International Update

BRAZIL

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On 22 December 2017 came into force the National Sanitary Surveillance Agency's (ANVISA) Service Orientation no. 43/2017 (OS 43/17), establishing objective and detailed criteria for evaluation and analysis of the registration and posterior modifications of name of drugs and biological products before ANVISA, to be executed by the General Drugs and Biological Products Management (GGMED). Such Service Orientation complements the prior Board of Directors' Resolution RDC no. 59/2014 – that establishes the criteria for drug name creation.

According to OS 43/17, ANVISA's analysis for granting new drug names shall gradually adopt the following procedures: (i) research in the POCA system, which comprises the ANVISA's database, and identifies graphic and phonetic similarities with previous marketing approvals; (ii) research in drugs database (Datavisa); (iii) research in the Brazilian Trademark Office's database, to verify the application/registration of the trade mark; (iv) evaluation, by the examiner, of graphic and phonetic conflict with prior marketing approvals in ANVISA's database; (v) search for eventual mistakes and (vi) evaluation of the safety of the proposed name, taking into consideration the risk of error in its prescription, distribution, administration or use.

The analysis will be performed in Portuguese and, in case of conflict, the following elements shall be considered: (i) intended use; (ii) directions on how to use; (iii) how it works; (iv) its benefits; (v) risks associated to its use; (vi) measures to ensure its safe use; (vii) its technical features, such as: name, Active Pharmaceutical Ingredient (API), indication, how to administer, frequency and quantity, target, restrictions, history of similar cases, previous orientations from the Board of Directors, among others.

If a conflict between drug names is identified, and based on the above-mentioned criteria, GGMED will analyze the risk of error or misleading prescriptions, with the help of a flowchart and a risk matrix. The flowchart helps in identifying the name availability and registrability, while the risk matrix provides a detailed analysis of the graphic and phonetic elements of the intended name and the potential conflicts with other already registered names. These tools aim to reduce subjectivity on the drug name analysis. If the possibility of confusion is confirmed, the comparative analysis will also take into consideration the distribution, administration and/or how to use it.

According to the OS 43/17, the registration of the name will be rejected only if there is risk of confusion, even if there is similarity between two names. The risk of confusion is the leading and predominant element in ANVISA's analysis.

It is possible to file the application form presenting more than one name option for registration. The analysis will follow the priority established by the applicant and the alternative name is analysed only after the final decision concerning the rejection of the first name option is rendered and sent, with its grounds, to the applicant. If the applicant identifies possible conflicts before filing its application, it is possible to present relevant information to the examiner, to increase the chances of registration.

On 27 February 2018, GGMED hosted a meeting with trade associations to clarify several aspects regarding the application of the OS 43/17, the flowchart and the risk matrix.

Lastly, it is important to point out that the registration of the drug name before ANVISA does not substitute registration before the Brazilian Trademark Office, which is still needed to grant exclusive rights to the owner, as well as to prevent third parties from using and exploring identical or similar trade marks.

CANADA

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In an effort to modernize Canada's IP landscape, the Canadian trade mark regime is set to undergo a significant overhaul as Canada is not far off from the coming into force of the amendments to the Trademarks Act, expected in 2019. The amendments will have a notable impact on trade mark owners across all industries, including the pharmaceutical industry, as outlined below.

Madrid Protocol

Through Canada's adoption of the Madrid Protocol, foreign-owned pharmaceutical companies will soon have the option of designating Canada as one of the countries to seek protection of their mark through WIPO, instead of applying directly in Canada. Conversely, adoption of the Madrid Protocol will permit Canadian applicants to streamline their global trade mark registration process by filing a single international application and designating multiple countries via the Protocol, resulting in more efficient and cost effective global trade mark protection.

Registration without USE

Currently, applicants are required to specify one or more filing bases (e.g. proposed use, use in Canada, use / registration abroad, etc.). For proposed use applications, a declaration of use is required before registration. This can impose obstacles and delays for pharmaceutical applicants who, in addition to compliance with the requirements of the trade mark registration process, must also seek approval from Health Canada to use the drug name. The Health Canada approval process can be lengthy (with no sales allowed until approval). Accordingly, pharmaceutical applicants often need to request multiple extensions of time for filing of their declaration of use with the Trademarks Office until the name is approved by Health Canada and use commences. Sometimes, applicants are even forced to re-file their applications, if they run out of extension requests while waiting for Health Canada approval.

The new trade mark regime will provide an opportunity for all applicants to obtain registration even if the trade mark is not in use in Canada, as applicants will no longer need to include a basis at filing and filing of a declaration of use for 'proposed use' applications will no longer be required. This will provide a major advantage for pharmaceutical applicants, as they will be able to obtain trade mark registration, without use, even if they are still awaiting Health Canada approval of the name. On the flip side, there may be challenges posed by the elimination of use, as the Canadian trade mark profession is already noting a rapid increase in the number of trade mark applications (often by 'trade mark squatters') covering a long and very broad range of classes (including pharmaceutical goods/services). This trend may ultimately result in increased hurdles in clearance, examination, opposition, and enforcement for legitimate brand owners.

