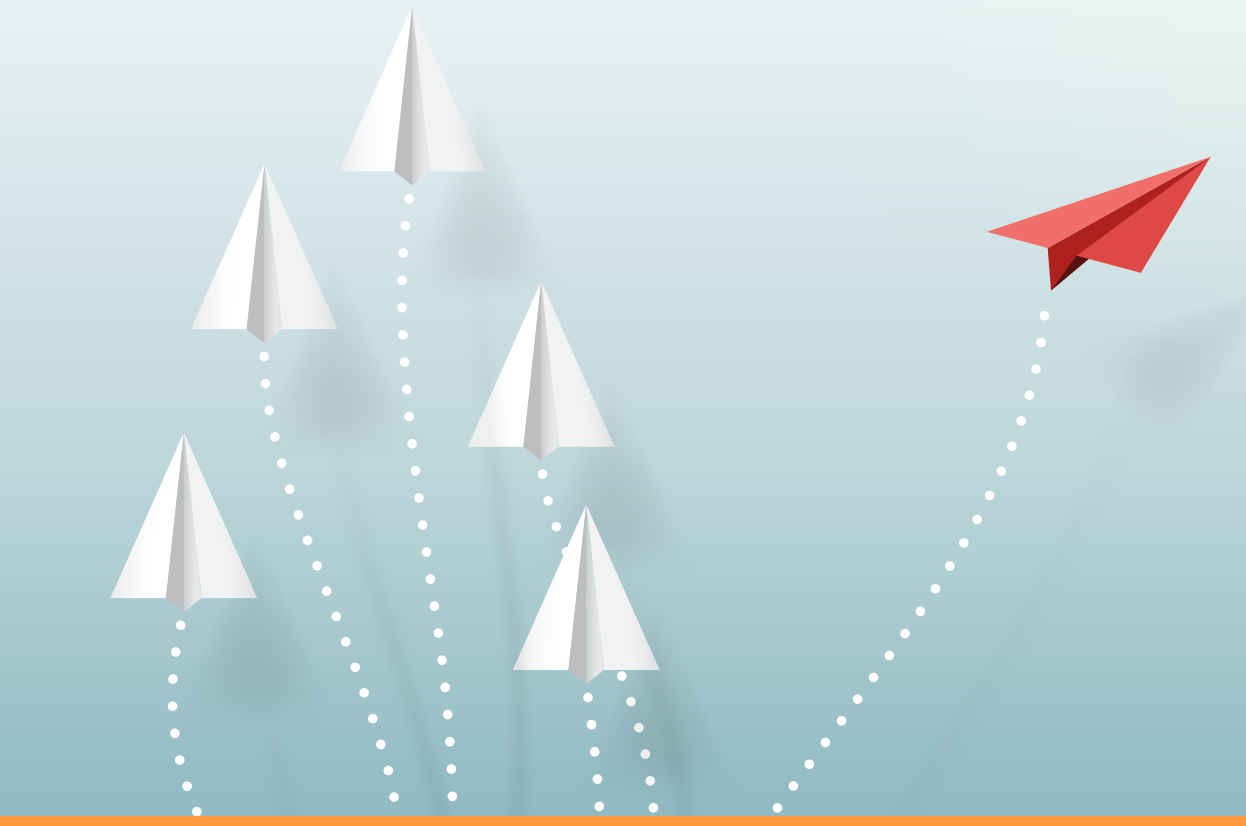
GÜN + PARTNERS
AVUKATLIK BÜROSU



PATENT LAW IN TÜRKİYE
KEY DEVELOPMENTS AND PREDICTIONS

2024

Patents and Utility Models

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Introduction

As Turkish patent law strides into 2024, it is met with a landscape brimming with innovation, regulatory shifts, and strategic challenges. This overview distills critical insights and developments, guiding our interested readers through the intricate fabric of this evolving legal domain.

The conversation around AI and inventorship heralds a new era for intellectual property, challenging traditional boundaries and prompting a reevaluation of legal frameworks both in Turkey and globally. This issue dovetails with the transformative EU pharmaceutical legislative reforms, creating a dual front where technological and regulatory changes demand agile and forward-thinking legal strategies. The emphasis on protecting the valuation and market position of original pharmaceutical products through legal innovations like partial preliminary injunctions is particularly poignant, reflecting a proactive approach to navigating competitive markets.

The EU pharmaceutical legislative reforms specifically address the Bolar issue and seek to expand the scope of the "Bolar Exemption." However, it is crucial to ensure that this expansion remains consistent with the law and the interests of all involved parties. In Turkish legal practice, challenges have arisen due to courts interpreting the Bolar Exemption more broadly than the provision's intended scope, creating difficulties for patent owners. Despite these challenges, recent optimism has emerged from a judicial decision that aligns with the law and balances the interests of both parties. This decision suggests a potential shift towards a fairer system, providing hope for improved clarity and fairness in the implementation of the Bolar Exemption in Turkish pharmaceutical law.

The anticipation of the Unified Patent Court (UPC) and the escalation of tactical patent invalidation tactics represent significant considerations for patent strategy and litigation, underscoring the need for a dynamic and informed response to protect intellectual assets. These developments underscore the importance of adaptability and strategic foresight in upholding patent rights and navigating legal complexities.

The dialogue on Standard-Essential Patents (SEPs) further illustrates the nuanced interplay between innovation promotion and intellectual property protection. This discussions reflect a broader trend towards reconciling the imperatives of technological advancement with the principles of fair access and competition, especially within the pharmaceutical sector.

