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PATENT LAW IN TÜRKİYE
KEY DEVELOPMENTS AND PREDICTIONS

2025

Patents and Utility Models

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

In addition to prosecution of national and international patent applications, we file and defend oppositions and appeals before the Turkish Patent and Trademark Office ("Office"), as well as challenging the Office's final decisions before 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.

Introduction

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

The discussions around AI and inventorship heralds a new era for intellectual property, challenging traditional boundaries and prompting a re-evaluation of legal frameworks both in Türkiye 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 such as partial preliminary injunctions is particularly poignant, reflecting a proactive approach to navigating competitive markets.

The European Union (EU) pharmaceutical legislative reforms specifically address the Bolar issue and seeks to expand the scope of the "Bolar Exemption". However, it is crucial to ensure that this expansion remains consistent with the law and also the interests of all involved parties. In Turkish legal practice, challenges have arisen due to courts interpreting the Bolar Exemption broader than the provision's intended scope, creating difficulties for patent owners. Despite these challenges, recent optimism has emerged from a court decision that aligns with the law and balances the interests of both parties. This decision of the Turkish Courts 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 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 further illustrates the nuanced interplay between innovation promotion and intellectual property protection. These 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 wider 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, characterised by a dynamic interplay between legal innovation, regulatory adaptation, and strategic litigation. For 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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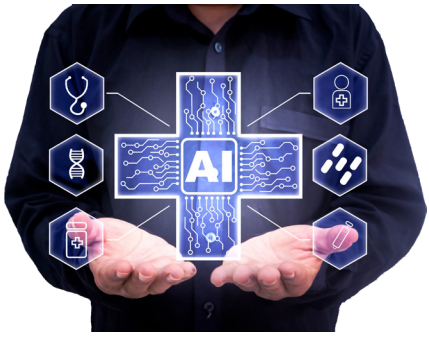
Artificial Intelligence and Pharmaceutical Industry: The Transformation in the Technology and Patent System Shaping the Future

Artificial intelligence influences every aspect of our lives and has revolutionary impact in the pharmaceutical industry, as well as in many other sectors. From DeepMind's AlphaGo success to Tempus' personalised approaches to cancer treatment, AI-enabled innovations offer, not only scientific achievements, but also wide-ranging advantages such as operational efficiency, cost reduction and risk mitigation. However, this technological leap also raises critical questions about the traditional processes of the pharmaceutical industry and the patent system.



According to data from the Tufts Center for the Study of Drug Development, it takes approximately 10 years for a pharmaceutical product to be developed and put on the market, and the cost is $2.558 billion. Clinical trials account for the majority of this cost, while the success rate is below 10%. These challenges drive the pharmaceutical industry to look for more sustainable and rapid solutions.

The discovery of new compounds and molecular design that takes months with traditional methods can be reduced to weeks thanks to artificial intelligence algorithms; clinical trial processes are completed 20% faster and at a lower cost. For example, BenevolentAI has demonstrated this potential by leveraging artificial intelligence platforms in the rapid discovery of a drug such as Baricitinib in the treatment of COVID-19.

It should be emphasised that the contributions of artificial intelligence to the pharmaceutical industry are not limited only to cost and time efficiency; artificial intelligence also provides a great transformation in areas such as customisation of treatment process, detection of side effects and analysis of patient data. IBM Healthcare's use of artificial intelligence in clinical trial matching is a good example of this.

Increased use of artificial intelligence in the pharmaceutical industry also raises new discussions in terms of patent protection and legal grounds. Although the Turkish Industrial Property Code No. 6769 ("IP Code") stipulates that computer programs are not patentable,

there is no regulation in the IP Code on how artificial intelligence-supported inventions will be evaluated in this context.

On the other hand, since Türkiye has been a party to the European Patent Convention since 2000, the European Patent Office's position on the patentability of artificial intelligence-supported pharmaceutical inventions has been binding for Türkiye. As a condition of its accession to the Convention, Türkiye accepts and undertakes that European patents granted by the European Patent Office shall be deemed to have the same legal effect as national patents registered in Türkiye.

