Pharmaceutical IP and competition law in Turkey: overview

by Kayra Üçer Hakan Ekim and Deniz Yetkin, Hergüner Bilgen Özeke Attorney Partnership

Country Q&A | Law stated as at 01-Mar-2021 | Turkey

A Q&A guide to pharmaceutical IP and competition law in Turkey.

The Q&A gives a high level overview of key issues including patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Turkey: overview*.

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

Industrial Property Code No. 6769 (Industrial Property Code), which abolished Decree Law No. 551 on the Protection of Patent Rights (Patent Decree Law), is the primary legislation regulating patents. To be granted a patent, an invention must meet the following conditions:

- Be new.
- Involve an inventive step.
- Be applicable to industry.

(*Article 82, Industrial Property Code.*)

Turkey is a party to the following international agreements regarding patents:

- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) (including the London, Washington, The Hague, and Stockholm texts. The Lisbon text is signed but has yet to be ratified).
- European Patent Convention 1973 (EPC).
- Patent Cooperation Treaty 1970 (PCT).
- WIPO Strasbourg Agreement Concerning the International Patent Classification 1971.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).

Scope of protection

The following are not covered by patent protection, because they are not inventions:

- Discoveries, scientific theories and mathematical methods.
- Plans, procedures or rules regarding mental acts, commercial or game-related activities.
- Computer software.
- Literary and artistic works, scientific works, and aesthetic creations.
- The presentation of information.

(*Article 82, Industrial Property Code*.)

The following inventions cannot be protected by patents:

- Inventions against public order or generally accepted moral values.
- Biological processes relating to plant or animal varieties or intended to generate plant or animal varieties, with the exception of micro-biological processes or products obtained through such processes.
- All types of treatment methods, including diagnostic and surgical methods to be applied on human or animal bodies.
- Discovery of one element of the human body, including a gene sequence or partial gene sequence in the various phases of its generation and evolution.
- Human cloning processes, processes that modify the genetic identity of the human sexual line, the use of a human embryo for industrial or commercial purposes, genetic identity modifying processes that may cause animals to suffer without providing any substantial medical benefit to humans or animals, and animals resulting from such processes.

Pharmaceutical product formulas are protected by patents.

2. How is a patent obtained?

Application and guidance

The Industrial Property Code changed the name of the Turkish Patent Institute to Turkish Patent and Trademark Institute (Institute). Patent applications must be made to the Institute. The Institute's website provides information on the fees and regulations for the application procedure in both Turkish and English (*www.turkpatent.gov.tr/TURKPATENT/?lang=en*).

It is also possible to apply for international or European patents to the World Intellectual Property Organization (WIPO) (under the Patent Cooperation Treaty) (*www.wipo.int/portal/en/index.html*) or the European Patent Office (EPO) (*www.epo.org/index.html*) and then extend the application to cover Turkey as a region under international treaties that Turkey is a party to. This route also grants patent protection in Turkey as soon as a patent is granted. This is generally the preferred route for international pharmaceutical patent owners to extend their patent protection into Turkey.

When filing for a patent, the applicant must disclose explanations about the invention, its features, and any pictures referred to under the explanations (among others). The name of the applicant is also included under the application documents (however it is also possible to file an anonymous application).

Process and timing

The key stages of a patent application, which typically takes two to six years, are as follows:

- A formal examination is conducted by the Institute to check if the necessary documents for the application have been included. The applicant is given two months to provide any missing documents, and failure to provide any missing documents to the Institute will be deemed a withdrawal of the patent application.
- The applicant must request a state-of-the-art search within 12 months of the date of application. Failure to request a state-of-the-art search within 12 months will be deemed a withdrawal of the patent application.
- After receiving the search report, if the applicant decides to continue with the application, the applicant must apply to the Institute to request an examination on whether the patent application complies with the Industrial Property Code, within three months of the Institute's notification of the state-of-the-art search report. Failure to request for a compliance examination within three months will be deemed a withdrawal of the patent application. The Institute will issue an examination report following its review. The examination report is also published in the Institute's *Official Patent Bulletin*.
- If the Institute concludes that the patent application complies with the Industrial Property Code, the patent will be granted and the Institute will notify the applicant.

