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MARMARA UNIVERSITY
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DATA EXCLUSIVITY in PHARMACEUTICAL DRUG PRODUCTS

LL.M. Thesis

ALİ DEMİRBAŞ

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LIST OF ABBREVATIONS

ANDA	Abbreviated New Drug Application
Art.	Article
BTA	Bilateral Trade Agreement
EMEA	European Medicines Agency
EC	European Community
EU	European Union
ECJ	European Court of Justice
EPC	European Patent Convention
EPO	European Patent Office
FDA	Food and Drug Administration
FTA	Free Trade Agreement
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IND	Investigational New Drug
IPR	Intellectual Property Rights
MA	Marketing Authorization
NAFTA	North American Free Trade Agreement
NCE	New Chemical Entity
NDA	New Drug Application
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

ABSTRACT

Data exclusivity in pharmaceuticals is one of the best protection systems among other type of regulatory drug product exclusivities such as patent protection, patent term extension and some other type of marketing exclusivities.

Data exclusivity provides the right holder protection on his undisclosed information, in particular the results of tests in humans and animals and clinical trials which are given to the national authorities in order to obtain marketing approval for the drug product for which the application is made. In this regard data exclusivity means that, the second applicant can not use or rely on that data during the exclusive time period in order to obtain marketing approval for the same drug product which was already granted marketing approval first time. Like the second applicant, national regulatory authorities also can not rely on that data in order to grant marketing approval to the second applicant for the same drug product during that exclusive time period. By this reason data exclusivity differs from other type of drug product marketing exclusivities since marketing exclusivity in pharmaceutical drug products may last after data exclusivity time period expires like in the EU system. In the EU normally, while there is 8 year data exclusivity, marketing exclusivity is 10 year. Also data exclusivity differs from patent protection.

In part one; firstly the focus is on the regulatory drug product exclusivities and then data exclusivity generally. In part two; data exclusivity is analyzed extensively in international law, in the EU law, in the U.S. law and lastly in Turkish law.

ÖNSÖZ

İlaç ürünlerindeki veri munhasiriyeti (tekeli), ilaç ürünlerine ilişkin patent, patentlerde süre uzatımı ve pazarda başkaca tekel hakkı tanıyan inhisari nitelikteki koruma tipleri arasında önemli bir yer tutmaktadır.

Veri munhasiriyetini, ilaçlara ruhsat ve pazar izni alınması amacıyla mahalli otoriterelere ilk defa verilen ve laboratuar araştırmaları ile insanlar ve hayvanlar üzerinde yapılan test sonuçlarını içeren gizli bilgilerin aynı ilaca ilişkin olarak sonraki başvuru sahipleri tarafından ve mahalli otorite tarafından belli bir süre zarfında sonraki ruhsat ve pazar izni başvurularında kullanılamaması ve o gizli bilgilere referans yapılamaması olarak ifade etmek mümkündür. Bu nedenledir ki, veri münhasiriyeti diğer koruma biçimlerinden olan pazar tekellerinden farklılık arz etmektedir. Zira Avrupa Birliği uygulamasında olduğu gibi veri koruması sona erdikten sonra da pazar koruması devam edebilmektedir. AB'de veri koruması 8 yıl iken Pazar koruması normalde 10 yıldır. Bu demektir ki, sekiz yılın sonunda ikinci başvuru sahibi ilk başvuru sahibinin test ve laboratuar verilerini başvurusunda kullanabilecek ancak 2 yıl daha geçtikten sonra pazara çıkabilecektir. Yine veri koruması patent korumasından da farklılık arz etmektedir.

Çalışmanın ilk bölümünde, ilk önce ilaç ürünlerine ilişkin tekeller sonra da veri munhasiriyeti üzerinde genel olarak durulurken, ikinci bölümde veri münhasiriyeti uluslararası düzeyde, Avrupa Birliği, ABD ve Türkiye ölçeğinde daha detaylı bir şekilde ele alınmaktadır.

Part One

REGULATORY DRUG PRODUCT EXCLUSIVITIES

1 INTRODUCTION

It is no doubt that health is one of the most important and basic subjects of humanity. Because of that fact medicine plays a great role in social, political and economic life. Not only patients, but state agencies and medical firms are also very interested in medicine. As a duty, states have to combat against new diseases and to protect public health. In this regard, so much time and source are spent in order to discover new chemical substances used for medical treatment. It is known that to manufacture and market a new medicinal drug product, it is required investing around $500 Million and also up to 15 years time period. This is the result of the nature of the sector. Meanwhile, invention of a new chemical entity is not solely enough to obtain a marketing approval. In addition to the invention based on intensive R&D studies, it is also required to be provided results of efficacy and safety test data and clinical trials of that drug product to the national regulatory authorities before granting marketing approval. All these procedures are not cheap and difficult to complete in a short period of time. But, $1 Million is enough to put a generic drug product on the market.

It is possible to say that, there are two stages in the issue. First stage is making invention of a new drug product (new chemical entity) which is usually protected by patent law. The other which is protected by data exclusivity is presentation of test results and clinical trials for the aim of proving efficacy and safety of drug product by the applicant in order to obtain marketing approval for which the application is made. Patent term is around 20 years around the world. The EU and Turkish law system also provide a 20-year patent term. But the other step (getting marketing approval) requires 5-

10 years and this time period is within the patent term. In this stage, originator drug producers want more extra time period after remaining patent term (if their drug product is under patent protection) namely “patent term extensions” in order to compensate their time lost during second stage.

Besides patent term extensions and other marketing exclusivities which are explained below, data exclusivity which has common use worldwide also stands as a fair solution of the problem. On the contrary to the needs of the originator drug producers, the generic companies argue that the repetition of tests in animals and humans is not ethic and wasteful. It is obvious that there is need to find out a solution for the problem in order to balance the benefits of the parties.

It is provided in order to balance the interests of the parties an exclusive time period for the protection of data submitted to the national authorities against disclosure and unfair commercial use. Before this time period expires only the originator drug producer or its licensees would be at the market, but after this time period generics also will be at the market

One of the basic problems in data exclusivity/ protection is the duration of protection/ exclusivity. While there is no any mentioned time period in TRIPS agreement, it varies in national law systems. For instance, while it is five years in the U.S. law system, in Turkish law system, six-year data protection is given with Implementation Regulation 2005 for the pharmaceutical drug products from the date of first marketing in one of the member states in the E.C.

2 REGULATORY DATA EXCLUSIVITY IN GENERAL

2.1 The Concept of Regulatory Data Exclusivity

In regulatory data exclusivity, before data exclusivity time period expires, no one uses even makes reference to the test results and clinical trials[1] which were submitted to the state authority by the first applicant for obtaining marketing approval. So, in order to market the same medicinal drug product[2] to the original drug product within data exclusivity time period, a generic company must be allowed by the originator drug producer or must present a different clinical test file[3].

In this regard, data exclusivity means that the protection of data which are the results of pharmacological and toxicological tests and clinical trials that must be submitted to the national regulatory authorities in order to be obtained marketing approval, in a limited time period. In other words, data exclusivity provides an exclusive protection[4], in a limited time period on test and clinical data which were produced and submitted by original drug producer to the national regulatory authorities before the marketing authorization is granted, against disclosure of that data by the governmental agencies and also against to be used or to be made reference in the procedure

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[1] Clinical trial is any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy (Article 2/I-a, Directive 2001/20/EC).

[2] Medicinal drug product is (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (Article 1, Directive 2001/83/EC).

[3] Hasibe Işıklı, **İlaçlarda Test ve Deney Verilerinin Korunması: Avrupa Birliği'nde Yeni Sistem,** Ankara: İktisadi Sektörler ve Koordinasyon Genel Müdürlüğü, 2005, p.9.

[4] Exclusivity of data protection is under discussion. See, para. 2.6.

of granting a second marketing approval for that drug product marketed before.

The subject matter of data exclusivity is "new chemical entity"[5] referred to as "new active substance" in the EU.

In the last decades, new methods, which make faster and cheaper to discover a new chemical entity, are developed. But tests and clinical trials are still needed[6].

2.2 Which Term: Data Protection or Data Exclusivity?

Both the terms of data protection and data exclusivity are used interchangeably indicating the same subject. While data exclusivity is used in the U.S., the term of data protection is preferred in the EU[7]. In this study both of them are used in the same meaning. It must be added that the term of data protection is also used for protection of personal data/ privacy. Thus, to avoid confusion the term of data exclusivity is usually used in this study.

However, both of the terms are sometimes used in different meanings. In this regard, while data protection term provides the protection of undisclosed information against disclosure and unfair commercial use in the framework of provisions about trade secrets and unfair competition based on TRIPS 39, data exclusivity sounds like providing a higher level of protection than data protection beyond TRIPS 39, similar IPR exclusivity, like in the case of patent term extensions.[8]

It should also be pointed out that the title of Article 39 of TRIPS is "Protection of Undisclosed Information".

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[5] See, para. 4.4.4 for the term of "New Chemical Entity- NCE".

[6] Carlos Maria Correa, **Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement**, 2nd Ed., Geneva: South Centre, 2004, p.1.

[7] Işıklı, p. 6.

[8] Karin Timmermans, "Intertwining Regimes: Trade, Intellectual Property and Regulatory Requirements for Pharmaceuticals", **the Journal of World Intellectual Property,** V. 8, No: 1/2005, p. 70.

2.3 The Similarities and Differences between Data and Patent Protections

In most cases as an intellectual property right, both data exclusivity and patent protection cover the same pharmaceutical drug product but each of them provides a different type of protection[9]. In other words, they differ from each other in some certain qualifications as follows:

i. As it is known in patent law, the invention must be novel, non-obviousness and useful. While in patent law the product must be new worldwide, in other words the same exact invention must not be sold, used or offered to sale before patent application or grace period if there is, in data exclusivity it is enough in order to gain the right if the application for obtaining marketing approval of new active substance is first in the country of application even marketing approval of that drug product had been granted in other countries before[10].

ii. There is also difference between patent and data exclusivity in the scope of right. In patent law, just the right holder has power manufacturing, selling, export and import of patented product in around 20 years. But in data exclusivity, the right holder has no like monopoly since the generic companies have opportunity getting marketing approval by presenting their test results and clinical trials[11] even though the undisclosed information is protected during it will be kept secret[12].

iii. In patent law, the right holder has power to exclude others from selling, import and export of patented product since patents confer property rights and the right holder obtains the exclusive use of his or her rights[13]; the state authorities have no duties to exclude others from using those rights

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[9] Deniz Ilgaz, "Turkey Aims at Full Harmonisation with the EU Acquis Communitaire in Intellectual Property as a Requirement of Membership", **Euro-Mediterranean Integration-The Mediterranean's Eurpean Challenge,** V. III, Edited by Peter G. Xuereb, European Documentation and Research Center, University of Malta, 2002, p. 378.
[10] Işıklı, p. 11.
[11] Işıklı, p. 11.
[12] Correa, p. 43.
[13] Correa, p. 43.

independently from the right holder. But in data exclusivity, the state authorities carry on their shoulders obligation to exclude others/ generic producers from using test data which were given them in order to obtain license and marketing approval by the first applicant/ original drug producer[14].

iv. In patent law, the invention for which the patent protection is granted is being published. But in data exclusivity, data submitted to the state authority in order to obtain marketing approval is secret and the state authority has obligation to keep that secrecy[15].

v. In data exclusivity, the molecules which are not patentable can still be subject of data exclusivity[16].

2.4 Test and Clinical Trials of New Pharmaceutical Drug Products

National regulatory authorities require applicants to present their pharmaceutical drug products' safety and efficacy test results along with other documents relating on such as qualitative and quantitative data of that drug product, for granting marketing approval.

Before clinical stage (preclinical stage), tests of new chemical entities are made in animals in order to establish safety.

In clinical stage, safety and efficacy tests are made in humans in several phases: *In Phase I*, a small group of human volunteers is tested for toxicity, bioavailability and pharmacokinetics of the New Chemical Entities. *In phase II*, the effectiveness of the NCEs is tested and also the proper dose is established. *In phase III*, the efficacy and side effects of NCEs are determined on a large group of patients. In addition to these phases to monitor safety and toxicity tests in animals are continued for a long time period[17].

[14] Işıklı, p. 12.
[15] Işıklı, p. 12.
[16] Işıklı, p. 12.
[17] Correa, p. 2.

2.5 Why Test Data Is Protected?

The main purpose of data exclusivity/ protection is maintaining confidentiality of data[18].