The European Patent Office adheres to conventional criteria when evaluating the patentability of artificial intelligence-supported inventions. For example, using the Problem-Solution approach, it is evaluated whether or not an artificial intelligence created invention is obvious to those skilled in the art. However, whether the problem-solution approach can always be applied in patentability of inventions in regard to artificial intelligence and artificial intelligence-supported pharmaceutical development processes is subject to controversy.

Artificial intelligence has taken on a ground breaking role in the pharmaceutical industry in terms of cost, speed and efficiency. However, this transformation requires a reinterpretation of the traditional patent system and a clearer drawing of the ethical and legal boundaries of technology. The pharmaceutical industry's ability to ensure human expertise remains at the centre while embracing the advantages offered by artificial intelligence will be the key to future success. An industry that can achieve this balance will not only be able to offer more effective treatments for patients, but shall also develop sustainable solutions for the global healthcare system.

Applying Presumption of Patent Infringement Against Biosimilars

Before filing actions to assert patent rights against generics or biosimilars, the patent holder essentially operates in the dark. This is because, particularly in cases where the summary of product characteristics ("SmPC") of the biosimilar/generic drug has not yet been published, or when it is not clear from the limited information in the SmPC whether the patent has been infringed. The relevant sections of the biosimilar/generic product's dossier must be examined to assess whether the patent has been infringed, which can only be done through a court order. The most important factor in persuading the court that such an examination is necessary and reasonable is the strong likelihood of patent infringement, in other words, the presumption of patent infringement.

According to the relevant provisions of the Licensing Regulation, it is possible for a generic product to obtain a marketing authorisation ("MA") by referencing the dossier of an original product whose data exclusivity period has expired and by claiming (and proving) that it is fundamentally similar to the reference product. Essentially, the presumption of infringement mentioned above arises precisely from this condition. In cases where the formulation, manufacturing process, indications, and similar characteristics of the original product are protected by patent(s), a generic product that claims and proves to be fundamentally similar to the original product in all these respects is also considered highly likely to infringe the patent(s). Based on this assumption, courts are inclined to examine and evaluate the relevant parts of the generic product's dossier through an expert panel to determine whether the patent holder's rights are potentially being infringed.

Given that the basis of the presumption of infringement, which is accepted in the context of generic products, lies in the fundamental similarity between the generic product and

the original product, the question arises whether such a presumption of infringement can be applied to biosimilar products, and if so, on what grounds.

Indeed, the market for biosimilar products is rapidly growing in Türkiye, as it is worldwide, and the risk of patent infringement on biological products is increasing.

In the Guideline on Biosimilar Medicinal Products ("the Guideline") which is a reflection of the "EU Guideline on Similar Biological Medicinal Products" in the European Union (EU) and essentially contains very similar provisions, a biosimilar medicinal product is defined as "a human medicinal product that shows a high level of similarity to a licensed biological reference medicinal product." It can be seen that the regulating body has raised the bar of being fundamentally similar for generic products to being highly similar for biosimilar products. Additionally, the Guideline mandates that the active substance of a biosimilar medicinal product must be highly similar to the active substance of the biological reference medicinal product on a molecular and biological basis.

In terms of dosage and route of administration, the Guideline requires that the biosimilar product must have the same dosage and route of administration as the biological reference medicinal product. Moreover, the pharmaceutical form, formulation, excipients, or presentation of the pharmaceutical form of the biosimilar medicinal product is expected, in principle, to be the same as that of the biological reference medicinal product. However, if this expectation is not met and there are some differences, the biosimilar medicinal product is expected to justify these differences with additional data, considering that variations in these areas may pose potential safety risks.

When all considered together, if the innovative elements related to the active substance, dosage, route of administration, pharmaceutical form, formulation, and presentation of the pharmaceutical form etc. of the biological reference medicinal product are protected by patents, it can be argued that a biosimilar product that claims and proves to be highly similar to the biological reference medicinal product for the purpose of obtaining a marketing authorisation, is highly likely to infringe these patents. In other words, there exists a presumption of patent infringement.

There is no doubt that some defence strategies commonly used in patent disputes between generic and original products will also be employed by biosimilar medicinal product manufacturers. The most commonly used and well-known of these strategies is the carve-out of patented features, such as dosage regimen and indications, from the SmPC of the biosimilar medicinal product.

