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PATENT LAW IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS - 2020

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

It has been three 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). Although it is too early for the implications of the new law to have come to light, working requirements and compulsory licensing remain the most questioned topics in terms of patent law.

While the mid-term 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 twelve specialized IP Courts in Turkey; six in Istanbul, five in Ankara, and one in Izmir. Due to the recent changes as to the appointment of judges, most of these Courts are headed by a single judge who may have any number of years of IP experience, or none whatsoever. As these judges do not have any technical background, the decisions are heavily dependent upon Court appointed experts' views. On the other hand, some of the judges now interpret the Discovery of Evidence applications more positively, and the two-layer appeal review introduced by the Civil Procedural Law is expected to lower the workload and raise the quality of the judgments. In 2019, the interpretation of the so-called Bolar Exemption for pharmaceutical products, 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 active and debated areas before the IP Courts.

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. It is anticipated that Court decisions will cast new light on the many aspects of the provisions of law, especially in questioned areas.

This paper provides an overview of the following topics:

- Declaration of Use and Compulsory License
- Difficulties of Enforcing Patent Rights on NPP Products
- Ex Parte Injunctions in Turkish IP Law
- Discovery of Evidence not being Subject to Bolar Exemption
- Impact of EPO Opposition on National Actions
- 2nd Damages Judgment 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. The Bulletin is a type of announcement that is made when a patent is not being 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 party 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. Patents that have not been used 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 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.

Difficulties of Enforcing Patent Rights on NPP Products

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, but patients are in need of it, it can be supplied via this special route. The entities that are authorised to import pharmaceuticals within the scope of the NPP are the Turkish Pharmacists' Association (the "TEB") and the Ibn-i Sina Health Social Security Centre Warehouse, established under the Social Security Institution (the "SSI Warehouses").

If the product is approved for the NPP, it is added to the Foreign Drug List of the Ministry of Health (the "MOH"), and the TEB and SSI will import the products on a named-patient basis.

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 some cases, the patent in question is a compound patent; therefore, an infringement claim as a result of the newly added NPP product is inevitable.

In these scenarios, the patent owner is quite certain of the patent infringement and is prepared to take legal action. However, the only known party to the patent owner who is causing the infringement would be either the TEB or SSI Warehouses, 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 TEB may be one of the potential named parties of the patent infringement action, as the importer of the infringing products.

However, the TEB or the SSI Warehouses are the business partners of the patent owner for supply of its patented product via the NPP. Consequently, the patent owner will prefer to bring an action against the company that offers the infringing product for sale to the TEB or SSI Warehouses. However, this information is not publicly available, and the authorities are reluctant to provide such information.

Another problem that patent owners face regarding NPP products is the threat of a compulsory licence due to insufficient use of the patented product. In the case of a third party demanding a compulsory license, they shall apply to the patent holder first to ask for a contractual licence, and if this demand is rejected or not responded to within a reasonable time, the issue shall be resolved before the Turkish IP Courts.

Ex Parte Injunctions in Turkish IP Law

Although ex parte injunctions are legally available, are quite rare in Turkish Patent Law practice. The IP Courts almost always reject requests for ex parte injunctions, preferring to evaluate the alleged infringement only after hearing both parties. However, in 2019, the Turkish IP Court unexpectedly granted a request for an ex parte injunction, due to the urgent nature of the matter.

The request for this ex parte injunction was filed against a company in Argentina. The company supplied and imported (what was assumed to be) infringing pharmaceuticals to Turkey. The alleged infringer had no affiliate in Turkey. As the international notification procedure, which may take at least two to three months, was used to notify the defendant Argentinian company of the patent holder's action complaint, the IP Court was convinced to conduct a patent infringement examination, ex parte, and referred the case to a Court-appointed expert panel to evaluate the technical aspects of the infringement.

If an injunction is granted ex parte, then as per IP Law, the other party will be notified of the decision and will be granted the right to appeal before the district court. The appeal will not suspend the execution of the decision.

