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Pharmaceuticals and intellectual property rights: A political economy of the recent policy changes across the developing world and in Turkey

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Abstract

This paper explores the sources of the recent policy changes from weaker to stronger intellectual property regimes (IPRs) for pharmaceuticals across the developing world, and in Turkey. Analysing the policy change from a political economy approach, the paper argues that the increased structural power of the transnational capital in the 1980s had been the most important common factor in setting the ground for changes in the IPRs for pharmaceuticals across the developing world. Against the state-centric theories that interpret the policy change primarily as a matter between the nation states from developed and developing countries, the paper contends that the nature and scope of policy outcomes on pharmaceutical IPRs have been shaped by the dynamics of the class struggles across the developing world. The latter argument is supported through an analysis of the Turkish public policy processes and outcomes which resulted in strengthening the IPR for pharmaceuticals. The paper concludes that rather than a mere external imposition on the ‘’Turkish state’’ by the advanced capitalist countries or the European Union (EU), the policy change in favour of stronger IPRs for pharmaceuticals was sustained and shaped by the Turkish conglomerate capital which pursued reintegration with the transnational capital as a political strategy.

Keywords: Drugs, pharmaceuticals, patents, data exclusivity, Turkey.

1. Introduction

The politics of intellectual property rights have always been driven by the material interests and struggles of various social forces,

and/or their fractions (c.f. Sell & May, 2001). The latest manifestations of such struggles are the policy changes that occurred in the global regulation of intellectual property during the last two decades. The most distinguishing characteristic of these policy changes was the shift from weaker to relatively stronger forms of intellectual property protection across the developing world. The conclusion of the ''Trade Related Aspects of Intellectual Property Rights'' (TRIPs) agreement during the GATT multilateral negotiations had been an important turning point in that regard.

In no other sector this shift towards stronger intellectual property regimes had been as controversial as it was in the case of pharmaceuticals. The vital importance of drugs for human health, restricted health budgets across the developing world, the research and development intensive nature of the global pharmaceutical industry and the leading role played by a handful of powerful transnational corporations in it, have certainly been factors that increased controversies and struggles on intellectual property rights in this sector.

The TRIPs agreement set global standards in a variety of intellectual rights such as copyrights, trademarks, geographical indications, industrial designs, undisclosed information, and patents. Of these, patents and undisclosed information (i.e. protection of pharmaceutical test data) had particular significance for the pharmaceutical industry. The TRIPs required the extension of patent protection to all areas of technology, including pharmaceuticals which had been until then exempt from patent protection in most developing countries. The agreement also entailed significant harmonization in the scope and duration of patent protection as well as the set of exclusive rights conferred across national patent regimes. Moreover, the TRIPs became the first international agreement which obliged all signatories to protect against unfair competition the results of pharmaceutical test data submitted during national registration of pharmaceutical products (Correa, 2002: 10). All these changes introduced by the agreement had profound implications for access to essential medicines across the developing world.

Still, precisely because of the highly contested nature of the negotiations on intellectual property, the agreement also allowed the national authorities certain flexibilities in its implementation. In relation to patent protection, such flexibilities concerned issues such as the conditions of ''compulsory licensing'', ''international exhaustion of rights'', and the determination of ''transitional periods''

after which the patent protection will be provided in developing countries.[1] As for protection of pharmaceutical test data, the broad definition contained in the Agreement text led to extensive contestations on its legal interpretation. In effect, the extent to which these areas of flexibility were exploited during the incorporation of TRIPs provisions into national intellectual property regimes varied significantly depending on the nature and dynamics of intra-class politics in each developing country. Thus, despite the general shift towards stronger IPRs for pharmaceuticals instigated by the TRIPs agreement, there are still important continuing differences in the relative strength of protection across the developing world (Watal, 2000:2).

This article has two simultaneous objectives. Firstly, it explores the common factors that underlie the recent changes from weaker to stronger intellectual property regimes for pharmaceuticals across the developing countries. In doing so, the analysis focuses on those aspects of intellectual property regimes that have been most vital for the pharmaceuticals, namely patent protection, and protection of pharmaceutical test data. Secondly, it analyses the nature of the public policy processes in Turkey which resulted in profound changes of the pharmaceutical intellectual property regime and the dynamics of the intra class struggles, which shaped the public policy outcomes therein.

I propose a three-fold argument to explain the sources of the recent policy changes in the pharmaceutical IPRs of developing countries and of Turkey. Firstly, an important factor, which increased the pressures on developing economies in favour of stronger intellectual property protection in the 1990s, was the profitability crisis that the transnational pharmaceutical capital incurred during the 1980s (c.f. Nogues, 1990). Secondly, a more important factor, which rendered these pressures effective, was the increased structural power of the transnational capital and the political, economic, and ideological transformations it generated in the global political economy during the 1980s and 1990s. Structural power of the transnational capital refers to its capacity to constrain governments, trade unions, and other social groups by its control over investment resources (Gill, 1991).

Finally, whilst the increased structural power of the transnational capital has been the common factor underlying the recent policy changes in the IPRs for pharmaceuticals, the nature and

[1] See section 4.4. for explanations of these terms.

scope of policy outcomes have been bounded by the dynamics of domestic class politics in developing economies. The paper supports this latter argument through an analysis of the Turkish public policy processes and outcomes which resulted in significant strengthening of IPRs for pharmaceuticals. It argues that the public policy processes and change on pharmaceutical patents in Turkey had been shaped by the conflicts between the domestic/protectionist fractions of the pharmaceutical capital and the internationalised fractions of the Turkish capital. The latter included not only the internationalised fractions of the local pharmaceutical capital but also the Turkish conglomerate capital that formed the hegemonic fraction in the Turkish power bloc during the 1990s. Hence, rather than a mere external imposition on the ‘’Turkish state’’ by the advanced capitalist countries or the European Union (EU) as argued by some policy makers (Yalçıner, 1999) the policy change for stronger intellectual property protection for pharmaceuticals and the under-exploitation of the flexibilities entailed in the TRIPs was shaped by those fractions of the local capital which pursued reintegration with the transnational circuits of the capital as a political strategy.

The rest of the paper is organised as follows. The second section provides a brief critical analysis of the previous studies conducted on pharmaceuticals, intellectual property rights, and developing economies. The third section analyses the political and economic context during the 1960s and 1970s, which initially sustained weaker intellectual property regimes for pharmaceuticals across the developing economies, and the outcomes of this policy. The fourth section analyses the sources of the changes in the patent policies of the developing countries in the 1990s, the substance of the TRIPs agreement and the implications of the flexibilities allowed for national authorities in its implementation. The fifth section focuses on how the conflicts between the domestic fractions of the pharmaceutical capital and the internationalised fractions of the Turkish capital as well as the state institutions that concentrated their interests shaped the policy outcomes on pharmaceutical IPRs.

2. State or class interests? A brief critical analysis of the recent studies on pharmaceutical IPRs and the developing economies.

Most of the recent studies conducted on the pharmaceutical industry, intellectual property rights and developing economies

focussed on the possible pros and cons of stronger protection for the developing economies (c.f. Lanjouw, 1997; 1999; Watal, 2000; La Croix & Kawaura, 1996; Lippert, 2002; Scherer & Watal, 2002; Nogues, 1993; Kabiraj, 1995; Wendt, 2001). Amongst the few studies that touched upon the sources of this extensive policy change towards stronger protection, two complementary strands of explanations can be identified. Those adopting a liberal institutionalist approach view the policy change towards stronger IPRs for pharmaceuticals as an outcome of the pressures exerted on the developing states by the advanced capitalist states (such as United States, European Union and Japan) in favour of stronger patent protection (c.f. Lanjouw, 1997:1; La Croix & Kawaura, 1996:110; Correa, 1997:3; South Centre, 1997; Kabiraj, 1995:2). Hence it is argued, "TRIPS was offered to all nations [by developed nations] on a take it or leave it basis. *Developing nations*….felt that TRIPS would provide absolute power to *developed nations* to rule over the *developing countries* in future trade and technology'' but nevertheless ''the member countries signed the treaty although *grudgingly*'' (Kabiraj, 1995:2 emphases mine).

A second interrelated explanation comes from rationalist/game theory proponents, which emphasise the bargaining procedures between the developing and advanced capitalist "states" during the multilateral GATT Uruguay negotiations. This approach views the TRIPS agreement, which emerged out of these negotiations as a concession which the developing states agreed in return for certain benefits they received on their agricultural and textiles exports. Hence, while analysing how the ''developing states'' responded to the TRIPs, Cohen (2002) argues that the extent of commitment to the TRIPs agreement by the developing country governments varied depending on the costs and benefits that the politicians of each country attached to the implementation of the TRIPs agreement. She further argues ''many politicians favoured making a commitment to the WTO and all of its conditions because it could help them to move their *country* more rapidly towards economic liberalisation … and the economic payoffs in the Agreement from which select group of countries could benefit'' (Cohen, 2002:126, emphasis mine)

As observed, both perspectives view the issue predominantly from a state-centred perspective. Intrinsic to these approaches is a tendency to represent the policy change on pharmaceutical patents as a competition or conflict between the nation states from advanced capitalist and developing countries, each trying to ensure their national interest, defined either as ensuring the competitiveness of their

national industries, or the health of their population. Hence, it is argued ‘’it was clearly in the interest of all industrialised countries to reinforce their dominant position in research, technological innovation, and industrial production vis a vis other countries by strengthening intellectual property rights and pressing for a world wide system (South Centre, 1997:6). ‘’Developing states for the most part did not support the protection of pharmaceutical patents because they needed to develop their pharmaceutical industry and to enhance competition in the market’’ (Correra, 2000: 5).

A common fallacy underlying both approaches is to view the state and society/markets as separate and competing realities. States are transposed as the prime actors and decision-making centres with their own independent agenda and set of interests. Within such constructions, state ‘’options’’, ‘’choices’’, ‘’policies’’, ‘’responses’’ are placed outside class politics. Instead, specific interests are ascribed as the states’ own or the national interests. If and when sources of policy objectives or outcomes are traced back to ‘’pressures by the interest groups’’ they are represented as ‘’adjusted’’, ‘’filtered’’, ‘’processed’’ in line with the state or national interest or the politicians´ own interests.

Theoretical approaches that counter pose state and society as separate and competing realities, however, are misleading as they provide only partial explanations. This is so for at least two reasons. Firstly, the absolute autonomy attached to the states or the bureaucrats as central explanatory variables proves highly inadequate in accounting for a) how and why some policies by the state or its rational bureaucrats or politicians come to be considered as compatible with the national interest whereas others are ruled out, b) which interests such policies foster or exclude and c) how and why those interests come to be defined as the national interest in the first place.