A noteworthy advancement in the legal landscape is the evolving approach to compensating damages for unfair preliminary injunction decisions, marking a progressive shift towards equity and justice in the pharmaceutical industry. This change is emblematic of a broader movement towards more balanced and fair legal practices in patent law.

This overview presents a holistic view of the challenges and opportunities within Turkish patent law in 2024, characterized by a dynamic interplay between legal innovation, regulatory adaptation, and strategic litigation. For in-house legal counsels, these insights underscore the critical importance of an integrated approach to intellectual property management, legal strategy, and regulatory compliance.

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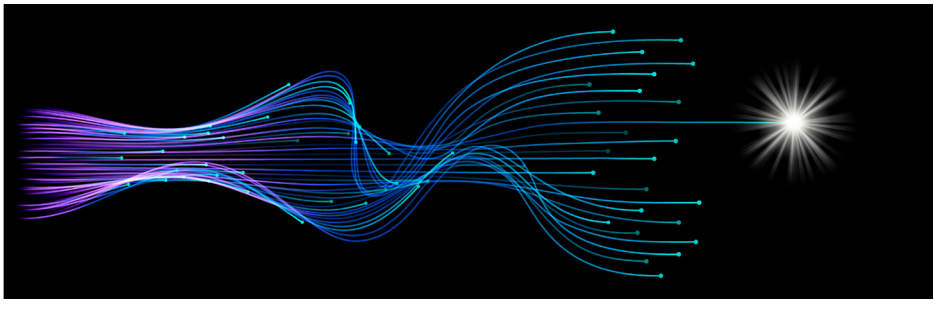
Inventorship of AI and Türkiye's Position



Artificial intelligence has begun taking over roles normally performed by humans with little difficulty, including the act of inventing. As a result, debates on whether artificial intelligence can be the owner of an invention have emerged across the global and are likely to open many novel discussions.

The debate on whether an artificial intelligence system can be an inventor began after the development of DABUS, the artificial intelligence system developed by Dr. Stephen Thaler. A team led by Dr. Thaler and Prof. Ryan Abbott have filed applications with patent offices worldwide for two separate inventions of DABUS.

An examination of applications for DABUS' inventions serves to illustrate developments and approaches to the issue of AI inventions at patent offices across different jurisdictions.

In July 2019, Thaler submitted patent applications for two DABUS inventions to the **United States Patent and Trademark Office** (USPTO), listing DABUS as the sole inventor. However, these applications were rejected on the grounds that the applications were incomplete due to the absence of a real human inventor. Following Thaler's requested review of the decisions, the Federal District Court concluded that an "inventor" under the Patent Act must be an "individual", and the meaning of "individual" is a natural person and also emphasized that inventorship is a concept that requires a mental act and thus, an AI cannot be the inventor. Thaler appealed the decision in 2022, and, subsequently, the Supreme Court held that "individual" refers to human beings, and therefore "inventors" must be human beings.

The United Kingdom Intellectual Property Office (UKIPO) rejected Thaler's DABUS applications on the grounds that DABUS is not a "person", and, thus, cannot be considered as the inventor. The UK High Court and the Court of Appeal upheld this decision of the UKIPO. A subsequent appeal to the UK Supreme Court was rejected by the Court's on the 20th of December 2023. The decision of the Court concluded that artificial intelligence is not a "person" and for this reason cannot be considered the owner of the invention.

Similarly, Thaler filed two European patent applications with the **European Patent Office** (EPO) in 2018, both of which were rejected upon EPO's determination that the inventor designated in a European patent must be a "natural person". Following the request for review by Thaler, the Legal Board of Appeal stated in its preliminary opinion that under the European Patent Convention, the inventor designated in a patent application must be a person with legal capacity. In December 2021, the Legal Board of Appeal dismissed Thaler's appeal. Thaler's divisional application, where he is named as the inventor, remains pending before the EPO.

The **German Federal Patent Court** took a different perspective on the issue of AI inventorship regarding DABUS applications. Upon an appeal filed before the Federal Patent Court concerning the rejection of Thaler's application to the **German Patent Office**, the Court acknowledged that AI inventions are patentable but stipulated that the inventor must be presented as a natural person in the application. This decision is significant, as it made it possible to include AI's involvement in a patent application, sidestepping the debate over who could be deemed the inventor. The Court set out that the one responsible for the invention must be identified as the inventor on the relevant paperwork, and details regarding the contribution of an AI system may be added as additional information.

While there is no specific regulation addressing the inventorship of artificial intelligence in Turkish Law, it is vital to note that there have been no legal precedents in Türkiye akin to the cases concerning DABUS patent applications, nor have there been any applications to the Turkish Patent and Trademark Office designating AI as the inventor.

Yet, Türkiye's approach is expected to be similar to that of the EPO. Indeed, if the DABUS applications filed before the EPO (which also encompasses Türkiye) had been registered by the EPO instead of being rejected, the patents in question would now be registered before the Turkish Patent and Trademark Office in accordance with the European Patent Convention.

The basis of the problems discussed in Türkiye (as in many other countries) regarding the inventorship of artificial intelligence lies in the determination of the legal status of the AI and the introduction of special legal regulations and precedence on the issue. Designating AI as the inventor in patent applications will pave the way for artificial intelligence to be recognized as the patent owner. In such a case, this will mark the beginning of a new era in patent law, especially in liability law.

EU Pharmaceutical Package - EU Pharmaceutical Legislative Reform and its Impact on Türkiye

On 26 April 2023, the European Commission (the "Commission") adopted a proposal for a new Directive and Regulation (the "Proposal") which revise and replace the existing general pharmaceutical legislation.