Any application filed in Turkey or in a signatory of the Paris Convention and TRIPS benefits from priority for 12 months from the application date.

As explained above, once the Institute completes its examination report, it is published in the Institute's bulletin. Until such date, the patent applications cannot be reviewed by third parties; however, if a third party claims that the applicant will use the patent protection against them and proves this allegation, the patent application may be reviewed by such parties before its publication.

Any third party may challenge the patent application by arguing that:

- The subject matter was in fact not patentable;
- The invention was not duly explained; or
- The explanations exceed the limits of the initial patent application.

Any challenges filed must also be notified to the applicant and the applicant can submit their reviews and explanations within three months from such notification. The Institute then reviews the objections after receiving the explanations of both parties.

Unless an objection is filed (or otherwise resolved), the Institute finalises its review and announces the patent in its bulletin again.

Apart from the process explained above, the patent applicant and/or patent owner of any related third parties can also file an objection against the decisions of the Institute within two months from its notification.

The Industrial Property Code abolished patent registration system without a substantive examination under the Patent Decree Law, which granted protection for a period of seven years.

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

Duration and renewal

Patent protection lasts 20 years from the date of filing of the application.

The subject of the patent will become public property following expiry of the patent protection period (*Article 140, Industrial Property Code*). Turkish law does not allow for the renewal of a patent. Patent holders must pay annual fees to maintain patent protection, and patent protection will lapse if the annual fees are not paid.

Extending protection

Turkish law does not allow for the extension of patent protection, and supplementary protection certificates are not granted or applied in Turkey.

4. How can a patent be revoked?

The owner of a patent can revoke a patent by giving up their patent rights by applying to the Turkish Patent and Trademark Institute.

Courts can revoke a patent if one of the following conditions is proven:

- The subject of the patent does not meet the patentability criteria.
- The subject matter of the invention is not described in a sufficiently explicit and comprehensive way to enable a person skilled in the technical field to use/apply the invention.
- The subject of the patent does not fall within the scope of the patent application.
- The patent holder does not have the right to request the patent.
- The scope of protection granted by the patent is exceeded.

(*Article 138, Industrial Property Code.*)

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

Conditions for infringement

The following acts constitute patent infringement:

- Imitating the invention product by producing the product partly or fully without the consent of the patent holder.
- Selling, distributing, commercialising, importing, possessing for commercial purposes, or using by applying products or making an offer to enter into agreements concerning products known or that should be known to be produced through imitation that cause patent infringement.
- Using the patented process or selling, distributing, commercialising, importing, or possessing for commercial purposes the output of the patented process that is known or should be known to be used without the permission of the patent holder, or using by applying such output or making an offer to enter into agreements concerning such outputs.

- Seizing the patent rights.
- Extending the scope of the rights granted through a licence or a compulsory licence, or transferring such rights to third parties without the permission of the patent holder.

(*Article 141, Industrial Property Code*.)

The following actions are not covered by the restrictions imposed by the patent protection, and therefore, do not constitute an infringement:

- Personal use that is not conducted for industrial or commercial purposes.
- Use for trial purposes.
- Use for experiments, including tests and experiments conducted for the licensing of pharmaceutical products.
- One-time pharmaceuticals generated in pharmacies upon a prescription.
- Use in construction or the operation of vessels, space vehicles, airplanes, and land transportation vehicles in the countries party to Paris Convention (on the condition that the vehicles in question are temporarily and incidentally within the boundaries of Turkey).
- Use under Article 27 of the International Air Transport Agreement 1944.

Claim and remedies

A patent holder or applicant can file an infringement lawsuit in specialised IP courts in Istanbul, Ankara, and Izmir, and in civil courts in other cities. The claimant can claim the following remedies:

- A ruling on the existence of infringement.
- Prevention of a possible infringement.
- Cessation of the acts causing the infringement granted through the patent.
- Termination of the infringement and reimbursement for material and immaterial damages.
- Confiscation of the products that caused the infringement or gave rise to the penalty and confiscation of tools, such as devices or machines used solely to produce these infringing products, to the extent that this will not prevent the production of products other than the ones constituting the infringement.
- Ownership of the confiscated products and devices.
- Preliminary measures to prevent infringement at the expense of the infringer, such as changing the shapes of confiscated products and devices, erasing the trade marks on them, or destroying them if necessary to prevent the infringement.
- Complete or partial announcement of the infringement decision in daily newspapers or through other means, or notification of the infringement to interested parties.

