The IP Media Group

European Union

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BEST Rechtsanwälte

Pharmaceutical Trademarks 2015/2016

World Trademark Review

A Global Guide

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Industry experience in private practice

Since 1999, BEST Rechtsanwälte in Frankfurt am Main, Germany, offers highly professional, competent and practical advice in the fields of intellectual property law and unfair competition. The main areas of expertise of this IP boutique are:

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- **Design Law**
- **Domain Law**
- **Law of Unfair Competition**
- **Copyright Law**
- **Data Protection Law**
- **Litigation**

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The partners, Dr. Michael Best and Udo Pfleghar, have a strong background in this field, having both also worked as in house counsel for many years. Together with three further highly qualified attorneys and a well trained team of paralegals and assistants, they provide service of the highest quality.

The firm represents and advises numerous multinational companies from the pharmaceutical, chemical, automotive, cosmetics and fashion sectors as well as utility companies and small and medium sized enterprises.

The services of the firm relating to trademarks and designs include legal availability searches, filing and prosecution, opposition proceedings and litigation. The firm also negotiates and drafts license agreements, assignments and prior rights agreements and carries out trademark collision watches.

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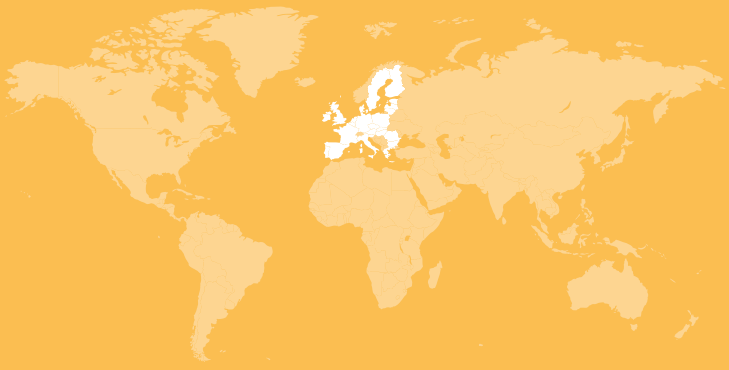

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Developing new names for pharmaceutical products in the European Union is an increasingly complex task which requires attention and know-how at all stages, from creation of the names to their submission to the regulatory authorities. This chapter retraces the process from the final marketing authorisation back to the creation of the name, highlighting the potential pitfalls to be considered and overcome.

Choosing an acceptable name

The development of names for pharmaceutical products is largely influenced by regulatory rules. This applies to invented names – as opposed to generic names or international non-proprietary names (INNs) – for pharmaceutical preparations to be marketed at a national level, but even more so to preparations that shall be marketed at EU or even global level. Not only can pharmaceutical companies obtain an EU-wide (centralised) marketing authorisation for new products, but in many cases it is compulsory to file a marketing authorisation application with the European Medical Agency (EMA). Under EU Regulation 726/2004, which governs the centralised marketing authorisation procedure, this particularly applies to:

- products developed by certain biotechnological processes;
- advanced therapy medicines (eg, gene therapy, somatic cell therapy or tissue-engineered medicines);
- products containing a new active substance that was unauthorised in the European Union at the time the regulation entered into force and with therapeutic indication for treatment of certain diseases (eg, cancer, diabetes, HIV);
- veterinary medicines for use as growth or yield enhancers; and
- products designated as orphan medicinal products pursuant to EU Regulation 141/2001 (ie, medicines used for rare human diseases).

If successful, the pharmaceutical company will be granted a marketing authorisation that is valid in both the European Union and the European Economic Area (EEA) (ie, Iceland,

Liechtenstein and Norway). There is also an option for pharmaceutical companies to apply for a centralised marketing authorisation for medicines comprising a significant therapeutic, scientific or technical innovation, or whose authorisation would be in the interest of public or animal health.

Applying for a uniform EU marketing authorisation requires the submission of a single name to be used for the product throughout the European Union (Article 6 of the regulation). The European Commission will grant a derogation from this principle only in exceptional circumstances. One of the EMA's key roles is to ensure the safety of the medicinal products for which marketing authorisation is sought. To achieve this, the EMA Name Review Group (NRG) evaluates the submitted invented names for a new medicinal product under the aspects of safety and public health, in particular with respect to potential medication errors. The relevant member state authorities are involved and can raise objections and comments with respect to the proposed invented names; such objections and comments are then taken into consideration during the NRG's review of the proposed name(s). The main criteria for the NRG review are that the invented name of a medicinal product should: "1. not be liable to cause confusion in print, handwriting or speech with the invented name of another medicinal product, 2. not convey misleading therapeutic and/or pharmaceutical connotations, and 3. not be misleading with respect to the composition of the product." In order to determine whether these criteria are met, the NRG looks into various aspects such as the indication, the patient population, the pharmaceutical form and the route of administration. Further, the invented name shall not be derived from an INN – as assigned to an active pharmaceutical substance by the World Health Organisation (WHO) – and shall not include an INN stem (which signifies a certain therapeutic class) in the stem position attributed to it by the WHO. A number of further rules must also be complied with to make a trademark acceptable as an authorised invented name in a centralised EU marketing authorisation procedure.

