

**TURKEY AIMS AT FULL HARMONISATION WITH THE
EU *ACQUIS COMMUNAUTAIRE* IN INTELLECTUAL
PROPERTY AS A REQUIREMENT OF MEMBERSHIP**

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I. Introduction

In the Turkish Republic, the aim of full membership in the European Union has been the driving force behind a 40-year old project of adjustment and development, adopted by all governments as part of the country's "westernization" program. The political and economic criteria which must be met by all candidate countries, as well as the *acquis communautaire* of the European Union to be fulfilled according to certain deadlines stipulated in official documents such as the Accession Partnership Document or the National Program of Turkey, in 2000 and 2001 respectively, helped to hasten and make more visible the work that has to be completed soon in all areas, including the subject of Intellectual Property Rights.

Turkey needs to evaluate intellectual property rights also from the global perspective. Economic and trade relations worldwide in this century have made it imperative that with a population of 70 million and a level of production that is well-integrated into the global economy, the Turkish Republic cannot afford to stay aloof from the dynamics of the current age. Turkey inevitably needs to

update all legal measures in relation to intellectual property, complete successfully the necessary institutionalization in this area, and devise a system whereby the public in Turkey is made fully aware of and responsible for the recognition and protection of intellectual property rights that also constitute an important dimension of human rights in general.

Protection of both economic and moral rights of inventors in technology, authors of all creative works and persons making contributions in industry, is clearly indicated in the provisions of a great number of international and regional agreements or treaties of intellectual property rights. The contents of such provisions need to be translated into real life in the form of respect and recognition by each member of the community for the rights of those who spend their time, effort and savings upon creative ideas and offer their inventions for the use of the public. However, it is not enough to realize only community support for the protection of creativity through organized or widespread education; there should also be an established web of legislative measures and a fully functioning system of intellectual property protection in the country, resting upon a well-equipped and properly functioning judiciary.

The practical consequences of protecting intellectual property is in the development of industry and the increase of exports, both dependent upon primarily the production of industrial and technology goods. High quality production requires the effective protection of costly Research-Development activities carried on domestically and at the same time the government has to provide for the legal protection of imported technology and know-how against unauthorized domestic use which disrupts fair competition and discourages the transfer of technology. Especially at a time when Turkey is seriously in need of foreign direct investments, Turkey has to provide the same level of protection for intellectual property as is available in other countries competing for foreign investors.

The Turkish Republic has already taken considerable strides in 1995, by means of the Customs Union established between the European Community and Turkey, in the Partnership Council

Decision No. 1/95, and its Appendix No. 8, entitled “Intellectual, Industrial and Commercial Property Rights.” Concurrently, Turkey has signed the Agreement Establishing the World Trade Organisation and its additional Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS). Under the requirements of these two important international commitments, Turkey has become a party to various treaties or signed their current texts as required, and also updated its laws according to European Community regulations or decisions.

A most important step has been Turkey’s participation, as the 20th member, in the European Patent Organisation, whereby the European Patent Convention went into effect in Turkey on 1 November 2000. The developments taking place in relation to the creation of a Community Patent within the European Patent system is of great interest to businessmen, scholars and lawyers, especially in respect of a new approach towards the issue of translations of patent documents including the claims and in the establishment of a central patent court for the Member Countries of the EU.

Turkey has not yet joined the two WIPO Treaties, known as “Internet Treaties”, one on the Rights of Authors and the other on the rights of Performers and the Producers of Phonograms, both dated 1996. Efforts on accession to these Treaties are being carried on, as well as works to join the Trademark Law Treaty (TLT). Another treaty Turkey works on joining is the Geneva text of the Hague Agreement on the International Registration of Industrial Designs. Other than these, Turkey attended the diplomatic conference on the Patent Law Treaty (PLT) and signed the Agreement, and shall start the procedure of ratification for membership after the Treaty goes into effect within the allocated time.

There were also some domestic measures that were taken in order to make intellectual property protection more effective inside the country. A novel system was put into effect by Law No. 4421, dated 1.08.1999, on Amendments to be made to the Turkish Penal Code and to the Procedural Law on the Execution of Penal Measures, which brought increases in the amount of fines.

According to this system, fines to be applied for the infringement or violation of intellectual property rights become more effective in preventing such acts, since the fines are reevaluated each year according to the inflation rate.

Other measures which were taken in order to improve the conditions with respect to the protection of intellectual property in Turkey include three important Official Communications: Communication No. 98/3, issued by Money-Credit and Coordination Council, on “Support for Registration Expenses for Patents, Utility Model Certificates and Industrial Designs”; Communication No. 2000/2 on “Educational Scholarships”; and, Communication No. 2000/3 on “Support for Activities Directed at Trademarking of Turkish Products Abroad, their Advertisement and Sustainability in Trade, and the Establishment of the Turkish Image.”

II. Harmonisation with the EU Acquis Communautaire in Intellectual Property

In the Turkish Republic, the following institutions are responsible for the applications of the different areas of intellectual property rights:

The Turkish Patent Institute: in the subject of all industrial property issues and the institutionalization of attorneyship for patents and trademarks.

