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# Standing Committee on the Law of Patents

**Thirty-Fourth Session**
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SUMMARY OF DOCUMENT SCP/34/5:  FURTHER STUDY ON THE SUFFICIENCY OF DISCLOSURE (PART I)

*Document prepared by the International Bureau*

I.      INTRODUCTION

1.      At its thirty-third session held in a hybrid format from December 6 to 9, 2021, the Standing Committee on the Law of Patents (SCP) agreed that a further study on the sufficiency of disclosure, as proposed in document SCP/31/8 Rev., would be prepared by the Secretariat, based on the information received from Member States and regional patent offices.  According to paragraph 11 of document SCP/31/8 Rev., a further study covers inorganic and organic chemistry, including pharmaceuticals, as well as microorganisms, artificial intelligence (AI) and any other technological sector in which the fulfilment of the sufficiency of disclosure requirement deserves special attention.

2.      Accordingly, the Secretariat prepared a further study on the sufficiency of disclosure, which is contained in document SCP/34/5.  The further study submitted to the thirty-fourth session of the SCP covers the issues concerning the sufficiency of disclosure regarding: (i) inventions relating to biological materials, such as microorganisms;  and (ii) AI-related inventions (inventions that form the AI technologies and inventions that involve the use of AI).  A second part of the study on the sufficiency of disclosure with respect to inventions having experimental nature in unpredictable art, such as chemistry and biotechnology, and inventions in any other areas that deserve special attention, will be submitted to the thirty-fifth session of the SCP.

3.      In view of the volume of document SCP/34/5, the present document is prepared as a summary of that document.

II.    OVERVIEW OF THE SUFFICIENCY OF DISCLOSURE

4.    The general principles of the sufficiency of disclosure, with references to relevant national and regional patent laws and practices are described in document SCP/22/4 (Study on the sufficiency of disclosure).  It contained the following elements:  (i) the enabling disclosure requirement;  (ii) the support requirement;  and (iii) the written description requirement.  Document SCP/34/5 is built on that earlier study, therefore they should be read together.

5.    Similarly to other patentability requirements, the legal provisions regarding the sufficiency of disclosure lay down general requirements that apply to inventions in any technical field.  Document SCP/34/5 thus emphasizes that the general guidance and methodologies for the assessment of the sufficiency of disclosure, which have been developed in each jurisdiction, also apply to inventions in all technical fields, including biotechnology, chemistry and AI.

6.    Following a brief explanation about the rationale of the sufficiency of disclosure requirements, the document notes that some patent offices provide administrative guidelines or manuals that articulate the application of procedural and substantive patent law requirements in various situations.  Such guidelines and manuals facilitate consistent examination of patent applications by patent examiners, and if published, also inform users of the patent system about the applicable laws and practice applied by the administration.  Furthermore, some patent offices issue more detailed guidance addressing specific technical fields in view of their special characteristics.

7.    Such supplementary information may be considered particularly useful in certain technical fields that can be characterized by their experimental nature, such as chemistry and biotechnology where research outcomes in these fields are less predictable.  Regarding inventions relating to biological materials, depositing such materials with an institution authorized by the applicable law has been a conventional means available for applicants to comply with the sufficiency of disclosure requirement.

8.    More recently, in conjunction with the patentability of inventions involving AI technologies, the sufficient disclosure of AI-related inventions is also addressed in various fora.  In general, new technologies pose particular challenges to meet the sufficiency of disclosure requirement.  Although time may be able to solve these issues, lack of prior art, case law and official guidance makes it difficult for IP offices and users alike to assess the compliance of inventions in new technology fields with the patentability requirements.  In the field of emerging technologies, the technical knowledge of a person skilled in the art can quickly evolve, which can, in turn, make it a particular challenge to determine the level and amount of information that should be disclosed in patent applications.

