The barriers to obtaining a patent for *Cannabis sativa*-based drugs

It is widely known that more than 400 chemicals can be produced from *Cannabis sativa*. Medicinal use of this has been increasing every year, particularly in patients with multiple sclerosis, Parkinson's disease, epilepsy, sleep disorder, anxiety, autism, chronic pain and schizophrenia; to relieve the pain caused by cancer and alleviate the symptoms of amyotrophic lateral sclerosis, among others.

Besides the concerns about the social-ethical conflicts, security and efficacy of cannabinoid-based drugs, the grant of patent applications related to *Cannabis sativa*-based drugs is still a controversial issue that is far from being resolved. The National Institute of Industrial Property (INPI) has been strict in interpreting the provisions of Article 18 (I) of Law 9279/96, by considering patent applications related to *Cannabis sativa*-based drugs, even if the term '*Cannabis sativa*' is only mentioned in the specification as non-patentable matter.

Further, Article 229-C of the same law foresees that the grant of pharmaceutical patent applications is subject to ANVISA's prior consent. For prior consent analysis, the Brazilian Health Surveillance Agency (ANVISA) considers some parameters related to public health. Pharmaceutical products listed on List E (proscribed plants that may give rise to narcotic and/or psychotropic substances) or List F (substances banned in Brazil) of Ordinance 344/1998 are characterised as hazardous to public health.

Accordingly, INPI has been definitively shelving a series of patent applications related to *Cannabis sativa*-based drugs without even examining them, based on ANVISA's denied prior consent, since the *Cannabis sativa* plant and derivatives thereof are included in the list of prohibited substances. As a result, these technologies fall into the public domain, discouraging the entry of pharmaceutical products into the Brazilian market.

Since 2015, ANVISA has been allowing the import of cannabidiol-based and other cannabinoid-based drugs, provided that this is for medical prescriptions. Roughly 7,200 requests for import authorisation have been submitted.

So far, only one *Cannabis sativa*-based drug, Mevatyl (widely known as Sativex), has been registered in Brazil – granted by ANVISA in 2017, which is used in multiple sclerosis treatment.

Motivated by the increasing demand for patients who use cannabis for therapeutic purposes and the need to import the product, ANVISA launched two public consultation proposals on 14 June 2019, which aim to create clear and transparent rules on technical requirements for cannabis-based drugs:

- *i. PC n° 654/2019 defining specific proceedings to register and monitor Cannabis spp.-based medicines, synthetic analogues and derivative thereof wherein requirements will be applicable to medicines which therapeutic indication is restricted to patients with severe and/or life-threatening debilitating diseases and without alternative therapy; and*
- *ii. PC n° 655/2019 regulating the controlled cultivation of Cannabis spp. for medicinal and scientific use, foreseeing some cultivation restrictions*

so as to meet regulatory standards such as planting site safety, handling, storage, transportation and distribution.

The public consultations, which concluded on 19 August 2019, received more than 1,000 contributions, which will be evaluated by ANVISA's Collegiate Board later this month. Moreover, a special committee was set up on 9 October 2019, in the Chamber of Deputies, to analyse the bill of Law PL 399/15, which makes it possible to commercialise medicines containing extracts, substrates or parts of the *Cannabis sativa* plant in its formulation.

Brazil urgently needs specific legislation and regulations on the use of medicinal cannabis. It is not about legalising marijuana, but rather improving the quality of thousands of lives.