The Ministry of Culture: copyrights and related rights.

The Ministry of Agriculture and Village Works: rights of plant breeders related to plant varieties.

The Ministry of Justice: in relation to the establishment of specialised courts on intellectual and industrial property.

Department of External Commerce: in relation to the application of the incentives system for foreign direct investments.

The Board of Competititon: in relation to license agreements concerning patents, trade secrets and know how in the transfer of technology.

The Ministry of Health and the Ministry of Agriculture and Village Works: in relation to the protection of undisclosed data (data exclusivity).

The Turkish Patent Institute (TPI), which was established on 24.06.1994 by Government Decree No. 554, is the organisation responsible for carrying on measures related to industrial rights protection. The TPI is connected to the Turkish Ministry of Industry and Trade but has an independent budget and is run by a personnel of 155. The institutional infrastructure of the Turkish Patent Institute needs to be upgraded in accordance with the EU standards, including the employment of experts, specially trained to deal with issues in separate units concerning patents, trade and service marks, industrial designs, geographical indications and topographies of integrated circuits. In general, the needs of the personnel in in-service training should be met in upgraded terms, while acquisition of new personnel should be made with a special concern for EU specialization of such persons.

On the subject of industrial property, the following Decrees were prepared and went into effect by their publication in the Official Gazette on 26.06.1995: Decree No. 551 on the Protection of Patent Rights (amended by Decree No. 566 which went into effect on 22.09.1995); Decree No. 554 on the Protection of Industrial Designs; Decree No. 555 on the Protection of Geographical Indications; Decree No. 556 on the Protection of Trade and Service Marks. Implementation Regulations relating to the said Decrees have also been published in the Official Gazette and went into force. A Law which organizes the penal measures in connection to the Decrees, Law No. 4128, went into effect on 7 November 1995.

Decree No. 551 on the Protection of Patent Rights was prepared in view of Turkish obligations under the TRIPS Agreement. Article 65 of the TRIPS Agreement acknowledges that Turkey, among

others, may postpone granting patent protection to pharmaceuticals until 2000 or 2005, according to the development level of the country. However, the later amendment which was made by the transitory provision 4 in Decree 566, took into consideration the need to harmonise the Turkish patent law with the applications in the European Community. According to Turkey's obligations arising from the Partnership Council Decision No. 1/95 which established the Customs Union, and Article 70 (8) of TRIPS Agreement, it was stipulated that patent protection for pharmaceuticals and veterinary products and processes would start on 1.01.1999. All patent applications for products and processes up to the said date were to be accepted by the TPI, and government would grant them the exclusive right to market the product in Turkey until the grant of the patent on 1.01.1999. The effects of this procedure have been as follows:

- a) All applications were treated as stipulated in the TRIPS under the criteria for the grant of the patent. However, in connection with the search for novelty, the state of the art at the time of application was not taken as the basis. Only at the time of search for novelty, the standards at the grant of the patent and the state of the art were evaluated;
- b) When the patent was granted after 1.01.1999, the period of protection would start from the date of application or the priority date.

There is the need to create the necessary infrastructure in order to carry on patent examination procedures in accordance with the requirements stipulated in the Turkish Patent Decree No. 551; the patent application procedures should be equally simplified in harmony with the applications in the European Patent Organization and within the international patent application system (the Madrid Agreement and the Protocol).

The Turkish Patent Institute has prepared a draft law, not yet approved by the Turkish Grand National Assembly (TGNA), based upon Council Directive EC 87/54 on the protection of the topographies of integrated circuits, which is one of the subjects that

was included in the list of measures to be created or be fully harmonized with EC law within three years after the realization of the Customs Union, resulting from the EC/Turkey Partnership Council Decision, No 1/95.

The Decree on the Protection of Industrial Designs was prepared according to the draft of the Council Directive, 98/71/EEC, which later went into effect in somewhat different form in relation to the subject of the manufacturing and sale of spare machine parts. The Turkish Decree is mainly in harmony with the said Directive, but as far as the manufacture and sale of spare parts is concerned, the draft of the Directive is closer to the Turkish text. The Decree on the Protection of Geographical Indications was prepared with a larger scope in view of the rich array of goods Turkey claims as having geographical significance; not just wines, spirits and foodstuffs as in the European Union legislation. The Turkish Decree therefore involves a wider area of application, including local arts and handicrafts, which may turn out to be more appropriate as discussions in the current WTO Councils may successfully end up with a more favorable approach to the international protection of rich local geographical specialties of many Third World countries.

In relation to the protection of know-how and trade secrets, there is no *sui generis* law in Turkey for the protection of such rights. However, there are effective provisions both in the Commercial Code, under provisions on unfair competition, and the Code of Obligations which can be resorted to for effective protection of know-how and trade secrets. The EC-Turkey Partnership Council Decision No. 1/95 included a provision that Turkey would pass the necessary legislation on this subject within three years after the coming into effect of the Customs Union in January 1996. No major legal shortcoming makes this issue an urgent matter right now, however Turkey should meet this obligation in the near future and create a *sui generis* law on know-how protection.

