



2 October 2013

(13-5282)

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Council for Trade-Related Aspects of
Intellectual Property Rights

Original: English

REVIEW OF LEGISLATION

RESPONSES FROM THE RUSSIAN FEDERATION TO QUESTIONS POSED BY SWITZERLAND

By means of a communication from the delegation of the Russian Federation, dated 19 September 2013, the Secretariat has received the following responses to questions posed by Switzerland, as circulated in document IP/C/W/587.

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?

1. The Protocol of Accession of the Russian Federation to the WTO was ratified by the State Duma of the Russian Federation on 22 August 2012. Since this date, the TRIPS Agreement became part of the Russian legislation system. Obligations of the Russian Federation, taken during the accession process, were implemented through amendments to the national legislation.

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.

2. In accordance with Article 1350 of the Civil Code of the Russian Federation, a technical solution in any area (we consider it as an invention in fields of technology) related to a product (including a structure, substance, micro-organism strain, or culture of cells of plants or animals) or a means (a process of conducting actions on a material object with the help of material means) shall be protected as an invention. An invention shall be granted legal protection if it is new, has an inventive level, and is industrially applicable.

3. The Article provides that legal protection for inventions shall not be granted to: varieties of plants, breeds of animals and biological methods of obtaining them, with the exception of microbiological methods and products obtained through the use of such methods.

4. We consider that these exceptions fully 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 licence subject to all the conditions enumerated in Article 31 of the TRIPS Agreement? Please cite the relevant provisions of the legislation.

5. Article 1362 of the Civil Code of the Russian Federation is devoted to the detailed regulation of questions of compulsory licensing. Quotas regulating compulsory licensing are founded on the provisions of the Paris Convention for the Protection of Industrial Property (Article 5 item A(2)) and the TRIPS Agreement (Articles 31 and 40).

6. Semantic maintenance of the notion "conditions corresponding to established practice" used in Article 1362 of the Civil Code of the Russian Federation and the notion "reasonable commercial conditions" used in Article 31(b) of the TRIPS Agreement, are the same.

7. In the case of insufficient use of an invention or industrial design during the four years since the date of granting of the patent or utility model – during three years since the date of granting of the patent and a patent holder's refusal to conclude licence contract with interested person on conditions corresponding to established practice, this person shall have the right to go to court with a suit against the patent holder for the granting of a compulsory simple (non-exclusive) licence for the use of an invention, utility model, or industrial design. In the demand for the lawsuit, the interested person must indicate the proposed of the granting to him of such a licence, including the scope and conditions of use of the patented object, the amount, procedure, and times of payments. The Court makes a decision about the granting of the compulsory licence if the patent holder does not show that non-use or insufficient use by him of the patented object is based on valid causes. All cases of using of patented object are defined in the court decision. The right provided in conformity with the compulsory licence may not be transferred to third persons.

8. In a case where the circumstances that were the basis for the granting of the simple (non-exclusive) licence cease to exist and their reappearance is unlikely, then acting of the compulsory licence may be terminated by judicial procedure on a suit by the patent holder. This quota corresponds to Article 31(c) of the TRIPS Agreement. A duty of proof of absence of these circumstances is charged to patent holder. In this case, the terms and procedure of termination of the licence and termination of the right is arisen with getting of this licence are established by the court.

9. Article 31(I)(ii) of the TRIPS Agreement foresees a "cross licence". Analogous quota is contained in item 2 of Article 1362 of the Civil Code of the Russian Federation. The present item establishes rules for a situation where the use of one patented invention is connected to the using of other patented invention or patented utility model. If other person have the patent to this other invention or utility model than using of first patented invention needs to get a permission from other patent holder. In case of refusal of other patent holder to get a licence, first patent holder shall have the right to go to court with a suit for the granting of the compulsory licence. Observation of conditions "an important technical achievement" and "a significant economic advantage" is directed to the protection of hindering patent holder's interests and this quota provides some balance of interests for both patent holders and the society in full, as long as society is interested in the creation of an important technical achievement, patenting them and their use.

