WIPO Circular C.9089

Contribution for the preparation of a study on the sufficiency of disclosure, as proposed in document SCP/31/8 Rev.

I. Legal Background and General Objective

Sufficiency of Disclosure is governed by Section 34 (3) and (4) of the German Patent Act:

> **Section 34 German Patent Act**
> (...)
> (3) The application shall contain:
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> 1. the name of the applicant;
> 2. a request for the grant of a patent, which shall clearly and concisely designate the invention;
> 3. one or more patent claims, which shall indicate what is to be protected as patentable;
> 4. a description of the invention;
> 5. the drawings referred to in the patent claims or the description.
>
> (4) The application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
> (...)

The invention shall be disclosed in the patent application, Section 34 (4) German Patent Act. Pursuant to Section 34 (3) German Patent Act, this shall include the request, the description, the claims and the drawings, all parts of the disclosure being equivalent.

In general, an invention is disclosed in a clear and complete manner within the meaning of Section 34 (4) German Patent Act if the information contained in the patent application provides the person skilled in the art with so much technical information that he is able to successfully execute the invention in practice using his specialist knowledge and skills, without undue burden and without needing inventive skill.[1] Hereby, the average person skilled in the art has to be taken into consideration.[2]

The decision as to whether an invention is sufficiently disclosed thus depends on:

- the skilled person particular for the invention under consideration,
- the special knowledge of the skilled person,
- the general technical knowledge available to the skilled person and
- the effort that can be expected of the skilled person in order to achieve the aim of the invention.[3]

[1] *Bundesgerichtshof* – BGH [Federal Court of Justice], judgement of 13 July 2010, ref: Xa ZR 126/07, GRUR 2010, 916 – *Klammernahtgerät*; BGH, judgement of 4 October 1979, ref: X ZR 3/76, GRUR 1980, 166 – *Doppelachsaggregat*.
[2] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 333.
[3] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 332.

II. Practical Issues

1. Assessing reproducibility

Reproducibility must comprise the complete scope for which protection is sought, and the requirement of reproducibility must be fulfilled at the filing date or priority date, whatever applies.[4] However, it is only necessary to indicate the decisive direction in which the skilled person may work on his own accord.[5] This requires that the invention is workable, i.e. that the technical result or the intended technical effect is achievable at all, that it is repeatable, i.e. cannot be realised merely by chance, and that it can be realised over the entire scope and with reasonable effort by the skilled person.[6]

Thus, it does not conflict with the clear and complete disclosure of an invention if the skilled person still has to carry out tests in order to achieve the desired result on the basis of the information pointing the way in the patent specification, as long as such tests do not exceed a reasonable extent in a given case.[7]

In this sense, the requirement of clear and complete disclosure does not require the description to contain indications of how to achieve all conceivable variants covered by a functional definition. Also, deviations that may occur during the attempted reproduction of the invention are insignificant if the skilled person recognises that the result obtained is identical to the promised result according to the meaning of the invention.[8]

Sufficient disclosure is also to be acknowledged if a skilled person arrives at the result according to the invention but finds that the application comprises suitable and unsuitable variants which he can, however, distinguish.[9] The same applies if some specific variants indicated in the application are not available or are unusable, but can be replaced by other variants which by knowledge of the skilled person have the same effect.[10] In this sense, it is also not necessary that all conceivable embodiments covered by the scope of the patent claim can be carried out. It is sufficient if the desired result is achieved in some cases which represent the whole scope, or if at least one practical way is disclosed.[11]

However, the generalisation must not go so far as to mention only those terms which merely circumscribe the problem of the underlying invention, without an apparent causal connection between the means used and the success sought. This would be an obstacle to technical progress leaving the skilled person unable to achieve the result according to the invention.[12] The same applies if success does not occur with some reliability, but only under favourable circumstances, or if the goal cannot be achieved with a statistically acceptable probability, i.e. if the error rate is too high.[13]

