ILN IP Insider

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Russia accession to the Protocol amending the Agreement on trade-related aspects of intellectual property rights

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In its meeting of April 27, 2017, the Russian Government has approved the Bill "On approval of the Protocol amending the Agreement on trade-related aspects of intellectual property rights" proposed by the Russian Ministry of Foreign Affairs and the Russian Ministry of economic development and trade, and endorsed its further introduction to the State Duma[1].

The WTO Protocol amending the Agreement on trade-related aspects of intellectual property rights (hereinafter – the "Protocol")[2] was adopted by WTO General Council on December 06, 2005, and

opened for signature by WTO member states until December 01, 2007, with further extension until December 31, 2017.

As of the current date, many WTO member states have acceded to the Protocol, inter alia the USA, Switzerland, Brazil, China and Australia[3].

The Protocol supplements the Agreement on trade-related aspects of intellectual property rights with provisions that allow WTO member states to use compulsory licensing system for production and export of pharmaceutical products to the territory of WTO member state in need.

According to the Protocol, application for compulsory license is allowed in case of the following: (1) national emergency or other circumstances of extreme urgency, or (2) for the purpose of public non-commercial use.

Pursuant to the Protocol, in order to implement the compulsory license system, the WTO member state should make a notification to the Council for Trade-Related Aspects of Intellectual Property Rights (hereinafter – the "Council") notification including the following obligatory information:

- names and expected quantities of the pharmaceutical products needed;
- confirmation of insufficient or no manufacturing capacities in the pharmaceutical sector for the pharmaceutical products in question;
- where a pharmaceutical product is patented, confirmation of granting or intention to grant a compulsory license.

The Protocol envisages the following conditions of compulsory license issuance:

- only the amount necessary to meet the needs of WTO member state in need may be manufactured under the license and the entirety of this pharmaceutical production shall be exported to the WTO member state that submitted relevant notification to the Council;
- pharmaceutical products produced under the license shall be clearly identified as being produced under the system through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price;
- before shipment begins, the licensee shall disclose the following information on its website or WTO website: (1) the quantities of pharmaceutical products being supplied under the license, including each destination; and (2) the distinguishing features of the pharmaceutical products made under the conditions of compulsory license issuance.

The Protocol's provisions were applied by its acceded WTO member states more than once that evidence actuality and effectiveness of compulsory license system applicability.

The Protocol ratification will provide the opportunity to use this mechanism in the framework of current legislation regulating the issues of compulsory licensing. Therefore, perhaps there will be no reason to implement the initiatives of some executive authorities proposing to revise current rules on compulsory licensing.

Currently the issuance of compulsory licenses in Russia is governed by the provisions of civil legislation, including those specified in articles 1360 and 1362 of the Russian Civil code.

[1] *http://government.ru/news/27498/*
[2] *Full text of Protocol is available on the official WTO website: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm*
[3] *According to the information from the official WTO website: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm*

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Headed by Eddie Powell of Fladgate LLP, London, and Norman Zivin of Cooper & Dunham LLP, New York, New York, the ILN's Intellectual Property Group provides the platform for enhanced communication, enabling all of its members to easily service the needs of their clients requiring advice on cross-border transactions. Members of the group meet regularly at ILN conferences and industry events, and have collaborated on discussions and publications of mutual interest.

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