(*Article 149, Industrial Property Code*.)

The claimant can also request compensation for the damages it has incurred as a result of the infringement. If the infringement has resulted in reputational damages, the claimant can also request additional compensation.

Under Article 151 of the Industrial Property Code, a patent holder is also entitled to claim compensation for damages and loss of income caused by an infringement of the patented rights. At the choice of the patent holder, the amount of damages will be calculated using one of the following methods:

- Potential revenue of the patent holder if there had not been competition from the infringer.
- Net revenue of the infringer arising from the infringing activities.
- Licence fee that would have been paid by the infringer if he/she had lawfully used the patent rights under a licence agreement.
- The economic value of the patent, the remaining term of protection at the time of infringement, and the type and number of outstanding licences are also taken into account when calculating loss.

The prescription period for civil law claims is two years from the date when the infringement is discovered by the right holder, and ten years following from the date of the infringement (*Code of Obligations*). The Industrial Property Code has removed criminal law proceedings for patent infringement.

Dispute resolution and settlement

Patent infringements are usually settled before the courts. If the dispute relates to the commercial activities of enterprises, the dispute is considered a commercial dispute and can only be brought to the courts after the mandatory mediation process is exhausted. However, this does not cover all claims related to one's commercial enterprise. For instance, lawsuits initiated against the Institute's decisions are not subject to mandatory mediation and may be heard before the administrative courts even if the patent belongs to a commercial enterprise. This rule is more related to commercial disputes between two or more commercial businesses.

Relevant international patent instruments and processes

Turkey is party to the EPC and the PCT, among others. Therefore, patent applicants in Turkey may also benefit from international and facilitated application processes offered by the European Patent Office and WIPO.

6. Are there non-patent barriers to competition that protect an originator's monopoly over an authorised medicinal product?

Patent protection prevents the entry of generics into the market if the patent protection period is in effect. However, patent protection does not cover marketing authorisation applications or other activities to obtain a marketing authorisation under Article 85/3-(c) of the Industrial Property Code (known as the Turkish Bolar exception).

Therefore, it is not possible to prevent generic marketing authorisation applications or other activities by generic manufacturers for the purposes of filing such applications.

Because of these restrictions, the only available route is to apply data exclusivity provisions. Under the Regulation on Licensing of Human Medicinal Products, the data exclusivity period is six years from the date on which a product received marketing authorisation for the first time in the Turkish-EU Customs Union area. It is only applied to products that received marketing authorisation after 1 January 2005 (and for products authorised for the first time after 1 January 2001 and for which no generic application was filed until 1 January 2005).

During this term, no abridged application can be made by using clinical data obtained from the clinical trials performed during the marketing authorisation application of the original pharmaceutical. Under Turkish law, the data exclusivity period for medicinal products is linked to the patent protection period, which commences after the application for patent protection. The data exclusivity period is limited by the patent protection period applicable in Turkey and ceases if the patent protection period expires. Since patent applications are filed long before an application for marketing authorisation, data exclusivity periods may not prove useful in practice when limited by the patent protection period.

There is no marketing exclusivity in Turkey. Generic companies can make abridged applications for obtaining marketing authorisation once the data exclusivity period ends.

7. Are any restrictions placed on licensing or transferring patents to foreign parties? Are intellectual property transfers for inventions funded, or partially funded, by public investment restricted?

The patent application process can also be conducted in confidentiality if the invention is vital for national security (*Article 124, Industrial Property Code*). In case of doubt, the Institute must notify the Ministry of Defence about the application. If the Ministry of Defence also believes that the subject matter of the patent is important for national security, not only will the patent application process be confidential, but the owner of the patent can also use the inventions only to the extent allowed by the Ministry of Defence (therefore, the use of the patent, including transfer, may be limited). In such a case, the patent owner can request compensation from the government for not using the patent.

Trade marks

8. 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?