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[4] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 347 and 355.
[5] BGH, decision of 21 December 1967, ref: Ia ZB 14/66, GRUR 1968, 311 – *Garmachverfahren*.
[6] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 343.
[7] BGH, decision of 21 December 1967, ref: Ia ZB 14/66, GRUR 1968, 311 – *Garmachverfahren*; BGH, judgement of 21 November 1975, ref: X ZR 29/75, GRUR 1976, 213 – *Brillengestelle*.
[8] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 376 and 392.
[9] BGH, decision of 9 October 1990, ref: X ZB 13/89, GRUR 1991, 518 – *Polyesterfäden*.
[10] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 345.
[11] BGH, judgement of 11 May 2010, ref: X ZR 51/06, ref: X ZR 51/06, GRUR 2010, 901 – *Polymerisierbare Zementmischung*; BGH, judgement of 3 May 2001, ref: X ZR 168/97, GRUR 2001, 813 – *Taxol*; BGH, jugement of 16 June 2015, ref: X ZR 67/13, BeckRS 2015, 14874 – *Übetragungspapier für Tintenstahldrucker*; Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 345.
[12] BGH, decision of 19 July 1984, ref: X ZB 18/83, GRUR 1985, 31 – *Acrylfasern*.
[13] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 346.

Likewise, general indications of ranges of physical properties going beyond the teaching disclosed in the application must not be overly generalised so that protection would be extended to hypothetically claimed broad ranges exceeding the contribution to the art by the invention.[14]

2. Inconsistencies

Usually, the disclosure can primarily be found in the description because it serves to represent the invention and shall be used to interpret the patent claims that determine the extent of the protection (cf. Section 14 German Patent Act).[15] The extent of the claims and the description may differ but the claim must contain all essential features that are indispensable for carrying out the invention. If there are any inconsistencies between the individual parts of the disclosure, the disclosure as it appears to the skilled person from the whole application received on the application (or priority) date is decisive.[16]

3. Burden of Proof

If there are reasonable doubts with respect to the reproducability of the invention by a skilled person, the Patent Office may request appropriate proof, for example the conduct of specific experiments.[17]

Models and samples may also serve illustrative purposes (e.g. in oral proceedings) or evidentiary purposes, e.g. to prove reproducability or the achievement of advantages. However, as they do not form part of the application in which the invention is to be disclosed (cf. Section 34 (4) German Patent Act), they cannot serve as means of disclosure on their own. Therefore, the reference to a model cannot replace the description of the invention. According to Secion 16 Patent Ordinance, models and samples must be filed only upon request of the DPMA.[18] For the deposit and furnishing of samples of biological material, namely microorganisms, see below.

In opposition and nullity proceedings, the burden of proof for lack of reproducibility is upon the opponent or nullity plaintiff.[19]

III. Special topics

1. Inorganic and Organic Chemistry, including pharmaceuticals

As any invention, a claimed chemical substance must be sufficiently disclosed so that it is possible for a skilled person (e.g. a chemist, biochemist or genetic engineer) to obtain a substance with reasonable effort.[20]

a) Identification of the claimed substance

For the identification of the claimed substance it is sufficient if the following information is provided in the application:[21]

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[14] BGH, judgement of 25 February 2010, ref: Xa ZR 100/05, GRUR 2010, 414 – *Thermoplastische Zusammensetzung.*
[15] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 204 and 295.
[16] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 108 and 313.
[17] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 357.
[18] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 224.
[19] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 357.
[20] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 383.
[21] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 384 et seq.

- Specification of the structural formula
- Specification of parameters:

  If the substance cannot be described by explicitly specifying its constitutional formula, it is sufficient to indicate such reliably establishable (or, measurable) characteristics (parameters) that can define the claimed substance.

- Specification as product-by-process:

  If a chemical substance or a biological product cannot be adequately defined either explicitly or by parameters, or if such a definition is entirely impractical, the substance may be specified by its manufacturing process. The manufacturing process must be reproducible and reliably lead to the claimed substance. If necessary for the skilled person to obtain the claimed substance, the starting materials, reaction conditions and the processing of the reaction mixture shall be indicated in addition to the process. However, reach-through claims for purpose-defined substances to be determined using a novel method are not permitted.[22]

The choice of the type of definition (constitution, parameters, product-by-process) is not at the discretion of the applicant, but has to be made according to objective criteria.[23]

b) Path to realisation of the claimed compound

The path for obtaining a claimed chemical compound must be indicated. The disclosure of at least one way to carry out the invention is hereby sufficient. In doing so, the applicant is not obliged to disclose the best mode to achieve the result. However, the one disclosed way must enable the realisation of the invention over the entire scope of the claims.[24]

Sufficiency of disclosure can not be denied if concrete sizes, quantities or dimensions have to be determined first or if further experiments or tests need to be carried out as long as these do not exceed the usual extent and do not require inventive reasoning.[25]

