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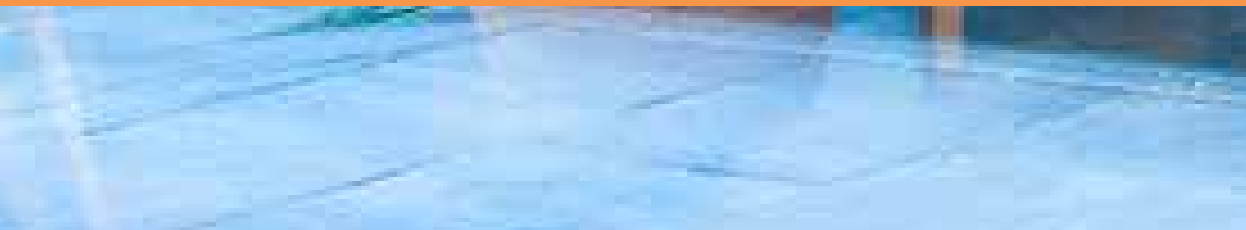
KEY DEVELOPMENTS AND PREDICTIONS FOR PATENT LAW IN TURKEY - 2019



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 offices 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 in Turkish and English and also work in German and French.

We invest 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.

Key Developments and Predictions for Patent Law in Turkey

When the Industrial Property Law came into force on 10 January 2017, the introduction of the post grant opposition procedure for national patent applications or the new "satisfying national market's need" criteria concerning compulsory license due to non-use of the patent appeared to be of the most significance. However, as usual, the devil was hidden in the detail. When we first put the new law into practice, we experienced that other provisions such as the use requirement of patents and filing a declaration on use before the Turkish Patent Office or employee inventions can have many different interpretations. Meanwhile, Discovery of Evidence and Preliminary Injunction (PI), Damages, Bolar Exemption, Impact of EPO Opposition on National Proceedings remained the hottest topics in relation to Patent litigation in Turkey.

It is worth noting also that the Judges appointed to IP Courts from other civil courts, and particularly from the commercial courts, interpreted the sole Discovery of Evidence (without PI demand) demands more positively. In respect of the patent right holder, this approach would mean that they would have greater benefit if the Court discovered and determined the evidence on infringement of the patent before taking the enforcement action on merit.

This Paper provides an outline of the key aspects of patent litigation in Turkey and the most important or challenging issues in Turkish Patent Law.

This paper provides an overview of the following topics:

- Declaration of Use and Compulsory License
- Employee Inventions
- Post-Grant Opposition System
- Discovery of Evidence and Preliminary Injunction
- Impact of EPO Opposition on National Actions
- First Damages Judgement in the Pharma Sector for Unjust PI

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 to expire. The Bulletin is a type of announcement, which shows when a patent is not being used. Third parties will then be aware that they can request a 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 party can request a compulsory license on the grounds that the patented invention is not being used or no serious and real measures have been taken to make use of the patented invention or the level of current use does not meet domestic demand.

The same applies to cases where there has been no use of a patent for more than three years without justified reason.

Additionally, patent holders are requested to file a declaration of use of the patent before the Turkish Patent Office ('the Office'). The Regulation on the Implementation of the Law rules that the declaration of the use of a patent should be submitted to the Office in accordance with the same legal terms as prescribed in the Law. Patents that have not been notified of their use within this period will be published in the Bulletin. The publication, however, does not lead to any direct negative consequences or benefits. Even if a patent was not listed in the list of non-used patents, a third party may still request a compulsory license, claiming that the patent is not used or no serious and real measures have been taken to make use of the patented invention or the level of current use does not satisfy domestic demand. Even if the patent is listed, it does not mean there will be an automatic grant of a compulsory license.

When requesting a compulsory license, there is a court procedure to follow, and the declaration of the patent's use filed before the Office can only be used as an indication of its use. The lack of such declaration does not affect the court procedure as the use can also be proven during court proceedings.

