MOROĞLU ARSEVEN

Overview of Pharmaceutical IP and Competition Law in Turkey (2015)

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Patents

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Under Turkish Law, IP rights are regulated by decree laws (issued by the Cabinet of Ministers) as opposed to laws (issued by the General Assembly). For patents, Decree Law 551 Pertaining to The Protection of Patent Rights (Patent Decree Law) applies. According to Article 5 of the Patent Decree Law, inventions which are novel, involve an inventive step, and which are applicable to industry can be protected by patents.

Turkey is party to a range of international agreements related to patents:

- Turkey has been a party to the Paris Convention for the Protection of Industrial Property since 1925 when it became a signatory to the London text, and later the Stockholm Text (1995).
- Turkey became a party to the Patent Cooperation Treaty on 1 January 1996.
- Turkey has been party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), effective from 31 December 1995.
- Turkey became a party to the European Patent Convention on 29 January 2000.

Scope of protection

If they meet the legislative criteria, all inventions regarding a product or process can be protected through patents.

The following cannot be protected by patents because by their nature they cannot be described as an invention:

- Discoveries, scientific theories, and mathematical methods.
- Plans, methods, schemes/rules for performing mental acts, for conducting business/trading activity, and for playing games.
- Literary and artistic works, scientific works, creations having an aesthetic characteristic, and computer programmes.
- Methods for collecting, arranging, offering/presenting and transmitting information/data which involve no technical aspect.

- Methods of diagnosis, therapy, and surgery applying to humans or animals. However, Turkish law allows products, compositions, and processes regarding these products or compositions used in connection with human or animal health to be patented.

Turkish law excludes patent protection for:

- Inventions whose subject matter is contrary to public order or generally accepted morality.
- Plant and animal varieties/species, or processes for breeding/plant or animal varieties/species, which are based mainly on biological grounds.

2. How is a patent obtained?

Application and guidance

The Turkish Patent Institute (TPI) receives applications and grants registrations for patents. The TPI's website lists regulations and fees in both English and Turkish (*www.tpe.gov.tr/TurkPatentEnstitusu/?lang=en*).

The information and documents required for a patent application in Turkey are:

- TPI patent application form.
- Description of the invention.
- Claims.
- Summary of the invention.
- Drawings.
- Bank receipt relating to payment of the TPI's official application fee.

Process and timing

Registration of a patent in Turkey generally takes between two and five years:

- The TPI conducts a formal examination of patent applications. The TPI initially checks whether all the required documents have been submitted and whether the documents meet the physical criteria (for example, whether the correct number have been supplied, or correct measurement units used). If the TPI finds any problem at this stage, the applicant is allowed three months to make the necessary corrections.
- The applicant must request the TPI to undertake a standard state-of-the-art search within 15 months following the application date (or priority date, if one has been claimed in the application) and pay the necessary fee for the search. If the applicant does not request such a search within the permitted time period, the patent application will be deemed withdrawn.
- The search report must include those elements of the state-of-the-art which are necessary for assessing or supporting the subject matter's novel characteristics or inventive step. The applicant can request the search to be made by the TPI, or by the patent offices in Russia, Austria, Sweden, and Denmark.
- The application will be published in the Official Patent Bulletin 18 months after the application, or priority date (if one exists), regardless of whether the applicant's search report has been prepared yet.
- Once the applicant receives notification of the search report, the applicant is allowed three months to choose between two patent registration systems. At the end of the three month period, the search report is published, including the applicant's choice of registration system. The two systems are the following.

With substantive examination. Under this approach:

- The applicant must request the substantive examination to be conducted within six months of the search report being published.
- Third parties can oppose the application on the basis that the application does not meet the patentability criteria. The applicant is allowed three months to respond to any third party oppositions. The applicant's response period can be extended by three further months, on request.
- The TPI begins its substantive examination once the response period has expired (or at the end of the three month period allowed for third parties to make oppositions, if there are no oppositions).
- If the TPI concludes the application meets the patentability criteria, the TPI will issue the patent (on payment of the necessary fees).
- If the TPI concludes that the application does not meet the patentability criteria, the applicant is allowed six months to either amend its claims or object to the TPI's report. The TPI will consider the applicant's objections or amendments and if the TPI stands by its previous decision, the applicant is allowed three months to make a second round of objections or amendments. The TPI's next decision on the matter is final.