The NRG assessment is fully independent from any consideration of similarity or infringement under trademark law. Thus, even invented names that are fully cleared from a trademark perspective may be blocked by potential safety issues detected by the NRG in its evaluation process.

As a result, pharmaceutical companies must develop names for their new medicinal products that not only are available throughout the European Union (ie, do not infringe or conflict with earlier third-party rights), but also are medically safe throughout the European Union. The latter aspect substantially complicates the name-finding process and leads to much frustration in cases where legally cleared trademarks are submitted to the EMA as invented names for new products, but are rejected on the basis of safety concerns raised during the name review process. The EMA's rejection rate for submitted names is close to 50%. Hence, during the name creation and evaluation process, pharmaceutical companies must not only consider the potential legal conflicts, but also conduct additional medical safety testing. This substantially complicates the process and makes it much more expensive. Despite such precautions, the EMA still rejects many proposed new invented names and it is thus necessary to have at least one (ideally more) back-up candidates available for submission should the first candidate be rejected.

Court rulings on drug names

The process described above and the associated risks become relevant only if the name has not been blocked at an earlier stage under trademark law. There are many potential hurdles to be crossed. Absolute grounds for refusal could apply if the names concerned are descriptive or devoid of distinctive character. However, this is not normally the major issue for prescription medicines. Rather, problems could arise regarding relative grounds for refusal and likelihood of confusion. During 2014, the EU courts ruled on this subject in a number of interesting decisions.

In *METABOL/METABOL-MG* (Case T-486/12, June 11 2014) the General Court issued a judgment in which it confirmed a likelihood of confusion between the marks METABOL

and METABOL-MG. This was based on the finding that the signs shared the common element 'Metabol', and that the additional 'mg' element played only a minor role in the overall impression created by the marks. The court rejected the argument that the weak word element 'metabol' (a rather obvious reference to 'metabolism') should not be monopolised by one company, holding that the validity of national trademarks may not be challenged in opposition proceedings. A likelihood of confusion was found to exist despite the weak distinctive character of the earlier mark.

On the same date, in *METABIOMAX/BIOMAX* (T-62/13), the General Court also found the existence of a likelihood of confusion, stating that the signs to be compared were visually and phonetically similar. Although situated at the beginning of the mark, the additional element 'meta' did not offset this similarity. Instead, it was held to be a common prefix that would not attract consumers' attention more than the element 'biomax', which was common to both marks. The court also upheld the finding of the Board of Appeal of the Office for Harmonisation in the Internal Market that the marks were conceptually similar, as they both referred to 'biology' and 'maximum'.

Also on the same date, the General Court issued its decision in *METABIOMAX/METABIAREX* (T-281/13). In this case, the court ruled on the scope of the German term '*Arzneimittel*', finding that the board had mistakenly limited its meaning to "medicines for human purposes". The court found instead that these goods are identical to "pharmaceutical preparations" and "veterinary preparations", and highly similar to "sanitary preparations" and "disinfectants", as '*Arzneimittel*' was held to be a general reference to drugs. The two signs were found to share the first five letters and the last letter, and their two first syllables. Further, the court held that the pronunciation of the syllable 'bia' was similar to the pronunciation of 'bio' for German-speaking consumers. While the contested mark was held to be laudatory and referred to 'biology' and 'maximum', no content was recognisable in the earlier right. This led to the finding that a low degree of similarity existed between the marks. Due to the high degree of similarity of the goods, which offset the low degree of similarity of the marks, a likelihood of confusion for pharmaceutical and veterinary preparations, sanitary preparations and disinfectants was found to exist.

In *OCTASA/PENTASA* (T-502/12, April 9 2014) the General Court assessed the board's ruling that the suffix 'asa' was descriptive. It held that the board had failed to establish such descriptive character from the perspective of the relevant end users. The board had relied, among other things, on an extract from Wikipedia. The court confirmed settled case law that a Wikipedia extract lacks certainty as a source of information. In addition, there was no reason to find that the medical publications submitted by the Community trademark applicant and taken into account by the board would be read by end users of the pharmaceutical preparations. The court also held that the principle that the first component of word marks may be more likely to catch consumers' attention than the following components cannot apply in all cases – the overall impression created by the signs is relevant. In this case the signs were held to show a certain degree of visual and phonetic similarity; while from a conceptual point of view, consumers would not understand the suffix 'asa' as a reference to mesalazine. For end users unaware of the Greek numbers represented by 'penta' and 'octa', there would therefore be no conceptual content at all. Interestingly, it was held that for end users who recognised the reference to Greek numbers, this would make the signs conceptually similar for that reason alone, even if this similarity was weak, since the numbers were different. The General Court concluded that the board had erred by finding the signs OCTASA and PENTASA to be dissimilar.