To produce a medicinal drug product and to obtain marketing approval for that medicinal drug product, it is required investing around $500 Million and also up to 15 years time period[19].

However, marketing a generic version of a brand name drug product costs only $1 Million[20].

The research-based industry argues that to encourage them to make investment, to invent and then produce new NCEs, it would be well grounded a data protection system for registered data required by regulatory drug authorities for granting marketing license/approval, since the investment and long term test studies must be rewarded. In contrast to research-based industry/ originator drug producers, generics manufacturers argues that making the same tests in humans and animals is not ethic and duplicate test results is wasteful[21].

In order to balance the parties' interests, during a certain time period the data submitted to the national authorities are protected. Until the end of this time period only the originator drug producer or its licensees would be at the market, but after this time period generics also will be at the market. In this way the original drug producers would be encouraged to make investment for R&D studies in order to invent new NCEs and also the generics will make the drug price lower which will make States and patients spend not so much money for medicine.

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[18] Correa, p. 5.
[19] Işıklı, p.5.
[20] Laura J. Robinson, "Analysis of Recent Proposals to Reconfigure Hatch-Waxman", **J. Intell. Propr. L.**, V. 11, No: 2/2004, p. 48.
[21] Aaron Xavier Fellmeth, "Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement", **Harvard International Law Journal**, V. 45, No. 2/2004, p. 448; Correa, p.5-7.

Data exclusivity/ protection is especially vital where if there is no patent protection for pharmaceutical drug products in the registration country or the drug product is not patented/ patentable such as biologicals or the patent term of the drug product has been expired[22]. This is also result of being shorter of data exclusivity time period than patents[23].

2.6 Does Test Data Protection Provide a Sui Generis and an Exclusive Right as Other IP Rights such as Patents?

According to one opinion, both of patent and data exclusivity protection systems confer on right holders exclusive rights. Except this exclusivity, there is no other essential similarity between these two kind of protection systems[24]. In other words, data exclusivity as an intellectual property right stands independently from patent law and gives the data holder some certain exclusive rights enabling them keep competitors away from the market in a limited period of time.

This opinion is represented by U.S., the Pharmaceutical Industry and the European Union. In this point of view, it is considered that the effective protection on test data is only provided by given exclusive time period for the use of that test data[25].

According to the EU, Article 39.3 obliges member countries provide exclusivity and not to rely on test data for a reasonable time period. The discretion of the member countries in the issue is only about the duration of that exclusivity[26].

Thus, the ECJ held in its judgment, that *"Directive 65/65/EEC art. 4/8 (a) (iii), as amended, must be interpreted as meaning that it confers on the owner of that product an exclusive right to make use of the results of the pharmaceutical and toxicological tests and clinical trials placed in the file on that product..."* (Case C-368/96, paragraph 81).

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[22] Correa, p.xii.
[23] Timmermans, p. 70.
[24] Işıklı, p. 10.
[25] Correa, p. 47.
[26] Correa, p. 49.

However, in this judgment (paragraph 77-86) the ECJ rejected the allegation of the abridged procedure infringing the principles of protection of innovation and respect for the right to property. This means that the right to property of innovative drug firms is restricted.

It is clear that, if the submitted test data is considered as property, it may not be used for the second application[27].

It must be paid attention to the nature of test data which differs from other types of IP rights regulated in TRIPS. An important point is that the test data are results of clinical trials and tests which do not contain an invention or creativity.

It is also considered that the undisclosed information which is the subject of data protection is not accepted as "property" by TRIPS[28]. And also exclusivity was not written explicitly in the said text contrary to provisions of patents, trade marks, industrial designs, copy rights and integrated circuits.

It must be also considered that the historical background of TRIPS Agreement negotiations which has been accepted by WTO jurisprudence as an interpretative source under Article 31 (2) of the Vienna Convention can be a vital evidence for interpretation of TRIPS provisions[29]. In this regard, the proposals which were submitted by U.S. and some other countries including the term "commercial or competitive benefit" instead of "unfair commercial use"[30] and the prohibition on reliance on the test data submitted by innovator were not accepted. This means that the exclusivity approach was rejected in TRIPS Article 39[31].

In the light of those facts, data protection can not be deemed as a sui generis exclusive right in the context of TRIPS (art. 39)[32].

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[27] W.R. Cornish, **Intellectual Property,** Third Edition, London: Sweet & Maxwell, 1996, p. 290.
[28] Correa, p. 44.
[29] Correa, p. 53.
[30] See, para. 4.3 for the term of "unfair commercial use".
[31] Correa, p. 54–55.
[32] Correa, p. 13-14.

3 OTHER TYPES OF REGULATORY DRUG PRODUCT EXCLUSIVITIES

3.1 Pharmaceutical Patents

As it is known, the term of patent is used in two meanings. One is used to describe the registered invention itself. Another is used to describe the exclusive right of the patent holder. In this sense, a kind of administrative award, which provides an exclusive right to avoid others from making, using or selling the patented product or process in a limited time period, is granted to the patent holder for his invention[33]. This time period lasts usually 20 years from the date of filing an application of registration with the patent offices.

Patent protection generally and mainly is harmonized at international level by the Paris Convention (1967) on the protection of Industrial Property and then Trade-Related Aspects of Intellectual Property Rights- TRIPS agreement annexed to WTO Agreement[34].

In the EU, European Patent is granted by the EPO but patent protection has not been harmonized yet[35]. However, it is possible to talk about an European Patent System consist of international agreements such as, *Strasbourg Agreement Concerning the International Patent Classification of March 24, 1971,as amended on September 28, 1979; Convention on the Grant of European Patents-European Patent Convention (EPC) signed in Munich in*

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[33] Tahir Saraç, **Patentten Doğan Hakka Tecavüz ve Hakkın Korunması (Infringement and Protection of the right derived from the Patent),** Ankara: Seçkin, 2003, p. 34-37.

[34] Cahit Suluk and Ali Orhan, **Uygulamalı Fikri Mülkiyet Hukuku (Practical Intellectual Property Law), V. II, Genel Esaslar, Fikir ve Sanat Eserleri (General Principles, Copyrights,** Istanbul: Arıkan Publishing, 2005, p. 40.

[35] Sami Karahan, Cahit Suluk, Tahir Saraç and Temel Nal, **Fikri Mülkiyet Hukukunun Esasları (Basics of Intellectual Property Law),** Ankara: Seçkin, 2007, p. 23.

1973[36]. Meanwhile, there is a proposal prepared by the Commission for the Community Patent Regulation[37].

It should be added that, in Turkish law system there was no patent protection for pharmaceuticals until the Decree Law No. 551 was enacted in 1995 after TRIPS[38].

Pharmaceutical Patents are not different from other type of patents generally. They also consist of products and processes[39]. Historically, in pharmaceuticals, after process patents, product patents were given patent protection[40].

In this regard, the assessment of pharmaceutical patent infringement is not different from other type of patent infringements[41]. However, in the U.S. law system, the Drug Price Competition and Patent Term Restoration Act referred to as Hatch-Waxman Act introduced an exception to the patent infringements by providing generic drug manufacturers to make and test the generic version of a brand name drug product for which the ANDA (Abbreviated New Drug Application) application is filed with the FDA[42] before

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[36] Ali Necip Ortan, **Avrupa Patent Sistemi (European Patent System), V. I, Avrupa Patenti Antlaşması -Münih Antlaşması (European Patent Convention-München Convention),** Ankara: Banka ve Ticaret Hukuku Araştırma Enstitüsü, 1991, p. 1.

[37] See, http://www.epo.org/patents/law/legislative-initiatives/community-patent.html.

[38] Ünal Tekinalp, **Fikri Mülkiyet Hukuku (Intellectual Property Law),** Forth Edition, Istabul: Arıkan, 2005, p. 506.

[39] "Typical pharmaceutical patents cover active drug compounds, their intermediates, metabolites, hydrates, salts and esters; combinations with other drugs; methods of manufacturing the active drug and its intermediates; different methods of medical treatment using the drugs including novel indications and dosage regimens; formulations for the drug including new dosage forms; devices containing the drugs such as skin patches, drug delivery systems, etc" Martin A. Voet, **The Generic Challenge**, Florida, USA: Brown Walker Press, 2005, p. 35.

[40] Uğur G. Yalçiner, "İlaç ve Patent Türkiye'de ve Dünyada Son Gelişmeler" (Pharmaceuticals and patent latest developments in Turkey and the world), **Journal of Intellectual Property and Competition Law-FMR** Volume: 2, Issue: 3/2002, p.23.

[41] Teresa O. Bittenbender and John W. Ryan, "Recent Developments in Pharmaceutical Patent Litigation", **Intellectual Property & Technology Law Journal**, V. 16, No. 9/2004, p. 6.

[42] The U.S. Food and Drug Administration (FDA) is the national agency that monitor that the nation's food supply is unadulterated and medicines and medical devices are safe and effective. The agency also grants marketing approval for a new or generic drug or Class III medical device or biological in the U.S. See, Voet, p. 41.

the patent term of that brand name drug product expires[43]. This is so-called *§271(e)(1)*[44] *exemption or Hatch-Waxman exemption* in the U.S. while it is referred to *Bolar provision or Roche-Bolar provision*, named after the case *Roche Products v. Bolar Pharmaceutical*, 733 F.2d 858 (Fed. Cir. 04/23/1984) which reversed and remanded the judgment the United States District Court 572 F. Supp. 255 for the Eastern District of New York held United States Patent No. 3,299,053 not infringed and denied relief[45]. After the Roche v Bolar judgment *Hatch-Waxman / bolar exemption* came into force in 1984[46].

The Hatch-Waxman Act allows generic drug manufacturers, without making them responsible for infringement, use a drug product or process which is under patent protection to make an application (but not to place on the market before the patent term of the original drug expires) in order to obtain marketing approval for a generic drug product for which the application is made before the FDA. In other words, the generic drug manufacturers are allowed to infringe patents of the innovative drug firms in order to obtain

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[43] Robinson, p. 52.

[44] 35 U.S.C. 271.(e)(1) provides the experimental-use exemption laying down that: *"It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.". http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_271.htm* (25.09.2007).

[45] See, http://biotech.law.lsu.edu/cases/IP/patent/roche_v_bolar.htm (25.09.2007): "*At stake in this case is the length of time a pharmaceutical company which has a patent on the active ingredient in a drug can have exclusive access to the American market for that drug. Plaintiff-appellant Roche Products, Inc. (Roche), a large research-oriented pharmaceutical company, wanted the United States district court to enjoin Bolar Pharmaceutical Co., Inc. (Bolar), a manufacturer of generic drugs, from taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to a patented brand name drug. Roche argued that the use of a patented drug for federally mandated premarketing tests is a use in violation of the patent laws.*" (para. 16).

[46] See, Research exemption, http://en.wikipedia.org/wiki/Research_exemption (25.09.2007).

marketing approval for the generic product for which the ANDA application is made[47].

As it is explained below[48], the bolar exception is also provided in the EU to make and test the generic version of a brand name drug product before the patent term or extended patent term (Community SPC)[49] expires (Article 10/6 of Directive 2001/83/EC amended by Directive 2004/27/EC).

There is also such an exceptional provision in Turkish law providing use and test the patented drug product in the aim of preparing an abbreviated application for obtaining marketing approval (Article 75/f of the Decree Law No. 551).

It is also under discussion whether or not clinical trials are "experimental use". If it is not, it is obvious that that avoids patentability of pharmaceutical invention for which the application is made. As it is known, if an invention is in public knowledge or in public use for more than one year, it is not patentable with the exception of experimental use.

In the U.S., the Federal Circuit held, in the *Smith Kline Beecham Corp. v. Apotex Corp*. case, that the clinical trials submitted to the FDA by the generic manufacturer *Apotex* avoided the originator firm *Smith Kline* from patent protection. In other words, according to that decision the clinical trials could not be deemed as an "experimental use". This decision results, on the contrary several other decisions of the Court, that unless if those clinical trials are made on a claimed element not on a compound itself, they are not experimental uses[50].

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[47] Jerome Rosenstock, **the Law of Chemical and Pharmaceutical Invention, Patent and Nonpatent Protection,** New York: Apsen Publishers, 2004, Chapter 6, p. 14.1.
[48] See, para. 6.2.
[49] See, para. 3.2.
[50] Bittenbender and Ryan, p.7.

3.1.1 Compound Patents

Compound patents consist of active drug compound along with its esters, salts and hydrates[51].