The proposal adopted by the Commission replaces the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on pharmaceuticals for children and rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC respectively).

In the Commission's press release on the Proposal, it was stated that the pharmaceuticals authorized in the EU are still not reaching patients fast enough and are not equally accessible across all Member States. The proposal aims to prevent pharmaceutical shortages and unmet medical needs due to high pricing of innovative treatments. In addition to addressing public health from a pharmaceutical access viewpoint, the proposal aims to adapt the rules to new technologies, reduce bureaucracy, and simplify marketing authorisation procedures for pharmaceutical products to ensure that the EU remains an attractive place for pharmaceutical investment and a world leader in the development of pharmaceuticals.

The revisions aim to achieve the following main objectives in particular:

- Establish a single market for pharmaceuticals to make sure all patients across the EU have timely and equitable access to safe, effective, and affordable pharmaceuticals;
- Continue to offer an attractive and innovation-friendly environment for research, development, and production of pharmaceuticals in Europe;
- Significantly reduce the administrative burden by considerably expediting procedures, and decrease the time required for pharmaceuticals' authorisation, enabling them to reach patients faster;

- Improve the availability of pharmaceuticals and ensure their availability to patients regardless of where they live in the EU through strict reporting systems on critical shortages of pharmaceuticals;
- Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach in the world and EU;
- Make pharmaceuticals more environmentally sustainable.

To achieve these objectives, the Proposal includes amendments regarding the entire lifecycle of pharmaceuticals. In this context, the Proposal includes the following amendments to incentivise pharmaceutical companies, especially regarding innovation:

- Encouraging comparative clinical research to develop pharmaceuticals to address unmet medical needs;
- Create an incentive system that rewards companies that develop pharmaceuticals that can cure irreversible diseases;
- Reconsidering market exclusivity for pharmaceuticals used to treat rare diseases and ensuring the availability of generics and biosimilars;
- Speeding up the marketing authorisation process for new pharmaceuticals, for example, by reducing the EMA's review period from 210 days to 180 days and reducing the Commission's approval period from 67 days to 46 days.

In addition, the Commission proposes reducing the current standard protection period for data exclusivity from 8 years to 6 years, with various possibilities for extension. This period may be extended by 2 years if the medicinal product is marketed in all 27 Member States, 6 months if the medicinal product fulfils an unmet medical need, 6 months if comparative clinical trials are conducted, and 1 year if the medicinal product has a new therapeutic indication. These provisions, which reduce the duration of data exclusivity, have been criticised by many institutions and organizations, notably the EFPIA (European Federation of Pharmaceutical Industries and Associations). It is argued that the Proposal reduces R&D incentives, contrary to what was announced, by stating that the criterion that the pharmaceuticals should be marketed in 27 countries is not always under the control of pharmaceutical companies and requires significant investment, in addition to the criteria on comparative clinical research and unmet medical needs failing to suffice in terms of the incentives they offer in relation to the costs and time incurred to achieve the objectives, and having narrow, unpredictable success criteria. In this light the Proposal appears to reduce R&D incentives, contrary to what has been announced.[1] The reduction of the standard protection period for data

exclusivity to 6 years is also of interest for Türkiye. Indeed, the Commission's 2023 Türkiye report states that *"Even though Türkiye has in place a regulatory data protection regime since 2005, the scope is limited and excludes biologics and combination products. The length is also limited, reducing the effective protection period in Türkiye."* [2]

Finally, the Proposal also proposes some amendments to the Bolar Exemption provision. Under the current regulation, the scope of the Bolar Exemption includes only acts for the purposes of obtaining marketing authorisation by generic manufacturers. The proposal stipulates a broadening of the exemption to include studies and trials to generate data for Health Technology Assessments (HTA), the pricing and reimbursement process, and activities necessary for these purposes, including by third parties. This proposal has been criticised on the grounds that generics are not obliged to produce any data for HTA or price and reimbursement. Additionally the concept of patent linkage, akin to patent-authorisation connection in the US, does not exist in the EU, requiring patent holders to consider price and reimbursement applications as the act that initiates patent infringement in order to prevent generics from entering the market by taking risks. Indeed, both in Türkiye and in many EU countries, price, and reimbursement applications may be considered as an imminent threat of infringement or an offer for sale. Therefore, the broadening of this concept will prevent the effective and timely enforcement of patent rights.

According to the most recent European Commission report, Türkiye is still a key partner and candidate country for the European Union. Therefore, EU pharmaceutical legislation is closely monitored, and amendments are reflected in our legislation as appropriate, albeit, to a large extent. Recently, the processes of marketing authorisation and the placing on the market of medicinal products were harmonised with EU Directive 2001/83/EC, and the Regulation on Marketing Authorisation of Medicinal Products for Human Use was published in the Official Gazette on 11 December 2021 and entered into force. The amendments to EU legislation introduced by the Proposal are being negotiated by both the European Council and the European Parliament and should be closely monitored for implications for Türkiye.