Indeed, according to the official website of the European Medicines Agency (EMA), for marketing authorisation applications for biosimilar drugs, information directly related to the patented indication can be deleted from sections 4.1. therapeutic indications, 4.2. posology and method administration and 5.1. pharmacodynamic properties of the SmPC.

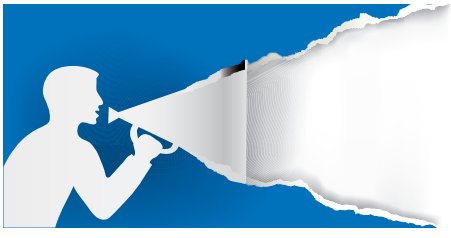
Although the Guideline or the Turkish Medicines and Medical Devices Agency ("Agency") has not addressed this issue with as explicit as that of the EMA, it is known that, according to practice over many years, generic products obtained marketing authorisation through abridged MA applications are permitted to omit information related to patented indications, dosage regimens, pharmaceutical forms, and similar aspects of the original product from the SmPC. It is clear that Agency's practice will also apply to biosimilar products.

However, another important point to note for the Turkish market is whether, from the perspective of the courts, the carve-out of patented indications, dosage regimens, and similar information from the SmPC alone is sufficient to eliminate the possibility of patent infringement or the presumption of patent infringement.

Just as the patent holder of the original product, the patent holder of the biological reference medicinal product can also present evidence demonstrating that the biosimilar product inevitably uses patented features, even if these features are carved-out from the SmPC, and demonstrate the presumption of infringement and prevent the biosimilar product from the market.

Although there have been no cases in Türkiye yet where patents for biological reference medicinal products have been enforced through the courts to remove biosimilar products from the market, it is clear that with the expiration of protection periods for relevant patents and considering the billion-dollar market share of biological/biosimilar products, patent disputes between biological reference products and biosimilars are likely to begin soon and will be quite intense. However, the advantage will depend not only on the "creative" solutions of the parties but also on what the regulatory authorities expect regarding safety and efficacy criteria, and, of course, the perspectives of the courts.

Jurisdictional Conflicts in Global FRAND Cases and the EU's WTO Complaint against China for Alleged Violation of TRIPs



Anti-suit injunctions ("ASI") issued by Chinese courts, which prevent parties of proceedings concerning standard-essential patents ("SEPs") from bringing proceedings against each other in different countries, have made the "jurisdiction of the court" a controversial issue.

As is known, in the case of SEPs, the first issue that confronts the patent holder and the company implementing the SEP is whether a licence has been requested, offered and/or granted on Fair, Reasonable and Non-Discriminatory terms ("FRAND") and how the licence fee should be determined. The court tasked with resolving such a dispute limited to the country in which it is located and the patents applicable in that country is often dealing with multinational companies with worldwide operations and a worldwide interest in the determination of FRAND terms and the licence fee. In such cases, the common view of the courts in Europe and the United States of America (USA) is that, since FRAND disputes are essentially contractual disputes, a global rate for the entire patent portfolio licensed under the contract can be determined by a single court.

In fact, in 2017, in the Unwired Planet v Huawei case, the UK Supreme Court held that it had jurisdiction to determine the terms of a global FRAND license agreement between the parties, covering not only the SEP holder's UK patents but also foreign patents valid in other countries covered by FRAND commitments. Similar decisions continue to be issued by US courts.

In such disputes, while a dispute regarding the license under FRAND terms is pending before a court in one country, the patent holder may file an infringement action in another country claiming infringement of the same patents, and while the parties have not yet resolved the license fee on FRAND terms, a preliminary injunction grounding on patent infringement may be granted by a court in another country. Thus, the notion that the court of a particular country determines the terms of a license that will be globally applicable to the parties has led to ASIs which prevents the patent owner from filing an action in foreign countries or enforcing the preliminary injunctions granted by foreign courts in favour of the patent holder.

