

Dear colleagues,

The National Center of Intellectual Property of the Republic of Belarus has considered C.8687 dated August 21, 2017 and informs the following.

On the issue of limitations and exceptions to patent rights in respect of acts related to obtaining regulatory approval from authorities.

Currently, the legislation of the Republic of Belarus stipulates limitations and exceptions to patent rights, which are reflected in the legislation of most countries of the world.

General information on limitations and exceptions to patent rights in the Republic of Belarus, posted on the website of the electronic forum of the SCP in the section “Revised Annex II to document SCP/12/3 Rev.2: Report on the International Patent System”, is relevant.

At the same time, the legislation of the Republic of Belarus does not fix limitations on patent rights regarding acts for obtaining regulatory approval from authorities.

At the same time, at the stage of discussion there is the issue of establishing a restriction permitting acts related to the preparation by the manufacturer of a generic drug for the introduction of such a drug into the civil circulation during the period of validity of the patent for the original medicinal product.

On constrains issues that countries are faced with in the full use of flexibilities in patenting and their impacts on access to affordable and, in particular, essential medicines for public health.

The Republic of Belarus takes decisive steps to ensure the balance of interests of the society and rights holders.

At present, proposals have been prepared to improve the patent legislation related to the expansion of the list of acts not recognized as an infringement of the exclusive right of the patent holder.

Thus, as an act not recognized as an infringement of the exclusive right of the patent holder, it is planned to fix the following: the conduct of preclinical studies and clinical trials of the medicinal product containing the invention, or experiment on medicines.

It seems that such a change in the patent law will help to ensure access to affordable and, in particular, essential medicines.

In addition, we inform you that the Republic of Belarus pays special attention to the issue of pricing for medicines, including regular monitoring of prices for these products.

On the issue of updating information on the current legislation.

Information available on the WIPO website at http://www.wipo.int/scp/en/annex_ii.html; and http://www.wipo.int/scp/en/revocation_mechanisms/, in relation to the Republic of Belarus is relevant.

On the issue of responding to the questionnaire “ Quality of Patents”.

The response to this questionnaire was previously sent to WIPO and is currently located at: http://www.wipo.int/export/sites/www/scp/en/meetings/session_26/comments_received/belarus.pdf.

Best regards,

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