10. In the case of granting compulsory licence by court decision, the second patent holder acquires the right to get from the first patent holder an analogous licence for such invention to procure the use provided by the compulsory licence. It is necessary to note that positions in this item do not provide any possibility to demand submitting the compulsory licence for procuring the possibility to use patented utility model. Such limitation is stipulated because the patent of a utility model is distributed without verification it is its patentability.

11. The provisions of Article 1362 of the Civil Code of the Russian Federation about the compulsory licensing in case of insufficient use the industrial design during four years do not contradict to Article 5(B) of the Paris Convention for the Protection of Industrial Property so long as the submitting of the compulsory licence of a patented industrial design does not mean a cessation of his legal protection.

12. A reconsideration of court decisions is realized in conformity with the Civil Procedural Code of the Russian Federation and the Arbitration Procedural Code of the Russian Federation.

13. The procedure for the reconsideration of a court decision on compulsory licensing, based on Article 1362 of the Civil Code of the Russian Federation, is provided in Procedural 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.

14. The principle of burden of proof in Russian patent legislation is incorporated in Articles 1350, 1351, and 1352 of Civil Code of the Russian Federation only on describing conditions of patentability of an invention, utility model and industrial design.

15. According to the provisions of these articles the burden of proof that the circumstances have taken place, by virtue of which the disclosure of information does not prevent the recognition of the patentability of the invention, utility model or industrial design, shall rest on the applicant.

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?

16. Article 18 of Federal Law FZ-61 d.d. 12.04.2010 has been complemented with section 6 of the following content:

"It prohibited to receive, disclose, commercially use and use for state registration any information on non-clinical research of medical products and clinical research of medical products, provided by the applicant for state registration of medical products without their permission for six years since the date of state registration of a medical product.

Non-observance of the prohibition stated by the above-mentioned section entails amenability in compliance with laws of the Russian Federation.

Turnover of medical products registered with violation of this section on the territory of the Russian Federation is illegal."

17. The above-mentioned section applies after 22 August 2012.

18. To observe the requirements of section 7 of Article 18 and prevent violations of exclusive rights of developers of medical products, the Ministry of Health of the Russian Federation, in its draft bill on "Amendments to Federal Law", "On Turnover of Medical Products" and "Article 333.32.1 of Part Two of the Tax Code of the Russian Federation", made an amendment to the composition of the registration dossier (Article 18, section 3) by including documents that verify:

12) Presence of intellectual rights;

13) Presence of consent of an applicant of an original medical product to use information about results of non-clinical and clinical researches of the original medical product in case less than six years has passed since the registration of the original medical product.

19. Article 26 FZ-61 d.d. 12.04.2010 "On Turnover of Medical Products" applies only to urgent production of expert evidence but not to urgent registration. Since rapid production of expert evidence may be applied to reproduce medical products provision of information obtained during non-clinical and clinical researches of the original medical product and published in specialized publications is possible during such procedure if the original medical product is not covered by patent protection.

20. Actually a series of amendments in the Law on Circulation of Medicines N61 is considered by the Government. Different provisions related to Article 18 will be introduced to avoid any possible misunderstanding of the provision.

21. At the same time, the Russian Federation, according to the Doha Declaration of 2001 on the TRIPS Agreement and Public Health in which a concern about the impact of intellectual property rights on medical products' prices was expressed and ultimately reserves the right to consider applying Article 8 of the TRIPS Agreement in terms of implementing the right to health, which states that: during drafting or amending of national laws or regulations, member-states can take measures necessary in protecting population's health, as well as Article 30 of the TRIPS Agreement which contemplates some exclusions from exclusive rights granted by patents, while barring unjustified limitations of rights of patent holders and third parties. In particular, the right to "early usage" does not contradict this Article (the so-called Bolar provisions) which allows generic drug producers to conduct all the procedures and trials necessary for the registration of a generic drug before the patent of the original drug expires (or exclusive research data regulations). As a result, they are guaranteed the possibility of entering generic product to the market right after the stated period has expired.

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.

22. According to Article 141 of Civil Procedural Code of the Russian Federation an application for providing for a claim shall be considered on the day of its arrival to the court, without notifying the defendant and the other persons taking part in the case. The judge or court shall issue a ruling on taking measures to provide for the claim.

