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FURTHER STUDY ON THE SUFFICIENCY OF DISCLOSURE (PART I)

Document prepared by the Secretariat

I. INTRODUCTION

1. At the twenty-second session of the Standing Committee on the Law of Patents (SCP), held in Geneva from July 27 to 31, 2015, the Committee discussed a study on the sufficiency of disclosure prepared by the Secretariat (document SCP/22/4). The study addressed the main general principles of the sufficiency of disclosure, with references to relevant national and regional patent laws and practices. It contained the following elements: (i) the enabling disclosure requirement; (ii) the support requirement; and (iii) the written description requirement.

2. At its thirty-third session held in a hybrid format from December 6 to 9, 2021, the Committee 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 deserves special attention. As a non-exhaustive list of topics to be covered, the said paragraph lists the following areas:

- Chemical compounds defined by Markush formula;
- Esters, ethers, salts, N-oxides;
- Stereoisomers (enantiomers, diastereomers, Cis-trans and E-Z isomerism);
- Pro-drugs;

- Compositions and formulations;
- Polymorphic forms and crystalline, co-crystals, hydrates, solvates;
- New use of a known compound;
- Manufacturing process of chemical products;
- Microorganisms (different aspects related to the implementation of the Budapest System);
- Artificial intelligence (AI).

3. Consequently, the Secretariat invited Member States and regional patent offices, through Circular Note C. 9089 dated January 14, 2022, to submit relevant inputs to the International Bureau.

4. Taking into account the information submitted by the Member States and regional patent offices in response to C.9089, the Secretariat prepared a further study on the sufficiency of disclosure, which is contained in this document. 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 further study on the sufficiency of disclosure, with respect to inventions having an experimental nature in unpredictable art, such as chemistry and biotechnology, and of any other areas that deserves special attention, will be submitted to the thirty-fifth session of the SCP.

5. As the further study on the sufficiency of disclosure is built on the earlier study contained in SCP/22/4, they should be read together.

II. OVERVIEW OF THE SUFFICIENCY OF DISCLOSURE

A. Summary of the Sufficiency of Disclosure Requirements

6. 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. While a couple of supplementary provisions are often found in respect of inventions relating to biological materials, these provisions are applicable to the extent that such inventions cannot otherwise meet the general requirements.[1] Consequently, the general guidance and methodologies for the assessment of the sufficiency of disclosure, which have been developed in each jurisdiction, apply to inventions in all technical fields, including biotechnology, chemistry and AI.

7. The sufficiency of disclosure requirement reflects one of the fundamental features of patent law: in exchange for the exclusive rights granted to a patentee on a claimed invention, the right holder must disclose the information relating to the invention to the public. It is through this requirement that the patent system facilitates the dissemination of and access to technological information contained in patent applications. Such a public disclosure mechanism is expected to result in the expansion of generally accessible technical knowledge, inducing technology transfer and avoiding duplicative R&D. Another common element in patent laws is that the scope of the claimed invention shall not extend beyond what was disclosed in the application and what had not been recognized and possessed by the inventor as of the filing date, thus foreclosing granting patents on speculative inventions.

[1] See paragraphs 53 to 56 of document SCP/22/4 (Study on the Sufficiency of disclosure).

8. In short, the general principles of the enabling disclosure requirement, the support requirement and the written description requirement may be summarized as follows.[2]

9. *Enabling disclosure requirement*: Overall, the enabling disclosure requirement requires an applicant to disclose the claimed invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This means that the assessment of the enabling disclosure requirement closely relates to the breadth of the claims. Based on the information disclosed in a patent application and the general common knowledge in the art, a person skilled in the art should be able to perform or reproduce the claimed invention without undue burden, effort or experimentation. The disclosure must be enabling for a person skilled in the art at the time of the filing date.

10. *Support requirement*: In general, the claims shall be fully supported by the description, thereby showing that the applicant only claims subject matter which it had recognized and described in the description on the filing date. In general, when determining whether a claim is supported by the description, the whole contents of the description, together with any drawings, shall be taken into account. Most claims are generalizations from one or more particular embodiments or examples as set forth in the description. In general, the extent of permissible generalization is a matter which has to be established in each particular case in the light of the relevant prior art.

11. *Written description requirement*: The written description requirement is a requirement provided under the law of the United States of America. The United States Code, Title 35, Section 112(a) requires that "[t]he specification shall contain a written description of the invention […]". To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail so that a person skilled in the art can reasonably conclude that the inventor possessed the claimed invention at the time the application was filed.

B. Application of the General Principles to Inventions in Specific Technical Fields

12. While in each country, legal provisions in the applicable law set forth the sufficiency of disclosure requirement, which may be detailed or nuanced, where appropriate, by case law, some patent offices provide administrative guidelines or manuals that articulate the application of procedural and substantive requirements in various situations. Such guidelines and manuals facilitate consistent examination of patent applications by patent examiners. If published, they also inform patent applicants, patent attorneys and other stakeholders about the applicable laws and practice applied by the administration.

13. Oftentimes, the general guidelines prepared by patent offices contain examples about how the substantive requirements are applied to inventions from various technical fields. In addition, some patent offices supplement the general guidance with more detailed and specific guidance on how to apply the general guidance to the assessment of the sufficiency of disclosure of inventions in a specific technical field, taking into account the special characteristics of these inventions. Case law also provides useful guidance on the application of law in some specific circumstances.

14. Such supplementary information may be considered particularly useful in certain technical fields that can be characterized by its experimental nature, such as chemistry and biotechnology. In general, research outcomes in these fields are less predictable, in comparison to, for instance, the electronic or mechanical field. For example, the technical effects of a chemical compound or a biological material are not always predictable only from its structure, and thus the purported technical effects may need to be verified and confirmed by

[2] See document SCP/22/4 (Study on the sufficiency of disclosure) for further explanations.

experimental data. In some cases, it may be possible to define a chemical product or a biological material by its properties, or by a method of preparing such a product, even if its structure has not been fully and clearly defined. In addition, compared to other fields of technology, a chemical or biological product with a particular structure could have a number of different and unpredicted properties (or utilities), while the functionality and utility of, for example, a hock could be predictably defined by its physical structure. For the determination of the sufficiency of disclosure, these characteristics may deserve a special attention.

15. With respect to inventions relating to biological materials, depositing such materials with an institution authorized by the applicable law has been a conventional, well-accepted means available for applicants to comply with the sufficiency of disclosure requirement. The deposit is considered part of the description to the extent that the requirements regarding the sufficiency of disclosure cannot otherwise be complied with. Where a patent application contains disclosure of nucleotide and/or amino acid sequences, submission of a sequence listing, or a reference to it, may be required.

16. More recently, some questions relating to the sufficiency of disclosure were raised in relation to inventions involving AI technologies.[3] Since the usage of the expressions such as “AI inventions” or “AI-related inventions” are often ambiguous, there is a need to clarify what is the relevance of AI to the claimed invention at the first place, before entering into substantive discussions on the assessment of the sufficiency of disclosure of such invention. For example, regarding the technologies that form AI, while an AI algorithm, a training model, a neural network architecture, a learning process etc. most likely fall under the category of software inventions or computer-implemented inventions, they may also relate to development of hardware components of AI, such as a Tensor Processing Unit (TPU). On the other hand, an inventor may utilize AI as a tool to create a new invention, or an inventor may be assisted by AI for the creation of a new invention. In such a case, the new invention could be anything from a bottle, a pharmaceutical compound to a business method or another software invention.

17. In general, AI technologies or other types of emerging technologies pose particular challenges to meet the sufficiency of disclosure requirement, i.e., to disclose inventions in a clear and complete manner and to draft clear and concise claims that adequately cover the scope of legitimate protection. Although time may be able to solve these issues, lack of prior art, case law and official guidance makes it difficult for the IP offices and users of the patent system to assess the compliance of inventions in new technology fields with the patentability requirements, including the sufficiency of disclosure. Furthermore, at the stage when the technology develops rapidly, a hypothetical “person skilled in the art” in that field also evolves very quickly. It is a challenging task to assess the level and amount of information that must be disclosed in a patent application from the perspective of such a moving target.

18. Despite the above paragraphs that highlight some areas for consideration regarding the sufficiency of disclosure in specific technical fields, it should be reiterated that the fundamental legal requirements relating to the sufficiency of disclosure are prescribed in the applicable law. In any technical field, whether an application meets the disclosure requirement is determined by considering each case on its own merits.

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[3] See, for example, SCP/31/8 Rev. (Revised proposal by the Delegations of Brazil and Spain) and SCP/30/5 (Background document on patents and emerging technologies).

III. INVENTIONS RELATING TO BIOLOGICAL MATERIALS, SUCH AS MICROORGANISMS

A. Particularities of the Disclosure of Biological Material

19. Inventions involving microorganisms, or broadly speaking, biological materials, follow the general principles of sufficiency of disclosure requirements, namely, the enabling disclosure requirement, support requirement and written disclosure requirement.[4] For the purpose of this document relating to the sufficiency of disclosure, the term "biological material" is used, since that term, which reflects the technological development in practice, is widely used in modern patent law.[5,6]

20. In principle, the sufficient disclosure of inventions is typically achieved by means of a written description, supplemented, where necessary, by drawings. However, in case of inventions involving the use of a biological material not available to the public, applicants may not be able to fully disclose such invention in a written application to the extent that meet the sufficiency of disclosure requirement. In other words, a person skilled in the art may not be able to repeat the effect of the invention, or to reproduce the invention, based on a written description alone. For example, in the case of a microorganism isolated from soil and modified by mutation and further selection, in some cases, it would be difficult to describe the strain and its selection sufficiently to guarantee a person skilled in the art to obtain the same strain from soil itself. In such a case, the microorganism itself might be considered to be an essential part of the disclosure.

21. Taking into account such a specificity of biological materials, as far as compliance with the requirement of the sufficiency of disclosure is concerned, 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 in a way of enabling a person skilled in the art to carry out the invention, the deposit of such material with an authorized institution is taken into consideration when determining whether the sufficiency of disclosure requirement has been met. The deposit is considered to be part of the description to the extent that the requirements

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4 See submissions of Singapore and the Czech Republic. Submissions of Member States are available at: https://www.wipo.int/scp/en/meetings/session_34/comments_received.html. For information on general aspects of the sufficiency of disclosure requirement, see document SCP/22/4.

5 Many national laws refer to the term "biological material" instead of "microorganism". It is considered that the term biological material is broader and can refer to any material containing genetic information capable of reproducing itself or being reproduced in a biological system. For example, in Annex B, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan, the "biological materials" are defined as "materials which have genetic information, and can replicate or breed by themselves or can replicate in vivo on the basis of the genetic information. Namely, the biological materials include nucleic acids (genes, vectors, etc.), polypeptides (proteins, monoclonal antibodies, etc.), microorganisms […], and animals and plants […], while microorganisms include "animal or plant cells (including stem cells, dedifferentiated cells and differentiated cells) and tissue cultures, in addition to fungi, bacteria, unicellular algae, viruses and protozoans. The microorganisms also include fused cells (including hybridomas) obtained by genetic engineering". Similarly, the submission from Brazil to SCP/34 states that the representative examples of biological material include bacteria, archaea, protozoa, viruses, fungi, algae, seeds, animal and plant cell lines, hybridomas, artificial chromosomes, and other vectors.

6 It is to be noted that the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure does not provide the definition of "microorganisms". The Guide to the Deposit of Microorganisms under the Budapest Treaty notes that, whether a deposited entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether the depositary institution will accept it (see page 4 of the Guide).

regarding sufficiency of disclosure cannot otherwise be complied with.[7,8] National and regional laws generally require that the deposit be appropriately referenced in the application. The depositary institution would then make the biological materials available to the public at the appropriate point in the patenting procedure in accordance with the applicable law.

22. It is to be noted that the purpose of depositing biological material is to supplement the disclosure of the application. Therefore, in many jurisdictions, it is clarified that a deposit of biological material cannot replace the description of the properties of the biological material in a patent application.

