Portuguese reply to C.8828

1- Member States and Regional Patent Offices are kindly invited to send to the International Bureau of the World Intellectual Property Organization (WIPO) any additional inputs for the preparation of the following documents:

(i) a draft reference document on the exception regarding compulsory licenses. The inputs may relate to, for example, challenges faced by Member States in implementing the exception and the results of the national/regional implementation;

ANSWER: According to Article 107.° of Industrial Property Code, compulsory licenses may be granted for a certain patent, in any of the following cases: lack or insufficient exploitation of a patented invention; dependency between patents; and reasons of public interest.

Compulsory licenses shall be non-exclusive and may only be transferred with the part of the company or establishment that exploits them.

Compulsory licenses may only be granted if the potential licensee has made efforts to obtain a contractual license from the patentee on acceptable commercial conditions and said efforts have not been successful within a reasonable period of time.

A compulsory license may be revoked without prejudice to the appropriate protection of the licensee's legitimate interests if and when the circumstances that gave rise to it cease to exist or are not likely to occur again. The competent authority may re-examine the continuation of said circumstances on duly justified request.

If a patent concerns semiconductor technology, compulsory licenses may only granted for a non-commercial, public purpose.

The patentee shall receive appropriate payment in each concrete case on the basis of the economic value of the license and a decision granting or denying payment is subject to judicial or arbitral appeal.

Furthermore, Article 111.° of Industrial Property Code establishes that compulsory licenses shall be requested at the National Industrial Property Institute. Applicants shall submit proof to justify their request.

Requests for compulsory licenses shall be examined in the order in which they are submitted to the National Industrial Property Institute. On receiving a request for a compulsory license, the National Industrial Property Institute shall give the patentee two months in which to say anything he sees fit and to submit proof.

The National Industrial Property Institute shall consider the parties' arguments and the guarantees of exploitation of the invention offered by the applicant for the compulsory license and decide, within two months, whether or not it should be granted. If it decides in favor, it shall give both parties one month to appoint an expert who, together with the expert appointed by the National Industrial Property Institute, shall agree, within two months, on the conditions of the compulsory license and the compensation to be paid to the patentee.

These compulsory licenses are provided to avoid abuse of the monopoly that is granted with a patent and obstacles to technological and economical development, but also to promote public health and guarantee national security.

Regarding challenges faced by Portugal in implementing compulsory licenses and the results of the national/regional implementation, INPI has no information.

(ii) a further study on inventive step (part 3), giving a particular attention to the topics suggested in paragraph 8 of Annex to document SCP/24/3 (proposal by Spain), in particular, assessment of inventive step in the chemical sector;

ANSWER: In Portugal, inventive step in the chemical field is analyzed in the same way as in any other technical field: applying the problem - solution approach. The problem-solution approach has 5 stages which are: (i) determine the closest prior art; (ii) identify the distinguishing features; (iii) establish the objective technical problem to be solved; (iv) assess whether the problem has been plausibly solved and (v) consider if the claimed invention is obvious.

When a novel chemical compound has a similar structural to known chemical compounds, we consider that the novel chemical compound is obvious if the skilled person knew, either from common general knowledge or from some specific disclosure, that the existing structural differences of the chemical compounds concerned were so small that they would have no essential influence on those properties, which were responsible for the unexpected technical effect and for solving said technical problem and could be ignored.

Furthermore, in Markush claims the unexpected technical effect could only be taken into account in the assessment of inventive step if it is achieved by all the chemical compounds claimed. If only some compounds claimed (and not all) exhibit a particular technical effect, the alleged technical effect of some of the claimed compounds is ignored when determining the objective problem underlying the invention and thus when assessing inventive step.

Regarding amorphous forms versus crystalline forms, in the absence of any unexpected property, the simple provision of a crystalline form of a pharmaceutically active compound already known could not be regarded as comprising an inventive step.

Related to enantiomers, if an enantiomer has the same pharmacological activity as the already known racemic mixture and doesn't exhibit an unexpected effect, the enantiomer invention lacks inventive step.

(iii) updated document on the confidentiality of communications between clients and their patent advisors, based on document SCP/29/5;

ANSWER: The information related with "Confidentiality of Communications between Clients and their Patent Advisors" available at the WIPO's website is updated (INPI PT's response to Circular C.8585 and C.8728). So our Office does not have any additional comments to send to the International Bureau of the world Intellectual Property Organization.

(iv) a document compiling information on patent law provisions and practices that contributed to effective transfer of technology in Member States.

ANSWER: Portugal provides seven models of Technology Transfer Research and Development Agreements to facilitate the creation of partnerships between universities and companies which are: unilateral confidentiality agreement; bilateral confidentiality agreement; exclusive patent exploitation license agreement; non-exclusive patent exploitation license agreement; technological development contract and research results sharing agreement .

These agreements are provided in INPI website in a simple and annotated version, containing negotiating principles and conditions that can be applied to different types of research cooperation projects. They are based on three principles: sharing of information, ownership of research results and definition of exploitation rules.

The Agreements must be adapted to the concrete circumstances of each collaboration, and do not exempt the consultation of a professional.