Without substantive examination. Under this approach:

- Third parties are allowed six months to submit their observations about the search report. Third party observations are notified to the applicant, who then has three months to submit counter arguments.
- After this three month period, the TPI decides whether to grant the patent without taking the search report or observations of third parties into consideration (if any).
- If the TPI decides not to undertake a substantive examination, on payment of the necessary fees, the TPI will issue the patent for a term of seven years and publish the issuance in the Official Patent Bulletin.

If the applicant fails to advise the TPI of its choice within three months of receiving notification of the search report, the patent registration procedure will continue without a substantive examination.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

Turkish law has two types of patent registration system (*see Question 2*) with different patent protection terms:

- Seven years for a patent without substantive examination (from the application's filing date).
- 20 years for a patent with substantive examination (from the application's filing date)

It is not possible to renew a patent under Turkish law. Upon expiry of the protection period, the patent's subject matter will become public property (*Article 133, Patent Decree Law*).

Patent holders must pay an annual maintenance fee. If the owner does not pay the annual fee within the allowed timeframes, the patent registration will eventually lapse.

Extending protection

At the moment, it is not possible to extend the patent protection period in Turkey. However, such a system is under discussion within the scope of the EU harmonization process.

4. How can a patent be revoked?

Invalidation of a patent can only be made through a decision by the competent courts and therefore must occur through court actions. The following are accepted as grounds for invalidation (*Article 129, Patent Decree Law*):

- The invention's subject matter does not meet the patentability criteria.
- The invention's subject matter has not been described in a sufficiently explicit and comprehensive manner so as to enable a person skilled in the technical field concerned to re-create the invention.
- The patent's subject matter exceeds the scope of the application.
- The patent covers several inventions, which should have been the subject of different patent applications.
- The patent holder does not have the right to a patent.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The following actions are considered patent infringement under Turkish law (*Article 136, Patent Decree Law*):

- Imitating an invention by producing the product in whole or in part, without the patent holder's consent.
- Where the person concerned knows (or should know) that such products are imitations in whole or in part but is still involved in:
    - selling, distributing, or commercializing products in any other way (as well as importing for such purposes);
    - possessing products for commercial purposes; or
    - using by applying products which were manufactured as a result of an infringement.
- Without the consent of the patent holder, using the patented process or selling, distributing, or commercializing the product in any other way (as well as importing for such purposes), or using by applying products directly obtained through the patented process.
- Enlarging the scope of the rights granted by the patent holder on the basis of a license agreement or granted by compulsory license or transferring such rights to third persons, without permission.
- Participating in the actions mentioned above, as well as assisting, inducing, encouraging, or facilitating their occurrence or perpetration in any way and under any circumstances.
- Refraining from declaring the source and manner of obtaining products found in a party's possession, which were unlawfully manufactured or commercialized.

Claim and remedies

In 2005 the Constitutional Court struck out an article in the Patent Decree Law which enabled infringers to be punished criminally. The basis for the Constitutional Court's decision was that crimes must be regulated by laws (issued by the General Assembly) rather than decree laws (issued by the Cabinet of Ministers). Turkey's Grand National Assembly has not yet regulated the issue again through laws.

Therefore, a patent right holder can only bring an infringement claim in a civil action. Patent applicants can also initiate infringement claims if its application has been published. Patent infringement cases are heard by

commercial courts, or by specialized IP courts and prosecution offices in cities where IP courts have been established (currently Ankara, Istanbul, and Izmir, with more cities expected in future).

In a patent infringement action, the claimant can claim:

- Cessation of the infringing actions.
- Elimination of the infringing actions.
- Compensation of material and immaterial damages.
- Confiscation of manufactured or imported products and devices used during production.
- Ownership of the ceased products and devices.
- Preliminary measures to prevent further patent infringement.
- Disclosure of the infringement decision to relevant persons or to the general public through publication.

