The Regulation and Patent Protection of Pharmaceuticals in Turkey

Türkiye'de İlaçların Regülasyonu ve Patent Koruması

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ABSTRACT Pharmaceuticals show unique characteristics compared to most goods i.e. they are directly related with human health, they show the features of 'credence goods' in that a recommendation or an opinion of a doctor or a pharmacist is required before usage, they have low price elasticity, they often constitute a large breakdown in state social security expenditures, and they are the outputs of continuous and costly efforts of research and development. This uniqueness gives them significance which constitutes a ground for their regulation. From marketing authorization to price regulation, almost every stage in the pharmaceutical sector is supervisioned and regulated by the regulatory agencies. As a governmental response to the former malpractice of the pharmaceutical companies, regulations verify that pharmaceuticals are safe, effective and of good quality. In addition to regulations, patent protection plays a key role in creating incentives to further research and developments, thereby foster innovation. This paper analyzes the current state of law, main regulations and the patent protection in the pharmaceutical sector in Turkey.

Key Words: Dictionaries, pharmaceutic; drug industry; legislation&jurisprudence; patents

ÖZET Piyasalardaki diğer ürünler ile karşılaştırıldığında, ilaçlar kendilerine has birtakım özellikler sergilemektedir. Örneğin ilaçlar insan sağlığı ile doğrudan ilgilidirler, itimada dayalı mal olma özelliğini gösterirler ve bu yüzden kullanmadan önce bir doktor veya bir eczacının tavsiyesi ya da fikrini almayı gerektirirler, talep esneklikleri düşüktür, devletin sosyal güvenlik harcamalarında önemli bir kalemi oluştururlar ve uzun ve masraflı araştırma ve geliştirme faaliyetleri sonunda ortaya çıkarlar. Tüm bu özellikler ilaçlara ayrı bir önem kazandırmakta, bu durum da ilaçların regülasyonuna dayanak oluşturmaktadır. İlaç sektöründe, ruhsat başvurusundan fiyat regülasyonuna kadar hemen hemen her aşamanın düzenleyici kurumlar tarafından denetlendiği ve regüle edildiği görülmektedir. İlaç şirketlerinin geçmişteki mesleki hatalarına ve ihmallerine devletin bir tepkisi olarak ilaç sektöründeki regülasyonlar, ilaçların güvenli, etkin ve iyi kalitede olduğunu doğrulamak üzere geliştirilmiştir. Regülasyonlara ek olarak, özellikle ilaç sektöründe, bilimsel araştırma ve geliştirme faaliyetlerinin özendirilmesi böylece yeniliğin teşviki açısından patent koruması anahtar rol oynamaktadır. Bu çalışmada Türkiye ilaç sektöründeki mevzuat, temel regülasyonlar ve patent koruması incelenmektedir.

Anahtar Kelimeler: Sözlükler, eczacılık; ilaç endüstrisi; yasama ve hukuk bilimi; patentler

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1. INTRODUCTION TO PHARMACEUTICALS

1.1. THE SECTOR AT A GLANCE

The pharmaceutical sector is a "*sui generis*" sector that is vital to the health of humans. As they are directly related with health, pharmaceuticals may entail potential benefits as well as significant risks to

people, all industrialized countries require that new pharmaceuticals meet certain safety standards as a condition of market access.[1] Therefore the need of regulating the sector is aroused, since the sector has to be forced to be 'transparent'.

In accordance with the rationale of free market economies, a sector is regulated if there is a permanent market failure which prevents that sector from reaching the level of perfect competition. Should the government not regulate these sectors, the maxim of "*laissez-faire*" may have destructive consequences on both companies as the supply side and consumers as the demand side. In order to reach economic efficiency, that sector needs to be regulated, provided that it does not possess a self-regulating nature. The asymmetric information between doctors or pharmacies and consumers which prevents making accurate evaluations; ineffective pharmaceuticals leading to wasted expenditures which is undesirable in coping with scarcity and so many patents which are used as an obstacle to price competition by the companies constitute some of the market failures in the pharmaceutical sector.