A *sui generis* legal measure still needs to be drawn up organising license agreements concerning the transfer of technology incorporating patents, trade secrets and know how. This should be

done in accordance with the Commission Regulation, EC 240/96, dated 31 January 1996, in relation to the Transfer of Technology.

The Turkish Republic should complete works toward accession to the UPOV Convention on the Protection of Plant Varieties. The structuring of the new establishment, planned to take place under the auspices of the Ministry of Agriculture and Village Works, in accordance with the Draft Law, needs to be realized in order to protect the rights of plant breeders in relation to new plant varieties. Furthermore, there is the need to adopt measures incorporating the recognition of certificates for Additional Periods of Protection for plant varieties, as stipulated in Council Regulation EC 1610/96. Similarly, the Council Regulation, EC 1768/92, allowing for certificates of Additional Periods of Protection for pharmaceutical products, has to be taken into account.

The Turkish Republic will be completing work on accession to the Geneva text of the Hague Agreement on the International Registration of Industrial Designs and, accession to the Trademark Law Treaty (TLT).

On the subject of copyrights and related (neighboring) rights, in order to smooth out the problems that arise from the lack of institutional infrastructure in this area, the existing unit under the auspices of the Ministry of Culture should be reconstructed to operate in a similar semi-independent way as the Turkish Patent Institute. Law No. 4630, dated 21.02.2001, makes some amendments to the 1951 Law No. 5846 on Literary and Artistic Works, that had been subjected to two earlier amendments. Among the changes made, new provisions were introduced with respect to the protection of owner's rights in cable and satellite broadcasting, in accordance with EC Council Directive 93/83. Law No. 4630 also deals with the unlawful circulation of copyright material through electronic means, such as computers and the Internet.

Not much success has been achieved in relation to a new Law on measures guaranteeing protection for the first recording of a work and its subsequent reproduction, as well as its renting or lending out, corresponding to measures envisaged in Council Directive EC

92/100 (392 L 0100/OJ L 346, 27.11.92); nor in relation to the protection of data bases by means of a *sui generis* law, as stipulated in EC Council Directive 96/9 (396 L 0009/OJ L 077, 27.03.96). Article 80 of Law No. 5846 on the Protection of Literary and Artistic Works is still not in full harmony either with the EC Council Directive 92/100, or with the Rome Convention, or with the TRIPS Agreement, in relation to the rights to be recognized for owners of related rights.

The latest amendment (Law No. 4630) to copyright law in Turkey, nevertheless, redefines the concept of the right holder, while it introduces new provisions in order to make more effective the prevention of unauthorized reproduction of literary and artistic works and to better combat widespread piracy of copyright works. The new law also increases the penal measures, with longer terms of imprisonment, and greater fines for those who violate the economic and moral rights of authors. It is, however, a shortcoming of the amending law that it fails to provide full terminological consistency. One example is the reference to “related rights”, where the reference is not in the new way of designating the said group of rights owners, “Performing Artists, Producers of Sound Recordings and the Rights of Radio-TV Broadcasting Establishments,” but in the old way of using the term “neighboring rights.” Moreover, the latest amendments to Law No. 5846 lack parallel measures that would fulfill requirements for harmonisation with EC Directive 2001/29 on Authors’ Rights and Related Rights in the Information Society, which brings in new measures in line with the passage of the European Union into the information society.

A Regulation Concerning the Use of Copyright Works on Television and the Radio Broadcasts, which aims to regulate the procedural law in connection with the protection of the rights of authors and related rights concerning rights of performers, producers of phonograms and broadcasting organizations, was published in the Official Gazette on 15.09.2001 and went into effect; similarly, another Regulation, which brought in security measures for the copyright protection of books and other publications by means of original and numbered stickers issued by

the Ministry of Culture, was published in the Official Gazette on 8.11.2001 and went into effect.

The Turkish Republic should complete accession to the two WIPO Treaties, known as the Internet Treaties: one on Copyrights and another one on Related Rights and the Rights of Performers and Producers of Phonograms.

There is the need to make further amendments to Law No. 3257 on the Protection of Cinematographic, Video and Musical Works, in order to bring it fully into line with international norms and make it compatible with the provisions of the Law on Literary and Artistic Works. Law No. 4629, dated 21.02.2001, eliminated the Fund for the Support of Cinematographic and Musical Arts, established by Law No. 3257, and created instead a new mechanism within the general budget in order to provide support for the said arts.

On the subject of trade and service marks, Decree No. 556 on the Protection of Trade Marks should be brought into full harmony with the Council Directive 89/104/EEC, in order to overcome the lack of convergence with respect to the following points:

The shape of the good and its getup (packaging): In the second paragraph of Article 5 of Decree No. 556, it is stated that “the trademark can be registered together with the good and its getup. In this case, the registration of the good and its packaging does not provide the owner with an exclusive right for the good and its packaging. This statement is in disharmony with Turkish Law No. 4128 which accepts “the shape of the good and the getup” as trademark; the statement also contradicts Article 4 of the Community Trademark Regulation.