Legislation and scope of protection

The Industrial Property Code No. 6769, which abolished the Decree Law No. 556 on the Protection of Trademarks (Trademark Decree Law), is the primary legislation regulating trade marks. The following can be registered as a trade mark, provided they are distinctive:

- Names, including persons' names.
- Words, shapes, colours, letters, numbers, and voices.
- Device marks.
- Shapes of goods or packaging.

(*Article 4, Industrial Property Code*.)

Turkey is a party to the following international agreements regarding trade marks:

- Singapore Treaty on the Law of Trade marks 2006 (signed but yet to be ratified),
- Trademark Law Treaty 1994.
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- WIPO Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973.
- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) (including the London, Washington, The Hague, and Stockholm texts. The Lisbon text is signed but is yet to be ratified).
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol).

The following cannot be registered as a trade mark:

- Signs without a distinctive character.
- Signs that incorporate the commercial type, variety, characteristic, quality, amount, goal, value, geographical source, or the characteristic property of the goods and services.
- Signs that are similar or indistinguishable from marks that have been registered or subject to a registration application with an earlier application date regarding the same or similar goods and services.
- Signs that include generic signs and names, or used to distinguish the members of a particular profession, art, or trade group, exclusively or as a base element.
- Signs that consist of the shape or other characteristics of the nature of the goods, a characteristic that is essential to obtain a technical result, or a shape or other characteristic of primary value to the goods.
- Signs that may deceive the public about the goods or services' properties, quality, manufacturing location, or geographic source.

- Trade marks not authorised by the competent authorities that are to be refused under Article 6 of the Paris Convention.
- Signs other than those covered by Article 6 of the Paris Convention that are of particular historical and cultural public interest, and signs containing badges, emblems, or escutcheons, which have not been authorised by the competent authorities.
- Signs that incorporate religious values and symbols.
- Signs that are against public order and principles of morality.
- Signs that consist of or include registered geographical indications.

(*Article 5, Industrial Property Code*.)

Medicinal brands can be registered as trade marks in Turkey. However, international non-proprietary names (INN) cannot be registered as trade marks since they are not distinctive and are not capable of being accepted as an original trade mark. It is also not possible to register phrases that are similar to INNs.

Pharmaceutical product brand names are controlled by the Turkish Patent and Trademark Institute during the trade mark registration process and by the Pharmaceutical Product and Medical Device Institution during the marketing authorisation process.

General conditions and specific rules for naming medicines

The following cannot be registered as a trade mark:

- Signs without a distinctive character.
- Signs that incorporate the commercial type, variety, characteristic, quality, amount, goal, value, geographical source, or the characteristic property of the goods and services.
- Signs that are similar or indistinguishable from marks that have been registered or subject to a registration application with an earlier application date regarding the same or similar goods and services.
- Signs that include generic signs and names, or used to distinguish the members of a particular profession, art, or trade group, exclusively or as a base element.
- Signs that consist of the shape or other characteristics of the nature of the goods, a characteristic that is essential to obtain a technical result, or a shape or other characteristic of primary value to the goods.
- Signs that may deceive the public about the goods or services' properties, quality, manufacturing location, or geographic source.
- Trade marks not authorised by the competent authorities that are to be refused under Article 6 of the Paris Convention.
- Signs other than those covered by Article 6 of the Paris Convention that are of particular historical and cultural public interest, and signs containing badges, emblems, or escutcheons, which have not been authorised by the competent authorities.
- Signs that incorporate religious values and symbols.

- Signs that are against public order and principles of morality.
- Signs that consist of or include registered geographical indications.

(*Article 5, Industrial Property Code*.)

Medicinal brands can be registered as trade marks in Turkey. However, international non-proprietary names (INN) cannot be registered as trade marks since they are not distinctive and are not capable of being accepted as an original trade mark. It is also not possible to register phrases that are similar to INNs.

Pharmaceutical product brand names are controlled by the Turkish Patent and Trademark Institute during the trade mark registration process and by the Pharmaceutical Product and Medical Device Institution during the marketing authorisation process.

9. How is a trade mark registered?

Application and guidance

Trade mark applications must be made to the Turkish Patent and Trademark Institute (Institute). Its website provides information on the fees and regulations regarding the application procedure in both Turkish and English (*www.turkpatent.gov.tr/TURKPATENT/?lang=en*).

