 'Innovation in the Pharmaceutical Sector' (2004) Belgium ENTR/03/28.

[13] ibid.

Thirdly, the majority of innovative drugs are developed by government-funded research institutes. According to the 2000 US Congress report, 15 out of 21 innovative drugs introduced between 1965 and 1992 were developed applying knowledge or techniques from federally funded research.[14] The most significant pharmaceutical discoveries of the 20th century, penicillin, insulin and the polio vaccine, for example, are derived from the laboratories of 'not-for-profit' institutions.[15]

The main purpose of this study is to investigate the impact of the TRIPS Agreement on the Turkish pharmaceutical sector. To this end, several performance criteria and self-generated patent data at the firm level are used and evaluated. This data demonstrates to what extent the TRIPS Agreement has impacted the Turkish pharmaceutical sector. Section two provides a brief historical overview of the latest developments in the international regulation of pharmaceutical patents. Section three provides a brief outline of global trends in the pharmaceutical industry, whilst section four explores trends in pharmaceutical firms in Turkey. Finally, section five examines various policy implications and provides concluding remarks.

II. LATEST DEVELOPMENTS IN THE INTERNATIONAL REGULATION OF THE PHARMACEUTICAL SECTOR

The Agreement Establishing the World Trade Organization (WTO), which came into force in 1 January 1995, was the result of the 1986–94 Uruguay Round negotiations, signed at the Marrakesh ministerial meeting in April 1994. The WTO not only created trade advantages for its Members, but also created obligations to provide certain intellectual property rights and procedures for their enforcement under the TRIPS Agreement. The TRIPS Agreement is one of the covered agreements of the WTO and as such is binding on all Members. TRIPS establishes minimum standards for intellectual property rights for Members, including patent protection of 20 years starting from the application date for a process or product patent, according to the established criteria of novelty, inventiveness and usefulness. Before TRIPS, patent protection of pharmaceutical products was often absent or less than 20 years under national legislation. Many countries provided patent protection for processes only before TRIPS.

The TRIPS Agreement sets universal rules for the adoption of intellectual property rights, but also includes some flexible rules specific to developing and least developed countries.[16] It specifically allows for a transition period for Members to accommodate their own intellectual property right systems and developmental needs. The transition period for developing countries was five years for process patents and ten years for product patents in the areas of technology not subject to patent protection before the TRIPS Agreement. These technology areas include pharmaceuticals and agro-chemicals.[17] The transition period for least developed countries was ten years and subsequently in 2001 the Doha Declaration[18] extended

[14] Mintzberg 'Patent Nonsense: Evidence Tells of an Industry Out of Social Control' (2006) Canadian Medical Association Journal 175 (4), August <http://wwwcmaj.ca/cgi/content/full/175/4/374>

[15] ibid.

[16] The TRIPS Agreement flexibilities provide for compulsory licences with the freedom to determine the grounds upon which licences are granted and the determination of what constitutes national emergency or other circumstances of extreme urgency and parallel importation (WTO, 2001).

[17] WHO 'Access to Medicines' (2005) WHO Drug Information, 19 (3), 236-241.

[18] WTO Members accepted a special Ministerial Declaration at the WTO Ministerial Conference in Doha concerning the TRIPS Agreement in 2001. The Doha Declaration states that Members recognize

the transition period for least developed countries from 2006 to 2016 for obligations related to patents, marketing rights and data protection for pharmaceutical products.[19]

The transitional period provided for developing countries under the TRIPS Agreement does not mean that pharmaceutical inventions were not protected during the transitional period. Under the TRIPS Agreement, Members are obliged to have adequate infrastructure to receive and store patent applications for new drugs. This means that countries should establish a 'mail box' for patent applications of pharmaceutical and agricultural chemical products.[20] These applications are to be examined until the end of the transition period (at the latest in 2005 for developing countries and 2006 for least developed countries) according to the patentability criteria and to be viewed as if they were being applied on the filing date of application.[21] The TRIPS Agreement provides that for inventions covered by mail box protection, exclusive marketing rights should be granted for a maximum duration of five years after obtaining marketing approval or until the patent is either granted or refused, whichever period is shorter.[22,23]

It is argued that the main outcome of the TRIPS Agreement is to introduce strong patent protection for developing and least developed countries, thus changing 'the distribution of financing so that a greater share is shifted to poorer countries'.[24] In another study, it is stated that the TRIPS Agreement may result in a small net revenue increase of pharmaceutical firms hence, rather than a redistribution effect of the TRIPS Agreement on poorer countries '(t)he same increase in incentive could be implemented in an alternative fashion with a positive welfare effect'.[25]

The obligations under the TRIPS Agreement applicable to all Members have been enhanced by other rules as well. National authorities generally require registrants to submit data relating to a drug's quality, safety, efficacy and its physical and chemical characteristics. Test data must be submitted to obtain marketing approval of pharmaceutical and agrochemical

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the importance of protection of intellectual property rights for the development of new medicines, but also 'recognize the concerns about its effects on prices' (WTO, 2001). Specifically, Members announced that patent rules restrict access to medicines, especially for those in developing countries. The Doha Declaration states that 'the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health'. Although the Doha Declaration aimed to mitigate the harmful effects of the TRIPS Agreement on pharmaceutical patents, it has not been successful in doing so. It is argued that the behaviour of rich countries weakened the Declaration's effects (Malpani and Kamal-Yanni, 2006).