23. According to Article 93 of Administrative Procedural Code of the Russian Federation an application for securing a claim shall be considered by an arbitration court trying the case. This is to be done by a single judge, at latest, on the day following the date when the application comes to the court, without notifying the parties thereto of it.

24. Thus, the court of law and arbitration court have the right to accept provisional measures immediately without notifying the party of dispute on which measures are imposed.

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.

25. The statement for acceptance security (provisional) measures can be submitted both simultaneously with the statement of claim and already in the course of judicial process.

26. By the general rule, an application for securing a claim shall be considered by an arbitration court trying the case. This is to be done by a single judge, at latest, on the day following the date when the application comes to the court, without notifying the parties thereto of it, including if the statement for claim maintenance is submitted simultaneously with the statement of claim (Article 93 of Administrative Procedural Code of the Russian Federation, Article 141 of the Civil Procedural Code of the Russian Federation). In that case, the question on acceptance of the statement of claim to consideration is examined by an arbitration court not later than the next day after the day of receipt of the statement of claim by arbitration court.

27. Upon the consideration of the statement for securing a claim, the arbitration court takes out a court decision on securing the claim or on refusal of claim securing.

28. Securing measures hold action for all periods of legal proceedings before their cancellation. In the case of satisfaction of the claim, securing measures hold the action upon execution of the judicial act which finalise this legal investigation. In the case of refusal of satisfaction of the claim, keeping the claim without consideration, cessation of case, securing measures hold the action upon the entering into force of the corresponding judicial act. After the entering into force of the judicial certificate the arbitration court, at the petition of the person participating in case, takes the decision on cancellation of measures on securing of the claim or specifies it in judicial act.

29. As measures of protection from the statement for securing a claim, the other party (respondent) can declare objections, in essence, in judicial session, when the specified petition is considered with a call of both parties. In other cases, the interested person has the right:

- To present counter security measures (Article 94 of the Administrative Procedural Code of the Russian Federation);
- to dispute imposition of security measures (Article 97 of the Administrative Procedural Code of the Russian Federation and Article 144, Civil Procedural Code of the Russian Federation);
- to request replacement of one security measure by another (Article 95 of the Administrative Procedural Code of the Russian Federation and Article 143, Civil Procedural Code of the Russian Federation);
- to file a suit on indemnification or payments of indemnification, caused by securing the claim (Article 98 of the Administrative Procedural Code of the Russian Federation and Article 146, Civil Procedural Code the Russian Federation).

30. According to Article 98 of Administrative Procedural Code of the Russian Federation, the respondent and other persons whose rights and/or legitimate interests are violated by securing a claim shall be entitled - after entry into legal force of the judicial act of an arbitration court on the refusal to allow the claim - to demand of the person that has applied for taking the precautionary measures, repair of damages in the procedure and in the amount provided for by the civil legislation or payment of compensation.

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.

31. Security (Provisional) Measures - the measures directed on maintenance of the claim or property interests of the applicant (claimant). Security measures can be accepted at any stage of consideration of the dispute in an arbitration court or court of law if non-acceptance of these measures could complicate or make impossible the execution of the judicial act, including if such execution is supposed outside the Russian Federation, and also with a view to the prevention of causing considerable damage to the applicant.

32. Under the statement of the person participating in judicial proceedings, and in the cases provided by agrarian Administrative Procedural Code of the Russian Federation and Civil Procedural Code of the Russian Federation, under the statement of other persons the arbitration court and court of law can accept urgent time security measures (measures on claim maintenance).

33. According to Part 1 of Article 91 of the Administrative Procedural Code of the Russian Federation and Article 140 of the Civil Procedural Code of the Russian Federation, Security Measures (measures on claim maintenance) can be:

- Forbidding the respondent, or other persons, to commit certain actions concerning the subject of the dispute;
- placing on the respondent the duty to commit certain actions for the purpose of preventing damage to, or deterioration of the condition of, disputable property;
- transfer of disputable property to the claimant, or other persons, for keeping custody thereof;
- end over measures.

34. According to point 2 of Article 1252 of the Civil Code of the Russian Federation, in the arrangement of the provision of security for a claim in a case of infringement of exclusive rights, the material media, equipment and materials that are allegedly involved in an infringement of the exclusive right, to the result of intellectual activity or means of individualization, may be subjected to the security measures established by the procedural legislation, e.g. seizure of material media, equipment and materials.