III.    INVENTIONS RELATING TO BIOLOGICAL MATERIALS, SUCH AS MICROORGANISMS

*Overview of a deposit of biological material*

9.    In principle, the sufficient disclosure of inventions is typically achieved by means of a written description, supplemented by drawings, where necessary.  However, in case of inventions involving the use of a biological material not available to the public, applicants may not be able to disclose such an invention in a written application to an extent that it meet the sufficiency of disclosure requirement.

10.    Consequently, most of the national laws state that, where the application refers to a biological material which is not available to the public and which cannot be described in the application to enable a person skilled in the art to carry out the invention, a deposit of such material with an authorized institution is taken into consideration when determining whether the

requirements of the sufficiency of disclosure have been met.  The deposit is considered to be part of the description to the extent that the requirements regarding sufficiency of disclosure cannot otherwise be complied with.  National and regional laws generally require that the deposit be appropriately referenced in the application.  The depositary institution would make the biological materials available to the public at the appropriate point in the patenting procedure in accordance with the applicable law.

11.     In order to eliminate the need to deposit a biological material in each country in which patent protection is sought, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure was concluded in 1977.  The main feature of the Treaty is that a Contracting State must recognize, for the purposes of patent procedure, the deposit of a microorganism with any "international depositary authority" (IDA), irrespective of whether such authority is on or outside the territory of the Contracting State.  The Regulations under the Budapest Treaty lay down in detail the procedures which depositors and IDAs must follow, the required duration of storage of deposited microorganisms and the mechanisms for the furnishing of samples.  The Regulations do not address the timing of deposit, which is left entirely to the relevant national law.  To a large extent, so are the timing and conditions of furnishing of samples.  Thus, while some of the national/regional law provisions on deposits reflect the provisions of the Budapest Treaty, in some other aspects where there is a freedom for Contracting States to determine their regime, the applicable provisions show divergence.

*Further details regarding the deposit of biological material*

12.     Since the purpose of depositing biological material is to supplement the written disclosure, a deposit of biological material and a mere reference to such a deposit in a patent application cannot replace the explicit disclosure of the invention in the patent application.  In many countries, applicants may need to describe, for example, the characteristics and properties of the biological material or a process for obtaining or using the biological material, in the description part of the application.   Document SCP/34/5 contains further details regarding this issue, summarizing the submissions received from Member States as well as guidelines of some IP offices and relevant case law[1].

13.     It also flows from the above that in order to meet the requirement of sufficient disclosure, the need to deposit the biological material does not arise in all the cases.  In general, the deposit is not required if the specification provides sufficient information that enables a person skilled in the art to carry out the claimed invention.  Broadly speaking, some laws state that where the biological material is available to the public and the person skilled in the art can access it, no deposit is required for the purpose of compliance with the sufficiency of disclosure requirement.  In some other jurisdictions, a deposit is not required if a biological material is regarded as "easily accessible/available" for a person skilled in the art.  In another country, biological material need not be deposited, if, *inter alia*, it is both "known" and "readily available to the public".  The aspect of "undue experimentation" necessary to make or isolate biological materials is also taken into account in some countries.  Document SCP/34/5 contains a summary of examination guidelines of some offices and/or submissions from some Member States that provide further details on specific cases when the deposit of biological material might be required or where it is not mandated, and how such biological material be described in the application.

14.     With respect to the depositary institution, many national/regional laws make a specific reference to institutions that have acquired a status of an IDA under Article 7 of the Budapest Treaty, and/or any other recognized depositary institutions.  Typically, the latter institutions

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[1]     For example decision T 418/89 of the EPO Technical Board of Appeal

include depositary institutions authorized by the competent national IP authority or those recognized through international agreements (such as a bilateral agreement).

15.     In most countries, the deposit has to be made on or before the filing date of the application.  Where the application claims priority from an earlier application, the deposit must have been made on or before the filing date of the earlier application.  Some variations to this rule are found in some national laws.  Under the law of the United States of America, whenever a biological material is specifically identified in an application for patent as filed, a deposit may be made at any time before filing the application for a patent or during the pendency of the application.   When the deposit is made during the pendency of the application, it must be made no later than the time period set by the examiner at the time the notice of allowance and issue fee due is mailed.

