



Pharmaceutical
Trade Marks Group

77th Conference - Istanbul

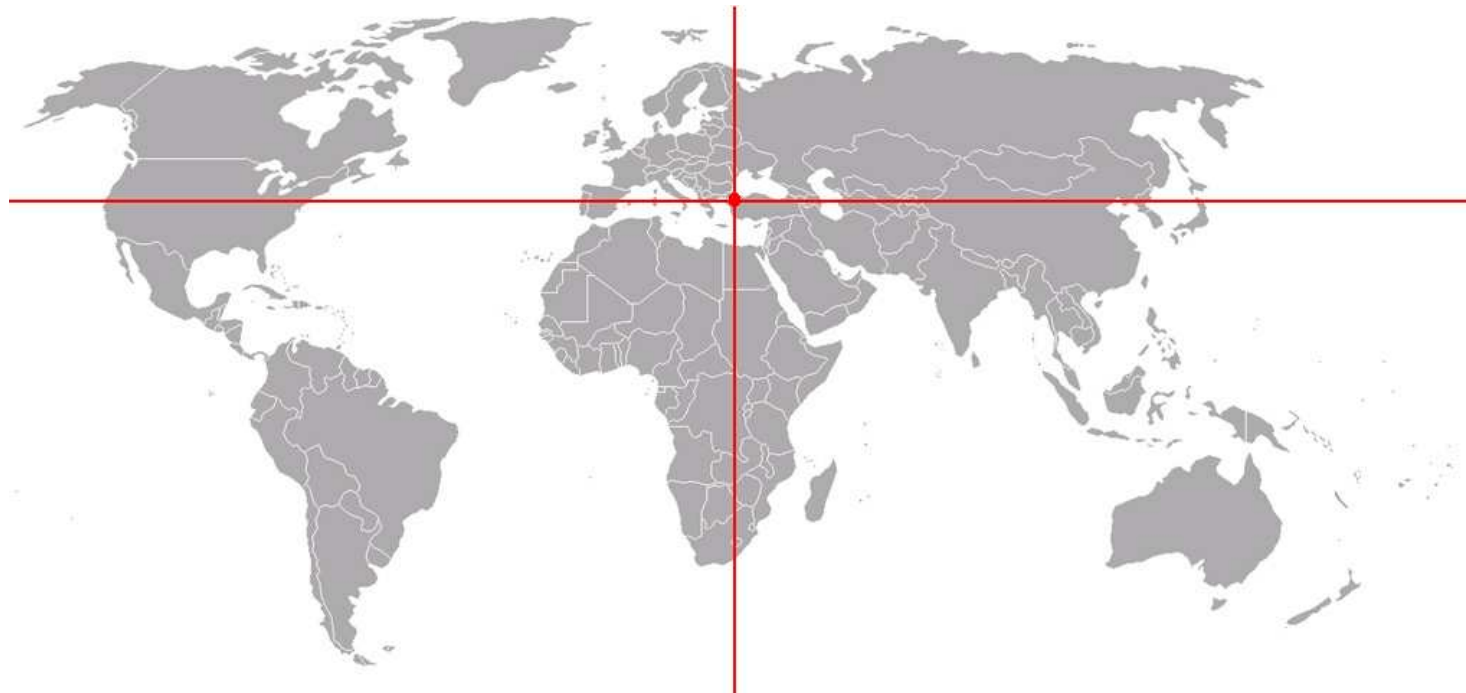
01 to 04 October 2008

*The situation of IP rights in relation
to the European Union legislation and the outline of
the IP environment in view of the ongoing accession
negotiations opened in October 2005
for the EU membership of Turkey.*



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For the geographical location





Figures about Turkey from the brochure of the Governmental Agency “Invest in Turkey”

