Germany

Meissner Bolte Patentanwälte Rechtsanwälte Partnerschaft mbB
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Pharmaceutical Trademarks 2020/2021

A Global Guide

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Selection, clearance and registration

On 21 February 2018 the Federal Patent Court held that the registration of the mark WUNDTHERAPIEZENTRUM, which is composed of three simple German words ('wund', 'therapie' and 'zentrum') in the usual linguistic and grammatically correct manner, is exhausted in a plainly descriptive reference to a therapy centre for wound treatment (Case 30 W (pat) 548/18).

The court ruled that the difference in the colours of the letters was insufficient to confer a distinctive character on the mark. The internal capitalisation – 'WundTherapieZentrum' – and font was also a common means of design widely used in product advertising, and was therefore insufficient to attribute to the trademark, by means of its figurative design, a function indicating its origin.

In contrast, on 22 November 2018 the Federal Patent Court decided that the stylised trademark GESUNDHEIT4FRIENDS is eligible for registration for pharmaceutical products, among other things (Case 30 W (pat) 42/16).

The court found that the graphic representation of the sign expressly applied for in black and white consisted of a number '4' in two different shades of grey, placed between the word elements 'gesundheit' ('health') and 'friends'. The size was clearly distinct from that of the word elements, in which crossing and contrasting coloured lines are perceived as representing a cross because of their separation from the vertical and horizontal lines of the number '4' and because of their contrasting colour in a much lighter shade of grey. The graphic element of the sign is therefore perceived as a whole as figure '4' with the integrated representation of a cross.

Confusion with INNs

International non-proprietary names (INNs) are used to identify pharmaceutical substances or active pharmaceutical ingredients and to provide health professionals with a set of international standards. The INNs are assigned by the World Health Organisation and can be used freely because they are in the public domain.

The use of INNs has an impact on the filing of trademarks comprised of INNs when assessing the likelihood of confusion.

On 20 July 2018 the Federal Patent Court found that a likelihood of confusion existed between the trademark ELYSIA AL and the opposing trademark ELIZA HEXAL (Case 30 W (pat) 1/16). The first element has an average inherent distinctiveness in relation to the relevant goods in the present case. In particular, 'Elysia' contains no descriptive echo of an active substance name (ie, INN) which weakens the distinctive character, particularly not of the oestrogen ethinylestradiol or estradiol normally present in contraceptives. To the extent that 'Elysia' is a female forename derived from Greek and Roman mythology and based on the ancient Greek term 'Elysium' meaning a 'state of perfect happiness', it is highly unusual that it would not be known either to the general public or specialised trade. Moreover, as in the case of the opposing mark ELIZA, the meaning of 'Elysia' did not affect the ability of that element to be perceived by the relevant public as a means of distinguishing the goods in question. The further component of the mark 'AL' is a company addition of the manufacturer, which is recognisable in the trade. In any event, it is only the element 'Elysia' of the challenged mark which is to be taken into account and the opposing mark shows a clear convergence in the sound image. With regard to the opposing trademark ELIZA HEXAL and the challenged trademark, there is a sufficient difference due to the different company-related additions 'HEXAL' and 'AL', which are known to the trade, and the differences between the components 'elysia' and 'eliza'.

On 4 April 2019 the Federal Patent Court decided that the trademarks CONTRACEP und CONTRAGEL are not confusingly similar with regard to pharmaceutical preparations (Case 30 W (pat) 512/17). Even if the element 'contra' could be protected because it was neither a common abbreviation nor a verifiable abbreviation of the term 'contraceptive', the mark cited in the opposition was ultimately limited to a combination of an element 'contra' with the generally known and widely used addition 'gel', which had no distinctive significance as an indication of the pharmaceutical form. Even though the opposing trademark as a whole could be protected, overall it clearly had below-average distinctiveness.

Non-traditional trademarks

Along with the introduction of the new EU trademark regulation, from 1 October 2017 (or since 14 January 2019 in Germany) the graphical representation requirement no longer applies when submitting a trademark application.

Since that time, a number of new trademark types (ie, multimedia marks and motion marks) have been filed seeking protection for pharmaceutical preparations in Class 5. In particular, Sanofi filed a number of motion marks for pharmaceuticals in Class 5.