[19] 'WTO Declaration on the TRIPS Agreement and Public Health' Ministerial Conference Fourth Session, (2001) Doha, 9-14 November WT/MIN (01)/DEC/W/2.

[20] Velazquez and Boulet, 'Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement' (1999) World Health Organization.

[21] ibid.

[22] ibid.

[23] Implementation of this provision needs two criteria. Firstly, a patent must have been granted for the same product in another Member country subsequent to the entry of the WTO Agreement into force. The second criterion is that the product must have obtained marketing approval in such other Member.

[24] Lanjouw and Jack, 'Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation' (2004:5) CGD Brief, November, Vol 4 issue 3.

[25] Jack and Lanjouw 'Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?' (2005:65) The World Bank Economic Review, 19(1), 45-67.

products.[26] Pharmaceutical firms attempted to protect this data and claimed that since the effective duration of patent protection is less than 20 years, they needed additional time for protection. Further, firms claim that data exclusivity not only constitutes an important incentive for the research and development of new medicines, but is also an important tool where there are no patents or where the patents are invalidated. Hence, many countries grant exclusive rights for data protection. Data exclusivity provides additional market protection for the company by precluding health authorities from accepting applications for generic medicines during the period of exclusivity, thus delaying the accessibility of generic medicines. This period is currently six or ten years[27] in Europe plus the time it takes to register and market the generic medicine i.e. an additional one to three years.[28]

When the TRIPS Agreement came into force, several Members adopted the exclusivity approach. Most Members permitted their national authorities to rely on test data submitted by the first applicant to approve subsequent applications on similar products.[29] Some countries (e.g. Argentina, Singapore, Chinese Taipei and Hong Kong, China) allowed national authorities to rely on a similar product having been approved or commercialized in a foreign country.[30] In such systems, the main motivation is to allow competition, so that the price is lowered and more people have access to pharmaceuticals. If subsequent applicants repeat the long and costly testing, this would delay the entry of the drug on to the market; in addition, competition from small and medium-sized enterprises would be prevented since these firms lack the necessary resources to undertake such testing.[31] Another motivation in the application of such a system arises from an ethical concern. When subsequent applicants repeat the long and costly testing process, part of that process requires testing of those medicines on animals and further on humans, which is unethical and unnecessary.

Data protection rules sometimes invalidate the rules in legislation relating to the duration of patent protection. The TRIPS Agreement recognizes a transitional period for the adoption of patent rules for pharmaceutical products for developing and least developed Members. Before the TRIPS Agreement came into force, those Members that granted process patents only had the opportunity to produce generic versions of the pharmaceutical product by inventing a different method or by reverse engineering. Pharmaceuticals patented before developing countries had implemented their TRIPS Agreement obligations were excluded from patent protection, thus allowing generic competition for least developed and developing Members.[32] In these countries, a data exclusivity system, in case of its adoption, may partially substitute for patent protection, hence invalidating the transitional period.[33] Further, allowing

[26] Correa 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement' (2002) South Centre, Switzerland, Printed by Sadag.

[27] Six years in Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Poland, Czech Republic, Hungary, Lithuania, Latvia, Slovenia, Slovakia, Malta, Estonia, Cyprus, Bulgaria, Romania and also Norway, Liechtenstein and Iceland; and ten years in Belgium, Germany, France, Italy, Luxembourg, the Netherlands, Sweden and the United Kingdom (EGA: 2012).

[28] EGA <http://www.egagenerics.com/igpa.htm> accessed 13 September 2012.

[29] Correa 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement' (2002) South Centre, Switzerland, Printed by Sadag.

[30] ibid.

[31] ibid.

[32] WHO 'Access to Medicines' (2005) WHO Drug Information, 19 (3), 236-241.

[33] Correa 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement' (2002) South Centre, Switzerland, Printed by Sadag.

product patents results in strong protection where it blocks the production of generic versions of patented pharmaceutical products.

