Introduction to Biological Deposits at the European Patent Office and under the Budapest Treaty

This introductory briefing sets out what a biological deposit is, why a biological deposit may be needed, and basic requirements for making a biological deposit and relying on it in a patent application, with a particular focus on practice before the European Patent Office (EPO). A complementary briefing goes on to consider strategic aspects relating to biological deposits, including how it might be possible to remedy certain deficiencies relating to them.

What is a biological deposit and why might it be required?

It is a fundamental requirement of patent law that, in exchange for a monopoly right, a patent must disclose the claimed invention in sufficient detail to allow a person skilled in the relevant technical field to reproduce the invention. This requirement is known as sufficiency of disclosure in European practice and enablement in the US.

Meeting this disclosure requirement can be problematic where an invention relates to biological material[1] that is not publicly available because of the potential difficulty in sufficiently describing the biological material in a patent application. This is not an issue for all biological inventions, as increasingly reproducibility can be assured via sequence data. However, where the invention relates to something that cannot be reproduced without physical access, for example a microbial strain or plant line, there is still a role for biological deposits. In these cases, a physical sample of the biological material must be appropriately deposited with a recognised depository institution.

Thus, for patent purposes, a biological deposit is often made to ensure that subject matter relating to the deposit is sufficiently disclosed. The sufficiency/enablement requirement is then satisfied by the depositary institution making samples of the deposit available to third parties on request[2].

When and where should biological deposits be made and by whom?

In order for a patent application to be able to rely upon a biological deposit at the EPO, it is necessary for the biological sample to be submitted as a non-confidential deposit[3] to a recognised depositary institution[4]. Such deposits are often referred to as Budapest Treaty[5] deposits, after the international system that regulates them and provides the legal framework for recognising valid depositary institutions, the time for which deposits must be stored and the process for releasing them to third parties. The deposit will then be recognised in all countries party to the Budapest Treaty[6]. There are however a number of countries that are not party to the Budapest Treaty, such as Taiwan, and if patent protection is to be pursued in those countries it will be necessary to ensure that a suitable biological deposit has been made specifically for those countries[7]. The deposit must be made not later than the date of filing of the relevant patent application[8]. If possible though, it is advisable to ensure that a biological deposit has been validly made in good time before filing a patent application to ensure that it is possible to cite the deposit accession number in the specification.

As a physical sample of the biological material must be provided to the depository institution, it is usually the applicant/inventor who makes the deposit. Indeed, as discussed in the next section, it is best if the biological material can be deposited by the legal entity who will be named as (one of the) applicant(s) for patent purposes. The depository institution will then assume responsibility for storing and furnishing the biological material. The depository institute will also issue a deposit receipt. To the extent that the biological deposit is relied upon in a patent application at the EPO, it is strongly recommended to provide the EPO with a copy of the deposit receipt[9].

It is also worth bearing in mind that the rules for depositing biological material can vary between jurisdictions. For example, at the USPTO, it may be possible to rely upon a biological deposit made after the filing date of the application, to respond to an enablement rejection during examination. For EPO purposes, however, it will always be necessary for the deposit to be made **on or before the filing date** for it to be relied on for sufficiency purposes, or before the priority date if priority is to be validly claimed for embodiments that rely on the deposit for sufficiency[10].

Thus, where patent protection before the EPO is envisaged and it is determined that it is necessary to make a biological deposit, it is important that a Budapest Treaty-compliant deposit is made before filing of the relevant patent application. As set out in the next section, it is also important that the correct statements about the biological deposit are made in the application, even if this is not necessary in the country where the application is originally filed[11].

Do I need to refer to the biological deposit and related information in the application?

Yes, certain statements about the biological deposit need to be made in the patent application. At an absolute minimum, to be able to rely upon a biological deposit at the EPO, it is necessary that the application as filed discloses "such relevant information as is available to the applicant on the characteristics of the biological material"[12]. This information generally consists of an indication and basic characteristics of the type of biological material deposited, and an indication of how the biological

material could be used to practise the invention. Strictly, the date of the deposit does not have to be given in the specification, as the requirement is just that the date is on or before the filing date. However, it is also normal to give the date of the deposit.