On the time limit for the commencement of proceedings on invalidity of trademark right: Decree No. 556 recognizes the right to start an invalidity action after the registration of the mark. However, in paragraph (c) of Article 4 of the Decree, where claims of invalidity are stated as possible in case the mark is not used for five consecutive years, the time limit within which a case may be

started is not stated. The said clause of the Turkish Decree should be made compatible with EC Council Directive 89/104 where it is clarified that the right to start a case is lost if an invalidity action is not started within five years, even though it is known to the third party that the mark has not been used.

Acquisition of distinguishing quality as a result of use: According to the second paragraph of Article 7 of the Decree, which was added by Law No. 4128, if a mark had been used before the date of registration and had acquired a distinguishing quality with respect to the goods or services subject to the said use, the registration of the mark can not be refused according to provisions (b), (c) and (d) of the same Article. This means that, according to paragraph 2, also in the case of an application for the registration of the same mark or a similar mark by a third party for the same type of goods and services [provision (b)] as a registered mark or a mark for which an application for registration has been made, and if the second applicant can prove that his use of the mark before the registration date had resulted in the acquisition of a distinguishing quality, this second request for registration can not be refused. Thus, the same mark is registered for the same goods and services in the name of two different owners, creating contradiction with Article 3/3 of the EC Directive 89/104, and should be eliminated.

Use of the terms “the same” and “same as to be indistinguishable” takes place in section (b) of Article 7 of Decree No. 556, under the title, “Absolute Reasons for Refusal of the Registration of Marks.” The term used in this provision, “same as to be indistinguishable” needs to be changed to “similar as to be indistinguishable,” in order to eliminate the confusion over the double use of the word “the same.”

The provision concerning collective marks in Decree No. 556 is not satisfactory since it fails to correspond to the applications of the collective marks in the European Union; it fails to be in harmony with Article 7 of the Paris Convention and the relevant article in the Community Trade Mark Regulation.

Condition of use in opposition: It is stipulated in Article 43 of the Community Trade Mark Regulation that previous trademark owners placing opposition for a published CTM ought to prove use of their marks. If the objecting former owner has not used the mark in five years, his opposition can not be valid. On the other hand, the Turkish Decree No. 556, in Article 35 on opposition, evaluates opposition for lack of use only in relation to failure of renewal of the mark within two years, and makes no general evaluation with respect to failure of use of the mark in five years. Harmonisation needs to be achieved with respect to provisions on the invalidity of the mark.

Limitations on trademark right in violation: Article 53 of the Community Trademark Regulation includes a provision which prohibits a trademark owner who had remained silent for five years against the unauthorized use of the trademark from commencing an action if the mark had been used in good faith. Such a limitation does not feature in the Turkish Decree No. 556; therefore, an amendment needs to be made.

Fees, costs, and Value Added Tax (VAT): The existing practice of three different payments in the form of fees, costs and the VAT in Turkey in relation to the protection of industrial rights does not correspond to practice in the European Union. The Turkish Patent Institute needs to solve the existing incongruency in the subject of payments. Tariff No. 8 in relation to industrial rights is organized by Law No. 492 of 2.07.1964, which has not been updated since, other than as regards the increase of the amounts of payments. Obsolete concepts and terminology in the Law do not correspond to the more recent terminology adopted in 1995 in the new industrial property Decrees. Moreover, there are no references in the Tariff with respect to the payments in connection with the registration and opposition mechanisms of industrial designs and geographical indications.

The Ministry of Industry and Trade issued an additional Communication of Payments, published in the Official Gazette No. 24286, dated 13.01.2001, which increases the official payments as fees, costs and the VAT, unlike the practice in the European Union.

In the procedures involving the protection of industrial property rights, the EU Member Countries do not resort to VAT. However in Turkey, foreigners who apply for registration of marks, for obtaining of patents or utility design certificates, and for industrial design registration are also required to pay VAT, as published in the Official Gazette No. 23948, on 29.01.2000.

On the subject of trade and service marks, Communication No. BİK/TPE: 2002/2, on the Classification of Goods and Services in Connection with the Application for Registration of Marks, which was published in the Official Gazette on 31.12.2001 and went into effect, made it possible to bring trade mark applications in Turkey into harmony with the international Nice Classification system.

A Memorandum of Understanding has been signed by the Community and Turkey in order to create parallel measures in law, administration and technical issues between the parties, concerning the inclusion of Turkey within the system of Community Trade Mark and Design, under the provisions of the Agreement signed between OHIM (the Office in Alicante, Spain) and the EU candidate countries.

