UNGRIA®

BRAZIL:

The end of ANVISA's prior consent for pharmaceutical patents

BRAZIL

The prior consent for pharmaceutical products or processes patents in Brazil was provided by article 229-C of the Brazilian IP Law (Law # 9,279/1996) and has always been a cause of intense debate regarding the double analysis on patentability requirements and also for the delay caused to the substantive examination of the Brazilian PTO.

However, the mentioned article was recently revoked by Law #14.195/2021, which was approved by Brazil's President and published in the Official Gazette, on August 27, 2021.

The prior consent, provided by article 229-C of the Brazilian IP Law, stated that:

Article 229-C - The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from the National Sanitary Supervision Agency (Agência Nacional de Vigilância Sanitária - ANVISA)." (Article included by Law #10.196, of 02.14.2001).

The issue of prior consent started in 2001 when such requirement was included in the IP Law, causing conflicts between ANVISA and the Brazilian PTO, mainly concerning the right of ANVISA to reject a patent application, which was sustained until 2017. Therefore, for more than (15) fifteen years it was common to receive double patentability requirements' analysis; a first one carried out by the Brazilian PTO and then a second one, carried out by ANVISA. This was one of the most important reasons why the Brazilian PTO experienced significant backlogs.

By means of Joint Ordinance #1/2017, the attributions of each counterpart were established, stating ANVISA's would analyze whether a subject matter of a patent application represents a risk to public health, such risk characterized as pharma product comprising, or pharma process resulting in a substance whose use is prohibited in Brazil, such as narcotic substances, whereas the Brazilian PTO's attribution is to analyze patentability requirements of the subject matter.

This new Law (#14.195/2021), which establishes the end of prior consent, is the result due to the Provisional Measure 1040/2021, which proposed the revocation of art. 229-C, based on the bureaucracy imposed in the process of examining patents for pharmaceutical products and processes in the country.

Hence, it is understood that this new Law can bring significant changes in the prosecution of patent applications in Brazil since they will no longer be sent to ANVISA— reducing the steps of the substantive examination, which can contribute to minimize the average time to obtain a final opinion on patentability.

It is also important to mention that the revocation of ANVISA's prior consent is a section of Law #14.195/2021, which aims to improve the business environment in Brazil. Among the amendments, the new Law also introduces rules to facilitate and reduce the bureaucracy to conduct business in the country.

Additional Resolutions and/or Guideline's procedures shall be published regarding this new Law.

Rest assure we will keep you duly informed.