16.     With regard to the time limit for including a reference to a deposited biological material in an application, according to the practice of many offices, such reference may be furnished within 16 months from the filing date (or the priority date), in principle.  However, some variations are also found in some national laws in this regard.

17.     Once a biological material is deposited with a depositary institution for the purposes of the patent procedure, the depositary institution will store the material in a manner that it is kept viable and uncontaminated.  It is also a task of the depositary institution to provide samples of the deposited material to interested parties, in accordance with the applicable law.  Although they are not part of the sufficiency of disclosure requirement as such, these aspects are also important for ensuring that a deposited biological material necessary for the practice of a patented invention would be available to the public so that the disclosure mechanism under the patent law functions properly.  Thus, document SCP/34/5 also discusses these matters briefly.

*Nucleotide and/or Amino Acid Sequence Listing*

18.     According to the practice of many patent offices, where the application discloses a nucleotide and/or amino acid sequence, it must include a sequence listing.  In general, where a sequence listing is required to be included in the application, this needs to be done in compliance with WIPO Standard ST.26.  In accordance with that standard, a sequence listing must not include, as a sequence assigned its own sequence identification number, any sequences having fewer than ten specifically defined nucleotides or fewer than four specifically defined amino acids.  Annex C of the Administrative Instructions under the PCT states that the sequence listing part of the description in international applications shall comply with WIPO Standard ST.26.

19.     The submission of Spain clarified that the submission of sequences is not required in all cases.  Specifically, the listing does not need to be provided where it is publicly available, and can be included in an application by providing the access number and version or release number as registered with a publicly available database.  However, the inclusion of sequence listings is recommended in cases where the sequences are either cited in one or more claims or are necessary to search for prior art.  Sequence listings should also be submitted in cases where nucleotide or amino acid sequences are fragments or variants of a known sequence associated with the state of the prior art.

IV.    AI-RELATED INVENTIONS

*Overview of AI technology and terms*

20.    After a short introduction, the document gives an overview of AI technology and terms.  In the document, the term "computer implemented inventions (CIIs)" is used when referring to inventions that involve the use of a computer.  In general, the term "artificial intelligence (AI)" is often used as a catch-all term that covers machine learning, evolutionary algorithms, and other technologies, such as rule-based systems.  At the high level of abstraction, one can describe AI as technology that attempts to mimic, at least partly, what is regarded as human intelligence.  The main part of AI applications comes down to predictions made by computational techniques, based on available information and software that has somehow been trained to make these predictions.

21.    Machine learning, which is the dominant AI technique included in more than one-third of all identified AI-related patent documents, can be seen as a subfield of AI, which works by identifying patterns in available data and then applying the knowledge to new data.  If a machine learning model contains a more complex architecture composed by a higher number of layers, it can be described as deep neural network or deep learning.  Considering the above, one can understand AI-related inventions as a specific form of CIIs that are however more sophisticated than other forms of software due to their ability to improve models to perform better predictions by analyzing many examples and iteratively feeding data into an algorithm to improve output.  In particular, once a learned function is generated, it can be used to make predictions for previously unknown data.

*Guidelines, practices and case law*

22.    From the guidelines and submissions of some Member States, the national/regional practices that have been developed in assessing sufficiency of disclosure of CIIs are often applied to AI-related inventions.  Additionally, express references to the sufficiency of disclosure of AI-related inventions are found in examination guidelines of some patent offices.  These guidelines sometimes provide case examples of AI-related inventions.  Document SCP/24/5 summarizes these explanations and case examples found in the materials from Brazil, China, Japan, the Republic of Korea, the United States of America and the European Patent Office (EPO).

23.    According to the information received from Member States, there is not yet much established national case law on sufficiency of disclosure with regard to AI.  The document summarizes two decisions of the EPO Technical Boards of Appeal[2] and a decision made by a U.S. District Court[3].  While the case law in this field has not been fully developed, the existing information collected from some jurisdictions seem to show that the assumed knowledge of a person skilled in the art, which could evolve quickly, is particularly highlighted in the assessment of sufficiency of disclosure of AI-related inventions.