As regards border controls against the violation of intellectual rights, the necessary measures have been taken in the Turkish customs Code, No. 4458, dated 5.02.2000, prepared on the basis of Council Regulation 3295/94 and Commission Regulation 1367/95 on counterfeit goods or unauthorized reproduction of trademarked goods.

New technologies in communications have created new problems in intellectual property violations and brought the necessity of devising new measures and making new arrangements for the detection and prevention of crimes connected with the technological vehicles of communication. In the age of the Internet, where no national boundaries exist, electronically processed personal data used on the Internet are under threat of being recovered and manipulated by unauthorized persons.

Within a wide framework of efforts to create a secure and dependable environment for informatics, the Turkish Ministry of Justice has prepared a proposal for a Law on the Protection of Personal Data. The model for this proposal has been the Swiss Federal Law of 19 June 1992 on the Protection of Data; the EC Directive 95/46 EC has been used as another source. In addition, the provisions and principles of the European Convention on Human Rights and Fundamental Freedoms have been the guiding elements.

There is a continuing effort to establish in a more appropriate structure the rights societies (occupational associations), which constitute one of the most important and basic functional elements of intellectual property protection, one that meets the needs of greater numbers. Nearly 16 associations exist in Turkey in the areas of scientific and literary works; the cinema and the fine arts; the right of performers, recorders of musical works and broadcasters on the radio/television.

Specialised courts to deal with intellectual property cases should be set up in greater numbers and dispersed throughout the country. The Ministry of Justice, with the financial support of the European Union, has embarked upon a project on the Effective Application of Intellectual Property Laws. The project, to be completed fully by 2005, includes the establishment of specialised courts in eight pilot areas. Initially, a specialised court was established in Istanbul on 25.01.2001, subsequently followed by other Intellectual and Industrial Rights Civil and Penal Courts in Ankara and Izmir, the next two big urban centers. The in-service training of judges and prosecutors is an important part of the project. Furthermore, a documentation center is to be established; and a network of computerised information exchange system is planned between the Ministries of Justice and Culture, the Turkish Patent Institute, the Department responsible from the Customs, the specialised courts and the documentation center.¹

¹ Fikri Haklar Konusunda AB Uyum Çalışmaları Durum Raporu (19 Nisan 2002). [Proposal on EU Harmonisation in Intellectual Property], TÜSIAD, Türk Sanayici ve İşadamları Derneği, Şirket İşleri Komisyonu, Fikri Haklar Çalışma

III.A. New Efforts at Approximation on the Road to Membership: the Protection of Undisclosed Information (Data Exclusivity)

What is the generally accepted rule about undisclosed and proprietary information that has intellectual property value? It is a category that takes a seemingly peripheral place in the spectrum of intellectual and industrial property rights; however, proprietorial information is secret know-how that has commercial worth, is part of the firm's property, and brings added value to the goods of the undertaking in terms of fair competition with other undertakings.

“Data Protection” or "Data exclusivity" is an intellectual property category which may overlap with patents in pharmaceutical and agricultural/chemical industries, but constitutes a right that is quite distinct from patents. While in the case of patent rights, the inventor is entitled to a period of protection in return for revealing willingly his/her invention, data exclusivity is a certain period of protection from imputation within which any other firm is prohibited from applying for obtaining a marketing permit in line with the studies and tests which a firm had carried on and submitted, upon lawful request, to a government authority in order to get the necessary permit for marketing a certain pharmaceutical or a chemical invention. The "lawful request" arises from the TRIPS Agreement, where a provision obliges governments of states parties to the Agreement to put effectively into application the said period of protection from imputations.

The TRIPS Agreement, in Article 1.2, defines the concept of data exclusivity as the protection of undisclosed information. In the case of an obligation to submit pharmaceutical or agro/chemical data in order to obtain official marketing approval, as stipulated in Article 39/3, WTO member states are expected to protect such data against the commercial use of them that would create unfair competition. The reason behind the said provision of the

Grubu, TS/ŞİR/02-190 (Report of Working Group on Intellectual Property, Association of Turkish Industrialists and Businessmen).

Agreement is the fact that the data submitted for official approval are the result of extensive investment in private research and experimentation.

The TRIPS Agreement aimed to create in Article 39.3 a certain period of time that needs to be observed by government officials as the proper length of time to keep the data secret, within which the owner of the invention and the tests has a chance to recoup the expenses of the clinical and experimental stages. Only upon the termination of this period, should local producers of a generic be allowed to have market approval of their goods based upon the clinical findings of the owner of the original product which had been submitted to health or other government officials. Then the producers of the generic alternative only need to carry on studies in order to prove the bio-equivalence of their products with the original product that has completed its period of data exclusivity.

Article 39/3 of the TRIPS Agreement does not restrict the publicizing of the said data. The data, concerning the tests and experiments carried out in relation to the pharmaceutical product for which marketing permission is requested from government authorities, is published and offered as knowledge to all interested parties; however, no unfair use of it is to be allowed to any domestic third party by the government officials.