New Chemical Entities (NCEs) are the most valuable part of a drug product and compound patents provide the best protection for the patent holder since it required to work so many times and invest so much money in order to invent NCEs and to make marketing them as a pharmaceutical drug product. For this reason, generic companies seek produce generic versions of original drug products without being completed all steps that are taken by innovator firms for obtaining marketing approval.

3.1.2 Formulation Patents

This kind of patents includes active drug agents in the specific formulation for use in the body. It provides the least desirable exclusivity for the patent holder because of it is easier to find out a new formulation compared to other type of pharmaceutical patents.

However, original drug producers have also power to avoid generic competitors getting marketing approval because of even a small change in the formulation or in the active drug agent, requires bioequivalence studies in order to (submit an ANDA/) obtain marketing approval. On the other hand, instead of making those bioequivalence studies, the generic companies would like to copy of originator drug product and then to try to invalidate of the formulation patent[52].

3.1.3 Medical Use Patents

Medical use patent provides protection on the approved medical use or indication of an approved drug product. It can also protect unapproved medical uses[53].

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[51] Voet, p. 35.
[52] Voet, p. 38–39.
[53] Voet, p. 36.

3.2 Patent Term Extensions

Patent term extensions, as another type of drug product exclusivities, provide innovative firms an extra time period in order to make up their time lost during the approving procedure of a new drug product.

However, patent term extensions are applicable for only the approved drug products. So, not all of the claims of a patented drug product, but just the claims granted marketing approval will benefit from the patent term extensions.[54]

As it is known, it takes up to fifteen years in order to obtain marketing approval for a patented or patent-off drug product and this reduce the patent term seriously. Hence, the innovative firms demand patent term extensions beyond the nominal patent term to carry on their monopoly on the approved drug product at the market and make more revenues in order to assist their R&D studies.

In this context, in the EU, in order to establish a uniform system a Supplementary Protection Certificate (Community SPC) is created by the Council Regulation[55] (EEC) 1768/92 of June 18, 1992.

The Community SPC was needed because of the imbalance between the pharmaceutical industry in the Community and its competitors in the U.S. and Japan[56].

The Community SPC which is granted by national patent offices provides patent term extensions for both national and European patents with respect to an active ingredient or combination of active ingredients obtained marketing approval in one of the member states of the Community and plus in the European Economic Area after Porto Agreement.

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[54] Voet, p. 7–8

[55] Regulation (EC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ No L 182 of 2.7.1992, p. 1).

[56] Robin Whaite and Nigel Jones, "Pharmaceutical Patent Term Restoration – The European Commission's Proposed Regulation", **European Intellectual Property Review- EIPR**, No: 9/1992, p. 324.

To make a Community SPC application, the drug product; must be under patent protection in force, must be given marketing authorization first time in the Community and also must not be subject of an old any other Community SPC application (Art. 3).

Applicants must make their application in corresponding member state within six months from the date of obtaining the marketing approval. If the marketing approval had been obtained before patent, the application must be made within six months from the date of obtaining the patent (Art. 7).

The duration of patent term extensions in the EU is fifteen years from the date of grant first marketing approval in the Community, or five years from the date of patent expiration[57]. Fifteen-year extension marketing exclusivity is limited with maximum twenty-five year protection from the date of patent application[58].

In the U.S., the Hatch- Waxman Act introduced patent term extensions for originator drugs (pioneer drugs) in order to balance the interests of innovative firms (pioneers) and generic firms by providing a simplified procedure for generics' approvals requiring only bio-equivalence studies without providing the results of safety and efficacy tests and clinical trials which were made before by an innovative firm (NDA applicant) in order to obtain marketing approval first time in the U.S.[59].

In the U.S. patent term extension is for up to five years[60].

However, in the U.S. the maximum five year patent term extension period is limited with fourteen year marketing exclusivity. Thus for instance, if the drug product' patent term lasts after thirteen years at the time of marketing approval was granted, this drug product will benefit only one year

[57]Adrian Zahl (Ed.), **International Pharmacentical Law and Practice,** U.S.: Matthew Bender, 2004, Chapter 7, p. 25-26.
[58] Yalçıner, p. 32.
[59] The Hatch- Waxman Act also has provided 180-Day marketing Exclusivity period in favor of generic companies (see, para. 3.4).
[60] Timmermans, p. 68.

patent term extension[61]. As a result, the original drug manufacturers compensate half of their time lost during clinical trials and FDA approval procedure[62].

In the U.S., in order to obtain a patent term extension, application must be made to the U.S. Patent and Trademark Office within sixty days of marketing approval. The Office grants patent term extension on the basis of the FDA's calculation based on the period of marketing approval delay[63].

Patent term extensions are also provided in Australia and Japan.

In Turkey, the patent holder has no such a marketing exclusivity (yet).

3.3 Pediatric Exclusivity

Under the U.S. law, the pediatric exclusivity provides six months extra marketing exclusivity to all the other marketing exclusivities. A pediatric exclusivity is only granted by the FDA if a clinical study which is done in children is required by the FDA[64].

In the EU, contrary to the U.S., there is no such a pediatric exclusivity. However, Directive 2001/20/EC[65], relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, lays down some principles in its Article 4 relating to the clinical trials on minors.

Like the EU, there is no such a pediatric marketing exclusivity in Turkish law. Nevertheless, in accordance with Article 8/I-d of Directive 29

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[61] Paul Burgess and John Lucas, "Which Generic Drug Would You Want to Use? The Federal Circuit's Interpretation of 'Active Ingredient', 'Active Moiety' and 'Approved Product", **Journal of the Patent and Trademark Office Society,** V. 87, No: 1/2005, p. 14.
[62] Robinson, p. 54.
[63] Burgess and Lucas, p.14.
[64] Voet, p. 60, 61.
[65] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use (OJ L No 121 of 1.5.2001, p. 34–44).

January 1993, to make clinical trials on minors under the age of eighteen, it is required the consent of their parents.

3.4 180-Day Generic Product Exclusivity

Under the U.S. law amended by Medicare Act, 180-day generic product exclusivity is granted to the generic company which is the first to file an ANDA for the drug listed in the Orange Book with a paragraph IV certification challenging at least one patent for that listed drug product. Before that 180-day exclusivity time period expires, for the same drug product and for the same indication, another ANDA may not be approved by the FDA[66].

The term of "same drug product" also covers dosage forms. In this regard, 10 mg tablet form is not the same drug product with 20 mg tablet form of the same active drug for the same indication[67].

180-day generic product exclusivity was designed to support patent challenges which were listed in the FDA's Orange Book in exchange the compensation[68] of challenger's costs in the process of invalidation of an inappropriate patent.

It is obvious 180-day generic product exclusivity aims to encourage generic manufacturers to enter into the market.

3.5 Product Improvements

In the U.S. for a new use or new formulation of a drug product may get a marketing exclusivity of three years. New indications for an old drug or new

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[66] Voet, p. 62.
[67] Voet, p. 62.
[68] The generic company's profit during this exclusivity time period will be higher than its profit in the rest of the market life of that generic drug product since the cost of copying an originator drug product is not expensive ($1 Million is enough to manufacture a generic drug product (Işıklı, p. 5.)) and the price of generics is lower than an originator one and also there will be no other competitive generic producer in the market for the same generic drug product. But an important issue is that, meanwhile an "authorized generic" drug product or another generic drug product marketed by the originator's own generic division so-called "branded generics" may be marketed to compete challenger.

methods of administration or new formulations or other labeling changes of an old drug can be subject to this exclusivity.

In the EU, one year data and marketing exclusivity is provided for new therapeutic indications[69].

3.6 Orphan Drug Exclusivity

In the U.S., the Orphan Drug Act which amended the "Federal Food, Drug and Cosmetic Act" through adding a new section namely "Drugs for Rare Diseases and Conditions" was codified in 1983, in order to support R&D studies and producing drug products for rare diseases (or orphan diseases) which have less than 200,000 patients in the U.S[70].

The duration of marketing exclusivity in the U.S. is seven years. This means that during these seven years there will be no other competitor at the market. The act avoids FDA from approving a NDA as well as an ANDA (or paper NDA) for the same active drug during the seven-year time period. However, FDA enjoys power to accept NDA or ANDA applications before the seven-year period expires in contrast to the rule for NCE (data) exclusivity. This law also grants a 50 % tax credit for research expenses[71]. Except two conditions (consent of the right holder or the right holder's insufficiency in quantity needed), the seven-year marketing exclusivity is granted for only the first applicant[72].

After U.S., EU and some other developed countries such as Japan have also enacted similar legislation[73].

In the EU, orphan drugs are regulated by the Regulation 141/2000/EC and the implementing Regulation 847/2000/EC. Under those regulations, if the rare disease affects not more than 5 in 10.000 persons in the Community when the application is made, ten-year marketing exclusivity

[69] See, para. 6.2.
[70] Rosenstock, section 6, p. 14.6-7.
[71] Voet, p. 43,58.
[72] Rosenstock, section 6, p. 14.7.
[73] Timmermans, p. 68.

is given to the applicant. In certain cases, this time period is reduced to six years (art. 8/1 of 141/2000/EC).

3.7 Trade Secret

TRIPS Article 39 obliges member countries to provide protection of undisclosed information (trade secret or know-how) which has commercial value because of it is secret and is kept secret. This protection is provided within the context of unfair competition rules[74]. Article 39.2[75] lays down the sorts of protected undisclosed (confidential) information. This was the first time the commercial value of undisclosed information was recognized in international public law[76].

In this regard, the relationship between confidential information and trade secret can be considered as while trade secrets have commercial value, confidential information is any other data which is confidential but may not have commercial value[77].

Trade secret does not provide protection in the case of reverse engineering, accidental disclosure or independent invention[78].

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[74] Mehmet Emin Bilge, **Ticari Sırların Korunması (the Protection of Trade Secrets),** Second Edition, Ankara: Asil Publishing, 2005, p.73.

[75] Article 39.2 lays down that *"2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:*
(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) has commercial value because it is secret; and
(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.
For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition."

[76] Duncan Matthews**, Globalising Intellectual Property Rights,** New York: Routledge, 2003, p. 64.

[77] J. Ian Lloyd, **Information Technology Law,** Third Edition, London: Butterworth, 2000, p. 259.

[78] Rosenstock, Section 6, p. 42.

NAFTA Article 1711[79] also provides protection for trade secrets in similar words and conditions to the TRIPS Art.39/2. This indicates that the rules laid down in NAFTA relating to the trade secrets incorporated into the TRIPS Art. 39.2.

It must also be pointed out that, the provisions of NAFTA relating to trade secrets are very similar to the U.S. trade secret law. In other words, the rules laid down in U.S. law relating to the trade secrets incorporated into NAFTA[80].

In Turkish law system, trade secrets are under protection within the context of unfair competition rules codified under the Turkish Commercial Code[81].

3.8 Trade Mark/ Trade Dress

If a drug product meets the conditions of trade mark or trade dress, surely it will be protected under those industrial property law like patent law protection.

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[79] NAFTA Article 1711 lays down that "*1. Each Party shall provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as:*
(a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question;
(b) the information has actual or potential commercial value because it is secret; and
(c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.
2. A Party may require that to qualify for protection a trade secret must be evidenced in documents, electronic or magnetic means, optical discs, microfilms, films or other similar instruments.
3. No Party may limit the duration of protection for trade secrets, so long as the conditions in paragraph 1 exist.
4. No Party may discourage or impede the voluntary licensing of trade secrets by imposing excessive or discriminatory conditions on such licenses or conditions that dilute the value of the trade secrets.
....."

[80]Deniz Ilgaz, "Know How ve Ticari Sırlar (Know How and Trade Secrets)", **Marmara Journal of European Studies,** V. 8, No: 1-2/2000, p. 176.

[81] Cahit Suluk, Ticari Sırlar (Trade Secrets), http://www.fikrimulkiyet.com/011.php (21.08.2007).

In the EU, there is no any specific provision for pharmaceuticals in the field of trade mark. The general rules are applied to pharmaceutical drug products in the EU system[82].

[82] Zahl, Chapter 7, p. 42.

Part Two

THE SCOPE AND CONDITIONS OF DATA EXCLUSIVITY

4 REGULATORY DATA EXCLUSIVITY AT INTERNATIONAL LEVEL

Since technological inventions last decades have made easy to copy products and processes subject to trade, developed countries started to impose developing countries providing intellectual rights more effectively and extensively. For instance in 1984, amended U.S. Trade Act of 1974 gave the U.S. President power to impose sanctions on the countries violate the IPR. In this regard, the provisions relating to patent and data protection in pharmaceuticals are placed in TRIPS[83].