A motion mark is a trademark consisting of, or extending to, a movement or a change in the position of the elements of the mark. A multimedia mark is a trademark consisting of, or extending to, the combination of image and sound.

It is now possible for both trademark types to file a video file or an audiovisual file containing the combination of image and sound.

So far, uncertainty exists with regard to the requirements for protection and the scope of protection of such trademarks since, to date, there has been no opposition, cancellation or infringement decisions available.

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A trademark owner may oppose a modification which involves any repackaging of a pharmaceutical product bearing its mark, which, by its very nature, creates real risks for the guarantee of origin of the pharmaceutical product

However, it remains to be seen how the applicants will accept the new possibilities.

Parallel imports and repackaging

In the European Court of Justice (ECJ) judgments of 11 July 1996 (Cases C-427/93, C-429/93 and C-436/93: Bristol-Myers Squibb, C-427/93, C-429/93 and C-436/93), the ECJ issued a milestone decision regarding the requirements of the exhaustion of rights of repacked pharmaceutical products. According to this decision, a trademark owner may oppose a modification which involves any repackaging of a pharmaceutical product bearing its mark, which, by its very nature, creates real risks for the guarantee of origin of the pharmaceutical product, unless five conditions are met:

- It is established that the use of the trademark rights by the trademark owner to oppose the marketing of the re-labelled products under that trademark would contribute to the artificial partitioning of the markets between member states;
- It is shown that the repackaging cannot affect the original condition of the product inside the packaging;
- The new packaging clearly states who repackaged the product and the name of the manufacturer;
- The presentation of the repackaged product is not such as to be liable to damage the reputation of the trademark and of its owner, thus the packaging must not be defective, of poor quality or untidy; and
- The importer gives notice to the trademark owner before the repackaged product is put on sale and, on demand, supplies it with a specimen of the repackaged product.

In *Debrisoft*, the German Supreme Court asked the ECJ whether the abovementioned principles were to be applied without restriction to the sale of repackaged medicinal products (ie, whether the sale of repackaged medicinal products cannot be prevented by the trademark owner only if all five conditions are fulfilled (6 October 2016, Case I ZR 165/15)).

The ECJ had previously decided that the term 'repackaging' included re-labelling.

In the present case, only an additional sticker was affixed which, in terms of content, function, size, presentation and placement, did not pose any risk to the guarantee of origin of the manufacturer's trademark. The mere affixing of such a sticker does not constitute repackaging.

Moreover, the statements made by the ECJ in its judgment in Case C-642/16 (17 May 2018), according to which the existence of repackaging should depend on the specific circumstances of the individual case, such as content, function, size, presentation and placement of the sticker, contradicted its previous view, according to which only the dangers inherent in the changes made should be taken into account.

The Federal Supreme Court has now implemented the ECJ guidelines issued following Case I ZR 165/15, *Debrisoft II* (11 October 2018). The ECJ decided that a trademark owner cannot oppose further marketing of a medical product in its original internal and external packaging by a parallel importer where the importer has affixed an additional sticker which, by virtue of its content, function, size, presentation and placement, does not pose a risk to the

guarantee of origin of the medical product bearing the trademark.

Based on the findings of the Federal Supreme Court, in Case 6 U 37/18 (7 March 2019) the Frankfurt Higher Regional Court decided that a trademark owner cannot, in principle, oppose marketing in Germany on grounds that the importer has affixed to the packaging a small sticker bearing its own central pharmaceutical number (PZN). That is also the case where that sticker conceals a label on the packaging bearing the trademark owner's particulars, in particular the name of the distributor, of which the trademark is a component. It does not matter whether the importer is dependent on this PZN for distribution in Germany.

On 20 December 2018 (Case 6 U 129/18), the court found that parallel imported medical devices (in this case, patches) were offered by the trademark owner in Germany in only one package size, but the parallel imported product was available only in other package sizes.

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In such situation, the parallel importer may produce new outer packaging, provided that the specific design does not damage the reputation of the trademark from the consumer's point of view. In particular, such damage to reputation cannot be seen solely in the affixing of a sticker with a PZN of the parallel importer.

Anti-counterfeiting and enforcement

Counterfeiting in medicines is a major threat to public health; it diverts resources from healthcare budgets and produces economic and social challenges to pharmaceutical companies.