However, if independent tests and experiments have been carried out for a domestically produced generic pharmaceutical product and the marketing permission has been obtained as based upon such independent tests, then there could be no objection to the marketing of the said good, in view of the condition that there exists no patent.

The limitation of the period of data exclusivity first entered the EU area in 1987, three years after it was applied in the USA, and is practiced by state officials. Continental Law in Europe defines the protection of data in relation to the marketing of pharmaceutical products as a *sui generis* right which needs a *sui generis* law that would bring measures for the prohibition on the use of such data until the end of a certain period of time. A report prepared by the

EU Commission in 2001 said that Article 39/3 of the TRIPS Agreement means without any doubt that there should be data exclusivity for a certain period of time, against unauthorized and unfair uses of such data. The Report added that there has been no request by any WTO Member in order to have an alternative system to the one devised in Article 39/3.

In the EU, the period of data exclusivity is ten years where Community procedure is applied; otherwise, reciprocal measures can be applied for six years, as in Austria, Denmark, Finland, Ireland, Greece and Portugal. There are various pharmaceutical products that could not meet the novelty criteria for patentability, however long years of experimentation had gone into its development, and a great deal of effort had resulted in proving its safety. Both unpatented and patented products therefore are entitled to the protection of ten-year (or less) data exclusivity period.

A Proposal which the Commission is submitting to the Parliament and the Council, aims to eliminate the six-year exclusivity and extend it to eleven years. Upon approval of new indications or formulations of a certain pharmaceutical product that has achieved important clinical benefits within the first eight years of its presence on the market, it will be possible to get an additional year of protection for all the indications submitted to the state officials.

Patents are covered in Part I, Section II of the TRIPS Agreement, while data exclusivity is covered in Section VII of Part II, in Article 39/3. But the two issues are parallel to each other in the subject of pharmaceuticals and agro/chemical inventions. Turkey's legal measures are not fully compatible as yet, in the area of pharmaceuticals, either with Article 39/3 of the TRIPS Agreement or with the European Union legislation in this subject. There is especially the need to make Article 9 of the Turkish Directive on the Licensing of Medical Pharmaceutical Products (which went into effect by its publication in the Official Gazette No. 22218 on 2.03.1995) compatible with both Article 39/3 of the TRIPS Agreement and the EU legal measures in the related subject.

In Turkish Patent Law, until the Decree of 1995, there was no patent protection for pharmaceuticals, or for chemicals, agricultural products and foodstuffs. The Patent Decree of 1995 brings patent protection for pharmaceutical products but does not recognize pipeline protection; that is, protection for pharmaceuticals that were already on the market before 1995. Possibly, with the going into effect of data exclusivity in Turkey, a product for which clinical and experimental data had been submitted to government authorities but for which there had been no patent application in 1992, will be eligible for marketing in 2003, and will also be entitled to another year of protection for indications and two more years of protection for generic product licensing. In this case, a domestic generic production that is the result of independently carried on clinical and experimental work for nearly the same or similar molecule and which is eligible for marketing can freely enter the market due to the lack of a patent.

Elsewhere, practice is as follows: in the USA, the government does not accept imputations for a generic product within five years; in Japan, until all the evaluation procedures in relation to an original pharmaceutical product are fully completed and a six-year period of reexamination is completed, no imputation on a drug is allowed to be marketed.

The creation of a new pharmaceutical product involves two basic procedures. First, long years of intensive research and inventive activity results in the finding of the basic molecule; later, there is the equally lengthy and laborious process of experimenting whether the invention is qualified, secure and effective for use upon the target group of patients. The data verifying the second process provide the proof for public authorities that the said product is suitable for marketing.

The patent obtained, which allows the right owner to prohibit the unauthorized production, use, export/import of the good by others for twenty years, provides in essence an incentive to the creator to carry on further research and show willingness to reveal the results of his/her findings. Data exclusivity is an additional intellectual property right, which is realized by the protection provided by

governments for the submitted information about the applicability of the patented product; or, in the case when patent laws in the country do not provide patent protection for a newly invented molecule, the highly costly R&D investments are still encouraged by means of data protection of secret information entrusted to government officials.

Lengthy studies upon thousands of molecules may prove to be successful only on one molecule. After the testing and experimentation period which in itself consists of several stages, the government health officials to whom the (secret) undisclosed clinical and experimental data is submitted may allow these findings to be used as the basis of some generic products of domestic producers who made no contribution to the testing and experimentation but seek to become free riders on the successful results (outcomes). This creates unfair competition.

From the legal perspective, data exclusivity is reflected in the TRIPS Agreement as the recognition of the big effort and financial investment by the inventor of a pharmaceutical product to be placed on the market; but this issue also has its protective health dimension and in addition needs to be evaluated from the perspective of keeping individuals and companies researching and producing in this sector.

The issue of data protection was the subject of heated discussions in the past both in the USA and in Europe; while the state claimed to act in the interest of the public good, it was also acting in favor of the competing generic producer who would be turned into a free-rider on testing and experimentation costs and efforts. Therefore, it was seen as a compensation for the original inventor to have the 10-13 year period of data exclusivity in order to recoup his investments under conditions of fair competition.