III. GLOBAL TRENDS IN THE PHARMACEUTICAL INDUSTRY

Owing to the critical importance of the pharmaceutical sector from the perspective of public health and the death or survival of human beings, most countries focus their attention on the development of this sector. The distribution of pharmaceutical production across OECD countries shows that the United States has dominated global production in the pharmaceutical sector over the years. The United States produces approximately half of all pharmaceutical products (the share accounts for around 46 per cent) followed by France (12.9), Italy (9.4), the United Kingdom (8.5) and Germany (8.3) as of 2002.[34] These countries have a consistently continuous higher share of pharmaceutical production compared to other countries over the years. Notably, the aforementioned data is specific to OECD countries, which excludes information on pharmaceutical production in countries such as India, China, Korea etc.

The distribution of exports across OECD countries is broadly similar to that of production. Germany, the United Kingdom, the United States, Switzerland and France had the highest share of pharmaceutical exports as a percentage of total OECD exports between 1985 and 2001.[35] The distribution of the largest firms around the world is similar to that of production among countries. Table 8.1 provides a ranking of the 15 largest pharmaceutical companies in 1990, 2006 and 2008. Companies originating from the United States, the United Kingdom, Germany and Switzerland dominated worldwide drug sales along with market shares. Merck, Bristol and Glaxo had the highest share in 1990, whereas Johnson & Johnson, Pfizer and Bayer had the highest share in 2006 (in terms of health care revenue). In 2008, although to some extent the ranking has changed, there were no significant changes to the list. Pfizer, along with Wyeth, Johnson & Johnson and Hoffmann-La Roche, were ranked as the top three in 2008. Mergers and acquisitions are dominant in the pharmaceutical sector, and the 1990s and the following years have witnessed large mergers in this sector.[36] With regard to mergers and acquisitions, most of the dominant firms in 1990 continued to prevail in 2006 and 2008 likewise.

[34] OECD Health Data, October <http://stats.oecd.org/wbos/default.aspx?DatasetCode=HEALTH> 16 January 2008.

[35] ibid.

[36] Sanofi-Synthelabo (the product of a merger in 1999) merged with Aventis (which was formed from a merger between Hoesch and Rhone-Poulenc in 1999) in 2004. Novartis (a merger of Ciba-Geigy and Sandoz in 1996), AstraZeneca (a merger of Astra and Zeneca in 1996), Pfizer (a merger of Pfizer and Warner-Lambert) and Pharmacia (Pharmacia merged with Upjohn and Monsanto in 2003) and GlaxoSmithKline (emerging from GlaxoWellcome [Glaxo merged with Wellcome, SmithKlineBeecham in 2000]) are other examples of mergers (CRA, 2004:106, 115). There were some other important mergers and acquisitions in 2007 and 2009. AkzoNobel sold Organon BioSciences to Schering-Plough Corporation in 2007 <http://www.rsc.org/chemistryworld/Issues/2007/May/Organon14BillionDollar.asp> (1 May 2012). In 2009 Pfizer acquired Wyeth company <http://www.pfizer.com/investors/shareholder_services/wyeth_transaction.jsp> (1 May 2012) and Merck & Co. was merged with Schering-Plough, with the new company taking the name of Merck & Co <http://en.wikipedia.org/wiki/Schering-Plough> (1 May 2012).

Table 8.1: The Largest Pharmaceutical Companies (1990, 2006 and 2008)

1990		2006		2008	
Company	**Country**	**Company**	**Country**	**Company**	**Country**
Merck	United States	Johnson & Johnson	United States	Pfizer with Wyeth	United States
Bristol/Squibb	United States	Pfizer	United States	J&J	United States
Glaxo	United Kingdom	Bayer	Germany	Hoffman-La Roche	Switzerland
Johnson & Johnson	United States	GlaxoSmithKline	United Kingdom	Novartis	Switzerland
Smith Kline Beecham	United Kingdom	Novartis	Switzerland	GlaxoSmith-Kline	United Kingdom
Ciba-Geigy	Switzerland	Sanofi-Aventis	France	Sanofi Aventis	France
American Home Products	United Kingdom	Hoffmann–La Roche	Switzerland	AstraZeneca	United Kingdom/ Sweden
Hoechst	Germany	AstraZeneca	United Kingdom	Abbott Lab	United States
Lilly	United States	Merck & Co.	United States	Merck& Co.	United States
Bayer	Germany	Abbott Laboratories	United States	Bristol-Myers Squibb	United States
Roche	Switzerland	Wyeth	United States	Eli Lilly and Co.	United States
Pfizer	United States	Bristol-Myers Squibb	United States	Boehringer Ingelheim	Germany
Sandoz	Switzerland	Eli Lilly and Co.	United States	Takeda Pharmaceutic-al Co.	Japan
Rhone Poulenc	France	Amgen	United States	Bayer	Germany
Upjohn	United States	Boehringer Ingelheim	Germany	Amgen	United States

Source: Sanford C. Bernstein and Co. in B. Achilladelis and N. Antonakis (2001:570) for the year 1990; <http://en.wikipedia.org/wiki/Top_50_pharmaceutical_companies> accessed 5 June 2008 for the year 2006; and on 1 May 2012 for the year 2008 (latest available data).

