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PATENT LAW IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS

2023

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Key Developments and Predictions for Patent Law in Turkey

After adapting to the changes brought by the Intellectual Property Law ("IPL") the Turkish patent system has entered a process of adapting to the changes that have occurred following the Covid-19 pandemic.

In keeping with the rest of the world, Turkish patent law as entered a new chapter focused on keeping patent rights in a reasonable balance with international epidemics. The extent to which patent rights can be waived has been discussed as part of this. In addition, in order to establish a basis for common practice, especially with the countries that are party to the European Patent Convention, new developments have come to the fore, and steps have been taken before the Turkish courts. A common approach for related disputes in the courts of appeal and intellectual and property rights has also been sought. These aims have only partly been achieved. In addition, various agendas have been proposed to keep pace with the rate of technological advancement.

Dynamic and controversial developments have occurred in the Turkish patent law system, particularly in the aftermath of the pandemic. The most prominent of these issues are discussed below:

This paper provides an overview on the following topics:

- Waiving from IP Rights in the Post-Covid Landscape
- Unified Patent Court - How It Will Resonate in Turkey?
- "Plausibility" in Turkish Patent Law and Its Impact on Invalidation Proceedings
- The Need for an Injunction in Cases Where the EPO Proceeding is held as a Pending Issue
- Preliminary Injunction Decisions against Patent Trolls to Prevent the Enforcement of Patent Rights
- Current Practice of Bolar Exemption in Turkish Patent Law
- REGIONAL COURT OF APPEALS: The Decision of the Turkish Medicines and Medical Devices Agency of Refusal of the Applications of the Original Medicine Owners to Obtain Information On Reference Product is Unlawful
- SEP: Navigating the Technology-Driven World
- Supply of Pharmaceutical Products from Abroad and Patent Rights

Waiving from IP Rights in the Post-Covid Landscape

As the effects of the pandemic fade, it may be a good time to look into the lessons learned and take the necessary precautions against the next one. Indeed, pandemics have been a fundamental part of human history since time immemorial and diligently addressing the reasons for their emergence and the problems they create is quite important. However, the problem of inequitable access to drugs and vaccines faced during the pandemic remains unsolved today, with discussions of the matter expected to continue in 2023.

The pandemic instigated many discussions related to intellectual property ("IP") rights form its outset. Compulsory licensing was the first solution depended on by the governments as it was thought that existing patent rights were the only obstacle to reaching a cure against Covid-19. Innovators and researchers were expected to develop an innovative cure in the shadow of the compulsory licensing threat. Meanwhile, many innovative pharmaceutical companies opened their patented technologies, IP rights and know-how to the public, sharing what they have for humanity's sake.

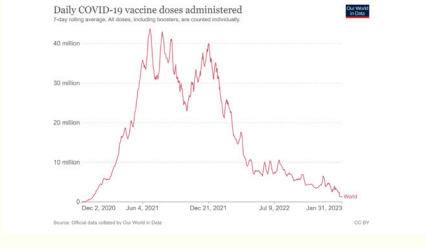
Eventually, BioNTech came up with the first Covid-19 vaccine, initiating another problem, which is yet to be solved: vaccine inequity. Intellectual property rights came back into focus during the discussions of reasons for vaccine inequity, and this time, waiver of these rights was discussed as a solution.

However, just as compulsory licensing was not the solution for developing a cure for Covid-19, waiving intellectual property rights was far from a solution for equitable vaccine access. India and South Africa brought in October 2020 via the World Trade Organisation ("WTO") a proposal to temporarily waive intellectual property protection for coronavirus vaccines. However, the proposal did not explain how the elimination of intellectual property rights disclosing the treatment of Covid-19 would suddenly enable states to produce vaccines and vaccinate their populations considering potential problems regarding manufacturing capacity, know-how, possession of suitable manufacturing sites, provision of adequate raw materials, informing and persuading people of the benefits of vaccination.

While these discussions preceded, countries in need were neither questioned as to why they did not utilise "granting compulsory licensing" provisions in their domestic laws, nor were they asked to justify claimed suitability of suspension of IP rights. In particular, India, as a co-leader for the IP Waiver proposal, had a special provision under Section 66 of its Patents Act, entitling the Central Government to revoke a patent in the public interest, which means that it had a direct legal tool to suspend all patents allegedly hindering its access to vaccines by a single act of government.