35. According to Article 1302 of Civil Code of the Russian Federation, on cases of infringement of copyrights and related rights, a court may forbid a defendant, or a person believed on sufficient grounds to be an infringer of copyright, from carrying out certain actions (i.e., manufacture, reproduction, sale, hiring out, importation or other use envisaged by the present Code, and also the transportation, storage or possession of copies of a work for the purpose of using them in civil law transactions, if the copies are understood to be counterfeit.

36. The court may also order the seizure of all copies of a work that is assumed to be counterfeit, as well as materials and equipment used or intended for manufacture or reproduction/playback thereof.

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.

37. In accordance with Article 306 and Article 307 of the Federal Law, from 27 November 2010, No. 311-FZ a rightholder, having sufficient grounds to believe that his/her/it's right may be infringed, is entitled to file an application with the federal executive governmental body empowered in the area of customs affairs asking for inclusion of the relevant intellectual property item in the customs register of intellectual property items, in accordance with the legislation

of the Russian Federation in connection with the import of goods into the Russian Federation, or the export thereof out of the Russian Federation, or when other actions take place involving goods being under customs control. On behalf of the rightholder, the actions envisaged by the customs legislation of the Customs Union and the present federal law may be committed by his/her/it's representative.

38. The Customs Register of Intellectual Property Items is the main protecting instrument. The following may be included in the Customs Register of Intellectual Property Items (hereinafter referred to as "the register"): the copyright law items, subjects of allied rights, trademarks, service marks and appellations of origin of products in respect of which the federal executive governmental body empowered in the area of customs affairs has taken a decision on taking measures relating to the suspension of clearance of goods. Inclusion in the register is free of charge. The register shall be kept by the federal executive governmental body empowered in the area of customs affairs in the procedure established by this body.

39. The intellectual property items, in respect of which the federal executive governmental body empowered in the area of customs affairs has taken a decision on taking measures relating to the suspension of release of goods, shall be included in the register on the condition that the rightholder ensures the performance of the undertaking mentioned in Part 5 of Article 306 of the Federal Law, by the methods envisaged by the civil legislation of the Russian Federation. Instead of security for the performance of the undertaking, the rightholder is entitled to file a contract of insurance for the risk of liability for infliction of harm for the benefit of the persons specified in Part 5 of Article 306 of the present federal law. In this case, the sum of security for the undertaking, or the insured amount, shall be at least 300,000 rubles.

40. If within one month after the date of despatch of a notice on the decision taken on measures relating to the suspension of clearance of the goods the rightholder fails to file a document confirming security for the undertaking, or a contract of insurance for the risk of liability for infliction of harm, the federal executive governmental body empowered in the area of customs affairs shall take a decision on refusal to include the intellectual property item in the register.

41. The federal executive governmental body empowered in the area of customs affairs shall ensure that the data in the register is published in its official publications and placed on its official internet website, in the procedure established by it.

42. In accordance of Article 309 of Federal Law, from 27 November 2010, No. 311-FZ customs bodies' decisions on suspension of the release of goods; extension of the term of suspension of release of goods; revocation of a decision on suspension of the release of goods; and also on the granting of the right to information and to the taking of samples and specimens, shall be taken by a customs body not later than the next working day after the date of discovery of signs of a breach of intellectual property rights, receipt of a relevant written application, or of the commission of another action deemed grounds for taking the relevant decision.

43. In accordance of Article 331 of Customs Code of Customs Union if during realization of customs actions related to the placing under customs procedures goods containing objects of intellectual property included in the customs register kept by the customs body of the member-state of the Customs Union, the customs body finds signs of infringement of the rights for intellectual property, the release of such goods is suspended for ten working days.

44. If there is a request from the rights holder or the party representing his interests, this period may be prolonged by the customs body, however, not more than ten working days, if the mentioned parties applied to the authorized bodies for protection of the rights of the rights holder, in compliance with the legislation of the member-states of the Customs Union.

45. Decisions suspending the release of goods and prolonging the period of suspension of release of goods are adopted in writing by the head of the customs body or the person authorized by him.

