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New Brazilian regulations concerning pharmaceutical trademarks: RDC 59/2014

By **Gabriel Leonardos | gabriel.leonardos@kasznarleonardos.com**

The Brazilian pharmaceutical regulatory agency ANVISA – National Sanitary Vigilance Agency recently approved new rules for the use of trademarks in pharmaceutical products, through RDC – Resolution of the Board of Directors #59, of Oct. 10, 2014.

Such new regulations are very important, inasmuch as all pharmaceutical products in Brazil must be registered with ANVISA for their sale to be allowed. ANVISA not only assesses the efficacy of the product and other health-related technical matters, but it also sets forth how the labeling should be done and it approves the use of trademarks in the package.

As in Brazil there is no linkage between the regulatory registration by ANVISA and the issuance of patents or trademark registrations by the Brazilian Patent & Trademark Office (BPTO), the rules approved by ANVISA are, in practice, the only rules that govern the approval for commercialization and labeling of pharmaceutical products. If there is a conflict between a decision by ANVISA and one by the BPTO (e.g. concerning the risk of confusion between two trademarks belonging to two competitors) it is usually up to the Courts to solve such conflict.

In the same day the RDC 59/2014 was published, two other important new sets of rules were also published by ANVISA, namely RDC 58 and 60. These deal, respectively, with the so-called "similar" pharmaceuticals (formerly known as "me too" products but, today, as all similar products must present the same bioavailability and bioequivalence tests as the generics need to present, it is more correct to call them "branded generics") and with the criteria for granting commercial approval for all 3 types of pharmaceutical products: the new (pioneer) product, the similar and the generic. These two other RDCs were the subject matter of our recent Newsletter #07.

RDC 59/2014 supersedes the previous regulations, namely the 11-year old RDC 333/2003, according to which the signs that appeared in the packages were "commercial names", an expression that created a lot of confusion because it was confused with the names of the companies. Under RDC 59/2014 the signs that appear in the packages are called "pharmaceutical names" and these are defined as "the designation of the pharmaceutical product, technically designed so as to differentiate itself from other pharmaceutical products" (Section 4, I). In other words, as if to stress the non-existence of any linkage with the BPTO, for the purposes of ANVISA, trademarks are called "pharmaceutical names".

Other important definitions from RDC 59/2014 are:

- **Identifying pharmacological substance:** the pharmacological material, or the ensemble of pharmacological materials in an association, that is responsible for the main therapeutic use, and that is present in all products of a given family of pharmaceuticals (Section 4, II);
- **Name complement:** the word used as a complementary designation to the pharmaceutical name, and that is of common (non-exclusive) use (Section 4, III);

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- **Family of pharmaceuticals:** the group of pharmaceutical products from the same company, with the same identifying pharmacological substance, with all products sharing the same pharmaceutical name and differentiated by individual name complements (Section 4, IV).

One of the main novelties introduced by RDC 59/2014 is the regulation of the families of pharmaceuticals because, under the old rules, it was not obligatory for all products of the same family to have the same identifying pharmacological substance. Under the old rules, it was common for products of the same family to share only the same therapeutic use, but not always the same pharmacological substance. The new regulations, however, shall not affect registrations previously issued by ANVISA under the old rules, unless in exceptional cases, if ANVISA detects a health risk for the consumers (Section 20).

The main rule concerning pharmaceutical names (= trademarks) is that they should "preferably be formed by one single word and their pronunciation, in Portuguese, must have a direct relation with the way it is written" and the name sought by an applicant "must have enough graphic and phonetic differentiation in comparison with other already registered designations of pharmaceutical products" (Section 7). As one may notice, the new rules protect the use of the Brazilian national language at the same time that it tries to simplify the trademarks by establishing that they be formed by a single word.

RDC 59/2014 does not contain any rule about the way in which the examination by ANVISA of requests of registration of pharmaceutical names (= trademarks) will be conducted. In that regard, we welcome the revocation of the old rule from Section 3.4 of RDC 333/2003, according to which a pharmaceutical trademark could coexist with other trademarks, as long as the new one had 3 or more different letters from the previous one. Such old rule was the cause of many disputes as, more often than not, it was not enough to avoid the risk of confusion, and the Brazilian Courts never accepted it, anyway.

RDC 59/2014 also gives several examples of how pharmaceutical names and complements must be formed and there are several details that we shall be glad to discuss with you, in case of interest. In order to have more information about these new regulations, please feel free to call or write to your regular contact in our firm, or to gabriel.leonardos@kasznarleonardos.com.