III.B. Harmonisation Starts With an Analysis of Existing Domestic Legal Measures and Implementation: the Example of Data Protection

Data protection emerges in Turkish law from a series of legal arrangements starting with the Constitution of the Republic. Article 5 of the Constitution stipulates that “the basic aim and obligation of the State is to base the Turkish economy upon a free economic order and to secure the right to fair competition.” Article 10/3 further stipulates that “the organs as well as the administration of the State, have to act in its application according to the principle of equality before the law.” Article 17 states that “individuals have the right to develop their material and moral existence.” Article 27 states that “individuals are free in science and the arts.” Article 48 states that “it is the responsibility of the state to take the necessary precautions in order to make it possible for private enterprises to work with confidence and security.” Article 40 states that the State shall pay compensation for the losses incurred by persons due to unfair acts or omissions of government officials. Article 35 states that every individual is entitled to property and inheritance rights.

The above are domestic constitutional legal measures that make data exclusivity a protectable right; as to the international measures, it should suffice to look at Protocol No. 1 of the European Convention on Human Rights and Fundamental Freedoms. The Article on property rights has been interpreted by the European Court of Human Rights as follows: “Rights related to moveable-immovable, tangible-intangible property are under constitutional protection (guarantee).”

All these provisions point to the unquestionably fair application of the following legal measure: “Not to pay attention to the protection of the inventor’s data in a way that would fail to prevent unfair use of such data by third parties would constitute a violation of property rights, which is essentially of the intangible kind.” Furthermore, if the State grants license to such use, it does not mean that the existing legal contradiction is eliminated, as observed from the perspective of the law of unfair competition in Turkey.

The provisions on unfair competition in the Turkish Commercial Code (TCC) are taken from the law of Switzerland.

The present framework Article 56 of the TCC states that “it is unfair competition to act fraudulently and in violation of the rules of good faith in competition,” in similar terminology with the definition of fair competition in Article 1 bis of the Paris Convention for the Protection of Industrial Property. While protecting the smooth and fair functioning of the system of competition, the provisions on unfair competition actually protect original effort and toil and prohibit acts which would constitute violation of goodwill so as to disrupt fair competition. In commercial and economic life, intangible property grows in importance. This has been the way patents, trade and service marks and, more recently, neighboring (related) rights have gained in importance in the last decades and have increased in significance with respect to the protection of the original effort and toil. Similarly, the protection of data, or “data exclusivity”, has gained in importance in the mid-1980s and aims to protect original and high quality effort and toil toward a specific goal which may be a pharmaceutical/chemical product that is patented or not.²

Protection of medical pharmaceutical data for the obtaining of a marketing license in the Turkish Republic depends on three basic health measures: Law No. 1262, dated 1928, on Medicinal Products; the basic Code No. 3359 on Health Services; and the Government Decree on the Organisation and Duties of the Ministry of Health. The last two include provisions to the effect that the Ministry of Health is competent and responsible for issuing marketing licenses for pharmaceuticals. The first does not include any direct provision on the subject; however, the Licensing Directive for Medicinal and Pharmaceutical Products, dated 2.03.1995, includes a provision on the protection of data in Article 36, entitled “Secrecy”. The Article states that, “concerning a

² Ali Necip ORTAN (Temmuz 2002). Küreselleşen Ekonomide Veri Korumanın Önemi, Panel, 31 Ocak 2002, Ankara, UPAV (Ulusal Politika Araştırmaları Vakfı), Ankara.

medical pharmaceutical product, the information that is submitted to the government by the owner seeking a marketing license for the product is secret, and it is the responsibility of the Ministry to protect the secrecy of the said information.”

This ‘objective responsibility’ means that the state, through its official personnel employed by itself, is responsible for acts that result in the revelation of such secret information due to failure to taking the necessary precautions. Moreover, in accordance with Article 40/3 of the Constitution, “the state shall make compensation for the losses caused by public institutions or public employees.”

In addition to the above, there is also a provision in the Turkish Penal Code, in connection with the security of secret information. In Article 364, it is stipulated that if a person, by means of his status and official duty, occupation or calling, is in possession of information related to scientific discovery or patents or industrial applications which he is bound to keep secret, but reveals this information; upon the complaint of the injured party, the former shall be liable to imprisonment for up to six months and the payment of a heavy fine. The legal interpretation of such a provision is to protect secret data with respect to scientific inventions and those having industrial significance, to prevent their unfair revelation and in this way to ensure public security for the protection of science and the arts.

Article 3 of the Licensing Directive points to the two basic Laws and to the Decree stated above. The Directive has a legal basis also in the Government Decree on the Protection of Patent Rights. A provision to the same effect takes place also in Article 39/3 of the TRIPS Agreement. As to the Turkish Patent Law, the present Decree includes, as a last minute addition to the proposal, a provision within Article 83, which states that with regard to the results of undisclosed research and experimentation concerning human and veterinary pharmaceuticals or agro/chemical drugs for which patent application has been made, and where in order to obtain the required permit from government authorities for the production and marketing of the said product, the relevant data is submitted, the authority in whose possession the said data lie, shall

take the necessary measures to prevent their unfair use by third parties.”