4.1 Trips Article 39

Article 39 of Trade-Related Aspects of Intellectual Property Rights-TRIPS agreement provides protection for undisclosed information in particular sub-paragraph 3 is directly related to the subject of data exclusivity. This article stipulates that *"SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION*

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

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[83] N. Lalitha, **India's Pharmaceutical Industry in the WTO Regime: A SWOT Analysis,** Ahmedabad, India: Gujarat Institute of Development Research, March 2002, p. 6.

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3. 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."[84]

4.2 Protection of Undisclosed Information against Unfair Commercial Use under TRIPS Article 39.1

Protection of undisclosed information under Article 39 is based on "unfair competition" rules, in the context of *Article 10bis of the Paris Convention (1967)* on the protection of Industrial Property, which is defined as *"any act of competition contrary to honest commercial practices in industrial or commercial matters"* (Article 10 bis (2) (general clause)).

As will be explained below, there is no an international rule describing certain activities such as relying on test data submitted to the national authorities by the innovator for obtaining marketing approval, as an unfair competition. This is because, it is under discussion whether such activity of national health authority is a kind of unfair commercial use or not. The issue will be discussed below.

In many countries, the misappropriation of trade secrets is deemed as an unfair competition as regulated in TRIPS[85].

In the light of Article 10bis of the Paris Convention, fairness in commercial activities is protected by unfair competition. In particular, "creating the risk of confusion, discrediting competitors through false allegations and making misleading indications or allegations about one's own

[84] http://www.wto.org/english/tratop_e/trips_e/trips_e.htm, (18.07.2007).
[85] Correa, p. 41.

goods"[86] activities are listed in a way not enumerative as unfair competition in Article 10 bis (3).

It must be also added that the pharmaceutical sector is sometimes under threat of anti-competitive acts and agreements relating to generic drug products[87]. In this regard, Collusive agreements classified under horizontal agreements are possible through paying to the generic drug manufacturers to make them delay to enter its generic drug product onto the market in exchange some amount of money[88].

4.3 Protection of Undisclosed Test or Other Data Submitted to Government or Governmental Agencies against Unfair Commercial Use and Non-disclosure Obligation of Such Undisclosed Information under TRIPS Article 39.3

Member states are under obligation of protection of submitted test data against unfair commercial use and except two conditions also under obligation of non- disclosure of such undisclosed information (test data).

One exception is the necessity of protection of the public. In this exception, member states have discretion to determine that necessity[89].

Another exception is the guaranteed situation against unfair commercial use. If a member state had taken steps to ensure that the data are protected against unfair commercial use, she could disclose any information. But the main question is what the conditions of unfair commercial use are and how to ensure against unfair commercial use.

4.3.1 "Unfair"

Determination of unfairness is depending on discretion of member countries since there is no an absolute international rule which describes

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[86] Correa, p. 42 with reference to Henning-Bodewig, 1999, p. 173.
[87] Ateş Akıncı, **Rekabetin Yatay Kısıtlanması (Horizontal Restriction of Competition),** Ankara: Rekabet Kurumu, 2001, p. 37.
[88] Robinson, p. 57.
[89] Correa, p. 21.

certain practices as unfair. Thus, the same certain practice will be evaluated in a different way by different member countries[90].

It could be a solution of this problem to harmonize rules relating to unfair practices at international level. However, the negotiation of article 39.3 was not affirmative for making such a harmonization. For instance, the U.S. proposal which obliges member countries to avoid others using of test data without the consent of the right holder or on payment of "the reasonable value of the use" was not accepted in the negotiation of article 39.3 and was not incorporated into the final text of article 39.3[91]. Because of that reason, many member countries do not consider, as an unfair commercial practice, that granting marketing approval which made reference to the first registration or relying on test data submitted to the national regulatory authorities by an innovator company. This consideration seems valid under article 39.3 since the member countries have power to judge whether or not such a practice is "unfair commercial practice"[92].

4.3.2 "Commercial Use"

Only commercial practices are under Article 39.3. If the entity that uses the test data is actually in commerce, that practice is deemed commercial[93]. So, in this sense, a governmental act which assesses the efficacy and toxicity of pharmaceutical or agro-chemical drug product may not be deemed commercial[94].

In contrast to this interpretation, some member countries, in particular developed countries, and their research- based industry are against this consideration. In this point of view, any practices which cause a benefit or

[90] Correa, p. 25.
[91] Correa, p. 27.
[92] Correa, p. 28.
[93] Correa, p. 29.
[94] Correa, p. 28.

commercial advantage for second registrants (generics industry) are under Article 39.3[95] even it has indirect commercial results[96].

However, the U.S. Supreme Court rejected this kind of interpretation in the *Ruckelshaus v. Monsanto CO.* case. The court held in its decision that national regulatory authority can rely on data submitted by the innovator in order to examine the application of second applicant for granting marketing approval[97].

Another important decision was given by the General Court of Appeal of Canada in the *Bayer* case. The court held in its judgment that the practice of the national regulatory authority was aiming to ensure whether the drug products of both of the originator and the second applicant were the same. The court also held that the data submitted by the originator were not requested or used in order to assess the second application by the national authority[98]. According to the court, just only the use of test data, submitted to the ministry, which are assessed in the examination of safety and efficacy of a generic drug product by the ministry in the name of a generic manufacturer, is required to apply minimum data protection time period. If the safety and effectiveness of a generic product is proved by a generic company on the basis of bioequivalence or bioavailability studies not relying on the test data submitted to the ministry by the innovator, there is no reason for providing five years data protection. Otherwise, comparing a generic product to the originator product by a generic manufacturer on the basis of public information can be deemed as a violation of data protection rules. It is obvious that, this kind of interpretation would make data protection in the level of patent protection[99].

In the *Bayer* case, the court's decision can be summarized like that under Canadian law and NAFTA, if the national regulatory authority actually uses or relies on the test data submitted by the innovator, on behalf of the

[95] Correa, p. 32.
[96] Correa, p. 29.
[97] Correa, p. 34-36.
[98] Correa, p. 36.
[99] Correa, p. 38-39.

generic manufacturer in order to examine the second application, data protection will be applied.

The opinion of the European Union in this issue is that there is difference between unfair competition and unfair commercial use. While unfair competition is between competitors regulated in Article 39.1 and 39.2 with a reference to Article 10bis of the Paris Convention on the protection of Industrial Property, unfair commercial use which includes governmental acts is regulated in Article 39.3. It also differ unfair commercial use from the obligation of non-disclosure of submitted test data which is regulated in Article 39.3 separately[100].

4.4 Conditions of Protection of Test Data Submitted to the Government or its Agencies under TRIPS Article 39.3

4.4.1 Requiring of submission of Test Data to the National Regulatory Authority

Article 39.3 obliges member states data protection if they require applicants' submission of test data to the national health authority as a condition of granting marketing approval of pharmaceutical or of agricultural chemical products which utilize new chemical entities.

The requiring submission of test data and other data is the first condition of Art. 39.3 protection. In this regard, in the case of not requiring of test data by the national health authority, given test data submitted voluntarily are not under Art. 39.3 protection[101].

4.4.2 The Subject Matter of Protection

Safety and efficacy test results and also "other data" such as manufacturing and packaging methods are the subject matter of data protection. This data must be necessary for getting marketing approval[102].

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[100] Correa, p. 28-29.
[101] Correa, p. 14-15.
[102] Correa, p. 14-15.

4.4.3 Undisclosed Information

Another condition of art. 39.3 protection is that the data must be undisclosed information. If the test data is public knowledge, the submission of that test data to the national health authorities does not meet the condition of art. 39.3.

4.4.4 New Chemical Entities

Art. 39.3 provides protection just on the "New Chemical Entities (NCE)" while in the USA there is also protection on the new indications of known drugs for a limited time period of three years either.[103]

In the context of TRIPS Art. 39.3, newness in the term of NCE is different from the novelty required for patents. NCEs are compounds their efficacy and safety are proved and were not approved as a drug product before.[104]

It is also not clear from the article 39.3 whether the newness would be absolute (worldwide) or relative (local)[105].

Within context of a certain regulatory system, a product can be deemed as a new chemical entity while that chemical entity was used before in another regulatory system. For instance, a chemical entity which had been used in chemical industry may have been used later in pharmaceutical sector. This chemical entity approved and granted marketing license by national health authority would be deemed new[106].

The date of application for obtaining marketing approval is taken into account when a chemical entity is considered whether it is new or not[107].

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[103] Timmermans, p. 69
[104] J. Jacques Gorlin, **Dünya Ticaret Örgütü Ticaretle Bağlantılı Fikri Mülkiyet Hakları Anlaşması Farmasötik Ürünlerle İlgili Hükümlerinin Analizi,** Banguoğlu Dil ve Danışmanlık Hizmetleri Ltd. Şti. (trans.), Istabul: Publication of EU-Turkey Cooperation Association-TURKAB, 2002, p. 40.
[105] Trevor M. Cook, **the Protection of Regulatory Data in Pharmaceutical and other Sectors,** London: Sweet & Maxwell, 2000, p. 6.
[106] Cook, p. 6.
[107] Correa, p. 16.

Member states have discretion to determine whether or not the chemical entity is new since the article 39.3 is not clear enough.

4.4.5 Investment

A considerable effort is one of conditions of data protection. According to art. 39.3 only data involved a considerable effort will be protected against unfair commercial use.

As it was mentioned before, the subject matter of data protection is test data which are not a result of an activity of invention or creativity. They are just results of clinical trials etc. In this regard, data protection is a reward for originator drug producer who invest so much money in order to produce test data for obtaining marketing approval.

Thus, the national regulatory authorities may request applicants proving their test data involved a considerable effort/ investment for protection that test data[108].

4.5 Practices of National Regulatory Authorities for Granting Marketing Approval

After granting innovator's marketing approval first, the second applicant's marketing approval may be granted by a national regulatory authority such in terms of follows[109]:

4.5.1 Repetition of Test Data or the Consent of Test Data Holder

National regulatory authority may require second applicants their own test data for granting marketing approval or the consent of first applicant whose test data is used.

In this case, it is undoubted that the data exclusivity rules are implemented well since the second applicants should produce their test data

[108] Correa, p.19.
[109] Correa, p.31.

or get the consent of originator drug producer who submitted his test data for obtaining marketing approval.

4.5.2 The Compulsory License

National regulatory authority may grant second marketing approval without the consent of originator against payment to him. This is so-called compulsory license[110].

In this case, the consent of the right holder is not received in order to be used his submitted test data in the procedure of granting second marketing approval. However, innovators' lost is also compensated. Thus, it can be deemed that in this situation the submitted test data are protected. In other words, data exclusivity rules are not violated in this case in terms of TRIPS Article 39.3.

For instance, the U.S. FIFRA provides such a use of submitted test data without the consent of the innovator but with payment of compensation[111].

However, in the case of bilateral agreements such as U.S. - Jordan bilateral trade agreement (BTA), a higher level of data protection standards than minimum standards provided in the TRIPS are imposed. This kind of BTAs limits such compulsory licenses[112].

4.5.3 Relying on test data by National Regulatory Authority

National regulatory authority may grant second marketing approval depending on test data submitted by first applicant.

In this case, the submitted test data are not used by second applicant (the competitor/ generic company) but they are relied on by the national

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[110] Tekinalp, Ünal. **Avrupa Birliği Hukuku (European Union Law).** Second Edition, Istanbul: Beta, 2000.
[111] Correa, p. 45.
[112] Timmermans, p. 70.

regulatory authority to determine second application for granting marketing approval. Thus, the practice of the national regulatory authority may be deemed as a violation of data exclusivity rules. However, as discussed above, since the member countries have power to judge whether such a practice is "unfair commercial practice" or not, this practice can also be deemed under Article 39.3 depending on the national interpretation.

4.5.4 Granting Marketing Approval without being considered Submitted Test Data

National regulatory authority may grant second marketing approval without depending on or evaluation submitted test data. In this case, submitted test data are not used in anyway.

In this case, there is also no commercial use of submitted test data since the national regulatory authorities rely on public knowledge or other old test data.

On the contrary, to interpret this kind of practice of national agencies as an unfair commercial practice means that every practice which provides generic companies commercial advantage or benefit is an unfair commercial practice and violation of Article 39.3. It is clear that this kind of interpretation would limit the legitimate competition[113].

