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AVUKATLIK BÜROSU

PATENT LAW IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS

2021

PATENTS AND UTILITY MODELS

We provide comprehensive advisory, transactional and litigation services covering the full range of patent and Utility Model issues including prosecution, litigation, transactional and advisory matters. Our team combines extensive industry and litigation experience with our market leading IP expertise, including patent related competition law, regulatory issues and data protection.

We advise and represent clients on innovative strategies, setting up patent enforcement and litigation structures, pursuing and defending infringement actions, negative clearance, nullity actions in amongst others, the pharmaceutical, chemicals, medical devices, consumer electronics, textile, lighting, optical technologies, electrical appliances, machinery, laser technology, automotive and software sectors.

We also assist with the unfair competition aspects of new products in the absence of any patent protection. We conduct state of the art searches, carry out IP due diligence, provide freedom to operate opinions and generally advise on patent and utility model compliance prosecution, enforcement and defence strategies.

In addition to prosecuting national and international patent applications, we file and defend oppositions and appeals before the Patent Institute, as well as challenging the Institute's final decision before the specialised Courts.

We draft and negotiate all types of transactions concerning innovative developments, patent and utility models, including collaboration joint research and development agreements, employee invention schemes and license agreements.

Key Developments and Predictions for Patent Law in Turkey

It has been more than four years since the Industrial Property Law, which combined different Decree Laws on specific IP rights, came into force. The fourth book of the Law 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 realized, IP law practitioners still agree that the most controversial issue is not the law, but the enforcement of it. There are eleven specialized IP Courts in Turkey; five 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 to this end, the decisions are heavily dependent upon Court-appointed experts' views. On the other hand, while it is expected that the two-layer appeal review introduced by the Civil Procedural Law 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, as compared with the past. As well, in the past year, the interpretation of the so-called 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 provide an outline of 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:

- Declaration of Use and Compulsory License
- Supply of Pharmaceutical Products from Abroad and Patent Rights
- Preliminary Injunction Granted to Prevent Indirect Use of Invention
- Arbitration Proceedings Regarding Determination of Reasonable Amount for Employee's Invention
- Discovery of Evidence Requests and The Scope of Bolar Exemption
- Impact of EPO Proceedings and EPC Provisions on National Actions

Declaration of Use and Compulsory License

The new IP Law (the "Law") numbered 6769 abolished the provisions on "The use requirement of patents," and "The evidence of use" of the Decree Law Pertaining to the Protection of Patent Rights. The Law now focuses on the requirements of use for patents within the provision of a Compulsory License.

Accordingly, a patent owner must make use of the patented invention within three years following 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 Law in accordance with Article 117/8 of the Regulation on the Implementation of IPL are published in the Bulletin. The Bulletin is a type of announcement that is made when a patent has not been used. Third parties are then aware that they may request the license over such patent.

When assessing actual 'use,' market conditions and conditions outside the control of the patent owner, 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 Law rules that the declaration of the use of a patent must be submitted to the Office in accordance with the same legal terms as prescribed in the Law. 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 as an indication of the intention to use it. The lack of such declaration does not affect the court procedure as the use may also be proven during court proceedings.

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. (the "USHAS"), the Turkish Pharmacists' Association's Economic Enterprise (the "TEB") and/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, is mostly imported by the TEB and SSI on a named-patient basis. If the reimbursement of the relevant product is decided by the SSI, the product is published in the Annex-4/C list of the Health Practices Communiqué of the SSI.

This exceptional 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 the SSI, as the importer of the infringing products. The Courts of Appeal have ruled that in cases of the supply of an infringing product via the NPP, the buyer of product in Turkey, the TEB, may 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 supply of its patented product via the NPP, it may not be preferred to bring an action against these institutions. In practice, the TMMDA, the TEB and the SSI do not share information about the supplier of the product that would create 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.