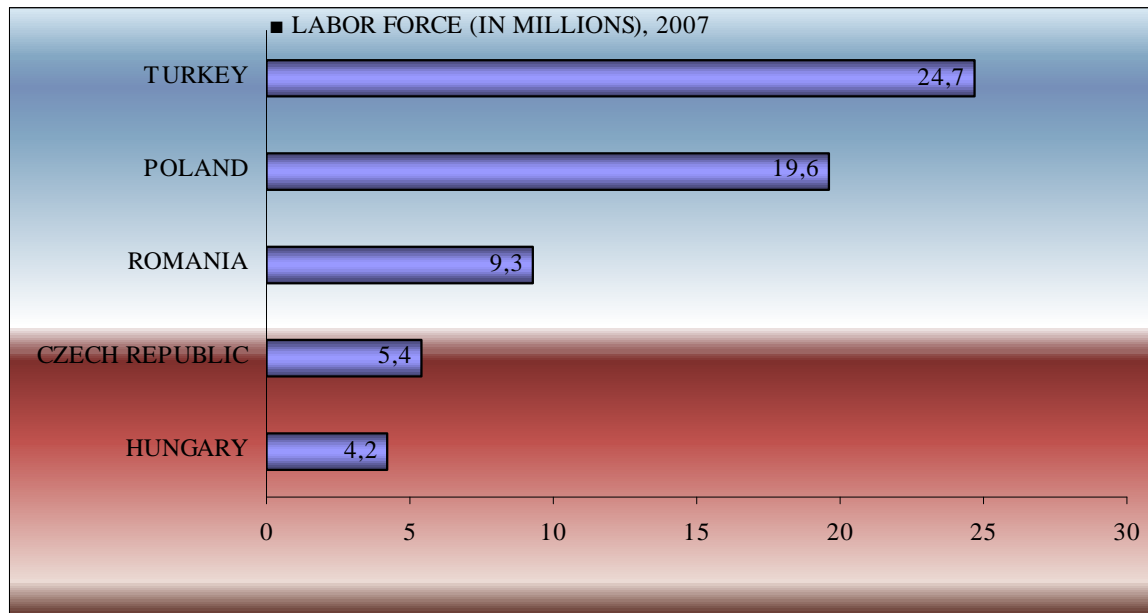
- **POWERAGE**

- ⇒ A population of 70 million people;
- ⇒ 65 % below 34 years old. Average age 28.3

- **EDUCATION**

- ⇒ Approximately 400,000 graduates from 116 universities per year;
- ⇒ 730,000 high school graduates in 2007, including one third with vocational, technical and professional high schools;
- ⇒ Over 24,7 million young, well-educated and motivated professional.

Figures about Turkey from the brochure of the Governmental Agency “Invest in Turkey”



- 4th largest labor force compared to 27 European countries.



Figures about Turkey from the brochure of the Governmental Agency “Invest in Turkey”

- **INFRASTRUCTURE**

- ⇒ New and highly developed technological infrastructure in transportation, telecommunications and energy;
- ⇒ As an energy transit country, Turkey currently has the capacity to transport 121 million tons of oil to the world market per annum. Once the ongoing projects are completed, the annual transit capacity will increase to 221 million tons of oil and 43 billion m³ of natural gas.

TRANSPORTATION 2007

Railway	10,984 Km
Highway	63,805 Km
Seaway Capacity	243,5 million tons/year
Total Airports	52 Airports (20 Int.)
Aircraft Passangers	70 Million
Air Cargo Capacity	1,5 Million tons/year