Article 83 includes this provision that is not related either to the functions of the Patent Institute nor to the granting of the patent itself, but to the granting of a marketing license for a pharmaceutical invention. The text of the Directive, which is of importance in the applications in Turkey concerning the marketing of pharmaceuticals, stipulates in Article 8 that all data, information and documents, results of tests and clinical research are to be submitted to government authorities for health inspection purposes; otherwise, the patented drug can not freely enter the market.

The Directive, in Article 9/1, includes the provision that data on original products already submitted concerning results of certain tests and experimentation will not be required in relation to alternative generics of bioequivalence produced by domestic firms.

IV. Conclusion

The framework of a pre-accession strategy was adopted for Turkey, and in particular the establishment of an Accession Partnership, dated 8.11.2000, which outlined the short term and middle term priorities for membership of Turkey in the European Union.³ In this document, the subject of intellectual property was included as a short term priority with a target date of the end of 2001, under the heading of the Single Market. Turkey was advised to carry further the positive and constructive efforts made in this area, underlining especially the need to concentrate on the prevention of piracy.

Among the middle-term priorities listed in the Accession Partnership Document, again on the subject of the Single Market, the protection of data bases and the harmonisation of laws in this

³ Pre-accession strategy for Turkey, Report on the proposal for a Council Regulation on assistance to Turkey in the framework of the pre-accession strategy, and in particular on the establishment of an Accession Partnership (COM (2000) 502 - C5-0468/2000 - 2000/0205 (CNS))

respect were emphasized, while it was underlined that the new measures should be focused on implementation. The importance of data protection was also stated under the subject of Justice and Home Affairs, with respect to the accession of Turkey into the Schengen Information System and Europol.

In the 2001 Regular Report on Turkey's Progress Toward Accession⁴, the subject of intellectual property is included under Company Law, and it is stated that Turkey has made some progress in this area, in particular concerning the legislation on Intellectual Property Rights (IPR), and has also made efforts to implement this legislation. Turkey is applauded for adopting legislation which aims to align the Turkish regime with the Directives on rental and lending rights and other rights related to copyrights. Approval is expressed also for harmonisation achieved with the Directive on the co-ordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission, and with the Bern and Rome Conventions, as well as with the TRIPS Agreement, the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.

The 2001 Report approved the Parliament adopting in March 2001 a Law establishing specialised Courts to deal with intellectual property issues in the major provinces, while the General Civil Courts and General Penal Courts have been authorised to handle cases related to IPR issues. It is added that Turkey ratified the European Patent Convention in November 2000 together with the Memorandum of Understanding in order to harmonise Turkish practices with those of the Office for Harmonisation in the Internal Market (OHIM). The Law on Customs adopted in February 2001 is praised since it contains measures aimed at fighting violations of IPR at the frontiers and contains measures concerning counterfeited and pirated goods.

⁴ 2001 Regular Report on Turkey's Progress Towards Accession, Commission of the European Communities, Brussels, 13.11.2001, SEC(2001) 1756.

The 2001 Report nevertheless advised Turkey to fully implement its commitments under the Customs Union, and added that Turkey is not a member of the WIPO Copyright Treaty nor of the WIPO Performances and Phonograms Treaty, and should advance its efforts to align with these. While the Report approved that the adoption of a Law on Protection of Topographies of Integrated Circuits was well underway, it stated that the piracy of audio-visual materials continues to be a serious problem, and that efforts to address this situation should be hastened. The Turkish Patent Institute is criticized for not being a fully independent body.

The previous Report, covering the period until 30 September 2000, had referred favorably to the adoption of Customs Law No. 4458 on the defence of IPR, which entered into force in February 2000, aiming to fight against counterfeiting trademarks and pirated copyrights. It had stated the need to pursue the process of substantive efforts to align legislation with the *acquis*. It had emphasized the creation of a coherent IPR enforcement system in Turkey, *inter alia*, to combat piracy. Adequate training had been advised for police officials, judges and prosecutors.

The 2000 Report had pointed out that enforcement of IPRs depended on the Ministry of Culture, which was said to be planning to set up a specialised institute with a wide range of powers. While it had been stated that piracy of audio-visual materials was a serious problem, Turkey had been advised to become a member of the WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty.

The 2000 Report had also referred to the protection of Topographies of Integrated Circuits, for which a proposal Law in Turkey, modelled upon the Council Directive, EC 87/54, dated 16.12.1986, was prepared for submission to the TGNA.

On its own initiative, Turkey should consider the extensive and widespread application of intellectual property education in the country, not only in the faculties of law but also as courses in secondary schools and in undergraduate programs of general arts

and sciences, engineering and architecture, industrial design and communications, as well as trade, commerce and economics.

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