6. Are there non-patent barriers to competition to protect medicinal products?

Turkey introduced a legislative data exclusivity regime in January 2005 in the Regulation on Licensing of Human Medicinal Products. Under this regime, data exclusivity exists for six years after the first marketing authorization application date of a new pharmaceutical in a country which is a member of the European Union Customs Union.

In Turkey, a pharmaceutical product for human use cannot be marketed unless it is authorized by the Ministry of Health. In granting a marketing authorization, the Ministry of Health requires drug producers to submit the results of their pharmaceutical products' safety and efficacy tests, along with other documents regarding the product. Data exclusivity provides original drug producers with protection for the information gathered from their clinical trials and studies. During the data exclusivity period, no other firm can apply for marketing authorization from the Ministry of Health by referring to the clinical data related to the new pharmaceutical, without specific permission.

Under Turkish Law, the data exclusivity period is linked to the patent protection period, if the pharmaceutical is also subject to a patent. Original pharmaceutical products which have been licensed in a country which is a member of the European Union Customs Union are subject to a data exclusivity period of six years (*Article 9, Regulation on Licensing of Human Medicinal Products*). The six-year term starts from the first marketing authorization of the original product in any of the Customs Union Member States. If a Turkish patent exists, the data exclusivity will end when the Turkish patent expires, even if this is earlier than six years. Therefore, the period of data exclusivity depends on the term of any Turkish patent which covers the active substance of the biological reference product. To determine the data exclusivity period in Turkey, it is important to know whether patent protection exists or not.

The Regulation on Licensing of Human Medicinal Products applies to:

- Original pharmaceuticals which apply for marketing authorization after 1 January 2005 in countries which are members of the European Union Customs Union.
- Original medicinal products which apply for marketing authorization after 1 January 2001 in countries which are members of the European Union Customs Union, provided that no applications have been made for marketing authorization relating to generic pharmaceuticals before 1 January 2005.

Marketing exclusivity is not regulated in Turkey. Therefore, once the data exclusivity term expires, generic companies are entitled to apply for marketing authorization by referring to the clinical data which was

previously protected by data exclusivity, as well as launch their product on the market.

Trade marks

7. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

Turkey regulates IP rights through decree laws (issued by the General Assembly) rather than laws (issued by the Cabinet of Ministers). The relevant legislation for trade marks is the Decree Law on the Protection of Trademarks 556 (Trade mark Decree Law).

Turkish law accepts a sign as a trade mark if the sign can be graphically represented and is capable of distinguishing an entity's goods or services from those belonging to others (*Article 5, Trade mark Decree Law*). The following are also accepted as a trade mark, provided they are distinctive:

- Words.
- Letters, numerals, and combinations of the two.
- Device marks (logos).
- Three-dimensional device marks (the shape of goods or their packaging).
- Slogans (provided it is distinctive, or contains a distinctive word/device mark).

Turkey is party to a range of international agreements related to trade marks:

- Turkey has been a party to the Paris Convention for the Protection of Industrial Property since 1925 when it became a signatory to the London text, and later the Stockholm Text (1995).
- Turkey became a party to the Patent Cooperation Treaty on 1 January 1996.
- Turkey has been party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), effective from 31 December 1995.

Scope of protection

The TPI conducts an ex officio examination of trade mark applications, checking whether any absolute grounds for refusal exist (*Article 7, Trade mark Decree Law*). Absolute grounds for refusal include:

- Signs which do not have distinctive character.
- Signs which refer to characteristics, quality, intended purpose, value, or origin of the covered goods or services.
- Signs which are identical (or almost identical) to earlier registered trade marks.
- Signs which are contrary to public policy or accepted principles of morality.
- Trade marks concerning the public and possessing historical and cultural value due to their incorporation of armorial bearings, emblems, or hallmarks, without the consent of the competent authorities (except for those within the scope of Article 6ter of the Paris Convention).
- Signs which constitute well-known trade marks within the meaning of Article 6bis of the Paris Convention and which have not been authorized by their owners.
- Signs containing religious terms, symbols, names of religious officials, holy words, and so on.

8. How is a trade mark registered?

Application and guidance

Trade mark applications are made to the TPI which is authorized to grant registrations in Turkey. The TPI's website lists regulations and fees in English and Turkish.