On June 17, 2022, two years after discussions began, during the 12th Ministerial Conference of the WTO, a ministerial decision was

issued on the flexibilities brought with TRIPS regarding Covid-19 vaccines by authorizing members of developing country status to use patented inventions necessary for Covid-19 vaccine production and supply, without the right holder's consent. However, the issue of vaccine access has still not been resolved 7 months later in February 2023. Indeed, according to "Our World In Data", 69.4% of the world population received at least one dose of the Covid-19 vaccine. However, only 26.4% of people in low-income countries had received at least one dose as of January 26, 2023.



One of the fundamental reasons that compulsory licensing mechanisms or IP waivers did not foster vaccine access is the limited information provided in the patent documents, especially in vaccine-related inventions. The patent document does not have to or need to disclose, for example, how to access the raw materials, without which it may not be possible to put a vaccine together. It is important to remember that compulsory licenses or IP waivers do not and cannot create legal mechanisms forcing patent owners to transfer their know-how or trade secrets. This emphasizes the importance of multilateral solutions and finding ways to persuade the patent owners to collaborate.

Additionally, compulsory licenses or IP waivers cannot provide or create manufacturing facilities, equipment and raw materials in vaccine manufacturing. If those are absent, then even the patent owner is hopeless. We should keep in mind that the vaccines that softened the blow of the pandemic were found thanks to research and development conducted for years before the pandemic with the aim of treating cancer. Without the existing body of research, tests or data, it would have been impossible to conceive and develop a vaccine within one year.

Therefore, if we want to be prepared against a possible new pandemic and extend the access to the vaccine, we need to encourage research and development and innovative activities today. Our most powerful tool is adequate intellectual property protection, which isn't meaninglessly threatened in every possible crisis. In addition to genuinely supporting R&D, we must find creative and efficient ways to incentivize the transfer of technology and know-how when needed, and we must think about the structures in which innovators/IP holders will be willing to cooperate and establish them starting today. This is the only proper solution if the sincere aim is preparing for another pandemic.

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Unified Patent Court - How It Will Resonate in Turkey?

The concept of the Unified Patent Court ("UPC") entered the lives of European Patent holders with the UPC Agreement, an international agreement dated February 19, 2013. The system is intended to begin operation on June 01, 2023. The courts in question constitute a big and important step towards ensuring the unity of the judiciary for European Union member states. With the completion of the approval processes for 17 European Union members, a few days before the start of the transition period called the "sunrise period", certain issues regarding the implementation of the system became apparent. There is also some uncertainty and hesitation around how the system will resonate with countries that are parties to the European Patent Convention ("EPC") but not members of the European Union. In this article, the possible effects of this system in Turkey, which is within the EPC countries but outside the UPC system, will be examined.

As a non-European Union country that is a party to the EPC, Turkey is essentially in the same position as Norway and Switzerland when it comes to the UPC. Likewise, the post-Brexit UK has joined the list of countries that are party to the EPC but not the UPC. It is not clear that the UPC system will directly affect these countries. As a matter of fact, European and national patent applications will continue to be made from these countries. In this respect, patent holders in countries that are not members of the European Union will also be able to include their European patents in the UPC system for UPC countries, or if they wish, they can keep their patents within the pre-existing European patent system with an opt-out procedure, and the national patent protection in their domestic jurisdictions. Today, considering the comprehensive jurisprudence database created by the EPO it appears that the UPC will benefit from the EPO case law until it forms its own established jurisprudence. In the same vein, the European intellectual property law circles anticipate that the UPC decisions may affect EPO case law.

Interestingly, there is no regulation that makes the appeal proceeding for a patent before the EPO a prejudicial matter to a revocation action before the UPC or vice versa.

It would not be wrong to say when it comes to invalidity proceedings against a European patent that the Turkish IP courts have started to reach a consensus on deeming the opposition and especially the appeal processes at the EPO a prejudicial matter before starting the

examination phase in their own decisions. In this context, the courts tend to wait for the decision of the EPO in order avoid unnecessarily burdening the judicial system since a revocation decision by the EPC would directly impact the validation of a patent in Turkey. The Turkish IP courts will decide that a case is devoid of essence without further examination. If the EPO revokes a patent already reflected in the registry in Turkey. On the other hand, if the EPO decides to maintain the European patent as granted or after amendments or limitations, the Turkish court will begin its national examination and then decide on the validity or invalidity of the Turkish part of the patent. As it is seen, the EPO proceedings carry great consequence for the Turkish judiciary when it comes to European patents validated in Turkey.

Although the law is silent on this matter, the link between UPC proceedings and EPO evaluations may lead to Turkish proceedings being affected by decisions made by the UPC regarding the validity of a European patent included in the UPC system which also has validation in Turkey. Thus, considering that 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 in effect set a precedent for Turkish proceedings. This situation raises the possibility that Turkish judges may slightly change their practice when it comes to deeming matters prejudicial.

