

DE – GERMANY

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1. Requirements for Deposit

The requirements of a valid deposit in Germany are set forth in 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- Biomaterial- Hinterlegungsverordnung- BioMatHintV*), published in the Federal Law Gazette (*Bundesgesetzblatt- BGBl*) Part I No. 6 of 28 January 2005 and in the official gazette *Blatt für Patent-, Muster- und Zeichenwesen (BIPMZ)* 2005, p. 102, and set forth in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, signed at Budapest on 28 April 1977, and the Regulations under the Budapest Treaty (German version: BIPMZ 1981, pp. 53, 59 and 237).

Under Sec. 1(1), BioMatHintV, the description required under Sec. 34(3) No. 4, Patent Law, will be deemed sufficient for granting patent protection for biological material or the use of biological material if, in addition to the description, the biological material has been deposited with a recognized depositary institution. Consequently, a deposit is to be considered if the invention cannot be described in such a manner as to enable a person skilled in the art to carry out the invention (Sec. 34(8) 1st sentence, Patent Law). The deposit may ensure that the requirement of disclosure of the invention under Sec. 34(4), Patent Law, is met.

The applicant has a choice of **two ways** of depositing biological material: the first option is a deposit **under the Budapest Treaty** and the Regulations with a recognized international depositary authority (Secs. 8,1, BioMatHintV).

Alternatively, the sample can be deposited outside the Budapest Treaty with a “recognized scientific institution” under Sec. 2, BioMatHintV. This scientific institution must guarantee that samples will be duly stored and furnished in accordance with the Ordinance on the deposit of biological material (*Biomaterial- Hinterlegungsverordnung*). The institution must be legally, economically and organisationally independent of the applicant and the depositor. International depositary authorities recognized under the Budapest Treaty and the Regulations meet these requirements.

2. Time of Deposit

The biological material must be deposited with a recognized depositary institution not later than the date of filing or, if a priority has been claimed, the priority date (Sec. 1(1) No. 1, BioMatHintV).

If the biological material has previously been deposited by a third party with a recognized depositary institution and is available to profession circles, and if it is ensured that it can be used for the duration of the prescribed storage period (cf. item 3), another deposit is not required (Sec. 1(3), BioMatHintV).

3. Duration of Storage

Where a deposit is made **under the Budapest Treaty**, the minimum storage period is five years after the most recent request for furnishing a sample of the deposited biological material was received by the depositary authority and, in any case, 30 years from the date of deposit (Rule 9.1, Regulations under the Budapest Treaty).

Where a deposit is made **outside the Budapest Treaty**, 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 (Sec. 7, BioMatHintV).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Where a deposit is made **under the Budapest Treaty**, samples of deposited biological material shall be available from the date of publication under the conditions provided for in Rule 11 of the Regulations under the Budapest Treaty. It is not necessary to issue a specific declaration of release. However, the depositor must undertake not to take back the material during the fixed storage period.

Where a deposit is made **outside the Budapest Treaty**, the applicant must issue an irrevocable declaration of release (Sec. 4, BioMatHintV) making the deposited biological material available without reservation to the depositary institution from the date of filing until the end of the period of storage for the purpose of issuing samples in accordance with Sec. 5, BioMatHintV. In case of a third party deposit, the applicant must furnish documentary evidence that the deposited biological material has been made available accordingly by the depositor (Sec. 4(1) 2nd sentence, BioMatHintV).

(ii) Restrictions Concerning the Furnishing of Samples

Where a deposit is made **outside the Budapest Treaty**, samples of the material will be furnished only to the depositor himself or to the German Patent and Trade Mark Office prior to the date of advertisement of the mention of the publication of the application (Sec. 32(5) Patent Law) concerning the patent whose subject matter involves the deposited biological material. During this period, third parties will receive a sample of the deposited biological material only by decision of the German Patent and Trade Mark Office granting file inspection under Sec. 31(1), 1st sentence, Patent Law, or by court decision (Sec. 5(1), No. 1c, BioMatHintV).

The deposited biological material shall be available upon request to any person from the date of advertisement of the mention of the publication of the application until the grant of the patent (Sec. 5(1), No. 2, BioMatHintV). For this period, however, the depositor may request that a sample of the deposited biological material be furnished exclusively to an independent expert, nominated by the requester (Sec. 5(1), No. 2, 2nd half-sentence, BioMatHintV). In case of this so-called “expert option”, the sample will be furnished to the nominated expert alone (Sec. 5(1), No. 2, 2nd half-sentence, BioMatHintV).

After the patent grant, samples of the deposited material will be furnished upon request to any person (Sec. 5(1), No. 3, BioMatHintV).

For gaining access to the deposited biological material, the requester must enter into an undertaking vis-à-vis the applicant, and in case of a third party deposit also vis-à-vis the depositor, not to make samples of the deposited biological material or a material derived from it available to third parties for the duration of validity of any IP right referring to the deposited biological material. He must also undertake to use the deposited biological material or a material derived from it for experimental purposes only (Sec. 6(1) Nos. 1 and 2, BioMatHintV).

The German language leaflet “*Merkblatt für die Hinterlegung von biologischem Material für die Zwecke von Patent- und Gebrauchsmusterverfahren*”, available at <http://www.dpma.de/docs/service/formulare/patent/x1200.pdf>, contains more information on this topic.