

Conselho Directivo

By email only

Mr. Francis Gurry
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Sua referência:

Sua comunicação de:

Nossa referência:

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GP 113/17

SUBJECT: C. 8687 - INPI PT Comments

Dear Francis,

In reference to your Circular C. 8687, dated August 21, 2017, the Portuguese Institute of Industrial Property (INPI PT) comments are as follows:

INPI PT doesn't have any additional inputs for the preparation of the draft reference document on the *exception regarding acts for obtaining regulatory approval from authorities*. In fact, according to Article 102(c) of the Portuguese Industrial Property Code, the rights conferred by a patent do not extend to acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them.

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal joining European Union and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. However, at that time, it only referred to "Acts performed exclusively for trial or experimental purposes", the remaining text was only added in 2003.

This exception is motivated by the defense of higher public interests, such as, the need to protect the realization of activities of scientific research based on the patented invention, under penalty of preventing scientific and technological progress.

Thus, with this exception is possible to start administrative processes required for the commercialization of generic drugs even during the validity of the patent, which allows a faster introduction of the generic drugs in the market.

To our knowledge, there have not been any challenges related to the practical implementation of this exception in our country.

I would like to inform you that INPI PT answered to the Circular C. 8585, in consequence the information related with "Certain aspects of the applicable national or regional patent law" and "national and regional laws on opposition systems" is updated.

In relation to the questionnaire sent with the Circular C. 8625, I would also like to inform that INPI PT has already submitted the responses to the said questionnaire.

Yours sincerely,



Leonor Trindade
President of the DC