Namely, when a national invalidation action is filed in Turkey 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 far more expedient. A distinction is likely to be made at this point: If the UPC decides to invalidate the patent, we expect the Turkish court to wait for the EPO to confirm the decision. However, if the UPC decides to uphold the patent, might the Turkish court, awaiting the EPO's confirmatory decision, decide not to wait and initiate national proceedings so as not to waste time?

The answer to this question will emerge depending on many factors, such as the emergent correlation between EPO decisions and UPC decisions, the speed at which UPC decisions are made, and the amount of UPC decisions the Turkish courts end up considering. We may say however that if the Turkish court decides to wait for the EPO's decision, despite a decision rendered by the UPC regarding the same patent, it is inevitable that one of the parties will request the withdrawal of this decision to wait for EPO

due to its position and strategies in the market, and this issue will have to be evaluated.

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"Plausibility" in Turkish Patent Law and Its Impact on Invalidation Proceedings

The grounds for the invalidation of a patent within the scope of Industrial Property Law No. 6769 are listed per the numerus clausus principle. The concept of plausibility – which has been the subject of numerous evaluations, especially by the European Patent Office ("EPO") and frequent debate in academic circles in recent years – has not yet found a place within the scope of any legal regulation in Turkey. Moreover, there is no consensus on a Turkish wording for an equivalent legal term. However, the concept of plausibility has started to be argued by the plaintiffs in Turkish invalidity proceedings and it has been the subject of important conclusions by the EPO Enlarged Board of Appeal within the scope of application No. G 2/21. As such, the place of the concept of plausibility in Turkish legal practice must be examined.

Plausibility can be defined as the ability to demonstrate the technical effect claimed by the invention credibly and convincingly with appropriate evidence to be submitted, or to deduce this situation from the state of the art or common general knowledge to avoid speculative patents that can be produced at the desk (Türk Patent Hukuku, Uğur Çolak, Adalet Yayınevi, Ankara, 2022; A Practitioner's Guide to European Patent Law, Paul England, Hart Publishing, London, 2019).

The requirement of plausibility, which is not defined as one of the invalidation grounds under Turkish law, is a particularly relevant issue for pharmaceutical patents. However, it is difficult to obtain all the clinical test data by the patent application date due to the long duration and complexity of efficacy tests.

Therefore, considering the inherent urgency of patent applications, there are issues around how much data indicating that the invention is applicable and working should be included in the patent application and to what extent post-published evidence can be used.

In other words, the concept of plausibility can be regarded primarily as a prohibition of speculative patent applications which do not disclose a technical effect of a chemical substance and/or disclose a technical effect which is not normally expected.

A similar effect to that of this requirement can be achieved in invalidation actions by asserting in the context of "sufficiency of disclosure" or "lack of inventive step" despite the lack of any such requirement in the Agreement on Trade-Related Aspects of Intellectual Property Rights or the European Patent Convention, to which Turkey is a party.

Indeed, arguments including the concept of plausibility before the intellectual and industrial rights law courts did so under both headings.

EPO Case law on Plausibility

The concept of plausibility is also associated with inventive step and sufficiency of disclosure in EPO case law. Even though the word "credible" was used instead of

"plausible" in Case T 939/92 (AgrEvo), there are opinions claiming that this decision, which concluded that a technical effect should be reasonably predictable and credible, was the first to use the threshold of plausibility.

Others argue that Case T 1329/04 (John Hopkins) was the first to establish the plausibility threshold in explaining that it was at least made plausible that the claimed invention could be carried out.

In contrast to these cases, Case T 609/02 (Salk) concerned the plausibility threshold about the sufficiency of disclosure, and it was concluded that there was a requirement to make the existence of a cause-and-effect relationship plausible.

Finally, in a more recent case, T 488/16 (Dasatinib/BRISTOL-MYERS SQUIBB), the EPO Enlarged Board of Appeal clarified that even though there is not always a requirement to have experimental data in an application, the technical problem must at least shown to be plausibly solved at the filing date.

The plausibility issue also raises a discussion regarding filing post-published documents. It is seen that there are many decisions of EPO Technical Boards of Appeal (see, in particular, T 578/06) addressing the plausibility issue together with evidence published after the date of filing. The majority of the decisions stress that post-published evidence can be considered on the condition that a certain effect was plausible at the filing date of the patent application.

Turkish Case Law Regarding the Plausibility Principle

Given that the concept of plausibility is only just gaining currency in Turkish law and that it has not been put forward as a sound argument by plaintiff parties, it has not yet been included in any high court case law and has not been evaluated in any decision by a court of first instance.