It is also possible to apply through WIPO or the European Union Intellectual Property Office for an international or EU trade mark, choose Turkey as a designated country, and extend a trade mark application to Turkey within the scope of the international treaties that Turkey is a party to.

The Ministry of Health is normally not engaged in trademark review before the Institute, as it usually reviews licencing applications filed under Regulation on the Licensing of Medicinal Products for Human Use (Licensing Regulation). In other words, even if the trademark is registered before the Institute, the Ministry of Health may decide that the name is not appropriate for licensing.

Process and timing

The key stages of a trade mark application, which takes ten to 12 months (if no opposition is filed), are as follows:

- A formal examination by the Institute to check that application complies with the applicable requirements. The applicant is given two months to amend any missing documents or information. Failure to provide missing documents or information within two months results in the cancellation of the trade mark registration application.
- The application is published in the Institute's *Official Trademark Bulletin*.

- Third parties can submit their opposition by stating why the application must not be accepted within two months from the date of publication. If no third-party opposition is submitted, the trade mark is granted.
- If the Institute accepts an opposition, the applicant is given two months to appeal (before the Institute decides the opposition, the applicant can file a response to the opposition. However, the practice of the Institute can vary due to ambiguity in the regulations). The appeal is examined by the Institute's Re-Examination and Evaluation Board (REEB).
- If the REEB rejects the appeal, the applicant can only request cancellation of the Institute's decision through a lawsuit.

Any application filed within Turkey or within the contracting parties of the Paris Convention and TRIPS benefit from priority for 6 months after the application date. To benefit from this priority, the applicant should either be a citizen or a resident of, or should have a commercial enterprise in, one of the contracting parties of the Paris Convention and TRIPS.

Unless an objection is filed (or otherwise resolved), the Institute finalizes its review and announces the patent in its bulletin again.

Apart from the process explained above, the patent applicant, patent owner, and any related third parties may also file an objection against the decisions of the Institute within two months from its notification.

10. How long does trade mark protection typically last?

A trade mark right is valid for ten years from the date of application. This period can be renewed at the end of each ten-year period for another ten-year period. There is no limit on the number of renewals. Registration of a trade mark is renewed upon payment of the renewal fee at the request of the trade mark owner or an authorised person.

A request for renewal must be submitted at least six months before the last day of the month in which the trade mark protection ends. If this deadline is not met, the request can still be submitted within six months from the date of expiry, subject to payment of an additional fee.

Trade marks that are not renewed within six months after expiry of the protection period become invalid.

11. How can a trade mark be revoked?

A trade mark can be revoked by a court based on any of the following grounds:

- Breach of absolute grounds for refusal, as stated in Article 5 of the Industrial Property Code (*see Question 7*).
- Breach of relative grounds for refusal, as stated in Article 6 of the Industrial Property Code. Relative grounds of refusal are, among others, if the trade mark applied for:
    - is identical or similar to a registered trade mark or a trade mark with an earlier application date for similar goods and services, and there is a likelihood of confusion by the public;
    - is identical or indistinguishably similar to another mark and the owner of such mark did not give consent to the registration;
    - is obtained for an unregistered mark or sign in commercial use before the application or priority rights of the trade mark applied for;
    - is identical or similar to well-known marks under Article 6 of the Paris Convention for the same or similar products or services;
    - is identical or similar to a registered trade mark or a trade mark with an earlier application date, and this may lead to an unjust benefit or damage the trade mark's prestige or its distinctive character in Turkey;
    - includes another person's name, trade name, photograph, copyright, or any intellectual property right;
    - is identical or similar to a common or guarantee trade mark within three years of the expiration of the protection period;
    - is identical or similar to a registered trade mark within two years from the expiration of the protection period if that trade mark has been used during that period; or
    - has been registered with malicious intent.

(*Article 25, Industrial Property Code.*)

Article 26 of the Industrial Property Code will come into force on 10 January 2024. The Turkish Patent and Trademark Institute will then have authority to decide on the cancellation of trade marks. However, before this date the courts will be able to cancel trade marks based on the reasons:

- The trade mark became generic for certain products and services due to acts of the trade mark owner.
- Possible confusion by the public as to the nature, quality, manufacturing place, or geographical source of the trade mark due to acts of the trade mark owner or a person authorised by the owner.
- Use of a guarantee mark against the technical specification.
- The trade mark is not used continuously without a valid cause within five years following the registration date of the trade mark.

