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PATENT LAW IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS

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PATENTS AND UTILITY MODELS

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Key Developments and Predictions for Patent Law in Turkey

It has been more than four years since the Industrial Property Law ("IP Code"), which combined different Decree Laws on specific IP rights, came into force. The fourth book of the IP Code introduces relatively new provisions regarding the patent system in Turkey that bring the national law into line with the European Patent Convention ("EPC") to some extent.

While the medium and long-term implications of the new law are yet to be realised, IP law practitioners still agree that the most controversial issue is not the law but its enforcement. There are fourteen specialised IP Courts in Turkey; eight in Istanbul, five in Ankara, and one in Izmir. Due to the changes made by the appointment of judges, most of the current cases are headed by judges with limited experience in the field of industrial property. As these judges do not have any technical background, the decisions heavily depend on court-appointed experts' views. On the other hand, while it is expected that the two-layer appeal review introduced by the Turkish Code of Civil Procedure will lower the workload of the courts and raise the quality of the judgments; it is observed that the appeal evaluation processes take longer, the appeal procedures are not shortened, and the content of the decisions has not changed much compared to the past. Besides, in the past year, the interpretation of the vaccine inequity, determination of royalty in case of compulsory license, protection of patent rights in pharmaceutical products that supplied from abroad, prevention of indirect use of a patent, Bolar Exemption for pharmaceutical products, the assessment of the discovery of evidence and preliminary injunctions, the impact of EPO Opposition Proceedings as to national infringement, as well as validity proceedings, have been the most debated areas before the IP Courts in the field of patent cases.

With this paper, we are pleased to outline the key aspects of patent litigation in Turkey and the most important and most controversial issues in Turkish Patent Law.

This paper provides an overview on the following topics:

- Patent Rights on Vaccines: Looking for a Scapegoat for Vaccine Inequity
- Declaration of Use and Compulsory License
- Determination of Royalty In Case of Compulsory License
- Supply of Pharmaceutical Products from Abroad and Patent Rights
- Preliminary Injunction Granted to Prevent Indirect Use of Invention
- Are Clinical Trials Excluded From Patent Protection in Turkey?
- Discovery of Evidence Requests and The Scope of Bolar Exemption – District Court in Turkey Rules on Preliminary Injunction Assessments
- Impact of EPO Proceedings and EPC Provisions on National Actions

Patent Rights on Vaccines Looking for a Scapegoat for Vaccine Inequity

It is the common goal to get through the pandemic, which endangers the health of all of humanity, and for that, all have been watching for a vaccine and treatment to overcome the pandemic as soon as possible. Scientists have managed to go beyond the known in a considerably short time, and multiple COVID-19 vaccines were developed.

At this point, the equal distribution of vaccines emerged as a vital problem that hindered global salvation from this pandemic. While some developed countries had the chance to store vaccines to meet multiple dosages, hundreds of less developed or developing countries have not been able to access vaccines at all. According to Our World in Data, 23.4% of the world population received at least one dose of the COVID-19 vaccine. However, only 0.9% of people in low-income countries received at least one dose as of June 30, 2021.

While the reasons for this undesired situation were being discussed, IP rights, especially on vaccines, and whether these rights were the cause of the injustice in access to the vaccine became a very important topic of discussion. On the other hand, patent rights have been made a "scapegoat" for the vaccine inequity experienced so far.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") is the most comprehensive multilateral agreement on intellectual property.

If a TRIPS signatory country does not protect IP rights in its own country and, for example, uses or benefits from patented technologies without the consent of the right owner, it may face an accusation of breaching its obligations arising from TRIPS. In case it is accepted to remove IP protection temporarily, then the members will not be able to subsequently claim violations of the TRIPS obligations by other countries that temporarily waived intellectual protection rights.

Considering solution proposals of the member states and in order to eliminate the vaccine inequity problem, the European Parliament suggested that the European Commission start negotiations in the WTO on a temporary waiver on IP rights on COVID-19 vaccines and other medical products. As can be seen, the IP right waiver on COVID-19 is considered a milestone to enhance global access to affordable COVID-19 vaccines. However, it is highly controversial whether this alleged solution of suspending the patent rights addresses the vaccine inequity problem.

First and foremost, the COVID-19 virus continues to mutate rapidly, and it is a mystery how much protection these vaccines provide or will provide against which mutations in the long run. Promoting science and innovation in this period, where the virus continues

to mutate or at least not breaking the existing incentives disproportionately, is very important for a successful policy in the long run.