Indeed, a plaintiff claimed in a recent patent invalidation action that the subject patent was not plausible in the context of insufficient disclosure. However, the plausibility requirement was erroneously defined because of the presence of evidence in the patent document that directly and undoubtedly proved that the technical problem had been resolved. However, according to the EPO's practices, for example, the submission of in vitro test results may be sufficient to make the solution to the technical problem foreseen in the patent plausible. In this respect, since the plaintiff could not prove their claim in accordance with the general principles of the law of proof, the court of first instance concluded that the invention was entirely and sufficiently disclosed. No evaluation was made regarding the plaintiff's plausibility argument and therefore no steps were taken to form case law on plausibility.

Unifying EPO Case Law Will Be Instructive to Turkish Courts

The current state of IP law in Turkey does not allow for advanced plausibility arguments or for the recruitment of case law as a criterion in plausibility evaluations to be made by the courts.

However, despite the fact that EPO case law does not constitute a direct precedent for Turkish courts, in our opinion, the decision issued regarding the G 2/21 application by the EPO Enlarged Board of Appeal following the oral hearing held on November 24, 2022, will help to establish a uniform approach to applications by that Turkish courts may follow, especially considering that Turkey is a party to the European Patent Convention. In this context, we believe that there will be a clearer practice before Turkish courts when the patent owner relies on the post-published evidence to support the inventive step criteria of the patent. However, the determination of the Enlarged Board that the question of whether or not an invention is sufficiently disclosed when post-published evidence is used in support of a technical effect should be evaluated on a case-by-case basis did not, of course, remove the uncertainty before the Turkish courts' assessments.

The industry is very excited to see the reflections of the decision of the EPO Enlarged Board of Appeal in Turkish IP law.

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The Need for an Injunction in Cases Where the EPO Proceeding is held as a Pending Issue

Although there is no explicit provision in Turkish Law for the acceptance of the ongoing opposition or appeal proceedings before the European Patent Office ("EPO") as a "pending issue", in practice due to the principle of procedural economy, pending issue decisions may be given by the Civil Courts of Intellectual and Industrial Property Rights on a case by case basis. As Turkey is party to the European Patent Convention, upon the issuance of a revocation decision regarding a European patent, the patent's validation before TÜRKPATENT is also revoked. Therefore, the revocation decisions rendered by the EPO are binding for Turkey. In addition, based on the principle of procedural economy set out in Article 30 of the Code of Civil Procedure ("CCP"), which governs the proceedings, and taking into account that EPO decisions are also binding and that the EPO may revoke the patent, it may be decided to postpone the proceedings before the national court to avoid unnecessary burdening of the judicial system. Since there is no specific provision in Turkish law on the obligation to regard EPO proceedings as a pending issue, the courts decide by considering the stage of the EPO proceedings, the type of the action, and the balance of interests among the parties.

Considering the length of EPO proceedings, it is necessary to consider the balance of interests among the parties in this process. In this context, if there is a request from the parties, it is essential to decide on provisional legal protection measures to prevent the damages that may arise due to the duration of the proceedings. Especially so considering that the patent protection period is limited to 20 years and that there is no regulation extending this period in Turkish Law.

Indeed, the Regional Court of Appeal issued a precedent-setting decision emphasizing this importance. In an infringement and counter-invalidation action, the court of first instance decided to wait for the outcome of the EPO appeal process because the opposition process regarding the EPO patent had been concluded, but the appeal proceedings were still ongoing. The court rejected the preliminary injunction request filed by the patentee to compensate for the loss of rights during the waiting for the EPO decision because the EPO appeal and objection processes directly concerned the infringement action, and the infringement action would affect the decision of the court. The patentee appealed this decision which was found unfair and unlawful on the grounds that the EPO appeal proceedings were concluded in favor of the patentee, the experts appointed by the

court determined the patent infringement, the patent protection period is limited, and cannot be extended. There is no need to wait for this process to issue an injunction.

The District Court, deeming the plaintiff's requests appropriate, ruled that "Although it is understood that the request for a preliminary injunction was rejected due to the pending EPO appeal proceedings, deeming the process a pending matter does not constitute an obstacle for the evaluation of the request for a preliminary injunction." Accordingly, the District Court revoked the decision of the court of first instance, noting that the request for a preliminary injunction should be evaluated while waiting for the conclusion of the EPO appeal proceedings to protect the balance of interests among the parties.