Early regulatory requirements focused on safety and efficacy. More recently pricing, marketing and expenditures are increasingly regulated, owing to policy concerns to control government expenditures under social insurance programs. During 20th century, the pharmaceutical sector had become highly regulated. Entry requirements such as obtaining a market authorization from the authority in charge; supervision of clinical tests, of production facilities and of other process of making the pharmaceuticals; market price of the product; issues relating to advertisement, promotion and other sales condition etc. are some elements of regulations in the sector.

Innovation, technological improvement and patent protection are key properties of this sector. The pharmaceutical sector is generally research and development (R&D) driven. There is an unusually high rate of R&D, which one can refer it to be "*sina qua non*" of pharmaceuticals. An innovator pharmaceutical company must maintain a portfolio of R&D projects because only one in four that enters clinical testing is ever marketed.[2] According to an empirical study conducted by Taylor and Silbertson, without the patent protection, the R&D rate in pharmaceutical sector would have been reduced by 64%.[3] This shows the significance of patent protection especially in this sector.

1.2 NATURE OF PHARMACEUTİCALS

Pharmaceuticals are classified as "credence goods". Lack of ability of buyers to evaluate the quality of the goods without someone else's recommendation or opinion constitute what is called credence goods.[4] Customers could not foresee the quality before they use the pharmaceuticals and may not evaluate their effects even after they use. The only thing is to consult a doctor or a pharmacist to obtain a recommendation or an opinion.

Besides, pharmaceuticals are also "price inelastic goods". The percentage change in the price of a pharmaceutical would result in a less change in the demand of that pharmaceutical. Owing to the fact that they are vital to human health, their consumption should not be interdependent on the price. Even if there would be an increase in the price, the consumption may remain unaffected, because the need to use pharmaceuticals would prevail over a price increase. One thing for sure that here inelasticity does not mean an indispensable demand for a certain pharmaceutical. Under specific conditions, there might be a relatively high degree of substitutability in the related product market and/or generic alternative of that pharmaceutical.

1.3 DEMAND FOR PHARMACEUTICALS

The law of demand states that an increase in the quantity demanded would result, *ceteris paribus*, in an increase in the price. However, in the pharmaceutical sector this law of demand does not function properly, due to the fact that likewise the price, the demand is also regulated by the state. Demand for a pharmaceutical is shown within the limits of the budget, specifically within the coverage of costs by social insurance or state social security schemes. However, the problem of "moral hazard" often occurs due to the fact that consumers do not cover the costs themselves; therefore, they are often price insensitive.

On the demand side of the sector, there are firstly the consumers. Unusually, the consumers are not the decision makers themselves; they are often advised by doctors or pharmacists because of the nature of 'credence goods'. Also the states, especially their social security agencies constitute a significant part in the demand side. Following some sort of national health schemes, tremendous amounts of pharmaceuticals purchased by the states. In most instances where there are such state health service schemes, the prices are also paid by the state, not by consumers. The supply side of the sector will receive separate consideration.

1.4 PHARMACEUTICAL COMPANIES AND -THEIR ASSOCIATIONS

On the supply side of the pharmaceutical sector, there are basically two different sellers: "Innovator" companies which are active in R&D and often engage in global markets and "Generic" companies which are not R&D based, but rather smaller in size and more sectoral or local in business scale.

Innovator companies can be defined as "locomotives" of the pharmaceutical sector. They often discover new products and take on a big role in innovation. New pharmaceuticals are taken through intensive clinical tests and their success comes from surviving these tests. They are then given exclusive protection, as a reward of continuous and costly efforts in innovation.

On the other hand, generic companies make use of pharmaceuticals whose patent protection and exclusivity were expired. Generic companies release perfectly supplementary pharmaceuticals to market and thus take active role in the competition with innovator companies. They usually charge lower prices which influence the sale of their products. What is more, generic pharmaceuticals are often being sold without prescriptions, in other words, they are "over-the-counter" (OTC). OTCs like analgesics, hypnotics, vitamins etc. help relieving the symptoms of simple insignificant illnesses for a short period of time, without requiring the mandatory opinion of doctors rather by pharmacists.[5]

In Turkey, both innovator and generic companies are currently taking part in the pharmaceutical sector. Generally speaking, they are organized as either trade unions or associations. "*Association of Research-Based Pharmaceutical Companies*" (*Araştırmacı İlaç Firmaları Derneği* (AİFD)) is the name of the organization of innovator companies, founded in 2003 with the aim of providing effective solutions to problems in the pharmaceutical sector of Turkey and giving Turkish citizens an access to new and original pharmaceuticals.