23. In addition, it also follows from the above explanation that, in order to meet the requirement of sufficient disclosure, a need to deposit the biological material does not arise in all the cases. An applicant may argue that a deposit of the relevant biological material is not necessary, because the specification gives sufficient information so as to enable the invention to be performed by a person skilled in the art. However, if the disclosure, in the absence of the deposit, is found to be insufficient during the examination procedure, such a deficiency cannot be cured subsequently after the filing date, as a patent application cannot be amended in a way that it contains a subject matter that extends beyond the disclosure in the application as filed.[9]

24. Thus, in general, assessment of whether a deposit has been necessary for the sufficient disclosure of the invention is part of the examination process for applications relating to biological materials. However, it is noted that while some assessment of the validity of deposit information may be made by a patent office insofar as it is possible, full forensic assessment of the deposit during the examination would be not possible or reasonably practicable by the patent office.[10]

B. Recognition of a Single Deposit

25. In order to eliminate the need to deposit a biological material in each country in which protection is sought, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereafter “Budapest Treaty”) 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.[11]

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7 A deposit of biological material is also taken into consideration in determining whether the support requirement, as provided under the applicable law, has been met. See, e.g., paragraph 6.18 of the PCT International Search and Preliminary Examination Guidelines.

8 Section E of the Guide to the Deposit of Microorganisms under the Budapest Treaty provides information on the statutory requirements and the practices of the industrial property offices of the States party to the Budapest Treaty and of Intergovernmental Industrial Property Organizations as regards the deposit of microorganisms for the purposes of patent procedure. The Guide is available at: https://www.wipo.int/budapest/en/guide/section_e/section_e.html.

9 With respect to general principles of the sufficiency of disclosure requirement, see document SCP/22/4. See also submission of the United Kingdom to SCP/34 in this respect.

10 The Budapest Treaty in Rule 11.1 states that any international depositary authority shall furnish a sample of any deposited microorganism to the IP office of any Contracting State, where an application referring to the deposit has been filed with that office, the application is pending before that office, and the sample is needed, and will be used, by the office for the purpose of a patent procedure. However, IP offices usually do not have technical facilities for carrying out any forensic assessment of the validity of the deposit. See also, e.g., the submission from the United Kingdom to SCP/34.

11 An IDA is a scientific institution, typically a culture collection that is capable of storing microorganisms. In order for a culture collection to obtain the status of an IDA, the Contracting State in the territory of which it is located shall send a communication to the Director General, including the declaration of assurances to the effect that the said collection complies and will continue to comply with the requirements of the Treaty (Article 7 of the Budapest Treaty).

26. 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.[12]

C. Deposit of Biological Material and Description of its Properties

27. While there are differences in national/regional laws with regard to the disclosure of biological material, most laws require that where the application refers to biological material, or an invention involves the use of or concerns biological material, which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed, as provided under the applicable law, if:

(i) a sample of the microorganism/biological material has been deposited with a recognized depositary institution;
(ii) the name of the depositary institution, accession number of the deposited microorganism/biological material, and the date of the deposit are stated in the application;[13] and
(iii) a description of the characteristics and properties of the microorganism/biological material, to the extent available to the applicant, is provided.[14]

28. With regard to the characteristics/properties of the biological material, as noted above, the purpose of depositing such material is to supplement the disclosure of the application, and the deposit cannot replace the requirement to describe the properties of a microorganism or a microbiological process in the application. In this regard, the PCT International Search and Preliminary Examination Guidelines states that “mere reference to the deposited material in an application may not be sufficient to replace the explicit disclosure of such material in the application in order to comply with the sufficiency of disclosure requirements”.[15] Likewise, the submission from Germany explains that with respect to the microbiological processes and products thereof, a sample of the biological material shall be deposited and a description indicating a reproducible manufacturing process using the biological material and/or of the properties of the biological material claimed shall be included in the application.[16] The Manual of Patent Practice of the United Kingdom states “when the claims are directed to the production of a new micro-organism (from or using available micro-organisms), a description as to how the new micro-organism has been obtained will be necessary to satisfy Section 14(3), even if a deposit of the new micro-organism has been made”.[17]

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12 For more information on the Budapest Treaty system for international deposit of microorganisms, see: https://www.wipo.int/budapest/en/.

13 In the United Kingdom, there is no longer a requirement to supply the date when the biological material was deposited at the depositary institution. It is explained that the date of making the deposit is readily ascertainable from the name of the depositary institution and the accession number. There is also no longer a requirement to mention any international agreement (e.g., the Budapest Treaty) under which the biological material is deposited. See Section 125A.07 of the Manual of Patent Practice of the United Kingdom.

14 See, e.g., the provisions of laws of Austria, Belgium, the Czech Republic, the Dominican Republic, Germany and Spain.

15 Paragraph 4.17 of the PCT International Search and Preliminary Examination Guidelines

16 Section 2a (2) No. 2 German Patent Act.

17 Section 125A.15 of the Manual of Patent Practice of the United Kingdom. See also submission from Türkiye to SCP/34 stating that: “it should be noted that the accession number from an international depositary

29. In this respect, the Guidelines for Examination of the European Patent Office (EPO) states that the examination division must, *inter alia*, check whether the application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material. The relevant information concerns:

- the classification of the biological material and significant differences from the known biological material. For this purpose, the applicant must, to the extent available, indicate morphological and biochemical characteristics and the proposed taxonomic description;

- the information on the biological material in question which is generally known to the skilled person on the date of filing, if necessary, has to be provided through experiments in accordance with the relevant standard literature;[18]

- information needs to be given on every further specific morphological or physiological characteristic relevant to recognition and propagation of the biological material, e.g. suitable media (composition of ingredients), in particular where the latter are modified;

- abbreviations for biological material or media must be avoided or written in full at least once;

- if biological material is deposited that cannot replicate itself but must be replicated in a biological system (e.g. viruses, bacteriophages, plasmids, vectors or free DNA or RNA), the above-mentioned information is also required for such biological system. If, for example, other biological material is required, such as host cells or helper viruses, that cannot be sufficiently described or is not available to the public, this material must also be deposited and characterized accordingly. In addition, the process for producing the biological material within this biological system must be indicated.[19]

30. The Boards of Appeal of the EPO have issued several decisions with respect to the requirement of sufficiency of disclosure in the biotechnological field. For example, in decision T 418/89, the characteristics of the monoclonal antibodies produced by the deposited strain were different from those mentioned in the claims. It was not possible to produce monoclonal antibodies from the deposited hybridoma using techniques recommended by the depositary institution. The requirements of Article 83 EPC 1973 were thus not met. A disclosure could not be regarded as sufficient if it was only possible to reproduce the invention after repeated requests to the depositary institution and by applying techniques considerably more sophisticated than those the latter recommended. Nor could the scope of the patent be restricted to what had been deposited, as the characteristics of the deposit differed from the written disclosure in the patent. Thus a mere deposit of a hybridoma without any corresponding

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authority cannot replace the written description. In order to comply with the sufficiency of disclosure requirements, the applicant should also provide the information available to the applicant to characterize the microorganisms as exhaustively as possible at the time of the application. Distinctive morphological, biochemical and taxonomical characteristics are examples to the information that the applicant can provide in order to characterize the microorganisms.”.

18 For characterizing bacteria, as an example, the Guidelines for Examination specifically refers to the work of R.E. Buchanan, N.E. Gibbons: Bergey's Manual of Determinative Bacteriology. See Part F, Chapter III.6.3(i) of the Guidance for Examination of the EPO.

19 Chapter III.6.3(i), Part F of the Guidance for Examination of the EPO, available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iii_6_3.htm.

written description did not provide a sufficient disclosure. Similar conclusions were reached in decisions T 495/89 and T 498/94.[20]

31. Similarly, with respect to a host material, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan states: "[i]f the description is not stated in such a manner that enables a person skilled in the art to produce a gene, a vector, a recombinant protein, a monoclonal antibody, an animal or a plant, etc. in relation to an invention thereof, deposit of them is necessary. In a case of depositing them, a transformant in which a produced gene or vector is introduced (including a transformant producing a recombinant protein), a fused cell (including a hybridoma producing a monoclonal antibody), a fertilized egg, a seed, a plant cell, etc. shall be deposited, and the accession number shall be stated in the originally attached description."[21]

32. Further, the Examination Handbook for Patent and Utility Model of Japan provides information on how different types of biological material can be described in the application to satisfy the enablement requirement. With respect to microorganisms obtained by means other than genetic engineering specifically, the Handbook explains:

> "In order to clearly explain an invention relating to a fungus or bacterium, for example, a generic (species) name with nomenclature of fungi or bacteria, or a strain name in which the generic (species) name is added, may be described. In relation to an invention of a new strain, the characteristics of the strain as well as the difference (microbiological characteristics) between the new strain and the publicly known strains within the same species to which the new strain belongs may be described. In relation to an invention of a new genus (species), the taxonomic characteristics such as fungi and bacteria may be described in detail, and the reason why the microorganism is decided to be a new genus (species) may be described. Namely, the difference between the genus (species) and the existing similar genus (species) may be clearly described, and grounds on the decision may be described. The taxonomic characteristics may be described with reference to "Bergey's Manual of Determinative Bacteriology" etc.
>
> In order to show that a fungus or bacterium can be produced in an invention relating to the fungus or bacterium, a production process, such as a screening means and a mutagenesis means, may be described.
>
> In order to clearly explain an invention relating to an animal or plant cell and show that the cell can be produced, the name of organism which is an origin of the cell may be described using the scientific name or standard Japanese name in accordance with zoological or botanical nomenclature, in principle. A combination of a specific gene or membrane protein of the animal or plant cell and the characteristics of the animal or plant cell, may be described. In order to show that the cell can be produced, a production process, such as a screening means and a mutagenesis means, may be described."[22]

33. The submission from the Czech Republic explains that the actual morphology of the microorganism (whether, e.g., it is shaped in rods (bacilli) or spheres (cocci)), is not essential.

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20 See case law of the Boards of Appeal at: https://www.epo.org/law-practice/legal-texts/html/caselaw/2019/e/clr_ii_c_7_6_1.htm.

21 Annex B, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan, p.10. In the United States of America, 37 CFR 1.804 also states that "viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.".

22 Annex B, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan, p. 5 and 6.

However, the properties of the microorganism that are essential for its industrial applicability must be described.[23]

D. New Deposit

34. Some laws contain provisions authorizing the applicant to make a new deposit within a period of time as specified in the applicable law where the biological material ceases to be available at the depositary institution, reflecting Article 4 of the Budapest Treaty.[24] Specifically, the laws require, *inter alia*, that a new deposit be accompanied by a statement signed by the applicant certifying that the newly deposited biological material is the same as that originally deposited.[25]

E. Cases Where Deposit of Biological Material is Not Necessary

35. As noted above, not all biological material involved in a particular invention must be disclosed. 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.

36. In this regard, the case law of the EPO provides further insights:[26]

- Rule 31(1) of the EPC[27] cannot be interpreted such that there is an obligation to deposit material to facilitate the reproduction if the invention can be repeated on the basis of the

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23 In this connection, the submission of the Czech Republic notes that the purpose of its use must be disclosed as it is not possible to grant a patent without potential industrial applicability.

24 Article 4(1) of the Budapest Treaty states: "(a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular, (i) where such microorganism is no longer viable, or (ii) where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions, that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited. (b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that: (i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority, either entirely or in respect of the kind of microorganism to which the deposited microorganism belongs, or where the international depositary authority with which the original deposit was made discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms; (ii) it may be made with another international depositary authority in the case referred to in subparagraph (a)(ii). (c) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law. […]"

25 See, e.g., Section 10bis of the Royal Decree of December 2, 1986 of Belgium and paragraph 8, Schedule 1, Rule 13(1) of Patents Rules 2007 of the United Kingdom.

26 The case law of the Boards of Appeal of the EPO referred to in this paragraph can be found at: https://www.epo.org/law-practice/legal-texts/html/caselaw/2019/e/clr_ii_c_7_6_1.htm.

27 Rule 31 of the EPC states: "(1) If an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 if: (a) a sample of the biological material has been deposited with a recognised depositary institution on the same terms as those laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 not later than the date of filing of the application; (b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material; (c) the depositary institution and the accession number of the deposited biological material are stated in the application, and (d) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is submitted to the European Patent Office providing evidence that the depositor has authorised the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with Rule 33.".

written description, even if this should be a much more cumbersome way than by merely growing the deposited micro-organism (see e.g. T 223/92).

- In T 412/93 the board stated that the need for a deposit cannot be introduced by reference to the concept of undue burden. This concept relates more to cases where the route that the reader is to follow is so poorly marked that success is not certain such as in T 418/89. If the road is certain but long and laborious, the patentee is under no obligation to assist the disclosure by making actual physical samples available. The board felt that to come to the opposite conclusion would be effectively to introduce a requirement to make the best mode immediately accessible to the public, and such a requirement is not part of the European patent system.