However, the disclosure of a chemical substance is not sufficient if its formula and the manufacturing process are specified but the skilled person does not know how to obtain the necessary starting materials and intermediate products. Information that can only be found through extensive research cannot be attributed to the expertise of the skilled person. Therefore, the disclosure in the original documents must not only cover the substance of the intermediate product, but also its further processing into the final product, if this is not familiar to the skilled person. If an intermediate is formed only temporarily in a reaction mixture, no substance claim can be addressed thereon if no way for its isolation is disclosed.[26]

c) Multiple substances (Markush Claims)

If several substances are claimed, each substance must be disclosed in such a way that a skilled person is able to obtain it. An implicit description of a substance is sufficient if it is

[22] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 354.
[23] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 391.
[24] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 392 and 394.
[25] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 398 and 353.
[26] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 429.

clear to the skilled person which substances are specifically meant by the general description used.[27]

General formulae, e.g. Markush formulae, disclose all substances that are recognisably covered by this formula for the skilled person, even if the circumscribed number of substances is large. The mere fact of the large number of compounds does not constitute a lack of sufficient disclosure and can therefore not be objected to as an "unrealistic breadth of the claim".[28]

A deficiency in the disclosure only exists if it is found that a skilled person is unable to carry out the invention over the entire claimed scope without undue burden and without inventive contribution. The same applies if certain compounds are covered by a formula which the skilled person could not produce at the priority date.[29]

Functional characteristics may be used to disclose substances or mixtures of substances if the invention, in objective terms, cannot be described more precisely without undue restriction.[30]

d) Use of Chemical Compounds or Pharmaceuticals

Sufficient disclosure of a claimed use requires that the new effect, function or purpose has been originally shown. If use for a therapeutic purpose is claimed, the invention must be disclosed so clearly and comprehensively that the skilled person does not perceive it as mere speculation and the claimed use seems at least plausible. This does not necessarily require experimental data or even clinical trials. However, the pharmaceutical use must not only seem possible. In the absence of data, a scientific reason should be given to support the claimed pharmaceutical effect or it should be derivable from general expert knowledge.[31]

Advantages and valuable properties should be disclosed originally. This is indispensable particularly if the invention acquires its actual meaning only through the mention of advantages and functional properties, i.e. if the advantages constitute the essence of the invention. The addition of advantages and valuable properties to the description of the application may be permissible in rare exceptional cases, e.g. if the advantages are not originally mentioned in the application, but the skilled person is able to recognise them from the overall content of the original disclosure even without their explicit mention.[32]

Functional statements require original disclosure under the same conditions as benefits and valuable properties. As with the latter, a subsequent submission of efficacy claims may also be permissible in exceptional cases.[33]

2. Biotechnological Inventions

Biotechnological inventions are inventions whose subject matter is a product consisting of or containing biological material or a process by means of which biological material is

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[27] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 388.
[28] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 389; *Bundespatentgericht* – BPatG [Federal Patent Court], decision of 27 September 1976, ref: 16 W (pat) 21/74, BPatGE 19, 83.
[29] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 389; BGH, decision of 20 October 1977, ref: X ZB 8/77, GRUR 1978, 162 – *7-Chlor-6-demethyltetracyclin*.
[30] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 390.
[31] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 422.
[32] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 323 et seq.
[33] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 325.

produced, processed or used. Biological material is any material containing genetic information, i.e. its structural design, and capable of reproducing itself or being reproduced in a biological system (cf. Section 2a (3) No. 1 German Patent Act). A microbiological process is any process involving or performed upon or resulting in microbiological material (cf. Section 2a (3) No. 2 German Patent Act).

Biological inventions are eligible for protection on the basis of the German Patent Act. The Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions stipulates harmonised provisions for the patenting of such inventions. This Directive was transposed into national law by the Act Implementing the Directive on the Legal Protection of Biotechnological Inventions (Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen) of 21 January 2005.

a) Deposit of biological material

In addition to Section 34 (4) German Patent Act, the disclosure in the case of applications concerning biotechnological inventions is governed by the Ordinance on the Deposit of Biological Material in Patent and Utility Model Procedures (*Verordnung über die Hinterlegung von biologischem Material in Patent- und Gebrauchsmusterverfahren*). According to Section 1(1) of this Ordinance, biological material shall be deposited with a recognised depositary institution if it is not available to the public and cannot be described in the patent or utility model application in such a way as to enable a skilled person to carry out that invention. This is also the case when the invention involves the use of such a biological material.