It should be borne in mind to address the issue correctly that one of the major problems regarding vaccine shortage and inequity in access to vaccines allegedly stems from the shortage of raw materials, production capacity constraints, and the extremely complex nature of the production of drugs. According to figures from the International Federation of Pharmaceutical Manufacturers and Associations, even a typical vaccine manufacturing plant uses approximately 9,000 materials sourced from 300 suppliers across 30 different countries. In this respect, it is argued that suspension of the patent rights will not yield more COVID-19 vaccine supply in 2021, considering that constraints are physical rather than legal.

As for patent rights, the scope of the suspension is also highly controversial. Indeed, although COVID-19 related patent applications have been filed, they are not published yet since the publication of the application only takes place after 18 months. As for the current patents, the scope of a potential suspension still seems to be problematic. Indeed, the suspension will not be limited to the rights related to COVID-19. The mRNA technology used in the BioNTech/ Pfizer vaccine is protected by patents that have already been granted, and these technologies also have useful applications, in cancer treatment as well. When patents on vaccines are suspended, such patents will go into the pot.

While TRIPS Article 30 regulates the general exemption provision to the patent right, the exemption foreseeing the invention's use by a third party or government without the patent owner's consent is regulated under Article 31 of TRIPS. TRIPS Article 31bis, on the other hand, paves the way for the compulsory license application foreseen for the internal market need to be issued to send to the countries in need.

Patent protection is not the main obstacle to access the vaccine considering all. If all patents were abolished, would the injustice in access to the vaccine be eliminated? The answer seems not affirmative. It will be much more effective for the patent owners to cooperate and provide each other with the necessary licenses within the framework of contractual relations. In particular, international alliances such as COVAX should be supported, the rapid transfer of existing vaccine stocks should be facilitated, and new international agreements should be concluded if necessary.

Declaration on Use of Patent and Compulsory License

The new IP Code numbered 6769 abolished the provisions on "the use requirement of patents" and "the evidence of use" of the Decree-Law About the Protection of Patent Rights. The IP Code now focuses on the requirements of use for patents within the provision of a Compulsory License.

Accordingly, a patent owner must use the patented invention within three years following the publication of its granted decision in the Official Bulletin ("the Bulletin") or within four years from the date of its application, whichever is the latest. The patents that are not declared to be used within the period prescribed in the IP Code in accordance with Article 117/8 of the Regulation on the Implementation of the IP Code are published in the Bulletin. The Bulletin is an announcement made when a patent is not being used. Third parties are then aware that they may request the license over such a patent.

When assessing actual "use", market conditions and conditions outside the patent owner's control, such as the need for pharmaceutical marketing authorisation, compliance with standards, and the lack of new applications in alternative fields should be considered. At the end of the prescribed terms, any interested person may request a compulsory license on the grounds that the patented invention is not being used, no serious and real measures have been taken to make use of the patented invention, or that the level of the current use does not meet domestic demand. The same applies to cases where no use of a patent has been made for more than three years without justified reason.

Additionally, patent holders are requested to file a declaration of use of the patent with the Turkish Patent Office ("the Office"). The Regulation on the Implementation of the IP Code rules that the declaration of a patent use must be submitted to the Office under the same legal terms prescribed in the IP Code. In 2020, the Office simplified the said declaration by marking the button that the patent is or is not used in its online system. Patents that have not been used within this period will be published in the Bulletin. The publication, however, does not lead to any direct benefits or negative consequences. Even if a patent is not listed as a non-used patent, a third party may still request a compulsory license, claiming that the patent is not used, or that no serious and real measures have been taken to make use of the patented invention, or that the level of current use does not satisfy domestic demand. Even if the patent is listed, it does not mean that a compulsory license will be automatically granted.

When requesting a compulsory license, court procedure must be followed, and the declaration of a patent's use filed with the Office may only be used to indicate the intention to use it. The lack of such declaration does not affect the procedures at court as the use may also be proven during court proceedings.

Determination of Royalty in Case of Compulsory License

TThe institution of "compulsory licensing", which is regulated firstly in Article 99 of the repealed Decree-Law No. 551 and then, under Article 129 et seq. of the Industrial Property Law ("the IP Code") in force, as a reflection of TRIPS Article 31, has not been needed to be implemented for long years in our country [Turkey].

However, with the outbreak of the COVID-19 pandemic, it has suddenly gained popularity since it is regarded as a "convenient" tool for abrogating patent rights which are seen as the main, almost the sole obstacle to access to vaccines and treatment.

Even though it has never been actually implemented; "compulsory licensing" has been mentioned and widely discussed not only as a convenient tool for reaching the vaccines or preventive medicines needed to combat the COVID-19 outbreak in the short term but also as a negotiation tool in the price negotiations of certain vital medicines, which are considered a burden on the public budget. Despite being highly popular and having been mentioned often as a negotiation tool, its conditions and consequences could not be fully grasped because it has never been implemented, and the wording of the IP Code is quite ambiguous.