[1] https://www.efpia.eu/media/gy5j1nkt/efpia-recommendations-on-the-revision-of-the-pharmaceutical-package.pdf
[2] https://www.ab.gov.tr/siteimages/resimler/T%C3%BCrkiye%20Report%202023.pdf

Preventing Price Decreases of Original Pharmaceutical Products with Partial Preliminary Injunctions

Timely and appropriately strategized action is key for owners of pharmaceutical patents wishing to maximise benefits of the rights granted to them. The Turkish Industrial Property Code regulates the exemption of patent rights concerning experimental acts regarding the product subject to the invention, as well as marketing authorisation, and the necessary testing and experiments within its scope. In practice, the Courts occasionally erroneously interpret the wording of the law concerned with the exemption (known as the Bolar Exemption), leading to the permission of applications to the the Social Security Institution (SSI) and even inclusion in the SSI reimbursement list. In such cases, the introduction of the generic pharmaceutical product to the market results in a decrease of 40% of the price of the original product and it is not always possible to reinstitute this decrease in price. Even if the price is reinstituted, the time consuming process results in significant financial loss for the patent holder. Therefore, especially in cases of pharmaceutical patent disputes, applications for preliminary injunction and fair injunctions, is of great importance for the protection of the rights of patent holders.

In 2023, the Civil Court for Intellectual and Industrial Property Rights rendered a most striking decision. It determined that patent infringement was present, and issued a partial preliminary injunction to prevent the patent owner from suffering damages due to the price decrease until an expert report clarifying the situation related to the alleged infringement could be obtained. This is considered an extremely valuable

precedent, especially for cases where highly complex legal, technical and procedural disputes exist simultaneously and several pieces of legislation come into play.

Within the scope of the patent infringement proceedings before the Ankara Civil Court for Intellectual and Industrial Property Rights ("Court"), a patent owner filed a request for discovery of evidence and preliminary injunction against the subject product which had completed all administrative processes necessary for its entry on to the market and which the patent owner argued had infringed their formulation patents.

One of the formulation patents had been approved by the European Patent Office but had yet to be validated by the Turkish Trademark and Patent Office. The patent owner informed the Gx pharmaceutical company of the invention and its scope by letter of notice sent via public notary in accordance with Articles 7 and 8 of the Regulation on Implementing the Convention on the Grant of European Patents in Türkiye and Articles 97(4, 5) of the Industrial Property Code and requested the cessation of the infringing acts. Although the company examined and interpreted the invention and its scope, it did not cease its acts of infringement.

The Court evaluated the request for discovery of evidence and preliminary injunction and deemed the request for discovery of evidence appropriate in the first stage, deciding upon an expert examination of the file. While the parties were waiting for the expert examination and preparation of the expert report, the infringing products were placed on the market. With the introduction of the Gx product to the market, pursuant to the Decision on Pricing of Medicinal Products for Human Use ("Decision"), the price of the reference product would have decreased by 40%. Taking this into consideration, the patent owner immediately purchased the infringing product with invoices and submitted this as evidence to the Court, proving that the infringing product was placed on the market. Subsequently, in the light of the available evidence, a request was submitted for a preliminary injunction to prevent the price decrease of the patented product to be accepted in the first instance by conducting an examination of the case file until the expert report is available, and that other requests for injunctions to prevent the commercialisation of the infringing product be evaluated after the preparation of the expert report.

The Court, taking into account the infringement on one of the patents (the basis of the request for injunction) confirmed by examination of the file and evidence of the presence of the infringing product being on the market, decided that the plausible proof condition was met and issued an interim injunction to prevent the price decrease of the patented product as a result of the request of the patent owner, in return for payment of a guarantee bond by the patent owner.

With this preliminary injunction, the patent owner was prevented from incurring damages due to the decrease in the price as a result of to the infringing product's entry into the market, but the infringing product was allowed to remain in the market until the infringement was established by an expert report. In this framework, a decision was made in accordance with the principle of justice and balance of convenience.

Following implementation of the preliminary injunction granted by the Court, the patent owner filed a case on merits in accordance with Article 397 of the Code of Civil Procedure, which regulates the procedures pursuant to the completion of the preliminary injunction. However, since the Code of Civil Procedure does not regulate partial preliminary injunction, there is no clear guidance in the law for the case at hand where the injunction issued by the court covers only one of the requests for preliminary injunction demanded and where the expert report is awaited for the decision to be rendered for the other requests for injunction. However, in accordance with the legislation, the case file on which a preliminary injunction is granted should be considered an annex to the case filed on merits. The Court applied this provision in line with this case and considered the case file in which the preliminary injunction granted as an annex to the case file on merits, and the expert examination process concerning the other requests for injunction of patent owner continued to be heard within the scope of the case file on merits.

This partial/preliminary injunction decision constitutes an important precedent in that an injunction can be granted in the fairest way possible to prevent the suffering of damages that may occur for both parties, especially in cases where the infringing product is put on the market without waiting for an expert report to be issued concerning the patent infringement.

[1] https://www.efpia.eu/media/gy5j1nkt/efpia-recommendations-on-the-revision-of-the-pharmaceutical-package.pdf
[2] https://www.ab.gov.tr/siteimages/resimler/T%C3%BCrkiye%20Report%202023.pdf

Possible Effects of a Unified Patent Court in Türkiye

The concept of the Unified Patent Court (UPC) entered the lives of European Patent holders with the UPC Agreement, an international agreement dated 19 February 2013. The Unified Patent Court started operating as of 01 June, 2023. The Unified Patent Court constitutes a big and important step towards unity of the judiciary for European Union member states. The Statistics and Trends Centre of the European Patent Office (EPO) reported that 17,788 unitary effect requests were made and 17,249 unitary patents were registered for inclusion in this system until 10 January, 2024.

In this article, the possible effects of this system in Türkiye, party to the European Patent Convention (EPC) but outside the UPC system, will be examined.