Employee Inventions

On 29 September 2017, the Regulation on Employee Inventions, Inventions Realised within Higher Education Institutions and Inventions Arisen from Projects Supported by Public Authorities ("the Regulation") came into force. This regulates the method used to determine compensation awarded to employees should their employer demand a full or partial right to their invention. The regulation stipulates the methods to be used to calculate the employee's award, which should be reasonable.

In principle, compensation will be determined via an agreement between both parties. Where there is a dispute, especially if the revenue of the invention cannot be determined, compensation can be determined by a comparison with other similar inventions, the potential profit resulting from the invention or according to a reasonable amount that the employer would pay, if he/she wanted to purchase it. In addition, revenue from inventions can be considered equal to revenue earned from a license or to the revenue received from the sale of the invention.

According to Turkish IP Law, when the employer claims the right to a work-related invention, they cannot refuse to pay the inventor compensation if they believe that the invention is not worth protecting.

However, if the patent is invalidated in an action filed against the patent before a competent Court, the employee can no longer request compensation. The lack of clarity in this provision has led to some employers having third parties file invalidation actions (on their behalf) against the patent so they can avoid paying the employee compensation. However, the relevant rule has now been clarified in that the period leading up to the finalisation of the invalidation action will be taken into consideration when calculating the employee's compensation.

Any dispute within the scope of the Regulation must be resolved via arbitration, which should either be agreed by both parties or it will be enforced by law. That said, there is a pending administrative lawsuit to cancel the arbitration provision of the Regulation, on the grounds that a mandatory arbitration must be imposed by law, not by an administrative regulation.

Post-Grant Opposition System

The post-grant opposition system was first introduced in the new IP Law, which came into force in January 2017. It is mostly aligned with the system regulated in Article 101 of the European Patent Convention ('EPC').

Accordingly, third parties are entitled to file oppositions against a patent within 6 months from the grant decision as published in the Bulletin. The patent holder may respond to the opposition within 3 months from this date and/or may file amendments. The Re-Examination and Re-Evaluation Board evaluates the opposition and the response from the patent holder and makes a decision on maintaining or revocation of the patent.

With regards to the post-grant opposition system, the Law also governs what happens in cases where an invalidation action is filed before the IP courts when an opposition on the same patent is pending. The Law states that the Court cannot issue a decision on the invalidation action until the outcome of the opposition has been published in the Bulletin or it has been confirmed that no opposition has been filed against the patent.

Unfortunately, the provision covers only national filings. It is at the discretion of the IP Court whether to delay the invalidation proceedings against a national validation of a European Patent; in cases where a post-grant opposition is pending before the EPO.

On the other hand, one key feature of the post-granted opposition system has not been included in the Law. The Law prohibits any amendment or limitation of the patent following the outcome of the patent office proceedings. This means that a patent can be amended or limited only during the examination or opposition procedures before the patent office. This provision explicitly precludes the possibility of amending or limiting a patent during invalidity proceedings. As well as being inconsistent with Article 138/(3) of the EPC and creating discrimination between European patents validated in Turkey and national filings, this provision makes the post-grant opposition system useless, or at least vulnerable to be used in bad faith. However, it is inevitable that third parties will prefer to challenge the patent via an invalidation action, where the patent holder will have no right to amend or limit the patent, rather than via an opposition, where the patent holder may be able to maintain its patent through permissible amendments and limitations.

Discovery of Evidence and Preliminary Injunction

Patent holders may initiate temporary legal protection measures by filing for discovery of evidence ("DoE") and/or a preliminary injunction ("PI"). PI requests may be placed either in an infringement action (at any time and any number of times) or preceding the infringement action as a standalone temporary measure application. Conditions and requirements to seek and obtain a PI are briefly; (i) prima facie illegality (i.e. infringement or a potential danger); and (ii) irreparable harm or damage if it is not prevented by a PI.