Overall, the global distribution of production, trade and pharmaceutical firms reflects the dominant role of some countries and firms. These countries and firms further enhanced their dominant role owing to at least two recent developments in the international arena. Firstly, the TRIPS Agreement provided a legal basis for the worldwide protection of pharmaceutical patents, which in turn gave exclusive rights for the production and distribution of pharmaceutical products. In this respect, those Members and firms producing pharmaceutical products and the holders of those patent rights stood to gain the most from the TRIPS Agreement. Secondly, the merger and acquisition of pharmaceutical firms further enhanced their position. Firms that were dominant in the 1990s became even more so in the first decade of the 21st century. Considering that production and distribution of pharmaceutical products are in the hands of few countries and some firms control the world markets and receive most of the generated revenue, there may be some significant implications for the determination of

worldwide prices and thus access to pharmaceuticals, especially for those with low purchasing power.

IV. THE PHARMACEUTICAL SECTOR IN TURKEY

Products that entered the Turkish market prior to 1995 were not protected by patent and hence were subject to competition by generic equivalents. As regards its obligations under the TRIPS Agreement, Turkey benefited from the transition period available to developing countries with respect to pharmaceutical patenting. However, as of 1 January 1999, Turkey started granting product and process patents which had been filed under the mailbox provision pursuant to Article 70.8 TRIPS since the entry into force of the WTO Agreement in 1995. Hence, Turkey did not take full advantage of the flexibilities contained in the TRIPS Agreement.

Turkey began granting data exclusivity rights to pharmaceutical products in 2005.[37] A data exclusivity period is six years beginning from the date of market rights granted for the first time within a country in the Customs Union. For the products which benefit from patent protection, six-year data exclusivity rights are limited to the protection term of the patent (Licensing Regulation of Medicinal Products for Human Use).[38] Test results and knowledge cannot be made publicly available by the national authority under the Turkish patent regulation (No. 551).

With the establishment, starting in 1952, of production plants, both domestic and with foreign investment, there was an increase in the production of pharmaceutical preparations, which were previously manufactured in pharmaceutical laboratories between 1928 and 1950.[39] Turkey now has the technological capacity to produce broad ranging pharmaceuticals, except in the area of biotechnology and a few new pharmaceutical production technologies.[40] There are approximately 300 entities, and among 49 manufacturing facilities, 13 of them are multinational firms.[41] Net trade in this sector is always negative, and the export to import ratio is decreasing over the years. However in 2010 and 2011, an upward trend becomes apparent, as reflected in Table 8.2.

[37] These rights are valid only if: (i) The original product has market rights in a country within the border of customs union beginning from 1 January 2001 and that there is no application of generic market rights for that product in Turkey until 1 January 2005; and (ii) The original product that will have the market rights for the first time at the end of 1 January 2005 is within a country in the border of customs union that will benefit from the data exclusivity rights.

[38] IS <http://www.istanbulsaglik.gov.tr/w/sb/ecz/mevzuat/mevzuatpdf/bturuhhsat.pdf> accessed 2 May 2012.

[39] IEIS <http://www.ieis.org.tr> accessed 2 May 2012.

[40] ibid.

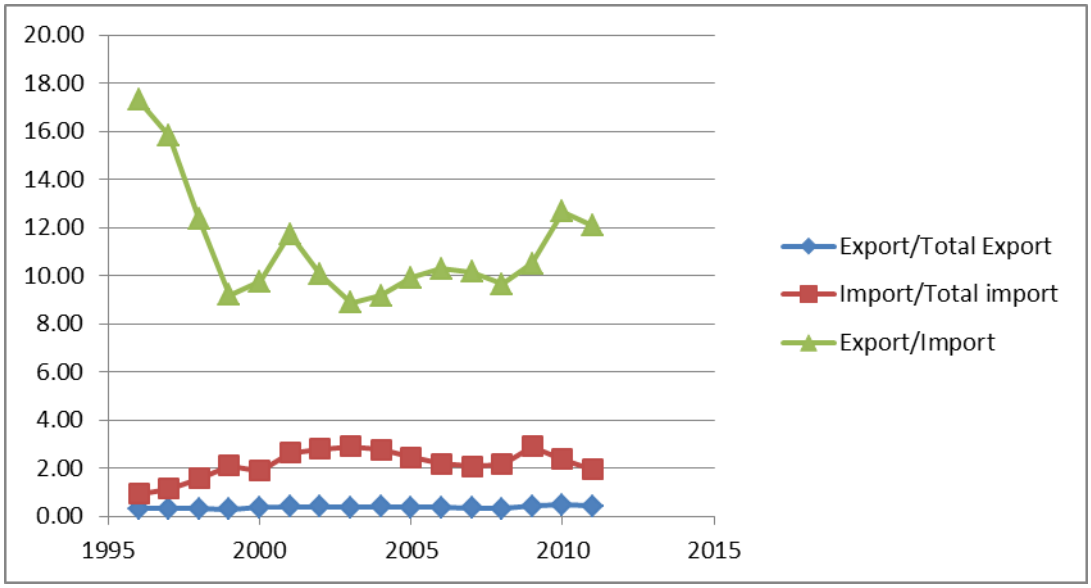
[41] ibid.