The first ASI decision concerning the determination of a licence fee on FRAND terms was rendered by the US District Court for the State of Washington in the Microsoft v Motorola case. In the case, Microsoft alleged that Motorola breached its commitment to offer Microsoft a licence on FRAND terms. While this case was pending, Motorola filed a patent infringement action against Microsoft in Germany. The German court upheld the patent infringement claim and enjoined Microsoft from selling the infringing products in Germany. In response to the decision, Microsoft applied to the US court just prior to enforcement of the judgement and sought an ASI decision to prevent Motorola from enforcing the decision. The US court ruled a decision to prevent Motorola from filing an action that would prevent it from enforcing the court decision obtained against Microsoft in Germany for patent infringement. The issue to be considered here is thus: ASI decisions of an "in personam" judgement bind the parties, not the courts. In the above example, the US court has issued an injunction that binds Motorola and has the power to impose sanctions on it within the authorisation and jurisdiction of the USA in case of non-compliance.

ASI's, which was frequently used by European and US courts until recently, was also applied by Chinese courts in 2020 and caused a great controversy.

In the patent infringement action brought by Conversant against Huawei and ZTE before the German courts, the German court found that Huawei and ZTE had infringed Conversant's SEPs and issued preliminary injunctions to remove the infringing products from the German market. In the meantime, however, Huawei and ZTE applied to the Supreme People's Court of China to prevent Coversant from enforcing injunctions obtained and succeeded in obtaining a judgement preventing Conversant from filing an action against Huawei and ZTE regarding its SEPs and from enforcing the injunctions.

Following this decision of preliminary injunction, Chinese courts continued to issue preliminary injunctions "to prevent litigation" within the scope of the Xiaomi v InterDigital, Oppo v Sharp and Samsung v Ericsson case files, preventing SEP holders from filing actions in foreign countries or enforcing preliminary injunction decisions issued by foreign courts. Following these developments, the European Union (EU) sent an official request for information to China, about the injunctions granted by Chinese Courts in the Xiaomi v InterDigital, ZTE v Conversant, OPPO v Sharp v Samsung v Ericsson cases and the legal basis for blocking the implementation of court decisions rendered in Europe, pursuant to Article 63.3 of the TRIPS Agreement, which regulates the obligation of member states to provide information in response to the written request of another member country that believes that a court decision or administrative decision in the field of intellectual and industrial property

rights or a bilateral agreement affects its rights under TRIPs.

The Chinese government stated that it was not obliged to respond to the EU's request for information under the TRIPs Agreement. Afterwards, the EU filed a request for consultation with the World Trade Organization ("WTO"), claiming that the practices of Chinese courts unfairly restrict patent rights and impede fair trade in violation of TRIPs provisions.

When the petition submitted by the EU to the WTO is examined, the fundamental problems of the conflict are determined as: the duration of ASI decisions issued by Chinese courts is subject to daily fines; the ban decision is valid worldwide; the Supreme Court of China has stated that it has the authority to determine a global license fee for a SEP subject to the action and that the ASI decisions were necessary to prevent license fees that would be too high for the Chinese; and finally, Chinese courts have recently been issuing such decisions systematically.

Although the EU may be criticized for complaining about the practice of Chinese courts considering that ASI decisions are also made in EU countries, it is seen that the ASI decisions issued by European and US courts are limited with a term which is necessary for the relevant European or US court to resolve the case and that these decisions have a nature that prevents a parallel case in a certain country in order not to render the solution of the FRAND case before European or US court meaningless and, most importantly, extremely high daily fines are not imposed as a sanction for non-compliance with the final decision.

In conclusion, considering that the evaluation to be made by the delegation will serve as a guide for all TRIPs countries on how ASI decisions should be approached, especially within the framework of TRIPs principles, the decision of the delegation is being closely monitored.

Implementation of Discovery of Evidence in Patent Law

One of the most important temporary protection measures regulated by Turkish law is the determination of evidence. The implementation of determination of evidence, which is regulated in Articles 400 et seq. of the Turkish Code of Civil Procedure No. 6100 ("CCP") and is subject to simple legal procedure, may be requested for the purpose of making a discovery, obtaining an expert examination or taking witness statements in order to determine facts that have yet to be examined in a pending action or that may be raised in a future action.

The most important condition for requesting the determination of evidence is the existence of legal interest. Pursuant to Article 400 of the CCP, legal interest is deemed to exist if it is likely that the evidence will be lost or significantly difficult to present if it is not immediately identified.

As can be understood from the provision of the law concerning the determination of evidence, the purpose of the article is essentially to ensure that the evidence is secured before the action on merits is filed. If the nature of the dispute requires, the evidence obtained within the scope of determination may be examined by an expert appointed by the judge. The examination report to be prepared by experts may also be considered as important evidence for the main action.