As a non-European Union member state that is a party to the EPC, Türkiye is essentially in the same position as Norway and Switzerland in relation to the UPC. Likewise, the post-Brexit UK has joined the list of countries that are EPC parties but not UPC countries. It is not possible to say that the UPC system directly affects these countries. As a matter of fact, just like before the UPC, European and national patent applications will continue to be filed from these countries. In this respect, patent holders in countries that are not member states of the European Union are also able to include their European patents in the UPC system for UPC countries, or if they wish, they can keep their patents within the classical European patent system with the opt-out procedure during the 7-year transition period (this period can be extended for up to a further 7 years), and they benefit from national patent protection in their own countries.

Today, considering the comprehensive jurisprudence database created by the EPO, the UPC, which has just started operation and has announced that it has received 160 cases from day one until the end of December 2023, stands to benefit from the EPO case law until it forms its own established jurisprudence. Likewise, the European intellectual property law circles anticipate that UPC decisions, may impact the EPO case law.

It is worth noting that where patents that are the subject of both the appeal process at the EPO and the revocation action at the UPC, there is no regulation to make the appeal proceedings at the EPO a prejudicial matter or vice versa.

It can safely be said that the Turkish IP courts have started to reach a consensus on deeming opposition and especially appeal processes at the EPO a prejudicial matter before starting the examination phase of the invalidation proceedings against a European patent in Türkiye. In this context, the courts

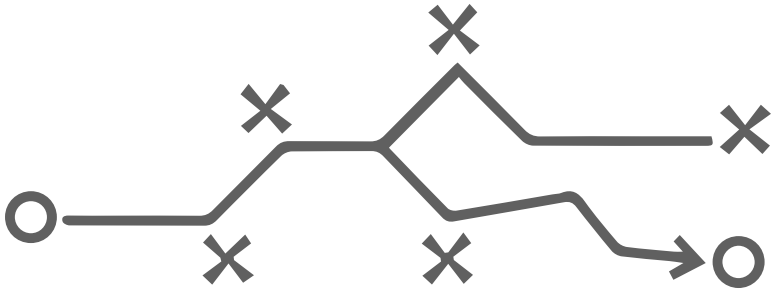
tend to wait for the EPO's decision to avoid unnecessarily burdening the judicial system since a revocation decision that the EPO may render will directly impact the patent validated in Türkiye. So, if the EPO revokes the patent after it is reflected in the registry in Türkiye, the Turkish IP courts decide that the case becomes devoid of essence without further examination. On the other hand, if the EPO decides to maintain the European patent as granted or after amendments or limitations, the local court starts the national examination and then decides on the validity or invalidity of the Turkish part of the patent. As it is seen, the EPO proceedings have great importance for the Turkish judiciary regarding European patents validated in Türkiye.

Despite absent legislation, our view is that the UPC proceedings and EPO evaluations have a high probability of affecting each other, and that the decisions to be made by the UPC regarding the validity of a European patent that is included in the UPC system and has validation in Türkiye may also affect the Turkish proceedings. Thus, considering that the decisions to be made by the UPC are expected to be concluded faster than the EPO process, it is possible to make the following inference: decisions made by the UPC regarding the validity of a European patent included in the UPC system will set a precedent before the EPO, so UPC decisions will now set a precedent in the Turkish proceedings. This situation raises the possibility that Turkish judges may slightly change their prejudicial matter practices.

Namely, when a national invalidation action is filed in Türkiye against a patent pending before the EPO, the local court will most likely decide to wait for the EPO process. If an invalidation action is also brought before the UPC at this time, the UPC decision will most probably be rendered before the EPO decision is made, as the UPC proceedings are expected to be concluded more quickly. A distinction is likely to be made at this point: If the UPC decides to invalidate the patent, we expect the Turkish court to continue waiting for the EPO decision, as it will expect that the EPO will also likely render a revocation decision. However, if the UPC validates the patent, will the Turkish court, expecting the EPO to follow this decision, initiate national proceedings to save time? Or will it continue to wait for the EPO's decision, even though it knows that the patent may be more likely to be validated by the EPO?

The answer to this question will depend on many emergent factors, such as the correlation between EPO decisions and UPC decisions over time, the decision-making speed of the UPC, and the amount of UPC decisions that Turkish courts will face. However, in such a case, one of the parties in invalidation actions may request the withdrawal of this decision to wait for the EPO's decision due to its strategy and its position in the market and this issue will have to be evaluated.

Fending Off Tactical Patent Invalidation Actions



Filing patent invalidation actions for tactical purposes, such as jeopardizing patent infringement actions of patent owners and gaining time by complicating the infringement proceedings, has become a common strategy of infringers in recent years. With this strategy, the parties infringing the patent may cause the patent owner to suffer due to the inability to enforce their patent as they are entitled to during the limited protection period of 20 years, even if the invalidity claims do not have a solid basis and they are filed on a 'try your luck' basis.

In a recent infringement action in Türkiye, the defendant company responded to the action with a very brief defence comprising a couple of paragraphs, stating that it does not infringe the patent and the patent should be invalidated. The defence omitted any grounds or evidence for the invalidation demand. In this sense, the defendant did not concretise their case within the scope of the Article 297 of Code of Civil Procedure.

It has been observed that in many similar cases, intellectual property courts continued to hear cases even when the applicant party did not fulfil the obligation to concretise their demand. Instead, the courts often appointed an expert panel, which should be appointed only to assist the court in the technical aspects of a case, and made the panel perform the concretisation duty that the applicant party is expected to fulfil. Normally, assessing the invalidity without concretising the case and without matching the prior art documents/arguments with the alleged invalidity ground should not be possible.