This decision has once again emphasized the purpose of the preliminary injunction to prevent the emergence of damages that occur during the trial that are difficult or impossible to compensate for later on. Furthermore, this decision makes it clear that the requests for a preliminary injunction should be decided on a priority basis to protect the patent rights of patentees in an effective and timely manner; deeming the EPO process a pending issue should not be an obstacle to the consideration of preliminary injunction requests. This decision sets an example for cases where the conclusion of the EPO opposition and appeal process is awaited to prevent the parties from losing their rights, potentially for years in prolonged cases.

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Preliminary Injunction Decisions against Patent Trolls to Prevent the Enforcement of Patent Rights

Patent and utility model rights, vital to incentivizing R&D and innovation, provide their holders with a significant advantage over their competitors and grant an absolute right for a certain period. However, as in every system, there are players in the patent and utility model ecosystem who use these rights contrary to the purpose and spirit of the system. These players, who obtain patent/utility model registrations by taking advantage of the loopholes in the system without contributing to the technique and who try to make a profit and put pressure on their competitors by asserting these registrations against their competitors, are known colloquially as Patent Trolls.

In cases where companies find it challenging to carry out their commercial activities and protect their commercial reputation against their customers in the face of patent trolls, some remedies are available under procedural law, the most important of which is injunctive relief requests. Although the types of preliminary injunction requests available depend on the type of dispute, it is fair to say that the one the most commonly resorted to in practice is a preliminary injunction request to prevent the enforcement of rights arising from the utility model or patent registrations or applications.

Undoubtedly, the scope and time of the preliminary injunction requests and before which court and when they should be brought forward, should be evaluated according to the characteristics of each case. Yet, certain decisions rendered in precedent setting cases have obviated the strategies of patent and utility model trolls.

For instance, in a recently finalised court decision a company that registered the basic principles of a technique in the textile printing field by taking advantage of the lack of extensive novelty examination in the utility model registration system, developed a strategy against the threat of prevention of its commercial activities by its competitors. Concerned that its commercial activities in Turkey would be disrupted and its reputation discredited, the company brought an invalidation action against the relevant utility model. The action requested that the other party be prevented from enforcing their rights arising from the utility model against the company. Upon receiving expert examination of the merits, the court of first instance accepted the request.

In a similar court decision, upon the utility model registration in bad faith of a technique commonly known in the textile industry, competitor companies were inundated with license requests from the bad faith utility model holder. This created concern for the companies involved similar to the aforementioned case. An adverse declaratory action was filed against the utility model holder on behalf of a competitor company, and a

similar injunctive relief was granted in this action. In this case, the court of first instance found sufficient explanations in the petition that there was no violation and accepted the request for preliminary injunction without even conducting an expert examination on the merits, thus providing relief to the wronged company. We would also like to point out that the preliminary injunction decision has been finalized upon appeal examination.

As seen, requests for a preliminary injunction are useful in different strategies in different ways, whether for the holder of the intellectual property right or the companies under threat due to the intellectual property right. In particular, taking correct and timely action against the absolute rights gained by patent trolls through the loopholes in patent and utility model registration processes and establishing the correct strategy is of great importance for companies in the long run.

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Current Practice of Bolar Exemption in Turkish Patent Law

Article 85(3)/(c) of the Industrial Property Law No. 6769 ("IPL") regulates the Bolar Exemption, which stipulates the exclusion of experimental acts containing the invention subject to the patent from the scope of the patent right, including the licensing of pharmaceuticals and the necessary tests and experiments thereof. Undoubtedly, the purpose of the Bolar Exemption is to ensure that a generic medicinal product can be put on the market without losing time once the patent expires and to prevent the de facto extension of the protection period granted for the patent.

Even though the wording of the article limits the scope of the Bolar Exemption to the licensing of pharmaceuticals and the tests and experiments necessary for this, the decisions of not only the intellectual and industrial property rights law courts in Istanbul, Ankara and Izmir but also District Court and Court of Cassation decisions indicate that the relevant provision is interpreted differently.

The courts interpret the Bolar Exemption very broadly and reject the request for determination of evidence and preliminary injunction grounding on the Bolar Exemption, even in cases where sales permission is granted to a generic medicinal product when price approval is obtained, and also when the product is included in the reimbursement list of the Social Security Institution ("SSI"). However, almost none of the above decisions include legally satisfactory and guiding reasoning and the uncertainty in the current situation the cause of a profound loss of rights for both patent rights holders and pharmaceutical companies manufacturing generic medicinal products.

Some courts consider the inclusion of the generic medicinal product on the reimbursement list of the SSI, which is not even a prerequisite for the launch of the medicinal products to the market, as being within the scope of the Bolar Exemption; however, such interpretations expand the implementation scope of the exemption granted to the right holders for a limited period.

