The law on access to genetic resources and the rush to find a vaccine against COVID-19

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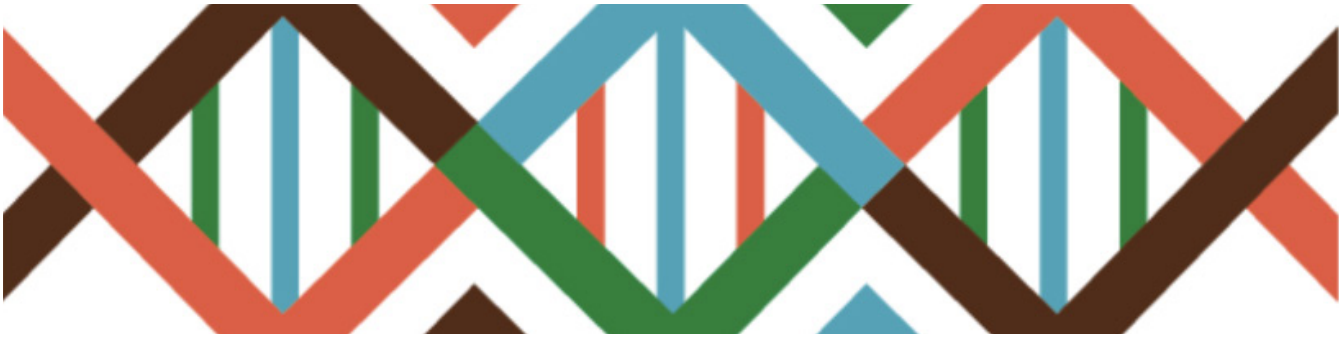

As scientists and pharmaceutical companies rush to find a vaccine against COVID-19, it is important to take into consideration not only the regulatory legislation on the development of new vaccines and drugs, but also to consider the applicability of laws on access to genetic resources. According to the Brazilian Law 13,123/2015, any microorganism, such as a virus, found in the country is subject to the country's rules on the matter.

Making a vaccine may require using information on the genome sequences for the different strains of the new coronavirus – Wuhan's and the Italian strains have been announced to be distinct. As the pandemic spreads around the world, further strains may be discovered, as the virus mutates.

In this context, if a sample of a virus strain found in Brazil is going to be used in the research and development of a new vaccine, registration at SISGEN should be carried out. This is the electronic database implementing a declaratory system devised to bring the agility longed for scientists and companies that replaced the prior approval required by the previous legislation. Without preempting research activities that may have already started, the registration should be made previous to: (i) remitting the sample; (ii) the application for any intellectual property right; (iii) marketing of the product in case it is deemed an intermediary one; (iv) publication of the final or partial results in scientific or communication means; or (v) the notification of a product if deemed a finished product.

On April 6, 2020, Ordinance 155 of April 3, 2020, was issued by the Ministries of Environment and Health and exempts from previous registration at the SISGEN the remittance of samples related to research and technological development linked to the epidemiologic situation caused by COVID-19 for as long as the national public health emergency lasts. The material transfer agreement required by the legislation must still be signed and the samples should be used only for this purpose. The research and development activities, as well as the remittance and notification of the finished product, should be registered in the system within a 1-year term from the end of the national emergency.

Publications of research and technological development carried out in the country related to epidemy are not subject to prior registration either. However, they may not be used for applying for any intellectual property right until registered at the SISGEN. The provisions of Law 13.123/2015 on the sharing of benefits deriving from the economic exploitation of the finished product are still fully applicable.

New synthetic drugs and diagnostic tools, on the other hand, are not within the scope of the legislation, as long as the research and development activities are restricted to attest the efficacy against the Brazilian strain which will be only used as a target.

The declaratory system implemented by Law 13,123/2015 had already provided a dynamicity that enabled the country to join efforts in this race for the development of a vaccine against COVID-19. The simplified procedure established by the new ordinance comes to settle it.