"Pharmaceutical Manufacturers Associations of Turkey" (*İlaç Endüstrisi İşverenler Sendikası* (İEİS)) is the name of the organization and rthe epresentative body of generic companies, founded in 1964 by generic companies with the aim of sustaining the development of the local pharmaceutical industry. The organization plays a role in healthcare policy-making and promotes the use of generic pharmaceuticals. It should be noted that in United States of America (US), the expression for the association of innovators is called *"The Pharmaceutical Research and Manufacturers of America"* (PhRMA). So the word "manufacturer" is ambiguous in that it represents the association of generic companies in Turkey and of innovator companies in US.

2. REGULATION OF PHARMACEUTICAL SECTOR IN TURKEY

2.1 REGULATORY FRAMEWORK

Within the framework of Act (*İspençiyarı ve Tıbbi Müstahzarlar Kanunu*) no: 1262 and came into force in 1928; from marketing authorization to price regulation, almost every stage is supervisioned and regulated by the Ministry of Health (Ministry). A unit within the Ministry called *"Pharmaceutical and Pharmacy Directorate General" (İlaç ve Eczacılık Genel Müdürlüğü)* is engaged in executing these stages on behalf of the Ministry. The Statutory Decree on the Organization and Duties of the Ministry of Health (*Sağlık Bakanlığının Teşkilat ve Görevleri Hakkında Kanun Hükmünde Kararname)* no: 181, enumerates the duties of the Ministry in Art. 2 and shows the central and district organization of the Ministry in Art.3-39.

According to the Art. 1, pharmaceuticals shall exclusively be sold in pharmacies and sale in any other stores, shops etc. are prohibited; Art. 3: a license from the Ministry has to be obtained before the market launch of the pharmaceuticals, that are either produced within the boundaries of or that are imported to Turkey; Art. 5: pharmaceuticals which are produced within the boundaries of Republic of Turkey shall be produced in a laboratory containing all the necessary scientific facilities which are subject to the control of the Ministry; Art 7: prices of the pharmaceuticals are under the control of the Ministry; Art. 10: samples of pharmaceuticals that are to be released to the market shall be given to the Ministry for an analysis; Art 11: all modifications made either in the formula, prospectus or name shall be notified to the Ministry; Art. 13: the advertisement of the pharmaceuticals that cannot be sold without a prescription is prohibited, unless advertised in journals of medicine.

Furthermore Health Services Act (*Sağlık Hizmetleri Temel Kanunu)*, no: 3359 and came into force in 1987, organizes the main principles of health services. The fundamentals of the health services, staff recruited in health services, health clinics, collection of costs of medical treatments etc. are within the scope of this Act.

Besides Act on Pharmacies and Pharmacist (*Eczacılar ve Eczaneler Hakkında Kanun)*, no: 6197 and came into force in 1953, contains provisions on requirements of being a pharmacist, as well as some necessary conditions and qualifications of pharmacies, where the pharmaceuticals have to be sold exclusively. A relatively older Act (*Ecza Ticarethaneleriyle Sanat ve Ziraat İşlerinde Kullanılan Zehirli ve Müessir Kimyevi Maddelerin Satıldığı Dükkânlara Mahsus Kanun)* no: 984 and came into force in 1927, also contains some provisions regarding pharmacies.

In addition to these fundamental acts related to pharmaceutical sector, other than price-oriented and marketing authorization-oriented acts, there are many other legal instruments regulating different areas such as by-law related to research (*İlaç Araştırmaları Hakkında Yönetmelik*, Official Gazette (OG) no: 21480), promotion and advertisement (*Beşeri Tıbbi Ürünlerin Tanıtım Faaliyetleri Hakkında Yönetmelik,* OG no: 25268), supervision and evaluation of the safety of pharmaceuticals (*Beşeri Tıbbi Ürünlerin Güvenliğinin İzlenmesi ve Değerlendirilmesi Hakkında Yönetmelik,* OG no: 25763), packaging and labeling (*Beşeri Tıbbi Ürünler Ambalaj ve Etiketleme Yönetmeliği,* OG no: 25904), classification (*Beşeri Tıbbi Ürünlerin Sınıflandırılmasına Dair Yönetmelik,* OG no: 25730) and control of hazardous waste materials (*Tıbbi Atıkların Kontrolü Yönetmeliği,* OG no: 21586).

