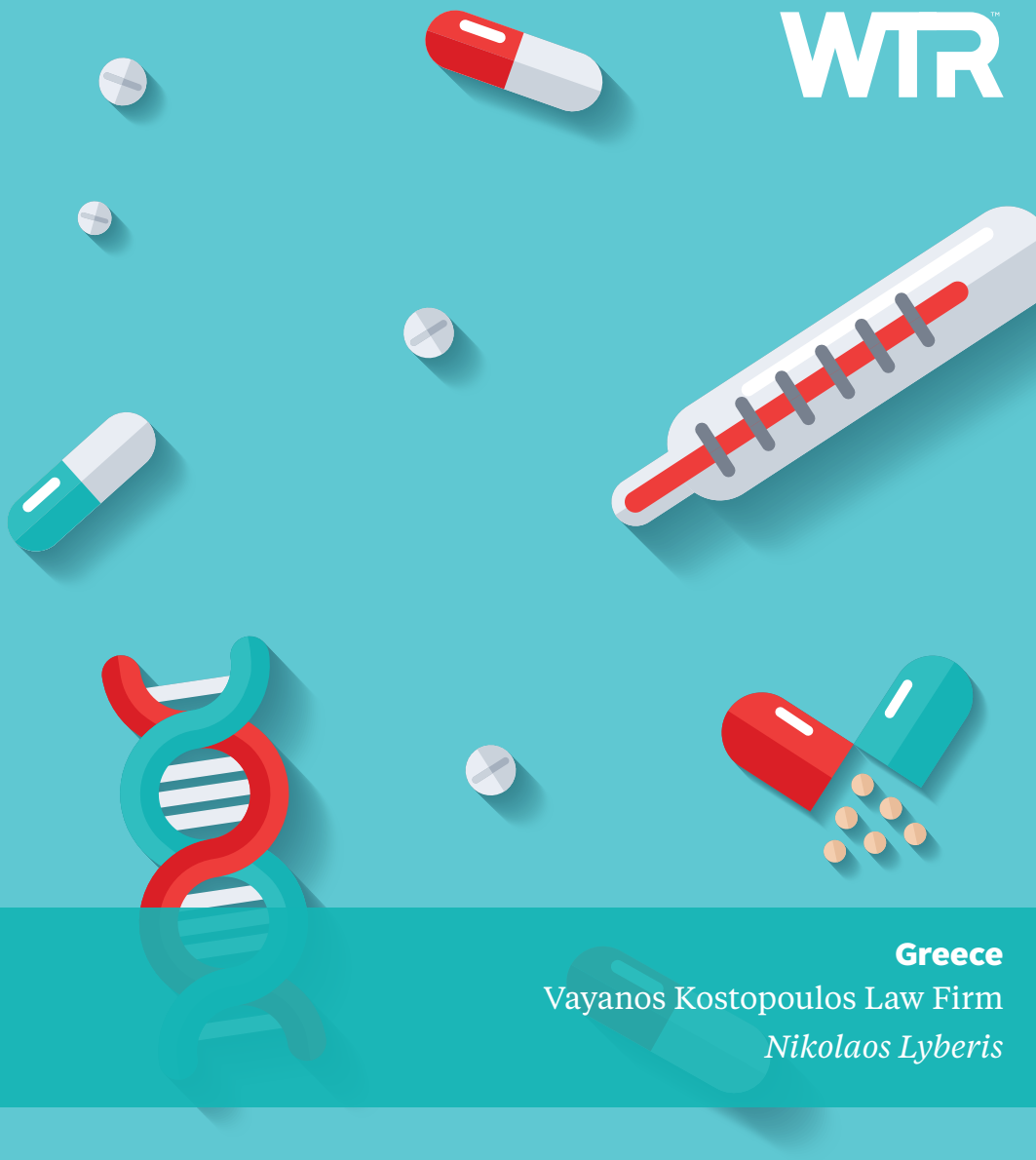

Greece

Vayanos Kostopoulos Law Firm

Nikolaos Lyberis

Pharmaceutical Trademarks 2020/2021

A Global Guide

Greece

Vayanos Kostopoulos Law Firm

Author
Nikolaos Lyberis

The strict austerity measures imposed on Greece's economy between 2010 and 2018 (known as the 'era of memorandums') began to gradually loosen from late 2018. The measures were considered necessary due to sovereign debt and high state-budget deficits. The situation had a significant effect on many areas, including:

- various aspects of public health policy, such as the restrictive pricing mechanism of medicines;
- limited state and pension fund contributions to global pharmaceutical expenditure;
- prescription policy based on active ingredients instead of on-patent drugs or even branded generics; and
- a drastic reduction of the net earnings of pharma companies through rebate and claw-back mechanisms.