As such, the term 'counterfeit' is used broadly, referring to medicines that are deliberately produced at sub-standard quality, fraudulently labelled with respect to their identity or origin, or otherwise tainted, adulterated or made ineffective or harmful. Fundamentally, counterfeit medicines are neither regulated nor quality controlled and therefore should be expected to be inferior as they move outside the safety of established, regulated supply chains.

As from 9 February 2019, for medicinal products subject to Directive 2011/62/EC in conjunction with EU Commission Delegated Regulation 2016/161 amending Directive 2001/83/EC, a unique identifier must be included on the packaging, as well as an anti-tempering device.

Prescription medicine products for human use, as well as parallel import products, may be placed on the German market only if the outer packaging bears safety features and a device to indicate possible tampering with the outer packaging.

Advertising

The requirements regarding health-related advertising are strict. Advertising is admissible only if the information that it contains is accurate, unambiguous and clear.

According to Section 10 of the Act on Advertising in the Field of Health, prescription-only medicinal products may be advertised only to doctors, dentists, veterinarians, pharmacists and persons authorised to trade in such medicinal products.

On 27 September 2018 the Stuttgart Higher Regional Court decided (Case 2 U 41/18) that the aforementioned provision is also applicable with respect to pharmaceutical compounding. Pharmaceutical compounding is the creation of a particular pharmaceutical product to fit the unique need of a patient. In the specific case, a pharmacist offered pharmaceutical compounding on its website.

The court also provided some guidance on the distinction between product-related advertising which is regulated by the Act on Advertising in the Field of Health, and general

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corporate advertising which is not subject to the act.

The aim of the Act on Advertising in the Field of Health is to avoid that a particular product could be misused or used without medical supervision, in particular where the public cannot assess the effects and adverse reactions. Moreover, it should avoid enabling the addressee of the advertisement to request the prescription of a particular medicinal product during visits to the doctor.

In contrast, corporate advertising is intended only to indirectly promote the sale of the company's products and not to draw the attention of the public to certain drugs.

Generic substitution

In Germany, generic substitution is not prohibited. Indeed, it is promoted in order to reduce costs in the healthcare system.

Pharmacists in Germany may soon be able to carry out automatic substitution of biosimilars. A biosimilar is a biologic-approved medical product that is almost an identical copy of an original product that is manufactured by a different company when the original product's patent expires. Unlike with generic drugs of the more common small-molecule type, biologics generally exhibit high molecular complexity and may be quite sensitive to changes in the manufacturing processes.

In November 2018 the Health Ministry introduced a draft bill on safety in the supply of pharmaceuticals, which aims, among other things, to provide a legal framework for the automatic substitution of biosimilars by pharmacists in Germany. The new law was introduced in order to increase adoption of biosimilars, due to the huge potential for cost savings. As few EU countries currently allow pharmacist substitution of biosimilars, this would represent a significant change in practice, particularly for Germany.

The law has still to be approved by the Federal Council and is due to enter into force mid-2019.

Online issues

On 18 January 2019 the Magdeburg District Court (Case 36 O 48/18) held that a pharmacist is allowed to sell prescription-free behind-the-counter drugs via the 'Amazon.de' trading platform.

The court ruled that although Amazon provides customer ratings – both for the medicines and the pharmacy itself – this does not result in a violation of the regulations on the advertising of medicines.

The trading platform is different from an online shop operated by a pharmacy owner, it incorporates further advertising elements in addition to the product description designed or selected by the seller. Nevertheless, the court assumed that the defendant had not violated the regulations regulating the pharmacist's advertising, because these are statements which cannot be attributed to the defendant and could also be seen by the consumer. The customer ratings were marked as such and were not attributed to the seller by the internet user.

Further, the court found that the main difference between placing an offer on the pharmacy owner's own online shop and using the Amazon trading platform is the fact that the trading platform influences the appearance and presentation of the drug.

Insofar as the presentation of the drug itself is affected, the court did not consider a

violation of legal regulations to be apparent. The seller decides on the presentation by either providing the pictures and information or by joining the presentation designed by another seller – who must also be a pharmacist. In the event of incorrect descriptions, the defendant may decide not to offer the product via Amazon. WTR

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