Secondly, as both liberal institutionalist and rational choice theories set off by taking certain variables as given (i.e. ‘’the developments in the international markets’’) but simultaneously ascribe primary explanatory power to the states, or the politicians as autonomous actors, they fail to adopt a wider political economy approach. With respect to analysing the sources of policy change on pharmaceutical intellectual property rights, this is reflected in the inability of the studies concerned to account for the reasons of the increased pressures on developing economies in favour of stronger protection in the 1990s, and why such pressures proved successful in

generating the desired policy outcomes now, despite their acute failures two decades ago.

In this paper, I adopt a political economy approach that focus on the dynamics of class politics underlying the policy changes on IPRs for pharmaceuticals across the developing world. This approach neither ignores the important role of the nation states in mediating policy change nor does it ascribe any independent source of power to the states therein. But rather it necessitates a conceptualisation of the state, and state policies that proceeds beyond the dichotomies (state versus society) adopted by the liberal institutionalist or rationalist theories. Following Poulantzas (1978:130), I adopt a theoretical conceptualisation of the state as a material condensation of class relationship of forces. Viewing the state as a relation is valuable because it recognizes that the struggles between the dominant and dominated classes are not confined to the civil society but are present and reproduced in the heart of the state. The concepts of ‘’power bloc’’ and ‘’centers of opposition’’ overcome the state society dichotomies by referring to the interactions of the dominant and dominated classes, and their fractions with the institutional structures of the state as internal relations. While the former concept signify the interrelations with the state institutions of the multiple politically dominant classes (and their fractions) under the domination of one hegemonic class or fraction (Polulantzas,1975:229), the latter refers to the state apparatuses that exhibit the struggles of the dominated classes (Ibid., 1978:142). Hence, contradictions amongst the different levels of the state structure do not simply represent the autonomous interest of the state elites, or its politicians as such but materialize the conflicts amongst the classes and class fractions. State policy is not autonomous state’s or its politicians’ own choices or preferences but the result of the contradictions and struggles of the classes that operate through it. As the state itself is the site of the class struggle and its policies are the result of class contradictions, it cannot perform in a rational or functionalist way or as a monolithic bloc with a set of internally consistent and coherent motives or responses (c.f. Poulantzas, 1978:130).

3. Weak intellectual property protection and pharmaceuticals across the developing world.

In their substance, intellectual property rights involve the commodification of knowledge and information (May, 2004a:821). Through the exclusivities conferred, the owners of intellectual

property rights can exclude competition from their rivals in the market, raise the associated monopoly rents, and prevent the widespread dissemination of knowledge. In view of the current hegemonic consensus formed around intellectual property protection, such short term costs (i.e. restriction of competition, monopoly rents, and the resulting higher prices) are necessary in order to stimulate the continuity of socially rewarding innovations and technological development. However, as May (2007:2) reminds us rather than a universal set of legal principles, the history of the development intellectual property rights is a continuing history of political contestation, which cannot be understood independently of the establishment of modern capitalism, and its current globalisation. Contrary to the current orthodoxy, strong intellectual property protection was hardly the norm across the advanced capitalist economies throughout their earlier stages of economic development. As Sell & May (2001) illustrate, in many of today's advanced capitalist economies, historical development of the approach towards the protection of intellectual property in general, and patent protection in particular, represented a penundulum that oscillated between two ends: the provision of exclusive protection and monopolies on the one hand, and public oriented dissemination and competition on the other. Historically, shifting policy choices on intellectual property protection, and knowledge ownership which forms its substance, were sustained by the material interests of the social forces that corresponded to each end of the pendulum. On the one end, were the owners or controllers of knowledge resources that sought to expropriate the surplus value attained from commodification of knowledge, acquire monopoly rents for their creation and exclude others' access to these rents. On the other end, were societal forces that aimed for the dissemination such knowledge and the redistribution of the rents that accompany it (Cf. May, 2004b).

Until the 1990s, many of the developing countries were characterized by weak intellectual property regimes which involved a) restrictions on the scope, range and duration of exclusivities conferred by intellectual property rights, or/and b) outright exclusion of certain strategic or vital sectors such as pharmaceuticals, from the scope of intellectual property protection. Such weaker forms of intellectual property protection promised to contribute to the development of local industrial capabilities by allowing faster and wider dissemination of foreign technology, development of local production capabilities and producers, and substantial savings on outflows of restricted foreign

exchange reserves. Provision of weak intellectual property protection for pharmaceuticals was justified by their particular characteristics such as the vital significance of drugs for public health, research and development intensive nature of the industry with extensive positive externalities etc. In fact, lax intellectual property protection for pharmaceuticals had been a common a phenomenon even in advanced capitalist countries until late into the second half of the 20th century. For example, full patent protection for pharmaceuticals were not provided until 1949 in the U.K, 1960 in France, 1968 in Germany, and 1978 in Switzerland, Sweden and Italy (Nogues, 1990).

Contemporary global controversies on intellectual property protection for pharmaceuticals are dominated by references to two particular intellectual property rights, namely, patent protection and protection of pharmaceutical test data.[2] However, the historical evolution and significance of these intellectual property rights for pharmaceuticals have been differential. Patent protection had been the earliest and most widespread type of intellectual property right, whereas the protection of test data emerged as a distinct form of exclusivity only in the late 1980s, due the developments in the pharmaceutical markets of the advanced capitalist economies. The analysis in this paper will also follow this historical order. Our analysis of intellectual property rights and pharmaceuticals until the negotiation of TRIPs agreement will mainly focus on patent protection, which will then be followed by an analysis of the emergence of data protection as a distinct form of exclusivity.

3.1. Political sustainability of weak intellectual property regimes for pharmaceuticals across the developing world: The case of patents

Patents have been the most widely used type of intellectual property right in the pharmaceutical industry. For the research-intensive transnational corporations (TNCs), which lead the global pharmaceutical industry, patent protection is the most important mechanism through which the costs of the drug research could be recouped. Patents -- which provide exclusive rights to produce, market and license products for certain time periods (i.e. twenty years) --

[2] Even though the protection of pharmaceutical test data has been recognized as an intellectual property right in the TRIPs agreement, there are important controversies as to whether it should be considered to entail exclusivities like other intellectual property rights. (C.f. Correa, 2002:14)

allow the innovators to earn monopoly returns on their investments. In the case of pharmaceutical innovations there are two main types of patents: product patents, and process patents. Product patents provide stronger forms of protection as they prevent the third parties from not only producing, and marketing a particular drug but also from using all other manufacturing processes through which the patented drug can be produced. Process patents are considered to provide a weaker form of protection as they protect only one particular manufacturing process that can be used to produce a patented drug.[3]

During the 1960s and 1970s most developing countries either weakened or abolished patent protection for pharmaceuticals. Weak protection systems, adopted in countries such as India, Spain, Greece, and Egypt, Soviet Union, Peru, Portugal Morocco, China Venezuela, Chile, involved the abolition of product patents for pharmaceuticals while providing process patents that are narrow in scope, short in duration and easy to revoke (Sequiera, 1998: Chapter 3). Abolition of patent protection in countries such as Turkey, Korea, Brazil, Iran, Mexico, Australia, and Colombia entailed the exclusion of both pharmaceutical products and processes from patent protection.

The political sustainability of non/weak patent regimes in developing countries should be understood as an offshoot of two interrelated factors. The first one of these is the dynamics of the post war political economy that integrated semi-peripheral economies into the international capitalist system. The second one is the corresponding historical configuration of class forces internal to developing countries at the time of the policy change.

The decision in developing countries to withdraw patent protection for pharmaceuticals during the 1960s and 1970s reflected dominant concerns (such as the creation of a local bourgeoisie, national self-sufficiency, and protectionism) of import substitution (ISI) policies pursued within the context of post war capitalist development. Capitalist development across semi-peripheral economies had been an integral part of post war politico economic system, which facilitated the internationalisation of productive capital based in the US, and other advanced capitalist countries. While this system was secured under the political and economic hegemony of the United States, and involved a congruence of ideas, policies, and institutions amongst leading advanced capitalist nations (Gill, 1991),

[3] Thus process patents allow third parties to produce a patented product through manufacturing processes other than the one protected by the patent.

the most important factor that cemented it was an alliance of transnational class forces, which included the US-based productive and financial capital, centrist political parties, bureaucrats, non-communist organised labour unions and their counterparts in Europe. This transnational class alliance was also expanded to include class forces from semi-peripheral economies through the dependency of the latter on continuing flows of capital and technology (Gill & Law, 1989:479).

While the implementation of ISI policies across the developing world was actively sponsored by the U.S. government, such support was not an independent initiative of U.S. politicians or state but was shaped through the economic interests and political lobbying of the export oriented transnationals in the U.S. (Maxfield & Nolt: 1990). As such, ISI policies implemented across the semi peripheral economies involved a dual contradiction (Bina and Yaghmanian, 1990:115) On the one hand; they facilitated the increased penetration and prospering of the activities of the transnationals behind the tariff barriers, with access to cheap raw materials, labour and subsidised plant investments. On the other hand; ISI policies represented the class struggle of the local capitalists in semi peripheral economies against both the precapitalist classes in their own economies and the transnational capital.

The withdrawal of patent protection for pharmaceuticals in many developing countries during the 1960s and 1970s represents this duality in the nature of relations between the transnational capital, and local capital throughout the post war capitalist development. During the 1950s and 1960s, most developing country governments encouraged transnational investments and the growth of a local pharmaceutical capital by providing protection from imports and subsidies for investment. On the one hand, the penetration of the TNCs into developing country markets involved the creation of links between the local manufacturers and TNCs through technology transfer agreements, supply of raw materials and chemical intermediates. On the other hand, the strategies of accumulation pursued by the pharmaceutical transnationals, and the struggle of the local capital to expand in home markets and compete with the transnational capital underpinned the contradictions in the relations. Patent protection, extensively used by the TNCs to protect their innovative technologies, control markets and sustain sales of their higher-priced products contradicted with the attempts of the local capital to enter the market and compete with the transnationals. When

this was combined with the limited purchasing power of popular masses and foreign exchange shortages for drug imports, most developing country governments abolished or weakened patent protection for pharmaceuticals.

Policy choice for weak or non patent protection systems was justified by the particularities of industrialisation in late peripheral capitalist contexts. Firstly, it was argued that the lack of basic research and development (R&D) infrastructure and innovative capabilities in developing countries resulted in prolonged monopoly positions for the transnationals and higher prices for vital drugs which could not be afforded by the lower incomes of population. Secondly, it was argued that, rather than stimulating local innovation, in the case of peripheral, production, marketing and licensing exclusivities provided by patents increased the entry barriers for the local firms and prevented them from acquiring learning capabilities, which could, in the absence of patents, be achieved through imitation and reverse engineering (See Sequiera, 1998 for a detailed illustration of these discussions).