4.6 The *ICH* Process

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or *ICH*[114] referred to as "international standards" introduced high-tech standards for registration requirements[115].

[113] Correa, p. 32.
[114] ICH consisted of innovative industry and the regulatory authorities from Europe, Japan and the U.S.
[115] Timmermans, p. 71.

4.7 NAFTA Article 1711

Sub-paragraph 5, 6 and 7[116] of Article 1711 of NAFTA is corresponding to the Article 39.3 of TRIPS. Both of the provisions provides the same protection for regulatory test data and requires the same conditions generally. This indicates that the provisions of the NAFTA Article 1711 regarding to data exclusivity under the title "Trade Secrets" is incorporated into the TRIPS Article 39 along with other provisions related to trade secrets/ undisclosed information provides protection against unfair commercial use and disclosure.

In Sub-paragraph 6 of the Art. 1711 is differs significantly from the TRISP 39.3 in duration condition. While there is no any minimum exclusivity time period in TRIPS, sub-paragraph 6 of Art. of NAFTA provides at least five-year data exclusivity explicitly. It is known that the developed countries such as U.S, E.U. and their research based companies demanded in TRIPS negotiations to put a minimum time clause in Article 39.3 of TRIPS similar to the NAFTA but they have no succeed against developing countries.

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[116] Article 1711/5, 6 and 7 of NAFTA stipulates that *"5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.*
6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.
7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on." http://www.nafta-sec-alena.org/DefaultSite/index_e.aspx?DetailID=169#A1711, (01 August 2007).

4.8 Bilateral Agreements

In the Morroco-U.S. Free Trade Agreement-FTA concluded in 2004, provides at least five-year data protection for the innovator firms. In addition to this five-year exclusivity, the agreement also provides additional three-year exclusivity for new clinical information. This agreement, as other bilateral FTAs, provides data protection beyond the TRIPS[117].

[117] Othoman Mellouk, "Struggling to Balance Free Trade with Access to Medicines in the post-TRIPS Era throughout the Arab World", **Intellectual Property Rights (IPRs), Innovation and Sustainable Development,** Alexandria, Egypt, 26/28 June 2005.

5 REGULATORY DATA EXCLUSIVITY UNDER U.S. LAW

5.1 Data Exclusivity before Hatch-Waxman Act- 1984

After the year of 1962 in order to obtain marketing approval in the U.S. for a new drug product, safety and efficacy of that drug product for which the application is made had to be proved[118].

In the same way, prior to 1984 it was also required a generic company to submit to the FDA its own results of tests and clinical trials as same as the innovative firm for which the application was made in order to prove its safety and efficacy before obtaining marketing approval for a generic drug product[119].

This results that in order to place a generic drug product on the market it was required costly and time consuming clinical trials. If the original drug product had been under patent protection, the generic companies had to wait until the patent term expired in order to start their study of tests and clinical trials not to infringe the patent. Since then the original drug manufacturers who had a patent relating to the original drug product, had marketing exclusivity more than their patent term because of lack of generic competence on the market by keeping generic companies under fear of patent infringement. The so-called Hatch-Waxman Act would allow generic companies start to their tests and clinical trials before the expiration of original drug's patent term.

5.2 Data Exclusivity after Hatch-Waxman Act

After Orphan Drug Act which provides marketing exclusivity enacted in 1983, the Drug Price Competition and Patent Term Restoration Act referred to as Hatch-Waxman Act also provides marketing exclusivity enacted in 1984 in order to simplify the FDA's generics marketing approval procedures[120]. This

[118] Rosenstock, section 6, p. 3.
[119] Bittenbender and Ryan, p. 5.
[120] The act increased the generic drug market share from nineteen percent to forty-seven percent in 2003 (Robinson, p. 48.).

act was designed to balance interests of research-based industry and generic makers.

According to Hatch-Waxman Act, there is no need for repetition of tests and clinical trials, which have already been submitted to the FDA by the NDA applicant before granting marketing approval for post-1962 drug products, by the second (/the Abbreviated New Drug Application- ANDA) applicant in order to obtain marketing approval for the same drug product anymore. Thus, the new system introduced ANDA which avoids the repetition of tests and clinical trials in animals and humans while at the same time providing marketing and data exclusivity and also patent term extensions in a limited period of time for the original drug manufacturers in order to compensate their time and money lost during development and completion of NDA. However, the ANDA applicant must prove that his/ or her drug product is bioequivalent to the original drug product and includes the same active ingredients[121].

Thus, the act made the generic firms enter into the market faster and cheaper by providing them to use the test data of innovative drug producer or to make reference to such data while it encourages the innovative firms to produce new drug products. On the other hand, the act has provided protection for the innovative firms against ANDA applicant by requiring ANDA applicants submitting a certification[122] to the FDA before obtaining marketing approval until the term of patents listed in the FDA Orange Book[123] expires and most importantly providing five year data exclusivity for new chemical entities.

Briefly, Hatch-Waxman Act found the middle ground providing innovative firms (pioneers) extended patent protection and five year marketing (and data) exclusivity and also extra six month marketing exclusivity in the

[121] Rosenstock, section 6, p. 3-4.
[122] See, para. 5.3.
[123] The FDA publication "Approved Drug Products and Therapeutic Equivalents" is usually referred to as "the Orange Book" where approved drugs and related patent and regulatory exclusivities are listed by the FDA (Voet, p. 114).

case of providing safety test relating to children[124] and providing generic companies ANDA or paper NDA procedure without requiring them to present the results of their own test and clinical trial studies and also 180-Day marketing exclusivity[125] for the first generic manufacturer.

So, the act grants generic manufacturers three main benefits namely; ANDA application, right to make and test generic drug product before the original drug product's patent term expires and 180-Day generic marketing exclusivity. On the other hand, it also grants pioneers patent term extensions and thirty-month stay provision.

5.2.1 New Chemical Entity Exclusivity

Today, U.S. law provides a five-year data exclusivity as well as marketing exclusivity for drug products containing a new chemical entity which has not been approved by the FDA before in any other application. This five-year exclusivity is provided for the drug products approved by the FDA after September 24, 1984. (ten-year year data exclusivity is provided for the drug products approved by the FDA between January 1982 and September 1984.)

During this time period, The FDA can not approve an ANDA or comparable paper NDA filed under 505 (b) (2)[126] in order to grant marketing approval of generic drugs for the same drug product[127]. In other words, before the exclusive time period expires, the FDA has no power to accept such a second application. But if the patent is listed in the FDA Orange Book, the FDA will accept such an ANDA or paper NDA one year earlier (at the end of fourth year)[128]. When it is taken into account that the procedure of the FDA marketing approval takes about 18 months, it will be clear that the real time

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[124] See para. 3.3 for pediatric exclusivity.
[125] See para. 3.4 for 180-Day marketing exclusivity.
[126] Means that "*A form of filing with FDA for a drug that refers to published data for safety and efficacy. Often used in place of an ANDA for copying an approved drug with some minor changes in the drug formulation or NCE.*" Voet, p. 109.
[127] On the contrary, the FDA may approve an NDA for the same drug product before the exclusivity time period expires.
[128] Rosenstock, chapter 6, p. 7.

period of data and marketing exclusivity in the U.S is more than 5 years actually.

This data and marketing exclusivity is granted for only the first approval of a NCE in a drug product in the U.S. Hence, any second drug product including the same NCE will not be subject to second five year exclusivity[129].

5.2.2 New Use or New Formulation Exclusivity

In the U.S. for a new use or new formulation of a drug product may get a data exclusivity as well as marketing exclusivity of three years. In this regard, new indications for an old drug or new methods of administration or new formulations or other labeling changes of an old drug can be subject to this exclusivity. But new clinical trials except bioavailability studies are also required for obtaining marketing approval[130].

5.3 Conditions of Abbreviated Application under the U.S. Law System

Under the Hatch-Waxman Act, in order to make an abbreviated application, the applicant must meet for the generic drug product for which the marketing approval is demanded those conditions (21 U.S.C. § 355):

i. The active ingredient or ingredients; use of conditions; the proposed labeling; the route of administration, the dosage form, the strength of the generic drug product must be the same as the original drug product,

ii. If there is, one of the active ingredients which is different from the original drug product must be an active ingredient of an already approved drug,

iii. The generic drug product must be bioequivalent to the original drug product. If it is not, it must be proved that the pharmaceutical or

[129] Voet, p. 59.
[130] Voet, p. 60.

therapeutic effects of the active ingredient or ingredients of the generic drug product is the same as the original drug product,

iv. It must be submitted to the FDA an ANDA or paper NDA which must be contained:

a. A components list includes the articles used in the generic drug product,

b. The composition of the generic drug product,

c. Methods and control mechanism used in the manufacturing cycle of the generic drug product,

d. Product and proposed labeling sample of the generic drug product,

v. It must be also submitted to the FDA a certification related to the patent status of the original drug product whether that original drug product is invalid and/ or non-infringed[131].

An ANDA applicant can submit one of the certifications mentioned in four paragraphs of 21 U.S.C. § 355 (j) (2) (A) (vii) numerated I through IV.

An ANDA applicant claims; by submitting Paragraph I Certification that there is no listed patent in the Orange Book; by submitting Paragraph II Certification that any listed patents in the Orange Book have expired; by submitting Paragraph IV that either listed patents in the Orange Book are invalid or not infringed by its drug product. By submitting Paragraph III, an ANDA applicant undertakes that not to place on the market its generic drug product until the original drug's patent will be expired[132].

The ANDA applicant who had submitted Paragraph IV Certification must notify the patent holder that such an application was made. Then the patent/ right holder may start an infringement action against the ANDA

[131] Rosenstock, Chapter 6, p.6.
[132] Burgess and Lucas, p. 12.

applicant in 45 days. In such a case, the district court determines whether there is or not an infringement. If there is such an infringement action, the FDA may not [133]approve the ANDA until the decision of the court is held or the patent of the original drug product expires or 30 month is passed after the patent holder was notified of the Paragraph IV Certification. In the absence of such an infringement action, the FDA may grant marketing approval for the drug product for which the ANDA application is made.

Meanwhile, the "Greater Access to Affordable Pharmaceuticals Act" which provides ANDA applicants to start a declaratory judgment action against the patent holder for its listed patent in the Orange Book was enacted in December 2003 after judgments of District Court at the issue[134].

Briefly Paragraph IV procedure provides the generic companies entering into the market before the expiry of the original drug patent term by challenging at least one patent for that listed drug product[135].

5.4 The U.S. Federal Insecticide, Fungicide and Rodenticide Act- FIFRA

Under this act, test data are protected relating to new agricultural chemical products.

Under the "exclusive use" provision, the data which must be new are protected exclusively in a period of ten year (The U.S. Federal Insecticide, Fungicide and Rodenticide Act- FIFRA 3 (c) (1) (D) (i)).

Under the "data compensation" provision, if the second applicant pay compensation to the originator, most data can be used by subsequent applicants for getting marketing approval (FIFRA 3 (c) (1) (D) (i)).

[133] Rosenstock, chapter 6, p.14.2.
[134] Bittenbender and Ryan, p. 7.
[135] See, para. 3.4 for 180-Day marketing exclusivity.

Under the "joint data development" provision, any number of companies can develop data which are needed for re-registration (FIFRA 3 (c) (2) (B) (ii))[136].

[136] Correa, p. 58.

6 REGULATORY DATA EXCLUSIVITY UNDER EUROPEAN UNION LAW

In the European Community (EC), the rules governing the marketing authorization (MA) of medicinal products were harmonized in 1965 by Council Directive 65/65/EC[137]. Subsequently, data exclusivity was codified first by Directive 87/21/EEC amending Directive 65/65/EEC and brought together in a single text, Directive 2001/83/EC[138]. The aim of that alteration was to protect originator drug products better and to avoid the repetition of tests and clinical trials in humans and animals unless necessary. This alteration has been the starting point for generic drug producers to reference to the data submitted by innovative drug producers through the abridged procedure[139].