Process and timing

The following documents and information are required to file a trade mark application in Turkey:

- Trade mark sample:
    - word mark: including the correct spelling of the word;
    - device mark: including a sample of the trade mark sample in electronic.JPG format. The sample must be at least 300 dpi, and minimum 5 x 5cm (590 x 590 pixels), maximum 7 x 7cm (825 x 825 pixels).
- The name, address, telephone, and fax number of the trade mark owner.
- List of goods and/or services which the subject trade mark application relates to.
- Priority document. If the application is based on a prior application, the prior application details are needed. The original or certified copy of the priority document must be submitted to the TPI within three months of the filing date.

If the TPI does not issue an office action or the application remains unopposed, the TPI's trade mark registration procedure generally takes between ten and 12 months.

Once the TPI receives an application, it conducts an ex-officio examination. The TPI checks:

- The required documents.
- The applicant's eligibility to apply for a trade mark.
- Whether absolute grounds for refusal exist.

If the application passes the TPI's ex-officio examination and finds no absolute grounds for refusal, the application is published in the Official Trademark Bulletin:

- Third parties are allowed three months from the publication to file oppositions against the trade mark application.
- If the TPI rejects the third party oppositions to the trade mark application and the third party does not appeal the TPI's decision, the trade mark registration will be granted.
- If the TPI upholds the third party opposition, the applicant is allowed two months to appeal this decision. The TPI's decision regarding the appeal is final.
- If the applicant's appeal is unsuccessful and the TPI stands by its decision, the only avenue available to the applicant is to seek cancellation of the TPI's decision through a court action.

If the TPI refuses the trade mark application after its ex-officio examination, the applicant is allowed to file an appeal within two months. The applicant's appeal is examined by the TPI's Re-Examination and Evaluation Board. The Board's decisions are final and the applicant can only request cancellation of the Board's decision through a court action.

9. How long does trade mark protection typically last?

Trade mark registrations in Turkey last ten years, starting from the application date.

Registrations can be renewed indefinitely. Renewal requests are made by submitting the appropriate form to the TPI and paying the necessary fee within the six months before the last day of the month in which trade mark protection ends. The period for requesting renewal can be extended by a further six months on payment of an additional fee.

10. How can a trade mark be revoked?

Cancellation (invalidation) of a trademark can only occur in Turkey through a decision made by the authorized courts.
Claimants can seek trade mark cancellation in Turkey on the following grounds:

- Breach of absolute grounds for refusal (see Question 7).
- Breach of relative grounds for refusal (Article 8, Trademark Decree Law).
- Sameness, similarity, or likelihood of confusion with:
    - an earlier, registered, or applied for trade mark;
    - an unregistered trade mark which was in use in Turkey before the subject trade mark's application date;
    - a guarantee or collective marks (this argument can be claimed within three years after the basis trade mark's expiry date);
    - an expired trade mark (this argument can only be made within two years of the basis trade mark's expiry date).
- Unauthorized filings by an agent or commercial representative.
- Dilution of a well-known trademark (the subject trademark takes unfair advantage of, or is detrimental to, the distinctive character or repute of the registered well-known trademark).
- Copyright infringement, in that the trade mark application infringes the rights arising from a name, photograph, copyrighted work, or any other industrial property rights owned by a third party.
- Non-use of the subject trade mark.
- The trade mark has become generic in respect of the goods or services as a result of acts by the trade mark's owner.
- As result of the trade mark owner's use (or a person authorized by the owner), there is a likelihood of confusion for the public as to nature, quality, place of production, or geographical origin of the goods or services which the subject trade mark is registered for.
    - Use of a guarantee mark which is contrary to the technical specification.

Trade mark cancellation actions must be filed within five years following the subject trade mark's registration date.

The non-use grace period for a trade mark in Turkey is five years, starting from the trade mark's registration date. Third parties can only initiate non-use actions after the fifth year of a trade mark's registration.

Generally, a trade mark cancellation in Turkey takes effect retrospectively, as if the trade mark was never registered. However, a recent decision by the Constitutional Court states that the effect of a cancellation decision based on non-use will apply from the date of the cancellation decision onwards (not retrospectively).

11. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

Under Turkish law, the following actions constitute trade mark infringement:

- Violations of the rights arising from trade mark registration (Article 9, Trade mark Decree Law), including use of any sign which:
    - is identical to a registered trade mark, in relation to goods and services which are identical to those which the trade mark is registered for;
    - because of its identity with or similarity to a registered trade mark and identity or similarity to the goods and services covered by the registered trade mark and sign, there is a likelihood of confusion for the general public, including likelihood of association between the sign and the trade mark;
    - is identical to or similar to the registered trade mark in relation to goods or services which are not similar to those for which the trade mark is registered, where use of that sign without due cause takes unfair advantage of or is detrimental to the distinctive character or the reputation of the registered trade mark.
- Imitating the trade mark by using a mark which is identical or indistinguishably similar, without the trade mark owner's consent.
- Selling, distributing, or otherwise trading products bearing the trade mark, or indistinguishably similar marks in violation of trade mark rights, or placing such products in Turkish customs territory, which are known (or should have been known) to be produced in violation of a trade mark.
- Expanding the scope of rights acquired by a trademark license contract, or transferring them to third parties.

Claim and remedies

Trade mark infringement is both a tort and a crime in Turkey. Therefore, a trade mark owner can initiate both criminal and civil actions against infringers. Cases are heard by specialized IP courts and prosecution offices in cities where IP courts have been established (currently Ankara, Istanbul, and Izmir, with more cities expected in future) or otherwise heard by general criminal and civil courts.

Civil action. Trade mark owners can start a lawsuit to eliminate and cease further trade mark infringement. Trade mark owners also have the right to request the following remedies:

- Preliminary injunction.
- Requests for determination of infringement.
- Cessation and prevention of infringement.
- Elimination of infringement.
- Seizure of counterfeit goods.
- Compensation for damages (both material and immaterial).
- Disclosure of the final decision to the public through a newspaper with mass circulation.

Criminal action. Trade mark infringement was defined as a crime under the Trade mark Decree Law. As a criminal offense, trademark owners can request the seizure of counterfeit or infringing goods. However, the provisions of the Trademark Decree Law establishing criminal liability were canceled by the Constitutional Court, on the basis that crimes and punishments must be regulated by laws (issued by the General Assembly) and not decree laws (issued by the Cabinet of Ministers). Subsequently, the General Assembly has regulated trademark infringement as a criminal offense through law and further detailed legislation is expected to

follow.

12. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

If the pharmaceutical brand is registered as a trademark, then producing, distributing, or selling counterfeit pharmaceuticals constitutes trademark infringement. Accordingly, the trade mark owner can initiate a civil or criminal action.

If the pharmaceutical is patented, counterfeit pharmaceuticals give rise to patent infringement. Accordingly, the patent owner can initiate an infringement action before the civil courts.

The Law on Veterinary and Medical Pharmaceutical Preparations 1262 states that producing or selling pharmaceuticals without marketing authorization is a criminal offense punishable by between one and five years' imprisonment. The offense includes making such pharmaceuticals available for sale or having them sold by another party.

IP and competition law issues

13. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The responsible authority in Turkey for enforcing prohibitions on anti-competitive actions and restraints is the Competition Authority (*www.rekabet.gov.tr/en-US/Pages/Turkish-Competition-Authority*). The Competition Authority is an independent regulatory authority with administrative and financial autonomy. Its decision-making body is the Competition Board. The Competition Authority fulfills its duties independently and no body, authority, or person can give commands or orders to influence the Competition Board's final decisions. Legal actions against the Competition Board's final decisions are brought before the administrative courts.

Competition law principles are primarily outlined by the Law on Protection of Competition 4054 (Competition Protection Law). Secondary legislation regarding competition law in Turkey represents localized versions of EU legislation. There is no single piece of Turkish competition legislation which directly and specifically addresses the pharmaceutical sector. Therefore, the Competition Protection Law along with the following communiqués and guidelines apply to competition law issues in the pharmaceutical sector (depending on the characteristics of each case):

- Block Exemption Communiqué number 2002/2 on Vertical Agreements.
- Block Exemption Communiqué number 2003/2 on Research and Development Agreements.
- Block Exemption Communiqué number 2008/2 on Technology Transfer Agreements.
- Block Exemption Communiqué number 2013/2 on Specialisation Agreements.
- Guidelines for Explanation of the Block Exemption Communiqué on Vertical Agreements.
- Guidelines for Horizontal Co-operation Agreements.
- Guidelines for Certain Toll Manufacturing Agreements Between Non-Competitors.

