World Trademark Review™

Pharmaceutical Trademarks 2017/2018

Turkey

Gün + Partners

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A Global Guide

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Selection, clearance and registration

Relevant national and international regulatory bodies and requirements

Pharmaceutical trademarks, like all other trademarks, are governed by Decree-Law 556 on the Protection of Trademarks. Before filing a trademark application, an availability search for the phrase to be filed should be conducted in the official database of the Turkish Patent Institute (TPI) to eliminate or reduce the risk of refusal or infringement. Searches of the Pharma-In-Use database and any publicly available lists of products authorised by the Ministry of Health should also be carried out.

After clearance, the trademark application is filed with the TPI and it is examined on absolute grounds within three to six months of the application date.

The main absolute grounds for refusal which relate to pharmaceutical trademarks are:

- the indistinct nature of the sign;
- the pre-existence of a trademark that is identical or indistinguishably similar to the later filing;
- the descriptive nature of the sign; or
- the deceptive nature of the sign.

The TPI may reject a pharmaceutical trademark application which contains a sign that has become customary within the relevant field of medicine – in particular, a trademark containing an international non-proprietary name (INN) as the major element.

Following the initial examination, if the application is found eligible for registration in terms of absolute grounds, it is published in the *Official Trademark Bulletin* for three months pending opposition. The relative grounds for refusal relate to the prior rights of senior rights holders. A registered mark owner may object to publication of a trademark application on the basis of a likelihood of confusion.

For pharmaceutical trademarks, the test for a likelihood of confusion is rather strict. Depending on whether the pharmaceutical is prescribed, the question arises of whether the higher level of attention of a healthcare professional or reasonable attention of the average consumer should be taken into account. The Court of Appeals' high threshold and the belief that healthcare professionals make no mistakes are erroneous interpretations. In a recent case,

despite comprehensive examination by a court-appointed expert panel regarding the similarity of the trademarks ALOXI and ALOXIS, the court followed established case law and denied the likelihood of confusion between the trademarks. However, in another case the court accepted the likelihood of confusion between the trademarks BUSTESIN and UBİSTESIN based on their undeniable similarity. Further, in another case the court accepted the likelihood of confusion between the trademarks OTRIVIN and OTRIMICIN. Despite the last two cases, the likelihood of confusion test remains strict.

Confusion with INNs

In order to eliminate confusion between pharmaceutical products, the tendency is to avoid the use of INNs, INN stems or terms derived from them as pharmaceutical names and trademarks. In this regard, health authorities intervene at the licensing stage when approving pharmaceutical names and trademark registration authorities do so when registering pharmaceutical trademarks.

In Turkey, Article 4 of the Regulation on Packaging and Labelling of Pharmaceutical and Medicinal Products clearly states that a pharmaceutical name cannot be confusingly similar to an INN or the widely used name of a product. However, there is no explicit provision in the Regulation on Licensing of Pharmaceutical and Medicinal Products 2005 which regulates the pharmaceutical licensing process, including the approval of pharmaceutical names by the Ministry of Health. While the regulation makes no provision, the ministry's practice is quite strict and it has already sent an official letter to the TPI to ensure that INN lists published by the World Health Organisation are followed and that INNs and INN-derived names cannot be registered as trademarks.

Even though explicit provisions exist, they are rarely applied. There is only one case on the issue: in a July 27 2006 decision (2004/774E, 2006/488K) the Ankara IP Court ordered the cancellation of the AZAPIN trademark registered in the name of a pharmaceutical company as it was confusingly similar to Olanzapin, listed on the World Health Organisation INN list. Further, the court held that the use of the '-apin' INN stem in the trademark would create confusion for healthcare professionals if used for products not containing this active substance.

Non-traditional trademarks

In principle, the three-dimensional (3D) shape of goods and/or their packaging can be registered and is subject to the same conditions as other types of mark.

However, in practice, the TPI's interpretation of 3D trademarks is stricter when compared with other types of

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trademark. The TPI's interpretation was quite strict four to five years ago when the vast majority of applications for 3D shape marks were rejected on the grounds of lacking inherent distinctiveness, without considering whether the mark had acquired distinctiveness. In contrast, the Turkish IP courts always conducted a broader examination of the registrability of 3D shape marks. The majority of applications rejected at the administrative stage were registered when the TPI's decisions were challenged before the IP courts.

Parallel imports and repackaging

The principle of national exhaustion is accepted under Turkish law. Article 13/1 of the Trademark Act provides that: "The acts related to a product containing the registered trademark shall not constitute a breach of the rights of a registered trademark where such acts have occurred after the product has been put on the market in Turkey by the proprietor or with its consent." Accordingly, once the rights holder or its authorised representatives release a trademark on the Turkish market, third parties may import genuine products

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into Turkey without committing trademark infringement. Thus, in principle, it is impossible to prevent parallel imports of genuine products. The only exceptions to this principle are cases in which the parallel import products are altered or damaged after they have been put on the market. In such cases, Article 13/2 of the Trademark Act allows the rights holder to prevent the commercial use of such products.

The Court of Appeals' approach is rather strict. Trademark rights are exhausted once any goods – irrespective of the particular model – bearing a certain trademark have been released on the Turkish market. A rights holder cannot prevent parallel imports even if a particular model of product has not previously been released on the Turkish market, unless the products are altered or damaged.