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

Conditions

The following constitute trade mark infringement:

- Violation of the rights of the trade mark owner, as stated in Article 7 of the Industrial Property Code.
- Imitation of a trade mark by using an identical trade mark without the trade mark owner's consent or using another trade mark that is indistinguishably similar.
- Selling, distributing, or otherwise trading products with the trade mark or indistinguishably similar marks in violation of trade mark rights, or placing such products in the Turkish customs territory or offering to enter into agreements concerning such products, which are known or should be known to cause trade mark infringement.
- Extending the scope of rights granted through a licence or transferring these rights to third persons without the consent of the trade mark owner.

(*Article 29, Industrial Property Code.*)

Claim and remedies

The following remedies can be requested by the trade mark owner through a civil lawsuit:

- A ruling on the existence of an infringement.
- Prevention of a possible infringement.
- Cessation of the acts causing trade mark infringement.
- Elimination of the infringement and reimbursement for material and immaterial damages.
- Confiscation of the products that caused the infringement or gave rise to the penalty and confiscation of tools, such as devices or machines, used solely to produce these infringing products, to the extent that this will not prevent the production of products other than the ones that caused infringement.
- Ownership of the confiscated products and devices.
- Preliminary measures to prevent infringement at the expense of the infringer, such as changing the shapes of confiscated products and devices, erasing the trade marks on them or destroying them if necessary to prevent the infringement.
- Complete or partial announcement of the infringement decision in daily newspapers or through other means, or notification of the infringement to interested parties.

(*Article 149, Industrial Property Code.*)

Under Article 151 of the Industrial Property Code, the trade mark holder is also entitled to claim compensation for damages and loss of income caused by an infringement of its trade mark rights. At the choice of the trade mark holder who suffered loss, the loss amount will be calculated based on one of the following methods:

- Potential revenue of the trade mark holder if there had not been competition from the infringer.
- Net revenue of the infringer arising from the infringing activities.
- Licence fee that would have been paid by the infringer if he/she had lawfully used the trade mark rights under a licence agreement.

The economic value of the trade mark, the remaining term of protection at the time of infringement, and the type and number of outstanding licences are also taken into account in the calculation of loss.

The prescription period for civil law claims is two years from the date when the infringement is discovered by the rights holder, and ten years from the date of the infringement (*Code of Obligations*).

Under Article 30 of the Industrial Property Code, on a complaint from the trade mark owner, the infringing party can be sentenced to imprisonment and a judicial fine.

Dispute resolution and settlement

Trademark infringements are usually settled before the courts. If the dispute relates to the commercial activities of enterprises, the dispute is considered a commercial dispute and such dispute can be carried to the courts only when the mandatory mediation process is exhausted. However, this does not cover all claims related to one's commercial enterprise. For instance, the lawsuits initiated against the Institute's decisions are not subject to mandatory mediation and may be heard before the administrative courts even if the trademark belongs to a commercial enterprise. This rule is more related to commercial disputes between two or more commercial businesses.

Relevant international trade mark instruments and processes

Turkey is party to the Madrid Protocol, among others. Therefore, patent applicants in Turkey may also benefit from international and facilitated application processes offered by WIPO.

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

Producing, distributing, or selling counterfeit pharmaceuticals is a trade mark infringement if the pharmaceutical brand is registered as a trade mark. The trade mark owner can take action in both civil and criminal courts (*see Question 11*).

Counterfeit pharmaceuticals also constitute patent infringement if the pharmaceutical is patented. The patent owner can take action in the civil courts.

IP and competition law issues

14. 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 Competition Authority (*www.rekabet.gov.tr/en*) is responsible for enforcing the Law on the Protection of Competition No. 4054 (Competition Law). The Competition Board is its executive body, and its final decisions can be challenged in administrative courts.