- With respect to the question as to whether the reproducibility of specific micro-organisms (e.g. plasmids or viral strains) was assured by the written description in the absence of a deposit, the board, after examination of the written disclosure, held in some cases that the information provided in the application was sufficient to lead the skilled person reliably to the same micro-organisms (T 283/86, T 181/87); in other cases, it was not (T 815/90, T 816/90; T 2542/12, T 1338/12,).

37. The United States Patent and Trademark Office's (USPTO) Manual of Patent Examining Procedure (MPEP) states that an applicant may show that a deposit of the specific biological materials is not necessary if those biological materials can be made or isolated without undue experimentation. Deposits may be required to support the claims if an isolation procedure requires undue experimentation to obtain the desired biological material.[28] No deposit is required, however, where the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test.[29]

38. In addition, some laws state that where the biological material is *available to the public* and the person skilled in the art can access it, no such deposit is required for the purpose of compliance with the sufficiency of disclosure requirement.[30]

39. The examination guidelines of some offices specify the following cases when the biological material is considered to be available to the public: the biological material may be known to be readily available to those skilled in the art (e.g. baker's yeast or Bacillus natto, which is commercially available); it is a standard strain (e.g. Escherichia coli); or, it is known to have been previously deposited in a recognized depositary institution and to be available to the public without restriction. Alternatively, the applicant may have given in the description sufficient information as to the identifying characteristics of the biological material and as to the prior availability in a culture collection, no further action is called for. [31]

40. In addition to the above, the submission from Spain explains that if a patent application bases its presentation of the invention on a previously published scientific article on use of the microorganism as a means to ensure sufficient disclosure, the microorganism is presumed to be

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28 Reference is made to *Ex Parte Jackson,* 217 USPQ 804 (Bd. App. 1982).

29 Reference is made to *Tabuchi v. Nubel,* 559 F.2d 1183, 194 USPQ 521 (CCPA 1977); *Ex Parte Hata,* 6 USPQ2d 1652 (Bd. Pat. App. & Int. 1987). See Section 2404.02 of the MPEP of the USPTO.

30 See, e.g. Article 2 of Enforcement Decree of the Patent Act of the Republic of Korea; and Section 125A.02 of the Manual of Patent Practice of the United Kingdom. The Boards of Appeal of EPO acknowledged in this respect that the disclosure of a microorganism need not depend on a deposit according to Rule 28 EPC 1973 where the microorganism is sufficiently disclosed by other means (T 2068/11; cited recently by T 1338/12).

31 See submission of Spain to SCP/34; Section 125A.10 of the Manual of Patent Practice of the United Kingdom. See also Part F, Chapter III.6.2 of the Guidance for Examination of the EPO.

available, even if not deposited, as from the date of publication of the article. Accordingly, if the patent application refers to the same microorganism, sufficiency of disclosure is fulfilled.[32]

41. Similarly, in Japan and the Republic of Korea, a microorganism is "easily accessible/available" for a person skilled in the art in the following circumstances:

(i) commercially available microorganisms;
(ii) microorganisms in cases where it has been evident, prior to filing, that the microorganisms have been stored at a reliable culture collection and are freely furnished from a catalog or the like issued by the culture collection. In this case, the name of the institution and storage number of the microorganism should be stated in the specification at the time of filing of the application;
(iii) microorganism that can be manufactured by a skilled person in the art on the basis of the description.[33]

42. In the United States of America, biological material need not be deposited, *inter alia,* if it is both "known" and "readily available to the public".[34] The MPEP explains that a material may be known in the sense that its existence has been published, but is not available to those who wish to obtain that particular known biological material. Likewise, a biological material may be available in the sense that those having possession of it would make it available upon request, but no one has been informed of its existence.[35] The Board of Patent Appeals and Interferences has held that a description of the precise geographic location of marine tunicates, as a biological material, used in a claimed invention was adequate to satisfy the enablement requirement of 35 U.S.C. 112.[36] The term "readily" used in the phrase "known and readily available" is considered appropriate to define that degree of availability which would be reasonable under the circumstances. If the biological material and its natural location can be adequately described so that one skilled in the art could obtain it using ordinary skill in the art, the disclosure would appear to be sufficient to meet the enablement requirement of 35 U.S.C. 112 without a deposit so long as its degree of availability is reasonable under the circumstances.

43. The MPEP further states that there are many factors that may be used as indicia that a biological material is known and readily available to the public. Relevant factors include commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, evidence of predictable isolation techniques, or an existing deposit made in accordance with the applicable rules.[37] Each factor alone may or may not be sufficient to demonstrate that the biological material is known and readily available. The Manual also notes that those applicants that rely on evidence of accessibility other than a

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32 Submission of Spain to SCP/34.

33 See Article 2 of Enforcement Decree of the Patent Act of the Republic of Korea and Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan (p.9).

34 37 CFR 1.802.

35 See Section 2404.01 of the MPEP of the USPTO.

36 See *Ex Parte Rinehart,* 10 USPQ2d 1719 (Bd. Pat. App. & Int. 1985).

37 With respect to "commercial availability", the Manual states: "[t]he Office will accept commercial availability as evidence that a biological material is known and readily available only when the evidence is clear and convincing that the public has access to the material. See the final rule entitled "*Deposit of Biological Materials for Patent Purposes*," 54 FR 34864, 34875 (August 22, 1989). A product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample. The relationship between the applicant relying on a biological material and the commercial supplier is one factor that would be considered in determining whether the biological material was known and readily available. However, the mere fact that the biological material is commercially available only through the patent holder or the patent holder's agents or assigns shall not, by itself, justify a finding that the necessary material is not readily available, absent reason to believe that access to the biological material would later be improperly restricted". See Section 2404.01 of the MPEP of the USPTO.

deposit take the risk that the patent may no longer be enforceable if the biological material necessary to satisfy the requirements of 35 U.S.C. 112 ceases to be accessible.

44. In general, if the applicant has given no sufficient information on public availability and the biological material is a particular strain not falling within the known categories, then the biological material is considered not to be available to the public. In addition, examiners also examine whether the biological material is described in such a manner as to enable the invention to be carried out by a person skilled in the art.[38]

45. In addition, submissions from some Member States note that some types of biological materials, as for instance, vectors (e.g., plasmids), need not be deposited if either a reproducible manufacturing process or a complete nucleotide sequence is indicated.[39,40]

F. Specific Examples Regarding Deposit of Biological Material

46. Examination guidance of some offices and/or submissions from some Member States 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. Some of those examples are described in the following paragraphs.

Brazil

- Regarding microorganisms that have nucleotide sequences different from those found in nature, the modified nucleotide sequence must be presented in the application through the sequence listing, or its name known in the art, or the data of the microorganism deposit. When they are essential to confer the inventive feature, information related to specific promoters, the place of insertion of the heterologous material in the genome, the methodology for obtaining the sample, among other essential characteristics, must also be present in the description, so that a person skilled in the art is able to carry out the invention.

- In cases where microorganisms are selected from random mutagenesis and genetic alterations that result in a differentiated effect, it is necessary that such microorganisms have been deposited with an IDA and that the data regarding the deposit of the biological material (such as declaration of deposit or name of the institution, number and date of deposit) is contained in the patent application.

- When the inventive characteristic obtained by the genetic alteration is achieved only with a specific strain used in the application under examination, it is considered that the microorganism itself is essential for the realization of the invention and, therefore, the

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38 See, e.g., Section 125A.10 of the Manual of Patent Practice of the United Kingdom. See also submission of Singapore to SCP/34 which states: “In cases where the microorganism or biological material used in a process is well known and the process is adequately described by written description, the specification is considered to be sufficient as long as the written description allows the skilled person in the art to perform the process in a repeatable manner and prepare the product without undue burden, even if the final product is a new biological material.”. The submission from the Republic of Korea also states in this regard that where a skilled person in the art can easily access a microorganism (i.e., no need for the deposit), a description of the invention shall be specifically described for a skilled person in the art to easily implement a process of obtaining the microorganism, a final product, from a starting material together with how to access microorganism, etc. to support the reproduction of the invention.

39 See submission of Germany to SCP/34. The submission from Brazil to SCP/34 also notes that, for example, polynucleotides and polypeptides must be described through their nucleotide and amino acid sequence.

40 An applicant may deposit the related microorganism and include a reference to it in the application even though the deposit is not required to satisfy the requirement of sufficiency of disclosure. See submission of Brazil to SCP/34 and Section 2404, Chapter 2400 of the MPEP of the USPTO.

deposit of biological material is mandatory. On the other hand, the deposit of biological material is not necessary when the inventive characteristic can be achieved with different strains or species of microorganisms available using the methodology described in the application. Thus, for situations in which well known organisms are merely transformed to express a new and surprising characteristic, it is sufficient to indicate the organism of interest, expressly relating it to the nucleic acid to be used in this transformation, and ensuring that this nucleic acid be described clearly and precisely.

- In cases where the invention does not reside in a microorganism or biological material itself, but in its use, modification or cultivation, and a person skilled in the art is not able to carry out the invention without having the sample referred to in the patent application, the deposit of the microorganism or biological material is also necessary.

Japan

- The inventors isolated the β-galactosidase from Streptomyces lividans xyz-1 strain by a specific approach. The Streptomyces lividans xyz-1 strain is a microorganism which was stored in ATCC, a reliable storage culture collection. The description states the storage number of the Streptomyces lividans xyz-1 strain, and it was obvious that the microorganism can be freely furnished by the ATCC prior to filing the present application. Accordingly, the Streptomyces lividans xyz-1 strain is a microorganism which is easily available for a person skilled in the art and thus a person skilled in the art can isolate the β-galactosidase according to Claim 1 by using the specific approach stated in the description. Therefore, it is not necessary to deposit the Streptomyces lividans xyz-1 strain.[41]

- The invention claims a Bacillus subtilis T-169 strain which was isolated from the sample Saline mud at Toyama Bay by a well-known method for a person skilled in the art. The taxonomical property of the Bacillus subtilis T-169 strain was analyzed in detail and the difference with the publicly known bacteria strain among the same species was examined. As a result, it was found that the Bacillus subtilis T-169 strain is a new bacteria strain. In addition, it was revealed upon performing experiments that the Bacillus subtilis T-169 strain can decompose dioxin with high efficacy.

  Usually, the types and amounts of microorganisms present in soil and sea water may vary, even when the soil and sea water are obtained from a specific region. Accordingly, even where a new microorganism is isolated using a sample collected from the soil, sea water, and the like in a specific region, it is difficult to obtain the new microorganism with reproducibility, as long as there is no reasonable basis that the new microorganism is present in the sample which is re-collected from the soil, sea water and the like. In this case, the description does not provide a reasonable basis that the Bacillus subtilis T-169 strain is present in the sample which is re-collected from the saline mud at Toyama Bay. Hence, since the Bacillus subtilis T-169 strain cannot be obtained with reproducibility without a person skilled in the art performing an additional test, the Bacillus subtilis T-169 strain is not a microorganism which can be manufactured by a person skilled in the art based solely on the statement in the description. Therefore, it is necessary to deposit the Bacillus subtilis T-169 strain, since the Bacillus

41 Case No.39, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan (p.104).

subtilis T-169 strain is not a microorganism which is easily available for a person skilled in the art.[42]

- A new antigen protein A was isolated and purified from an outer membrane of a virus X. Since the antigen protein A reacts only with serum derived from a person infected with the virus X, the antigen protein A is useful for identifying people infected with the virus X. In addition, a partial amino acid sequence of the antigen protein A was determined and a gene encoding the antigen protein A consisting of an amino acid sequence represented by SEQ ID No. 1 was cloned by well-known gene engineering approaches based on the partial amino acid sequence.

  In this case, the monoclonal antibody according to Claim 2 is a monoclonal antibody specified only by an antigen. Generally, when a protein having immunogenicity is obtained, it is common general knowledge that a monoclonal antibody against the protein can be obtained by the well-known hybridoma method using the protein as an immunogen. In addition, based on the statement in the description, a person skilled in the art can obtain a gene encoding antigen protein A, express the gene using a well-known gene engineering approach and prepare the antigen protein A consisting of the amino acid sequence represented by SEQ ID No. 1. Furthermore, it is obvious that the antigen protein A has immunogenicity. Hence, based on the statement in the description, a person skilled in the art can prepare the antigen protein A, and can obtain a monoclonal antibody and a hybridoma producing the same by the well-known hybridoma method using the antigen protein A as an immunogen. Accordingly, the hybridoma is a microorganism which can be manufactured by a person skilled in the art based on the statement in the description. Therefore, it is not necessary to deposit the hybridoma, since the hybridoma is a microorganism which is easily available for a person skilled in the art.[43]

United Kingdom

- If the biological material is not available to the public and if it is not described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, and paragraph 3 of Schedule 1 to the Patents Rules 2007[44] has not been adequately complied with, then objection under Section 14(3) will be necessary.[45] The view is taken that it is virtually impossible to comply with Section 14(3) only by the deposit of biological material in accordance with paragraph 3, where the invention concerns a new species or higher classification of micro-organisms. Consequently, overly broad claims to a new species or higher classification of micro-organism should not normally be allowed.