Discovery of Evidence Is Not Subject to Bolar Exemption

Discovery of evidence and actions for determination of evidence are separately regulated under the Civil Procedural Law. Discovery of evidence is a preliminary step taken before any action on the merits, and it only serves to discover and record the evidence that may be relevant to an ongoing or future action on the merits.

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 the Turkish Code of Civil Procedure rules that the party requesting discovery of evidence must have a legal interest in the discovery/determination of the evidence, 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.

The discovery and the collection of evidence is monitored and executed by the IP Court. Especially in the enforcement of pharmaceutical patents, the patent owner, constantly blocked from enforcement 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, as per the latest interpretations of the IP courts, Bolar immunity is extended only 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 by the same court that conducted the discovery of evidence.

Impact of EPO Opposition 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 three months after its first granted decision by the Examination Board of the EPO. For EPs, the Turkish Patent and Trademark Office (the "TPMO") acts only as a procedural agency. Thus, the TPMO does not examine the EPs at any level, nor it does it hear any post-granted oppositions. On the other hand, two provisions of the Law contradict the EPC. The first is that a patent may be subject to invalidity proceedings before Turkish IP Courts after the decision has been granted. 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 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.

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. 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 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.

2nd Damages Judgment in the Pharma Sector for Unjust PI

In 2018, the Istanbul IP Court decided on a generic pharmaceutical 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. 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 expert's report, which found that no infringement had been made. 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. 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. The experts calculated the market share based on a comparison of in-market sales data for similar product markets.

A second case that was similar in kind was recently decided and, as the generic pharmaceutical company started selling the product in question after the PI was lifted, the basis of the damages calculations were that the IMS data related to the term after the PI had been lifted. However, the most difficult part was the determination of the profit margin of the claimant generic pharmaceutical company.

A 'one size fits all' approach for the calculation of damages is inappropriate for this kind of action since case-specific parameters must be considered. Both decisions are first instance court decisions, subject to appeal by the parties of the case.

In these damages actions due to unjust PI, the unconstitutionality of the claims is also a point of discussion due to the poor wording of the relevant provision of the Civil Procedural Law. Procedurally, a lower degree of proof is sufficient for the Court to issue a PI decision. However, Article 399 of the Civil Procedural Law provides that the party who was granted the PI shall be obliged to compensate the other party for damages in the event that the PI is lifted. According to this law provision, the person who exercises the right to request a preliminary injunction, within the framework of legal rules and protection afforded to him/her, is held liable for compensation, without examination of fault or bad faith. Therefore, the requesting party, at the beginning of the trial, is imposed with the obligation to predict the final decision, to be established by the Court.

KEY CONTACTS

MEHMET GÜN
PARTNER

Patents and Utility Models
Life Sciences
Intellectual Property
Dispute Management
Corporate and M&A

mehmet.gun@gun.av.tr

ÖZGE ATILGAN KARAKULAK
PARTNER

Patents and Utility Models
Life Sciences
Intellectual Property

ozge.atilgan@gun.av.tr

SELİN SİNEM ERCİYAS
PARTNER

Patents and Utility Models
Life Sciences
Intellectual Property

selin.yalincakli@gun.av.tr

AYSEL KORKMAZ YATKIN
PARTNER

Patents and Utility Models
Intellectual Property
Dispute Management

aysel.korkmaz@gun.av.tr

MARAL SAYAN
SENIOR ASSOCIATE

Patents and Utility Models
Intellectual Property

maral.sayan@gun.av.tr

PINAR ARIKAN
DIRECTOR

Intellectual Property
IP Prosecution

pinar.arikan@gun.av.tr

BURCU SUCUKA
SENIOR ATTORNEY

Intellectual Property
Patent and Utility Models
IP Prosecution

burcu.sucuka@gun.av.tr

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.

GÜN + PARTNERS
AVUKATLIK BÜROSU

Kore Şehitleri Cad. 17
Zincirlikuyu 34394
İstanbul, Turkey

T: + 90 (212) 354 00 00
F: + 90 (212) 274 20 95
E: gun@gun.av.tr

www.gun.av.tr