The misperception that the compulsory licenses shall be granted "for free" or "at rates far below the actual license fees" lies behind this environment of discussion and negotiation. However, all compulsory licensing regulated in the IP Code, including the grant of compulsory licenses for the public interest, could be implemented if a royalty, to be calculated "considering the economic value of the patent", is paid to the patentee. Nevertheless, it is a greater mystery what "the fee which will be determined by taking into account the economic value of the patent", as worded in the IP Code Article 133/1, shall be and how this fee shall be calculated.

Neither TRIPS Article 31(h) nor the IP Code Article 133 provides a method for calculating the "adequate remuneration, taking into account the economic value of the patent." Another point to be addressed before proceeding with the common approaches in this field is that TRIPS Article 31(h) refers to the "economic value of the authorisation" while the IP Code Article 133 refers to the concept of the "economic value of the patent". The word "authorisation", as used in TRIPS Article 31/h refers to "the consent/authorisation to be granted by the patentee for using such patent, right to use, namely the license, to be voluntarily conferred"; as the heading reads as "Other Use Without Authorisation of the Right Holder". In parallel, it would be appropriate to interpret the phrase "economic value of the patent" as used in the IP Code Article 133, as a value originating from a license voluntarily granted to use such patent. This

is because, in principle, the IP Code Article 133 is not intended to confer less protection than the limits outlined in the TRIPS. On the other side, the phrase "economic value of a patent" refers to the remuneration to be paid to the right holder if the patent in question is subject to a contractual license. Accordingly, contrary to expectations, the remuneration to be paid to the patent holder in the case of compulsory licensing shall not be lower than the "commercial" license value to which the patent holder becomes entitled if a license is granted under normal circumstances and competitive market conditions.

The only exception is the compulsory license granted for humanitarian aid purposes, as necessitated by public health problems in other countries, regulated under the TRIPS Article 31(f) and corresponding Article 129/1(ç) of the IP Code. It is explicitly stated by the legislator that the economic value of such use (license) in respect of the importing country "taking the non-commercial and humanitarian purposes into consideration" shall be taken as basis in determination of the remuneration to be paid for compulsory licenses, which shall be granted in referred cases. This explicit statement also indicates that the remuneration payable to the patent holder for compulsory licenses shall be in a "commercial" nature, namely for "profit".

While there are no guiding regulations in the Turkish Law as to how the "adequate remuneration to be determined, considering the economic value of the patent" shall be calculated; in the international law, certain frames are attempted to be drawn as to how the remuneration payable for the compulsory license to be granted under the TRIPS Article 31(h), shall be determined by member states. Within this scope; it is seen that the "Tiered Royalty Method" which has been mentioned for the first time in the "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies", published by the United Nations Development Program ("UNDP") and the World Health Organization ("WHO"), is often cited by the World Trade Organization ("WTO") as well.

The Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies is a document drafted in 2005 to consider appropriate options for adequate remuneration of patent holders in cases of compulsory licensing for medicines, medical devices and all kinds of medical technologies. Referred Guidelines address contractual license experiences, often observed in the private sector, and underline that the compulsory license royalties should be calculated based on these experiences. Another finding from the Guidelines is that the average rate for the pharmaceutical sector is at 4-5%, even though the rates reported for different industries may greatly vary. Both the "Tiered Royalty Method" and other methods

followed for setting the remuneration payable to the patent holder for compulsory licensing are referred in the Guidelines to reach this conclusion.

For instance, in the UNDP Evaluation Guidelines dated 2001, payment of a standard license royalty of 4% is suggested with a deviation rate of 2%, depending on the therapeutic value of the concerned product and the government's contribution to the related R&D expenses. Regarding the government-owned patents , rates are given between 0% and 6% in the JPO Guidelines on Royalty Rates, released in 1998. In this model, rates vary depending on the profit which is expected to be obtained from the licensed product, the importance of the patented invention in respect of the final product, the amount of additional research required for the release of the invention into the market, the presence of public interest in the use of the patent, and the novelty of the product and other factors. Adaptation of this model for medicaments would mean considering certain other factors such as the extent to which relevant invention has benefited from the publicly funded research, therapeutic value of the invention and the requirement for fulfilling the needs concerning public health. The Canadian Guidelines for Exporting Health Products (2005), on the other side, sets the upper limit for license royalties as 4% within the scope of the regulations in the TRIPS Article 31(f) and then lowered this rate based on the rating of the importing country in the United Nations Human Development Index. All these approaches introduce a significant restriction, setting the license royalties based on the value of the generic products.