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42 Case No.40, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan (p.106).

43 Case No.42, Chapter 2 of the Examination Handbook for Patent and Utility Model of Japan (p.108 and 109).

44 Paragraph 3 of Schedule 1 to the Patents Rules 2007 reads: "(1) The first requirement is that - (a) on or before the date of filing of the application, the biological material has been deposited in a depositary institution; and (b) that institution will be able to furnish subsequently a sample of the biological material. (2) The second requirement is that before the end of the relevant period - (a) the name of the depositary institution and the accession number of the deposit are included in the specification; and) where the biological material was deposited by a person other than the applicant ("the depositor") - (i) a statement is filed which identifies the name and address of the depositor, and (ii) a statement by the depositor has been filed, which authorises the applicant to refer to the biological material in his application and irrevocably authorises the making available to the public of the biological material in accordance with this Schedule.[…]".

45 Section 14(3) of the Patents Act 1977 of the United Kingdom reads: "The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.".

- Until such matters are tested in the courts, no guidance can be given as to what extent deposit will be necessary in other circumstances, e.g., when claims are directed to a new micro-organism produced by genetic manipulation from a known micro-organism. It could be argued that in this case the new micro-organism (which is the product of the process disclosed) is not necessary for the performance of the invention. The prudent applicant, however, will in general resolve any doubts as to whether a deposit is needed by making the deposit.

- So long as paragraph 3 of Schedule 1 to the Patents Rules 2007 is satisfied in respect of a deposited strain, then claims may be allowed to the deposited strain and to mutant or variant strains derived therefrom provided that those mutants or variants produce the desired product (e.g. antibiotic) identified in the specification. If specific methods of producing such mutants or variants are not given in the description, it is considered that the courts will construe such claims as being restricted to mutants or variants produced by standard or conventional methods well known to those working in the micro-organism field and thus as being unobjectionable. If, however, the claims are restricted to a single strain of a micro-organism, then deposition of a sample and disclosure of the species name of the micro-organism can be sufficient to meet the requirements of paragraph 3.

- Where the obtaining of novel biological material, e.g. a novel microorganism, depends on a random event with little likelihood of repetition, the requirements of Section 14(3) are not regarded as satisfied unless a deposit has been made. In particular, since a cell line is dependent for its origin on the random selection of a cell, a deposit will be necessary when an invention requires a cell line for its performance.[46]

United States of America

- "The description in the Lundak application as filed (U.S. Patent No. 4,594,325) provides a suitable illustration of the specific identification and description which are required in an application as filed. In that application, an immortal B-cell line was disclosed and claimed. The cell line was referred to in the application, as filed, as WI-L2-729 HF2. The methods of obtaining and using this cell line were also described in the application as filed. A deposit of the cell line was made with the American Type Culture Collection (ATCC) about a week after the application was filed in the United States. The United States Court of Appeals for the Federal Circuit held that the requirements of access by the Office to a sample of the cell line during pendency, and public access after grant, were met by Lundak's procedures. The Court further held that the addition of information designating the depositary institution, accession number, and deposit date of the deposited cell line in ATCC after the filing date did not violate the prohibition against new matter in 35 U.S.C. 132 […]. However, it must be clear from the application as filed that the invention claimed and described in the specification "was fully capable of being reduced to practice (i.e., no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remained in order to obtain an operative, useful process)."[47]

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46 Section 125A.11-14 of the Manual of Patent Practice, United Kingdom.

47 See Section 2406, Chapter 2400.01 of the MPEP of the USPTO.

G. Depositary Institution

47. With respect to the depositary institution, many applicable laws make a specific reference to institutions that have acquired a status of an IDA under Article 7 of the Budapest Treaty, [48] and/or any other recognized depositary institutions.[49]

48. Regarding other institutions, the submission from the Republic of Korea refers to an institution designated by a country which is not a Contracting State to the Budapest Treaty but the agreement has been made between the head of the patent office of that country and the KIPO Commissioner.[50] Brazil recognizes deposits made, *inter alia*, at "an institution authorized by INPI or indicated in an international agreement". In Germany, in addition to IDAs, the recognized depositary institutions are those scientific institutions which guarantee that the deposited biological material is stored, and its sample is furnished, in conformity with the Ordinance on the Deposit of Biological Material and which are legally, economically and organizationally independent of the applicant and the depositor.[51] In the United States of America, with respect to "any other depository recognized to be suitable" by the USPTO, it is explained that suitability will be determined by the Commissioner on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes.[52]

H. Timing of Deposit and of a Reference to the Deposit in a Patent Application

49. 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.[53] However, some variations to this rule are found in some laws. For example, in Paraguay, the deposit shall be made no later than 60 days from the filing date of the application or where the priority is claimed, the date of filing of the priority application.[54] In Cuba, the deposit shall be made at the time of filing the patent application or three months thereafter.[55]

50. 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 patent or during pendency of the application for patent.[56] When the deposit is made during the pendency of the application, it must be made no later than the

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48 Contracting States to the Budapest Treaty, which allow or require the deposit of microorganisms for the purposes of patent procedure, recognize, for such purposes, the deposit of a microorganism with any International Depositary Authority (See Article 3 of the Budapest Treaty).

49 See, e.g., Brazil, Mexico, Colombia, Paraguay, the United Kingdom and the United States of America.

50 See submission of the Republic of Korea to SCP/34.

51 See submissions from these countries to SCP/34.

52 The Commissioner may seek the advice of impartial consultants on the suitability of a depository. The depository must: (i) have a continuous existence; (ii) exist independent of the control of the depositor; (iii) possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated; (iv) provide for sufficient safety measures to minimize the risk of losing biological material deposited with it; (v) be impartial and objective; (vi) furnish samples of the deposited material in an expeditious and proper manner; and (vii) promptly notify depositors of its inability to furnish samples, and the reasons why. See 37 CFR 1.803.

53 See, e.g., the applicable provisions of laws of Brazil, Colombia, Czech Republic, Germany and Singapore.

54 Article 16, Law no.1.630/2000. See submission of Paraguay to SCP/22.

55 See Section E of the Budapest Treaty Guide with respect to Cuba.

56 See 37 CFR 1.804(a). 37 CFR 1.804(b) further requires that when the original deposit is made after the effective filing date of an application for patent, the applicant must provide corroboration that demonstrates that the biological material that has been deposited is a biological material specifically identified in the application as filed.

time period set by the examiner at the time the notice of allowance and issue fee due is mailed.[57]

51. With regard to the time limit for including a reference to a deposited microorganism in an application, according to a practice of many offices, such reference may be furnished within 16 months from the filing date (or the priority date).[58] Some offices' rules also state that, *inter alia*, where an applicant requests publication of its application earlier than 16 months from the priority date, such reference can be submitted not later than that request.[59]

52. In China, an applicant shall submit, at the time of filing, or at the latest, within four months from the filing date, a receipt of deposit and the viability proof from the depositary institution.[60] In the Philippines, if the depositary institution and the deposit number are not stated in the application at the time of filing the application, such information shall be submitted within two months from the request of the examiner.[61]

I. Storage of Deposited Material and Furnishing of Samples by Depositary Institutions

53. 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 the following paragraphs briefly discuss these matters.

Duration of the storage of the deposited biological material

54. In many countries, the duration of the storage of the deposited biological material is that required under the Budapest Treaty, which sets a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the IDA and, in any case, a period of at least 30 years after the date of the deposit.[62] The Treaty, however, is silent about the treatment of the deposited material by IDAs after the expiration of the term of storage stipulated in Rule 9 of the Regulations under the Treaty.

55. In the United States of America, if the 30 year term would terminate within the period of enforceability of the relevant patent (i.e., the patent term plus six years to include the statute of limitations), the deposited material must be stored under agreements that would make it available beyond the enforceable life of the patent.[63]

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57 However, a necessary deposit need not be made by an applicant until the application is in condition for allowance so long as the applicant provides a written assurance that an acceptable deposit will be made on or before the payment of the issue fee. This written assurance must provide sufficiently detailed information to convince the examiner that there is no outstanding issue regarding deposits that needs to be resolved. See 37 CFR 1.804.

58 See, e.g., the provisions of laws of Austria, Hungary, Italy, Türkiye, the United Kingdom and the European Patent Convention.

59 E.g., Canada, Denmark, Finland, Germany, United Kingdom and the Eurasian Patent Office.

60 Rule 25(1) of the Implementing Regulations of the Patent Law of China.

61 Publication of the application under Section 44 of the IP Code shall be held pending until the submission of such information. See Rule 408(b) of the Revised Implementing Rules and Regulations for Patents, Utility Models and Industrial Designs of Philippines.

62 See Rule 9 of the Regulations under the Budapest Treaty and Section E of the Guide to the Deposit of Microorganisms under the Budapest Treaty.

63 See Section 2408, Chapter 2400 of the MPEP of the USPTO.

56. Under the patent practice of Japan, with regard to national deposits, a deposited microorganism should be maintained at least until the expiration of the relevant patent, whereas, with regard to international deposits made under the Budapest Treaty, the duration of storage of microorganisms is at least 30 years from the date of deposit.[64] In Germany, where a deposit is made outside of the Budapest Treaty regime, the deposited biological material must be stored for a period of five years from the receipt of the most recent request for furnishing a sample of the deposited biological material and, in any case, for at least another five years after expiry of the maximum statutory term of protection of all IP rights referring to the deposited biological material.[65]

57. In the Philippines, the depositary institution should be under contractual obligation to place the culture in its permanent collection.[66]

Furnishing of samples to interested parties

58. Rule 11 of the Regulations under the Budapest Treaty deals with the issue of furnishing samples of deposited microorganisms by IDAs. Specifically, IDAs shall furnish samples to the depositor, to anyone having the depositor's written authorization, and to any "interested" industrial property office (i.e., an office that deals with a patent application concerning the deposited microorganism and which provides the IDA with a declaration to that effect). Rule 11 also contains a provision regarding furnishing of samples to legally entitled parties other than the above. However, national law largely determines when, to whom and under what conditions samples are to be furnished to these other parties.

59. Accordingly, the national/regional law provisions with respect to access to the deposited biological material show some differences. Many laws state that a deposited biological material shall be made available to *any person* making the request from the date of publication of the patent application.[67] In some laws, such access to a biological material is subject to conditions that the person making a request for a sample shall not make the biological material or any biological material derived therefrom available to any third party and use that material for experimental purposes only, until such time as the patent application is refused or withdrawn or deemed to be withdrawn, or before the patent has expired, unless the applicant for or proprietor of the patent expressly waives such an undertaking. [68,69] In some countries, if the applicant so requests, access to the sample of the biological material may only be provided to an independent expert appointed according to the rules provided under the applicable law.[70]

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64 See Section E of the Guide to the Deposit of Microorganisms under the Budapest Treaty with respect to Japan.

65 Section 7 of the Ordinance on the Deposit of Biological Material.

66 See Section E of the Guide to the Deposit of Microorganisms under the Budapest Treaty with respect to the Philippines.

67 For example, in Colombia and the Philippines, *any interested person* is entitled to have access to a sample of the material during the period as prescribed under the applicable law. See submissions from these countries to SCP/34.

68 See Section 81a of Patent Law of Austria; Regulation 3.25C of the Patents Regulations of Australia; Section 10, paragraphs 2, 5 and 6 of the Royal Decree of Belgium; Subsection 104(4) of Patent Rules of Canada; Rule 33, Chapter V, Part II of the Implementing Regulations to the Convention on the Grant of European Patents. Similar conditions are also found in, e.g., Article 4 of the Enforcement Decree of the Patent Act of the Republic of Korea and Article 65(3) of Industrial Property Code of Portugal.

69 The requesting party, in some countries, are allowed to have access to the sample of the biological material for other purposes, e.g. opposition proceeding relating to an application or patent in question. See, e.g., Regulation 3.25C of the Patents Regulations of Australia.