The primary piece of legislation governing anti-competitive practices is the Competition Law. The following block exemption communiqués also apply:

- No. 2002/2 on Vertical Agreements.
- No. 2016/5 on Research and Development Agreements.
- No. 2008/2 on Technology Transfer Agreements.
- No. 2013/3 on Specialisation Agreements.

As stated in the Competition Authority's Report on the Pharmaceutical Sector, the pharmaceutical sector was one of the first sectors to be subject to competition law in Turkey. Merger control and competition law violations are major aspects of the Competition Board's workload in this sector. Between 1999 and 2019, the Competition Board imposed TRY53,147,809 in fines on companies in the pharmaceutical and health services and products sector. In 2019, the Competition Board issued eight competition law violation decisions and 13 merger control rulings in the pharmaceutical sector.

15. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products? What compliance issues do parties to pharmaceutical technology licences and pharmaceutical distribution agreements need to consider?

Under Article 6 of the Block Exemption Communiqué No. 2008/2 on Technology Transfer Agreements, technology transfer agreements that include the following restraints cannot benefit from a block exemption:

- Restriction of a party's right to determine its sales prices.

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

The market shares of parties are essential in determining whether an agreement with restraints can benefit from the technology transfer block exemption. To benefit from the exemption, the total market share of the parties must not exceed 30% (for competitors) or 40% (for non-competitors) of the relevant technology and product market. The exemption will continue as long as the protection granted to the intellectual property rights over the licensed technology is valid.

Commercial agreements signed by pharmaceutical companies may include several structures or provisions which, at first sight, resemble restrictions of competition as listed in the Competition Law. Some examples may be customised distribution systems, exclusivity provisions or export restrictions. However, depending on the nature of the restriction, these restrictions may benefit from either block exemptions or may be cleared by the Competition Board after an individual exemption application is filed by the applicants. The Competition Board reviews numerous individual exemption applications of this nature.

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

Based on the Competition Authority's Report on the Pharmaceutical Sector, there are generally no specific competition issues associated with the generic entry of pharmaceuticals on the market. In theory, an abuse of dominant position could occur if the undertaking with rights over the original pharmaceutical product decides to prevent the generic brand from entering the market.

Although in Turkey patent litigation is initiated by the original product owner against generic manufacturers, the Turkish Bolar exception (*see Question 6*) prevents these actions against generic product applicants for marketing authorisations that are in the application phase. In this respect, there are no specific barriers against generic entry.

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

Although Competition Law prohibits the abuse of dominant position, it does not provide a certain percentage of market share as a benchmark for a dominant position. The Guideline on Market Abuse states that it is very unlikely for entities with a market share of less than 40% to be considered to have a dominant position in the market. However, the Competition Board has issued a number of decisions where it has held that an entity with a market

share of less than 40% had a dominant position. In these decisions, it took the structure, specialities, and dynamics of those markets into consideration.

Article 6 of the Competition Law lists several types of market abuse, as follows:

- Preventing, directly or indirectly, another undertaking from entering into the area of commercial activity, or actions aimed at complicating the activities of competitors in the market.
- Directly or indirectly discriminating by offering different terms to buyers with equal status for the same and equal rights, obligations, and acts.
- Imposing the purchase of another good or service together with a good or service, or subjecting a good or service demanded by buyers acting as intermediary undertakings to the condition of the display of another good or service by the buyer, or imposing limitations on the terms of purchase and sale in case of resale, such as not selling a purchased good below a particular price.
- Actions that aim to distort competitive conditions in another market for goods or services through exploiting financial, technological, and commercial advantages created by dominance in a particular market.
- Restricting production, marketing, or technical development to the prejudice of consumers.

Each year, a number of complaints are filed against pharmaceutical companies (mostly by pharmaceutical warehouses) for abuse of dominance allegations. For example, Novartis, Roche, and Daiichi Sankyo are some of the pharmaceutical companies that have faced allegations of this nature. The complaints mostly result from a pharmaceutical company's refusal to provide pharmaceutical products or certain commercial terms that the pharmaceutical companies impose on the warehouses (for example, imposing export restrictions). However, only some of those complaints are accepted by the Competition Board. For example, the Competition Board has decided that Sanofi Aventis decreasing its payment terms from 60 to 180 days down to 15 days was a clear abuse of its dominant position. Sanofi Aventis was ordered to pay an administrative fine of TRY3,648,045 (*Decision 09-16/374-88, 20 April 2009*).