Table 8.2: Trade in the Pharmaceutical Sector

Year	Export/Total export percentage	Import/Total import percentage	Export/Import percentage
1996	0.31	0.94	17.30
1997	0.33	1.13	15.80
1998	0.33	1.57	12.38
1999	0,30	2.11	9.19
2000	0.36	1.90	9,75
2001	0.41	2.63	11.73
2002	0.40	2.79	10.05
2003	0.38	2.91	8.89
2004	0.39	2.78	9.16
2005	0.38	2.44	9.93
2006	0.37	2.17	10.30
2007	0.33	2.07	10.15
2008	0.32	2.16	9.66
2009	0.42	2.90	10.51
2010	0.49	2.38	12.66
2011	0.42	1.95	12.07

Source: TUIK: <http://www.tuik.gov.tr>

Graph 1: Trade Indicators in the Pharmaceutical Sector



There have been some important developments in the Turkish pharmaceutical sector. Firstly, the size of the pharmaceutical sector with foreign entry into the Turkish pharmaceutical market has been increasing over the years. Table 8.3 lists the largest pharmaceutical firms ranked among the top 500 firms in Turkey. Roche, Glaxo, Fako, Ilsan, Eczacıbaşı, Abdi İbrahim, Deva and Bilim İlaç are consistently among the 500 top firms over the years. Ciba Geigy merged with Sandoz to become Novartis, which is also among the largest 500 companies.

The second development in the Turkish pharmaceutical sector is the acquisition of domestic firms by multinational corporations (MNC), especially after 1999, once Turkey began to grant pharmaceutical patents. Fako's percentage of ownership dropped to 10 per cent in 2004 and was acquired in its entirety by Actavis in 2006, whereas its percentage of ownership was 100 per cent until 2004. Ilsan's percentage of ownership was 100 per cent in 1995 and dropped to 1 per cent in 2000. Deva was purchased in 2006 by the partnership created by GEM (Global Equities Management), and EastPharma company was incorporated to manage the venture. The percentage of Deva's ownership was 47.42 per cent in 2006 and dropped to 17.8 per cent in 2012. Citigroup Venture Capital International (CVCI) and fellow investor Partners in Life Sciences (PiLS) bought Biofarma in 2007. Until 2007, Biofarma was a 100 per cent domestically owned firm.

Furthermore, one of the largest domestic companies, Eczacibasi, sold its majority share (75 per cent) in its generics business to Zentiva (which originates from Czech Republic, however, Sanofi Aventis is Zentiva's biggest shareholder with approximately a 25 per cent share) in 2007. The majority share of I.E. Ulagay was purchased by the Italian Menarini group in 2001 and from 2007 the share of I.E Ulagay's ownership dropped to 12 per cent. On 25 April 2012, Mustafa Nevzat, one of the top domestic pharmaceutical companies, was sold to the US company Amgen.

Table 8.3: Largest Pharmaceutical Companies among the Top 500 Firms in Turkey

1995		2000		2004		2006	
Company name	**Ranking among the largest 500 firms**	**Company name**	**Ranking among the largest 500 firms**	**Company name**	**Ranking among the largest 500 firms**	**Company name**	**Ranking among the largest 500 firms**
Roche	75	Novartis	62	Eis Eczacibasi (TR)	77	Abdi Ibrahim (TR)	77
Eis Eczacibasi (TR)	81	Eis Eczacibasi (TR)	67	Abdi Ibrahim (TR)	78	Bayer	128
Ciba Geigy	155	Roche	69	Ilsan	112	Bilim (TR)	131
Fako (TR)	161	Abdi Ibrahim (TR)	95	Roche	139	Novartis	154
Abdi Ibrahim (TR)	174	GlaxoWellcome	108	Sanovel (TR)	170	Sanovel (TR)	165
Sandoz	185	Fako (TR)	133	Bilim (TR)	171	Nobel (TR)	196
Deva (TR)	209	Deva (TR)	134	Fako	173	Fako	212
Bilim (TR)	253	Bilim (TR)	171	Novartis	181	Sandoz	233
Bayer	282	Ilsan	205	Mustafa Nevzat	183	Roche	313
I.E.Ulagay (TR)	306	Sanovel (TR)	265	Nobel (TR)	191	Deva	317