The pharmaceutical sector is a key sector for competition enforcement in Turkey. The Competition Board's enforcement actions mainly focus on merger control and anti-trust. A sector inquiry report which specifically considered the pharmaceutical sector was published by the Competition Authority in 2013 and states that the

Competition Board conducted nine investigations which were directly related to the human medicine market. Five of the investigations focused on the conduct of wholesalers and retailers operating in the pharmaceutical sector. The Competition Board investigated suppliers in the remaining four investigations. According to the Competition Authority's 2014 activity report, the Competition Board undertook eight investigations, 13 negative clearance/exemption cases and 11 merger control cases in the pharmaceutical, health services, and products sector. During 2014, the Competition Board imposed a total of TRY31,312,527 in fines on undertakings in the pharmaceutical, health services, and products sector.

A recent decision by the Council of State relates to the pharmaceutical sector and states that two e-mails between undertakings are sufficient to prove infringement (decision dated 20 January 2014, numbered 2010/2450; confirming the Tender Boycott decision dated 19 January 2007, numbered 07-07/43-12).

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context.

Block Exemption Communiqué number 2008/2 on Technology Transfer Agreements outlines exemption conditions for technology transfer agreements, as well as the restraints which trigger exclusion from the scope of the block exemption.

Prohibited restraints which cause competition issues are mainly:

- Resale price maintenance.
- Restriction of production and sales volumes of products.
- Allocation of markets and customers.
- Restriction of a licensee's right to use its own technology or the restriction of a party's right to carry out research and development activities, unless such restriction is necessary to prevent disclosure of the licensed know-how to third parties.

The restrictions outlined above may not apply if they do not fall foul of the Communiqué's requirements. Information about the parties' market share (both licensor and licensee) is essential for the Competition Board's assessment and determination of whether an agreement containing anti-competitive restrictions can benefit from the Communiqué's exemption.

For an agreement to be considered as a candidate for a block exemption under the Communiqué, the parties' market shares must be under 30% if the parties are competitors, or under 40% for non-competitors. The exemption will apply for as long as the protection granted to the intellectual property right regarding the licensed technology remains valid. The know-how exemption will continue to be valid as long as the know-how is not disclosed. If the know-how becomes publicly known because of the licensee, the exemption will continue to apply for the term of the agreement.

Horizontal agreements (such as agreements between competitors) are subject to stricter scrutiny. Therefore, price fixing, allocation of markets, and output restrictions are all prohibited in horizontal agreements.

15. Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

Unlike the EU or US, the Competition Board has not launched any investigation, nor rendered any decision specifically addressing competition issues arising from agreements or unilateral actions which restrict the generic entry of pharmaceuticals.

Despite no specific Competition Board decision on this issue, agreements and actions which prevent the generic entry of pharmaceuticals would be assessed under the general principles of the Competition Protection Law. If the undertaking which owns the original pharmaceutical restricts the entry of generic alternatives, this could be considered to be an abuse of a dominant position. To constitute abuse in this way, the relevant undertaking must actually have a dominant position and either directly or indirectly prevent generic market entry (*see Question 16*).

16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

Article 6 of the Competition Protection Law prohibits abuse of a dominant position. Turkish legislation is closely modeled on Article 102 of the Treaty on the Functioning of the European Union. The Competition Protection Law defines dominant position as the power of one or more undertakings in a particular market to determine economic parameters such as price, supply, the amount of production and distribution, by acting independently of their competitors and customers.

Similar to EU anti-trust law, Turkish anti-trust rules have no specific market share thresholds to give an indication of when a dominant position should be inferred. The Guideline on Abuse of Dominance states that undertakings with a market share below 40% are not deemed to have a dominant position. However, there are some Competition Board decisions which held the undertakings to have dominant positions, despite their market shares being below 40%. In these decisions, the Competition Board took into account the structure, characteristics, and dynamics of the relevant markets in reaching its conclusion.