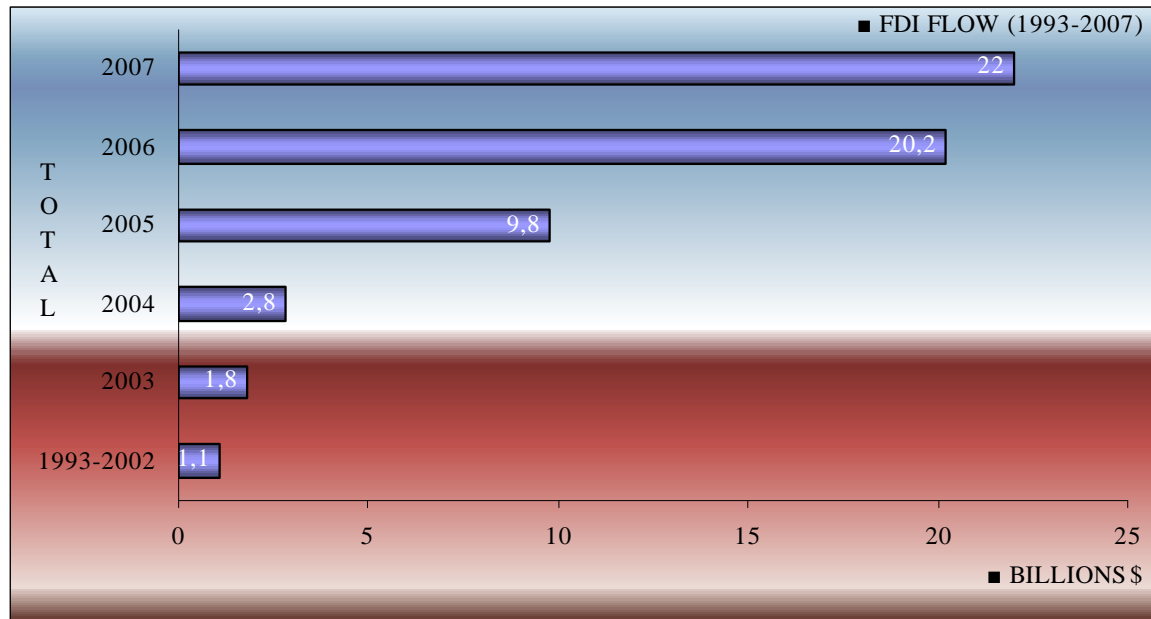
TELECOMMUNICATION CAPACITY 2007

Number of Mobile Telephone Subscribers	63 Million
The Public Switched Telephone Network Capacity	21.1 Million
Number of Internet Users	22 Million
Number of Broadband Subscriber	4.7 Million

Figures about Turkey from the brochure of the Governmental Agency “Invest in Turkey”

- **ECONOMY**

- ⇒ 15th largest economy of the world and the 6th largest economy compared to the 27 EU Countries in 2007 (IMF-WEO)
- ⇒ 15th among the most attractive FDI countries in 2006 (UNCTAD)





Figures about the Turkish Pharmaceutical Industry

(Taken from the website of “Turkish Pharmaceutical Manufacturers Association”)

- **The place where drug industry in Turkish Economy stands**

Approximately, there are 300 firms that actively serve in Turkish drug sector. 53 of those have manufacturing facilities. 14 firms out of 42 with foreign capital are doing their production at their own facilities. Currently, Turkish Pharmaceutical Manufacturers Association (TISD) has 38 members.

There are very few drug industry which works compatibly with WHO`s rules (GMP) in the world. Turkish drug industry has been reached to the technology level to produce any kind of product except the products that require special production technology (e.g. biotechnology, etc.). As it is the case in other European countries, there are international norms and standards being applied in our country. Setting the technology and quality standards up to the European level is a necessity and mandatory pre-requirement which has been submitted.

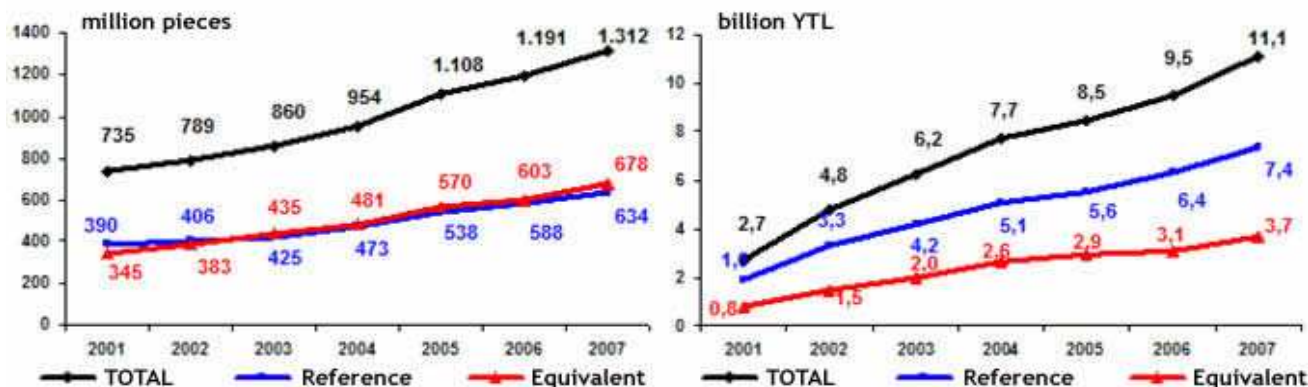
Figures about the Turkish Pharmaceutical Industry

(Taken from the website of “Turkish Pharmaceutical Manufacturers Association”)

