

Dear SCP Secretariat,

In reference to the above-mentioned Circular dated January 18, 2022, we have the pleasure to send you the comments of the Portuguese Institute of Industrial Property (INPI PT) to the questions (i) and (ii) on the exceptions regarding exhaustion of patent rights:

**(i) Draft reference document on the exception regarding the exhaustion of patent rights**

*Concerning exhaustion of patent rights, the applicable provision is the article 104.<sup>o</sup> of the Industrial Property Code. This article establishes that:*

*“The rights conferred by a patent do not allow its holder to forbid acts related to the products protected by it, after its sale, by the patentee or with his consent, in the European economic area, unless there are legitimate grounds for the patent holder to object that the products continue to be marketed”.*

*Regarding challenges faced by Portugal in implementing exhaustion of patent rights and the results of the national/regional implementation, INPI has no information.*

**(ii) Study on the sufficiency of disclosure, as proposed in document SCP/31/8 Rev. Inputs with respect to inventions in the technology sectors in which the fulfillment of the sufficiency of disclosure may deserve special attention, for example: inorganic and organic chemistry, including pharmaceuticals; microorganisms; and artificial intelligence.**

*According to the article 62.<sup>o</sup> of the Industrial Property Code, “the description shall give a clear indication, with no reservations or omissions, of everything that defines the object of the invention and contain a detailed explanation of at least one embodiment of the invention, so that any person skilled in the art may carry it out. “*

*Furthermore, the article 66. <sup>o</sup> of the Industrial Property Code, directed at sufficiency of disclosure, also establishes that the patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.*

*In this way, the description shall disclose any feature essential for carrying out the invention in sufficient detail to become it apparent to the person skilled in the art how to put the invention into practice. In some fields, a single example in the description could be enough, but where the claims cover a broad field the requirement of sufficiency of disclosure is not usually fulfilled, unless the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims. So, in the cases where the claims cover a broad field, the application must contain, in addition to the examples, sufficient information to allow the person skilled in the art, using common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill.*

*Concerning pharmaceutical inventions where the therapeutic effect, such as the treatment of a specific disease, is in the claim (medical use claims), the patent application must make said therapeutic effect plausible to fulfill the requirement of sufficiency of disclosure, i.e the application must disclose suitability of the product for the claimed therapy. Simple verbal statement about the effect in the application is not enough to fulfill the requirement; the application must provide information, e.g tests or any kind of data, as long as they clearly and unambiguously reflect the therapeutic effect, to show that the claimed compound has direct effect on the mechanism involved in the disease. This mechanism must be known from prior art or demonstrated in the patent application per se.*

*It is sufficient to show pharmaceutical effect in vitro if for the person skilled in the art there is a clear and accepted established relationship between shown physiological activities and disease (i.e the effect directly and unambiguously reflects the therapeutic application).*

*When the patent application involves multiple compounds claimed under a Markush-type formula, the embodiments of the invention described in the examples should be representative of all the compounds claimed, for a sufficient disclosure of the invention.*

*In applications relating to biological material, such as microorganisms, if an invention concerns biological material is not accessible to the public and cannot be described in the patent application so that a person skilled in the art could carry it out, or entails the use of a material of this type, the description shall only be considered sufficient for the purpose of obtaining a patent if the biological material has been deposited up to the date of submission of the patent application at a recognized depositary institution, such as international depositary institutions that have acquired this status under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of patent procedure of 28 April 1977. The application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material deposited. The depositary institution and the accession number of the deposited biological material are stated in the application.*

*Regarding Artificial intelligence and machine learning, they are 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. In this way, computational models and algorithms need to make a technical contribution.*

*In the field of artificial intelligence and machine learning, the patent application needs to disclose how the artificial network was trained and which input data are suitable for training the artificial network according to the invention, or at least one data set suitable for solving the technical problem, for the application to have sufficiency of disclosure. 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.*

Moreover, we would like to inform you that updated information on the topics (i), (ii) and (iii) will be sent by May 16, 2022.

Best regards,

**Madalena Reis Martins**

**Técnica Superior**  
Senior Officer

**Departamento de Relações Externas**  
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