Tiered Royalty Method is different from the 2001/UNDP, 1998/JPO and 2005/Canadian methods in that the royalty rate is not based upon the price of the generic product. Instead, the royalty rate is based upon the price of the patented product in the high-income country. The base royalty is 4% of the high-income country price, which is adjusted to account for relative income per capita or, for countries facing a particularly high burden of disease, relative income per person with the disease. It is considered that this method can be implemented without extensive data or analytical resources. Therefore, it seems convenient for administrative purposes.

Providing transparency, predictability and ease of implementation lie behind the countries' need to prepare and implement remuneration guidelines on compulsory licensing, without a doubt. Even though "Tiered Royalty Method" could establish a balance to a certain extent for fulfilling this need; it provides a royalty calculation method, which fully ignores the "legal" criterion mentioned in both TRIPS Article 31(h) and Article 133 of the IP Code, in respect of setting compulsory license remuneration, namely "economic value of the patent". Therefore, a calculation to be made

according to this method will carry the risk of providing rates that are non-compliant with the criteria introduced by TRIPS and IP Code.

In conclusion, if a compulsory license is issued in light of the applicable legal regulations of Turkish Law, the fundamental criterion to be taken into account in setting the remuneration payable to the patent holder shall be the economic value of the patent. According to the common view of the doctrine, the basic indicator for setting the economic value of a patent is the royalty rate which will be calculated based on the market value provided that the patent in question is subject to a contractual license. Nevertheless, none of the methods covered in this article pays regard to this criterion. These calculation methods take the economic value of either a generic product or a patented product as a basis. On the other hand, the economic value of a patent (namely license) and the economic value of a patented product are not equal concepts, and they do not point at equal figures. Accordingly, for calculating a lawful and fair remuneration, a "compulsory license rate" should be determined according to individual requirements of each case in the light of the conditions requiring compulsory licensing, based on the remuneration payable to the patent holder should a contractual license be granted. The ultimate aim should be finding the balance between the inventor's right to take economic advantage of the invention, encouraging the inventor to search for and to develop novel products, yielding such economic advantage, and the benefit to be obtained from the public's access to such invention in a shorter period. The mechanism which would serve this aim in the truest sense of the word is the determination of the remuneration to be paid to the patent holder for a contractual license, as the compulsory license royalty. For this purpose, earlier license contracts executed for similar products or derived income or royalties payable for the same patent in different markets should be taken as basis.

[1] Compulsory Licensing System Introduced by the Decree-Law on the Protection of Patent Rights No. 551, Arslan Kaya, page 361); (Dr. Ayşegül SEZGİN HUYSAL, Marmara University, Department of Commercial Law, Pharmaceutical Patent, Vedat Kitapçılık, Istanbul 2010, pages 238-239)

[2] Government-owned patents exist on inventions that have come from government-funded research.

[3] (551 Sayılı "Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname" ile Getirilen Zorunlu Lisans Sistemi, Arslan Kaya, page 361); (Dr. Ayşegül SEZGİN HUYSAL, Marmara University Department of Commercial Law, İlaç Patenti, Vedat Kitapçılık, İstanbul 2010, pages 238-239)

Supply of Pharmaceutical Products from Abroad and Patent Rights

The supply of pharmaceutical products to Turkey via the Named Patient Programme (the "NPP") is one of the exceptional importation regimes for pharmaceutical products. Where a pharmaceutical product is not granted marketing authorisation in Turkey, or it is granted marketing authorisation but not found in the market, but patients need it, it can be supplied via this special route by physician request. The entities that are authorised to import pharmaceuticals within the scope of the NPP are the International Health Services Inc. ("USHAS"), the Turkish Pharmacists Association's Economic Enterprise (the "TEB") or the Ibn-i Sina Health Social Security Centre, established under the Social Security Institution (the "SSI").

If the product is approved for the NPP, it is added to the Foreign Drug List of the Turkish Medicines and Medical Devices Agency (the "TMMDA"), and nowadays, mostly imported by the TEB and SSI on a named patient basis. If SSI decides the reimbursement of the relevant product, the product is published in Annex-4/C list of the Health Practices Communiqué of SSI.

This unique supply method causes some problems for the protection and enforcement of patent rights in Turkey. The patent owner, who also supplies the patented product via the NPP, is made aware of the competitor product by its inclusion on the foreign drug list.

In cases where the existence of a patent infringement is suspicious or unavoidable, the patent owner intends to exercise its legal rights but cannot access supplier information that is not publicly shared. The only known party to the patent owner who is causing the infringement would be either the TEB or SSI, the importer of the infringing products. The Courts of Appeal have ruled that for the cases of the supply of an infringing product via the NPP, the buyer of product in Turkey, the TEB, would be one of the potential named parties of the patent infringement action, as the importer of the infringing products. However, since the relevant institutions are the solution partners of the patent owner for the supply of its patented product via the NPP, it may not be preferred to bring an action against these institutions. In practice, TMMDA, TEB and SSI do not share the information about the product's supplier, who carries the risk of infringement. In order to ensure that patent rights are used effectively in this field, the foreign drug supply and reimbursement processes should be carried out more transparently.