Some courts interpret the Bolar Exemption in a way that prevents even requests for determination of evidence made after the grant of the marketing authorization of the generic medicinal product. This situation eliminates the only way provided to the patent owner with the IPL to determine evidence that the court can only collect on the patent infringement.

Patent owners are unable to properly exercise their patent rights because they cannot obtain evidence only available through the courts, such as: information on price approval, sales permission of the generic products and the product's inclusion to the SSI's reimbursement list, and examination of the marketing authorization dossier of the generic medicinal product. As a result, in accordance with the current legislation, without considering whether there is any patent infringement, medicinal products for human use may be launched on the market, and following the release of a generic version of the patented medicine, the price of the patent owner's product automatically decreases by 40% in accordance with the Ministry of Health legislation. Moreover, even if it is determined that the generic medicinal product infringes the patent rights after the said price decrease decision, the price decrease decision cannot be reversed.

In addition to all of these, uncertainties about the point at which the actions of pharmaceutical companies that make significant investments in the production and marketing of generic medicinal products will constitute patent infringement adversely affect their market entry strategies.

The lack of unity in the interpretation of the Bolar Exemption and the erroneously broad interpretation of the relevant provision is the biggest obstacle for patent owners wanting to protect and enforce their property rights and also for manufacturers of generic medicinal products looking to launch their products on the market without the threat of patent infringement. Therefore, the fair implementation of the Bolar Exemption by the courts in accordance with the wording and purpose of the exemption is essential for developing and protecting the health sector in Turkey.

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REGIONAL COURT OF APPEALS: The Decision of the Turkish Medicines and Medical Devices Agency of Refusal of the Applications of the Original Medicine Owners to Obtain Information on Reference Product is Unlawful.

As per Article 9 of the Regulation on Licensing of Human Medicinal Products ("Licensing Regulation"), which regulates "Abridged Application[s]", if a pharmaceutical has been authorized before, it is not necessary to repeat the tests and research, and the data of these tests doesn't have to be submitted for authorizing again. Referencing the authorization information of the original pre-licensed pharmaceutical is sufficient.

However, because the subject product must be essentially similar to the original patented product, a significant risk of infringement emerges against the patent rights. Even though the authorization procedures are exempted from the patent right, the patent holder should be informed of such applications to enable them to analyse whether the activities to be undertaken after granting authorization to the reference product would create a risk of patent infringement and to ensure that the patent rights can be used effectively. Within this context, the attorneys of the pharmaceutical companies that own the patented product, according to Article 2 of the Attorneyship Act, may request information from the Ministry of Health Turkish Medicines and Medical Devices Agency ("Agency") on whether the new product application and/or abridged authorization application or import permit application has been filed. If so, they may request the number of these applications and applicants, document registry information, dates thereof, whether the applications are pending, withdrawn, dismissed, or returned for any purpose. They are also entitled to request information concerning whether authorisation has been granted.

In fact, in 2007, we brought two cases before the State Council on behalf of our clients and on our behalf as a proxy after the attorneys of the patent owner pharmaceutical companies requested this information and the Ministry of Health rejected these requests of information. The Council of State decided to cancel the individual decision and actions of the Ministry of Health on refusing to provide information, and it held that the information of "whether an abridged authorization application has been made by referring to the authorization of the plaintiffs, and if so, the number of them and by whom" should be provided (State Council 10th Civil Chamber decision dated 06/03/2007 and numbered 2004/10375 E (Merits), 2007/891 K (Decision). This decision of the State Council was followed and the requests fulfilled by the Agency.

Despite no change to the circumstances, a second administrative action became necessary due to the Agent's sudden renunciation of its legal personhood which left the right holders in the dark on how to protect their rights. Its response to new information request applications was "The requested information is included in the Authorized Pharmaceuticals List and Active Substance

List published on the official website of the Agency".

As a matter of fact, critical information such as whether the abridged authorization application has been made, who the applicant is, the application date and the status of the application are not included in the Authorized Pharmaceuticals List or Active Ingredient List the Agent referred to. These lists include nothing but the number of applications and have led to a serious decrease in the protection offered by patent rights.

In the second action filed, the legal ground of the case was determined wrongfully, and a majority vote dismissed the case. However, in the dissenting opinion annotated in the decision, it is stated that the documents and information requested are not trade secrets, so rejecting the request for information instead of accepting it is against the law.