1995		2000		2004		2006	
Company name	**Ranking among the largest 500 firms**	**Company name**	**Ranking among the largest 500 firms**	**Company name**	**Ranking among the largest 500 firms**	**Company name**	**Ranking among the largest 500 firms**
Ilsan (TR)	318	Bayer	283	Deva (TR)	228	Biofarma (TR)	379
Dogu	343	I.E.Ulagay (TR)	333	Glaxosmithkline	235	Santa Farma (TR)	445
GlaxoWellcome	376	Sanofi Dogu	369	Santa Farma (TR)	323	I.E. Ulagay	482
Abfar (TR)	495	Nobel (TR)	403	Biofarma (TR)	440		
		Santa Farma (TR)	416	Kocak Farma (TR)	475		

Source: ISO, Top 500 Companies in Turkey in CD format.

The third development trend in the pharmaceutical sector can be distinguished by examining some of the performance criteria of domestically owned and foreign-owned firms. Table 8.4 lists the performance indicators for pharmaceutical firms ranked among the top 500 firms in Turkey for several years. The concentration ratio of the four largest firms (according to sales from production) is consistently higher than 40 per cent, indicating an oligopolistic market structure in the pharmaceutical sector.[42] Profit to sales, equity and assets ratios of domestic firms were higher than those of foreign firms in the years 1995 and 2006 and lower in the years 2000 and 2004. The figures in Table 8.4 show a striking trend in the relative performance of domestic firms over the years. The table shows the declining profit to sales, equity and assets ratios for domestic firms, whereas the reverse is true for foreign firms. These trends are more distinct especially after the TRIPS Agreement entered into force.

Table 8.4: The Share of Private and Foreign Pharmaceutical Firms

Year	Company	Profit/Sales percentage	Profit/Equity percentage	Profit/Assets percentage
1995	Domestic	11.15	21.58	10.89
	Foreign	2.23	10.84	2.90
Concentration Ratio-4 firms	43.91			
2000	Domestic	5.70	17.97	5.91
	Foreign	7.50	34.92	10.01
Concentration Ratio-4 firms	48.33			
2004	Domestic	7.62	9.36	5.97
	Foreign	9.31	16.54	8.91
Concentration Ratio-4 firms	42.85			
2006	Domestic	4.67	10.87	4.6
	Foreign	3.32	5.04	2.24
Concentration Ratio-4 firms	48.76			

Source: Calculated from ISO, top 500 Companies in Turkey in CD format.

[42] The concentration ratio is calculated using data for pharmaceutical firms ranked within the top 500 firms.

Lastly, a trend towards development in the pharmaceutical sector can be observed in patents granted in Turkey. Table 8.5 shows the country distribution of pharmaceutical patenting activities in Turkey. The share of Turkey in pharmaceutical patents is negligible (no country bias is observable in the case of the pharmaceutical sector). The number of resident patent applications and grants is so small that the share only accounts for about 1 per cent of applications and grants in total. The United States, Germany, Switzerland and United Kingdom have the highest share in applications and grants. This trend is broadly similar to the global distribution of production and export share of countries in the pharmaceutical sector.

Table 8.5: Distribution of Pharmaceutical Patents among Countries, 1995-2006

	Applications		**Grants**	
Countries	*Frequency*	*Percentage*	*Frequency*	*Percentage*
Belgium	64.0	3.3	47.0	4.3
Canada	15.0	0.8	11.0	1.0
Switzerland	213.0	11.0	110.0	**10.1**
Germany	332.0	17.2	192.0	**17.6**
Denmark	150	0.8	14.0	1.3
Spain	15.0	0.8	10.0	0.9
France	113.0	5.8	82.0	**7.5**
United Kingdom	176.0	9.1	92.0	**8.4**
Ireland	23.0	1.2	15.0	1.4
Italy	47.0	2.4	28.0	2.6
Japan	60.0	3.1	41.0	3.8
Netherlands	54.0	2.8	31.0	2.8
Sweden	108.0	5.6	73.0	6.7
Turkey	15.0	0.8	10.0	0.9
United States	614.0	31.7	288.0	**26.4**
Other Countries	70.0	3.6	47.0	4.3
Total	1934.0	100.0	1091.0	100.0

Source: Calculated by the author from raw data kindly provided by the Turkish Patent Institute (TPI).