To give an example from a precedent that was held last year, in the particular case, an action with a request of preliminary injunction was filed for the determination, prevention, and cessation of infringement against a product included in the Foreign Drug List containing the active ingredients protected by the patents protecting molecules. Upon

the investigation of the preliminary injunction claim made on the file, the Court found that the products included in the Foreign Drug List infringed both patents and granted a preliminary injunction in consideration of guarantee, in this context, in addition to other injunctions, it has decided to prevent the supply of products.

Following the trial, the Court accepted the action, the determination of the patent infringement and the removal of the infringing drugs from the Foreign Drug List. Besides, the Court decided to prevent the products with the patented active ingredient from including in the Foreign Drug List regardless of their tradename during the term of the patent protection.

In principle, it is essential to decide only on the products subject of the case. However, our defence against the possibility of inclusion of the infringing products in the Foreign Drug List by changing their name was accepted, and the court prevented the inclusion of the products with the same active ingredient to the list under any name or trademark.

In this particular case, it is seen that the decision was held by taking into account the characteristics of this special drug supply method. Therefore, it is an extremely important decision that ensures the effective protection of patent rights through the court, according to the circumstances of the case.

Preliminary Injunction Granted to Prevent Indirect Use of Invention

One of the most striking developments of 2020 is a preliminary injunction decision given due to implementing the provision "Prevention of the Indirect Use of Invention" regulated in Article 86 of the IP Code .

Although the expression "Indirect Use of Invention" is often confused with the "Indirect Infringement of Patents" concept, indirect patent infringement is not explicitly regulated in our law. Because as is known, the Turkish IP Code numbered 6769 ("IP Code") lists the acts that constitute patent infringement in Article 141, according to the numerous clauses principle. The actions constituting "indirect" infringement of a patent or acts of inducement, help, contribute to infringement are not mentioned among the actions listed in Article 141. However, IP Code has a provision in Article 86, which is similar to the "indirect infringement" provision in Article 60(2) of the UK Patents Act (1977) and the provision regarding "Prevention of the Indirect Use of Patent" regulated under Part 10 of the German Patent Law.

This issue, which can be defined as **"contributory infringement" or "indirect infringement" in different laws, is regulated in Article 86 titled "Prevention of the indirect use of the invention"** in the IP Code as follows:

"The patent owner shall be entitled to prevent third persons from giving the elements and instruments related to a part of an invention which enables the implementation of the invention which is subject to the patent and constitutes the essence of the invention, to persons who are not authorised in the use of the invention subject to the patent. The referred third persons must know that these elements or instruments are sufficient to implement the invention and that they will be used for these purposes or this condition should be sufficiently clear for this provision to be applicable".

As far as is known, Article 86 has been firstly implemented in a court action where the patentee demanded determination and prevention of indirect use of their patent, disclosing a combination of active ingredients (X) and (Y), and protection scope of the patent did not require the presence of these combination partners in the same pharmaceutical form, or it did not introduce any other similar limitation at all. Considering ongoing use and increasing damages, the patentee asked for a Precautionary Injunction ("PI") decision.

The challenge of the case lay with the fact that the defendant was manufacturing and marketing a drug including API (X) only as it certainly knew and counted on that the API (X) will be prescribed, used, and traded together with the API (Y) in practice. Therefore, the defendant aims at the combination market, which constitutes %95 of the whole market. That is to say that the defendant knows that

the API (X) is not being used solely for the relevant patient population, and even it is, the patient population using API (X) only is around %5, which does not commercially justify manufacturing and marketing a drug with API (X) only. However, this fact needed to be proven and until then, it did not stop the defendant from arguing that it does not indirectly use the patent as it manufactures and markets a drug with API (X) only, and to accuse the patentee of abusing the patent rights as it comes up with this lawsuit after expiration of the compound patent protecting API (X).

The Court successfully determined that the expired compound patent is not the subject of the case but the combination patent, and it agreed to collect the evidence required to be collected by the patentee as there was no other way to reach the necessary evidence. In this respect, the Court sent writs to Social Security Institute and the three biggest hospitals in Turkey asking them to inform the Court if the defendant's drug, having API (X), is only being used, prescribed and/or reimbursed together with the API (Y).

All responses from SSI and hospitals confirmed the fact that the drug of the defendant is used/prescribed/reimbursed in combination with API (Y). Specifically, the SSI emphasised that among 234 patients, only 43 were prescribed with API (X) only, and 113 were prescribed with API (Y).