As a result of the appeal brought against this decision, the District Court dismissed the decision of the court of first instance and echoed the State Council's aforementioned judgment;

- As per Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and Article 28 of the Licensing Regulation, the rule of confidentiality of information regarding applications made for obtaining a license for a product is limited to preventing the information and documents in the file from being viewed by others and protecting information that has an economic value from being shared.
- It is possible to check whether the data submitted to the original pharmaceutical authorization file by the inventors are effectively protected against unfair competition by the administration only through access to information on the abridged authorization applications made regarding the pharmaceutical authorizations they have,
- Within this context, concluding that the applications made for receiving information by the manufacturer invention owners are trade secrets would mean restricting the efficient use of the right to legal remedies.

The court ordered the cancellation of the response given by the defendant, the Agency.

The unlawfulness of the Agency's non-responsiveness to requests for information was already determined by the State Council decisions years ago, and as a matter of fact, responding to the information request applications that are duly filed according to the decision of the State Council has turned into a settled administrative practice. However, the fact that the Agent suddenly stopped providing the requested information

in return for the applications for information contrary to the decision of the State Council, its practices, and the law has surprised the sector. Receiving a decision in the same direction about this practice, the illegality of which was previously determined by the decisions of the State Council strengthened the institution regarding the request for information of the original authorization holder company on reference authorization applications. With this second decision, arbitrary changes in the administration's attitude ended, and an administrative entity was prevented from becoming an obstacle to the protection and oversight of patent rights.

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SEP: Navigating the Technology-Driven World

Standard-Essential Patents ("SEP" or "SEPs") are the 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 Organizations ("SDOs") determine the technical specifications and standards, including sets of technical specifications in the relevant industry and aim to make such 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 the SDO members of their patents that may be essential to the SDOs' standards. When a member identifies a potential 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 vary across different SDOs and may also vary between patent holders. 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, causing the SEP holder to have a significant advantage over the party wishing to implement the standard.

SEP Licensing

The proliferation of SEPs has seen numbers of related litigations also increase. Although litigants suffer from the lack of detailed and case-by-case laws governing licensing in the FRAND terms, the widely known and cited Huawei Technologies v. ZTE (Case C-170/13) and Nokia v. Daimler (Case 4c O 17/19) decisions and others from different jurisdictions shed some light on practice in this area.

In addition, last year, on February 14, 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. The European Commission is expected to

evaluate the sector's feedback in the second quarter of 2023.

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 product in which the standard is used. However, this concept is criticized 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 as a result of 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.

Turkey's Position

Turkish Standards Institution (the "TSE") and the Information Technologies and Communications Authority in Turkey (the "BTK") are the two central government-backed organizations dealing with standards in Turkey. The TSE has full membership of the International Organization for Standardization ("ISO"), and International Electrotechnical Commission (IEC), the Standards and Metrology Institute for the Islamic Countries ("SMIIC"), European Committee for Standardization ("CEN") and European Committee for Electrotechnical Standardization ("CENELEC"). The relations of Turkey with standard organizations in the field of international telecommunications are conducted through the BTK, which is an observer status member at the European Telecommunications Standards Institute ("ETSI").

Although TSE and BTK have memberships in SDOs, these institutions do not take an active role in setting standards in Turkey or publishing policies regarding intellectual property rights. The Technology Standards and Standard-Based Patents Task Force, established in 2020 under the Turkish Industry and Business Association, leads the required infrastructure process to carry out standard-setting studies in Turkey and to expand SEP licensing with reports published in 2022 as a result of its extensive work, and with the support of public institutions such as TSE and

the Turkish Trademark and Patent Institution. Turkish courts have not yet issued a detailed decision on FRAND licenses and/or SEPs. However, on December 26 2019, the Turkish Competition Authority ("TCA") issued its first decision regarding SEPs in the Vestel v. 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 FRAND principles were implemented even 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 fiscal year 2018.

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 continue to increase the number of production facilities in different parts of the world every day by following an expansionary policy with the effect of globalization and shortage crises.

Given the investments and incentives in different industries and its high market potential, Turkey may soon become one of the jurisdictions to handle SEP litigations. While the Competition Board surprisingly dug into 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 Turkey and if they will follow the Boards approach in dealing with FRAND terms.

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Supply of Pharmaceutical Products from Abroad and Patent Rights

The supply of pharmaceutical products to Turkey via the named patient programme (the "NPP") is one of the exceptional importation regimes for pharmaceutical products. Where a pharmaceutical product is not granted marketing authorisation in Turkey, or it is granted marketing authorisation but not found in the market where there is a patient need, it can be supplied via this particular route by physician request.

If the product is approved for the NPP, it is added to the Foreign Drug List of the Turkish Medicines and Medical Devices Agency ("Agency"), and nowadays, imported by the Turkish Pharmacists Association ("TEB") and the Social Security Institution ("SSI") on a named patient basis. If SSI decides on the reimbursement of the relevant product, the product is published in Annex-4/C list of the Health Practices Communiqué of SSI.

