

Dear SCP Secretariat,

In reference to the Circular C. 9199 dated December 7, 2023, we have the pleasure to send you some inputs from the Portuguese Institute of Industrial Property (INPI PT) for the preparation of the following documents and webpage:

- (i) a draft reference document on the exception regarding extemporaneous preparation of medicines. The inputs may relate to, for example, relevant court cases, challenges faced by Member States in implementing the exception and the results of the national/regional implementation**

Concerning the exception regarding extemporaneous preparation of medicines, the applicable provision is the article 103(1)(b) of the Industrial Property Code. This Article establishes that: "The rights conferred by a patent do not extend to: The extemporaneous preparation of medications for individual cases in pharmacy laboratories in accordance with a medical prescription or acts concerning the medicine so prepared".

As for challenges faced by Portugal in implementing the exception regarding extemporaneous preparation of medicines and the results of the national/regional implementation, the INPI PT has no information.

- (ii) a study on various aspects of the unity of invention, including divisional application**

Concerning unity of invention, the Portuguese Industrial Property Code establishes in the article 73 that:

"1- In the same application form, it is not possible to apply for more than one patent nor a single patent for more than one invention.

2- A number of inventions that are interconnected in such a way as to constitute a single general inventive concept are considered a single invention.

3- Applicants may, on their own initiative or following examination that reveals that the application does not respect unity of invention, divide the application into a certain number of divisional applications, where each application maintains the original date of application and, if applicable, the priority right.

4- A divisional application can only contain elements that do not go beyond the content of the initial application."

The Implementation Manual of the Industrial Property Code clarifies that where a group of inventions is claimed in one application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution that each of the claimed inventions, considered as a whole, makes over the prior art. This manual also indicates that the determination whether a group of inventions is linked to form a single general inventive concept is made whether the inventions are described in separate independent claims or as alternatives within the same claim.

Furthermore, the Order n° 6142/2019 of INPI PT's President, regarding formal requirements, also establishes that:

“2.1- The claims which define the object of the required protection, must meet the following requirements: (j) allow two or more independent claims in the same category (product, apparatus, process or use), provided that the unity of invention is maintained and only if the claimed subject-matter involves one of the following: a plurality of interrelated products; different uses of a product or apparatus; alternative solutions to a particular problem, where it is inappropriate to cover these alternatives by a single claim.”

The unity requirement could be analyzed *à priori* or *à posteriori*. If there is no common matter between the claims, the Portuguese Office considers that there is no unity between them.

To assess if an application meets the unity requirement (*à posteriori*) the Portuguese Office uses two approaches: the single general inventive concept or the special technical features.

The single general inventive concept approach has the following steps:

- Identify the independent claims;
- Formulate a single general concept. (If there is no single general concept, there is no unity of invention);
- Decide if there is a Single general inventive concept;
- Group the inventions.

The special technical features approach has the following steps:

- Identify the separate inventions;
- Identify differences over the prior art;
- Identify special technical features;
- Decide if the special technical features are the same or corresponding;
- Group the inventions.

If the examiner finds that the claimed invention does not meet the requirement of unity of invention, the search report and the written opinion on the patentability should focus only on the first invention (or inventions that are interconnected in such a way as to constitute a single general inventive concept) claimed (i.e. in these cases the Portuguese Office only does a partial search and a partial examination). The written opinion should contain the identification of the different inventions present in the application and the reasons for non-unity findings. The written opinion should mention the possibility of the applicant to apply for divisional applications for the other inventions identified.

Non-unity objections can be raised during the stage of Search Report with written opinion and/or during the stage of Examination of the invention.

If a non-unity objection is raised the applicant, not agreeing with the objection, can argue in favour of the unity of invention. On the other hand, if he or she agrees with the objection, the application can be divided into a certain number of divisional applications.

A patent application may originate more than one divisional application. A divisional application may itself originate one or more divisional applications.

However, a patent application cannot be divided into a utility model and vice versa; and cannot be divided into a provisional patent application.

The subject-matter of the divisional application may not be equal to or extend beyond the content of the parent application as filed.

(iii) compilation of laws and practices relating to the patentability of artificial intelligence (AI)-related inventions (update of document SCP/30/5)

Inventions regarding Artificial Intelligence (AI) are considered "computer-implemented inventions". Thus, AI-related inventions could be granted if they meet certain requirements.

Therefore, like as any other kind of invention, a computer-implemented invention, in order to be patentable, must not be excluded from patentability and must meet the patentability requirements of novelty, inventive step and industrial application. The technical character of the invention is important when assessing if these requirements are fulfilled.