Depending on the responses from SSI and hospitals, the patentee argued that all requirements of Article 86 were fulfilled since the defendant as a third person within the meaning of the provision sells/trades/provides the generic product containing the API (X) to the unauthorised parties, which constitutes the essential element of the combination patent and enables implementation of the patent by unauthorised persons like pharmacists, pharmaceutical warehouses. Consequently, the patentee demanded the Court grant a PI to prevent the defendant's drug reimbursement by SSI when prescribed with API (Y). The patentee explicitly stated that it requires no measures preventing reimbursement (or any use, market or else) of the defendant's drug, when prescribed, used or marketed, not together with API (Y).

The defendant tried to defend itself by referring to paragraph 2 of Article 86, which says that if the elements or instruments stipulated in clause one are always available on the market, the provision of clause one shall not apply unless third persons provoke/induce unauthorised persons to perform the referred acts. Accordingly, the defendant argued that API (X) is such an element of the invention that can always be found on the market and the defendant does not provoke/induce anyone to implement the invention by using API (X). Unfortunately, there is no case law in Turkey about the interpretation of when/which elements should be deemed to

be always available on the market. However, the patentee depended on the German and UK case laws. In German Law, it is accepted that the meaning of "product, readily available in the market" constitute all kinds of basic material for daily use, which are generally kept in stocks. Also, per German Law, collective, daily and multitude of products, whether personal or commercial, which are a part of permanent personal needs and may be used in many other ways, in other words, are not described for any special purpose, constitute these products.

Along with this, in British Law, it is stated that the meaning "product, readily available in the market," was "products, which may be needed daily and which may generally be provided" and in addition, "they must be products, supplied for various commercial uses." In this context, British courts consider "readily available products" as "basic commercial products," including raw materials. Therefore, it is impossible to consider a pharmaceutical compound as a basic commercial product as per British law doctrines and case laws.

The patentee claimed that it is impossible to hear the claim that the products comprising API (X), which may only be provided from pharmacies on prescription and used when treating specific conditions, may not be deemed as readily available products, referring to these case laws.

The Court granted PI depending on its legal evaluation on the file without referring the case to a expert examination and without ordering for a guarantee bond. The PI decision mainly suspended the defendant's drug reimbursement when prescribed with API (Y).

The action on merits is still ongoing, and when concluded, it will have a significant contribution to shed light on Article 86 of the Turkish IP Code.

Are Clinical Trials Excluded From Patent Protection in Turkey?

The Turkish IP Law (6769) rules on acts that constitute patent infringement and acts that are excluded from patent protection. However, when it comes to evaluating whether clinical trials in Turkey should be excluded from patent rights, it is important to take the experimental use exemption under Article 85/3(b) and the Bolar exemption under Article 85/3(c) into consideration. Unfortunately, this is easier said than done. No case law in Turkey clarifies which acts are included in the experimental use exemption.

Concerning the Bolar exemption, existing case law focuses on marketing authorisation acts and rules that all kinds of regulatory acts, such as price approval, sales permission and applying to the Social Security Institute ("SSI") to be included in their reimbursement list should be interpreted within the scope of these rules.

Although no case law in Turkey analyses the differences between the experimental use exemption and the Bolar exemption, Turkish legal scholars generally hold that experimental acts regulated under the Bolar exemption have a commercial purpose. In contrast, those under the experimental use exemption do not.

So, when it comes to a clinical trial conducted for filing a marketing authorisation application, it is important to evaluate whether the marketing authorisation application should be led in Turkey or whether the clinical trial is still exempt from patent rights even if the marketing authorisation application has not been led in Turkey.

It is useful to examine the purpose of the Turkish IP Law to answer the above. The reason behind the experimental use exemption under Article 85/3(b) reads as follows: *"Experimental acts comprising the invention which is subject for a patent are excluded from the scope of patent protection on the ground that such acts may improve technological progress."*

Concerning the legal purpose for bringing experimental use exemption in Turkey, the legislator focused on "improving technological process" and did not mention the need for a marketing authorisation application. Therefore, this suggests that clinical trials in Turkey improve technological progress, and their goal is less associated with commercial purposes.

The legal reasoning behind the Bolar exemption under Article 85/3(c) reads as follows:

"it is regulated that patented medicines can be used for the tests and experiments for registration of generics provided that mass production other than those required for registration is not carried out, stored and offered for sale. Thus, the period for generics to enter the market will be shortened at the

expiry date of the patent production. Further, experimental acts comprising the invention within this subparagraph are excluded from the scope of patent protection since such acts may improve technological progress".