2.2 PRICE REGULATION

Under Turkish legal system, the price of pharmaceuticals is regulated. As a duty of being a social state, and with the aim of excluding budget deficits, controlling state expenditures incurred from the purchases by state social security agencies, government intervenes in the pricing of the pharmaceuticals. The legal ground for regulation of prices of pharmaceuticals comprises Act no: 1262 (Art 7. lit f) and Act no: 3359. However, the said acts only show the main framework and do not contain detailed information on how the regulation of price would be made. Having their legal ground on the said acts, Council of Ministers issues non-periodic Decrees on the determination prices. Based on these decrees, the Ministry performs its duty to regulate the price of the pharmaceuticals.

Beginning with 1956, in 1957, 1968, 1972, 1984, 2002 and 2004, a total of 11 non-periodic Decrees were issued. Latest decree entitled Decree on The Determination of Prices of Pharmaceuticals *(Beşeri İlaçların Fiyatlandırılmasına Dair Bakanlar Kurulu Kararı)* came into force in 2007. In addition to these decrees, the Ministry published a communiqué (*Beşeri Tıbbi Ürünlerin Fiyatları Hakkında Tebliğ,* OG no: 25391) that came into force in 2004 and organizes more detailed information on the regulation of prices. According to the Art. 43 of the Statutory Decree no: 181, the Ministry shall draft by-laws, communiqués, circular and other administrative instruments to perform its legally obliged duties.

The regulation of the price of pharmaceuticals is based on "reference pricing". The regulation works as follows: First, the Ministry determines and announces at least five and at most ten different countries among European Union (EU) Members as reference countries, then pharmaceutical companies propose a list which includes the actual prices of their product(s) in these pre-determined reference countries, and finally the Ministry chooses the one having the least cost. Here the actual price means the wholesale price, without the profits added thereon by warehousers and pharmacies, of a pharmaceutical having market authorization and actually being sold in markets. If that pharmaceutical is produced in or exported to a country other than EU Members and the actual price therein is lower than those in reference countries, it is at the discretion of the Ministry to adopt this price. (Decree 2007, Art. 2, prg. 1).

In Turkey profits made from the sale of pharmaceuticals are also regulated. According to the Art. 7 of the Decree 2007, the annual profit made in the retail sale by the warehousers and pharmacies shall not exceed the limits of 9% and 25% of the regulated price respectively, which was finalized through reference pricing process. Countries like US, United Kingdom (UK) and Germany do not intervene in determining the price of patented pharmaceuticals; whereas countries like France and Italy, similar to Turkey, intervene and enforce strict regulation when determining the price and the profit.[3]

Before the newly introduced price regulation based on reference pricing, the prices were regulated based on the "cost plus" method. This system starts by determining the costs of the company, this is then multiplied by a fixed rate (rate of return), following which the regulated price of a product is determined. This regulation type was heavily criticized due to its cost-based application, in that it created incentives to add more costs to increase the price in the regulation process, even though such costs were irrelevant to the production of that product.[3]

The determination of the price of a pharmaceutical has to precede its market authorization, in order for that pharmaceutical to be released to the market. In other words, determination of price constitutes a precondition for market launch.

2.3. MARKETING AUTHORIZATION

Not all pharmaceuticals enjoy entry to markets. Before the market launch, an authorization from the regulatory agency in charge is required. Failure to obtain a marketing authorization would result in a 'barrier to entry' to the market.

The regulation of market entry is in fact a governmental response to the former malpractice of the pharmaceutical companies. Increased pressure for both profits and medical relief causes many pharmaceuticals to be rushed to the market. This can manifest in several destructive situations i.e. disregard of the potential side effects of the pharmaceuticals, errors in the production process, misleading prescription, wrong dosage amount, improper packaging and mislabeling etc. Since these consequences are generally severe and even life-threating, in order to maintain public health standards, marketing authorization procedures verify that pharmaceuticals are safe, effective and of good quality.