The same approach applies to computer-implemented inventions related to AI. Given that Artificial Intelligence is based on computational models and algorithms which are per se of an abstract mathematical nature- irrespective of whether they can be "trained" based on training data- it is necessary that computational models and algorithms make a technical contribution (i.e solve a technical problem in a field of technology) in order for computer-implemented inventions related to AI to be granted.

For example, a technical solution to a technical problem can be provided when the invention is directed to a specific technical implementation of AI, i.e. one which is motivated by technical considerations of the internal functioning of a computer. Another example, of AI that makes a technical contribution, is the use of a neural network in a heart-monitoring apparatus for the purpose of identifying irregular heartbeats.

In addition, in the field of AI, in order to have sufficiency of disclosure, the patent application needs to disclose how the artificial network was trained and which input data are suitable for training it according to the invention, or at least disclose one data set suitable for solving the technical problem. Thus, it is important to ensure that the patent application includes sufficient details of the training dataset and must clearly disclose which input data are suitable for training the artificial network, so that this training could be reworked by the person skilled in the art, and therefore the skilled person could carry out the invention.

(iv) a dedicated webpage on the expedited examination program of Intellectual Property Offices (updating the contents of document SCP/35/6)

As INPI PT reported in circular C.9141, at the Portuguese Office, there are some mechanisms/programs for accelerating the examination of patent applications in any technical area, though not specific for Covid-19 related patent applications, namely:

- Patent Prosecution Highway (PPH). Portugal has bilateral agreements with China, Mexico, and Brazil and a global PPH agreement with an extensive network of partners including US, Japan, EPO, and others. This mechanism enables worksharing between the partners,

which contributes to accelerate the patenting process, to increase the quality of decisions and to harmonize them for the joint territory of the partners. The participation in PPH is free of charge.

- Anticipation of publication of the patent application: the Portuguese legislation (Article 69 of the Industrial Property Code) establishes that the publication may be brought forward at the applicant's express request, upon payment of a fee.

(v) a document updating SCP/26/5 (Constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact on the access to affordable especially essential medicines for public health purposes in those countries)

Not applicable

(vi) a document updating SCP/25/4 (compilation of court cases with respect to client-patent advisor privilege)

Regarding client-patent advisor privilege Portuguese court cases, the INPI PT has no information.

(vii) a document updating SCP/32/6 (patent law provisions that contribute to effective transfer of technology, including sufficiency of disclosure)

Concerning patent law provisions that contributed to effective transfer of technology, as the Portuguese Office reported in the circular C.8940, the Portuguese legislation has a provision related with Transfer (article 30 of the Industrial Property Code) that establishes that the rights emerging from patents, utility models can be totally transferred free of charge or against payment. A transfer between living persons shall be proven by a written document. However, if the annotation of the transfer is requested by the transferring party, the recipient must also sign the document proving it or make a statement accepting the transfer.

(viii) a study on patent inventorship and ownership issues arising from collaborative research

The Portuguese Industrial Property Code only establishes in the article 57 "General Rule on the Right to patent" that:

"1- The right to patent shall belong to the inventor or his successor in title.

2- If two or more persons have made an invention, any of them may apply for a patent on behalf of all "

Additionally, the article 59 "Research and development activities" establishes that:

"1 – Inventions created by the employees or staff members of the public collective legal person as a result of their research activities shall belong to the collective legal person whose statutory scope includes research and development activities.

2 – The author of the inventions referred to in the previous paragraph shall give notice of them to the public collective legal person that the employee or staff member works for within three days.

3 – The inventor shall, in any case, have the right to participate in the economic benefits accruing to the public legal person from the exploitation or assignment of the patent rights; the types and terms of this participation shall be provided for in the articles of association or intellectual property regulations of these legal persons.

4 – A public legal person may transfer ownership of the inventions referred to in paragraph 1 to the inventor and may reserve the right to retain ownership of a non-exclusive exploitation licence that is non-transferrable and free of charge.

5 – If in the case stipulated in the previous paragraph the inventor obtains economic benefits from exploiting an invention mentioned in paragraph 1, the public legal person shall be entitled to a percentage of those benefits in accordance with the terms of its articles of association or the industrial property regulations of the respective institution.

6 – Where the employee or staff member obtains the invention during and as a result of the enforcement of a contract with a private or public entity that is different from the public legal person that he or she is an employee or staff member of, said contract shall stipulate who becomes the owner of the patent of that invention.

7 – The participation of the employee or staff member in the economic benefits ensuing from exploitation of the inventions referred to in paragraphs 2 to 6 shall not be of a remunerative or salary nature.

8 – The provisions of the present Article shall apply without prejudice to stipulations or provisions to the contrary.”

Best
regards,

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