The legal purpose of bringing the Bolar exemption in Turkey is to provide the market with cheaper, generic pharmaceuticals, improve R&D and technology in the country and take advantage of the know-how and the profit gained via clinical trials. Having said that, the connection between marketing authorisation applications and clinical trials is quite strong for the Bolar exemption since the wording of Article 85/3(c) explicitly mentions the registration of medicines.

In this respect, where a clinical trial is conducted to obtain marketing authorisation in Turkey, it should benefit from experimental use exemption and the so-called Bolar exemption. Although a case-by-case evaluation should be made, clinical trials should be exempt from patent rights in Turkey under the experimental use exemption in Article 85/3(b) and the Bolar exemption.

Discovery of Evidence Requests and the Scope of Bolar Exemption

Discovery of evidence requests are specially regulated under the Turkish Code of Civil Procedure No. 6100. The discovery of evidence enables determining a fact that is not yet examined in an ongoing action or a fact that will be put forward in a future action.

It must be emphasised that, unlike the US and UK systems, there is no full and frank disclosure procedure under Turkish civil law. In other words, the parties may decide, at their discretion, which documents they will or will not submit to the court; thus, it is not mandatory to disclose all information. Therefore, discovering evidence from a third party via court proceedings is crucial. Article 400 of the Turkish Code of Civil Procedure No. 6100 rules that the party requesting discovery of evidence must have a legal interest, and it is accepted that a legal interest exists if the evidence is lost, or that it will be difficult to depend on that evidence unless it is immediately revealed, except for the cases explicitly stipulated in the law.

Especially in the enforcement of pharmaceutical patents, the patent owner, who is prevented from filing an action due to the so-called Bolar exemption, may use the discovery of evidence tool to complete the preparations of an enforcement action. However, in our opinion, some of the IP courts interpret the limits of the Bolar exception quite broadly and may decide that the Bolar exception continues until the Gx product launches and, within this period, the patent holder cannot take any action. However, as the discovery of evidence is not an action on the merits, it is not blocked by the Bolar exemption and assists the patent holder to discover the evidence of infringement beforehand. The courts may also accept ex parte discovery of evidence upon the patent holder's request if the conditions under Article 403 of the Turkish Code of Civil Procedure are met. Since the discovery of evidence is not an action as to the merits, no appeal mechanism is available. However, the counter-party may oppose the decision of discovery of evidence on the grounds that the conditions under Article 400 have not been met. This objection is examined and concluded according to the circumstances of the incident by the same court conducting the discovery of evidence.

Speaking of the Bolar exception and discovery of evidence, it would be beneficial to refer to the 16th Chamber of Istanbul Regional Court of Justice's recent decision on how the requests of interim measure should be evaluated. In terms of the cases regarding intellectual property rights and specifically patent disputes, which are heard by Civil Courts of Intellectual and Industrial Property Rights, decisions on interim injunction play a key role due to the highly technical nature of the issue, commercial reasons, time pressure, or else.

As it is known, the preliminary injunction,

which appears as a way out in cases where the definitive protection is not sufficient, and temporary legal protection is needed, can be requested before an action is filed as per Article 390 of the Code of Civil Procedure ("CCP"), or it can be requested after the action is filed. In this context, a preliminary injunction can be defined as a temporary, broad or limited legal protection regulated against the damages that may occur in the legal situation of the plaintiff or the defendant during the proceedings until the final decision. However, it is noteworthy that a recent practice of rejecting the preliminary injunction requests without any examination is adopted by the Istanbul Civil Courts for IP courts contrarily to the legal regulations, definitions and purpose. However, in patent and, more specifically, pharmaceutical patent disputes, where technical examination and evaluation are very critical, and much information has not been made public, it is obvious that there is a need to determine the evidence in order to decide on whether to file the main action in the first place. Again in this direction, while it is stipulated by the clear regulation of the law that the preliminary injunction can be granted before filing an action, it is not lawful to give a decision of rejection by stating that the main action should be filed without making any evaluation as if there was no such provision. It was not possible to grant a preliminary injunction without filing the main action.

It should be kept in mind that either filing a preliminary injunction application or the main action together with a preliminary injunction does not make any difference, since, in both ways, the court should bring the expert report to render their decision on such request considering technical examination is inevitably required in such patent cases. An IP court's refusal decision was recently appealed before the district court, which was given with this reasoning. The district court dismissed the decision on the grounds that "while the preliminary injunction conditions should be evaluated in line with IP Code Article 159 and CCP Article 389 and the following articles, the decision to reject the preliminary injunction request because it requires a full trial" was not correct, and sent the file back to the Court of First Instance for consideration of the request after receiving an expert report regarding the conditions of the preliminary injunction and the request.