The Competition Protection Law provides a non-exhaustive example list of different types of abuse (*Article 6*):

- Preventing (directly or indirectly) another undertaking from entering the area of commercial activity.
- Actions intended to complicate competitors' activities in the market.
- Directly or indirectly discriminating between purchasers with equal status by offering different terms for the same rights, obligations, or acts.
- Tying practices, such as:
    - purchasing another good or service together with a good or service;
    - tying a good or service demanded by purchasers acting as intermediary undertakings to the condition of displaying another good or service by the purchaser; or
    - imposing limitations with regard to the terms of purchase and sale in case of resale, such as not selling a purchased good below a particular price.
- Actions intended to distort the competitive conditions in another market through exploitation of financial, technological, or commercial advantages created by dominance in a particular market.
- Restricting production, marketing, or technical development to the prejudice of consumers.

One of the Competition Board's most significant decisions on the abuse of dominance in the pharmaceutical sector is the Sanofi Aventis decision (*dated 20 April 2009, numbered 09-16/374-88*). In 2008, Anfa Aventis amended its sales conditions and shortened the payment terms from between 60 and 180 days, down to 15 days. The amendment led to stock problems due to financial difficulties for pharmaceutical warehouses purchasing pharmaceuticals from Anfa Aventis. The amendment could also have led to exclusion of small and medium-sized warehouses from the market.

The Competition Board concluded that Sanofi Aventis had violated Article 6 of the Competition Protection Law. It held that Sanofi Aventis had infringed competition at the wholesale distribution level in related markets

through implementation of its new sales conditions. Anfa Aventis was ordered to pay an administrative fine of TRY3,648,045.

17. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Rights conferred by a patent will not extend to acts committed with regard to a product under patent protection after the product has been put on sale in Turkey by the patent right holder or with his consent (*Article 76, Patent Decree Law*).

Acts related to a product containing a registered trademark will not constitute a breach of registered trademark rights where such acts have occurred after the product has been put on the market in Turkey by the proprietor or with his consent (*Article 13(1), Trademark Decree Law*).

The domestic exhaustion principle applies in Turkey, which essentially states that if original goods are sold in Turkey, there is no limitation on resale of these goods. The principle applies to both trade marks and patents. Accordingly, if the parallel imported goods are original and legitimately sold in Turkey, any subsequent sale of the goods is also legitimate. Therefore, the right holder cannot prevent parallel imports of legitimate goods once these have been sold in Turkey.

Parallel imports are subject to the main competition rules under the Competition Protection Law, as there are no specific competition regulations in Turkey for parallel imports. Provided these transactions are in accordance with the general competition rules, parallel import of pharmaceuticals will not raise competition law issues in Turkey.

The Competition Protection Law prohibits actions or agreements which prevent parallel imports, although not specifically. It is prohibited in Turkey to do the following in any sector (*Article 4, Competition Protection Law*):

- Complicate and restrict the activities of competing undertakings.
- Exclude undertakings operating in the market by boycotts or other behaviour.
- Prevent potential new entrants to the market.

Similarly, directly or indirectly preventing another undertaking from entering the area of commercial activity, or actions aimed at complicating the competitors' activities are considered to be an abuse of dominance (*see Question 16; Article 6, Competition Protection Law*). Therefore, any such activities relating to parallel imports are prohibited by the general provisions in the Competition Protection Law.

The Competition Board has not specifically addressed parallel import restrictions in the pharmaceutical market, but it has made decisions on parallel imports in other sectors.

18. Does a patent or trademark license and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a license made enforceable?

No specific regulation exists in Turkey regarding royalties in relation to intellectual property. Foreign licensors are not required to be approved or accepted by a government or regulatory body.

Any patent or trademark license agreement can be registered before the TPI, regardless of whether or not one party is foreign. Similarly, any bonafide third party can claim against such agreements, even if they are

foreign.

Related Practices

- Antitrust and Competition
- Patents and Utility Models
- Trademarks

Related Attorneys

- IŞIK ÖZDOĞAN, LL.M.