Especially in cases where it is imperative for the effective and timely protection of the rights of the claimant, for example where there may be a risk of elimination of evidence by the natural or legal person against whom the evidence is to be collected if they become aware of determination of evidence, it is also possible for the judge to rule for ex parte determination of evidence, so that the determination of probable evidence can be conducted securely.

Determination of evidence, as in many areas of law, is a tool of crucial significance in patent law in terms of determining evidence that will impact upon the chance of success in action on merits. During the period of patent protection, which is granted to patent right holders for a limited period of time, the determination of the evidence of infringing activities at the right time and in the correct manner plays a decisive role in the determination of patent infringement and compensation cases to be filed, and especially for the actions to be filed after the acts of infringement have ceased.

For example, in pharmaceutical patents, the determination of whether generic pharmaceutical

products suspected of infringing patents protecting the original product are indeed covered by the patent rights before filing the main action can only be made through the determination of evidence. However, the marketing authorisation dossiers of the generic products comprising aspects of the patent before the Turkish Medicines and Medical Devices Agency ("Agency") are confidential and can only be accessed as a result of a Court decision.

In addition, the practice of determination of evidence plays a significant role in the protection of patent rights of innovative companies that have a patent portfolio and carry out R&D activities in telecommunications, electrical appliances, chemistry, the automotive sector and a variety of other sectors.

As patent rights are protected for a limited period of time, in cases where the patent right holder is aware of infringing acts shortly before the expiry of the patent protection period or in cases where the infringement is not continuous, it is only possible to determine whether there was infringement during the patent protection period, or if the products produced or the processes used infringe the patent rights by means of determination of evidence.

Hence, in regard to requests for the determination of evidence based on patent rights, which generally require a technical examination, it should be emphasised that it is essential to submit the necessary requests to the competent courts for the appropriate preservation and testing of the evidence in order to conduct a sound examination.

On the other hand, determination of evidence comprises a number of difficulties. The party against whom the evidence will be determined may try to prevent the officials from fulfilling their duty to determine evidence, and may display a resistance to the judge, attorneys of the plaintiff or experts so that the products or processes subject to the determination cannot be carried out. In such cases, it is crucial that the judges and attorneys take all necessary measures to achieve the purpose of determination of evidence and, if necessary, rely on the services of law enforcement agencies.

A recent decision for ex parte determination of evidence has enabled an innovator company, which became aware of patent infringement one month before the expiry of the patent protection period, to seize the infringing products in the production facility of the company against which the determination was made while the patent protection period was still in force, for reasons concerning a future damages action. Within the scope of this file, it was ensured that experts could collect evidence and information regarding infringing acts by taking into account the nature of the evidence, carrying out the necessary analyses and considering the storage conditions of the products.

This decision is an example of the importance of prompt and fair assessment by the judges of the civil courts for intellectual and industrial property rights regarding the interests of the related patent holders who file requests for the ex parte determination of evidence.

What Will be The Fate of The Guarantee Provided For The Preliminary Injunction Decision?

The Turkish Code of Civil Procedure No. 6100 ("CCP") regulates the granting of a preliminary injunction in return of a guarantee. However, the focus of this study is on the fate of the guarantee provided for a preliminary injunction in the event that a compensation action is filed after the finalisation of the action in which guarantee is given. Yet there is neither a specific provision in the CCP on this issue, nor a concrete, established practice on how this important issue is resolved in practice.

Pursuant to Article 392 of the CCP, the court, which renders the decision to accept or decline a request for preliminary injunction, may award a guarantee by considering the possibility that the requesting party may be unjustified at the end of the action and the possible damages to be incurred by the counterparty and third parties. Again, according to Article 87 with reference to Article 395 of the CCP, in the event of a change in the circumstances and conditions requiring the guarantee, the judge may decide to reduce, increase, change or remove the guarantee. The CCP also partially regulates when the guarantee amount deposited for a preliminary injunction shall be returned. According to Article 392(2) of the CCP, "the guarantee shall be returned upon non-filing of a compensation action within one month following the finalisation of the judgment on the main action or the removal of the preliminary injunction". Therefore, if there is a compensation action filed within the time limit, the guarantee shall not be returned.