70 In some countries, such request may be made before the grant of the patent, in other countries, before the completion of the technical preparation for the publication of the application. See, e.g., Section 81a of Patent Law of Austria; Regulation 3.25C of the Patents Regulations of Australia; Patent Rules 1995, Schedule 4, paragraph 3(1), (3), (4) and (5) of Singapore; and Section 5(1) No.2 of the Ordinance on the deposit of Biological Material of Germany.

60. The above national/regional law provisions on furnishing samples of the deposited biological material appears to ensure access to the samples of the deposited biological material for third parties, while taking due consideration of the particularity of such material, such as the potential environmental risk and biological safety as a result of releasing the samples from depositary institutions.

J. Nucleotide and/or Amino Acid Sequence Listing

61. 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.[71]

62. 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[72]. 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.[73]

63. In this respect, Annex C of the Administrative Instructions under the PCT provides instructions relating to the presentation of nucleotide and amino acid sequence listings in international applications. Annex C states that the sequence listing part of the description shall comply with WIPO Standard ST.26. Specifically, that standard shall apply to any nucleotide or amino acid sequence disclosure in an international application, notably with regard to:

(i) whether such disclosure is to be included in a sequence listing;
(ii) the manner in which disclosures are to be presented;
(iii) the qualifiers for which "free text" is permitted as a value and the identification of those qualifiers for which such free text is considered language-dependent[74]; and
(iv) the Document Type Definition (DTD) for a sequence listing in XML (eXtensible Markup Language).

64. Similarly, according to the Guidance for Examination of the EPO, "if nucleotide and amino acid sequences within the meaning of Rule 30(1)[75] are disclosed in the European patent application, they are to be represented in a sequence listing which conforms to the applicable WIPO standard".[76]

65. The submission from Spain clarified that the submission of sequences is not required in all cases.[77] Specifically, the listing does not need to be provided where it is publicly available. In such case, the sequence listing 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

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71 See, e.g. United Kingdom (Rule 13(2) and Schedule 1 to the Patents Rules 2007).

72 Standard ST.26: Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listing Using XML (Extensible Markup Language). The Sixty-Second Session of WIPO General Assembly approved the implementation date of WIPO Standard ST.26, July 1, 2022, at national, regional and international levels. Thus, applications filed on or after July 1, 2022, disclosing amino acid and nucleotide sequences should contain an ST.26 XML compliant sequence listing (see paragraph 45 of document A/62/12).

73 Paragraph 8 Standard ST.26.

74 Reference is made to paragraphs 87 and 88 of WIPO Standard ST. 26 and Section 6, Table 5 and Section 8, Table 6 in Annex I to that Standard.

75 Rule 30(1) states: "[i]f nucleotide or amino acid sequences are disclosed in the European patent application, the description shall contain a sequence listing conforming to the rules laid down by the President of the European Patent Office for the standardised representation of nucleotide and amino acid sequences".

76 Part A, Chapter IV.5 of the Guidance for Examination of the EPO.

77 See submission from Spain to SCP/34.

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. The database and/or sequences in question shall be fully disclosed in the application to meet the enabling disclosure requirements, as provided under the applicable law. [78] According to the general rule of patent law, their submission subsequently shall not broaden the scope of the original application as filed.

66. With respect to presentation of sequences, the Guidance for Examination of the EPO states that the sequence listing should, where it is filed together with the application, be placed at the end of the application.[79] In this respect, Annex C of the Administrative Instructions under the PCT states that, where sequences are included in a sequence listing, Offices may not require that the sequences also appear in the main part of the description. However, in specific cases, the applicant may have valid reasons for setting out some sequences from the sequence listing in the main part of the description, claims or drawings, for example, where the claimed invention comprises nucleotide or amino acid sequences.[80] In the United Kingdom, a sequence listing may be set out either in the description or at the end of the application, but if it is set out at the end of the application, Rule 12(4) shall not apply.[81]

IV. AI-RELATED INVENTIONS

A. Introduction

67. In the field of AI-related inventions, the sufficiency of disclosure requirement is one of the key discussion points, together with the requirements of patentable subject matter and inventive step/non-obviousness as well as AI inventorship.[82] Some even argue that the sufficiency of disclosure requirement was one of the first trans-jurisdictionally discussed issues brought up in the legal literature concerning AI-related inventions,[83] whereas others are of the opinion that compared to other requirements, the sufficiency of disclosure of AI-related inventions has not received much attention[84]. As indicated by some Member States,[85] the statutory requirements regarding the sufficiency of disclosure of AI-related inventions need to be fulfilled in the same way as any other inventions, and no additional requirements concerning the disclosure of AI-

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78 Spain, *Ibid*.

79 Part A, Chapter IV.5 of the Guidance for Examination of the EPO.

80 Paragraph 8 of Annex C to the Administrative Instructions under the PCT further states: "[w]here any sequences are presented within the main part of description, claims or drawings, they may be set out in the manner considered most appropriate to present the information for the relevant purpose. In the description, claims or drawings of the application, the sequences included in the sequence listing shall be referred to by the sequence identifier preceded by "SEQ ID NO:", even if the sequence is also embedded in the description, claims or drawings. Similarly, sequences too short to be included in the sequence listing may be presented in the manner considered most appropriate by the applicant".

81 Rule 13(7) of the Patent Rules 2007 No.3291. Rule 12(4) states: "(4) The specification mentioned in section 14(2)(b) must be preceded by the title of the invention and must be set out in the following order - (a) description;(b) the claim or claims; and (c) any drawing referred to in the description or any claim."

82 See document SCP/30/5 (Background Document on Patents and Emerging Technologies).

83 Slowinski, Rethinking Software Protection (June 1, 2020). Draft chapter. Forthcoming in: Lee, Liu, Hilty (eds.), Artificial Intelligence & Intellectual Property, Oxford, Oxford University Press, 2020, Max Planck Institute for Innovation & Competition Research Paper No. 20-17, 3.2.3 with further references in footnote 45. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3708110.

84 Vijay/Devesh et al., AI and Indian Patent Law- Sufficiency of Disclosure for Artificial Intelligence-based Patents, International Journal of Mechanical Engineering, Vol. 7 (Special Issue, Jan.-Feb. 2022), p.341, available at: https://kalaharijournals.com/resources/SP%20Jan_Feb_43.pdf ; Ebrahim, Artificial Intelligence Inventions & Patent Disclosure, Penn State Law Review, Vol. 125:1 (2020), p. 147. Available at: http://www.pennstatelawreview.org/wp-content/uploads/2020/11/Article-4-Tabrez-Ebrahim-AI-Inventions-and-Patent-Disclosure-FORMAT-3.pdf.

85 Submissions of Singapore and the United Kingdom, available at: http//www.wipo.int/scp/en/meetings/session_34/comments_received.html.

related inventions are found in national legislations. As information technology has become a fundamental element of any industry, some patent offices have already developed structured approaches to, and guidelines for, patent examination of inventions that may be implemented by software. Since inventions involving AI can be regarded as an extension of computational technology, in general, patent practice regarding AI-related inventions may be built on the practice and guidance developed in the field of information technology. In addition, Member States have been engaging in cooperation activities in this area[86] or publish, for example, data files containing patent document data in order to assist researchers and policymakers focusing on the determinants and impacts of AI inventions[87].

B. Sufficiency of Disclosure Regarding AI-related Inventions

(1) Overview of AI technology[88] and terms

68. Inventions that involve the use of a computer, computer network or other programmable apparatus, where one or more features are realized wholly or partly by means of a computer program, are nothing new. To name these inventions, different terms, such as computer implemented inventions, computer software-related inventions etc., have been used. In this document, in order to generally address these inventions, the term “computer implemented inventions (CIIs)” is used for the sake of convenience.

69. AI is a branch of computer science, whereas the term AI is often used ambiguously and is a catch-all term that covers machine learning, evolutionary algorithms, and other technologies, such as rule-based systems. However, due to the frequent overlap of different subfields, the exact delineation is difficult and a subject of controversy among researchers.[89] At the high level of abstraction, one may be able to define AI as technology that attempts to mimic at least partly what is regarded as human intelligence.[90] The main part of AI applications comes down to predictions made based on available information and software that has somehow been trained to make these predictions.[91] Basically, an AI is a computer program that consists of algorithms.[92] An algorithm may be defined as, for example, a finite sequence of steps for solving a logical or mathematical problem or performing a task.[93] Once the algorithm has been coded to achieve a certain result (whereas the same algorithm can be written in different coding language), it becomes part of the computer program.[94] Only deterministic algorithms present the same results when run multiple times, while so-called nondeterministic algorithms will present different results on each run. Therefore, only looking at an outcome does not necessarily allow an expert to determine the algorithm that came up with the result.[95]

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86 For example: Cooperation initiative between INPI and EPO, exchange of knowledge between INPI and DKPTO and a study within the scope of IP BRICS. For further details, see: submission of Brazil, available at: https://www.wipo.int/scp/en/meetings/session_34/comments_received.html. In addition, IP5 has been working on a comparative study on examination practices in NET/AI inventions.

87 USPTO, Artificial Intelligence Patent Dataset. The first data file identifies U.S. patents issued between 1976 and 2020 and pre-grant publications published through 2020 that contain AI technology components. The second data file contains the patent documents used to train the ML models. Available at: https://www.uspto.gov/ip-policy/economic-research/research-datasets/artificial-intelligence-patent-dataset.

88 A brief introduction to AI technology is also found in document SCP/30/5.

89 Drexl/Hilty et al., Technical Aspects of Artificial Intelligence, Max Planck Institute for Innovation and Competition Research Paper No. 19-13, p.3, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3465577.

90 Slowinski, loc. cit., at 1. with further references.

91 Ibid.

92 Slowinski, loc. cit. at 2.1.

93 See: Microsoft Computer Dictionary, 5th ed., 2002, available at: https://burmastarrecords.files.wordpress.com/2009/12/microsoft_computer_dictionary__fifth_edition1.pdf.

94 Slowinski, loc. cit. at 2.1.

95 Ibid.

70. Machine learning is a subfield of AI,[96] which works by identifying patterns in available data and then applying the knowledge to new data.[97] It is the dominant AI technique disclosed in patents and is included in more than one-third of all identified inventions.[98] Machine learning processes exist in different variations, depending on the data they build upon, and their task.[99] One can describe machine learning in three stages: first, a model architecture is programmed; second, a model is developed through the training process based on a training algorithm and training data sets; third, the model is applied to new data to produce a specific output.[100] Artificial neural networks, whose structure imitates the functioning of a human brain, are one type of such a model.[101] Machine learning models are based on an architecture, which is a hyperparameter, i.e. a feature of a model fixed before the training process that does not evolve.[102] The architecture usually is defined by a programmer before the training process and consists of layers of neurons[103] connected by weights, which are trainable parameters.[104] A more complex architecture composed by a higher number of layers, can be defined as deep neural network or deep learning.[105] In this regard, deep learning may be considered as a subfield of machine learning that, in the practice, may differ from classical/non-deep machine learning in terms of, for instance, the amount of training data, learning methods[106], or a level of human intervention.[107] In this document, machine learning without any qualifier refers to the generic term, which includes deep learning.

71. Considering the above, one can define AI-related inventions as a specific form of CIIs. AI, however, is more sophisticated than other forms of software, since it has the ability to improve models to perform better predictions by analyzing many examples and iteratively feeding data into an algorithm to improve output. AI generates a learned function - an algorithm that produces the least amount of error and that closely approximates the actual outputs of the inputs - when there is a large enough set of inputs and outputs. Once a learned function is generated, it can be used to make predictions for previously unknown data.[108]

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96 WIPO Conversation on Intellectual Property (IP) and Artificial Intelligences (AI), WIPO/IP/AI/2/GE/20/1 REV (2020), par. 11.

97 European Commission, Artificial Intelligence for Europe, COM(2018)237 final, p. 10, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0237&from=EN.

98 WIPO Technology Trends 2019: Artificial Intelligence, p. 14, available at. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1055.pdf.

99 Drexl/Hilty et. al, loc. cit., p.4.

100 Ibid.

101 Drexl/Hilty et. al., loc. cit., p.5.

102 Drexl/Hilty et al., loc. cit. p. 5-6, p.12.

103 This can be defined as: Mathematical functions transforms inputs (the numeric value of the upstream weights) into an output (the numeric value of the downstream weights. See: /Drexl/Hilty et al., p.5, p.12.