Policies of non-patentability or weak patent protection for pharmaceutical products provided two benefits to developing countries. Firstly, non-patentability of pharmaceutical products fostered the emergence and development of domestic pharmaceutical industries. It allowed the entry of the local producers into the market and enabled them to compete with the subsidiaries of the TNCs in their home markets (Chudnovsky, 1979:52; 1983:188; Chaudhuri, 1999:11). Secondly, the non-recognition of product patents opened up important opportunities for saving scarce foreign exchange and providing cheap drugs to the public by providing a legal context for the importation of patented pharma-chemicals at much lower prices from other non-patented sources. Foreign exchange savings contributed towards satisfying an important precondition to continue import substitution industrialisation. Meanwhile, the provision of cheap drugs fulfilled two objectives. On the one hand it integrated the interests of the popular masses to what is defined as the national interest (i.e. industrialization). On the other hand, it contributed to the long-term reproduction of the labor force, partly compensating for the weak health infrastructure in the developing economies.

The withdrawal of patent protection certainly was not greeted as a welcome act by the pharmaceutical TNCs. Any intervention in intellectual property regimes throughout the post war era was resisted

with intense lobbying by the pharmaceutical transnationals.[4] In most cases, however, these pressures were not effective in generating the desired effect of strengthening pharmaceutical patent protection. Hence, one can conclude that the dynamics of the post war capitalist expansion allowed a wider potential for the persistence of conflicts and contradictions between the transnationals and local fractions of the pharmaceutical capital in the developing economies.

3.2. The Non-patentability of pharmaceutical products and processes in Turkey

The abolition of patent protection provides the local pharmaceutical manufacturers with opportunities to engage in both upstream and downstream activities in the industry by allowing them to imitate the patented formulations and pharma-chemicals or molecules developed (mostly) by the transnationals. The imitation of patented formulations or pharma-chemicals as such, however, requires a local firm to develop production processes without the assistance of the technology supplier. This is relatively easier in the upstream sector of the industry, i.e. the formulation sector, which processes various pharma-chemicals into final drug forms. As one production method can be used to process several pharma-chemicals and active ingredients, production in the formulation sector is technologically less intensive. The production of pharma-chemicals --active ingredients used in formulation sector-- is more vigorous as production of each pharma-chemical or patented molecule requires a different production process and hence technology (Chaudhuri, 1984). This downstream activity therefore is much more technology intensive and requires the accumulation of learning and process technologies by local manufacturers (through reverse engineering). One alternative for local formulation producers that cannot acquire technology to produce pharma-chemicals is to import them from other non-patented foreign sources at much cheaper prices. The sustainable development of the industry as a whole, however, necessitates simultaneous progress in both streams of activity.

Patent protection for pharmaceutical products and processes was abolished by a decision of Constitutive Assembly in 1961 in Turkey.

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[4] Chowdhury (1995) and White (1983), document several other strategies (i.e. persuasion, trade sanction threats) employed by the transnationals and the US government to offset the interventions of the developing country governments with national industrial property regimes.

The most important driver behind the policy outcome was a group of local manufacturers that felt threatened by the growth of the transnationals in the domestic market (Cf. Kırım, 1985a: 349). A favorable foreign investment regime introduced during the 1950s and certain privileges provided to the pharmaceutical transnationals in fields of pricing and profit transfers resulted in attracting the country's highest portion of foreign direct investment into the pharmaceutical industry (SPO, 1973:59). Although the entry of the transnational capital opened up collaboration opportunities for bourgeoning local capital (i.e. subcontracting agreements) on the whole they felt threatened by the increasing transnational presence in the domestic market.

The abolition of patent protection proved to be one of the most important measures that enabled the growth of local manufacturers and productive capabilities in Turkey. In the two decades following the abolition of patent protection, ninety percent of pharmaceutical consumption was met by local production. Compared with other developing countries, a much larger percent of the both pharmaceutical production and sales were controlled by nationally owned firms.[5] However, the abolition of patent protection did not prove sufficient to halt the dependency of all local manufacturers on foreign technology and imports of pharma-chemicals.

One benefit of the abolition of patent protection was the access it provided for local pharmaceutical manufacturers to unpatented sources of technology and supplies of pharma-chemicals. In other words, the absence of patent protection allowed alternative means of market existence for local firms other than collaborating with the transnationals. The decades following the abolition of patent protection witnessed the evolution of two fractions of local capital in the Turkish pharmaceutical industry differentiated from each other in terms of acquisition of their technology and size (c.f. Kırım, 1986; 1985a:171-4). The first was the domestic fractions of the pharmaceutical capital whose product portfolios were largely dominated by copy products. Compared to the internationalised

[5] In 1984, before the consolidation of the liberalisation policies in the industry, the sales share of the transnationals in the Turkish pharmaceutical market was thirty-seven percent. (Ministry of Health, 1990). Across the developing world, Turkey was the third country, after South Korea and India, where the transnationals had the lowest market share. One should also note that in South Korea and India where the sales share of the TNCs were 17 and 23 percents respectively, the expansion of transnationals were restricted through more restrictive measures than in Turkey, which required the transnationals to reduce their equity shares in their own subsidiaries (UNTC,1984).

fractions of the local pharmaceutical capital, these local firms were less dependent on the transnationals for their purchases of technology (Ibid).[6] The domestic fractions of the local capital were heterogeneous with respect to their size and type of activity. Firstly, numerous small firms specialised on formulation production benefiting from the restrictions imposed on the entry of the foreign capital into this sector. These firms relied on imports of patented pharma-chemicals from abroad and imitated the patented formulations of the transnationals. Secondly, number of large size local firms expanded their formulation activities into pharma-chemicals production benefiting from the incentives and subsidies provided for the development of this sector in the 1970s. The most common form of technology acquisition by these firms was purchases of production technology from unpatented sources mostly from Eastern Europe. The main appeal of this option for the local manufacturers was the dossiers associated with such purchases that provided a detailed description of the production technology, and other necessary information required for registration purposes (Eren, 2002).

Another group of manufacturers --the internationalised fractions of the local capital --continued to rely on technology transfer and licensing agreements with the transnationals. Although this group of firms also produced a wide range of copy products (i.e. through imitative production) their product portfolios were mostly dominated by licensed products of transnationals (Kirim, 1985a:171).[7] Technology transfer and licensing agreements promised these local

[6] In 1975, out of a total of 2117 drugs in the formulation market, 732 were produced by the transnationals, while the remaining 1985 drugs were produced by the local firms (TIB, 1975:55-59). Out of the latter, 1385 drugs were produced under local manufacturers' own brands (i.e. copy products) while the remaining 600 were licensed products. Domestic fraction of the local capital is those firms that entirely or predominantly produced copy drugs with their own brands. For example, firms such as Nobel, Ilsan, Husnu Arsan, Münir Sahin that produced only copy drugs can be considered in the former subcategory while others such as Deva (94 drugs of its own brand, 15 licensed drugs), Mustafa Nevzat (67 drugs of its own brand, 2 licensed drugs), Biofarma (19 drugs of its own brand,3 licensed drugs) Ibrahim Ethem (84 drugs of its own brand, 26 licensed drugs) Iltas (53 drugs of its own brand, 7 licensed drugs) can be placed in the latter.

[7] For example in 1975 the leading licensee firm Eczacıbası's product portfolio consisted of a total of 171 drugs, 134 of which were produced under licenses from several transnationals while the remaining 37 drugs were the firm's own brands (i.e. copy products). Another licensee firm Adeka which had a 33 drug portfolio produced 18 of these under license while the remaining 15 were its own brands. Out of the 55 drugs in its portfolio another licensee firm Santa Farma produced 33 of them under license(TIB,1975:56).

firms lower costs and fewer uncertainties not only because they facilitated constant access to the licensor during the implementation of the technology acquired through the license but also because they involved the provision of updated product related information that are essential during the registration of the product with the regulatory authorities and the subsequent marketing stage (Kırım, 1985a: 165). Whilst the internationalised section of the local capital viewed licensing and technology transfer agreements as a more profitable strategy, the abolition of patent protection, and the restrictions imposed on the entry of the foreign capital into the formulation sector of the industry by the state during the 1970s shifted the preferences of the transnationals in favour of licensing agreements. Throughout the 1960s and 1970s, benefiting from their partnerships with the transnationals, the local licensee firms grew both in size and in number, and emerged as the most powerful fraction of the local capital.

A second and interrelated form of dependency in the Turkish pharmaceutical industry has been the reliance on pharma-chemical imports. Although throughout the 1970s, the development of the pharma-chemical production was promoted through import protection, investment subsidies, and a series of restrictions imposed on the transnationals, the industry continued to remain dependent on pharma-chemical imports.[8]

[8] Production of pharma-chemicals was realised by the end of 1970s but this production was able to meet only three percent of the local demand(SPO, 1977b: 7). In the 1980s, under continuing protection (i.e. investment incentives, import protection provided for pharma-chemical production, export incentives) the quantity of pharma-chemical production and types of products produced recorded some ımprovement (c.f.Eren, 2002; 66). Following the elimination of investment incentives and trade protection in the 1990s, the local production of pharma-chemicals became unable to compete with cheaper imports which resulted in significant contraction in capacity utilisation, quantity, and types of locally produced pharma-chemicals. The number of firms operating in the industry declined from twenty-five in 1987 to eleven in 1998 and the production of a range of pharma-chemicals was stopped including the semi-synthetic penicillins which formed an important fraction of production and exports during the 1980s. Alongside local firms, the transnationals, which invested in the sector during the 1970s, also exited the sector. Out of six transnationals, which were operating in the industry, there is currently only one left (i.e. Baxter) (interview with local company executive). Thus, the average annual growth rate of pharma-chemical imports in the period 1994-1999 reached fifteen percent (Eren, 2002:65). Paralleling the restriction in capacity utilisation, the production investments in the sector have also declined from thirty-two percent of all investments in 1987 to a mere three percent in 1998 (Eren, 2002:56).