• Turkish Prescription drug market

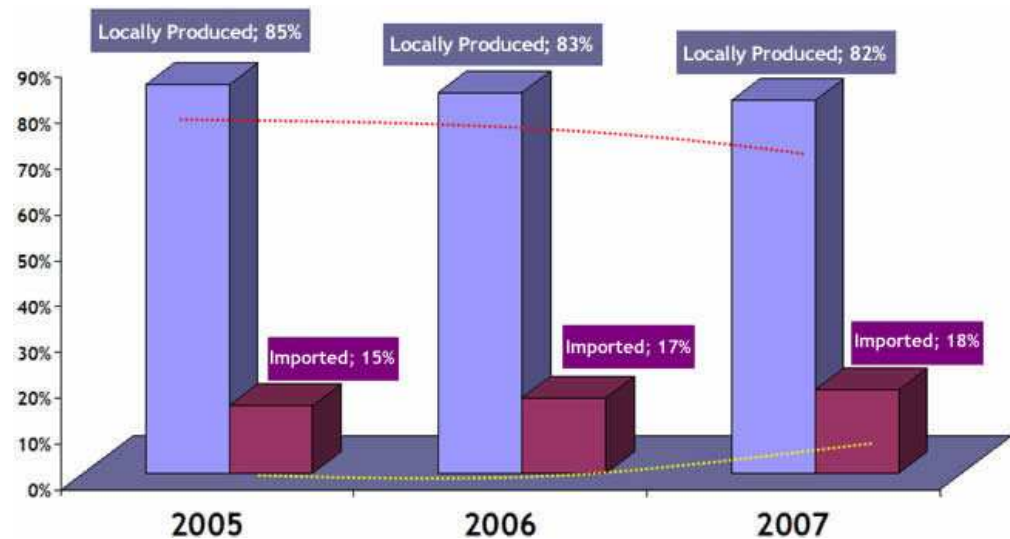
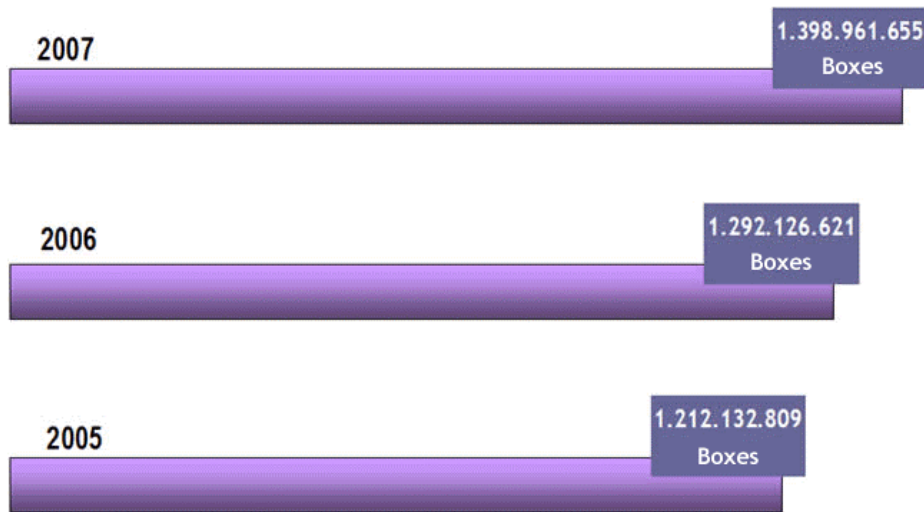
In 2007, there has been in terms of value of sold drugs 11 milliards YTL (6,2 milliards Euro) and in terms of sold boxes 1,3 milliards boxes sold in Turkish prescription drug market. The market shares in terms of value of consumption have increased %17, and volume of consumption increased %10. Major factors that derive this increase are the extension which has been achieved by new drugs entered the market in 2007 and the increased access to drug by improved health care services.

As in 2006, market shares of generic medicines in terms of volume were %50,7 and value of consumption were %32,8, this has been increased in terms of volume to %51,7 and in terms of value of consumption to %33,4 in 2007.