104 Drexl/Hilty et. al, loc. cit., p.5-6, 12.

105 Drexl/Hilty et. al, loc. cit., p.6.

106 See examples for different learning methods for example at: Drexl/Hilty et al., loc. cit., p.7-8.

107 According to practitioners in the AI-field, deep learning is capable to use large data sets and can extract useful patterns from (unstructured) data in an automated way that eliminates some of the human intervention required. Whereas classical machine learning is more dependent on human intervention to learn and usually requires more structured data to learn than deep learning. In classical machine learning, human experts generally determine the hierarchy of the features to understand the differences between data inputs. A deep learning model generally requires more data to improve its accuracy whereas a classical machine-learning model relies on less data given the underlying structure. See with further details: Eda Kavlakoglu, AI vs. Machine Learning vs. Deep Learning vs. Neural Networks: What's the difference? (May 27,2020) p. 6-7, available at: https://www.ibm.com/cloud/blog/ai-vs-machine-learning-vs-deep-learning-vs-neural-networks.

108 Ebrahim, loc. cit., p.169-170.

(2) Guidelines and practices of sufficiency of disclosure of computer implemented inventions and AI

72. In general, many Member States apply their examination practices and guidelines on CIIs for the assessment of sufficiency of disclosure of AI-related inventions.[109] Additionally, some Member States expressly refer to the sufficiency of disclosure of AI-related inventions in their examination guidelines[110] or provide case examples of AI-related inventions[111].

Brazil

73. Concerning CIIs, the Guidelines for Examination of Patent Applications state that short excerpts from the source code may be presented, if they are useful for understanding the description of the invention, so that the invention is clear to a person skilled in the art to the extent that it can reproduce the invention.[112]

China

74. Following the Announcement No. 343 (December 31, 2019) by the China National Intellectual Property Administration (CNIPA), the amendment to the Guidelines for Patent Examination entered into force on February 1, 2020. It stipulates how to draft the description of an invention patent application involving, among others, AI. The description of a patent application containing algorithmic features or business rules and method features shall clearly and fully describe the solution adopted by the invention to solve its technical problems. In addition to incorporating technical features, the said solution may further include algorithmic features or business rules and method features that are functionally supportive and interactive with technical features. Further, the description shall indicate how technical features work together with algorithmic features or business rules and method features that are functionally supportive and interactive with technical features, and produce advantageous effects. In addition, the description shall indicate the advantageous effects of the invention over prior art clearly and objectively. If the user experience has been objectively improved (from the user's perspective), this may also be mentioned in the description, explaining how this improved user experience is brought about or generated by technical features of the invention, as well as algorithmic features or business rules and procedural features that functionally support and interact with the technical features.[113]

Japan

75. In Japan, the Examination Handbook for Patent and Utility Model (Examination Handbook) offers information on patent examination of CIIs, including the enabling disclosure requirement applied to CIIs[114], and provides examples that do not comply with the disclosure

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109 In particular, Brazil, Mexico, the Philippines, Japan, Türkiye, the United States of America referred to their practices on CIIs.

110 For example: Submissions of China and the Republic of South Korea. Further, it is noted that some Member States have updated their guidelines with regard to patentable subject matter and AI inventions, for example: EPO, Examination Guidelines, G-II 3.3.1. Available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_3_1.htm.

111 For example: Japan: Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., cases 46-50. available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/handbook_shinsa/document/index/app_a1_e.pdf

112 INPI/PR No. 411/2020, Paragraph [037], available at: https://www.gov.br/inpi/pt-br/servicos/patentes/legislacao/legislacao/PortariaINPIPR4112020_DIRPAInvenesImplementadasemComputador_05012021.pdf.

113 Submission of China.

114 Examination Handbook for Patent and Utility Model for Japan, Annex B, Chapter 1 Computer Software-Related Inventions, 1.1.1. , available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/handbook_shinsa/document/index/app_b1_e.pdf .

requirement[115]. In addition, case examples concerning the treatment of the enablement and the support requirement[116] in relation to AI technology[117] are provided. Further, the Japan Patent Office (JPO) published the Examination Guidelines in Manga: AI/IoT Edition.[118] In Chapter 5, it explains the description requirements for CIIs and the case examples related to AI in a concise and visual manner.

76. With regard to CIIs, it is stressed that the description may be required to indicate how technical procedures or functions, mentioned in the claims, are executed or implemented by hardware or software, so that a person skilled in the art can understand the invention based on the common general knowledge at the time of filing.[119] For example, if the claims contain steps of operating a computer based on a computer's display screen, but the description does not describe how that could be implemented, and a person skilled in the art cannot understand the implementation of the steps by applying the common general knowledge at the time of filing, the enablement requirement would not be fulfilled.[120] Further, the Examination Handbook states that there are cases where the description of hardware or software that implement the functions of the claimed invention by a functional block diagram or a schematic flow chart may not be sufficient to satisfy the enablement requirement. This is the case, if a person skilled in the art, taking into account the common general knowledge at the time of filing cannot understand by the functional block diagram or a schematic flow chart how the hardware or software is configured and therefore cannot carry out the invention.[121]

77. The case examples concerning the enablement and the support requirement in relation to AI technology concern machine learning.[122] Case 46 concerns a sugar content estimation system comprising a model generation means for generating a determination model through machine learning to which a face image of a person is input and from which a sugar content of a vegetable produced by the person is output, using training data containing the face images of the people stored in the storage means and the sugar contents of the vegetable. The description particularly outlines that the determination model is generated through a supervised machine learning, using a known machine learning algorithm such as a convolutional neural network (CNN) by learning correlation between a face image of a person and a sugar content of a vegetable produced by the person. The description only discloses that there is a certain correlation between a face image of a person and a sugar content of a vegetable produced by the person and does not disclose any correlation or the like between them, for example, by disclosing that a face feature is characterized by a head length, face width, nose width, and lip width. It is assumed that even in view of a common general technical knowledge at the time of filing, a person skilled in the art cannot presume a correlation between a face image of a person

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115 Examination Handbook for Patent and Utility Model for Japan, Annex B, Chapter 1 Computer Software-Related Inventions, 1.1.1.1.

115 English translation at: https://wipolex.wipo.int/en/text/585163 .

116 The support requirement is considered to have the same meaning as the written description requirement in Japan, see: Submission of Japan.

117 See Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., cases 46-51. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/handbook_shinsa/document/index/app_a1_e.pdf .

118 Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/comic_ai_iot_e.html .

119 Examination Handbook for Patent and Utility Model for Japan, Annex B, Chapter 1 Computer Software-Related Inventions, 1.1.1.1. (1).

120 Examination Handbook for Patent and Utility Model for Japan, Annex B, Chapter 1 Computer Software-Related Inventions, 1.1.1.1., example 2.

121 Examination Handbook for Patent and Utility Model for Japan, Annex B, Chapter 1 Computer Software-Related Inventions, 1.1.1.1. (2).

122 Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., cases 46-50. available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/handbook_shinsa/document/index/app_a1_e.pdf; In addition see the visualization at the Examination Guidelines in Manga: AI/IoT Edition, chapter 5, slides 7-14, available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/document/comic_ai_iot_e/05.pdf .

and a sugar content of a vegetable produced by the person. The application would therefore be refused since it would not comply with the enablement requirement.[123]

78. Case example 47, which concerns a business plan apparatus and an estimation model trained through machine learning, and case example 48 that relates to an autonomous vehicle having a driver monitoring device, also describe inventions, in which a specific correlation among multiple types of data in a training data is not disclosed in the description.[124] However, differently to case 46, the correlation can be understood by a person skilled in the art in view of a common general technical knowledge at the time of filing. Therefore, in both case examples the enablement requirement is met.[125]

79. Case 49, which relates to a body weight estimation system, highlights how a narrower dependent claim (claim 2 of case 49) that provides information on a feature value and is also supported by the description can be sufficiently disclosed in contrary to the wider claim (claim 1 in case 49).[126] Case 49 especially demonstrates that an expansion or generalization of a claim to the extent that there is no support for the correlation, may risk non-compliance with the support and enablement requirement.[127]

80. Case 50 concerns an AI that estimates how likely a test substance is to cause contact dermatitis in humans,[128] or more technically put, a method for estimating an allergy incidence rate of a test substance. The application in case 50 also contains two claims, and the finding that the invention according to the narrower claim with corresponding description fulfills the support and enablement requirements whereas the broader claim with corresponding description does not.[129] Case 50 particularly highlights that even when AI performance evaluation supports the correlation among training data, a claim expansion may risk non-compliance with the description requirements.[130]

81. Case 51 concerns a composition of an anaerobic adhesive composition with a particular, i.e. rapid, curing strength. The description only discloses that a trained model predicted that, as long as a composition meets the combination ratio prescribed in Claim 1, the composition has the curing strength equal to or exceeding 30% of the curing strength after 24 hours have passed, within 5 minutes from the start of curing. Further, the accuracy of an estimation value by the trained model is not verified, and there was no common technical knowledge at the time of filing that an estimation result by a trained model can be a substitution for an actual experimental result.[131] The case suggests that with no common general technical knowledge in the relevant field at the time of filing that an AI predictive result can substitute an actual experimental result, a mere allegation of a prediction by an AI is not sufficient. This seems to be particularly the case, if according to common knowledge on the filing date the respective prediction is difficult, due to, for example, various manufacturing conditions involved.[132]

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123 Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., case 46 with further details.

124 See Japan Patent Office, newly Added Case Examples for AI-Related Technologies (January 30, 2019), slide 14.

125 Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., cases 47 and 48 with further details.

126 Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., case 49 with further details and explanation:

127 See visualization at: Examination Guidelines in Manga: AI/IoT Edition, Chapter 5, slides 8 – 9.

128 See loc. cit., slide 10.

129 See with further details and explanation: Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., case 50.

130 See visualization at Examination Guidelines in Manga: AI/IoT Edition, Chapter 5, slides 10 – 11.

131 Examination Handbook for Patent and Utility Model in Japan, Annex A, 1., case 51 with further details and explanation.

132 See visualization at: Examination Guidelines in Manga: AI/IoT Edition, Chapter 5, slide 13.

Republic of Korea

82. The Korean Intellectual Property Office (KIPO) refers to the Examination Practice Guide by Technical Field (December 2020). It is outlined that in an AI-related invention, an enablement requirement shall be determined based on whether a description of the invention is as clearly and concisely described as a person skilled in the art can easily implement the invention based on technological common knowledge at the time of the filing of the application.[133] The concrete improvement concerning AI to embody in the invention should be disclosed, so that a person skilled in the art clearly understands, in particular, a certain means, a technical problem of the invention and its solving means. A certain means for implementing an AI-related invention encompasses training data, data processing method, training model, loss function, etc. However, it is highlighted that even without a substantial description or a drawing of certain means for implementing an AI-related invention it is possible that the invention can fulfill the enablement requirement[134] if a person skilled in the art according to the general technical knowledge at the filing date can clearly understand the invention.[135]

83. KIPO gives three examples of non-compliance with the sufficiency of disclosure requirement for AI-related inventions. Namely:

(i) abstract disclosure of technical steps or function corresponding to the claimed invention in the description without specifying how to implement or realize the said steps or the said function with a hardware or a software (if a person skilled in the art cannot easily figure out the claimed invention based on the general technical knowledge);

(ii) the description only discloses a hardware or a software for implementing a function of the claimed invention as a block diagram (if a skilled person cannot easily figure out how hardware or software is implemented based on the block diagram or flowchart and understand the claimed invention);

(iii) there is no specific disclosure of a correlation between input data as a specific means implementing an AI-related invention, and output data of a trained model.

With regard to the third example, KIPO clarifies that the following conditions should be met in order to demonstrate that a correlation between input and output data of a trained model is “specifically described”. First, the training data is specified. Second, a correlation for solving a technical problem posed by an invention exists between characteristics of the training data. Third, a training model or a training process is specifically described and fourth, a training model is generated for solving a technical problem posed by an invention by way of the training data or the training process. However, it is highlighted that if a person skilled in the art assumes or understands such a correlation through an embodiment disclosed in a description based on technological common sense at the time of filing, the enablement requirement is deemed to be satisfied.[136]

84. In addition, the Guide provides some indications for patent applications in the field of machine learning. It highlights that even if only a general process of machine learning is described, and a training model or a training process is not specifically described, the enablement requirement is deemed to be satisfied if the invention can solve a technical problem by utilizing a general process of machine learning and the effect of the invention is verified.

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133 Submission of the Republic of Korea.

134 See with regard to enablement requirement in general: KIPO, Patent Examination Guidelines 2021, page 147. Available at: https://www.kipo.go.kr/upload/en/download/Patent_Examination_Guidelines_2021.pdf.

