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**Council for Trade-Related Aspects of  
Intellectual Property Rights**

Original: English

## REVIEW OF LEGISLATION

### QUESTIONS POSED BY SWITZERLAND

By means of a communication from the delegation of Switzerland, dated 2 April 2013, the Secretariat has received a copy of the following questions that it has communicated to the Russian Federation.

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#### RUSSIAN FEDERATION

#### GENERAL

1. Are the provisions of the TRIPS Agreement, as far as not implemented in national law, directly applicable in the legal system of the Russian Federation?

#### PATENTS

2. Does the legislation of the Russian Federation grant patent protection for inventions relating to products and processes in all fields of technology? Are there any exceptions? If yes, please indicate these exceptions and explain how they comply with Article 27 of the TRIPS Agreement.

3. Does the legislation of the Russian Federation, in accordance with Article 27.1 in combination with Article 31 of the TRIPS Agreement, consider importation as "working" a patent and therefore preclude compulsory licensing, if a product is being imported?

4. Does the legislation of the Russian Federation make the granting of a compulsory license subject to all the conditions enumerated in Article 31 of the TRIPS Agreement? Please cite the relevant provisions of the legislation.

5. Does the legislation of the Russian Federation provide for the principle of the reversal of burden of proof in patent litigation? Please cite the relevant provisions of the legislation.

#### PROTECTION OF UNDISCLOSED INFORMATION

6. According to Article 18.6 of Federal Law No. 61-FZ "On the Circulation of Medicines", in force since 22 August 2012, Russia implemented the obligation under Article 39.3 of the TRIPS Agreement to protect undisclosed information in marketing approval procedures against unfair commercial use by granting a term of protection of six years against reliance by a second applicant. Please explain how this protection is being implemented and enforced in practice, and whether a new administrative regulation addressing the practical aspects of the application of Law No. 61-FZ is going to be put in force.

7. Can you confirm that, despite an accelerated procedure for generic products registration as provided for in Article 26 of Law No. 61-FZ, the Russian marketing approval authorities do not allow reliance on the data submitted by their originator for the full term of protection of six years from the date of state registration of the medicinal product?

#### PROVISIONAL MEASURES

8. Do the judicial authorities of the Russian Federation have the authority to adopt, on the request of a rightholder, a provisional measure *inaudita altera parte* before an action leading to a decision on the merits of the case has been lodged? Please cite the relevant provisions of the legislation.

9. Does the legislation of the Russian Federation provide for any restrictions for obtaining provisional measures? If so, what are these restrictions? Please cite the relevant provisions of the legislation.

10. Please describe the provisional measures provided for in the legislation of the Russian Federation, including those for combatting counterfeiting and piracy. Please describe the procedures that must be followed and cite the relevant provisions of legislation.

11. Please describe the measures provided by the legislation of the Russian Federation to combat counterfeiting and piracy at the border. Please explain whether the competent authorities are empowered to act *ex officio* and, if so, please indicate the enforcement actions that may be taken. Please cite the relevant provisions of the legislation.

#### ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

12. Please describe how the legislation of the Russian Federation meets the requirements of Article 41 of the TRIPS Agreement. Please cite the relevant provisions.

13. Please indicate the authorities responsible for the application of the measures provided by the legislation of the Russian Federation to combat counterfeiting and piracy. Please explain whether the competent authorities are empowered to act *ex officio* and, if so, please indicate the enforcement actions that may be taken. Please cite the relevant provisions of the legislation.

14. Please describe any new initiatives that are planned to improve the enforcement of intellectual property rights in the Russian Federation. Is there a particular action plan in place?

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