Pursuant to Article 399(2) of the CCP, the competent court for the compensation case arising from an unfair preliminary injunction is the court that decides on the preliminary injunction. The legislator has introduced this provision considering that the court that first decided on the preliminary injunction and then rendered the judgment on the merits can best adjudicate the compensation action. The fact that the court deciding the action on the merits and the court deciding the compensation action are the same court is based on the fact that there is an organic connection between these two cases.

However, the legislator who established this connection, has not made any comment with respect to the assignment of the guarantee provided for the preliminary injunction in the main action to the compensation action. Therefore, the fate of the guarantee in the main case, which remains in the finalised and closed file.

Although there are opinions in the doctrine that in case the party in whose favour the unfair preliminary injunction is decided is obliged to pay compensation to the plaintiff as a result of the compensation action arising from the unfair preliminary injunction, the plaintiff will first receive this compensation from the guarantee paid by the defendant for the execution of the preliminary injunction, it is not clear how this connection will be established in practice.

If the court decides to accept the damages action arising from an unfair preliminary injunction, the plaintiff will be able to enforce the judgment through judicial enforcement. According to the procedure specified in Article 36 of the Execution and Bankruptcy Code, it is possible to stop the execution of the court decision that is subject to enforcement proceedings before it is finalised, if the decision is appealed. In this case, the defendant will be required to deposit a guarantee for the stay of execution in order to stop the execution of the decision when it is appealed. In other words, the defendant, must deposit the amount of the debt as guarantee.

In practice, the enforcement offices determine the amount of guarantee by calculating the outstanding debt of the file for 3 months later (the amount of debt and 3-month interest amount). Therefore, the party in favour of whom an injunction has been decided, who has already provided guarantee in order to pay the same possible debt in the main case, is faced with the obligation to provide guarantee once again for the same debt. This guarantee amount includes the debt, as well as the interest amount. On the other hand, the guarantee provided for the preliminary injunction continues to remain in another finalised file of the same court. In other words, the original file in which the guarantee was provided is not considered as an "accessory" of the ongoing compensation file.

In this case, the guarantee provided to ensure the possible damages of the defendant and third parties that may arise from the preliminary injunction and the even larger amount of guarantee provided for the second time in order to stop the execution of the decision given in the compensation action inevitably results in an unfair situation.

The fact that the guarantee provided in the main action in which the preliminary injunction was granted and the guarantee filed in the compensation action remain in the file for a long time to ensure the same possible damage, will lead to a result that is not in line with the purpose of the law, such as the right to property in the first place, as well as the almost punitive nature of the preliminary injunction.

On the other hand, in this process, the problem arises as to which the court will evaluate and decide on the requests such as reducing the amount or changing the type of guarantee provided pursuant to the

preliminary injunction. This is because, in the event that the main case involving the guarantee is finalised, the requests regarding the guarantee may be rejected on this ground since the file is closed. Can the judge of the compensation action adjudicate the claims regarding the guarantee?

In our opinion, considering the intense cause-and-effect relationship between the action in which the guarantee is filed and the compensation action, the claims regarding the guarantee should be adjudicated by the court that hears the compensation claims.

In summary, the claims and problems within the scope of the guarantee between the compensation action filed based on the unfair preliminary injunction and the main file containing the preliminary injunction granted in return of a guarantee, the competent court, and the fate of the guarantee during the execution phase, and to point out the points that are expected to be resolved.

Does the "Long-Arm" of the UPC Reach Türkiye?

After long years of deliberation, the Agreement establishing the Unified Patent Court ("Agreement") was accepted on majority of the European Union (EU) member states in 2013 and entered into force on 01 June 2023.

The Unified Patent Court (UPC) was envisaged as a common court for member states party to the Agreement. And thus, the UPC became part of the judicial system of the member states party to the Agreement and was authorised to resolve disputes concerning European Patents with unitary effect and European Patents granted by the European Patent Office (EPO).

As the scope of the jurisdiction of the UPC shall include European Patents granted by the EPO, the question arises whether countries that are party to the European Patent Convention ("EPC") but cannot be a party to the Agreement are affected by the decisions of the UPC concerning European Patents.