6.1 Abbreviated Application Before 2005 (6 or 10 years protection time period)

Article 10/1 (a) (iii)[140] of Directive 2001/83/EC[141] of the European Parliament and of the Council of 6 Nov. 2001 on the Community code relating to medicinal products for human use provides that under certain conditions, the second marketing authorization[142] can be obtained by generic companies without being required to provide the results of toxicological and pharmacological tests or clinical trials[143] if it can be demonstrated that the medicinal product is a generic version of a reference medicinal product which

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137 Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ L No 22 of 9.2.1965, p. 369).
138 Zahl, Chapter 7, p. 54.
139 Işıklı, p. 26.
140 Corresponding to Directive 65/65/EEC art. 4/8 (a) (iii).
141 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001on the Community Code Relating to Medicinal Products for Human Use (OJ L No 311 of 28.11.2001, p. 67–121)
142 "A marketing authorization may only be granted to an applicant established in the Community" (Article 8/2 of Directive 2001/83/EC).
143 The first applicant must submit *"Results of: - pharmaceutical (physico- chemical, biological or microbiological) tests, - pre-clinical (toxicological and pharmacological) tests, - clinical trials"* (Article 8/3 (i) of Directive 2001/83/EC) to the competent authority in order to obtain marketing authorization in EU.

has been authorized in a member state or in the Community before. This procedure is so-called "abridged procedure".

6.1.1 Conditions of abridge application

If a medicinal product is "essentially similar" to a product which has been granted marketing authorization (MA) within the Community, for not less than six years or ten years in the case of high-technology medicinal products, that medicinal product (a generic one) will have an opportunity to be subject to an abridged procedure without being provided the results of pharmacological and toxicological tests or clinical trials (Case C-368/ 96, Paragraph 20)[144].

6.1.1.1 "Essentially Similar Product" Requirement

The European Court of Justice (ECJ) held in its judgment, Case C-368/ 96, that the concept of essentially similar product can not be interpreted in such a way that the abridged procedure may not meet the requirements of safety and efficacy of medicinal products and added that the aim of *"that procedure is merely intended to reduce the time needed to prepare an application for authorization by freeing the applicant from the obligation to carry out the pharmacological and toxicological tests and clinical trials referred to in Article 4.8 of Directive 65/65, the objective of which is to prove the safety and efficacy of medicinal products* (paragraph 23)*"*.

In this case, the ECJ described the term of "Essentially Similar Product" as *"a medicinal product is essentially similar to an original medicinal product where it satisfies the criteria of having the same qualitative and quantitative composition in terms of active principles, of having the pharmaceutical form and of being bioequivalent, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety and efficacy* (Paragraph 36)*"*. In the subsequent paragraph of the same judgment, the ECJ held that in the absence of those three criteria

[144] Judgment of the ECJ (Fifth Chamber) of 3 December 1998, Case C-368/ 96, http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61996J0368, (10 August 2007).

mentioned, the competent authority of a Member State can not determine whether a particular medicinal product is essentially similar to an original medicinal product.

The ECJ laid down in the said Case that the abridged applicant may obtain marketing authorization for all therapeutic indications (Paragraph 53), for all dosage forms, doses and dosage schedules already authorized for that product (Paragraph 56).

The ECJ also rejected in this judgment the submission of the Commission on the issue which provides an autonomous data exclusivity for the therapeutic indications representing "major therapeutic innovation" on the ground that the term of "major therapeutic innovation" is insufficiently precise and also this kind of protection is contrary to the wording of the provision at issue (paragraph 45-48).

6.1.1.2 Expiry of Six or Ten Year Data Exclusivity Time Period

Before six (or ten) year exclusive time period from the date of the original drug product was being granted MA in the Community had been expired, an application of abbreviated MA could not be made by a subsequent applicant for the drug product essentially similar to that original drug product (Article 10/ 1 (a) (iii)).

Six or ten year data protection term was in the discretion field of member states if the products were approved by the mutual procedure. In the case of centralized recognition procedure, data protection term was ten-year for all member states[145].

[145] With adoption of Regulation 2309/93 and Directive 93/41, a new application system which came into force in 1995 was established in the EU. This new system provides to make a MA through the EMEA (centralized procedure) or by the national agencies recognized by each other (mutual recognition procedure).

6.1.1.3 Marketed in the Application Country

Another condition, mentioned in the said article in order to obtain marketing authorization for a medicinal product which was essentially similar to the original one which had been authorized for not less than six years in the Community, was that that original drug product must have been marketed in the member state where the abridged application was made.

Consequently, in the EU before 2005 under Article 10/1 (a) (iii)[146] of Directive 2001/83/EC if those three criteria mentioned were met for a generic drug product and that generic drug product was not significantly different from the original drug in terms of efficacy and safety, there was no need to supply the results of pharmacological and toxicological tests or of clinical trials to receive marketing authorization for a generic drug product.

6.2 Abbreviated Application After 2005 (8 year data exclusivity plus 2 year marketing exclusivity plus 1 year for new therapeutic indications marketing exclusivity)

On the date of 31 March of 2004, ***Regulation (EC) No 726/2004***[147] *of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and also* ***Directive 2004/27/EC***[148] *of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use* has been adopted. This new phase is the result of the 2001 review studies started with the European Commission.

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[146] Corresponding to Directive 65/65/EEC art. 4/8 (a) (iii).
[147] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency (OJ L No 136 of 30.04.2004, p. 1–33).
[148] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use (OJ L No 136 of 30.04.2004, p. 34–57).

Under new system, the innovative drug producers have eight-year data and also marketing exclusivity plus two more (8+2) years (in certain cases 8 + 2 + 1 = 11 year) marketing exclusivity. This time period is valid for both mutual recognition and centralized procedures.

In other words, an original drug product has eight year marketing and data exclusivity from the date of obtaining marketing approval in the Community but after this eight year only marketing exclusivity maintains for two years. This means that, after that eight year, a generics firm can make an abridged application without waiting the ten-year marketing exclusivity time period expires and it will have an opportunity to place its generic drug products on the market when that ten-year (eleven year in certain cases) marketing exclusivity time period for initial authorization of the reference product expires[149].

In the EU legislation, one more year (1+10 year) extra marketing exclusivity time period is added to the originator drug product for one or more new therapeutic indications authorized in the first eight years of that ten year while in the U.S. that extra time period is added to only new indication in question not also to the originator drug product[150].

Also in the EU legislation, one more year data protection is provided for new indications of well-known substances (Article 10/5 of Directive 2001/83/EC amended by Directive 2004/27/EC). It is no matter whether the applicant is originator drug producer or generic drug producer[151].

[149] See, Article 10/1 (sub-paragraph 2) of Directive 2001/83/EC).
[150] Işıklı, p.30.
[151] Işıklı, p.32.

7 REGULATORY DATA EXCLUSIVITY UNDER TURKISH LAW

7.1 Historical Background of Data Protection in Turkish Law System

Turkey, as a candidate to the EU today, has a relationship with the EU in two separate spheres. One of them is on the level of association relation between Turkey and the Community established by the Ankara Agreement[152] signed in 1953 and the latter is on the level of candidacy[153] on the basis of Copenhagen Summit, December 2004. Both of the relationships were established on the ground of aiming full membership[154].

In this context, duties of parties derived from the Association Agreement are continued. As a result of Additional Protocol[155], in 1994 the Customs Union has been established between Turkey and the Community by the Decision No. 1/95 of Turkey-EC Association Council which also covers the fields of competition law, IPR and state aids before Turkey became a full member of the EU.

Until the Decree Law No. 551 concerning the Protection of Patent Rights was enacted, there was no patent (and also data) protection for

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[152] Agreement establishing an Association between the European Economic Community and Turkey, signed at Ankara, 12 September, 1963, (OJ No L 361 of 31.12.77, p. 1-33). The Agreement provides three stages take Turkey to full membership to the Community. With the completion of Customs Union between EC and Turkey, the transitional stage has been completed and it is also reached to the last (final) stage.

[153] The application of full membership of Turkey was made in 1987.

[154] See, Ankara Agreement, art. 28 "As soon as the operation of this Agreement has advanced far enough to justify envisaging full acceptance by Turkey of the obligations arising out of the Treaty establishing the Community, the Contracting Parties shall examine the possibility of the accession of Turkey to the Community".

[155] Additional Protocol and Financial Protocol signed on 23 November 1970, annexed to the Agreement establishing the Association between the European Economic Community and Turkey and on measures to be taken for their entry into force (OJ No L 293 of 29.12.1972, p. 4–56). Additional Protocol was signed in 1970 and came into force in 1973. The Protocol started the transitional stage and providing the establishment of a customs union between Turkey and the Community.

pharmaceuticals in Turkey. Article 3 of the "Law of Patents of Invention" of 23 March 1879 in force between 1879 and 1995 years had excluded pharmaceutical compounds and all sorts of medicine and items of remedy from patentability[156]. The scope of article 3 was extended to the process patents in 1961[157]. Several times, Article 3 had been subject to invalidation before the Constitutional Court. The Court held that Article 3 was not contrary to the Constitution since the common interest prevail the individual interest in question[158].

Patent protection in pharmaceuticals was granted in Turkey in January 1, 1999. However, applications for pharmaceutical patents had already been examined since January 1, 1995[159]. This was the result of the Article 70/8 of the TRIPS Agreement[160] requiring member countries which would not provide patent protection for pharmaceuticals to examine the patent applications in pharmaceuticals from the date of January 1, 1995.

Under the Article 49[161] of the Decree Law No. 551, patent applicants hold a right of priority of twelve months in certain conditions. This means that in some cases the actual date to examine the pharmaceutical patent applications started from the date of January 1, 1994. As a result, pharmaceutical products patented before 1994 in any country in the World could not be subject to patent protection in Turkey.

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156 Arman S. Kırım, "Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry", **World Development,** V. 13, No: 2/1985, p. 232, footnote 6.

157 Tekinalp, **Fikri Mülkiyet Hukuku (Intellectual Property Law),** p. 506.

158 Decision of the Turkish Constitutional Court, June 28, 1995, Case No: 1994/77, Decision No: 1995/24, http://www.anayasa.gov.tr/eskisite/KARARLAR/IPTALITIRAZ/K1995/K1995-24.htm, (13 August 2007).

159 Yalçıner, p. 17; Tekinalp, **Fikri Mülkiyet Hukuku (Intellectual Property Law),** p. 506–507.

160 Turkey signed the Agreement Establishing the World Trade Organization (WTO) and its annex TRIPS Agreement in April 15, 1994 and Grand National Assembly of Turkey ratified it in January 26, 1995.

161Article 49/1 of the Decree Law No. 551 concerning the Protection of Patent Rights lays down that "*Natural or legal persons who are nationals of any State party to the Paris Convention, or when not nationals, who are domiciled or have an active business in these States, shall enjoy a right of priority of twelve months as from the date of filing an application for the grant of a patent or a utility model certificate before the authorized bodies of these States, for the purpose of filing an application for obtaining a letter's patent or utility model certificate in T*urkey".

Turkey has also rejected the so-called "pipeline protection" for pharmaceutical products which was brought by the U.S. and EU several times before Turkey, on the basis that there is no such a kind of protection either in international law and Turkey is not a Member State of the EU[162].

7.1.1 Article 8 of the Decision No. 1/95 and Article 1 of the Decision No. 2/97 of Turkey-EC Association Council

By Article 8/1 of the Decision No. 1/95 of EC–Turkey Association Council[163], Turkey was required to adopt her legislation to the Community instruments relating to the removal of technical barriers to trade within five years[164] (this means to the end of year 2000) from the date of said Decision will be in force.

Article 8/1 and 2 of the Decision No. 1/95, and Article 1/2 of the Decision No. 2/97 of Turkey–EC Association Council[165], require Turkey to adopt her legislation to the Community instruments relating to the removal of technical barriers to trade (Art. 1/1, Decision No. 2/97) which also contains EC Regulations and Directives relating to the Data Protection listed in the Annex to the said Decision No. 2/97.

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[162] Yalçıner, p.30: "pipeline protection" as a bilateral agreement provides patent protection for the drug products which were patented several yeas ago but are still in force in the main country or other country, to be protected in the country where there was no patent protection before the agreement.

[163] Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (OJ NO L 35 of 13.2.1996, p. 1).

[164] Article 8 of the Decision No 1/95 of The EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (96/142/EC), under the section I Elimination of customs duties and charges having equivalent effect is that: *"1. Within five years from the date of entry into force of this Decision, Turkey shall incorporate into its internal legal order the Community instruments relating to the removal of technical barriers to trade. 2. The list of these instruments and the conditions and detailed arrangements governing their implementation by Turkey shall be laid down by decision of the Association Council within a period of one year from the date of entry into force of this Decision. 3. This provision shall not preclude the application by Turkey, with effect from the date of entry into force of this Decision, of Community instruments deemed to be of particular importance. 4. The Parties stress the importance of effective cooperation between them in the fields of standardization, metrology and calibration, quality, accreditation, testing and certification."*

[165] Decision No 2/97 of The EC-Turkey Association Council of 4 June 1997 establishing the list of Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey (97/438/EC), (OJ NO L 191 of 21.7.1997, p. 1-67).