This exceptional supply method causes some problems in protecting and enforcing patent rights in Turkey. For example, the owner of the patent for a product in Turkey, would only be made aware of the importation of an infringing product by the NPP by its inclusion on the foreign drug list.

In cases where the existence of a patent infringement is suspected or unavoidable, the patent owner wishing to exercise its legal rights cannot access supplier information as it is not made public. The only party related to the infringement that can be discovered by the patent owner would be the TEB or SSI, the importer of the infringing products. The Courts of Appeal have ruled that for the cases of the supply of an infringing product via the NPP, the buyer of the product in Turkey, the TEB, would be one of the potential named parties of the patent infringement action, as the importer of the infringing products. However, since the relevant institutions are also obligatory solution partners of the patent owner for the supply of its patented product via the NPP, it may not be preferred to bring an action against these institutions. In practice, the Agency, TEB and SSI do not share information about the product's supplier, who carries the risk of infringement. This information is only shared when requested through the courts. Until February 2023, the fact that the NPP and the reimbursement processes were not carried out transparently led to the ineffective use of patent rights in this field.

The Guidelines on Supply of Pharmaceuticals from Abroad regulated the exceptional import regime in question until recently. The Regulation on Supply of Medicines from Abroad ("Regulation") was published in the Official Gazette No. 32093, dated February 3, 2023, and the old guidelines were repealed. With the new Regulation, new provisions have been introduced regarding the registration of the persons and organisations involved in the procurement process and the traceability of the drugs supplied. In this way, the suppliers of the product residing abroad and the

representatives of these suppliers residing in Turkey will also be registered with the Agency. In addition, the lists of drugs procured by this method will now be published by the authorised suppliers, the TEB and the SSI.

For example, in a precedent that from last year before the publication of the Regulation, an action with a request for preliminary injunction was filed for the determination, prevention, and cessation of infringement against a product included in the Foreign Drug List containing the active ingredients protected by the patents protected molecules. Upon the investigation of the preliminary injunction claim made on the file, the court found that the products included in the Foreign Drug List infringed both patents and granted a preliminary injunction in consideration of the guarantee, in this context, in addition to other injunctions, it is decided to prevent the supply of products.

Following the trial, the court accepted the action, determining the patent infringement and removing the infringing drugs from the Foreign Drug List. Besides, the court decided to prevent the products with the patented active ingredient from being included in the Foreign Drug list regardless of their tradename during the term of the patent protection.

In principle, it is essential to decide only on the subject product of the case. However, our defence against the possibility of inclusion of the infringing products in the Foreign Drug List by changing their name was accepted, and the court prevented the inclusion of the products with the same active ingredient to the list under any name or trademark.

In this particular case, it is seen that the decision was held by taking into account the characteristics of this special drug supply method. Therefore, it is a crucial decision that ensures the effective protection of patent rights through the court. With the effect of the provisions introduced by the new Regulation, it is hoped that effective protection of both patent and other intellectual property rights will be ensured in disputes concerning the NPP, and especially the Industrial Property Law in Article 3 of the Regulation in which the relevant legislation is listed.

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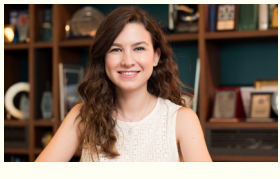

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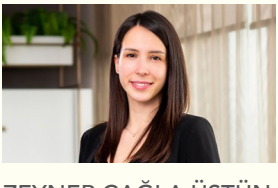

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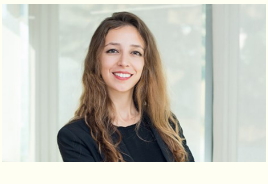

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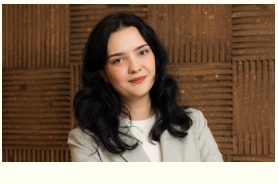

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FIRM OVERVIEW

We are one of the oldest and largest business law firms in Turkey and are ranked among the top tier legal service providers. We are widely regarded as one of the world's leading IP law firms.

Based in Istanbul, we also have working and correspondent office in Ankara, Izmir and all other major commercial centers in Turkey.

We advise a large portfolio of clients across diverse fields including life sciences, energy, construction & real estate, logistics, technology media and telecom, automotive, FMCG, chemicals and the defence industries

We provide legal services mainly inn Turkish and English and also work in German and French.

We invect to accumulate industry specific knowledge, closely monitor business sector developments and share our insight with our clients and the community We actively participate in various professional and business organisations.

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