According to Supreme Administrative Court Decision 3450/2015, rebate (ie, the retroactive reduction of the prices of medicinal products) is lawful given that manufacturers can control volume and predict sales. In the same ruling, the court confirmed that rebate is in compliance with the constitution, as it was introduced as an emergency measure in order to protect the sustainability of the public health system, which is a supreme goal of public interest.

The draft new trademarks law, transposing EU Directive 2436/2015 into Greek law, is expected to be enacted by the end of 2019. It is anticipated to have a positive impact on pharmaceutical trademarks (eg, by introducing new forms of trademark, such as motion, hologram or multimedia marks).

Selection, clearance and registration

The Greek pharmaceutical market is strongly regulated. The two authorities dealing with pharmaceutical trademarks are the Trademarks Office (TMO) and the Health Registration Authority (EOF). The TMO is competent for the examination, grant and maintenance of trademark rights in compliance with Greek, EU and international trademark law. The EOF regulates and enforces public health issues including the grant, suspension or withdrawal of market authorisations (ie, public order issues). In view of the different roles that these

two authorities must fulfil, it may happen that a trademark distinguishing Class 5 goods is granted by the TMO but is later reviewed and rejected by the EOF. This will be the case if, for example, a name for a medicinal product has been chosen that is considered to be similar to another medicinal product's name for which a market authorisation has already been granted for the treatment of a different disease and possible confusion results due to an oversight in the prescription or administration of either drug which could prove fatal to the patient.

The Institution of Examiners (in place of the three-member Administrative Trademarks Committee), which was introduced by the Trademarks Law 4072/2012 (amended by the Law 4155/2013), has accelerated the prosecution of a trademark application. The examiner has one month in which to raise any objections based on absolute or relative grounds of refusal. In the absence of such objections, the application is accepted and proceeds to e-publication in the TMO's official website for opposition purposes. The three-month opposition term begins on the date of e-publication. In the absence of opposition, the application is registered.

This clearance and registration procedure is generally short and reliable. However, infrastructure measures still need to be taken by the TMO regarding the back-office services and the update of data, including changes to legal status appearing in the TMview, which may in some cases be outdated or incorrect.

Access to the TMO's physical facilities (not the e-filing platform and website, which remain accessible) is not available on Thursdays, as of 6 June 2019 and until further notice. This should be kept in mind when a deadline for action (eg, for late submission of a priority document) falls on a Thursday. The TMO's announcement reassures that on request a relevant remark will be made by the competent officer if the documents are filed with the TMO on the next working day. This is, however, of ambiguous legal value, since the extension of a legal term falling on a usual working day (not a national holiday) can be provided for by substantial law (eg, ordinary law or a normative act in terms of a ministerial decree based on a legislative authorisation by Parliament), not by a mere announcement of a department of administration.

Absolute grounds for refusal

Cannabis trademarks are a recent topic that the TMO has had to deal with as far as absolute grounds for refusal are concerned. Before the introduction of legislation on medical cannabis the TMO basically invoked the rules of public policy to reject them. Recently, the TMO has adopted a neutral approach regarding medical cannabis products, applying already existing grounds of refusal:

- rejected applications opposing public order principles:
  - green iced-tea cannabis and device (class 32); and
  - cannabis and device (classes 32 and 33, conversion of a European trademark application);
- rejected due to descriptiveness and lack of minimum required distinctive character:
  - Cannabis Republic and device (classes 3, 16, 18 and 25); and
  - medical cannabis, simplified (classes 35, 41, 42 and 44); and
- accepted applications:
  - Cannabee and device depicting the cannabis plant (classes 30 and 33);
  - Cannabis Beauty (class 3); and
  - Medical Cannabis Cannamedica SA (classes 5, 31, 40, 42 and 44).

From a regulatory viewpoint, on 1 July 2019 the EOF announced that to date, no market authorisation had been granted for any cannabis product for medical use, but such procedures are pending. The EOF also clarified that the existing legal framework specifically concerns the final products of pharmaceutical cannabis of the cannabis varieties Cannabis Sativa L containing Tetrahydrocannabinol (THC) at more than 0.2% for medical use. However, it is a market reality that there are a number of shops that promote and sell edible or other unregulated cannabinoid products (eg, cannabidiol, cannabidiolic acid and cannabichromine) containing THC at less than 0.2%. The EOF is concerned that consumers may be misled into believing that such products might have preventive or healing properties that only authorised pharmaceuticals contain.

Relative grounds for refusal

When assessing the risk of confusion in pharmaceutical trademarks, case law takes into account various criteria, including:

- the degree of prevalence of the prior mark;
- the average consumer's perception; and
- whether it is a prescription or an over-the-counter medicine.