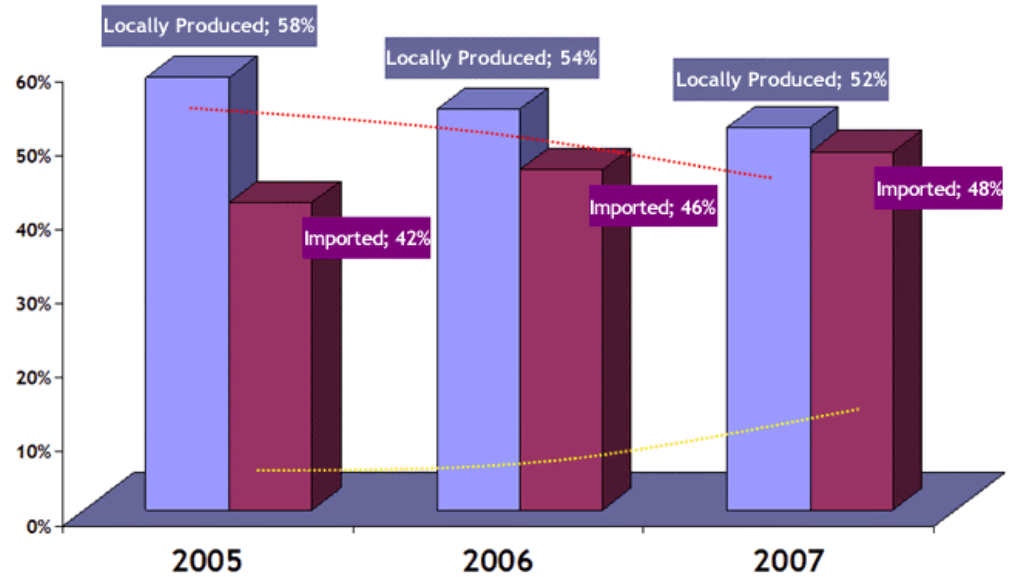
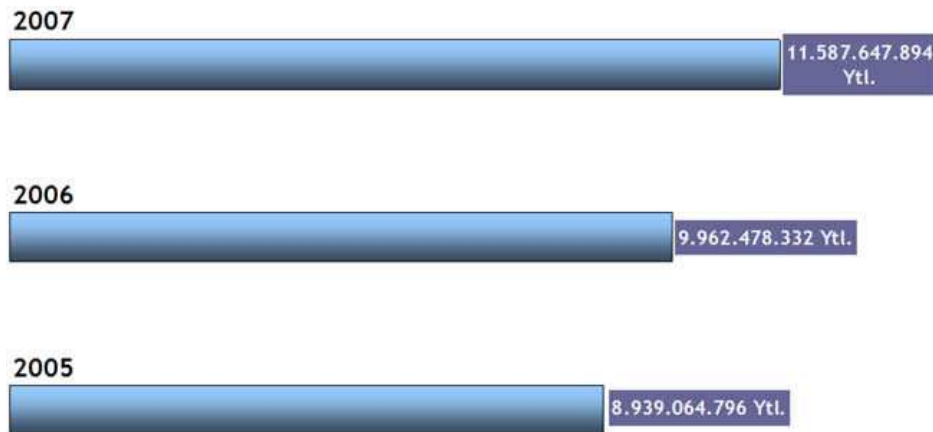
Figures about the Turkish Pharmaceutical Industry
 (Taken from the website of “Turkish Pharmaceutical Manufacturers Association”)

Development of drug market in terms of sold boxes



Figures about the Turkish Pharmaceutical Industry
 (Taken from the website of “Turkish Pharmaceutical Manufacturers Association”)

Development of drug market in terms of YTL





The Historical Context with the European Union and the Continental European Legislation:

1. The Association Agreement between Turkey and the then EEC signed in 1963 and in force since December 1964.
2. The Customs Union between EU and Turkey formed according to the decision of the “Turkey-European Union Association Council” - No. 1/95 of 6 March 1995.

The historical background of the harmonization
of the Ottoman/Turkish legislation with the
Continental European Legislation



Current Legislation on IPRs

Patents/Utility Models, Trade/Service Marks,
Industrial Designs, Geographical Indications/Signs

- * Unlike many countries, instead of amending gradually its IP legislation, Turkey has enacted on 27 June 1995 an entirely new series of Decree-Laws No. 551 for the protection of patents/utility models, No. 556 trade/service marks, No. 554 industrial designs and No. 555 geographical indications/signs, with a view to prepare for its European Union Candidacy, to address the needs of its varied and expanding industry and economy and to fully harmonize its IP legislation not only with the legislation of the European Union but also with the international Conventions of which it is signatory.
- * The Decree-Law No. 556 on Trade/Service Marks is in conformity with the Directive No. 89/104 regarding the harmonization of EU member countries trademark legislation and with the council regulation No. 40/94 concerning the community trademark.