Recently, American innovator company *Pfizer* agreed to a $2.3 billion settlement in the lawsuit concerning its product *Bextra*, which was withdrawn from the market in 2005. Pfizer was alleged to market *Bextra* for uses and in doses that the US Food and Drug Agency (FDA) had previously rejected. This put patients at risk for serious health problems such as heart attack, stroke and pulmonary embolism. *Pfizer* was also blamed for influencing doctors to recommend *Bextra* before and after surgeries; however, *Bextra* failed to pass the relevant clinical tests for its usage before and after surgeries. This case shows how marketing authorization procedures safeguard the public health and ensure that the pharmaceuticals are safe to human use.

According to the Art.3 of the Act no: 1262, the Ministry is in charge with granting marketing authorization to pharmaceuticals. The Act states that if the safety, efficiency and as well as the price and

name of the pharmaceutical are approved by the Ministry, marketing authorization would be granted. In addition to vague standards set forth in this Act and its surprisingly long history since it came into force in 1928, more certain scientific and assessable criteria, such as a by-law, were largely required.

The By-law related to Market Authorization of Medicinal Products for Human Use (*Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği,* OG no: 25705) came into force in 2005, aims at solving the above problems and harmonizing Turkish legislation with that of the EU. It is stated in Art.3 that the said By-law was drafted in accordance with the EU Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use. This By-law repealed the older and previous By-law related to market authorization entitled *"Tıbbi Farmasötik Ürünler Ruhsatlandırma Yönetmeliği"* which came into force in 1995 (OG no: 22218)

Art. 5 states that unless an authorization from the Ministry is obtained, no pharmaceutical shall be released to the market; Art. 7 set requirements for applicants; Art. 8 lists the necessary information and materials that have to be added to the application file; Art. 13-27 organize the procedure of obtaining an authorization and Art. 28 secures the confidentiality of these information and materials. An annex to this by-law details the necessary information and materials stated in Art. 8.

The validity of market authorization of a pharmaceutical is limited to 5 (five) years (Art. 21). For a renewal, at least 3 (three) months prior to the termination of the authorization, the Ministry has to be petitioned. The By-law does not include a maximum time for marketing authorization procedures to be completed. Therefore, it is likely to happen that market launch of pharmaceuticals would face significant delays.

Once the marketing authorization is granted, the last step for the market launch would be to obtain a "*sales authorization*" from the Ministry (Art. 26). To obtain a sales authorization, two samples of the pharmaceutical, for which a market authorization is granted, have to be presented to the Ministry for an analysis in terms of the validity of its prescription, package and labeling, and appropriateness of its price.

One thing which causes significant delays in the market authorization process is that some countries require generic companies to do the costly and time-consuming clinical tests which the innovators had done previously. This process is illustrated as a total of 12 years comprising 6 years of laboratory and animal studies, 1 year of clinical studies, phase one: safety studies, 2 years of clinical studies, phase two: testing effectiveness and 3 years of clinical studies, phase three: extensive clinical testing.[2]

Global measures have been taken to hinder or at least reduce the need to duplicate the clinical tests carried out during the R&D process. Within this context, *The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH), created in April 1990 by EU, US and Japan, brings together the regulatory authorities and experts in the pharmaceutical sector to discuss scientific and technical guidelines and requirements of pharmaceutical product registration. The objective of ICH is to increase international harmonisation of technical requirements to ensure that safe, effective, and high quality pharmaceuticals are developed and registered in the most cost-effective way, so that public health could be promoted and unnecessary duplication of clinical trials could be prevented.

Also the data exclusivity, which will be dealt with separately below, is another source of delays especially for generic companies, since the innovators' clinical test results and other datas have to be kept secret.

2.4 DATA EXCLUSIVITY

Data exclusivity is about protecting the pharmaceutical companies' documentation through copyright laws and other legal provisions by granting a right to the owner to exclude any use by others. It guarantees that the results of clinical tests and data obtained thereof shall not be lawfully disclosed to and\or used by others without a prior consent of

the owner of the data. In practice, data exclusivity hinders applications for market authorization made by others for the same or similar bioequivalent pharmaceuticals.

