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PD 52 | D521 Patent Law and Procedures

Request from WIPO's Standing Committee on the Law of Patents

TOP (ii) A further study on the sufficiency of disclosure (Part II), relating to inventions having an experimental nature in unpredictable art, such as chemistry and biotechnology, and any other areas that deserve special attention.

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Introduction/background

Request from WIPO's Standing Committee on the Law of Patents (SCP) to provide the IB with additional input for the preparation of a further study on sufficiency of disclosure.

This paper addresses the SCP request with respect to the requirements of sufficiency of disclosure as applied at the European Patent Office (EPO).

1. Sufficiency of disclosure

The general practice at the EPO in relation to the requirement of sufficiency of disclosure is laid down in the following sections of the Guidelines for Examination in the European Patent Office:

- F-II, 4.1 General remarks
- F-III and subsections Sufficiency of disclosure
- F-IV, 6.4 Lack of support vs. insufficient disclosure

2. Sufficiency of disclosure in areas that deserve special attention

The above-mentioned SCP request relates in particular to inventions having an experimental nature in unpredictable art, such as chemistry and biotechnology, and any other areas that deserve special attention, as proposed in document SCP/31/8 Rev.

In that document, Brazil and Spain proposed a non-exhaustive list of topics for the study on sufficiency of disclosure, which is dealt with in the following from the perspective of examination practice at the EPO.

2.1. Chemical compounds defined by Markush formulas

Markush formulas containing claims have long been accepted in EPO practice as a form of claims. Decision T 1020/98 of the technical boards of appeal established that a Markush formula is the most concise means of defining a class of chemical compounds in a claim. More details on the requirement of sufficiency of disclosure and Markush formulas are provided in GL F-III, 5.1.

2.2. Esters, ethers, salts, N-oxides

The approach that applies to these four types of compounds with respect to the requirement of sufficiency of disclosure is the same as for any chemical compound (see GL F-III, 5.1). An enabling disclosure is required in all cases (a definition of enabling disclosure is provided in GL G-IV, 2).

2.3. Stereoisomers (enantiomers, diastereomers, Cis-trans and E-Z isomerism)

The approach that applies to stereoisomers with respect to the requirement of sufficiency of disclosure is the same as for any chemical compound. An enabling disclosure is required in all cases (a definition of enabling disclosure is provided in GL G-IV, 2).

2.4. Prodrugs

Prodrugs and metabolites are examined in a similar manner and are a form of a functional definition of a product. A lack-of-clarity objection may apply if their chemical structure is not well defined (for cases where ambiguity in the claims leads to insufficiency of disclosure, see GL F-III, 11).

2.5. Compositions and formulations

For compositions comprising many components in various proportions, an approach similar to that adopted for any claim comprising many alternatives is followed (see GL F-III, 5.1). In cases where it is found that an application is sufficiently disclosed according to Art. 83 only in respect of a part of the claimed subject-matter, this may have led to the issuing of a partial European or supplementary European search report according to Rule 63 (see GL F-III, 1; for the partial search report, refer to GL B-VIII, 3.1 and B-VIII, 3.2).

2.6. Polymorphic forms and crystalline, co-crystals, hydrates, solvates

Polymorphic forms and crystals are typically defined by their chemical composition and/or parameters (X-ray diffraction, solid state IR, NMR, etc.). According to EPO practice, the same criteria are applied to examine the sufficiency of disclosure of either polymorphic forms and crystals or any other parametric definition (see GL F-III, 11 and F-IV, 6.4). Depending on the formulation of the claim, a similar approach to that used in the case of derivatives or salts will be applied (see point 2.2 above).

2.7. New use of a known compound

In the context of medical use claims, Art. 54(4) and (5) of the European Patent Convention (EPC) apply. According to GL G-VI, 7.1, the patent application must either provide suitable evidence for the claimed therapeutic effect or this effect must be derivable from the prior art or common general knowledge.

Furthermore, GL G-VI, 7.2 deals with second non-medical uses. There are no particular issues as regards sufficiency of disclosure in the EPO's examination practice.

2.8. Manufacturing process of chemical products

Process claims are a well-established category of claims in the examination practice at the EPO (see GL F-IV, 3.1). No specific practice applies to the manufacturing processes of chemical products at the EPO: the steps of such manufacturing processes must be well defined and the starting material(s) and end product(s) must be clearly identified.

2.9. Microorganisms (different aspects related to the implementation of the Budapest Treaty)

Rule 31(1)(a) EPC explicitly refers to the terms laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms. See also GL F-III, 6.3.

2.10. Artificial intelligence

The EPO's examination practice in the fields of computer-implemented inventions and artificial intelligence is well established and described in GL G-VII, 5.4 and subsections.