Current Legislation on IPRs

- * European Patent Convention, Turkey has ratified **EPC 2000**,
- * but holds back its signature on the **London Protocol** concerning the issue of the translation of the European Patents.
- * Turkey is signatory of TRIPs but has not ratified the amendment for the introduction of new Art. 31 bis.



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Current Legislation on IPRs

- * **Common characteristic** of the currently in force Decree-Laws, is that they are **similar in their structures and that some of their provisions are similar/identical** such as: -the necessity of obtaining a registration for benefiting from the protection provided by the act - persons entitled to obtain protection in Turkey, -priority, -exhaustion of rights, -status changes, -litigation, -compensation, -competent courts, -infringement evidence, -establishment of experts' opinion through the court in determination of evidence/facts of infringement, the declaration of non-infringement/similarity, -injunctive relief upon court order, -procedural law, -border measures. **With said Decree-Laws, Turkey has enacted a fully integrated and coherent body of industrial property legislation with acts having parallel structures and provisions.**



Current Legislation on IPRs

Drafts of new laws for repealing and replacing the currently in force Decree-Laws.

- * It must be said that the series of Decree-Laws enacted on 27 June 1995 have been rushed through to meet the deadline originating from the Customs Union formed in 1995 between Turkey and EU with the intention to enact the respective laws through the Parliament at a later date to replace the Decree-Laws. At the moment the situation is unchanged as the Decree-Laws in question continue to be in force.
- * In this regard the drafts prepared by the TPI for the new laws on Patents/Utility Models, on Trade/Service Marks, on Design Patents and on Geographical Indications to repeal and replace the respective Decree-Laws are waiting their turn before the parliamentary commission.



Current Legislation on IPRs

Concerns The Pharmaceutical Industry

- * Having regard to pharmaceutical products, the Turkish legislation does not provide for (SPC) “**Supplementary Protection Certificate for Medicinal Products**” on the basis of the EU Directive 1768/92/EEC of 2 January 1993. Accordingly, there is no instrument/act permitting to extend the full term protection of 20 years as of the Decree Law No. 551 on Patents and Utility Models.



Current Legislation on IPRs

Concerns The Pharmaceutical Industry

- * Amendment of the Article 75 of the Decree-Law No. 551 on Patents/Utility Models introducing the **“Bolar provision”** into the Turkish patent protection system. New paragraph (f) has been added to Article 75, reading **“obtaining the regulatory authorization for pharmaceutical products and acts for experimental purposes pertaining to the invention subject of regulatory authorization including testing and experimentation necessary therefore.”**



Current Legislation on IPRs

- * In the matter of Data Protection, the “Regulation for Regulatory Authorization of Medical Pharmaceutical Products” in the matter of “**Data Protection**” has entered into force on January 19, 2005 upon its publication in the Official Journal no. 25705, bringing the Turkish legislation in line with the European Directive 2001/83/EC.



Current Legislation on IPRs

⇒ In an action instituted in 2002 against the Ministry of Health where the plaintiff asserted that **undisclosed information belonging to a medicament which has obtained the first authorization has also been used for the finalization of the equivalent medicament has been rejected in 2004 by the Tenth Chamber of the Turkish State Council (High Administrative Court) on grounds that according to the subject Regulation as it is not question to disclose the information submitted by the firm having obtained the first authorization from the Ministry to an other firm interested to obtain the equivalent medicament authorization,** the assertion of the plaintiff has not been found acceptable, as the court held that the **assertion that the Ministry (of Health) does not protect such undisclosed information has not been evidenced.**



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Current Legislation on IPRs

⇒ For more information, you may visit our web site deris@deris.com.tr where you can find under "Court Decisions" the details of this specific case as well as the details of **the case for "Patent Infringement and Unfair Competition"** where the **2nd Istanbul Court of Intellectual and Industrial Rights** has ruled that the filing by a generic firm of shortened application for regulatory authorization can not be deemed as an act of patent infringement and unfair competition thereby rejecting the request of the plaintiff.