*Issues that Often Arise*

24.    Following the description of the guidelines, practices and case law found in some Member States, the document summarizes the issues that are often raised in this area.  The discussions appear to suggest that the facts of each case, such as the nature of the specific AI-related invention, significantly influence how and in which depths the description must reveal, for instance, training data sets or the correlation between input and output data.

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[2]    T 0161/18 and T 1191/19, EPO Technical Boards of Appeal.
[3]    Centripetal Networks, Inc. v. Cisco Systems, Inc., United States District Court for the Eastern District of Virginia Norfork Division.

25.     The correlation between input and output data is discussed as an essential point when assessing sufficiency of disclosure regarding AI-related inventions.  The uncertainties surrounding AI-related applications and the sufficient disclosure of a correlation between input and output data may be related to the above-described difference between an AI-related invention and general CIIs, i.e., AI is capable to learn and the output is not always predictable.  However, it is also underlined that even the most "intelligent" machine learning models are not autonomous and need to be fine-tuned by machine learning experts.  Their functioning can be understood by experts, even though it is not always possible even for experts to precisely explain how the concrete output is generated based on the given input.  This is particularly the case for deep neural networks, since humans do not have the capability of processing such large amounts of data.  In particular, the examples provided in the guidelines of the Japan Patent Office (JPO) and the Korean Intellectual Property Office (KIPO) suggest that it may decisively depend on the general knowledge of the person skilled in the art on the filing date whether and to which extent the description of the patent application needs specific explanation of the correlation between input and output data to fulfil the enablement requirement.

26.     The issue of the black box is closely related, if not considerably overlapping, to the issue regarding the correlation of input and output data, addressed above.  The term "black box" can be described as the inability to fully understand an AI's decision-making process and to predict the AI's decisions or outputs.  It is noted that Member States may see considerable difficulties in granting "black box patents" due to their lack of sufficiency of disclosure, whereby the relation between sufficiency of disclosure and patent eligibility (technical effect) in this context is specifically underlined by some.  A submission of Germany stated that in examination practice, the black box phenomenon inherent to many AI algorithms usually does not pose a problem regarding the assessment of sufficient disclosure of the invention, as long as sufficient details are given about which AI algorithm to use and how to train it.

27.     As outlined in the context of input-output correlation, it can be understood from the discussed examination guidelines, exemplary cases and case law that the required amount of detailed information on the AI-related features to be described in AI-related patent applications depends, to a large extent, on the knowledge of a person skilled in the art at the filing date.  Similarly, what is considered as a black box also significantly depends on the general knowledge in the corresponding field.  One researcher considered that black boxes which cannot be practically reverse engineered (strong black boxes) may be more suitably protected by technical measures combined with trade secrets and prevention of unfair competition than through patent protection.  At the same time, practitioners try to develop best practices of drafting AI-related patent applications to avoid the "black box phenomenon" and, as a consequence, the lack of sufficiency of disclosure.

28.     The disclosure of training data sets is another topic that is widely discussed when it comes to patent applications concerning machine learning.  In general, training data seem to be the most valuable element of the machine learning process, since they significantly influence the accurateness of trainable parameters and hence the preciseness of the output.  The submission of Member States and provided case examples as well as the discussed case law of the EPO Technical Boards of Appeal underline that insufficient example sets of training data can be, among other factors, a reason for the lack of sufficient disclosure.  However, whether the data used to train the algorithm need to be disclosed in the patent application and the level of detail in which it needs to be described depend on the nature of the claimed invention and the knowledge of the person skilled in the art.

29.     The submissions of some Member States also show that another problem of assessing sufficiency of disclosure may be the use of terms without precise meaning.  In particular, the submission of Türkiye considers that one of the main issues with AI-related applications is that technical terms regarding AI are used in the description and claims with neither their definitions nor detailed explanation about their implementation in the AI-related invention.


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