During this exclusivity period other companies, in particular generics, shall not lawfully produce or file a market authorization for a pharmaceutical, even though a patent protection for the said pharmaceutical does not exist. Owing to this fact, the function of data exclusivity is independent of the fact that whether a pharmaceutical is patentable or enjoys patent protection.

Annex 1C of the World Trade Organization's (WTO) Foundation Agreement, Trade Related Aspects of Intellectual Property Rights (TRIPS) requires the contracting states to adopt protection for datas against unfair uses and illegal disclosures. After it was signed by Turkey in 1994, this international Treaty became a part of the current state of law in Turkey through an Act (*Dünya Ticaret Örgütü Kuruluş Anlaşmasının Onaylanması Hakkında Kanun*) no: 4067 ratifying its enforcement in 1995. Subsequently, Turkey was entered into an obligation to adopt "data protection" for pharmaceuticals until 01.01.2000.

Art. 39, prg. 3 of TRIPS states that *"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."* In the text, neither "data exclusivity" nor "data protection" is explicitly mentioned. This fact woke controversy among authors and some claimed that TRIPS actually did *not* oblige Turkey to adopt data exclusivity,[6] while some authors claimed that Turkey *is* under an obligation to adopt data exclusivity under TRIPS.[7]

In my opinion, under TRIPS, Turkey was rather designed to provide protection against unfair commercial uses or illegal disclosures, which is called "data protection". Data protection is a different concept than data exclusivity in that its aim is not to grant an ability to exclude others for a period of time, but only to provide protection of data against unfair and illegal use. So data exclusivity is reminiscent of intellectual property concepts, whereas data protection is of unfair competition. Under TRIPS, a limited period of time for protection of data was not specified. Since data exclusivity does not provide ultimate protection and evidently requires a limited period of time, Art 39 prg. 3 of TRIPS should be interpreted simply as data protection. Deriving the meaning of data exclusivity would be a little far-fetched.

On the other hand, Turkey's obligation towards EU to adopt "data exclusivity" for pharmaceuticals has experienced a controversial change. Although the Association Council Decision no: 1/95 which confirmed the membership of Turkey to Custom Union, does not directly oblige Turkey to adopt EU directives on data exclusivity for medicinal products, Association Council Decision no: 2/97 Annex 2 Art. 13 increased the scope of applications of Association Council Decision no: 1/95 and obliged Turkey to adopt "data exclusivity" for pharmaceuticals. Subsequently, Turkey agreed and undertook to adopt "data exclusivity" after 01.01.2001. However, only 4 years later, in 2005 Turkey fulfilled this obligation.

The By-Law related to Market Authorization of Medicinal Products for Human Use constitutes the main framework of data exclusivity. According to Art. 9 lit. 3, 6 (six) years of data exclusivity shall be granted for a pharmaceutical which had obtained market authorization after 01.01.2005 within one of the member states of Custom Union. This article retroactively includes the pharmaceuticals which had obtained marketing authorization after 01.01.2001, on the condition that a marketing authorization for its generic version was not filed until 01.01.2005 within Turkey.

This 6-year of data exclusivity starts from the first issue of market authorization within one of the member states of Custom Union. Therefore, the pe-

riod may either retroactively begin before or proactively begin after the By-law comes into force. Although data exclusivity does not depend on patent protection, Art. 9 lit. 3 creates an exception to this principle and states that for pharmaceuticals enjoying patent protection in Turkey, the 6-year data exclusivity is limited with the duration of their patent protection. Owing to this fact, data exclusivity in Turkey might not have negative effects on generic companies in the short run; however, generic companies should also give importance to do more R&D in the long run, in case of a possible amendment to the said By-law in the future.[7]

Before the said By-Law, data exclusivity was not being properly enforced. Although there were some provisions in several acts i.e. Turkish Commercial Code Art. 56-57 related with unlawful acquisition of private data resulting unfair competition and Turkish Criminal Code Art. 239 related with criminal penalty given to unlawful disclosure of information and documents containing a trade secret, banking secret or customer confidential information, these were inadequate and could not truly replace the effective protection provided by the data exclusivity.