However, some entities playing an important role in the pharmaceutical sector are also under scrutiny by the Competition Board for market abuse. For example, in 2019, the Competition Board held that the exclusivity provision included in an agreement of the Turkish Pharmacists Association (the association authorised to supply pharmaceutical products from foreign countries) constituted an abuse of dominance. The Turkish Pharmacists Association was ordered to pay an administrative fine of TRY18,062,307.32 (*Decision 16-42/699-313*).

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

The Industrial Property Code does not directly address the status of parallel imports.

However, industrial property protection does not apply to actions regarding products sold in Turkey by the industrial property right holder or with their consent (*Article 152, Industrial Property Code*).

Therefore, as long as these products are not put in the market in Turkey by the patent or trade mark owner or with their consent, it is possible to prevent parallel imports. As soon as they are put on the market by the owner or with their consent in Turkey, it is usually possible to block parallel imports.

However, due to the special status of pharmaceutical products, which require a local marketing authorisation or similar authorisation from the Pharmaceutical Product and Medical Device Institution, parallel imports of pharmaceutical products are not allowed, except by persons or entities with such authorisation.

However, for CE marked medical devices, free circulation cannot be prevented as long as the registration obligation for the import company and for certain devices is met by registration in the National Database of the Institution (TITUBB). Other medical devices are subject to the general conditions applicable to other products, provided that the registration obligation is met by the relevant importer.

The Competition Law does not specifically regulate parallel imports. However, Article 4 of the Competition Law specifically prohibits an entity from implementing boycotts or other activities to exclude opponents from the market and to prevent additional entries to the market. Similarly, abuse of a dominant position is also prohibited by Article 6 of the Competition Law.

19. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? Are there any formalities or other requirements that must be complied with to make the licence enforceable?

Under Turkish Law, patent or trade mark licences or the payment of royalty fees do not have to be approved or accepted by a regulatory body. Such agreements become enforceable when put into force between the parties. However, patent or trade mark licences can be registered with the Patent and Trademark Institute, regardless of whether the parties are foreign, if the parties wish to make their licence enforceable against third parties.

Contributor profiles

Kayra Üçer, Partner

Hergüner Bilgen Özeke Attorney Partnership
T +90 212 310 18 27
F +90 212 310 18 99
E *kucer@herguner.av.tr*
W *www.herguner.av.tr*
Professional qualifications. Georgetown University Law Center (LLM, 2000); Marmara University School of Law (Law Diploma, 1998)

Areas of practice. Corporate and commercial matters, including mergers and acquisitions, labour law, compliance law and anti-corruption practices.

Languages. English, French

Professional associations/memberships

- Istanbul Bar Association.
- Saint-Joseph Alumni Association.
- Georgetown Alumni Association.
- Transparency International Association.
- Turkish Corporate Governance Association.
- President of ILI, the Istanbul International Law Association.

Hakan Ekim, Associate

Hergüner Bilgen Özeke Attorney Partnership
T +90 212 310 18 63
F +90 212 310 18 99
E *hekim@herguner.av.tr*
W *www.herguner.av.tr*
Professional qualifications. Istanbul Bilgi University (MSc in Financial Economics, 2020), Yeditepe University Faculty of Law (Law Diploma, 2015)

Areas of practice. Banking and finance matters with a particular focus on regulatory compliance; corporate and commercial matters, including mergers and acquisitions, corporate governance, and labour law.

Languages. English

Professional associations/memberships. Istanbul Bar Association; Yeditepe University Alumni Association, Istanbul Bilgi University Alumni Association.

Deniz Yetkin

Hergüner Bilgen Özeke Attorney Partnership
T +90 212 310 18 00
E *dyetkin@herguner.av.tr*
W *www.herguner.av.tr*
Professional qualifications. Université Paris II – Panthéon-Assas (LLM, 2017); Bilkent University, Faculty of Law (Law Diploma, 2016)

Languages. English, French, Turkish

Professional associations/memberships. Istanbul Bar Association; Bilkent University Alumni Association.

END OF DOCUMENT