In *Aspirin v Anopyrin*, the first-instance administrative court rejected the application as being confusingly similar to the ASPIRIN mark. The court found that the opponent's mark enjoys protection due to the fact that it has a strong, distinctive character and has been long established in the pharma market without becoming generic. Further, consumer understanding cannot be confined to that of a pharmacist, but must also include the average consumer, especially if the compared marks are non-prescription pharmaceuticals. This finding concerning consumer understanding to include both medical professionals (eg, physicians and pharmacists) and the average consumer was also confirmed in *Roferon v Roverin Plus*.

In the case of a German collective trademark in *Pharmacy-A v KAN-PHARMA*, a local pharmacy in Crete was using the well-known 'A' of the German association of pharmacists, together with signs connected to the applicant's name (Kanakakis). On summoning a warning letter raising cease and desist claims, the applicant withdrew his trademark application and acknowledged the prior rights of the association.

Judicial review

Rejection by the examiner regarding a national trademark application or an international registration extension to Greece can be challenged through an administrative appeal before the Administrative Trademarks Committee (ATC), which will review the legal conformity of the decision.

The ATC's decisions are subject to recourse before the Athens ordinary administrative courts of first and second instance. Adjudication before said courts is subject to strict admissibility requirements which need special attention by the proxy attorney and may render judicial review burdensome for interested parties, especially those from foreign jurisdictions different from the domestic one. Such admissibility requirements include, among other things, full documentation with regard to:

- the power of representation of the involved legal entity (eg, a pharma company) through a person such as a CEO, CFO or another party specifically authorised to represent the company; and
- the statutory power of said legal representative to grant authorisation to an (external) attorney to file legal means on behalf of the company before (foreign) courts.

INN protection

One of the major structural reforms by the memorandums referred to the international non-proprietary name (INN) prescription as the main instrument for the penetration of generics in the Greek pharma market.

According to prevailing case law, signs consisting exclusively of an INN are devoid of any distinctive power and relevant trademark applications are rejected on absolute grounds. There is no unanimous approach of case law when signs consist of invented names resembling INNs to a varying degree, or containing word elements that are included in INNs (so-called 'stems') to indicate that the active ingredients belong to a group of pharmaceuticals with similar pharmacological activity. As such, an opposition against a trademark application for TIMANIB was rejected although it resembled the INN 'imatinib'. The opponent filed a recourse against the rejection and the applicant subsequently abandoned TIMANIB. The trademark application for LEFLOXACIN was rejected as an abbreviation of the INN 'levofloxacin'. However, an opposition versus trademark application for SPORILEN based on the INN stem '-sporin' was rejected. An opposition against trademark application RIVASTIPLUS based on the INN stem 'rivasti-' of the INN 'rivastigmine' was rejected. A recourse hearing is pending. The decision on the recourse filed against the decision that accepted trademark application VALSADIVOL is awaited, in view of its approaching similarity to the INN 'valsartan'.

Non-traditional trademarks

Although the new draft trademarks law, prepared in light of EU Directive 2436/2015, contains

provisions for the abolishment of the graphic representation and the introduction of new forms of trademark, it still remains to be seen how case law will apply such legislative novelties.

Slogans

Advertising slogans were introduced as registrable trademarks by Law 4155/2013 and are gaining importance for branding and the promotional policies of pharmaceuticals. Case law has started forming the criteria to be applied for the acceptance of such trademark applications. Given that slogans are phrases composed mainly of common words, their registrability is not always predictable and many such applications are addressed to be adjudicated by the higher trademark courts. In principle, the trademark courts tend to reject pharmaceutical slogans which are deprived of even the slightest distinctiveness in terms of origin indicator. The choice of the words *per se*, their particular sequence and the need for elaborate thought in order to convey the message to the consumer, are some of the tests applied by the courts. As such, the slogan 'Η Χαρά της Κίνησης' meaning 'the joy of movement' (for a pain reliever) was accepted for registration by a decision of the second-instance administrative court. Likewise, accepted was the slogan 'lose weight, gain life' (for a diabetes treatment). However, the trademark application for the slogan 'Αλλάζουμε το διαβήτη' and a colour device (meaning 'changing diabetes') was rejected by the ATC due to a lack of the minimum required distinctive power and a recourse is pending before the first-instance administrative court.

Parallel imports and repackaging

In Greek law and case law following the principle of European exhaustion (of the European Economic Area), the re-packaging of parallel imported pharmaceuticals can be prohibited by the trademark owner if the state of the goods is altered or has deteriorated as soon as they are put into circulation.