In our opinion, the district court's decision is extremely accurate and sets a precedent against similar decisions of the IP courts of first instance. In reality, as mentioned above, the preliminary injunction is one of the means of temporary legal protection under Articles 389 et al. of CCP and regulated by the legislator against the damages that may occur in the legal situation of the plaintiff or the defendant in relation to the subject of the case, during the trial that continues until the final decision.

Therefore, the decision to reject the request, stating that the decision on this matter will be made at the end of the full trial, without any examination and evaluation, is an inconsistent practice and has no bearing on the purpose and nature of preliminary injunction protection and the patent protection, which is an intangible property right guaranteed by the constitution. On the other hand, Turkey's Industrial Property Code also states that "Persons who have the right to file a lawsuit according to this Code may request the court to grant a preliminary injunction to ensure the effectiveness of the final decision to be given, provided that they prove that the use subject to the lawsuit is taking place in the country in a way that constitutes an infringement of their industrial property rights or that serious and effective studies have been carried out for in this way." Within the scope of all these provisions of the law, ignoring the provisions of the relevant codes by not considering the evidence and the claimant's request, who collects and submits the evidence based on the request for a preliminary injunction, does not constitute an acceptable practice. Therefore, the latest decision of the district court in this regard has great importance.

[4] Pekcanıtez/ Atalay/ Özekes, Turkish Code of Civil Procedure, Ankara 2015, s. 619

Impact of EPO Proceedings and EPC Provisions on National Actions

Since Turkey's inclusion as a member of the EPC, a hot topic has been the enforcement or invalidity of Turkish validation of European Patent(s) ("EP") while proceedings before the European Patent Office (the "EPO") are pending.

Once an EP is validated in Turkey, it becomes a national patent. For EPs, the Office seems to have transferred its powers and duties to the European Patent Office; therefore, it functions as an institution that carries out only some procedural transactions. Thus, the Office does not examine the EPs at any level or hear any post-granted oppositions. Such that, the Office does not operate post-registration opposition process for EP patents validated in Turkey that is operated for national patents.

On the other hand, in the IP Code , there are provisions that we can qualify as contradictions or even discriminatory between European Patents and national patents. The first is that while the Courts cannot decide on an invalidation action until the national opposition proceedings conclude, EPs have no such immunity. The second is that no amendment to the claim is allowed following the grant decision. EPs validated in Turkey are directly exposed to invalidation actions, although they may be amended during EPO opposition proceedings and the amendments are automatically reflected to the Turkish validation. These patents can be directly subjected to invalidation actions without waiting for the opposition proceedings, and even they can be concluded without granting the patent owner the right to amend the claim.

EP owners are advised to request the national Court to delay the trial till to the outcome of the EPO opposition proceedings. Although these requests are not always accepted on the grounds that the process before the EPO takes a long time, the rights given by the EPC to the patent owner to keep the patent alive should be observed.

Article 138/3 of the EPC is binding upon the national Court to allow EP holders to limit the patent by amendment and that the patent, as thusly limited, will form the basis for the invalidation proceedings. Although the amendment procedure in Article 138/3 is still not straightforward for the IP Courts and the Office, the IP Courts are increasingly inclined to examine such requests and instruct the Office to decide the limitation.

Recently, upon an application to it, the Office accepted the request for limitation of claims by applying the provision of EPC 138/3 and informed the competent Court in the ongoing action about the current scope of the claims and sent the new limited claim set to the court. Based on the information provided by the Office, the relevant court agreed to consider the limited set of claims in the invalidity action and assigned the experts to examine the limited set of claims.

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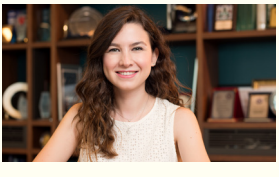

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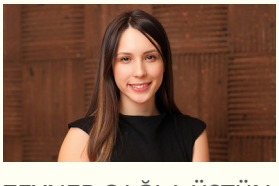

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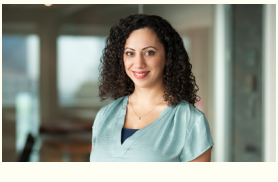

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FIRM OVERVIEW

We are one of the oldest and largest business law firms in Turkey and are ranked among the top tier legal service providers. We are widely regarded as one of the world's leading IP law firms.

Based in Istanbul, we also have working and correspondent office in Ankara, Izmir and all other major commercial centers in Turkey.

We advise a large portfolio of clients across diverse fields including life sciences, energy, construction & real estate, logistics, technology media and telecom, automotive, FMCG, chemicals and the defence industries

We provide legal services mainly inn Turkish and English and also work in German and French.

We invect to accumulate industry specific knowledge, closely monitor business sector developments and share our insight with our clients and the community We actively participate in various professional and business organisations.

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