In *FEMIVIA/FEMIBION* (T-324/13, July 16 2014) the General Court held that since the marks in question covered all member states, examination could not be limited to the English-speaking public. Instead, the court confirmed that the board had been entitled to limit its assessment to the Spanish-speaking portion of the public for reasons of procedural economy. While the prefix 'fem' was considered to be weak, as it would be seen as a reference to '*femenino*', the court held that

it could still hold an autonomous position in the overall impression created by the mark and therefore the signs had to be taken into account in their entirety. Thus, the finding of an average degree of visual similarity and a high degree of phonetic similarity between the signs was confirmed. In view of the identical nature of the goods, the similarity of the signs was found sufficient to confirm the existence of a likelihood of confusion. The court held that although the relevant consumers might be more attentive to the identity of the producer or provider of the goods, this did not mean that these consumers would examine the marks concerned in detail, or even compare the marks against each another in great detail.

These 2014 decisions demonstrate the complexity of the factors which may influence a finding of likelihood of confusion by the EU courts. As at the regulatory level, the risk of candidates failing due to conflicting earlier rights from the point of view of trademark law is also very real.

Avoiding rejection

As the case law demonstrates, close attention must be paid to names filed as trademarks for pharmaceutical preparations and the scope of protection sought for these marks. In terms of goods – pharmaceutical preparations in Class 5 and medical apparatus in Class 10 – or even services such as clinical trials, applications should

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Udo Pfleghar studied and trained in Melbourne, Australia and Regensburg, Germany. He joined the Office for Harmonisation in the Internal Market (OHIM) in 1999, where he worked as a Community trademark examiner and an instructor. After leading the Boehringer Ingelheim domain and trademark group, in 2009 he joined BEST Rechtsanwälte as a partner. He deals with questions relating to trademark, design and domain law, as well as data protection issues. Mr Pfleghar is a lecturer in law at the University of Applied Sciences in Frankfurt am Main and a panellist for '.eu' alternative dispute resolution proceedings. He is a member of the Law Committee of ECTA, MARQUES and other professional organisations.

be filed to claim the relevant goods without making the specifications too narrow or too wide.

The signs themselves must also be carefully considered, looking at both possible meaning and a lack thereof in EU member states. The results should then be used to determine the relative strength or weakness of the signs or parts thereof, as this can be of crucial importance in a potential conflict.

These complexities mean that a first-choice name and possible back-ups should be chosen in order to clear both the legal and regulatory hurdles. Acceptance can be ensured only by carefully screening the names for availability within the European Union. Such screening should cover all relevant trademark registers – Community trademarks, the World Intellectual Property Organisation and the Benelux and national offices – as well as databases covering pharmaceutical names on the market, generic names, domain names and company names. These registers should be screened by specialised companies and the results analysed by legal advisers, all with experience in the pharmaceutical field, as the naming and clearance process is quite different from that in other industries.

Carrying out all this screening requires substantial time and resources. Therefore, projects for the creation of pharmaceutical trademarks covering the European Union should – if possible – always be given sufficient time. Only then is it possible to carry out the screening and searches in the most economically possible way: by cascading the candidates. Often, the first phase of the search will cover the home country of the pharmaceutical company driving the project. Possibly, some key markets may be added at this stage if time is short. If not, only the candidates which remain feasible once the relevant registers for the home country have been checked will proceed to the second phase, which will cover key countries and markets. Only those candidates which survive this search will then move forward to the third phase, which could cover the remaining EU and EEA states. Should the mark also be intended to be used outside the European Union – which is frequently the case – the search must also be extended to these countries at some stage during the process. Even when the candidates are cascaded, this is a long and costly process and many candidates will not proceed all the way.

It is thus necessary to ask the name creation agency to create a sufficiently high number of available candidates and – should too many candidates fail along the way – to create more names to replace those which were found to be unavailable without charging additional fees. Here also, sufficient time should be calculated – even to include some leeway for another creation and screening round.

To ensure that pharmaceutical trademarks can be launched in Europe, all of these steps must be strategically planned and coordinated, making use of in-house expertise and expert advisers from the earliest possible stage. This should prevent unnecessary hold-ups and pitfalls, and ensure that all aspects which come into play are considered.

If marketing, the name creation team and legal and regulatory advisers work together closely from an early stage, this can result in a speedy and cost-efficient process, in which the risk of failing to obtain an acceptable name for the product can be reduced as far as possible. **WTR**

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