In the one case, the patent owner, who was faced with a tactical invalidation action, filed a defence focusing on the procedural deficiencies in the counter party's invalidation request, thus ensuring the rejection of the strategic and essentially malicious invalidity action.

The patent owner explained in detail that the fact that the party infringing the patent merely requests patent invalidity does not fulfil its obligation to concretise the invalidation application within the meaning of Article 297 of the Code of Civil Procedure. Subsequently, the patent owner requested the Court decide on the separation of the invalidity case from

the main infringement case and to impose a definite period on the defendant who infringed the patent for the concretisation of the separated invalidity case.

Considering the procedural objections of the patent owner, the court decided to separate the invalidity action from the main infringement action and to impose a definite period of time on the party requesting the invalidity of the patent to concretise their case.

However, the party requesting the invalidity of the patent, purely due to the patent infringement action, did not concretise the invalidation case within the definite period given by the court. Upon this situation, the Court deemed the separated the invalidity case to have not been filed.

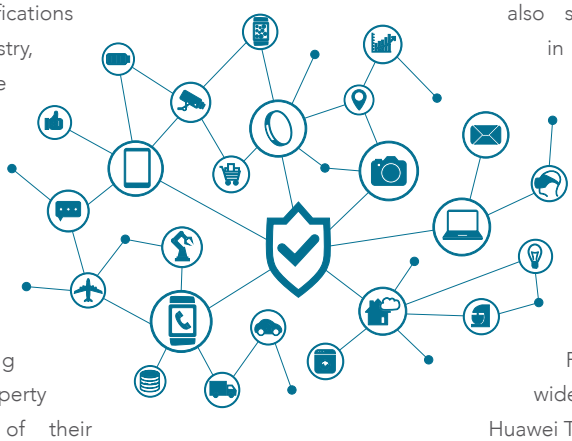
This decision is important and will set a precedent in the prevention of future malicious and tactical invalidation actions that put unnecessary burden of concretising the case on the court and jeopardize the infringement action of the patent right holder without legitimate reason.

SEP: Navigating the Technology-Driven World

Standard-Essential Patents (SEPs) is a concept arising from the interaction between patent rights, which provide exclusive use of an invention and "standards" aimed at the widespread and mandatory use of this innovation in the relevant market. Considering the upward trend in patent litigation arising from SEPs, it would be fair to say that SEP has become patent law's new buzzword.

Licensing SEPs: FRAND Terms

Standard Developing Organisations ("SDOs") determine the technical specifications and standards, including sets of technical specifications in a certain industry, and aim to make these standards accessible to all players in the industry. In this sense, SDOs typically publish their policies regarding intellectual property rights as part of their governing rules.



Among these policies is the identification by SDO members of patents that may be essential to the SDOs' standards. When a member discloses that it has a patent with a potential to become a SEP, it is also asked to declare whether it will agree to license the patent on FRAND ("Fair, Reasonable, Non-Discriminatory") terms and conditions.

The terms of FRAND declarations may vary for different SDOs and may also vary between declarants. In this regard, as their main goal is to increase the number of members and make SEPs available to as many industry players as possible, SDOs do not impose rigid policies regarding intellectual property rights on their members to encourage them to declare a greater number of patents as SEPs, advantaging the SEP holder over the party wishing to implement the standard.

SEP Licensing

The proliferation of SEPs has also seen an increase in the number of related litigations. Although litigants suffer from a lack of detailed and case-by-case laws governing licensing in the FRAND terms, the widely known and cited Huawei Technologies v. ZTE (C-170/13) and Nokia v. Daimler (4c O 17/19), Nokia v. Oppo (21 O 11522/21), and Sisvel Haier (K ZR 35/17) decisions and others from different jurisdictions of Germany can shed light on practice in this area.

Additionally, on 14 February 2022, the European Commission initiated a public consultation process to establish a fair and balanced licensing framework for SEPs, asking

industry stakeholders to provide feedback on policy options for a sustainable, transparent, and predictable SEP licensing ecosystem.

One of the most discussed concepts in SEP is "access to all" and "license to all", which try to answer at which point in the production supply chain to license an SEP. The "access to all" approach allows SEP holders to choose at which level of the production chain to license their patents, which is usually the end-product stage. Accordingly, a license fee is requested per end-product in which the standard is used. However, this concept is criticised by end-product manufacturers as it allows companies at different levels of the value chain to access the standard without paying a license fee. The concept of "licensing for all", which envisages the reflection of the value of a standard on the parts of the end-product and granting FRAND licenses to parts manufacturers (or suppliers at different levels of the supply chain) instead of the end-product manufacturers, emerged due to these criticisms.

Another heated discussion in SEP cases is the interpretation of the "unwilling licensee" concept. The prevailing question is when a company using the SEPs becomes an unwilling licensee. There are many possible answers to this question, such as when the alleged infringer is aware of the SEP but continues to use the standard without a license or when the alleged infringer walks away from the licensing negotiations, although the license terms were FRAND. Within this scope, as a result of the proceedings, the standard implementer may be found to have infringed the patent and responsible for damages.

Finally, one of the most talked about topics of discussion regarding the SEP at present is the anti-suit injunctions imposed by Chinese courts, which prevent SEP proceedings from being brought in other countries. These preliminary injunction decisions prevent SEP holders from filing lawsuits in countries other than China and even prohibit the request for enforcement of injunction decisions ruled in other countries, such as Germany. Following the decisions, the European Union filed a complaint with the World Trade Organization ("WTO") on 18 February 2022, alleging that the practices of the Chinese courts unfairly restrict patent rights and prevent fair trade in violation of TRIPS provisions. Since the consultation process between the parties through the WTO did not yield any results, the dispute was referred to arbitration and the arbitration process is currently ongoing.