Likewise The Statutory Decree on the Protection of Patent Rights (*Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname*) no: 551, creates a room for data protection, rather than data exclusivity, for pharmaceuticals. According to the Art. 83 prg. 3 of the said Statutory Decree undisclosed information and test results presented to authorities in charge for their production, sale and\or marketing, and sales authorization shall be kept confidential, and the said authority requiring these information and test results shall take necessary measures for their protection against unfair uses. It can be said that all these provisions served as means to protect the datas against unfair disclosures, but not to grant exclusivity for a certain period of time.

Despite of being independent of patent protection, in practice data exclusivity often serves as pre-protection for a pharmaceutical for which a patent has not yet granted. In the pharmaceutical sector, patent applications shall be made during the market authorization process; therefore, significant part of the protection term is exhausted within this process.[1]

3. PATENT PROTECTION IN THE PHARMACEUTICAL SECTOR

3.1. ROLE OF PATENT PROTECTİON

Patents are generally thought to be more important to foster innovation in the pharmaceutical sector than in most other industries.[2] A pharmaceutical shall enjoy patent protection if a new and nonobvious chemical (product patent) or production method (process patent) is discovered or an existing production method is furthered by using a different active substance. Actually neither the pharmaceutical itself, nor the idea behind it, but the active substance of the subject matter is patented.

The rationale for granting patent protection, in other words the ability to exclude others from using, selling, offering to sell, modifying, importing etc. the subject matter of the patent, is to create incentives to innovate, to reward the continuous and costly R&D process and to recover the huge initial investment costs by charging a price of what is more than its marginal cost. Patent protection for innovators mean that the first entry to the market, high amount of sales, the ability to set the price above its marginal costs, and production and product technology secrecy.[8] To have these advantages, patent protection creates incentives to invest in R&D.

Innovator companies, generally holding a great number of patents in their portfolio, may make use of the patented chemicals or production methods either themselves or license them to generic companies at a certain royalty. Due to the patent protection, generic penetration is blocked so long as the patents expire. However, sometimes generic companies challenge the validity of the patent before courts by obtaining a judgment against the innovator companies. In these cases, generic companies do not wait for the expiration of the patent and start releasing generic versions of that pharmaceutical at their own risk, dependent on the actual invalidity of the patent.

The period of patent protection is a tender issue. The monopoly power and exclusivity that innovators enjoy prevent competitive entry to the market; however, it creates incentives to invest in R&D. So there should be a cost-benefit analysis between the upside and downside of the patent protection: In terms of period of time, if patent protection is lower than it should be, innovators would not fully cover their R&D costs, thus would be reluctant to invest any further. Likewise if patent protection is more than it should be, then innovators would have the opportunity to charge high prices which would create a welfare loss to the society due to lack of competitive entry.

3.2 LEGAL GROUND OF PATENT PROTECTION IN TURKEY

Early legislation in the protection of patents dated back to 1879, when the first Act (*İhtira Beratı Muvakkat Kanunu)* concerning the patent protection was enacted. This first Act provided patent protection for certain goods, but not for pharmaceuticals. Up until 1990s patent protection for pharmaceuticals had not yet existed. However, both TRIPS (Art. 70 prg. 8) and Association Council Decision no: 1/95 (Annex 8 Art. 4 lit. 2) require Turkey to provide patent protection for products or production methods including for pharmaceuticals.

In 1995, Statutory Decree on the Protection of Patent Rights (*Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname*) was passed and the current state of law was renovated. According to the temporary Art. 4 of the said Statutory Decree, provisions on patent protection for pharmaceuticals or production methods would be in force after 01.01.1999.

Art. 4 retroactively granted patent protection for pharmaceuticals effective from the publication of the said Statutory Decree in OG, provided that patents were granted after 01.01.1995. Consequently pharmaceuticals whose patent was taken out outside Turkey before 01.01.1995 shall not enjoy patent protection in Turkey.

In Turkey between the years 1995-2001, among 2310 patent applications to Turkish Patent Office (TPO), 702 patents were granted.[9] According to another source, between 1995 and 2002, 3637 patent applications were made and 1636 of them were granted patent protection.[10] In both cases, more than 70 % of these applications made and patents granted belong to innovator companies originated in US, UK, Germany and Switzerland.