Thus, Turkey should provide data protection for pharmaceuticals at latest by the end of the year 2000. In this regard, as it is given details bellow, Turkey enacted the first Directive in the field of data protection for pharmaceuticals in 1995 and also enacted the second one in 2005 which is in force.

7.1.2 Article 83/3 of the Decree Law No. 551 concerning the Protection of Patent Rights

Article 83/3 of the Decree Law No. 551 lays down that *"Where an application for patent has been filed for pharmaceutical or veterinary products/drugs and for chemicals destined to agriculture, the authorities issuing authorizations/licenses for the manufacture and sale of such products and requesting for this purpose information and test results, that were not disclosed to the public and the realization and accumulation of which requires considerable expenses and efforts, shall keep such information and test results secret/confidential. The authority asking for such information and test results shall take the necessary measures to prevent unjustified/unlegitimate use thereof."*[166].

This provision contains the same principles laid down by the TRIPS Article 39.3 in basically similar words. Thus, this provision has been taken into account when data protection rules are considered in Turkish legislation. But neither in Article 39/3 of TRIPS or in Article 83/3 of the Decree Law No. 551 there is no any time period mentioned for data protection. So, without time limitation it is not possible to constitute a data protection system. On the other hand it is under discussion whether or not that provision provides data protection in pharmaceuticals. However, after the provision Article 9 (explained below) of Directive 19 January 2005 which clearly provides data protection for a limited time period enacted in 2005, the importance of the discussion around Article 83/3 of the Decree Law No. 551 has decreased.

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[166] Cahit Suluk, Ahmet T. Keşli and Ali Orhan, **Uygulamalı Fikri Mülkiyet Hukuku (Practical Intellectual Property Law), V. I, Mevzuat (Laws and Regulations),** Istanbul: Arıkan Publishing, 2005, p. 319.

7.1.3 Abbreviated Application and Data Exclusivity in Turkish Law System

The Directives No 22218 of 02 March 1995[167] and No 25705 of 19 January 2005[168] both confer on applicant abbreviated application procedure for pharmaceutical products under some certain different conditions. Like in the EU, in those abbreviated application procedures, applicants are not required to present their own pharmaceutical and toxicological test results and clinical trials related to their pharmaceutical products for which the abbreviated application is made to the Ministry of Health in order to obtain producing license and marketing approval. However, the Directive dated 2005 contains more detailed provisions relating to abbreviated applications.

7.2 Article 56 and 57 of the Turkish Commercial Code

Articles 56 to 65 of the Turkish Commercial Code lay down unfair competition rules. According to Article 56, misuse of economic competition in any way contrary to good faith is unfair competition. Some of the acts are listed in Article 57 as an example of unfair competition. In this regard, the act of taking an unlawful benefit from trading or manufacturing secrets which are obtained or learnt contrary to good faith (Art. 57/8) is also listed such as an unfair competition. As a result, undisclosed information is under protection of Turkish Commercial Code under the title of unfair competition[169]. In fact as it is pointed out above, Turkey is under obligation to provide protection for undisclosed information independently from the internal provisions under TRIPS provisions and the EU legislation through the Decision No. 1/95 and the Decision No. 2/97 of Turkey –EC Association Council. In this sense, Art. 57/8 is corresponding to the Art. 39.2 of TRIPS which provides protection for trade secrets. However, data protection was enacted in another sub-paragraph Art. 39.3 independently. Thus, Art. 57/8 provides protection for trade secrets

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[167] Directive No 22218 of 2 March 1995 concerning the Licensing of Medicinal Pharmaceutical Products. http://www.psikofarmakoloji.org/dernek/kanunveyonetmelikler11.asp, (20 August 2007).

[168] Directive No 25705 of 19 January 2005 concerning the Licensing of Medicinal Pharmaceutical Products. http://www.mevzuat.adalet.gov.tr/html/23079.html, (23 August 2007).

[169] Tekinalp, **Fikri Mülkiyet Hukuku (Intellectual Property Law),** p. 20.

more than test data. But Art. 56 describes unfair competition as any act contrary to good faith and counts under Art. 57 such kind of acts not in exhausted manner. So, in certain cases, data protection can be considered under Art. 56 and 57. However, it is seriously under discussion to implement unfair competition rules to IP rights along with them or independently.

7.3 Abbreviated Application Before 2005

In Accordance with Article 9 of Directive 02 March 1995, it was enough to meet one of two conditions mentioned in said article to make abbreviated application and to obtain license (and marketing approval).

Art. 9/I-a of said Directive states as first condition that the applicant's pharmaceutical product must be exactly the same product which was granted license by the Ministry before. In this context, the pharmaceutical product subject to abbreviated application has to be the same qualitative and quantitative composition, in the same form, used in the same way with and proved its bioequivalence to the original drug product approved before upon requirement, according to related Regulation if it is required.

The second independent condition mentioned in Art. 9/I-b of said Directive is that the applicant must prove efficacy, safety and common pharmaceutical use of new active substance/substances in question by reference to the published literature.

In both conditions, Art. 9/II of said Directive requires that the applicant must present to the Ministry of Health published literature information about the safety and efficacy of the pharmaceutical product in question. Meanwhile, it must be added that there was no time period mentioned for Data Exclusivity in said Directive.

The Turkish Council of State in 2004 held in a Decision[170] that, Article 9 of the Directive 1995 which had provided abbreviated application for generic

[170] Decision of the Tenth Chamber of the Turkish Council of State, April 26, 2004, Case No: 2002/3812 Decision No: 2004/4064, (**FMR,** year: 4, Volume: 4, Issue: 4/2004, p.166–182).

drug products was not contrary neither to the TRIPS nor the national legislation.

The claimant, claimed in this case, invalidation of the Article 9 of Directive 1995 and the decision, March 21, 2002, No 1999/69 of the Ministry of Health granted license and marketing approval for the drug product namely Tarden in 40 mg form, the generic version of originator drug product namely Lipidor containing the active ingredient called Atorvastatin, based on Article 9 of Directive 1995 on the basis that both of the Article 9 and Decision No 1999/69 of the Ministry are contrary to the obligations of Turkey derived from the international agreements, TRIPS 39 and Decisions of Turkey–EC Association Council and also to the national legislation.

The main argument of the claimant and intervener beside the claimant is that the alleged Article 9 of Directive 1995 creates unfair competition in the context of Art. 56 and 57 of the Turkish Commercial Code since that Article 9 provides generic firms to manufacture and to place on the market generic version of originator drug products effortless.

On the contrary to the claimer and intervener, the defendant (the Ministry of Health) argued that both of the Article 9 and Decision of the Ministry are not contrary to neither superior norms nor the TRIPS. In addition to the defendant, the interveners beside the Ministry argue that the data which were used in order to manufacture the generic drug product in question were obtained from the published literature; test results of bioavailability/ bioequivalence studies according to Article 9, are provided; the claimer has not any lost result from neither the Article 9 nor Decision of the Ministry in question.

The Tenth Chamber of the Turkish Council of State held its judgment on the basis that the submission of test data and clinical trials for which the abbreviated application was made, was within the discretion of the Ministry of Health. The court also said that the submitted test data in the hand of the Ministry of Health have not been used in order to manufacture a generic version of that innovative drug product since the bioequivalence must be

proved in order to find out whether or not a certain amount of an active ingredient has the same effectiveness with a different amount of the same active ingredient. The court also added that, bioequivalence studies must be submitted to the Ministry by the abbreviated applicant before the marketing approval granted.

Meanwhile it is highly remarkable of the court's point of view stating that the active ingredient and the effectiveness of the generic version of the original drug product are known and not undisclosed information since all this information would become in public knowledge when the original drug product was granted marketing license. Thus, Article 9 of the Directive 1995 is not contrary to the TRIPS 39 and the claim relating to the invalidation of Article 9 must be rejected.

Plenary Session of the Administrative Law Divisions of The Turkish Council of State in 14.04.2005 upheld[171] an essentially similar Decision[172] of the Tenth Chamber of the Turkish Council of State, April 26, 2004, Case No: 2002/3813 Decision No: 2004/4066, concerning the same generic drug product with 20 mg form, on the basis of the reasons decided by the Tenth Chamber of the Turkish Council of State. There is no any explanation in this judgment except the sentence in the last paragraph saying "the Decision of the Tenth Chamber of the Turkish Council of State is in conformity with the law and legal procedure and the claims of appellant are not enough to overturn the Decision of the Tenth Chamber."

According to Article 141/3 of the Constitution of the Republic of Turkey "The decisions of all courts shall be made in writing with a statement

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[171] Decision of the Plenary Session of the Administrative Law Divisions of the Turkish Council of State, April 14, 2005, Case No: 2004/2665 Decision No: 2005/267, http://www.danistay.gov.tr/kerisim/container.jsp, (23 August 2007).

[172] Decision of the Tenth Chamber of the Turkish Council of State, April 26, 2004, Case No: 2002/3813 Decision No: 2004/4066, rejected the claims concerning to invalidation of the Article 9 of Directive 1995 and the decision, March 21, 2002, No 1999/68 of the Ministry of Health granted license and marketing approval for the generic drug product namely Tarden in 20 mg form, http://www.danistay.gov.tr/kerisim/container.jsp, (23 August 2007).

of justification"[173]. Under this constitutional clear provision, the said decision of the Plenary Session is contrary to the Constitution since it has no any explanation about the reasons based on by the Plenary Session in its Judgment and why the claims of appellant are not enough to overturn the Decision of the Tenth Chamber.

In the light of above mentioned provision and its implementation it is difficult to say that there was an effective data protection consistent with the EU legislation in Turkish law system before Directive 2005 since the provision did not provide any time period for the protection of submitted data, even though the Directive 1995 had made the Ministry (of Health) responsible[174] for protection of marketing approval data submitted by the first applicant.

In granting a generic drug product license and marketing approval, without requiring re-given test results and clinical trials made before by the applicant of originator drug product, as referred to abridged procedure, before the data exclusivity time period expires, it makes no sense making the Ministry responsible for protection of the data received from the applicant of originator product when the second applicant makes reference in published literature to that marketing approval data. So, in the case of absence of such an exclusive time period for data protection, the generics applicant could make abbreviated application without submitting test and clinical trials made before by the first applicant and would be granted license and marketing approval for the generic pharmaceutical product in question without waiting for the expiry of data protection time period.

7.4 Abbreviated Application After 2005

Like the Directive dated 02 March 1995, Directive 19 January 2005 also provides abbreviated application for generic drug products with the exception of related provisions of the Decree Law No 551 concerning the Protection of Patent Rights.

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173 http://www.anayasa.gov.tr/images/loaded/pdf_dosyalari/THE_CONSTITUTION_OF_THE_REPUBLIC_OF_TURKEY.pdf, (23 August 2007).

174 See, Art. 36 of the Directive No 22218.

In Accordance with Article 9/I-a of Directive 19 January 2005, it is enough to meet one of three conditions mentioned below for abbreviated application and granting marketing license. So, applicants do not have to present, the results of toxicological and pharmaceutical tests and clinical trials to the Ministry for making abbreviated application and granting marketing license if they can prove one of three conditions explained below.

However, if a generic drug product differs from the originator drug product in a way of having different way of use; different therapeutic indication and different dosage form, applicants have to present results of clinical trials and if required, they also have to present toxicological and pharmaceutical test results in order to make that abbreviated application (Art. 9/I-a-3/sub-prag.2).

Applicants have to present the results of their toxicological and pharmaceutical tests and clinical trials of new drug products which contain known compounds which have not been used as a combination for therapeutic use before in order to make abbreviated application. But it is not required to present references for every single compound article (Art. 9/ I-b).

The conditions of Article 9/I-a of Directive 19 January 2005, for making abbreviated application and granting marketing license, are listed below:

7.4.1 Established Safety and Efficacy Use of constituent or constituents of Drug Product

If the constituent or constituents of a drug product has/have a well established medicinal use in a way that provides reasonable efficacy level and acceptable safety which is fixed by the way of detailed scientific bibliography, the generic company will be able to obtain marketing license (Art. 9/I-a-2) without presenting their own test results or clinical trials.

If an abbreviated applicant chooses this way for making the abbreviated application, application must be made according to appendix 1 of the Directive (Art. 9/II).