Current Legislation on IPRs

Acts regarding other IPRs

- * The Act No. 5042 pertaining to the **Protection of Breeder's Rights concerning the New Plant Varieties (Plant Variety Act)** has entered into force on January 15, 2004 to provide protection for “all plant varieties.
- * **The Act No. 5147** pertaining to the **Protection of Integrated Circuit Topographies** has entered into force on 30 April 2004.



Current Legislation on IPRs

Acts regarding other IPRs

- * Copyright protection is secured by the **“Law on Intellectual and Artistic Works” (Copyright Act)** No. 5846 of 5 December 1951 as amended by Law No. 4630 of 21 February 2001 to bring it in conformity with TRIP’s and further amended by the Law No. 5101 of 03 March 2004 particularly increasing the criminal sanctions.



Legal Remedies – Civil & Criminal

The infringement involves the unauthorized production, sale, offer for sale, use, keeping in hand and importation for such purpose of goods and services identical or similar to a registered industrial property right. Likewise refusal to disclose information as to the producer(s) and supply channel(s) of counterfeits constitutes in itself an act of infringement according to the Decree-Laws which under parallel provisions provide cumulative routes for civil and criminal proceedings.

Unfair Competition

Infringement of Industrial property rights constitutes at same time an act of unfair competition according to the Turkish Code of Commerce. The action for unfair competition which can be engaged through civil and/or criminal proceedings can be instituted also in the absence of trademark registration and/or design patent in Turkey.



Criminal Remedies and Proceedings

The Turkish IP legislation contains various criminal sanctions such as imprisonment, pecuniary fines, the ban of exercising the professional activity and the closure of the infringer's premises in case of violation of the protected IP rights.

The Criminal proceedings are initiated upon the filing of a complaint with the Public Prosecutor by the IP right holder.

Enforcement Shortcoming

The Law No. 5271 in force since 17 December 2004 repealing and replacing the "Criminal Procedural Law" rules that the stating/announcing of the decision can be postponed when the accused is convicted to imprisonment of up to 1 (one) year or to pecuniary fine in which case the decision of the court will not have any legal effect on the convicted. This provision has been amended by Law No. 5728 in force since 08 February 2008, whereby the conviction limit for imprisonment is increased to 2 years, bringing many of the criminally punishable acts regarding IP rights, within the scope of this provision in the sense that for all such cases the court may decide to postpone the stating/announcing of the decision. That is to say that for all such cases all such decisions even if they involve imprisonment charges or pecuniary fines will have no legal effect on the convicted.



Border Measures (suspension of release procedure)

Although Turkey has not enacted a specific act for border measures, the above referred Decree-Laws, The Copyright Act as well as the Customs Act No.4458 include specific and parallel provisions according to which, the right holder may ask the relevant Customs Authorities to suspend the release of counterfeit or pirated goods bound for importation or exportation. The Implementing Regulation dated 31 May 2002 of Customs Act No. 4458, takes into account the related Council Regulation (EC) No. 3295/94 as it provides two routes for activating the procedure: upon application of the right holder and ex-officio Implementation by the Customs.

Enforcement Shortcoming

For want of a centralized organization/authority for taking nationwide action before all custom ports/authorities simultaneously, complaints and applications requesting border measures are to be filed and followed up separately before each customs port/authority.



Injunctive Relief

In Turkey, only the civil courts are empowered to order injunctive relief within the context of civil proceedings.

Enforcement Shortcoming

In this regard, one important point to mention is that the courts refuse outright the requests for injunctive relief when the defendant is holder of trademark / industrial design/ patent registration in its own name since according to the Supreme Court case law, the use based on such registration is not deemed to be an infringement unless and until such registration is cancelled by a finalized court ruling.



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The Administration

- * The **T.P.I.** is the administrative authority for the establishment of Industrial Property Rights whereas the **Ministry of Tourism and Culture** is the administrative authority dealing with copyrights.
- * Other administrative authorities such as the **Ministries of Health, of Agriculture and the Customs.**
- * Having regard to the **Company Law**, also the **Trade Registries** should be mentioned.
- * The “**Intellectual and Industrial Property Rights Coordination Board**” depending from the Prime Minister’s Office has been newly created as published in the Official Journal No. 26882 of 21 May 2008.