Preliminary Injunction Granted to Prevent Indirect Use of Invention

One of the most striking developments of 2020 is a preliminary injunction decision given as a result of the implementation of the provision, "Prevention of the Indirect Use of Invention," regulated in Article 86 of the IPL. Although the expression "Indirect Use of Invention" is often confused with the concept of "Indirect Infringement of Patents," in fact, indirect patent infringement is not clearly regulated in our law. Turkish IP Code numbered 6769 ("IP Code") lists the acts that constitute patent infringements in Article 141, according to the numerus clauses principle. The actions constituting "indirect" infringement of a patent, or acts of inducement, help or contribute to infringement, are not mentioned among the actions listed in Article 141. However, the IP Code has a provision in Article 86 that is similar to the "indirect infringement" provision in Article 60(2) of the UK Patents Act (1977), and to 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 IPL, as follows:

"The patent owner shall be entitled to prevent third persons from giving the elements and instruments related to a part of the invention that enables the implementation of the invention, which is subject to the patent, and constitutes the essence of the invention, to persons who are not authorized in the use of the invention that is subject to the patent. It is necessary for the referred third persons to 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."

Article 86 was first implemented in a court action where the patentee demanded determination and prevention of indirect use of its patent, disclosing a combination of active ingredients (X) and (Y), and the protection scope of the patent did not require presence of these combination partners in the same pharmaceutical form, nor it did introduce any other similar limitation, whatsoever. Considering the ongoing use and increasing damages, the patentee asked for a Precautionary Injunction ("PI") decision, as well.

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 API (X) will be prescribed, used, and traded together with API (Y), in practice. Therefore, the defendant is focused on the combination market that constitutes 95% of the whole market. That is to say that the defendant knew that API (X) is not being used solely for

the relevant patient population and even if 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 accused the patentee of abusing the patent rights as it filed 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 that is required to be collected by the patentee as there were no other means through which to obtain the necessary evidence. In this respect, the Court sent writs to the Social Security Institute and the three largest hospitals in Turkey asking them to inform the Court if the defendant's drug, API (X) is being used, prescribed and/or reimbursed, alone, or together with API (Y). All responses from the SSI and the hospitals confirmed the fact that the drug of the defendant is used/prescribed/reimbursed in combination with API (Y). Specifically, the SSI emphasized that among 234 patients, only 43 of them were prescribed with API (X), alone, and 113 of them were prescribed it, together with API (Y).

Depending on the responses from the SSI and the hospitals, the patentee argued that all requirements of Article 86 had been fulfilled since the defendant, as a third person within the meaning of the provision as one who sells/trades/provides the generic product containing the API (X) to unauthorized parties, which constitutes the essential element of the combination patent, enabled implementation of the patent by unauthorized persons, such as pharmacists and pharmaceutical warehouses. Consequently, the patentee demanded the Court to grant a PI to prevent reimbursement of the defendant's drug by the SSI when it is prescribed together with API (Y). The patentee explicitly stated that it requires no measures preventing reimbursement (or any kind of use, market, etc.) of the defendant's drug, when it is 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 unauthorized 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 interpretation of when/which elements should be deemed to be always available in the market. However, the patentee depended on German case law and UK case law. In German Law, it is accepted that the meaning of "product, readily available in the market," constitutes all kinds of basic materials, for daily use, which are generally kept in storage. Also, in accordance with German Law, collective, daily and a multitude of products, whether personal or commercial, which are a part of permanent personal needs, and which may be used in many other ways, in other words, which are not described for any special purpose, constitute these products.

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

Referring to these 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 through prescription, and used for the treatment of specific conditions, may not be deemed as readily available products.

The Court granted PI depending on its legal evaluation on the file without referring the case to a court expert examination, and without ordering a guarantee bond. The PI decision mainly suspended re-imbursement of the defendant's drug when it is prescribed with API (Y).

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

Arbitration Proceedings Regarding Determination of Reasonable Amount for Employee's Invention

In 2020, an arbitration judgment was held in accordance with the ISTAC serial arbitration procedure regarding the compensation request for employee invention and, as far as it is known, this is the first and pilot file in which the Regulation on Employee Inventions, Inventions in Higher Education Institutions and Public Funded Projects, will determine the price tariff for employees' inventions and the arbitration procedure to be followed in case of dispute.

Within the scope of the dispute in question, the employer company requested full right ownership for the patent of which the employee supporting the R&D studies within the company he works for was the inventor, and the employee duly requested that he be paid an equitable price for the patents he invented in accordance with Articles 22, 24, 25 of the abrogated Decree Law No. 551, which was in force on the date of the full right ownership request, along with Article 115 of Law No. 6769.

Verbal and written requests made by the employee for the payment of a reasonable amount and the warning letter sent were not taken into account by the employer and, eventually, the employee's employment contract for an indefinite term was terminated. Following these developments, an indefinite damage claim and declaratory action was filed by the employee for the determination and compensation of a reasonable amount.