As for the term of the patent protection, Art. 72 states that for pharmaceuticals as well as for other patentable products or production methods, patent protection lasts for 20 (twenty) years starting from the filing date of application, which is compatible with EU and US patent protection of 20 (twenty) years. With the enactment of Statutory Decree no: 551, Turkey fulfilled its obligation of adopting a patent protection of 20 (twenty) years starting from the filing date of application as stated in Annex 8, Art. 4 lit. 2 of the Association Council Decision, no: 1/95. Similarly Sect. 5 (Art. 27-35) of TRIPS is devoted to patents and imposes obligation on contracting states to adapt these provisions in their domestic legal systems. According to Art. 33 of TRIPS *"The term of* (patent) *protection available shall not end before the expiration of a period of twenty years counted from the filing date."*

However, the actual patent protection may be much lower, because of the process of regulatory approval in patent applications. The time between filing a patent application and market launch can be significantly longer. In some cases, it would be necessary to extend the period of patent protection for products, in particular for pharmaceuticals.

In some countries, the innovator company is granted an extension period of patent protection to offset any losses due to possible delays in the market authorization procedure. In order to encourage and further costly and time-consuming researches made in the pharmaceutical sector, an additional period of patent protection seems to be a real requirement. For example in the EU, patent protection can last up to 20 years from the date of a patent application and for the pharmaceutical sector, where the time between filing a patent application

and market launch can be significantly longer than in other sectors, supplementary protection certificates (SPC) may be issued.

According to the Council Regulation EC No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products no: 1768/92, an extra period of 5 (five) years of SPC could be issued for pharmaceuticals, due to the fact as stated in the Introduction that *"medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection top encourage such research".*

Current state of law in Turkey does not provide such an extensive period for patent protection for pharmaceuticals. Although neither TRIPS nor Association Council Decision, no: 1/95 and binds Turkey to adopt SPC for the time being; whether in the near or distinct future, as the integration of Turkish legislation to that of the EU progresses, Turkey would be under an obligation to harmonize its patent protection period with this supplementary protection period.

4. CONCLUSION

During 20th century, the pharmaceutical sector had become highly regulated. Entry requirements such as obtaining a market authorization from the authority in charge; supervision of clinical tests, of production facilities and of other process of making the pharmaceuticals; market price of the product; issues relating to advertisement, promotion and other sales condition etc. are some elements of regulations in the sector.

Within the framework of Act no: 1262 and came into force in 1928; from marketing authorization to price regulation, almost every stage is supervisioned and regulated by the Ministry of Health. Furthermore Health Services Act no: 3359 and came into force in 1987, organizes the main principles of health services. In addition to these price-oriented and marketing authorization-oriented acts, there are many other legal instruments regulating different areas such as By-law related to research, promotion and advertisement, supervision and evaluation of the safety of pharmaceuticals, packaging and labeling, classification and control of hazardous waste materials.

In Turkey, the legal ground for regulation of prices of pharmaceuticals comprises Act no: 1262 and Act no: 3359. The Ministry of Health published a communiqué that came into force in 2004 and organizes more detailed information on the regulation of prices. Furthermore, the Council of Ministers issues non-periodic Decrees on the determination prices. The regulation of the price of pharmaceuticals is based on "reference pricing".

Not all pharmaceuticals enjoy the entry to markets. Before the market launch, an authorization from the regulatory agency in charge is required. Regulation of market entry verify that pharmaceuticals are safe, effective and of good quality According to the Act no: 1262, Ministry of Health is in charge with granting market authorization to pharmaceuticals.

The By-Law related to Market Authorization of Medicinal Products for Human Use also constitutes the main framework of data exclusivity. It guarantees that the results of clinical tests and data obtained thereof shall not be lawfully disclosed to and\or used by others without a prior consent of the owner of the data.

Patents are generally thought to be more important to foster innovation in the pharmaceutical sector than in most other industries. Up until 1990s patent protection for pharmaceuticals had not yet existed in Turkish legal system. In 1995, Statutory Decree on the Protection of Patent Rights was passed and the current state of law was renovated. Patent protection for pharmaceuticals lasts for 20 (twenty) years starting from the filing date of application to Turkish Patent Office. Current state of law in Turkey does not provide an extensive period for patent protection for pharmaceuticals.

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