46. No later than within one working day following the day of adoption of the decision suspending the release of goods containing objects of intellectual property, the customs body shall notify the declaring party and the rights holder or the parties representing their interests of such suspension, the reasons and periods of suspension, as well as report to the declaring party

the name (full name) and the place of location (address) of the rights holder and/or the party representing his interests, and to the rights holder or the party representing his interests the name (full name) and place of location (address) of the declaring party.

47. Upon the expiry of the period of suspension of the release of goods containing objects of intellectual property, the release of such goods is renewed and is carried out according to the procedure specified in the Customs Code of the Customs Union, except for the cases when the customs body gets documents confirming the withdrawal of goods, their arrest or confiscation, or other documents in compliance with the legislation of the member-states of the Customs Union.

48. Customs bodies may suspend the release of goods containing objects of intellectual property not included in the customs register; kept by the customs body of a member state of the Customs Union and the joint customs register of objects of intellectual property of member states of the Customs Union, without application of the rights holder, according to the procedure specified in the legislation of the member-states of the Customs Union.

49. The rights holder shall be held liable, in compliance with the civil legislation of member-states of the Customs Union for property damage incurred on the declaring party, the owner, the recipient of the goods containing objects of intellectual property as a result of suspension of the release of goods in compliance with the present Chapter, if violation of the rights of the rights holder is not found.

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.

50. Different provisions of following legislative acts: the Civil Code of the Russian Federation, the Code of the Russian Federation on Administrative Offences; the Criminal Code of the Russian Federation; the Arbitration Procedure Code of the Russian Federation; the Civil Procedure Code of the Russian Federation; the Criminal Procedural Code of the Russian Federation; the Federal Law from 27 November 2010, No. 311-FZ "On Customs Regulation in the Russian Federation"; the Federal Law from 26 July 2006, No. 135-FZ "On Competition Protection".

51. In order to increase the effectiveness of IPR litigations, in March 2013, an Intellectual Property Arbitration Court was created.

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.

52. In the Russian Federation, the authorities responsible to combat counterfeiting and piracy are: the Ministry of Interior; the Investigation Comity, the Prosecutor, and the Federal Customs Service.

53. In accordance to the third part of Article 20 of the Criminal Procedural Code of the Russian Federation, criminal cases related to the illegal use of objects of copyright or related rights, as well as: the acquisition, storage or carriage of counterfeited copies of works or phonograms for the purpose of sale carried out on a large scale; illegal use of an invention, useful model, or industrial design; disclosure of the essence of an invention, useful model, or industrial design without the consent of its author or applicant, and before the official publication of information about them; illegal acquisition of authorship, or the compelling to co-authorship, are considered as criminal cases of the private-public prosecution and are initiated only upon application from the victim, or from his legal representative, but are not subject to the termination in connection with the victim's reconciliation with the accused, with the exception of the cases envisaged in Criminal Code of the Russian Federation.

54. In accordance to the third part of Article 20 of Criminal Procedural Code of the Russian Federation, the head of an investigative agency, the investigator, as well as the enquirer with the consent of the procurator, shall institute a criminal case on any crime indicated in parts two and three of this Article and in the absence of an application of the victim or his legal representative, if the crime has been committed with respect to a person who, due to his dependent or helpless state or for other reasons cannot defend his rights and legal interests. The other reasons shall also include the case of commission of a crime by a person the information about whom is unknown.

55. All other acts committed under Articles 146, 147 and 180 of Criminal Code of the Russian Federation are criminal cases of public charge and are raised in an order established by Article 146 Criminal Procedural Code of Russian Federation.

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?

56. There is no particular action plan on intellectual property rights enforcement in the Russian Federation. Every competent body has a goal to promote and increase the protection of IPR.

57. However, some initiatives have recently been realized. First of all, the creation in March 2013 of the Intellectual Property Arbitration Court.

58. The second initiative is the fight against internet piracy. The first step was done in July with the adoption of Federal Law No. 187-ФЗ. The new "Antipiracy Law" introduces the principle of liability of internet service providers, mechanisms for blockage of illegal content by a court decision. For the moment, the scope of the Law is limited to films, but different amendments concerning the extension of scope of protection are in the stage of public discussions.