Table 8.6 illustrates the distribution of patenting activities in the pharmaceutical sector among firms in Turkey. In the table, firms are grouped according to mergers and acquisitions of firms occurring in the 1990s. GlaxoSmithKline, Sanofi-Aventis, Roche, AstraZeneca and Pfizer have the highest share of patent applications, and Sanofi-Aventis, GlaxoSmithKline, AstraZeneca, Roche and Pfizer have the highest share of patents granted. The trend of applications and patents granted is broadly similar to the worldwide ranking of pharmaceutical firms. In sum, country and firm distribution of patents granted in Turkey is similar to the global distribution of production, trade and pharmaceutical firms. There are more similarities than differences in the distribution of firms in the pharmaceutical sector in Turkey and throughout the world, and the similarities are more visible, especially after the TRIPS Agreement entered into force.

Table 8.6: Distribution of Pharmaceutical Patents among Firms in Turkey, 1995-2006

Firms	Applications		Grants	
	Frequency	Percentage	Frequency	Percentage
Others	630	32.6	345.0	31.6
GlaxoSmithKline (United Kingdom)	191	9.9	102	**9.3**
AstraZeneca (United Kingdom)	136	7.0	85	**7.8**
Roche (Switzerland)	147	7.6	76	**7.0**
Pfizer (United States)	117	6.0	75	**6.9**
Sanofi-Aventis (France)	182	9.4	112	**10.3**
Eli Lilly (United States)	104	5.4	65	**6.0**
J&J (United States)	50	2.6	37	3.4
Novartis-Sandoz (Switzerland)	64	3.3	32	2.9
Bayer (Germany)	50	2.6	30	2.7
Beohringer (Germany)	35	1.8	27	2.5
Abbott (United States)	44	2.3	25	2.3
Merck (United States)	41	2.1	24	2.2
Schering (United States)	35	1.8	14	1.3
Akzo Nobel	37	1.9	21	1.9
Procter&Gamble (United States)	58	3.0	10	0.9
Wyeth (United States)	7	0.4	7	0.6
Bristol-Myers Squibb (United States)	6	0.3	4	0.4
Total	1934.0	100.0	1091.0	100.0

Source: Calculated by the author from raw data, TPI.

Taking Tables 8.5 and 8.6 together, it is clear that foreign firms primarily hold Turkish patents. The so-called spillover effects of patents may not have occurred in the Turkish market, since there was no increase in domestic applications. This could be attributed to the lack of the necessary indigenous infrastructure developed by the domestic pharmaceutical sector, and hence the inability to follow international leaders. On the other hand, the high propensity to patent in the Turkish pharmaceutical sector by non-residents may indicate that these firms have enough legal power given by patent rights to produce, import and export patented drugs and set the prices.[43]

V. CONCLUSIONS AND POLICY IMPLICATIONS

The TRIPS Agreement set global standards for patent protection, including in the pharmaceutical sector. The examination of the global trend in the pharmaceutical sector shows that production and trade are clearly concentrated in the hands of a few countries and MNCs. With the mergers and acquisitions of firms, dominant firms in the 1990s continued to dominate through the first decade of the 21st century as well. New regulations mandated by the TRIPS Agreement set universal standards around the world, which further strengthened the position of pharmaceutical firms. With these new regulations and strict rules, developing countries have

[43] Thirty pharmaceutical firms (among them are Abbott, Abdi Ibrahim, Roche, Bayer, Glaxo Smith Klein, Pfizer, Lilly, Novartis) were accused of selling drugs with higher prices to the Turkish government in 2007.

less room for policy implementations compared to the years before the TRIPS Agreement came into effect. This is the case for Turkey as well.

The analysis of Turkey's pharmaceutical sector shows that the distribution of dominant countries and firms is in line with the worldwide distribution of pharmaceutical production among countries and firms. It also shows that there has been a decline in the economic performance of Turkish firms, while the reverse is true for foreign firms, and this trend is more observable post-TRIPS. Further, with regard to mergers and acquisitions, the share of domestic firms in the Turkish pharmaceutical sector has been declining over the years. As far as patents are concerned, the share of non-residents in Turkey in patenting activities is high, such that the domestic share is negligible. By obtaining patents, firms are assured of gaining a foothold in the Turkish market. No other firms can produce, export or import a product or process that is patent protected. When the patenting trend and firm level indicators are considered together, it may be argued that firstly, domestically owned firms are unable to compete on the same terms with foreign-owned firms. Essentially, this may result in a dependence on imports and production by foreign-owned firms; secondly, these trends have serious implications for firms' long-term pricing strategy and access to drugs.