The continuing intensity of licensing agreements in the formulation sector was one of the factors that hindered the development of pharma-chemicals sector (c.f. Savaş, 1969; Kırım, 1985a: 361). By obliging the local manufacturers to purchase their inputs exclusively from their transnational licensors, licensing agreements significantly reduced the incentives by local manufacturers to engage in pharma-chemical production. A second hindrance for the backward integration of pharma-chemical production -- i.e. the absence of a local organic chemical industry-- was common to many developing countries.[9] One solution to this problem in some developing economies was extensive public investment in the production of organic chemicals and drug related research and development. In India, for example public investment in production of organic chemicals and R&D not only reduced reliance on foreign sources of technology but also spurred the growth in the production of pharma-chemicals (Chaudhuri 1999; 1984; Mehrotra, 1989, Ramachandran &Rangarao 1972)

As any type of state policy, however, the existence or absence of particular forms of state intervention results from a specific balance of class forces. The social base of direct state intervention in the pharmaceutical industry, of the sort observed in India for example (c.f Eren-Vural, 2007), did not exist in Turkey. During the initial stages of the development of the pharmaceutical industry all fractions of the local pharmaceutical capital strongly resisted any form of direct intervention and instead insisted on mere regulatory intervention in the form of investment subsidies and import protection. Thus, rather than public investment in pharma-chemical industry, the State Planning Office reports prepared in cooperation with industry representatives proposed joint ventures between local manufacturers as the main policy to overcome the hurdles of high cost pharma-chemical investments (SPO, 1963:335;1965:225;1968:428-30). In the short term, regulatory intervention allowed a lucrative business for local manufacturers that invested in pharma-chemical production. Those investors that started the production of a pharma-chemical from its latest stage (importing most of the chemical intermediates) benefited not only from investment subsidies but also an absolute market monopoly ensured by import protection. Profits accruing from

[9] In the absence of organic chemical industry that provides inputs and intermediates in the manufacturing of pharma-chemicals, production remains dependent on imported inputs and intermediaries, and the progress towards technologically more intensive methods of production is seriously hindered.

such production were diverted into reinvestment into the production of profitable consumer products rather than pharma-chemicals. It was only in mid 1970s when a large group of small manufacturers became increasingly critical of the market monopolies provided to big firms (c.f.SPO,1977) that a provision on public investment in an integrated organic chemical plant that would produce inputs for local production of pharma-chemicals (and also dyestuffs) was inserted into the state plans. Although this suggestion was repeated in subsequent annual development plans it was never realised. (c.f. SPO, 1975:171; 1976:44; 1977:51; 1978:120; 1979:369). During the 1980s, when state involvement in the manufacturing sector was significantly reduced, the matter disappeared from the development plans.

To conclude, although the abolition of patent protection and the accompanying regulatory incentives provided throughout the import substitution era contributed to accumulation by the local capital, the latter continued to remain dependent on foreign technology, and imports of pharma-chemicals. In other words, the market survival by local firms remained conditional on not only regulatory state intervention but also access to technology and imports of pharma-chemicals from either the transnationals or other foreign unpatented sources. The main effect for interest formation of this reliance on foreign technology and imports of pharma-chemicals was the underdevelopment of powerful set of independent class interests by the local manufacturers. The significance of the absence of such class interests became more obvious during the shifts in the alliances between the local manufacturers in the further stages of policy making on pharmaceutical patents during the 1990s.

4. Policy change towards stronger pharmaceutical intellectual property regimes across the developing world

4.1. The sources of increased pressures in favour of stronger intellectual property protection

During the 1980s and 1990s, the pressures imposed by the transnational pharmaceutical capital on developed and developing country governments in favor of stronger intellectual property protection intensified enormously. An important source of the increased pressures was the profitability crisis, which the transnational pharmaceutical capital incurred since the early 1980s. While being a

part of the general profitability crisis of the capitalist production of the period, the crisis encountered by the transnational pharmaceutical capital was caused by three developments in the drug markets of the advanced capitalist economies (Nogues, 1990).

Firstly, from 1960s onwards in the US and Europe tighter regulatory controls were imposed on pharmaceutical companies to prove the safety and efficacy of their products. The stricter regulatory environment not only increased the cost of the R&D incurred by the pharmaceutical firms, but also increased the time lag between product innovation and its market launch (Comanor, 1986:1179; Balance, 1992).

Secondly, from 1980s onwards both in the US and in Europe governments tried to contain increasing public drug expenditures by promoting the use of cheaper generic products. The regulatory measures introduced to this end made it easier for generic firms to enter the market immediately after patent expiry, and presented a significant competitive challenge for the sales and market shares to the original producers (Nogues, 1990; UNIDO, 1996: 99).

Thirdly, from the 1970s onwards, the productivity of drug research (i.e. the number of new chemical components innovated by transnational corporations) recorded a significant decline compared with the previous decades. This caused alarm in the industry about the further erosion of profits when the patents on existing products expired (Balance et.al, 1992). [10]

The political strategy adopted by the global pharmaceutical capital in the face of declining profit margins was to increase pressures in favor of stronger intellectual property protection worldwide (Nogues, 1990; Balance, 1992, Camonor, 1986). This strategy involved distinct forms with respect to developed and developing country markets. In relation to developed country markets, such as the U.S. and the EU, where a relatively strong intellectual property protection already existed, this strategy involved seeking to extend the range, duration, and scope of exclusivities allowed through intellectual property rights. In relation to developing country markets, which were characterized by much laxer protection, it entailed the generation of a transformation from weaker to stronger intellectual property regimes.

[10] Balance (1992) reports that the number of new chemical entities founded declined from 844 in the period 1961-1970 to 665 in the period 1971-1980, and further down to 506 in the period 1981-1990.

Throughout the 1980s, strong industry lobbying in the U.S. and by then the European Community (EC) resulted in a series of legislation that extended the scope, duration, and range of exclusivities provided through intellectual property rights. The Hatch Waxman Act, introduced in the U.S. in 1984, for example, prolonged the effective term of patents for an additional five years, to compensate for delays incurred during the regulatory procedures (Nogues, 1990). Moreover, the legislation introduced a new form of protection and exclusivity, to compensate the original drug producers that bear the costs of expensive clinical tests to prove the safety and efficacy of a new drug. Later came to be known as pharmaceutical data exclusivity, this procedure effectively prevented the health authorities (in this case Food and Drug Administration Authority in the U.S.) from relying on health and safety information submitted by the originator companies to evaluate the health and safety properties of similar subsequent generic drug applications for a period of five years. While providing a de facto market exclusivity to the originator firms, at the end of the exclusivity periods, the legislation aimed at fastening the entry of generic products into the market by allowing them to register their drugs by claiming bioequivalence to the original drug, instead of requiring them to repeat the costly safety and efficacy tests (Mossinhoff, 1999). While the Hax Watchman Act had been thus portrayed as an effective balance between the conflicting interests of the public, generic and original drug developers, it also became the first legislation to innovate a new form of exclusivity, which will during the 1990s become the focus of international debates on pharmaceutical intellectual property.

In 1987, the EC followed the U.S. suit by issuing a regulation requiring the member countries to provide either six to ten years of data exclusivity. Unlike the U.S. regulation, the EU regulation also allowed the member states to bind the provision of data exclusivity with the patent term, thus allowing member states to leave patented drugs outside the scope of data exclusivity. In 1992, the EU also issued a regulation to restore pharmaceutical patent terms to compensate for delays incurred during the regulatory procedures.

The second strategy adopted by the global pharmaceutical industry was to increase pressures and lobbying to enforce stronger and more stringent intellectual property protection across the developing world (Nogues, 1990). As will be outlined in section 4.3., the associations of pharmaceutical transnational capital achieved this end not only through their own intensive lobbying activities on

developing country governments, but also by urging their host governments in advanced capitalist countries to enforce stronger patent protection in developing countries. Still there have been more fundamental factors which rendered all these pressures in favour of stronger patent protection effective on developing country governments. The next section is concerned with highlighting these factors.

4.2. Why were the pressures on developing countries more effective?

The most important factor that rendered the pressures on developing countries more effective during the 1980s was the increased structural power of the transnational capital. The structural power of the capital relates to its capacity to constrain governments, trade unions, and other social groups by its control over investment resources (Gill 1989, Winters, 1996). This power is essential to the operation of the capitalist system but it varies depending on its size, scale, and relative mobility and scarcity. During the 1980s, the rise in the structural power of the capital was underpinned by two factors. The first one of these was the growth in the scope and scale of transnational financial capital (Gill, 1989; Holloway, 1994), while the second one was general profitability crisis of capitalist production.

One important outcome of rising economic dominance of financial fractions of transnational capital was the increased mobility of the transnational capital as a whole (Holloway, 1998; Winters, 1996). The rapid developments in transport, communications, and data processing also promoted the capacity of financial capital to relocate investment resources across jurisdictions. Another important corollary of the growth and rising economic dominance of financial fractions of transnational capital was the formation of a new transnational class alliance (Gill, 1991). The members of this new transnational class alliance included the top owners and key executives of transnationals in capital intensive and high-tech industries, central and international bankers, politicians and civil servants in most advanced capitalist countries (Ibid).

During the recessionary atmosphere of the 1980s, increased mobility of large amounts of transnational capital (in the form of foreign direct investment, short-term capital flows, and long term portfolio movements) obliged governments to become more responsive to their needs and requirements. Economic recessions

characterised by declining profitability of capitalist production, low growth, high levels of inflation and rising unemployment led to a fiscal crisis in the welfare structures and collapse of the consensus over the appropriateness of demand management policies. Within this context the increased structural power of the transnational capital emerged as the prime motor behind the neo-liberal ideologies and policies which were revived in the US and Western Europe to overcome economic recessions. These policies represented a significant departure from the post war politico-economic settlement and resulted in an economic, political and ideological restructuring of the global political economy.

The impacts of the increased structural power of the transnational capital and the corresponding shrinkage in the power of territorially bounded actors (i.e. nation states, local capital and labour) has been more commanding in the semi-peripheral economies. This was so due to two interrelated and reinforcing processes.

The first relates to the reduction in the availability to developing country governments of sources of external finance other than transnational capital. The end of political and military rivalries in the aftermath of the Cold War significantly restricted the extent of external finance (i.e. military and political aid) that had been available during the era of superpower politics. Secondly, the recessions of the 1970s and the debt crisis of the 1980s eliminated the favourable terms over the remaining sources of external borrowing. During the 1980s, the continuation of the flows of external credit was made conditional on the implementation of economic liberalisation and structural adjustment policies which generally involved the creation of a more favourable atmosphere for the transnational capital. These policies not only reinforced the declining power of the state to engage in economic initiatives, but also increased the exposure of the semi-peripheral economies to world markets and the pressures from transnational capital.

Far from externally imposed on the developing economies, this change in the mode of capital accumulation was sustained by restructuring of the power bloc in the developing economies. Hence, for example, in Turkey, the prime beneficiaries of the previous import substitution policies emerged as the main advocates of neo liberal policies, which they saw as the strategy for overcoming the crisis.

4.3. The outcomes of transnational lobbying for stronger patent protection.

When compared to its performance in the 1970s, the most important political achievement of transnational pharmaceutical capital during the 1980s was the leading role it played in the creation and implementation of a mechanism for the systematic enforcement of bilateral trade sanctions against the export competitive sectors of the developing countries that failed to provide patent protection. In 1984, the lobbying efforts by the transnational pharmaceutical capital's association, PhRMA, succeeded in introducing significant revisions to Section 301 of the US 1974 Trade Act.[11] In its revised form, Section 301 of the Trade Act allowed the US Trade Representative (USTR) to revoke (within the U.S. Generalised System of Preferences) the privileged status of countries which failed to provide effective safeguards for intellectual property rights.[12] In the years that followed Section 301 became a powerful tool for the US government and the transnational pharmaceutical capital for pressurizing developing countries to strengthen their patent systems.[13]

The intense lobbying efforts by the transnational pharmaceutical capital in 1984 and 1985 was also one of the most important driving forces behind the inclusion of intellectual property protection in the GATT Uruguay Round trade negotiations (Ellsworth, 1993). Throughout the negotiations, which started in 1986, the advanced capitalist country representatives insisted on the extension of the scope of patent protection to pharmaceuticals. The representatives of the US, the EU and Japan defended the stronger patent systems as the requirement for the future inflows of foreign direct investment and transfer of technology into the developing countries.