If it is filed as a standalone application and the Court grants a PI in favour of the party requesting the DoE and/or PI, the requesting party must file a main action for patent infringement within two weeks from the date of the delivery of the PI order. Otherwise, the PI order is automatically lifted. It may also be noted that a dismissal of an infringement action may cripple the patent holder until there is a change in circumstances and when there is a further standing to file an action. Dismissal of PI requests on the other hand has no such downside. Processing of DoE and PI applications may take between 3-4 weeks to 3-4 months depending on the complexity of the infringement issue and the time the Court appointed experts take to prepare their expert report.

Where the court rules in favour of a PI, the patent holder is usually ordered to deposit a bond, which may vary depending on the value of the product in question. The bond would remain in place for the duration of the PI. If the PI turns out to have been unfairly granted, the bond is then utilised towards an action for damages, which may be filed by the defendant.

Bolar Exemption in Pharmaceutical Patent Litigation

Article 85/III(c) of the Intellectual Property Law (IP Law) ensures pending marketing authorisation applications for medicinal products are exempt from patent infringement. Unfortunately, the limits of the Bolar Exemption is not so clear. Although the process and act of licensing (obtaining marketing authorisation) are exempt, the IP Courts are more frequently requesting further commercial activities by generic companies before hearing a DoE / PI or any infringement claim. Any promotional activities or attempts to sell or offer for sale such as applications for reimbursement and obtaining regulatory price approvals may be accepted as evidence, although they are not conclusive.

Impact of EPO Opposition on National Actions

Ever since Turkey became 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 (EPO) are pending.

Once an EP is validated in Turkey, it becomes a national patent three months from its first granted decision by the Examination Board of the EPO. For EPs, the Turkish Patent and Trademark Office (TPMO) acts as a procedural agency only. Thus, the TPMO does not examine the EPs at any level nor it does it hear any post-grant oppositions. On the other hand, the Law has two provisions that contradict with the EPC. The first is that a patent may be subject to invalidity proceedings before Turkish IP Courts since the granted decision. While Courts cannot decide on an invalidation action until the national opposition proceedings come to an end, there is no such immunity for EPs. The other is that no claim amendment is allowed following the grant. 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 to the Turkish validation.

To avoid any Turkish Court decision on validity, EP owners are advised to ask the Court to wait for the outcome of the EPO opposition proceedings.

If this is not accepted by the Court due to the length of the EPO proceedings, it is worth asking the Court to apply Article 138/3 of the EPC.

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

First Damages Judgement in the Pharma Sector for Unjust PI

In 2018, the Istanbul IP Court decided on a generic company's damages claim based on an unjust PI, in what appears to be the first decision of its kind by the Turkish IP courts within the pharmaceutical sector. This is a first instance court decision, subject to an appeal from parties to the case.

The dispute between an originator firm and a generic firm derived from an infringement claim. The Court had issued a PI, which was lifted after 13 months based on the findings of an experts' report, which found that there had been no infringement. The generic company then filed a compensation action for damages due to the fact that it had not been able to launch the generic product during the 13-month PI term. However, as the generic product was never released to the market – even after the dismissal – it was difficult for the Court appointed experts to calculate the amount of compensation due.

The patent holder argued that in order to calculate the hypothetical market share of the generic company, the Court should compare other similar products across various markets during the same period; it submitted the in-market sales data for two example products, which had a 6.7% and 16% market share as the first generics. It also challenged the generic company's calculation of a 37.5% market share, suggesting that any company used as a model should be of a similar size and reputation in the market, and that the sales should have taken place during the same period.

After reviewing the evidence, the experts calculated the market share based on a comparison of in-market sales data for similar product markets. They also tested different hypothetical scenarios in which the generic firm would have had, for example, a 6.7%, 16%, 37.5% or 50% market share. The experts concluded that the generic firm would most likely to have had 16% market share. Therefore, the court awarded damages based on this figure.

A 'one size fits all' approach for the calculation of damages is not appropriate for this kind of action as certain case-specific parameters must be considered. Among others, these include the conditions for pricing and sales of the products within the relevant period; the therapeutic area of the drug; the size and sales potential of the pharmaceutical company; brand loyalty; and the substitutability of the generic with the original product.

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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.

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