Before TRIPS, pharmaceutical products could be produced and imitated, but after the Agreement came into force this was no longer possible. However, this does not signify that there is no scope for the adoption of policies. There are at least two areas in which the Government can have a significant effect on the development of the Turkish pharmaceutical sector. Firstly, Turkey can and should enlarge its production of the generic version of drugs and export to less developed countries. It is proposed that the Turkish patent regulation (No: 551) should be amended, according to the options and flexibilities provided for in the TRIPS Agreement, allowing compulsory licensing for pharmaceutical products, with the aim of exporting to least developed and developing countries that lack the capacity to produce those products.[44]

Canada and Norway opted to change their law, in order to allow compulsory licensing for the export of pharmaceutical products to countries that lack the capacity to produce them. Turkey could do the same. A new Turkish Patent Law was prepared and the draft law was delivered to the Government to be submitted to the Turkish Parliament. The draft provides for compulsory licensing for the export of pharmaceutical products to developing countries lacking capacity[45], which is in accordance with WTO rules[46]. These amendments, which not only benefit countries that cannot produce pharmaceuticals, also allow for the development of the pharmaceutical sector. The pharmaceutical sector would develop by enhancing production,

[44] TUSIAD 'Fikri Mülkiyet Hakları Alanında Gündemdeki Konular: İş Dünyası için Yol Haritası' <http://www.tusiad.org/__rsc/shared/file/fikri.pdf> accessed 2 May 2012.

[45] TPI 2012.

[46] The WTO decision on 30 August 2003 waives countries' obligations under a provision of the TRIPS Agreement. TRIPS Article 31(f) states that production under compulsory licensing must be predominantly for the domestic market, which limits the ability of countries that lack the capacity to produce pharmaceutical products to import such products from countries where pharmaceuticals are patented. The statement by WTO Director-General Supachai Panitchpakdi on 30 August 2003 indicated that the system will allow 'poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people' <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm> accessed 10 September 2013.

employment and exports; build human capital and physical capital indigenous capacity; and allow investment in production and R&D facilities.

The second area that the Government should continue to promote is the collaboration of university and business, which began almost ten years ago. While promoting the pharmaceutical sector, it is necessary to monitor and regulate, when necessary, the price of pharmaceuticals. Empirical evidence worldwide shows that the prices of patented drugs are much higher than those of drugs without patent protection. Hence, it is necessary to monitor and regulate patented drugs with the aim of decreasing drug expenditures as a country and access to medicines of those who have less purchasing power.

BIBLIOGRAPHY

Achilladelis B and Antonakis N, 'The Dynamics of Technological Innovation: The Case of the Pharmaceutical Industry' (2001) Research Policy 30, 535–588

Carey J, Barrett A, and Weintraub A, 'Drug Prices: What is Fair?' (2001) Business Week December 10, 60-68

Correa C M, 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement' (2002) South Centre, Switzerland, Printed by Sadag

CRA, 'Innovation in the Pharmaceutical Sector' (2004) Belgium ENTR/03/28
EGA, http://www.egagenerics.com/images/factsheet/EGA_factsheet_03.pdf.
accessed 3 September 2012

Jack W and Lanjouw J O, 'Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?' (2005) The World Bank Economic Review, 19(1), 45-67.
IEIS, <http://www.ieis.org.tr>, accessed 2 May 2012

IS, <http://www.istanbulsaglik.gov.tr/w/sb/ecz/mevzuat/mevzuatpdf/bturuhhsat.pdf>, accessed 2 May 2012

Kukrus A and Kartus R, 'Patent Protection of Pharmaceutical Products in the Globalizing World Economy' (2005) TUTWPE, No: 136

Lanjouw J O and Jack W, 'Trading up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation' (2004) CGD Brief, November, 4(3)

Malpani R and Kamal-Yanni M, 'Patents Versus Patients: Five years after the Doha Declaration' (2006) Oxfam Briefing Paper, November

Mintzberg H, 'Patent Nonsense: Evidence Tells of an Industry out of Social Control' (2006) Canadian Medical Association Journal 175 (4), August
<http://wwwcmaj.ca/cgi/content/full/175/4/374>

OECD Health Data, October <http://stats.oecd.org/wbos/default.aspx?DatasetCode=HEALTH>, accessed 16 January 2008.
TPI <http://www.tpe.gov.tr/dosyalar/taslaklar/Patent_Kanun_Taslagi.pdf> accessed 2 May 2012

Trouiller P, Olliaro P, and Torreele E, 'Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure' (2002) Lancet, 359:2188-2194

TUSIAD 'Fikri Mülkiyet Hakları Alanında Gündemdeki Konular: İş Dünyası için Yol Haritası' <http://www.tusiad.org/__rsc/shared/file/fikri.pdf> accessed 2 May 2012

WHO, 'Access to Medicines' (2005) WHO Drug Information, 19 (3), 236-241

WTO, 'Declaration on the TRIPS Agreement and Public Health' (2001) Ministerial Conference Fourth Session, Doha, 9-14 November WT/MIN (01)/DEC/W/2

Velasquez G and Boulet P, 'Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement' (1999) WHO