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[11] Although the PhRMA's membership criterion requires US-based operations, a large number of pharmaceutical transnationals from both sides of the Atlantic meets this criterion. The PhRMA in this sense can be conveniently viewed as the voice of the pharmaceutical transnational capital rather than merely the US based transnationals.

[12] U.S. Generalised System of Preferences (GSP) initiated first in 1976, is a program that grants duty-free treatment to specified products imported mostly from developing countries. Other industrialised countries such as the EU have similar programs that provide tariff preferences to imports from developing countries.

[13] Section 301 provides a domestic procedure whereby the affected US manufacturers/exporters can petition the US Trade Representative to initiate investigations in countries where their intellectual property rights are violated. Many researches-based pharmaceutical companies and their association PhRMA used this petition procedure against countries such as Argentine Brazil, Taiwan, and many others.

The consistent use of the trade sanctions throughout the GATT negotiations had been an important means, which ensured compliance of several developing countries. In 1988, while the Uruguay negotiations for patent protection were underway, the PhRMA succeeded in convincing the US Congress to introduce a second change to the Section 301 of Trade Act 1974 that significantly relaxed the conditions under which the United States Trade Representative (USTR) could impose retaliatory trade sanctions against foreign countries (c.f. USTR, 1994). Between 1988-1992, acting upon the petitions filed by the PhRMA, the USTR initiated a series of investigations against several developing countries, including Brazil, Argentina, Mexico, and Taiwan (c.f. Gwyn, 1988; USTR, 1999). Thus, by 1992, even before the conclusion of the GATT negotiations, the majority of the developing countries had changed their policy stand over the issue of pharmaceutical patents.[14] The TRIPS (Trade Related aspects of Intellectual Property Rights) Agreement was concluded in 1994 against the background of these increased pressures on developing countries in the multilateral trade negotiations.

4.4. Flexibilities allowed for national authorities in the TRIPs agreement and their significance

The TRIPs agreement introduced international standards on a wide range of intellectual property rights, and thus had a transformative impact on the extent of protection provided through intellectual property regimes across the developing world. In relation to pharmaceuticals, the agreement's provisions on patent protection and protection of pharmaceutical test data were of utmost importance. In relation to patents, the TRIPs harmonised the scope and duration of protection as well as the set of exclusive rights conferred by patents across national patent regimes. Due to the highly contested nature of the negotiations at the Uruguay Round, however, TRIPs also entailed some flexibilities to national authorities in certain areas of their patent regimes. Some of these were related to permanent arrangements such as the conditions of compulsory licensing, and parallel imports while

[14] The success of trade sanctions in generating almost uniform compliance from the developing country governments has been due to their distinct financial and political impacts. On the one hand, trade sanctions imposed against the export competitive sectors of developing country economies deprived the governments of precious foreign exchange earnings. On other hand, by imposing penalties on industrial sectors other than pharmaceuticals, trade sanctions significantly increased the extent of domestic pressures on developing country governments.

others included provisional procedures such as the determination of transitional periods after which the patent protection would be provided in developing countries.

Depending on the ways they were devised by the national authorities, the aspects of the patent system mentioned above had profound implications for the survival of local pharmaceutical industries, and access to essential drugs across the developing world in the post TRIPs era. For example, the determination of the provisions on compulsory licensing --an administrative or judicial procedure, that forces the patent holder to license the patented innovation to a third party in return for remuneration-- had profound importance for providing public access to essential drugs at more competitive prices (c.f. Watal, 2000; Correra, 2000; South Centre, 1997). Compulsory licensing is also significant for the opportunities it provides to the local manufacturers in developing economies to bypass the exclusivities provided by the patent. Decision to issue a compulsory license by a government opens up commercial opportunities for local manufacturers in any developing country to produce the patented product for domestic use or exports.

The principle of international exhaustion of rights, on the other hand, is important for preventing the accumulation of excessive market power by patent holders. The international exhaustion of rights allows a third party to import the patented product of a right holder from a market where it has been marketed by the patent holder, or its licensees into other markets, where it is marketed at higher prices. Article 6 of the TRIPs allows the member states to provide for the international exhaustion of rights and parallel imports. Similar to compulsory licensing, the principle of international exhaustion of rights opens up commercial opportunities to third parties in the developing world.

The third area of flexibility allowed by the TRIPs was the length of transitional periods. The developing and least developed countries were allowed transitional periods of ten and fifteen years respectively to delay the provision of patent protection for pharmaceutical products and processes. (Articles 65.2, 66.1 and 65.4, 65.5). The transitional periods were important for the local industries in the developing world to adjust to the new conditions of competition, to shift the composition of their outputs to compensate for the products that would become patentable, to initiate new commercial networks (i.e. entering into limited equity or non-equity arrangements with the transnationals) or

to update their basic R&D infrastructure and personnel to survive in the market (c.f. South Centre, 1997).

As the length of transitional periods involved a risk (or opportunity) for the replication of the drugs patented during the transitional periods, the issue emerged as one of the most controversial topics in the years following the conclusion of the TRIPs agreement. The negotiators of the advanced capitalist countries aimed to deter that risk by inserting two articles (Articles 70.8 & 70.9) in the agreement that required developing countries benefiting from transitional periods to provide exclusive marketing rights for patent applications that were granted protection and marketing approval in another WTO member country after 1.1.1995. However, the exclusive marketing rights safeguard still involved a regulatory loophole. By definition, exclusive marketing rights are confined to domestic market sales and unlike patents, they do not prevent third parties from manufacturing the patented products. In other words, even when the exclusive marketing rights were in force, the potential existed for producers in developing countries to manufacture the products patented during the transitional periods and export them into other developing country markets where such products were also not patented (Watal & Mathai, 1995:5)[15].

The TRIPs was also the first international agreement that imposed obligations on its signatories on pharmaceutical data protection. Article 39. 3 of the agreement required national authorities to protect against unfair commercial use, and disclosure the pharmaceutical test data submitted during the registration of pharmaceutical products. However, as with the provisions on patent protection (i.e. parallel importing and compulsory licensing), the contestations between parties concerned, (representatives of the EU, the U.S. and the transnational pharmaceutical capital on the one hand, and the representatives of the developing country governments which crystallised the interests of the local pharmaceutical capital in their countries on the other), resulted in a highly ambiguous and broad definition of protection. As a result, Article 39.3 does not specify

[15] The realisation of this potential depended to a large extent on the length of the transitional periods and the number of countries that preferred to provide long transitional periods. From the perspective of the transnationals, the longer the transitional periods across the developing countries, the larger were the potential export markets for such products, and the higher were the risks of potential sales, profits and loss of exclusivities. This regulatory loophole and the risks associated with it was partly the reason behind the continuing pressures on the developing countries after the conclusion of the TRIPs agreement.

whether the protection include data exclusivity – that is provision of market monopoly to originators of pharmaceutical test data that proves the safety and efficacy of a new drug, or merely an obligation on national authorities to protect data against disclosure and fraudulent use by third parties. (c.f. Pugatch, 2004, Correra,. 2002). Data exclusivity approach which had been legislated in the U.S. and the EU during the 1980s, had been endorsed by the transnational capital and the representatives of the EU, and the U.S. during the TRIPs negotiations, and afterwards. Market monopoly in data exclusivity is conferred by preventing health authorities to rely on the data submitted by the originator of the drug to assess the safety and efficacy of other generic drug applications, and thus preventing the entry of generic drugs into the market throughout a predetermined period of time. From the point of view of the transnational capital, the central importance of data exclusivity lies with those products which are not patentable, and/or are about to come out of patent protection. Data exclusivity, therefore, provides an extra or an alternative way to extend exclusivities when other intellectual property rights such as patents are not available. Compared with patents the scope and duration of protection and exclusivities conferred by data exclusivity is much narrower. While the patents prevent the third parties from both producing and marketing innovative products for a period of at least twenty years, data exclusivity does not prevent the generic producers to produce the same data for the licensing of the product in global or national markets, and the term of protection ranges between five to ten years. The cost of generating that safety and efficacy data nevertheless acts as a significant barrier for the market entry of generic producers (c.f. Pugatch, 2004:4)

In stark contrast to the exclusivity approach, the representatives of developing country governments, international non governmental organisations, and fractions of local pharmaceutical capital across the developing world, insists that TRIPs requires merely the protection of data submitted by drug firms against disclosure and fraudulent use. This approach therefore advocates that data protection entailed in the Agreement should not prevent health authorities to rely on data submitted by the originator drug firms to evaluate generic drug applications' safety and efficacy. This approach thus does not entail the provision of market exclusivity for originators of test data, and it does not prevent the entry of generic drugs into the market. (c.f. Pugatch, 2004, Correra, 2002).

4.4. Aftermath of TRIPs: Continuing contestations on IPRs.

Rather than finalising the controversies on intellectual property, the TRIPs provided a new global framework for continuing contestation on the strength of intellectual property protection. Following the enactment of the agreement, the transnational pharmaceutical capital and the governments of advanced capitalist countries, such as the U.S. and the EU, which materialise their interests, closely monitored the political processes through which TRIPs provisions were integrated into domestic intellectual property regimes. In many cases, the U.S. and EU succeeded in gaining much stricter protection for intellectual property rights through bilateral agreements. Such attempts were countered by the alliances forged between the fractions of the local pharmaceutical capital in some developing countries (such as India, Brasil), and non governmental organisations in international development, (such as Medicine Sans Frontier, Oxfam, Consumer Project on Technology), that aimed at reintroducing a more public oriented interpretation of intellectual property rights and the TRIPs. The governments of India and Brazil, in particular, became the institutional channels through which the concerns of this latter group of societal forces were expressed at the international level.

Doha Declaration on TRIPs and Public Health that was negotiated subsequently (14^{TH} November, 2001), can be seen as a major step for those seeking to loosen the implementation of TRIPs. The declaration asserted the right of developing countries to make full use of TRIPs flexibilities, in particular parallel imports, and compulsory licenses, to protect public health. Moreover the declaration initiated the creation of a mechanism that enabled the least developed countries with insufficient local manufacturing capacity to import patented drugs from other WTO member countries through cross border compulsory licensing. (C.f. WTO, 2001)

The pro-public health approach that was asserted by the Doha Declaration, however, prompted another attempt by the transnational pharmaceutical capital, the U.S. government and the EU to initiate a new battle on the basis of Article 39 of TRIPs. Central objective underlying such attempts was to offset the opportunities, which the Doha Declaration allowed for generic manufacturers in developing countries, by providing new exclusivities that would delay registration of generic drugs. (Baker, 2004). Paradoxically, rather than finalizing the controversies over IPRs for pharmaceuticals, the post TRIPs

scenario involves a new global framework for continuing contestation on the strength of intellectual property protection.