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The Judiciary

In compliance with the provisions of the above referred Decree-Laws and Acts, specialized **Criminal and Civil Courts of Intellectual and Industrial Property Rights** have been established in the cities of **Istanbul, Ankara and Izmir** for hearing cases in all IP matters whether for invalidation or enforcement. The specialized Court of Ankara hears all the appeals filed against the decisions of the Turkish Patent Institute. In the remaining cities of Turkey the third Civil and Criminal Courts in each city have been determined to serve as the specialized court in all IP matters including enforcement.



The Profession

- * As for the legal representation of rightholders, only attorneys-at-law can act before the Courts in all IP matters, whereas **only patent and trademarks attorneys** having been cleared by and **registered with the T.P.I. can represent the rightholders before the T.P.I..**
- * For representing their clients before the Turkish Patent Institute, the patent and trademark attorneys must undergo an **examination organized by the T.P.I. and must be registered with the T.P.I.**
- * Even though, the Registered Patent and Trademark Attorneys gain their qualification by examination by the T.P.I., there is **no legislative text and rules of conduct/of best practice** to which they are subject to in terms of professional conduct and no body/authority to monitor their professional conduct and from thereon, there is **no nationwide umbrella organization -Institute-** grouping them as a profession.
- * In the beginning in 2008, the so-called **“Sectorial Assembly of patent and trademark attorneys”** has been established under the aegis of TOBB which is the **“Union of the Turkish Chambers of Commerce/Industry and Exchanges”**.



Enforcement and legal predictability/certainty

- * On the enforcement side it can be said that Turkey disposes a relatively rich, steady and fairly well reasoned case law especially with regard to trademarks and unfair competition, the case law on patents being relatively thin.
- * Yet in our opinion, the issue of predictability and legal certainty is the one of importance as it conditions directly what is achievable and what is not in terms of establishment of industrial property rights with the T.P.I. and in connection with it the enforcement or the defense of such rights, in consideration of the fact that the right holder's primary concern is the efficiency of enforcement to the extent it deters, prevents and stops the infringement and recovers damages and litigation costs within a reasonably acceptable time frame. The Turkish IP system should possibly be made to function interactively to increase legal certainty so as to increase predictability as to the expected result of the action whether before the various administrative authorities, principally T.P.I. or the Courts.



Enforcement and legal predictability/certainty

* It seems to us that one of the main reasons of the wanting level of legal certainty and from thereon predictability either before the various administrative authorities or before the courts is that the officials in each administration do take their decisions as of their proper understanding/reasoning without always taking into account the aim and the institutions of IP protection in their particular applications.

We believe this is more a matter of stance than a matter of administrative shortcoming.

In so far as we see it, the disfunctions of the IP system are not so much caused by the shortcomings of the administrative capacity in itself than the stance/attitude taken especially by the administrative authorities, mainly the T.P.I. for the establishment of IP rights by registration in understanding and applying the letter of the law by taking into account also its spirit.

An important shortcoming in term of administrative capacity concerns the Trade Registries, which are organized regionally and have no centralized referencing organization with a view to monitor and avoid the establishment of companies with similar/overlapping names.



To our opinion the following points, affect negatively enforcement in this country:

- * Excessive reliance by the Courts on expert's opinions may unduly extend proceedings and, depending on the level of qualification and understanding of the expert(s), may negatively affect the outcome of the action for improperly and/or insufficiently reasoned expert opinions.
- * The courts are rather conservative in ordering injunctive measures especially when the defendant owns a registration.
- * The public prosecutors are difficult to convince in accepting the complaints to engage criminal proceedings and ordering police raids at short notice.
- * Greatly reduced deterrent and preventive effect of criminal proceedings and sanctions because of the changes in the legislation and the attitude of the courts towards IP Right offences.



**To our opinion the following points, affect negatively enforcement
in this country :**

- * Insufficiency of compensations granted, especially for moral damages, and difficulties for evidencing the injuries suffered, especially having regard to the reputation.
- * Difficulties for evidencing use/non-use by the defendant registrant patentee due to the silence of the act on clearly defined discovery/disclosure rules and other evidence collecting tools on infringement such as saisie-contrefaçon, search.
- * Insufficient recovery of court expenses determined in the court decision as they do not reflect fully the charges and especially the lawyer's fees effectively paid.



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Thank You.

M. N. Aydın Deriş



INTELLECTUAL PROPERTY ATTORNEYS

DERİŞ PATENTS & TRADEMARKS AGENCY A.Ş.
&
DERİŞ LAW OFFICE