7.4.2 Consent of the Marketing License Holder of Originator Pharmaceutical Drug Product

If a pharmaceutical drug product is essentially similar to the pharmaceutical drug product which was granted marketing license in Turkey before and also toxicological, pharmaceutical and/or clinical references existing in the file of that originator drug product can be used with the consent of the marketing license holder of that originator drug product for the aim of examination of the application in question, the generic company will also be able to obtain marketing license without presenting their own test results or clinical trials.

In other words, according to Article 9/I-a-1 of Directive dated 19 January 2005, without having consent of license holder (the originator pharmaceutical product producer) the generic companies can not obtain marketing license and marketing approval based on the submitted test data of that originator pharmaceutical product before the data exclusivity time period which will be explained below expires.

There was no such a permission condition in the former Implementation Regulation (see, sub-paragraph Art. 9/I-a of Directive 02 March 1995). As mentioned above, in the said former Implementation Regulation it was enough being the same product as the original one to obtain license and marketing approval for generic drug products. Such a provision not requiring consent of the license holder was not consistent with the provisions either of the TRIPS and the Decisions No. 1/95 and No. 2/97 of Turkey –EC Association Council.

7.4.3 Lack of Consent of the License Holder of Originator Pharmaceutical Drug Product

In the event of expiration of the data exclusivity period of the licensed originator drug product based on the provisions pending, there is no need to get consent of the license holder in order to grant license and marketing approval if the drug product in question is basically similar to that originator

drug product (amended article 9/I-a-3). The issue of the data exclusivity time period in Turkish law system is subject to following sub-paragraph of this Thesis.

There is also an exception provision in the last (2005) Directive. According to last sub-paragraph of Article 9, the Ministry (of Health) has power to determine about the generic drug license applications based on the clinical, pharmaceutical and toxicological data published in the literature without getting consent of the license holder when there is a serious threat against the public health. This provision is consistent with both TRIPS and Decisions of Turkey –EC Association Council since that kind of implementation is provided in those systems. It must also be added that the consideration of the public health is in the discretion of Turkish authorities.

7.5 Data Exclusivity Time Period in Turkish Law System

Today, Turkish law system provides six-year data exclusivity for originator pharmaceutical products. This six-year time period is limited with patent time period for the patented products registered in Turkey (amended article 9/I-a-3).

According to Gorlin[175], the national provisions which limit the exclusive data protection term with the life of patent are obviously inconsistent with the TRIPS Article 39.3 since the data exclusivity is an independent right from other type of industrial property rights such as patent. Gorlin also says that the term of "trade secret" is not used in the Article 39.3. indicating the situation of the data exclusivity to be an independent right. In this context according to Gorlin's point of view, limitation of data exclusivity time period with the duration of patent term of drug product such as provided for Greece and Portugal in the E.U. is inconsistent with Article 39.3.

On the contrary, the limitation of data protection with the duration of patent term in Turkish law system is consistent with the provisions of the TRIPS since the Article 39.3 of TRIPS does not impose a minimum time period

[175] Gorlin, p. 40.

for data protection. This limitation is also consistent with the Decision No. 1/95 and the Decision No. 2/97 of Turkey–EC Association Council since the Article 10/1 (a) (iii) of Directive 2001/83/EC had provided *"Member States are at liberty not to apply the six-year period beyond the date of expiry of a patent protecting the original medicinal product."*

While there was no such a time period for data exclusivity in the Directive No 22218 of 02 March 1995, today Directive No 25705 of 19 January 2005 provides mentioned six-year data exclusivity time period for originator pharmaceutical drug products.

In accordance with article 9, amended[176] sub-paragraph I/a-3 of Directive No 25705 of 19 January 2005, six-year data exclusivity time period is provided for the originator drug products which would get license after the date of 1 January 2005 in one of the member countries of the Customs Union and for the originator drug products which had been granted license first time after 1 January 2001 in one of the member countries of the Customs Union with the condition of that there is no generic license application for that originator drug product until 1 January 2005 in Turkey. Six-year time period starts from the date of granting license first time in the area of the Customs Union.

7.6 Protection of Marketing Data against Disclosure

Article 28 of Directive dated 19 January 2005 states that data which is submitted to the Ministry (of Health) by the applicant for obtaining marketing license (and marketing approval), is secret and that secrecy is protected by the Ministry (of Health). Art. 36 of Directive dated 02 March 1995 had also provided that kind of protection in similar words.

It should also be added that people who violate the provisions of the Regulation are punished according to the provisions of Turkish Criminal Code and other Turkish criminal rules (Art. 29, Directive 2005).

[176] This provision was amended by article 1 of Directive No 25842 of 11 June, 2005.

7.7 Conclusion

In Turkish law system today there is a data exclusivity system established after Regulation 2005 consistent with TRIPS 39.3 but it is not totally in harmony with the EU legislation today. Within the framework of Article 8/1 and 2 of the Decision No. 1/95, and Article 1/2 of the Decision No. 2/97 of Turkey–EC Association Council, Turkey adapted her legislation to the EC legislation. In this regard, Directive 2001/83/EC was incorporated into the Turkish legislation as Regulation 2005.

However, EU have continued to put into effect new Regulations and Directives related to the subject, namely Regulation (EC) No 726/2004 *laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and also* Directive 2004/27/EC *amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.* These new legislation put forward data exclusivity time period for more than provided in Directive 2001/83/EC and also in Regulation 2005 in Turkish legislation in force. So, it is apparent that in order to harmonize fully Turkish legislation with the EU legislation, there is need to incorporate Directive 2004/27/EC into Turkish legislation.

Besides data exclusivity time period amendments, other type of marketing exclusivities for innovator firms and rules which provide benefits for generics are also needed in Turkish law system.

In this regard, marketing exclusivities such as patent term extensions, product improvements, pediatric exclusivity and orphan drug exclusivity should be adopted for the benefit of originator drug product manufacturers along with rules providing generics firms preparing and making an abbreviated application for obtaining marketing approval but not marketing before data exclusivity time period expires.

Such kind of legislation and proper implementation will establish a fair competition and make balance between the benefits of innovator and generics firms. In addition, that will make Turkish firms more competitive and

innovative. Investment much more in R&D studies and finding out new chemical substances and remedies are not the only benefits for innovator firms but also for the public and even for the generics firms. R&D studies will make Turkey also more powerful in the international area since as State providing data exclusivity established and implemented well, will bring more foreign investment and other several advantages.

8 CONCLUSIONS

It is obvious that the data protection/ exclusivity rules are not only related to financial terms, it is also related to the public health and social and ethic issues. Because of this fact, a pharmaceutical drug product is not an ordinary product on the market. On the contrary, as a medicinal product it must have a high level of qualitative and quantitative qualifications and also it must be proved that that medicinal drug product is safe and effective for human use. Thus, the national regulatory authorities require applicants to present their toxicological and pharmacological test and clinical data made in animals and humans for the medicinal product for which the application is made in order to grant marketing approval. There is no debate on this matter. The problem appears when the second applicant seeks to use or rely on that test data submitted by the first applicant in order to obtain marketing approval for the same medicinal drug product as a generic version of pioneer drug.

So, the answer must be given to the question of whether national health authorities enjoy power to grant second applicant marketing approval by relying on the submitted test data or whether the second applicant may use or relies on the submitted test data.

It is fact that under TRIPS 39 and Article 10bis of the Paris Convention rules, the submitted test data, as undisclosed information, are under protection against unfair commercial use and also member states are under obligation to protect that kind of undisclosed information against unfair commercial use and also they have obligation to keep that secrecy.

When national regulatory authorities actually use or rely on the test data submitted by the originator drug producer in order to examine the subsequent application for granting marketing approval or if generic companies use or rely on that undisclosed information submitted by the innovator in order to prove the safety and efficacy of their pharmaceutical drug products for the aim of obtaining marketing approval on the basis of

bioequivalence or bioavailability studies before data exclusivity time period expires, the provisions of data exclusivity will be applied.

On the other hand, if national health authorities do not actually use or rely on the results of tests or the clinical trials, in order to assess the second entrant's application for granting marketing approval, or if the second entrant obtains marketing approval on the basis of public information or other data published, the provisions of data exclusivity will not be applied since there is no unfair commercial practice as explained above.

The U.S., the EU, and also some other developed countries and their research-based pharmaceutical industries demand such a data protection and minimum exclusive time period in order to assist the research-based pharmaceutical industry. This exclusive time period for pharmaceutical drug products is up to eleven (8+2+1) years in the EU while in the U.S. five years for the pharmaceutical drug products. However, normally in E.U. ten year exclusive time period is provided for marketing exclusivity. The data exclusivity lasts only eight years. This means that in the E.U. after eight years from the date of approval of a pharmaceutical drug product, a second applicant may apply to the EMEA in order to obtain marketing approval for his generic drug product similar to the originator drug product but this marketing approval will not be granted by the EMEA before the ten-year marketing exclusivity time period expires. In certain conditions extra one more year marketing and also data exclusivity time period is also granted.

On the contrary to the developed countries, developing countries and some other developed countries such as Canada and generic companies interpret the data protection rules more flexibly.

The generics industry demand to make reference freely to the test data submitted to the national regulatory authorities by the innovator firms in order to obtain marketing approval without being under obligation for repetition of those tests in humans and animals and clinical trials. Such an interpretation sounds ethical first but there must be a balance point between the benefits of the parties.

In this regard, an originator drug producer who invests so much money and spend so much time in order to invent a new drug product and to obtain marketing approval of that drug product, must be supported by patent and data exclusivity protection in order to encourage him or her to invest much more money in order to invent other new drugs. But after patent and data exclusivity time period, generics companies should make reference freely to the data which was submitted to the national drug authorities for obtaining marketing approval. Making reference to the data freely, excludes making the same clinical tests in animals and humans again. It also results paying lower fee for the same drug product. This is the balance point found as a compromise today between the parties and used internationally.

In the international level, particularly TRIPS Art. 39 which is directly related to data exclusivity has importance and influence in the legal orders of the member countries.

However, TRIPS 39 is not clear enough to establish a data protection system well since it contains no any certain exclusive time period for data protection unlike NAFTA. In addition, it has not been accepted as an exclusive and independent IP right like patents etc. by some member countries. But it has been legislated under an independent provision as other IP rights. This indicates that the legislation, in international level, related to data exclusivity has not been completed yet. In domestic level, most of the developed countries and also EU and research based companies accept data protection as an exclusive and sui generic IP right like other IP rights such as patents, trade marks etc.

Data exclusivity, as an independent right, has some certain differences from the patents. These differences are important since both the data exclusivity and patent protection provides similar protection for pharmaceutical drug products. Meanwhile data protection is vital where patent protection is not provided or the substance which is subject to protection is not patentable.

In the case of Turkey, under the provisions lay down by Art. 83/3 of the Decree Law No. 551 and Directive 2005 and also under the provisions of TRIPS Art. 39 and Article 8/1 and 2 of the Decision No. 1/95, and Article 1/2 of the Decision No. 2/97 of Turkey–EC Association Council which require Turkey to adopt her legislation to the Community instruments contains EC Regulations and Directives relating to Data Protection, it is clear that data protection is provided as an exclusive and sui generis right.

Six-year data exclusivity remains behind the EU legislation. Providing (8 + 2 + 1 = 11 year) data exclusivity time period will make our data protection system better. But this decision should be made in time by politicians on the basis of national benefits. In other words, it is more related to the national policy whether or not a full harmonization with EU legislation in question before entry into the EU will be completed.

Besides data exclusivity, some other types of protection systems are provided in some major countries and in the EU. For instance, patent term extension is one of the most important ones. Contrary to the US and EU there is no patent term extension in Turkey yet. This kind of legislation provides patent holders to make up their time lost during the procedure of obtaining marketing approval from the national authorities. Adopting such legislation will also make our Intellectual property system better.

Finally, it should be answered to the question of whether the innovative firms after the data exclusivity time period can or can not rely on unfair competition rules. As it is known cumulative system, which is also provided in our IP law, let the right holder to rely on one more than IP rights at the same time independently if their conditions are met. This is also valid for unfair competition rules. But after IP rights are exhausted, data exclusivity time period in this case, if there is not any indication which may create confusing in relation to the origin of the product (originator drug product), unfair competition rules (Articles 56 to 65 of the Turkish Commercial Code) can not be applied. This is also the balance point between the benefits of the

parties, in exchange of an exclusive data protection system, using or relying on test data freely after that exclusive time period.

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