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Delay in marketing approval by pharmaceutical regulatory agency is a legitimate reason for lack of use of a trademark under Brazilian IP Law.

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The Brazilian trademark registration system is attributive of rights. A registration issued by the Brazilian Patent and Trademark Office entitles the owner with rights to use the trademark throughout the Brazilian territory, on an exclusive basis.

In return for this privilege, the issuance of a registration generates for the owner the obligation to use its trademark, regularly and effectively, in Brazil. Use must start within first 5 years of validity of the registration and may not be interrupted for a period longer than 5 consecutive years, under penalty of cancellation of the registration, unless the lack of use may be justified under “legitimate reasons”, as stated by the Brazilian IP Law. The BPTO, however, is extremely strict in analyzing such excuse and commonly rejects a defense based thereupon.

In what concerns trademarks of pharmaceutical products, particularly medicines, it is to be noted that commercialization must be preceded by marketing approval by ANVISA, the Brazilian Pharmaceutical Regulatory Agency.

This was the scenario within which Farmoquímica S/A from one side, and Wyeth Whitehall Ltda. and the BPTO on the other side, have contended in a leading case that recently reached the Superior Court of Justice to discuss whether a pending request for license from ANVISA for approval and sale of a medicine protected under a registered trademark would be considered as a valid excuse to avoid the forfeiture of the registration on the grounds of non-use, based on the concept of the “legitimate reasons” of the Brazilian IP Law.

Farmoquímica S.A. requested the forfeiture of one of the Whitehall's trademark registrations as an attempt to have it cancelled due to non-use and open the way for its own trademark application. The BPTO rejected to declare the forfeiture of the registration sustaining that Whitehall had justified properly the lack of use of its trademark.

It is not that Whitehall had never used its trademark. However, it was only able to launch the medicine in the market after the first five-year period of validity of the registration. The delay was due to bureaucracy problems to obtain authorization from ANVISA for commercialization of the medicine.

On May 5, 2016 the 3rd Chamber of the Superior Court of Justice upheld the BPTO's decision, concluding that Whitehall did not abandon its trademark. According to the Sanitary Surveillance Act, the manufacture and sale of a pharmaceutical product may be suspended anytime, if suspicious of being hazardous to human health. Whitehall preferred not to put its trademark at risk and refrained from launching it until getting authorization and approval from ANVISA for the commercialization of its pharmaceutical product. It was the Court's understanding that the pending request for marketing approval of the medicine by ANVISA proves the non-occurrence of inaction or negligence on the part of the owner in starting use of the trademark, and that there have been serious and effective efforts made to this end. So, the Court ruled that the delay in obtaining registration with ANVISA is within the concept of “legitimate reasons” of the Brazilian IP Law to avoid the cancellation of the registration due to non-use of a pharmaceutical trademark.

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