5. Policy change on pharmaceutical IPR in Turkey

5.1. The initial emergence of the patent issue on the agenda

In Turkey, the emergence of the patent issue in the policy agenda coincided with the restructuring of the Turkish power bloc in the early 1980s and the subsequent radical shift towards the export-oriented model of capital accumulation. The most important societal force that laid behind this shift was the Turkish conglomerate capital, which emerged as the hegemonic fraction in the Turkish power bloc during the 1980s. In stark contrast to the small and medium sized firms that formed the majority within the Turkish capital, the conglomerate capital consisted of a group of capitalists, which bourgeoned benefiting from the import substitution policies in the 1960s and 1970s and which combined different functions in the total circuit of capital (money, productive, and commerce) within the organisational form of holding companies (Ercan, 2002). Conglomerate capital saw the export oriented model of capital accumulation, and the liberalisation of the Turkish economy as an important means to overcome the aggravated crisis they faced in the 1970s and rearticulate with the transnational circuits of capital (Ibid).

Throughout the 1980s, the equal treatment of domestic and foreign capital was declared as the core of the government's foreign investment policy (Koseoglu, 1994). Patent protection for pharmaceutical products first appeared on the national agenda in early 1984, against the background of these initial attempts at economic liberalisation (Atay, 1992). In response to the intense lobbying activities of the transnationals, the Ministry of Trade and Industry, agreed to include pharmaceuticals within the scope of patent protection. In this earlier appearance of the issue in the agenda, the policy change in favour of stronger patentability was prevented by the united position of all local pharmaceutical manufacturers (including the licensee and independent firms) against the patentability of pharmaceutical products and processes. Despite supporting all other economic liberalisation policies in the industry alongside their transnational partners (such as liberalisation of restrictions on the prices and quantities of imported raw materials, and the liberalisation of the price control scheme), the licensee firms were united with other

local firms over the issue of non-patentability (interviews). Hence, the provision of patent protection for pharmaceuticals was dropped off the agenda together with the new patent law that was being drafted.

5.2. Realignment of class alliances and policy stands

In the following years, the antipatent alliance between the domestic and internationalised fractions of the local pharmaceutical capital gradually dissolved. The inclusion of the pharmaceutical patents within the scope of the GATT Uruguay multilateral negotiations in 1988, formally imposed the issue on the Turkish policy agenda. In the early 1990s, the shift in the policy position of the internationalised fractions of the local capital in favour of patent protection alongside their transnational partners constituted one of the most important turning points in the policy making process. The most important factors underlying this shift were the consolidation of economic liberalisation policies and the differential impacts of patent protection over the different fractions of the local pharmaceutical capital.

Amongst the economic liberalisation policies, the liberalisation of the FDI regime in 1986 was the most important one in terms of its impacts on the pharmaceutical patent policy process. The main effect of this reform was a substantial change in the balance of forces between the transnationals and internationalised fractions of the local pharmaceutical capital. In the thirteen-year period, 1986-1999, a total of thirty new transnationals started to operate in the formulation sector of the pharmaceutical industry (Eren, 2002:59). The market entry by transnationals accelerated especially in the 1990s: out of the thirty new transnationals, twenty-three of them entered the market during the 1990s (See Table 1). The substantial influx of foreign capital into the pharmaceutical industry intensified the transnational presence in the industry and the pressures for the revision of the patent policy. More importantly, the full liberalisation of imports and foreign investment regimes shifted the leverage away from the local licensee firms (which had until then served as the bridge to the foreign capital willing to enter the market) towards the transnationals, which now had the option to recapture the market directly rather than licensing their products to local firms.

Towards the end of the 1980s, the internationalised fractions of the local pharmaceutical capital, which had previously opposed patent protection together with the domestic fractions of the capital, came

under increasing pressure from their transnational partners. Some of the transnationals even threatened to cancel their licensing agreements and enter the market directly benefiting from the liberalisation of the investment regimes (interviews).[16] Moreover, the successes of transnational lobbying and US government in forcing the changes in patent laws of other strongholds of weak patent protection (such as Korea, Brazil, Taiwan, Thailand, Argentina, and Mexico) as well as inclusion of Turkey in the Special 301 watch-list (under which the retaliatory trade sanctions against foreign countries are imposed) (cf. USTR, 1994) hammered home the necessity for the licensee firms to revise their position on the patent issue (interviews).[17]

An interrelated factor, which contributed towards the shift in the policy position of the internationalised fractions of the local pharmaceutical capital, was the diverse implications of the introduction of patent protection for the capabilities of local firms to survive in the market under the new circumstances. As all local firms lacked innovative capacity, patent protection involved increased dependence of local producers on the transnationals. As they would no longer be able to replicate or import the pharma-chemicals developed by the transnationals, under patent protection the local firms would not be able to launch new drugs unless they entered into non-equity (licensing agreements, subcontracting) or equity (joint ventures) arrangements with the transnationals. Although they would still be able to produce ex-patent drugs and the drugs launched to the market before the enforcement of patent protection, as these are unaffected by the patent protection, the inability to launch new products significantly reduced the scope of independent operations by the local manufacturers.

Despite these overall negative prospects, the relative impacts of patent protection varied considerably between the two fractions of local pharmaceutical capital. In an environment where new product launch depends on partnerships with transnationals, the licensee firms encountered lower risks and adjustment costs to maintain their market position than the domestic fractions of the local capital. Whilst the liberalisation policies and the prospect of patent protection challenged the central role that the internationalised fractions of the local capital once held in the industry, they also offered prospects for increased

[16] This point was emphasized as ''off the record'' information during several interviews with leading licensee firms.

[17] This information was provided off the record by a high level executive of a leading licensee firm in the industry.

collaboration with the transnationals, access to new technologies, products and hence lucrative sales.

The new pattern of foreign capital entry into the industry during the 1990s, (that aimed at highest profits with minimum levels of investments), was indicative of such opportunities for the internationalised fractions of the local capital. Approximately fifty percent of the new foreign entrants in the pharmaceutical industry contracted the manufacturing of their products to local producers, a practice known as toll manufacturing in the pharmaceutical industry. The other forty percent operated as trading firms, importing their products directly from abroad and marketing them locally (See Table 1). Due to the particular requirements of pharmaceutical marketing and its disproportionate importance in commercial success, all transnationals were interested in co-marketing arrangements with local firms whose established local marketing networks were an important asset to the transnationals. On the part of the local firms, however, abidance with the intellectual property rights had emerged as an important precondition for this new form of articulation with the transnational capital (interviews).[18] Hence while the post patent scenario involved new openings for the internationalised fractions of the local capital to maintain their market presence by expanding their alliances with the transnationals, the domestic fractions of capital whose portfolios were dominated by copies of patented and ex-patent drugs confronted the real costs of patent protection.

5.3. Revival of the patent issue in the agenda

The discussions on pharmaceutical patents took place within the framework of a draft patent legislation that the government had started preparing following the initiation of GATT multilateral negotiations. The draft legislation was finalized in four years, and transferred to the Turkish Grand National Assembly (TGNA) for legislative discussions towards the end of 1992.

The split amongst the fractions of the local pharmaceutical capital discussed in the previous section not only significantly reduced the political influence of the anti-patent coalition but also confined the policy focus. Rather than opposing patent protection as earlier, the associations of the domestic fractions of the local capital (Pharmaceutical Manufacturers Association of Turkey [PMAT] and

[18] Off the record information received during personal interviews with executives of the four prominent licensee firms.

Local Pharmaceutical Manufacturers Association [LPMA]) came to concentrate more on the terms of patent protection.[19] This new focus was reflected in the parliamentary debates. Unlike it had been five years ago, the main issue centered on not whether to include the pharmaceuticals within the framework of the new legislation but rather on the terms of patent protection, and the extent to which the flexibilities allowed under TRIPs will be exploited. Moreover, the internally divided nature of the local pharmaceutical capital also confined the political influence with which it can press for a wide range of flexibilities allowed under TRIPs. Unlike the case of other developing countries, for example India, where important flexibilities, such as conditions of compulsory licensing, the issue of parallel imports the definition of novelty etc., constituted the core of policy debates (c.f. Eren Vural, 2007), in Turkey, throughout the two and half years that the legislation was reviewed in several parliamentary committees, the debates almost exclusively centered on one of the most temporary aspects of the patentability, that of the length of transitional periods. In the draft decree the government proposed a five-year transitional period for both pharmaceutical products and processes. During the discussions in the parliamentary committees, three main positions emerged on the length of the transnational periods. The representatives of the transnational pharmaceutical firms insisted on immediate provision of patent protection without any transitional periods. Moreover, they pressed for the inclusion of a pipeline protection clause in the patent legislation that provides retroactive protection for pharmaceutical products that were patented during the 1990s (TBMM, 1993:35-8:47-51). The internationalized fractions of the local capital including, The Association of Turkish Industrialists and Businessmen (TUSİAD), Employers Union of Pharmaceutical Industry (EUPI), the spokesman of the Ministry of Trade and Industry insisted that transitional periods provided for the pharmaceuticals should be within a time range that would not create problems for Turkey in its relations with the EU, the EFTA countries, and the US (TBMM, 1993:16-17:44-46:79-80). Meanwhile the domestic fractions of the local capital and their associations (PMAT, LPMA), the Chamber of Medical Doctors, the Association of

[19] During the mid-1990s, somewhat ironically professional organizations, especially the Union of Chambers of Pharmacists, emerged as the fiercest opponents of patent protection and the only groups that consistently maintained their policy position on complete exclusion of pharmaceutical products and processes from the scope of patent protection.

Consumer Rights, the Union of Turkish Chambers of Commerce and Industry (TOBB), and the spokesman of the Ministry of Health, contended that the longest possible transition period should be provided for the pharmaceuticals in line with the rulings of TRIPs. (TBMM, 1993:11-15:39-43:59-75:85-99).

Initial parliamentary discussions of the draft patent legislation took place in the Trade and Industry Committee which was known by all participants to be the stronghold of the transnational and internationalised fractions of the local capital (interviews). The deliberations in the committee resulted with proposals which were more radical than that of the government. The committee proposed the reduction of the five year transitional period suggested by the government draft to four years, and the inclusion of a new provision that provided *pipeline protection* for pharmaceuticals (TBMM, 1995:50-53).

Following their defeat in the Trade and Industry Committee, however, local pharmaceutical manufacturers, Turkish Chamber of pharmacists, and the Ministry of Health managed to initiate a rediscussion of the draft legislation in the Health Committee, which was more favourable to their cause. The review of the draft legislation in the Health Committee resulted in the complete reversal of the Trade and Industry Committee's decision over the length of transitional periods. The Health Committee suggested that the transitional periods allowed by the government and the Trade and Industry Committee were not enough for the local pharmaceutical industry to adjust to the new terms of competition. Instead, the Committee increased the transitional periods to ten years for both the pharmaceutical products and processes. It also dropped the pipeline protection provision inserted to the draft by the Trade and Industry Committee (TBMM, 1995:54-56).