Türkiye's Position

As far as is known, Turkish courts have not yet issued a detailed decision on FRAND licenses and/or SEPs. However, on 26 December 2019, the Turkish Competition Authority ("TCA") issued its first decision regarding SEPs in the Vestel v. Koninklijke Philips investigation (19-46/790-344). The Competition Board evaluated Vestel's application by referring to the decisions of the European Union Commission, especially the European Union Commission's Apple v. Motorola (AT.39985) decision and the Samsung (At.39939) decision

and the European Union Court of Justice's Huawei-ZTE decision (C-170/13). However, The Competition Board has applied the FRAND principles by interpreting them more strictly on some points in comparison to the EU jurisprudence above.

In its decision, the Competition Board concluded that Koninklijke Philips N.V abused its dominant position in the relevant TV technology market due to the provisions of the TV Patent License and Settlement Agreement signed by the parties upon a series of SEP litigations and imposed on Koninklijke Philips N.V a penalty of 0.75% of its annual gross income generated by the end of the 2018 fiscal year.

Although the annulment action filed by Koninklijke Philips NV before the administrative court against the decision of the Competition Board was accepted, the Council of State subsequently reversed the decision of the court of first instance.

The Council of State, in the reasoning of its reversal decision, analysed in particular the contractual provisions regarding the non-suitability of the invalidity of the patent as grounds and explained that the SEP user should always be free to file a lawsuit on the validity of the patent. It also stated that the patent owner's attempt to prevent SEP user from challenging validity of a patent would constitute a breach of competition in the context of abuse of dominant position.

Increase in SEP Litigation

It appears that SEP litigations will continue to proliferate in the upcoming years. Although we see that SEP holders mostly prefer German, USA and UK courts to enforce their SEPs due to the reliability and predictability of these jurisdictions, this trend may change in the future as technology companies seek enforcement in jurisdictions used to export infringing products following an expansionary policy with the effect of globalisation and shortage crises.

Given the investments and incentives in different industries and its high market potential, Türkiye may become one of the jurisdictions where SEP cases are heard. While the Competition Board surprisingly examined the specifics of the patent law in its only case law regarding SEPs, we will be keeping a close eye on whether a case will be heard in an IP Court in Türkiye and if the courts will follow the Boards approach in dealing with FRAND terms.

A New Slant on the Implementation of the Bolar Exemption in Turkish Patent Law

The Bolar Exemption falls under the provision of Article 85(3)/(c) of the Industrial Property Code No. 6769 (IP Code) and regulates the marketing authorisation of pharmaceuticals, the testing and experiments required for this purpose and the exemption of experimental acts involving the patent subject to the invention from the scope of rights protected by the patent. The aim of the Bolar Exemption is to ensure that Gx pharmaceutical products can be put on the market without delay when the patent protection period expires, thus preventing the de facto extension of the period of patent protection.

While the wording of the provision in question clearly sets the boundary of the scope of the Bolar Exemption, limiting it to marketing authorisation and the testing and experiments required for this purpose, the provision has been interpreted in a way extending the scope of the provision by the Istanbul, Ankara and Izmir Civil Courts for Intellectual and Industrial Property Rights, as well as before District Courts and Courts of Appeal.

The Civil Courts for Intellectual and Industrial Property Rights interpret the Bolar Exemption too broadly and refuse requests for discovery of evidence on the grounds of the Bolar Exemption, even in cases where the Gx pharmaceutical product has received marketing authorisation, price approval and the product is placed on the reimbursement list of the Social Security Institution ("SSI").

If the Bolar Exemption is applied according to this broad interpretation, there is an extremely limited window of time for patent owners to determine whether there has been an infringement of their patent rights and to exercise their legal rights before the 40% price decrease of the original pharmaceutical as a result of the introduction of the Gx product to the market and the Bolar threshold is deemed to have been exceeded.

Although a case can be filed even after the Gx product has entered the market, it is often not possible to reverse the price decrease and market loss, and even when it is possible, this is quite a time consuming process which results in significant financial loss to the patent owner.

Therefore, the Bolar Exemption should be applied in accordance with the wording and purpose of the relevant article, and to allow for the pharmaceutical patent owner to use the only legal remedy available (i.e. discovery of evidence) for determining whether their patent rights have been infringed. By doing so, patent owners may not be forced to file

lawsuits on merits due to not being able to request discovery of evidence (which cannot be applied due to the broad interpretation of the Bolar Exemption) as a means of determining whether their patent rights have been infringed upon, and the number of lawsuits on merits can be reduced and settlements may instead be reached.

A recent discovery of evidence ruling has raised hopes that the Bolar Exemption will be interpreted in accordance with the clear wording of the legislation, in line with the purpose intended by legislators, and that sound rulings will be rendered.

In the relevant case, the patent owner requested discovery of evidence based on a strong indication of patent infringement upon becoming aware that a Gx pharmaceutical product obtained price approval in addition to marketing authorization, and requested discovery of evidence by an examination of the marketing authorisation file of the product, which cannot be done without a court order.

Upon the examination of the request, the Ankara Civil Court of Intellectual and Industrial Rights concluded that the patent owner had a legal interest in accordance with Articles 400 (et seq.) of the Code of Civil Procedure No. 6100 and deemed it obligatory to for the immediate protection of its rights and ruled to accept the request for discovery of evidence in accordance with the law. Subsequently, an examination was carried out with the participation of the party attorneys and experts regarding the relevant sections of the marketing authorisation files of the Gx pharmaceutical product before the Turkish Medicines and Medical Devices Agency. As a result of this examination, the patent owner was able to assess whether there was an infringement and determined that the counterparty's products did not infringe their patent rights, preventing unnecessary disputes.

