Medical Cannabis regulation and related patents in Brazil

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In recent years, several studies have been published worldwide regarding the efficacy of the use of medical Cannabis in the treatment of a number of diseases, for example: Parkinson's disease, epilepsy, Alzheimer's disease, chronic pain, as well as neurological disorders and conditions in general. Current scientific research is mostly focused on the active compounds present in *Cannabis sativa*, the so-called cannabinoids, in particular, cannabidiol (CBD) - due to their positive therapeutic effects - with the exception of the presence of tetrahydrocannabinol (THC), due to the psychotropic effect of the latter.

In addition, more than forty countries already have specific regulations for the import, manufacture and marketing of Cannabis-based drugs and products. Pioneering countries in this area are: Israel, Canada and Uruguay. In Brazil, this regulation was established by the National Health Surveillance Agency (ANVISA) only in the end of 2019.

From this regulation, there is a significant increase on the filing of patent applications addressed to cannabis-based drugs with the National Institute of Industrial Property (INPI) – Brazilian PTO. Also, according to the INPI's online database, there are at least 340 patent applications related to medical Cannabis.

Among these, the main Applicants are foreign private companies, in particular, pharmaceutical industries. In general, the subject matter involved in the applications currently pending before the Brazilian PTO refers to:

- pharmaceutical compositions comprising cannabinoids;
- methods of producing cannabinoids;
- genetically modified Cannabis-based plants;
- cannabis extracts; among others.

The first Brazilian granted patent related to this technological field (BR 11 2018 005423 2), jointly owned by Prati, Donaduzzi & Cia Ltda and Universidade de São Paulo, had its issuance published in the Brazilian Industrial Property Gazette (RPI) on June 23, 2020. However, after the filing of some Administrative Nullity Proceedings by third parties alleging the obviousness of the invention , the Brazilian PTO decided to revoke the patent that had been previously granted, so that the decision for the nullity of the patent was published in the RPI of July 27, 2021.

Therefore, there is a growing interest related to this theme in various niches of the population, that is, researchers, physicians, patients, start-ups, associations, among others. Yet, it is important to highlight that, in the

Brazilian territory, the purchase and import of cannabis-based drugs is only allowed to patients who have a medical prescription for their use and, also, a prior authorization from ANVISA, since the planting and cultivation of the plant in natura are illegal in the country.

It is clear that the increase in the number of applications filed and any potential granted patents related to Cannabis accompany the interest of the population in view of the promising results already identified for its application in the pharmaceutical sector. In this sense, the patent system gets distinction, as it can help the population in the marketing context of medical Cannabis.

To date, there are not many final decisions on patents related to medical Cannabis in Brazil. However, there is no doubt that the direct consequence of an increase in the allowance rate will result in greater interest and investment by national and foreign companies focused on the research and development of such drugs. This result would lead to the technological evolution of the medical application of Cannabis and to the Brazilian socioeconomic expansion, since the international market for Cannabis already grows exponentially at rates of up to 15% per year.

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