135 Submission Republic of Korea.

136 Ibid.

85. Further, in relation to a machine learning based AI-related invention, data processing for transforming collected raw data to training data is deemed, in some cases, to be a main feature of the invention. In these cases, if a description of the invention neither discloses how to implement or realize a data processing step or function for producing, changing, adding or deleting collected raw data into training data, nor specifically describe a correlation between collected raw data and training data, a requirement of enablement is deemed not to be satisfied.

86. As for an AI-related invention based on reinforcement learning, where a process for reinforcement learning, including a correlation between agent, environment, state, action and reward, etc., is not specifically described, the enablement requirement is deemed not to be satisfied. However, where a person skilled in the art can clearly figure out a claimed invention related to the reinforcement learning through embodiments disclosed in the description based on the technological common sense at the time of filing of the application, the enablement requirement is deemed to be satisfied.[137]

United States of America

87. In connection with the sufficiency of disclosure requirement regarding CIIs, the MPEP of the USPTO points out that examiners should determine whether the specification discloses the computer and the algorithm (e.g., the necessary steps and/or flowcharts) that perform the claimed function in sufficient detail. A person of ordinary skill in the art must be able to reasonably conclude that the inventor possessed the claimed subject matter at the time of filing. In this regard, it is not enough that a person skilled in the art could write a program to achieve the claimed function, because the description must explain how the inventor intends to achieve the claimed function to satisfy the written description requirement.[138] If the description does not provide a disclosure of the computer and algorithm in sufficient detail to demonstrate to one of ordinary skill in the art that the inventor possessed the invention (35 U.S.C. 112(a) [139] or pre-AIA 35 U.S.C. 112, first paragraph[140]) the application will be rejected for lack of written description.[141]

88. The full scope of a CII functional claim limitation is enabled according to 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112 if the description teaches a person skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation”.[142] The MPEP particularly underlines with cited case law that a full enablement of the scope in the description does not mean that the description must “expressly spell out every possible iteration of every claim”, which means, for instance, that what is well known in the art does not need to be disclosed.[143] This is particularly important for CIIs due to the high level of skill in the art and the similarly high level of predictability in generating programs to achieve an intended result without undue experimentation.[144]

89. Further, the MPEP provides examples of enablement issues with regard to computer programming cases. While there is no specific, generally applicable rule for recognizing an insufficiently disclosed application involving computer programs, in general, the sufficiency of

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137 Ibid.

138 MPEP 2161.01 (Computer Programming, Computer Implemented Inventions, and 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, First Paragraph [R-10.2019]), at I., available at: https://www.uspto.gov/web/offices/pac/mpep/s2161.html.

139 Applicable to patent applications filed on or after September 16, 2012, see: https://www.uspto.gov/web/offices/pac/mpep/s2161.html.

140 Applicable to patent applications filed before September 16, 2012, see: https://www.uspto.gov/web/offices/pac/mpep/s2161.html.

141 MPEP 2161.01, at I.

142 MPEP 2161.01, at. III.

143 MPEP 2161.01, at. III. with further references.

144 MPEP 2161.01, at III.

disclosures which do not include the programmed steps, algorithms, or procedures that the computer performs to produce the claimed function, may be challenged. A flowchart, which delineates the sequence of operations the program must perform, can be a way of sufficient disclosure if understood by the person skilled in the art. Where the disclosed software involves only a flowchart, a lack of disclosure becomes as more probable as the complexity of the functions and the generality of the individual components of the flowchart increases, and thus the disclosure may be considered insufficient since more than routine attempts will be required to create a working program from such a flowchart.[145]

90. It is not always self-evident how a particular component(s), which are old according to the applicant's prior art citations, are to be interconnected to function in a disclosed complex manner.[146] The commercial availability of an identified prior art computer system can be very pertinent to the question of enablement. For example, even if each of the enumerated devices or labeled blocks in a block diagram disclosure were old, this would not make it self-evident how each would be interconnected to function in a disclosed complex combination manner. Therefore, it is required that the description discloses the integration of the prior art; otherwise, it is probable that undue experimentation, or more than routine experimentation would be required to implement the claimed invention.[147]

91. In addition, it is not uncommon in computer applications for the claimed inventions to involve more than one technology. The examiner therefore, when determining the sufficiency of disclosure, needs to refer to the knowledge of a person skilled in the art in all relevant technologies.[148]

92. In relation to affidavit practice, in computer systems or programming cases, the MPEP points out that problems with a given affidavit relating to the sufficiency of disclosure issue generally involve affiants submitting few facts to support their conclusions or opinions.[149] For an affidavit to be relevant to the determination of enablement, it must be probative of the level of skill of the person of ordinary skill in the art as of the time the applicant filed the application.[150]

European Patent Office (EPO)

93. With regard to the sufficiency of disclosure requirement according to Article 83 EPC, Rule 42(1)(c) and Rule 42(1)(e), the guidelines for examination of the EPO highlight the formal requirements of the description relating to computer programs, i.e., program listings in programming languages cannot be relied on as the sole disclosure of the invention. The description should be written substantially in normal language, possibly accompanied by flow diagrams or other aids, so that a person skilled in the art who is deemed not to be a specialist in any specific programming language, but does have general programming skills, may understand the invention. Further, it is highlighted that short excerpts from programs written in commonly used programming languages can be accepted if they serve to illustrate an embodiment of the invention.[151] For the requirements of Article 83 and of Rule 42(1)(c) and (e) EPC to be fully satisfied, it is necessary that the invention is described not only in terms of its structure but also in terms of its function, unless the functions of the various parts are

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145 MPEP 2164.06(c) (Examples of Enablement Issues – Computer Programming Cases [R-10.2019]) at II, available at: https://www.uspto.gov/web/offices/pac/mpep/s2164.html.

146 MPEP 2164.06(c) at I.

147 MPEP 2164.06(c) at IV.

148 MPEP, 2164.06(c).

149 MPEP 2164.06(c) at III. with further references.

150 See *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402, 406 (CCPA 1976).

151 EPO Guidelines for Examination, F, II., 4.12, available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_ii_4_12.htm.

immediately apparent. In the field of computers, a clear description of function could be more appropriate than an over-detailed description of structure.[152]

(3) Case law

94. In general, based on the information received from Member States, there is not yet much established national case law on sufficiency of disclosure with regard to AI.[153] Below, some examples of case law regarding AI-related inventions are summarized.

EPO

95. The decision of the Technical Board of Appeal, T 0161/18 of May 12, 2020 relating to EP 1955228 (A2), concerns an AI-related invention. EP 1955228 derived from a PCT application WO 2007/053868. The alleged invention relates to a method for determining cardiac output from an arterial blood pressure curve, which is measured at the periphery, during which the blood pressure curve measured on the periphery is arithmetically transformed into the corresponding central blood pressure curve, and the cardiac output is calculated from the central blood pressure curve. The transformation of the blood pressure curve measured on the periphery into the corresponding central blood pressure curve is undertaken with the aid of an artificial neural network whose weighting values are determined by learning.[154] The Examination Division rejected the application due to lack of inventive step.[155] The Technical Board of Appeal considered that the invention is not sufficiently disclosed, since the training of the artificial neural network according to the invention is not executable due to lack of appropriate disclosure of input data to be used for training the neural network.[156] In addition, the Technical Board of Appeal pointed out that in the present case, the claimed method differs from the prior art only by an artificial neural network whose training is not disclosed in detail. Thus, the use of the artificial neural network does not lead to a special technical effect that could justify involvement of inventive step.[157]

96. Another recent decision of the Technical Board of Appeal, T 1191/19,[158] also concerns an AI-related patent application, which lacked – among others – sufficiency of disclosure according to EPC Article 83 (enabling disclosure requirement).[159] The patent application concerns a computer-implemented method for optimizing predictions for personalized interventions for a determined user in processes the substrate of which is the neuronal plasticity. The method

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152 EPO Guidelines for Examination, F.III.1, available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iii_1.htm .

153 This has been particularly pointed out by the submissions of the Czech Republic, France and Germany.

154 Abstract of WO 2007/053868 A2, available at: https://register.epo.org/application?documentId=ELY7EN8G0224FI4&number=EP06804383&lng=en&npl=false.

155 EPO examining division, grounds for the decision (annex) at II.1. Available at: https://register.epo.org/application?documentId=E0QR1XBO2859DSU&number=EP06804383&lng=en&npl=false.

156 EPO technical boards of appeal, T 0161/18 (Äquivalenter Aortendruck/ARC SEIBERSDORF) of 12.5.2020, “Orientierungssatz 1”, available at: https://register.epo.org/application?documentId=E4WS4H2G0021DSU&number=EP06804383&lng=en&npl=false. The Board notes that the application only disclosed that the input data must cover a broad spectrum of general factors, such as patients of different ages, sexes, constitutional types, health conditions etc., which was not considered sufficient for a person skilled in the art to carry out the invention.

157 EPO technical board of appeal, T 0161/18, “Orientierungssatz 2”.

158 EPO technical board of appeal, T 1191/ 19 - 3.5.05 Neuronal plasticity/INSTITUTGUTTMANN of 01.04.2022, available at: https://www.epo.org/law-practice/case-law-appeals/pdf/t191191eu1.pdf .

159 EPO technical board of appeal, T 1191/ 19 - 3.5.05 at 4.

contains a meta-learning scheme, which requires training data[160] and validation data[161] as input. Further, claim 1 refers to "a respective set of heuristic or deterministic rules different from that of the other classifier"[162] and "[meta-classification based on] at least heuristic or deterministic rules"[163]. According to the Technical Board of Appeal, a skilled person cannot reproduce, without undue burden, the claimed method comprising the meta-learning scheme without the disclosure of any example set of training data, validation data and the minimum number of patients, from which training data should be compiled to be able to give a meaningful prediction, and the set of relevant parameters, the heuristic bases A and B for training classifiers A and B for the solution of the problem, and the structure of the artificial neural networks used as classifiers, their topology, activation functions, and conditions or learning mechanism.[164]

United States of America

97. One practitioner was of the opinion that in the United States of America, sufficiency of disclosure issues typically arise in litigation and will often be decided by means of contradicting expert witnesses.[165] A decision of an U.S. District Court, *Centripetal Networks, Inc. v. Cisco Systems, Inc*. may provide an AI-related example for the importance of expert witnesses in relation to sufficiency of disclosure and in particular, the written description requirement.[166] The case concerns the alleged infringement and invalidity of asserted patents that deal with systems that engage in complex computer networking security functions.[167] The accused product incorporated a cognitive threat analytics (CTA), which is a software that monitors a computer network for, among others, security breaches within the network by using machine learning.[168] Among others, the accused product was found to infringe U.S. Patent 9,560,176 (hereinafter referred to as US 176)[169], which concerns a technology of the development of a system for identifying malware-infected computers through the use of correlation.[170] The invalidity defense of the (found) infringer concerning US 176 is based on, among others, lack of sufficient written description.[171] The expert witness on the side of the (found) infringer argued that US 176 was invalid because its specification contained no description of CTA, machine learning, [or] artificial

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160 EPO technical board of appeal, T 1191/ 19 - 3.5.05, claim 1: "database with information regarding a plurality of users at least in relation to interventions to be performed".

161 EPO technical board of appeal, loc. cit.,claim 1 a) "generating at least two groups of candidate predictions related to possible interventions to be performed or to which the determined user is to be subjected by performing at least two steps of classification learnt in a set of validation data (…)".

162 EPO technical board of appeal, loc. cit., step a1 of claim 1.

163 EPO technical board of appeal, loc. cit., step c of claim 1.

164 EPO technical board of appeal, loc. cit. at 4.1, 4.2.

165 Phelan, A Tale of Two Jurisdictions: Sufficiency of Disclosure for Artificial Intelligence (AI) Patents in the U.S. and the EPO, available at: https://www.patentnext.com/2021/11/a-tale-of-two-jurisdictions-sufficiency-of-disclosure-for-artificial-intelligence-patents-in-the-u-s-and-the-epo/ .

166 The United States District Court for the Eastern District of Virginia Norfolk Division, Oct. 5, 492 F. Supp. 3d 495 (E.D. Va. 2020); available at. https://casetext.com/case/centripetal-networks-inc-v-cisco-sys/case-details; Due to 28 U.S.C. § 455(b)(4), the U.S. Court of Appeals for the Federal Circuit has reversed the Opinion & Order denying Cisco's Motion for Miscellaneous Relief, vacated the Opinion & Order re Infringement and Damages, and the Opinion & Order Denying Post-Judgment Motions & Declaring the Case Final, and remanded for further proceedings before a newly appointed judge, who shall decide the case without regard for the vacated opinions and orders; See The United States Court of Appeals for the Federal Circuit Centripetal Networks, Inc. v. Cisco Sys. Inc. (2021-1888) of June 23, 2022, conclusion, available at: https://cafc.uscourts.gov/opinions-orders/21-1888.OPINION.6-23-2022_1968538.pdf .