This ruling, which was rendered in accordance with the law and the balance of interests of the parties, has strengthened the opinion that a fairer system can be adopted regarding the discovery of evidence. No doubt, applying of the wording of the law and foreseen purpose will ensure that justice is rendered in accordance with the law and will thus be to the advantage of all parties.

The First of its Kind: Compensation for Damages Caused by Unfair Preliminary Injunction Decisions in the Pharmaceutical Industry

One must have deep knowledge and experience in many different disciplines to play a role in the solution of complex and multi-layered patent law disputes. One of the most important examples of this situation are compensation actions filed following the abolition of preliminary injunctions in patent disputes related to the pharmaceutical industry. As a matter of fact, the decisions of the courts of first instance and the Court of Appeal in these types of cases give direction to deep debates both in sectoral, commercial and legal terms, and it is observed that these discussions gain more importance with each new decision.

In 2018, the first known decision of a court of first instance on a compensation action for the damages arising from unfair preliminary injunction in the pharmaceutical sector, and upon the appeal of this decision, the first district court decision was also given in 2022, establishing the first precedents of different degrees in this field.

The events giving rise to the action can be summarised as follows: The patent owner companies requested a preliminary injunction decision to be granted due to the imminent danger of infringement of the patent by a local pharmaceutical company's generic product (the Gx product). The court granted the preliminary injunction and decided to suspend the manufacture of the Gx products depending on the outcome of a court appointed expert panel's report. The patent owner then filed the infringement action on merits and the preliminary injunction was maintained throughout the proceedings. Finally, the infringement action on merits was rejected and the decision became final following the appeal process. The Gx Company then filed an action claiming compensation for damages, alleging that it incurred a loss of profit for not being able to manufacture the Gx products due to the unfair preliminary injunction.

The court of first instance, firstly, ruled that in order to be held liable for compensation of damages incurred due to the preliminary injunction decision, it is sufficient that the main action (infringement case in this example) is rejected and that there is no need to investigate whether the patent owner is faulty as per the related article of the Turkish Civil Procedural Law. Secondly, while calculating the loss of the Gx company, the court decided that the Gx product, which was the first Gx to enter into the market and was blocked by the preliminary injunction decision, would have had a market share of 16%, taking into account the market conditions at the date of the preliminary injunction decision, the legal

regulations on the market at that time, the reputation and reliability of the Gx company and the pharmaceutical era in which the product would have entered the market for the first time.

Nevertheless, the court ignored the very important issue that the mandatory discount rates were to be made on the initial price of the Gx product as per the relates regulation, despite all the objections of the patent owner. However, the alleged financial loss cannot be calculated assuming that generic products will be sold at the highest price approved by the Ministry of Health. Therefore, a higher-than-actual loss amount was calculated, as the mandatory discount rate was overlooked.

Both parties appealed the decision of the first-instance court. In 2022, and the District Court decision found all the above-mentioned inferences of the first-instance court correct.
Shortly after the District Court's decision, another first-instance decision was rendered on the compensation of damages due to unfair preliminary injunction. Although the new precedent estimating that the first Gx Company will achieve a maximum market share of 16% was shared with the court of first instance, it ignored the case-law and decided that the Gx firm would gain a 33.86% market share and made the compensation calculation accordingly. Thus, despite the availability of prior jurisprudence based on the sound assessment that a cancer drug Gx will gain 16% market share and the District Court's approval of this assessment, it was decided that a generic osteoporosis drug would reach a market share of 33.86%. However, considering that the average prices of an osteoporosis drug and a cancer drug are quite different, we are of the opinion that the second decision of the court of first instance, departing from the prior decision, was not correct.

It is worth noting that there are two points common in the decisions of the Courts: both courts considered the obligation to compensate for the damage caused by the preliminary injunction decision as a strict liability and both courts disregarded the mandatory discount rates that must be applied based on the initial price of Gx products.

Under these circumstances, it is clear that Türkiye needs many years to adopt uniform jurisprudence on this issue. Undoubtedly, the biggest role in the formation of this case-law fall to the guidance and evaluation of conscious lawyers who have a good command of different legal disciplines and the sectoral dynamics of their clients and competent experts.

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Firm Overview

We are one of the oldest and largest law firms in Turkey and are considered internationally to be among the top-tier of legal services providers.

We are a full-service law firm leading the intellectual property field among others, providing dispute management, advisory, transactional, prosecution, investigation, and regulatory markets law services to domestic and multinational corporations.

We are based in Istanbul, with working and correspondent offices in Ankara, Izmir and the major commercial centres in Turkey.

We operate mainly in Turkish and English and also work fluently in German and French.

We advise a large portfolio of clients in numerous fields of activity including life sciences, insurance and reinsurance, energy, construction & real estate, logistics, technology, media and telecoms, automotive, FMCG, chemicals and the defense industries.

Our vision is to be the leader in the services we provide, sensitive to wider society, the environment, and our employees as an innovative and sustainable institution.

Our clients' success is at the heart of our own success. We closely monitor developments in the business sectors in which our clients operate and invest in accumulating industry specific knowledge to understand their changing needs. We actively participate in professional, trade and business organisations in Turkey and internationally.

We are committed to adapt to our clients' changing business needs by delivering innovative, high quality and commercially prudent legal solutions.

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