Although the UPC shall be a competent court for resolution of disputes related to European Patents, it would not be contrary to the logic of law to discern that the countries party to the EPC but not to the Agreement should be excluded from the proceedings of the Court. A decision of the UPC on the infringement or invalidity of a European Patent will not be binding before the Turkish courts or the Türkiye in accordance with the principle of territoriality of the jurisdiction of the courts.

However, in the case of European Patents, one of the patents falling within the jurisdiction of the UPC, the EU did not want the Court to limit its jurisdiction solely to the countries party to the Agreement, arguing that as the patent in question is a European Patent, then the jurisdiction of the UPC should be able to extend to all countries in which a particular European Patent is valid, even if the country is not a party to the Agreement.

Since the UPC, as a common court for the Member States party to the Agreement, is not subject to Regulation (EU) No. 1215/2012 of the European Parliament and of the Council on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (known in short as "Brussels IA"), the Brussels IA Regulation was amended by Regulation (EU) No. 542/2014 of the European Parliament and of the Council of 15 May 2014 ("Brussels IB") and with such amendments, it was integrated into the EU judicial system.

Through the Brussels IB amendment, the jurisdiction of the common court has been

regulated and it has been stated that where the courts of a Member State party to the Agreement would have jurisdiction in a matter regulated by the Agreement, the common court would also have jurisdiction. Hence, it has become clear that the UPC shall be a competent court in all cases where the national courts of the EU Member States party to the Agreement are competent in matters regulated by the Agreement.

The Article 71b, paragraph (3) of the Brussels IB Regulation, granted the UPC jurisdiction over defendants who are not domiciled in an EU state in respect of acts of patent infringement occurring in countries that cannot become parties to the Agreement because they are not members of the EU, by granting the UPC "property-based subsidiary international jurisdiction" if certain conditions are met.

Before amendments of Brussels IB 71b(3) were finalised, an example of a "Turkish defendant" was specifically discussed during the travaux preparatoires on Art. 71b (3) Brussels IB for the proposed amendment, "For instance, with respect to the Unified Patent Court, the asset-based jurisdiction would ensure that the Court would have jurisdiction vis-à- vis a Turkish defendant infringing a European patent covering several Member States and Türkiye."

This example states that the purpose of the provision is to allow the UPC to award damages against a defendant for infringing a European patent, even if the defendant is domiciled in a country that is a party to the EPC but not a party to the Agreement establishing the UPC.

Although not explicitly clear in the provision, by the nature of the proceedings, the UPC must first conduct an infringement trial and establish the existence of the infringement before exercising the jurisdiction conferred under Article 71b(3) to award damages.

Article 71b(3) of the Brussels IB Regulation, which does not require or condition its application on an infringement ruling by the competent courts of a non-EU state, in fact grants the UPC the authority to determine the existence of an act of infringement of a European patent occurring in a non-EU state. It also allows the UPC to award compensation for damages incurred by the patent holder within or outside the EU as a result of such an act.

As noted above, the UPC is a common court for the European Union. However, for a non-EU state such as Türkiye, no such transfer of authority exists. Nevertheless, with the regulation introduced by Article 71b(3) of the Brussels IB Regulation, it has become possible for a Turkish defendant, who is not domiciled within the EU, to be held liable for damages by the UPC. The extent to which this person can exercise their right of defence in the context of the UPC proceedings is left unclear. In the European Commission's proposal explaining the necessity of the

regulation introduced by Article 71b(3) of the Brussels IB Regulation, it was stated that the provision serves to "balance" the situation arising when a defendant in a European patent infringement case is not located within the EU. However, how this balance would be ensured in the case of a Turkish defendant, as illustrated by the example presented during the travaux preparatoires was not discussed. Since Turkish citizens were specifically mentioned during the travaux preparatoires regarding Article 71b(3) of the Brussels IB Regulation, it is likely that defendants will seek certain countermeasures before Turkish courts. One such measure that comes to mind is the anti-suit injunction ("ASI"), which has gained significant popularity in recent years.

Although Turkish courts have not yet issued an ASI, in principle, it is possible to issue such a measure based on the general provisions governing interim injunctions. A Turkish defendant facing the long-arm jurisdiction of the UPC may file an action before Turkish courts and request a preliminary injunction to prevent the party alleging patent infringement from filing an action before the UPC or, if an action has already been filed, to prevent them from seeking interim or similar measures in that case.