The purpose of depositing biological material is to supplement the disclosure of the application,[34] but a deposit cannot replace the requirement to describe the properties of a microorganism or a microbiological production process in the application. Therefore, microbiological processes and products thereof (cf. Section 2a (2) No. 2 German Patent Act) can be protected by patents, if a sample of the biological material is deposited and a description indicating a reproducible manufacturing process using the biological material and/or of the properties of the biological material claimed is included in the application.

In turn, no deposit is required, if the application contains the description of a reproducible manufacturing process for a biological material.

b) Requirements for a deposit

The biological material must be deposited with a recognised depositary institution not later than on the date of filing or the priority date (cf. Section 1 (1) of the Ordinance on the Deposit of Biological Material).

Among the depository institutions recognised are the international depositary authorities which have acquired that status unter Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 (hereafter referred to as "Budapest Treaty") as well as recognised scientific institutions which guarantee that samples are duly stored and furnished in conformity with the Ordinance on the Deposit of Biological Material and which are legally, economically and organisationally independent of the applicant and the depositor (cf. Section 2 of the Ordinance on the Deposit of Biological Material). The application documents as originally

[34] BGH, judgement of 12 February 1987, ref: X ZB 4/86, GRUR 1987, 231 – *Tollwutvirus.*

filed must always contain the relevant information on the properties of the deposited biological material, known to the applicant, as well as the depositary institution and the file number of the deposit (cf. Section 1 (1) Nos. 2 and 3 of the Ordinance on the Deposit of Biological Material).

From the first publication of the patent application, the biological material is made available, upon request, to any person by the furnishing of a sample, notwithstanding any subsequent revocation or declaration of invalidity of the patent or supplementary protection certificate (Section 5 (1) Nos. 2 and 3 of the Ordinance on the Deposit of Biological Material). However, before the grant of the patent, the depositor may restrict access to the deposited biological material by furnishing a sample only to an independent expert appointed by the person filing the request (so-called “expert solution”; Section 5 (1) No. 2, half sentence 2, of the Ordinance on the Deposit of Biological Material).

The deposited material must be stored for five years from the receipt of the last request for the furnishing of a sample, but at least five years longer that the legally stipulated maximum term of protection of all industrial property rights referring to the deposited biological material (Section 7 of the Ordinance on the Deposit of Biological Material). For biological material deposited under the Budapest Treaty, the minimum storage period of 30 years from the date of deposit is applicable (Rule 9.1 Budapest Treaty).

c) Genetic engineering methods

In accordance with the general requirements set out above (cf. “Assessing reproducibility”), for the disclosure of a genetic invention it is sufficient if at least one way is described how the skilled person can carry out the invention. However, what is claimed must be reworkable in its entirety by the skilled person. If a (too) broad scope is claimed, of which only part is workable, the whole scope cannot be considered sufficiently disclosed.[35]

E.g., the description of a non-deposited plasmid without detailed structural information that makes it distinguishable from other plasmids, the need for extensive screening procedures to identify a specified compound with desired properties (such as the search for enzymes of unknown structure) or the generation of an antibody that is only specified as being intended to correspond to a known deposited antibody would be considered as insufficiently disclosed.[36]

Vectors, as for instance, plasmids, need not be deposited if either a reproducible manufacturing process or a complete nucleotide sequence is indicated.

3. Artificial Intelligence

In the case of inventions in the field of artificial intelligence, the question may arise to what extent an AI algorithm, a training model, a neural network architecture, a machine learning method, training data or hardware components, etc. must be disclosed in the patent application in order to fulfil the requirement of Section 34 (4) Patent Act. The assessment of sufficience of disclosure of AI-inventions thus faces new challenges for which no specific national case law has been established to date.

From a human perspective, machine learning methods are often regarded as "black box" systems because the way in which a certain result is achieved is often difficult to comprehend and explain. On the one hand, this is due to the large amount of data that is

[35] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 377.
[36] Moufang, in: Schulte, Patentgesetz, 11th edition 2022, Section 34 marginal number 379.

processed in a highly complex manner. On the other hand, the gain in knowledge in machine learning procedures essentially arises from statistical correlations rather than logical conclusions. In certain cases, it can therefore be very difficult to rationally explain the result of machine learning procedures in a simple way. Slight changes in the training data used, in the architecture or other mathematical parameters of a machine learning method can bring about different results.

However, 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. In other words, 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. Also, 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, namely of the general inventive concept, as long as sufficient details are given about which AI algorithm to use and how to train it.

For assessing the sufficiency of disclosure of an AI-related invention, the circumstances of the individual case are therefore of particular importance.