If trademark infringement is proven various enforcement possibilities are made available to the rights holder, such as cease and desist claims, withdrawal of infringing goods, destruction of the goods, damage claims, removal of the trademark from the goods, publication in the press of the court's decision in summary, as well as criminal law penalties (Articles 150, 156 and 157 of the Trademarks Law).

Anti-counterfeiting and enforcement

According to Article 182 of Law 4512/2018, mandatory mediation was introduced as an admissibility requirement for every lawsuit against trademark infringement. However, severe doubt was expressed by involved parties regarding adding unnecessary costs to the proceedings and forcing claimants and defendants to make steps even in cases where none would be willing to follow. Consequently, this measure was suspended until September 2019 in order to enable its careful review. It is

Nikolaos Lyberis
Partner
n.lyberis@vklaw.gr

Nikolaos Lyberis is an attorney at law admitted at the High Courts of Administrative and Civil Matters. He holds a PhD in European economic law from the University of Hamburg. As the managing director of the oldest and one of the leading IP law firms, Dr Lyberis specialises in litigation for trademarks, patents and other IP rights. He also handles contract law, IP licensing, consumer and unfair competition matters. Dr Lyberis lectures regularly on IP law at the Law School of the European University Cyprus. Between 2014 and 2015 he served as a member of the board of directors of the Greek Patent Office and as a member of legislative committees on trademarks law. Dr Lyberis has authored numerous articles on key topics of IP law and is fluent in German and English.

supposed that mediation will be re-introduced as an optional procedure for the benefit of the involved parties and the system as a whole.

Advertising

Prescription pharmaceuticals

The advertising, in any way, of prescription pharmaceuticals is prohibited, including medical cannabis products. Offering samples of such products to the public – even for free – is not permitted.

According to Article 258 of Law 4512/2018, use of the word 'φαρμακείο' (pharmacy) *per se* or of its derivatives, as well as the sign of the green cross in every variation are reserved for legally licensed pharmacies. Accordingly, any violation is fined €15,000, or €30,000 in case of repeated violation.

Generic substitution

Generic substitution by pharmacists was introduced in compliance with Greece's first memorandum of understanding with the country's international lenders (Law 3845/2010). This rule was challenged before the Supreme Administrative Court which, by virtue of Decision 3802/2014, confirmed its conformity with the constitution. In the same ruling, INN prescription was found to be constitutional. Pharmacists are obliged to deliver to the patient the most inexpensive pharmaceutical containing the prescribed active ingredient. Such a pharmaceutical is chosen from the so-called 'positive list', meaning the list of products that are classified as reimbursed as opposed to those which are not reimbursed (Law 3816/2010).

As an exception, the prescribed substance may be referred to in combination with a branded product in two categories of case:

- for certain limited categories of cases of pharmaceuticals provided by the law (eg, drugs potentially causing allergies or other reactions); and
- in case of patients suffering from chronic diseases (eg, cardiovascular disease).

In exceptional cases where the active ingredient may be accompanied by a branded pharmaceutical, the doctor must provide explicit reasoning, which is to be entered in the electronic prescription system (IDIKA, Law 3892/2010). These exceptions are allowed for up to 15% of the doctor's prescriptions. In case of violation of the INN prescription rule, a penalty is provided for against doctors. The cost of medicines going beyond the level of INN prescriptions must be borne by patients.

The Supreme Administrative Court (Decision 1749/2016 (in plenary session)) found that Law 4052/2012 (the second memorandum of understanding) was anti-constitutional by content, thus abolishing *de facto* the 15% upper prescription limits for branded products and rendering the INN prescriptions by physicians inactive until further notice.

Online issues

Establishing e-pharmacies is exclusively permitted to pharmacists who are holders of a licence to establish and operate a pharmacy (Law 4316/2014). Implementing provisions have also been issued. However, there is a considerable number of pharma e-shops that operate without fulfilling the minimum legal requirements. This is due to the lack of proper market supervision, which must be intensified.

In the infringement case *Ikea v ikeapharm.gr*, the rights holder was a relative of the pharmacist. The rights holder was using images of Ikea transport vans in connection with the promotional idea that his products were delivered to the home of consumers. The choice of the word 'Ikea' was attributed to the fact that 'ikia' in Greek means 'home' and pharmacies often deliver their products to the homes of older or infirm people who cannot visit a pharmacy themselves. On suing the domain holder, he announced that he would change his website address and would comply with the trademark owner's rights. WTR

Vayanos Kostopoulos Law Firm
37 Stournara Street
Athens 106 82
Greece
Tel +30 210 38 08 501
Fax +30 210 38 16 685
Web www.vklaw.gr