Definition of 'trade mark' and Distinctiveness Examination

The definition of a 'trade mark' will change as the amended Trademarks Act will

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recognize an expanded definition to include various non-traditional marks (e.g. scents, tastes, textures, moving images, holograms, figurative elements and the positioning of a sign, etc.). While an expanded definition is a welcome change in Canada, all trade marks will be subject to examination for distinctiveness. With the amended Act, if the examiner is of the view that the mark is not 'inherently distinctive', applicants will be required to provide evidence that the mark has 'acquired distinctiveness' in Canada as of the filing date in Canada, in order to achieve registration.

Examination for distinctiveness will impose a new level of scrutiny of particular importance for the pharmaceutical industry, where protection is often sought for non-traditional marks such as the colour of a pill or tablet, or the shape of a device, potentially making it more difficult to register such non-traditional marks.

While the full impact of the new Act remains to be seen, it is clear that some of the changes will bring on new opportunities for pharmaceutical companies, while others may impose challenges to trade mark protection in Canada.

ROMANIA

PETOSEVIC

On 12 January 2018, the Romanian PTO published the first draft of the new trade mark law, aimed at transposing the Directive (EU) 2015/2436 into national legislation. The most important changes are listed below.

Absolute Grounds for Refusal or Invalidity

The draft law extends the absolute grounds for trade mark refusal or invalidity by adding the words 'or another characteristic' to the relevant article in the law, meaning that now the restrictions apply not only to shape signs but to other types of signs as well. Namely, according to the draft law, signs can be refused if they consist exclusively of the shape, or another characteristic, which (i) results from the nature of the goods themselves, (ii) is necessary to obtain a technical result, or (iii) gives substantial value to the goods.

Earlier Rights

The draft law widens the scope of earlier rights to include traditional terms, guaranteed traditional specialties and plant variety rights, along with the already covered designations of origin and geographical indications.

Trade mark Infringement

The draft law broadens the concept of trade mark infringement by establishing additional uses of a similar or identical sign that may be prohibited by the trade mark owner and are not specified in the current trade mark law, namely:

- Use of a sign as a company name or as part of a company name (however, the draft law does not clarify, like Directive (EU) 2015/2436 does, that in order to be prohibited, such use has to be made for the purposes of distinguishing goods or services);
- Use of a sign in comparative advertising in a way contrary to the provisions of the Misleading and Comparative Advertising Act No. 158/2008; and
- Use of a sign on packaging, labels, tags, security or authenticity features or devices, and placing these on the market.

Goods in Transit

Regarding the issue of goods in transit, the draft law prohibits third parties from bringing goods bearing an infringing sign into Romania, even if there is no intention to commercialize the goods in the country. According to the current law, counterfeit goods can only be seized if they are intended to be placed into circulation in Romania.

Revocation and Declaration of Invalidity

The draft law enables the Romanian PTO to handle applications for revocation and declaration of invalidity, which are now handled by the Bucharest Tribunal. Applications will be reviewed by a board consisting of three members of the PTO's legal department. The board's decisions have to be issued within three months of their pronouncement and can be challenged before the Bucharest Tribunal within 30 days of their communication date. The Tribunal's decision is subject to appeal only before the Bucharest Court of Appeal.

Directive (EU) 2015/2436 provides that the deadline for establishing the administrative procedure for revocation and declaration of invalidity is 14 January 2023, which leaves sufficient time for the relevant authorities to implement an efficient system.

The Romanian PTO only offered interested parties 10 days to provide their comments on the draft law, which is a very short term, but it is still open to debate and subject to numerous amendments. It remains to be seen how the draft law will progress and how the authorities will go about implementing the proposed substantive changes.

RUSSIA

PETOSEVIC

Following the recent Moscow Arbitration Court's decision in line with the Federal Antimonopoly Service's (FAS) stance on parallel imports, in a 13 February 2018 ruling, the Russian Constitutional Court clarified the conditions under which courts may authorize parallel imports into Russia. From now on lower instance courts will probably apply these guiding principles when considering parallel import cases, which may make the right holders' goal to prevent parallel imports more complex.

Following a complaint raised by the Russian parallel importer PAG LLC against Sony Corporation, the Constitutional Court examined the constitutionality of Civil Code provisions prohibiting parallel imports and ruled that, while the provisions do not contradict Russia's constitution, the principle of regional exhaustion of rights in Russia should not be automatically applied to all cases without considering the facts and circumstances related to every case.

In particular, parallel imports may be authorized for public interest reasons such as the protection of health or if the right holder acted in bad faith or abused his trade mark rights, for instance if the actions of the trade mark owner constitute unfair competition or are in favor of economic sanctions against Russia. The ruling can, however, give rise to various interpretations, and even a right holder's failure to reply to a permission request from an importer may be considered 'abusive'.

The Constitutional Court also ruled that, when imposing remedies, courts should distinguish between parallel imports and counterfeit goods. As a general rule, remedies, especially monetary fines, for parallel imports should not be as severe because losses incurred are generally not as high as in the case of the importation of counterfeit goods. Seizure and destruction of parallel imports should only be applied if the goods do not meet the required quality standards and can undermine public health and security.

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