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ANVISA publishes Guidelines regarding the examination and prior consent of patent applications for pharmaceutical products and processes

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The Brazilian Health Surveillance Agency (ANVISA, in its Portuguese acronym) published, on 19 November 2020, Guidelines regarding the examination and prior consent of patent applications for pharmaceutical products and processes.

As currently required by Article 229-C of Brazilian IP Law, ANVISA continues to issue prior consent over a Patent application for pharmaceutical products or processes, since ANVISA limits its analysis to the risk of the product or process to the public health.

The aim of this Guideline is to establish a standard and clear procedure regarding the actions performed by ANVISA. This Guideline covers the procedure and is divided in four sections, one for each of 4 (four) different stages:

I. Identification of patent applications for pharmaceutical products and processes which require prior consent;

II. Health risk analysis in patent applications for pharmaceutical products and processes under prior consent;

III. Identification and analysis of patent applications for pharmaceutical products and processes under prior consent that are subject to the offer of subsidies for the BRPTO (Brazilian Patent and Trademark Office) patentability examination; and

IV. Examination of patentability requirements by BRPTO of patent applications for pharmaceutical products and processes with prior consent.

The first section includes examples of subject-matter that would not fall under the provisions of Article 229-C of the IP Law, such as products for in vitro diagnostics, veterinary products, cosmetics, hygiene products, food, non-active pharmaceutical ingredients, or pesticides, among others. Therefore, patent applications related to at least one of the matters listed above are not subject to prior approval by ANVISA.

The second stage refers to the analysis of public health, which will assess whether the claimed subject-matter describes substances/products contained in the list of banned plants that can give rise to narcotics and/or psychotropic substances and/or the list of substances for prohibited use in Brazil. If the patent application is deemed to represent a risk to public health, an office action or requirement will be formulated, and the applicant will have 60 (sixty) days to file its arguments/response.

The third section shows a list of therapeutic applications that may result in subsidy opinions. In general, patent applications directed to neglected diseases, degenerative diseases, mental illnesses, cancer, immunosuppressants, vaccines, serums, blood products, and products obtained through biological routes would be likely to receive a subsidy opinion from ANVISA.

Finally, the fourth section summarizes the patentability aspects in case of subsidies.

It is important to bear in mind that this content has been published to clarify both the ANVISA procedure as well as the fact that ANVISA can only deny the prior consent on those cases that present a risk to public health.

If necessary, the links of said for portions of Portuguese Guidelines are:

https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/propriedade-intelectual/manual-de-exame-de-pedidos-de-patente/manual-1/view

https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/propriedade-intelectual/manual-de-exame-de-pedidos-de-patente/manual-2/view

https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/propriedade-intelectual/manual-de-exame-de-pedidos-de-patente/manual-3/view

https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/propriedade-intelectual/manual-de-exame-de-pedidos-de-patente/manual-4/view