The Regional Administrative Court's Decision On Trade Secrets And The Administration's Responsibility Against Unfair Competition

Protecting patent rights in a timely manner is crucial for original pharmaceutical product manufacturers, particularly in being informed of potential infringements before an infringing product enters the market.

However, information requests submitted by legal representatives of original drug marketing authorisation (MA) holders regarding the authorisation files of generic companies—who seek approval through an abridged application referencing the original pharmaceuticals—are consistently denied by the Turkish Medicines and Medical Devices Agency ("Agency") on the grounds that such applications may contain trade secrets.

In 2007, a landmark decision of the Council of State ruled that attorneys representing original authorisation holders must be granted access to information regarding generic applications referencing original authorisations. The court specifically referenced the Attorneyship Law, emphasising that legal representatives require access to critical data—including the applicant's identity, product name, application date, and status of the generic applications—to provide adequate legal services to their clients.

In accordance with this decision, the Agency responded to information requests from attorneys regarding generic applications until 2019. However, from that year onward, the Agency ceased responding, citing publicly available lists of active substances and authorised products as sufficient sources for obtaining the requested information.

As the 2007 Council of State ruling accurately emphasised, in order for a lawyer to effectively represent their client, they must have access to critical information regarding a generic license application, even at the application stage. This includes details such as the identity of the applicant, the product name, the application date, and the current status of the application. However, the active substance list and licensed product list referenced by the Agency do not provide the essential information needed by the lawyer to deliver comprehensive legal services to their client.

Consequently, the matter was once again brought before the judiciary in 2019, resulting in an action before the 23rd Administrative Court of Ankara seeking annulment of the Agency's refusal to provide information. During the proceedings, the court ruled that while the term "trade secret" is not explicitly defined in existing regulations, the 11th Civil Chamber of the Court of Cassation has determined that the primary characteristic of a trade secret is its confidentiality from both the public and competitors within the relevant industry. The court further

argued that providing information to legal representatives of original pharmaceutical product MA holders could allow competitors to gain insight into the commercial strategies of generic drug applicants, thereby classifying the requested data as trade secrets.

Additionally, the court dismissed claims that disclosure of abridged MA applications was necessary to prevent unfair competition. It reasoned that proving unfair competition requires evidence of unlawful interference, and since the products in question had not yet entered the market, there was no basis for claiming unfair competition at that stage.

This decision was subsequently appealed to the Regional Administrative Court.

The Regional Administrative Court overturned the lower court's ruling, mandating that the Agency resume providing responses to attorneys' information requests, including details such as the generic authorisation applicant, product name, application date, and application status. The court also made critical determinations regarding the contested definition of "trade secrets" and reinforced the obligation of the Agency to protect the proprietary data submitted by original product MA holders from unfair competitive practices.

In its ruling, the Regional Administrative Court defined trade secrets as information encompassing scientific data, financial and economic conditions, and marketing strategies held by commercial enterprises. The court further clarified that, under Article 39 of the TRIPS Agreement and Article 28 of the Licensing Regulation, confidentiality protections apply strictly to preventing unauthorised access to proprietary documents and safeguarding commercially valuable information. The court explicitly stated that "categorising information requests submitted by patent owners for informational purposes as trade secrets would effectively restrict the right to legal recourse."

This high court ruling provided clarity on two long-debated issues:

1. The information sought by attorneys on behalf of original product MA holders—specifically, whether an abridged MA application referencing the original drug file has been submitted, the number of such applications, the identities of the applicants, the application dates, and the current status of the applications—does not qualify as a trade secret.
2. Under Article 39(3) of the TRIPS Agreement, since the Agency mandates the submission of undisclosed test data or other proprietary information as a prerequisite for authorising pharmaceutical or agricultural chemical products containing new chemical substances, it is legally obligated to protect such data from unfair commercial exploitation. Consequently, ensuring regulatory transparency and

> safeguarding against unfair competition necessitates that information requests concerning abridged MA applications referencing original authorisations be granted.

This ruling reaffirms the need for transparency in regulatory processes while maintaining a balanced approach to trade secret protections, ensuring that legal recourse is not unduly obstructed.

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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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