Although it is understood from Article 115/11 of the IPL regulating that "the price tariff for employee inventions and the arbitration procedure to be followed in case of dispute is determined by the regulation," which is the basis of the employee's case, that a legally compulsory arbitration is not stipulated, the Istanbul Civil Court of Intellectual and Industrial Property Rights dismissed the case on procedural grounds, taking into account the provisions of the Regulation that entered into force during the proceedings, and which regulates the compulsory arbitration procedure regarding employee inventions and the price tariff.

Upon the aforementioned decision of the Istanbul Civil Court of Intellectual and Industrial Property Rights, an arbitration process was initiated by the employee who had no other option but to apply for arbitration before the ISTAC. It was decided by the Arbitrator appointed for the resolution of the dispute to implement the Regulation, which includes the current Regulations, in determining the reasonable amount.

In the report prepared as a result of the expert examination made by the Arbitrator in the continuation of the process; it was determined that the employee was an inventor, was legally entitled to compensation, and that the employers' product could not have been released to the market without the invention of the employee, the economic value of the

patent was high, the employers sold the product with a very high profitability, and they earned a very high profit of… million TL from the invention. However, as a result of the application of extremely mixed price determination criteria in the Regulation prepared with a casuistic understanding, it was determined that the compensation to which the employee is entitled to is an amount that cannot even cover the expenses of the arbitration.

The arbitrator conducting the arbitration proceedings concluded that the amount determined in accordance with the Regulation is not in accordance with the letter and spirit of the provisions of Articles 115/5, and 6 and 7 of the IPL, considering all of the conditions of the concrete case, and that the completely formal calculation method, which does not comply with the expression and definition of the "reasonable amount" specified in the IPL of the Regulation, renders this reasonable amount meaningless. In this context, the arbitrator increased the amount that was determined by implementation of the Regulation by five times in accordance with the principle of equity, on the grounds that the determined amount is not only proportional to the profit obtained by the defendant employers from the patent, but also not proportional to the minimum level of labor and expense required in the process of applying to litigation to obtain the right.

In other words, the arbitrator realized that the provisions of the Regulation to be applied to the resolution of the current dispute caused very low compensation to the inventor against companies that earned high profits, thanks to the employee inventor, and did not find this application fair.

Discovery of Evidence Requests and the Scope of Bolar Exemption

Discovery of evidence requests are specially regulated under Civil Procedural Law No. 6100. Discovery of evidence serves the purpose of determining a fact that has not yet been 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, discovery of evidence from a third party via court proceedings is crucial. Article 400 of 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 clearly 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 at least to complete the preparations of an enforcement action. However, in our opinion, some of the IP courts misinterpret the Bolar exception deciding that the Bolar exception continues until the Gx product launches and, within this period, the patent holder cannot take any action. However, as 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 request of the patent holder if the conditions under Article 403 of the Civil Procedural Law are met. Since 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 that conducted the discovery of evidence.

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 Turkish Patent and Trademark Office (the "TPMO") 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 TPMO does not examine the EPs at any level, nor it does it hear any post-granted oppositions. On the other hand, under IPL, there are provisions that we can qualify as contradictory 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, there is no such immunity for EPs. 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, in spite of the fact that they may be amended during EPO opposition proceedings, which will be automatically reflected upon the Turkish validation. These patents may be directly subjected to invalidation actions without waiting for the opposition proceedings, and they may even be concluded without granting the patent owner the right to amend the claim.

To avoid any Turkish Court decision as to validity, EP owners are advised to request the Court to await the outcome of the EPO opposition proceedings. Although these requests are not always accepted on the grounds that the process before the European Patent Office takes a long time, the rights given by the European Patent Convention 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 TPMO, the IP Courts are increasingly inclined to examine such requests and instruct the TPMO to decide as to the limitation.

Last year, upon an application to it, the TPMO 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 TPMO, the relevant court agreed to consider the limited set of claims in the invalidity action and assigned experts to examine the limited set of claims.

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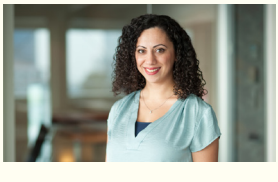

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FIRM OVERVIEW

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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