However, for pharmaceutical products, the import regime is strictly regulated. The Pharmaceutical and Medical Preparations Law (1262) regulates the import, export and manufacture of pharmaceuticals and indicates the penalties for non-compliant products. Article 3 indicates that market authorisation from the Ministry of Health must be sought before a product's release on the market for products manufactured in Turkey and before the import or export of products produced abroad.

In order to import pharmaceutical products, the importer must have market authorisation. In principle, the market authorisation of a certain product can belong only to one entity. Therefore, the parallel import of pharmaceutical products is not possible. Further, Article 19 of Law 1262 stipulates that the import of pharmaceutical products without market authorisation constitutes smuggling and will be punished according to the Anti-smuggling Law (5607).

The packaging and labelling of pharmaceutical products are also strictly regulated under Law 1262 and its regulations. All information on packaging and labelling must be in Turkish and repackaging is forbidden without permission from the Ministry of Health.

Anti-counterfeiting and enforcement

Under Article 18 of Law 1262, the sale of counterfeit pharmaceuticals is subject to an administrative fine of between TRY100,000 and five times the aggregate of the annual sale proceeds of the counterfeit pharmaceutical in question. An administrative fine of twice the amount of the original fine will be issued for repeat infringements. In a situation where the counterfeit pharmaceuticals are sold or distributed online, access to the infringing website will be blocked.

The counterfeiting and illegal distribution of pharmaceuticals are subject to the Criminal Code. According to Article 186, any person who sells, procures or stores decayed or transformed foodstuffs, beverages or pharmaceuticals that cause risks to life or health will be punished with imprisonment for between one and five years and a fine of up to TRY150,000. The punishment is increased by one-third if the offence is committed by a person who is qualified as a professional in his or her business area (eg, if the concerned person is a pharmacist).

Further, under Article 187 of the Criminal Code, any person who produces or sells pharmaceuticals that risk life or health will be punished with imprisonment for between one and five years. The punishment is increased by one-third if the offence is committed by a physician or pharmacist, or within the scope of a professional activity.

On the other hand, if the name of the pharmaceutical is registered as a trademark in Turkey, the use of the trademark on counterfeit products is subject to Decree-Law 556 on the Protection of Trademarks. Under Article 61 of the decree-law, the use of the same or a confusingly similar trademark without the consent of the rights holder is considered to be an infringement of the trademark.

Further, if counterfeit pharmaceuticals are imported into Turkey without being subject to customs procedures, Article 19 of Law 1262 stipulates that these products will be subject to the Anti-smuggling Law.

The key procedure for monitoring dangerous counterfeiting is the Ministry of Health's Pharmaceutical Track and Trace System. The system is designed to track the location of every pharmaceutical unit to ensure the reliable supply of pharmaceuticals to patients. Therefore, all pharmaceuticals on the market are traced by notifications in

all phases, from production to consumption. The aim is to prevent the sale of falsified pharmaceuticals, stolen pharmaceuticals and barcode scams. In addition, pharmaceuticals can be recalled from the market due to traceability of stock if required.

Advertising

In Turkey, advertising pharmaceutical products is governed by Law 1262 and the Regulation on Promotional Activities of Medicinal Products for Human Use. Further, the Act on Protection of Consumers, the Regulation on Principles and Fundamentals of Practices Regarding Commercial Advertisements and Announcements and the Code of Obligations apply where a matter is not regulated under Law 1262 or the regulation.

In addition, the Supreme Council of Radio and Television is authorised to examine which radio and television ads breach the principles set out in the Law on Establishment and Broadcasting of Radio and Television Institutions (6112). As per Article 11/2 of the law, no advertisements for prescribed medical products or treatments can be broadcast. There are also three industry-based associations in Turkey – the Turkey Pharmaceuticals Industry Association, the Association of Research-Based Pharmaceutical Companies and the Pharmaceuticals Manufacturers Association – which have their own codes of promotional practices.

The fundamental rule is that it is strictly forbidden to promote pharmaceutical products for human use to the general public. Over-the-counter products are categorised as non-prescribed products and are subject to the same promotional principles as prescribed products.

While promotional activities are allowed for healthcare professionals, there are some strict rules. Certain pharmaceutical products can be given to healthcare professionals, but the presentation must include objective, informative and factual medical data to enable the healthcare professionals to form their own opinion about the product. The promotional activities must not be used to encourage the unnecessary use of a product and the promotion must be made by certified representatives. Further, it is forbidden to provide, offer or promise benefits by way of promotional activities, and advertisements directed at healthcare professionals must contain information that is consistent with the products approved and an updated summary of product characteristics.

Generic substitution

After the legal protection period (either the patent protection period or the data exclusivity period) has expired, generic pharmaceuticals can be released on the market. A generic pharmaceutical should contain the same active substance in the same quantity as the original and its bioequivalence with the original drug should be proven.

The substitution of an original product with its generic equivalent is forbidden unless the substitution was prescribed by a doctor. In other words, pharmacists are not allowed to substitute the original product without an explicit prescription from a doctor.

Online issues

Pharmaceutical trademarks may be registered and used on websites which are specifically designed for healthcare professionals given the strict advertisement prohibitions. The general public should not have access to such websites, so only healthcare professionals should be given the relevant passwords.

In Turkey, pharmaceutical products are sold in pharmacies only. The sale of pharmaceuticals online is a crime under Law 1262. **WTR**

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