In addition, in order to maintain the information collected through the activities of the SCP up-todate, Member States and Regional Patent Offices are invited to submit updated information on:

(i) certain aspects of the applicable national or regional patent law, available at: <u>http://www.wipo.int/scp/en/annex_ii_html;</u>

ANSWER: The Portuguese legislation (Industrial Property Code) was revised and is partially in force since 1st January 2019. The remaining dispositions will take effect on July 1st, 2019. So, we would like to update, at the WIPO's website, the matter related with prior art, inventive step, exclusions from patentable subject matter and exceptions and limitations of the rights (these changes will come into force on July 1st, 2019).

Prior art

1. Everything made available, inside or outside the country, to the public by description, use or other means before the filing date (priority date).

2. Contents of non-published patent and utility model applications of a previous date than that of the patent application with effect in Portugal, **provided that they are published on the same date or on a date subsequent to the date of the patent application**.

Inventive step

1. The invention is not obvious to a person skilled in the art having regard the state of art. The state of the art consists of everything made available to the public by a written or oral description, use, displaying or disclosure in any other way before the filing date (priority date).

2. In order to assess the inventive step the contents of non-published patent and utility model applications of a previous date than that of the patent application with effect in Portugal shall not be taken into consideration.

Exclusions from patentable subject matter

- 1. Discoveries, scientific theories and mathematical methods.
- 2. Materials or substances already existing in nature and nuclear materials.
- 3. Aesthetic creations.

4. Schemes, rules or methods for intellectual acts, playing a game or doing business and computer programs, as such, with no **technical** contributions.

5. Presentations of information.

6. Inventions whose commercial exploitation is against the law or contrary to public policy, public health or morality are not patentable and their exploitation may not be considered as such due to the simple fact that it is forbidden by law or regulations.

7. Processes for cloning human beings.

8. Processes for modifying the germinal line genetic identity of human beings.

9. The use of human embryos for industrial or commercial purposes.

10. Processes for modifying the genetic identity of animals which may cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.

11. The human body, at the various stages of its formation and development and the simple discovery of one of its elements, including the discovery of a sequence or partial sequence of a gene. (However a new invention that involves an inventive step and is susceptible of industrial application relating to any isolated element of the human body or produced in any other way by a technical process, including a sequence or partial sequence of a gene, even though the structure of this element is identical to that of a natural element, provided that the industrial application of a sequence or partial sequence of a gene is expressly observed and specifically described in the patent application).

12. Plant and animal varieties as well as the essentially biological processes for obtaining plants or animals, **and the plants or animals obtained exclusively through such processes.**

13. Surgical or therapeutic methods for treating the human or animal body and diagnostic methods used on the human or animal body, though products, substances or compositions used in any of these methods may be patented.

Exceptions and limitations of the rights

1. Private acts done for non-commercial purposes.

2. The preparation of medicinal products performed at the time and for individual cases on the bases of a doctor's prescription at pharmaceutical laboratories or acts relating to the medicinal products prepared in this way.

3. Acts performed exclusively for trial or experimental purposes, **related to the object** of the patented invention, including experiments for the preparation of the administrative processes required for the approval of products by the competent official authorities, though industrial or commercial exploitation of these products may not start before the patent protecting them expires.

4. The use of biological material for the purpose of cultivating or discovering and developing new plant varieties.

5. Use on board of vessels from other countries belonging to the Union or WTO of a patented invention in the hull, machinery, rigging, gear or other accessories of the vessel, if they temporarily or accidentally enter the waters of the country, provided that said invention is used exclusively to serve the ship's needs.

6. The use of a patented invention in the construction or operation of aircraft or land vehicles of other countries belonging to the Union or WTO or their accessories, if temporarily or accidentally enter national territory.

7. The acts set forth in Article 27 of the Convention of 7 December 1944 concerning international civil aviation if they have regard to aircraft from another state to which the provisions of said article apply.

8. The use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, provided that the plant propagating material was sold or otherwise commercialised to the farmer by or with the consent of the patent proprietor for agricultural use.

9. The use by a farmer of protected livestock for an agricultural purpose, provided that the breeding stock or other animal reproductive material were sold or otherwise commercialised to the farmer by or with the consent of the patent proprietor.

10. The acts and use of the information obtained in the terms allowed by the current legislation on the legal protection of computer programs, in particular by their decompilation and interoperability provisions.

11. The protection conferred by a patent relating to a biological material or to a process for producing a biological material or to a product which contains genetic information or consists of genetic information shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

(ii) national and regional laws on opposition systems and other administrative revocation and invalidation mechanisms, available at:

http://www.wipo.int/scp/en/revocation_mechanisms/; and

ANSWER: The information related with "national and regional laws on opposition systems" sent to the International Bureau of the world Intellectual Property Organization is updated.

However, we would like to mention that the minor amendments to the information contained in the document SCP/18/4 requested in the circular C.8585 have not yet been made.

(iii) international worksharing and collaborative activities for search and examination of patent applications, available at: <u>http://www.wipo.int/patents/en/topics/worksharing/</u>.

ANSWER: The information related with "international worksharing and collaborative activities for search and examination of patent applications" available at the WIPO's website is updated (INPI response to Circular C.8585).