Hence, although the split of the license firms significantly reduced political power of the domestic fractions of the pharmaceutical capital, the latter still succeeded in shaping the policy outcomes in line with its interests so long as policymaking was confined to the parliamentary platform. However, before the patent legislation could have been voted in the Parliament, the outcomes of the policy process on pharmaceutical patents conflicted with a political strategy pursued by the dominant fraction in the Turkish power bloc-- that is the conglomerate capital.

During the 1980s, conglomerate capital recorded significant development through intensifying their collaboration with the

transnational capital. More importantly, through deepening relations with the transnational finance capital, and the banks they established, this group of capitalists increased their control on money capital. Although the rising dominance of the conglomerate capital, and the political strategies they adopted to that effect (such as outward oriented mode of capital accumulation, and integrating with the transnational circuits of capital) intensified the contradictions of political and economic interests between this group of capitalists, and the small and medium sized firms within the Turkish capital (Ercan: 2002), the conglomerate capital continued to press for further internationalisation of the Turkish economy. From the mid-1980s onwards, integration with the European Union became an important component of the outward oriented accumulation strategy adopted by the conglomerate capital. They were the most important force behind government's application for EU membership in 1987. During the 1990s, they took a leading role in facilitating the rapprochement between EU and Turkey for the formation of a Customs Union.

But most importantly, throughout this period, the conglomerate capital succeeded in reconstituting European integration as a hegemonic project in the Gramscian sense of the term. Throughout the 1990s, the intellectual and moral leadership exercised by the conglomerate capital and a variety of associated civil society organisations successfully mobilised and reproduced the active consent of the dominated classes to the European integration. Integration with Europe was presented as the only and the most effective solution both for the day to day needs and interests of the popular masses (higher levels of employment, lower levels of inflation, greater wealth, and social justice) and their political aspirations (greater freedoms, and democracy). Customs Union was presented as the pioneering step towards that integration. Possible negative impacts of the Customs Union on the Turkish economy, (and hence on the popular masses, or other dominant classes in the Turkish power bloc), or a variety of political conditionalities imposed by the EU for the implementation of the Customs Union (the acceptance of which hitherto proved unacceptable), were underplayed either as necessary sacrifices to be made on the road to become a more competitive and efficient economy, or as requirements of becoming a part of free democratic European society. Such ideological reframing of the European integration proved extremely useful as many of the political barriers that reflected the contradictions of interest between the dominant classes within the Turkish power bloc, as well as the

contradictions between the dominant classes and the popular masses, were avoided by constant reference to their possible impacts on European integration.

These efforts culminated in the signing of the Association Council Decision No: 1/95 (ACD) between the EU and Turkey in March 1995, which set January the 1st, 1996, as the final date for the completion of Customs Union (CU) between the parties. Following the conclusion of the ACD, the policy process for pharmaceutical patents overlapped with the completion of the requirements for the initiation of the Customs Union between EU, and Turkey. Before the patent legislation could have been voted in the Parliament, the government requested a mandate from the Parliament to issue executive decrees. This was justified by the necessity of finalising a large portfolio of legislative changes before the October meeting of the EU –Turkey Association Council, which was to decide the sustainability of Customs Union depending on Turkey's performance in completing the harmonisation requirements. The provision of this mandate to issue executive decrees by the Parliament provided a powerful mechanism for averting domestic opposition to the controversial aspects of the regulatory reforms introduced during the two month period before the October Association Council Meeting. The mandate stripped the Council of Ministers from any accountability to the Parliament about the negotiations on the Customs Union. Moreover, by shifting the policy-making arena away from the legislative committees that were accessible to popular groups to the Council of Ministers, which concentrated the interests of the conglomerate capital, the mandate significantly centralised the decision making process.

The patent legislation was introduced in 27th of June 1995, with this mandate alongside a series of other decrees which harmonised the Turkish competition and commercial laws with those of EU. Initially, the executive decree on patents passed by the Council of Ministers reflected the consensus reached in the legislative committees of TGNA over the length of transitional periods. The decree stated that patent protection would start in 1 January 2000 for pharmaceutical processes, and in January 2005 for pharmaceutical products.[20] When three months later, the European Commission declared that longer

[20] Although the decree appeared to have reduced the transitional periods for pharmaceutical processes to five years (compared with the ten years s uggested by the legislative committees in the TGNA) this was compensated by a provision which equipped the Council of Ministers with the authority to extend it for another five years.

transitional periods advocated by the Parliamentary committees was in breach of Turkey's Association Council Decision, and that the issue may cause problems for the initiation of the Customs Union, the longer transitional periods demanded by the local pharmaceutical came to directly threaten the Turkish conglomerate capital's political strategy of integrating with the EU. In the event, the Turkish government issued a second executive decree(19th of September 1995), which reduced the ten years of transitional periods provided for both pharmaceutical products and process in the previous decree to a total of only three years. Hence, rather than a mere external imposition on the ''Turkish state'' by the European Union (EU), the policy change reducing the length of transitional periods was effected by those fractions of the local capital, which pursued reintegration with the transnational circuits of the capital as a political strategy. The day after this decree was issued, on 20th of September, the collapse of the government coalition between the right wing True Path Party and the social democrat Republican People's Party was announced.

5.3.1. The policy process on pharmaceutical data protection

The policy process and outcomes on pharmaceutical patents have been legally framed first by Turkey's international obligations under the TRIPs agreement and then by its ongoing Customs Union negotiations with the EU, although the latter became determinative on policy outcomes. Meanwhile, the policy process and outcomes on pharmaceutical data protection was entirely shaped within the framework of Turkey's membership negotiations with the EU. In effect, this meant that many of the TRIPs compliant safeguards that are currently being proposed in the international policy circles to generate greater public access to medicines (c.f. Correa, 2002) under data exclusivity regimes were automatically foregone.

Although the provision of data exclusivity for pharmaceutical products was included in the Association Council Decision 2/97, the emergence of the issue in the Turkish policy agenda coincided with the growing negative impacts of the policies to curtail public drug expenditures on the higher priced products of the transnationals. At the turn of the 2000s, successive crises of the Turkish economy, soaring budget deficits and the conditionalities entailed in IMF standby agreements, urged public social insurance organizations to introduce cost containment policies to reduce their drug expenditures. It is important emphasize that up until the early 2000s, coherent and

effective measures to control public drug expenditures were almost non existent in the Turkish context, and the policies introduced at this time constituted a decisive policy shift towards consistent cost containment. A common characteristic that underlied these measures was the reimbursement of only the cheapest generic versions of original drugs in each therapeutic group which seriously disadvantaged the higher priced original products of the transnationals vis a vis the generic products of local manufacturers. Pharmaceutical transnationals saw the increasing prevalence of these measures together with a couple of other regulatory practices the Ministry of Health, such as the pricing and licensing of imported drugs, as an important threat against their sales in the Turkish market. Against the background of these developments a group of EU based transnationals filed a complaint to the European Commission through the agency of the European Federation of Pharmaceutical Industries Associations (EFPIA). The central tenet of the complaint was that the failure of the Turkish government to fulfill its obligations under Association Council Decisions (1/95 and 2/97 in particular) constituted a barrier to trade for the operations of the EU based transnationals in the Turkish market, and resulted in commercial losses amounting to 250 million Euros annually. In particular, the complaint alleged that the Turkish Ministry of Health failed to protect the secrecy of the test data entailed in the licensing dossiers submitted by the transnational firms, discriminated against imported drugs marketed by transnational firms during their pricing and licensing and finally failed to introduce data exclusivity despite the obligations of the Turkish government under the Association Council Decisions (Demirdere, 2004).

In terms of the intra class relations between the different fractions of pharmaceutical capital, the most important aspect of the policy process on data exclusivity has been the rupture in the political alliance between the internationalized fractions of the Turkish pharmaceutical capital, and the transnational capital. As noted earlier, the support of the internationalized fractions of the pharmaceutical capital in favour of stronger protection, together with their transnational partners, have been an important turning point in the policy process on pharmaceutical patents. However, unlike the patent case, the internationalized fractions of the local pharmaceutical capital strongly diverged from the transnational capital in their resistance to the introduction of the data exclusivity. Alongside with other fractions of the local pharmaceutical capital, the internationalized fractions of the local pharmaceutical capital, argued that introduction of data

exclusivity will seriously hinder generic drug licensing by local firms, and will increase foreign dependency in access to medicines (Isveren 2004, Turan, 2004).

The united opposition by local pharmaceutical capital against data exclusivity can be explained by the profound significance of generic production for their market presence. In a market characterized by regulatory and competitive challenges presented by the European integration on the one hand, and a strong patent regime where new product launch depends on enhancing alliances with the transnationals on the other, generic production, emerged as one of the few remaining areas where local manufacturers can hope to maintain some albeit restricted scope of independent action and lucrative sales. As the main impact of data exclusivity is to extend exclusivities beyond innovative products, to include either unpatentable drugs, or drugs that are about to come out of patents, the attempts of the transnational capital to expand exclusivities at this end of the market thus generated strong opposition. Although the local pharmaceutical capital was aware of the inevitability of data exclusivity in line with Turkey's obligations under Association Council Decisions, they were nevertheless adamant in receiving the most lenient provisions possible in conformity with the European legislation. Hence both the internationalized and domestic fractions of the local pharmaceutical capital argued that Turkey should implement transitional periods at least until the end of 2007 and/or postpone the introduction of data exclusivity at least until full membership in the EU (Isveren, 2004).

Meanwhile, restricting generic competition on a greater range of products was precisely why the transnational capital insisted that data exclusivity should be introduced immediately and in a retroactive manner to cover products licensed since 2001 (Suvak, 2003). The persistence of the disagreement between the internationalized fractions of the local pharmaceutical capital and the transnational capital on the issue of data exclusivity resulted in the split of the transnational corporations from the Employers Union of Pharmaceutical Industry, and the foundation in April 2003 of an independent association for the representation of the interests of the transnational capital in the Turkish pharmaceutical industry. This signaled an important turning point as since the 1960s the Employers Union of Pharmaceutical Industry (EUPI), had been an important platform which mediated the conflicts between the internationalized fractions of the local capital and the transnational capital and coordinated their joint political action. Throughout the policy process

on data exclusivity, however, the Employers Union of Pharmaceutical Industry came to be increasingly associated with the interest representation of the local pharmaceutical capital, while the newly founded the Association of Research Based Pharmaceutical Manufacturers Association became the representative of the interests of the transnationals.