167 United States District Court for the Eastern District of Virginia Norfolk Division, loc. cit. mn. 510.

168 United States District Court for the Eastern District of Virginia Norfolk Division, loc. cit. mn. 517.

169 See: https://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=9560176.PN.&OS=PN/9560176&RS=PN/9560176.

170 See United States District Court for the Eastern District of Virginia Norfolk Division, Oct. 5, 492 F. Supp. 3d 495 (E.D. Va. 2020), mn. 549; available at: https://casetext.com/case/centripetal-networks-inc-v-cisco-sys . United States District Court for the Eastern District of Virginia Norfolk Division, loc. cit., IV. Conclusions of Law regarding Validity, mn. 556 – 558.

intelligence.[172] The U.S. District Court followed the patent owner's expert witness, and found that it had not been proven by clear and convincing evidence that the US 176 lacked (among others) sufficient written description.[173] The patent owner's expert witness argued that to a person skilled in the art that reads the written description would understand both disputed elements of claim 11 ("correlate" and "responsive to"). [174]

C. Issues that Often Arise

98. As described above, practices that have been developed in assessing sufficiency of disclosure of CIIs are often applied to AI-related inventions. Some IP offices refer to AI-related inventions in their guidelines concerning sufficiency of disclosure or provide particular example cases on AI-related inventions in assessing the sufficiency of disclosure. 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. Against this backdrop, the following paragraphs summarize the issues that are often raised in relation to sufficient disclosure of AI-related invention. 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.

(1) Correlation between Input and Output Data

99. The correlation between input and output data appears to be an essential point when assessing sufficiency of disclosure regarding AI-related inventions.[175] The difficulties with 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 – AI may learn and the output is not always predictable. This simplified particularity of AI-related inventions is illustrated by the case of *AlphaGo*. After its creation, *AlphaGo* lost against decent *Go*[176] players, whereas six months later, legendary players were defeated by moves that were not predicted by *AlphaGo*'s creators.[177] This shows that when it comes to machine learning and in particular deep learning applications, the humanly predicted output may differ from the actual output due to available computing power, sources of data, the scale and amount of new use cases, and the ability to use developments in algorithms to perform complex computations and provide customization.[178]

100. However, it needs to be underlined that machine learning is based on human input that mainly consist of choosing or developing a training algorithm, setting the hyperparameters, data labelling and developing the model architecture[179] and the output is generated by merely relying on probability calculations.[180] Even the most "intelligent" machine learning models are not autonomous and need to be fine-tuned by machine learning experts. Their functioning can be

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172 United States District Court for the Eastern District of Virginia Norfolk Division, loc. cit. mn. 558.
173 See ibid.
174 Ibid with further details citing expert testimony with reference to (for the correlate element of claim 11): column 8, lines 46-63 and (for the response to element of claim 11): column 12, line 55 - column 13, line 13, and column 8, lines 46- 63.
175 See for example the submissions of Brazil and Mexico.
176 An ancient board game, which is considered to be one of the most complex games ever devised, see with more details: Google AI, The Story of Alpha Go, available at: https://artsandculture.google.com/story/kQXBk0X1qEe5KA.
177 See with more details: Google AI, The Story of Alpha Go, available at: https://artsandculture.google.com/story/kQXBk0X1qEe5KA; Vijay/Devesh et al, loc. cit, p.340 and 343.
178 See: ibid. with further references.
179 See Drexl/Hilty et al., loc. cit, p. 10 with further details.
180 See Drexl/Hilty et al. , loc. cit, p.11.

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, which is particularly the case for deep neural networks, since humans do not have the capability of processing such large amounts of data.[181]

101. The above-discussed case examples provided by the JPO[182] 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 fulfill the enablement requirement. This is also underlined by the examples of non-compliance with the enablement requirement provided by the Guide issued by KIPO. It states in general that the enablement requirement is deemed to be satisfied if a person skilled in the art assumes or understands a correlation between input data as a specific means implementing an AI-related invention and output data of a trained model through an embodiment. In that case, the four steps that generally need to be followed to sufficiently disclose a correlation between input and output data of a trained model do not need to be followed.[183]

(2) Black box

102. Closely related, if not considerably overlapping, to the above-discussed correlation of input and output data is the issue of the "black box", which is also particularly referred to by Member States as a problem of sufficiency of disclosure of AI-related inventions.[184] The term can be defined as inability to fully understand an AI's decision-making process and the inability to predict the AI's decisions or outputs.[185] In the submission of the United Kingdom, "black box disclosures" are explained as situations where the creator of the algorithm does not know how the AI algorithm derives its output. The submission of Germany points out that the difficulties with machine-learning methods, which are often regarded as a black box, are related to two factors: (i) the highly complex processing of large amounts of data; and (ii) the fact that the gain in knowledge in machine learning procedures essentially arises from statistical correlations rather than logical conclusions.

103. 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.[186] For example, the submission of Türkiye notes that "purely black box inventions", which Türkiye defines as models created directly from data by an algorithm and even those humans who design them cannot understand how variables are being combined to make predictions, will most probably lack the sufficiency of disclosure requirement. In contrast, the submission of Germany states that in examination practice, the black box phenomenon inherent to many AI algorithms usually does not pose a problem regarding the sufficient disclosure of the invention, as long as sufficient details are given about which AI algorithm to use and how to train it.

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181 Ibid.

182 See in particular cases 46 – 48, above para. 77-78.

183 See above submission of the Republic of Korea, para. 83.

184 See submissions of Brazil, Germany, Türkiye and the United Kingdom, available at: https://www.wipo.int/scp/en/meetings/session_34/comments_received.html.

185 Bathaee, AI Black Box: Failure of Intent & Causation, Harvard Journal of Law & Technology Volume 31, Number 2, Spring 2018, p. 905, available at: https://jolt.law.harvard.edu/assets/articlePDFs/v31/The-Artificial-Intelligence-Black-Box-and-the-Failure-of-Intent-and-Causation-Yavar-Bathaee.pdf. The United Kingdom defines in its submission "black box disclosures" as situations, when the creator of the algorithm which the AI uses does not know how the AI algorithm derives its output.

186 Submissions of Brazil and Türkiye.

104. As outlined in the context of input-output correlation, it can be understood from the discussed examination guidelines, exemplary cases, and case law that it depends to a large extent on the knowledge of a person skilled in the art at the filing date how much detailed information on the AI-related features must be described in AI-related patent applications. Similarly, what is considered as a black box also significantly depends on the general knowledge in the corresponding field. Such general knowledge can rapidly evolve, since understanding machine learning processes is a major research topic.[187] One researcher argues that so-called "Strong Black Boxes" (i.e., black boxes that practically cannot be reverse engineered,[188] and seem to be the major part of AI applications and in particular Deep Learning applications[189]) can be more suitably protected through technical measures combined with protection through trade secrets and prevention of unfair competition.[190] At the same time, it is noted that practitioners try to develop best practices of drafting AI-related patent applications to avoid the "black box phenomenon" and the lack of sufficiency of disclosure.[191]

(3) Disclosure of machine learning training data sets

105. The disclosure of training data sets is another topic that is widely discussed when it comes to patent applications concerning machine learning.[192] As outlined above, in a machine learning process, a model is developed through a training process based on a training algorithm and training datasets.[193] Training data generally seems to be the most valuable element of the machine learning process since it influences significantly the accurateness of trainable parameters and hence the preciseness of the output,[194] whereby the latter is also influenced by the model architecture and the training algorithm.[195]

106. The submission of Colombia underlines that it is necessary to evaluate the relevance of training data from the perspective of a person skilled in the art who needs to be able to reproduce the invention based on the description in the patent application. Similarly, as described above, the Guide published by KIPO also stressed the importance of the understanding of a person skilled in the art.[196]

107. The submission of Germany also acknowledges the relevance of training data by underlining that slight changes in, among others, the used training data may lead to different results in machine learning processes. However, it emphasizes that in typical practical cases, the inventive idea often does not depend on the exact reaction of the trained system to a certain set of data input values, meaning that usually the skilled person can carry out the invention and reproduce its essential benefits without having the exact same set of training data as the inventor. In this context, on the other hand, sufficient details about the algorithm and how to train it must be provided.

108. The submission of Portugal also states that a patent application needs to disclose how the artificial network was trained and which input data are suitable for training according to the invention, or at least one data set suitable for solving the technical problem. In this regard, Portugal emphasizes the importance of ensuring that sufficient details of the training dataset

187 Ibid.
188 Yavar Bathaee, loc. cit., p. 906 with further details.
189 Peter R. Slowinsky, loc. cit., p. 18, 19, 23, 24.
190 Ibid.
191 For example: Chau/Dasgupta et. al. Protecting Inventions relating to Artificial Intelligence: Best Practices, available at: https://ipo.org/wp-content/uploads/2022/02/AI-Patenting_white-paper_final.pdf.
192 For example submissions of Colombia, Germany, Portugal, Republic of Korea, and Türkiye.
193 Drexl/Hilty et al., loc. cit., p.4.
194 Drexl/Hilty et al., loc. cit., p.8.
195 Drexl/Hilty et al., loc. cit., p.9.
196 Submission of the Republic of Korea and above para. 19-21.

and a clear disclosure of the kind of input data, suitable for training the artificial network, are provided by the patent application from the perspective of the person skilled in the art.

109. The submission of Türkiye highlights that a person skilled in the art needs information as to how the model is actually trained in the case of an applications claiming that an AI model is specifically trained for a certain specific purpose in order to derive a credible technical effect. In this context, a person skilled in the art would need details about the training data of the implemented AI model, whereby explaining the weights[197] of the trained model is considered to be useful. Among others, examples of training data and experimental data to these examples is highlighted as useful inclusions in patent application concerning AI-related inventions.

110. The case examples summarized above provided by the JPO[198] also show the importance of information on training data in the description, in particular when it comes to understanding the correlation between input and output data training data. However, based on the provided example cases that do not lack sufficiency of disclosure, it can be assumed that the disclosure of particular training data in the application seems not to be imperative, whereby the importance of the knowledge of a person skilled in the art at the filing date needs to be kept in mind.[199]

111. Similarly, the above discussed decisions of the EPO Technical Board of Appeal show in practice that insufficient example sets of training data can be, among other factors, a reason for the lack of sufficient disclosure.[200] However, in this context, the EPO has highlighted that whether the data used to train the algorithm needs to be disclosed in the patent application and the level of details in which it needs to be described depend on the nature of the claimed invention.[201]

(4) Use of terms without precise meaning

112. The submissions of Brazil, Colombia, Mexico and Türkiye point out that it can be a problem for assessing sufficiency of disclosure if the terms mentioned in the claims and the description of a patent application concerning AI-related inventions do not have a precise technical meaning. Namely, the submission of Brazil particularly refers to a necessary technical analysis of the terms, parameters, and hyperparameters. The submission of Colombia stresses the importance of understanding functional characteristics of terms that are generally defined by the inventor in the application. The submission of Mexico underlines that one case of lack of sufficient disclosure of AI-related inventions may be the use of terms in the description which are not common in the technical field of AI, and that do not have a precise technical meaning regarding the technical characteristics. It also highlights the difficulties of establishing the state of the art due to unclear terms, and the interconnection between lack of clarity and novelty of the claims, as well as the sufficiency of disclosure requirement and unclear technical terms. The submission of Türkiye considers one of the main problems with AI-related applications to be that technical terms regarding AI are used in the description and claims, but no details are provided about these terms and their implementation in the process of the invention. In this context, it also points to the interconnections between the assessment of sufficiency of disclosure and inventive step.

[End of document]

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197 A weight can be described as a numeric value that is first randomly allocated and then optimized during the training process. It is trainable parameters that connect neurons in a given architecture. See: Drexl/Hilty et al., loc. cit., p. 12.

198 See above paragraphs 77-78.

199 See Ibid.

200 See above paragraphs 92-93.

201 See WIPO Conversation on Intellectual Property (IP) Artificial Intelligence (AI), Second Session, July 7 to 9, 2020, Comments of the EPO, available at: https://www.wipo.int/export/sites/www/about-ip/en/artificial_intelligence/conversation_ip_ai/pdf/igo_epo.pdf.