The debates on data exclusivity occupied the Turkish policy agenda for two years throughout 2003 and 2004. The Ministry of Health regulation, which eventually provided for data exclusivity in December 2004, was to a large extent shaped during several meetings which brought together interested parties from the industry and bureaucracy. In addition to the meetings coordinated by the Ministry of Health that brought together experts from Ministry of Finance, Undersecretariat of Foreign Trade, Ministry of Industry, State Planning Organisation, and Ministry of Foreign Affairs, a special subcommittee was founded under the Council for Evaluation of Economic Problems at the Ministry of Industry and Trade to evaluate the impacts of data exclusivity. Formal joint meetings were accelerated following the initiation of a formal investigation by the European Commission against Turkey in December 2003. In these meetings the local pharmaceutical capital adopted a united policy stance which included demands for the provision of transitional periods until the end of 2007 before the introduction of the data exclusivity regime, the restriction of the term of exclusivity to the shortest available in the EU member states, and binding of the term of data exclusivity with that of the patents (Isveren, 2004). Meanwhile the transnational pharmaceutical capital insisted on exclusivity term of ten years, immediate and retroactive implementation of data exclusivity to cover products licensed since 2001(Demirdere, 2004). The most important concerns of the Ministry of Health and Ministry of Finance were the added burden of data exclusivity on public drug expenditures. A report commissioned to an independent research company, projected that during the first six years of its introduction, the data exclusivity will lead to an increase of 1.2 billion dollars in public drug expenditures (IEIS, 2004).

Data exclusivity was introduced as part of a new regulation dealing with drug licensing issued in December 2004. In line with the demands of the transnational corporations, and the European Commission, the regulation introduced data exclusivity in a retroactive way starting from the 1st of January 2001. However, it exempted from its scope licensing applications of generic drugs which

had been submitted between 01.01. 2001 and 31.12.2004. At the time of the issuing of the regulation there were approximately three hundred files waiting for licensing authoritisation at the Ministry of Health (Istanbul Hekim Postasi, 2005). Hence, although the local capital as a whole failed to attain the transitional periods that they requested before the application of data exclusivity, some fractions of local capital was successful in attaining exemptions for their applications, even though for a restricted period of time.

Following the Mediterranean model (Spain, Greece, Portugal) in the EU, the Turkish regulation set the term of data exclusivity as six years and restricted the term of data exclusivity with that of the patents. Both shorter exclusivity terms and the restriction of exclusivity term with the term of patents were safeguards demanded by the local pharmaceutical capital. The latter means that for those products benefiting from patent protection, data exclusivity periods cannot be used to extend the patent term, in other words, data exclusivity terms cannot be added beyond the term of a patent, a practice usually referred to as evergreening of patents. Binding of the term of data exclusivity with that of the patents, certainly does not mean that data exclusivity periods will not be used to provide market exclusivity for drugs outside patent protection. As noted earlier, an important advantage of data exclusivity from the point of view of the transnational pharmaceutical capital is that it allows market exclusivity for unpatented drugs. A final safeguard entailed in the regulation concerned the starting date of data exclusivity which was set as the first marketing approval in the Customs Union area. By adopting a larger geographical market, this provision aims to ensure both preventing unnecessary extensions in the duration of market exclusivity and encouraging the earlier introduction of the product in the national market.

The outcomes of the policy process on pharmaceutical data exclusivity reveal that united rather than divided (as in the case of pharmaceutical patents) political action by the local pharmaceutical capital can achieve more favorable outcomes in terms of integrating their demands and shaping the policy outcomes. But this is only possible to the extent that such demands and their outcomes are not of a nature that would threaten the realization of the greater project pursued by the Turkish conglomerate capital, i.e. the realization of European integration. This is the source of the binding nature of the pressures exerted by the European Union and transnational corporations.

Ironically, however, data exclusivity provisions introduced in the 2004 Turkish licensing regulation will have to be readjusted in line with the 2004 revisions of the EU data exclusivity legislation. The declared objectives of these revisions were to raise the competitiveness of the EU pharmaceutical industry, and in particular EU generics industry (Isikli, 2005:15) As for the term of data exclusivity, the revisions eliminated the time frame discretion of six to ten years, allowed to Member states by the earlier regulations, and introduced a standardized and longer term of ten years of data exclusivity across the European Union. As such, the EU data exclusivity legislation became even more stringent than the one in the U.S.(Ashurst, 2005) The question now stands is what will happen to the restricted gains acquired by the local pharmaceutical capital during the adjustment of the regulation in line with the changes in the EU legislation.

6. Conclusion

There has been a transition from weaker to stronger forms of intellectual property protection across the developing world. Orthodox explanations of this policy change is characterized by a state centric approach which uses the dynamics of inter state struggles between the developed and developing countries as the central explanatory variable. This paper instead tried to reveal the intra (transnational capital versus local capital and their fractions across the developing world) and inter class (capital versus dominated classes across the developing world) struggles that underlie the policy changes. It traced how the changes in the material interests of the transnational capital in general, and pharmaceutical capital in particular transformed the global political economy during the 1980s, and drove the struggles for strengthening of intellectual property regimes across the developing world since the 1990s. Focusing on two intellectual property rights, patent protection and data exclusivity, which had formed the substance of controversies on pharmaceuticals and which had developed at different historical periods, it traced the factors which had facilitated weaker intellectual property regimes for governing pharmaceuticals during 1960s and 1970s across the developing world, and how the new conditions in the global political economy during the 1980s and 1990s have reshuffled the available policy options in favour of the shift towards more stringent intellectual property protection.

In Turkey, the transition to a stronger intellectual property regime for pharmaceuticals, and the inabilities to benefit from the

TRIPs flexibilities have been explained by the pressures and conditionalities imposed by the European Union. Hence, reduction of transitional periods for patent protection have been presented as a condition for the realisation of Customs Union, and likewise the introduction of data exclusivity was explained as deriving from Turkey's obligations under Association Council Decisions. Instead, while analysing the nature of the public policy processes that led to stronger intellectual property regime for pharmaceuticals, this paper developed an explanation which focused on the specific conjuncture of class relations in Turkey. Rather than conceptualising Turkey's Customs Union and membership negotiations with the EU, as an expression of the interstate relations, we emphasized its class nature, and argued that EU membership became a class project of the hegemonic fraction in the Turkish bloc, especially from the 1990s onwards. We argued that the particular form taken by the policy outcomes in relation to pharmaceutical patents and data exclusivity provisions were shaped by two factors. The first one of these was the political capacity of the local pharmaceutical capital while the second one was the compatibility of their policy demands with the hegemonic project of the dominant fraction – the conglomerate capital—in the Turkish power bloc. Firstly, we argued that the high levels of external dependency of the local pharmaceutical capital, restricted its political capacity and prevented the formation of policy coalitions which can generate alternative policy options independent from those of the transnational corporations. This had been most clearly seen during the incorporation of TRIPs provisions in relation to patent protection into the national legislation. High level of external dependency restricted the relative gains that were attributed to the exploitation of TRIPs flexibilities by the local pharmaceutical. Internal divisions within the local pharmaceutical capital, and splits from the anti patent alliance, resulted in a significant restriction of political influence and confined the policy focus. Hence, rather than focussing on permanent and fundamental aspects of patent regime, such as the conditions of compulsory licensing, or the parallel imports, the Turkish pharmaceutical capital tended to insist on policy options that bring only short term benefits, such as the length of transitional periods. Meanwhile a more united policy stand adopted by the local pharmaceutical capital against the data exclusivity resulted in the inclusion in the subsequent legislation of a greater proportion if not all of their demands. The latter points out the significance of a second factor which set the boundaries of the policy outcomes on

pharmaceutical patents and data exclusivity: compatibility of the demands of the local pharmaceutical capital with the dominant fraction in the Turkish power bloc. United political action by the local pharmaceutical capital can make a difference to the policy outcomes, to the extent the overall flow of the policy does not threaten the realisation of the integration with the EU which had been a class project pursued with growing vigour by the conglomerate capital since the 1990s.

Table 1
Transnationals Entering the Turkish Market: 1986-1999

Year of Entry	Transnational	Origin	Activity
1986	Servier	France	Toll Manufacturing
1987	Abbott	USA	Toll Manufacturing
1988	Procter & Gamble	USA	Production
1988	Rhone Poulenc	France	Toll Manufacturing
1989	Knoll	Germany	Toll Manufacturing
1989	Sanofi	USA	Toll Manufacturing
1989	Schering	Germany	Toll Manufacturing
1990	Pasteur Miereux	France	Importation
1990	Fresenius	Germany	Toll Manufacturing
1991	Alcon	USA	Importation
1991	Novo Nordisc	Denmark	Importation
1991	Union-Chemique-UCB	Belgium	Toll Manufacturing
1993	Eli-Lilly	USA	Toll Manufacturing
1993	MSD	USA	Toll Manufacturing
1993	Synthelabo	France	Toll Manufacturing
1994	Bristol Myers	USA	Toll Manufacturing
1994	Boehringer Ingelheim	Germany	Importation
1994	Eczacıbası Baxter	USA	Joint Venture
1994	Guerbet	France	Importation
1994	Schering Plough	USA	Importation
1995	Glaxo-Wellcome	Britain	Production
1995	SmithKline Beecham	Britain	Importation
1996	Pharmacia Upjohn	USA	Toll Manufacturing
1996	Pierre Fabre	France	Toll Manufacturing
1997	Warner Lambert	USA	Importation
1997	Zeneca	Britain	Toll Manufacturing
1998	Merck	Germany	Importation
1998	Serano	Swiss	Importation
1998	Fournier	France	Importation
1999	Lundbeck	Denmark	Importation

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Özet

İlaç ürünleri ve fikri mülkiyet hakları: Gelişmekte olan ülkeler ve Türkiye'deki siyasa değişikliklerinin siyasal iktisadı

Bu makale son yirmi yılda gelişmekte olan ülkeler ve Türkiye de ilaç ürünlerine zayıf koruma sağlayan fikri mülkiyet hakları rejimlerinden güçlü koruma sağlayan rejimlere doğru geçişi içeren siyasa değişikliklerinin sebeplerini irdelemektedir. Bu alandaki siyasa değişikliklerini siyasal iktisat yaklaşımı çerçevesinde inceleyen makale ilaç ürünlerine yönelik fikri mülkiyet rejimlerinde değişime yol açan en önemli sebeplerden birinin uluslarötesi sermayenin özellikle 1980'lerden sonra artan yapısal gücü olduğunu ileri sürmektedir. Siyasa değisikliklerini devletlerarası iktidar ilişkileri çerçevesinde açıklayan devlet merkezli ya da kurumsal teorilerin aksine, makale de ilaç ürünlerine yönelik fikri mülkiyet rejimlerinin şekillenmesinde gelişmekte olan ülkelerdeki sınıf mücadelelerinin dinamiğinin belirleyici olduğu önerilmektedir. Bu önerme makale içerisinde Türkiye de ilaç ürünlerine yönelik fikri mülkiyet hakları rejiminin güçlenmesine yol açan siyasa süreçlerinin ve sonuclarının incelemesi ile desteklenmektedir.

Anahtar kelimeler: İlaçlar, ilaç ürünleri, patentler, Türkiye.