In practice, it is also highly desirable for the application to specify the depositary institution and the accession number of the deposited biological material[13]. Although this information can generally be validly provided within sixteen months after the initial filing date (or priority date if priority is relied upon), it is highly advisable to include this information in the application as filed. This is because it is easy to forget this requirement and, for international applications filed under the Patent Cooperation Treaty (PCT), this requirement cannot generally be complied with "late" in the European regional phase[14]. In turn, this means that, in PCT-based cases, the deadline can expire before any filing is actually made with the EPO (and hence before a European representative is normally available to advise on this aspect of EPO practice). Failure to provide this information on time is usually irretrievable and, if the deposit is necessary to sufficiency, therefore leads to refusal of the application.

In addition, where the biological deposit has been made by a legal entity other than the applicant[15], the name and address of the depositor must be stated in the application as filed[16]. Further, it is necessary to have in place a suitable authorisation evidencing that the depositor has authorised the applicant to refer to the deposited biological material in the application and has given his or her unreserved and irrevocable consent to the deposited material being made publicly available[17]. Again, the deadline for submission of this authorisation is generally sixteen months from the filing date (or priority date if priority is claimed) but the deadline is easy to miss and, in PCT-based cases, generally has to be met at the International Bureau during the international phase of the PCT application.

In cases where the an authorisation is needed but is not provided and filed on time, it may sometimes be possible to circumvent this issue[18] but this is by no means guaranteed, so lack of a timely authorisation can also easily lead to refusal of the European application. To ensure that such an authorisation can be relied upon, it is in practice highly advisable to prepare and submit such an authorisation when initially filing the application. However, it is best of all for the deposit to be made in the name of the patent applicant if at all possible.

Conclusions

Whenever an invention relates to biological material that is not publicly available and/or cannot be adequately described in words and figures, consideration needs to be given as to whether or not a biological deposit needs to be made when preparing a new patent application.

If a biological deposit is needed for patent purposes, then this should be made pre-filing[19] under the Budapest Treaty at an approved International Depositary Authority (IDA). If patent protection is to be pursued in a country that is not a signatory of the Budapest Treaty, it will be necessary to ensure that a suitable biological deposit has been made specifically for those countries. It should be ensured that the patent application contains the correct statements relating to the deposit. It is recommended to include the following information in the patent specification as filed:

(i) the name and the address of the depositary institution with which the deposit was made;

(ii) the date of deposit of the biological material with that institution;

(iii) the accession number given to the deposit by that institution;

and, if the applicant and depositor are not the same, also:

(iv) the name and address of the depositor,

and to submit a declaration from the depositor to allow the applicant to rely on the deposit[20].

We also recommend routinely making use of the so-called "expert solution" upon filing of a patent application to mitigate possible downsides associated with making a biological deposit, which inevitably involves the applicant committing to release of its material to third parties[21]. This is discussed further in our complementary briefing on strategy relating to biological deposits, along with other strategic considerations and how it might be possible to remedy certain deficiencies relating to deposit receipts.

Thus, in order to be able to rely on a biological deposit at the EPO, it is necessary to furnish certain information relating to the biological deposit. Some of this information needs to be present in the originally filed application and cannot be validly provided after filing, and some can be provided later but should desirably be provided on filing as in practice problems tend to arise in cases where it is not provided at the outset.

Finally, given that the requirements relating to biological deposits can differ between jurisdictions, it can be beneficial to have a local patent attorney review a priority application or priority-claiming application ahead of filing to make sure that it, and any associated biological deposits, meets local requirements.

Annex A

Sample Declaration form the Depositor to allow the Applicant to rely on the Deposit

Declaration

The undersigned, [NAME AND ADDRESS OF DEPOSITOR AS INDICATED ON THE DEPSOIT CERTIFICATE] has deposited biological materials with the [NAME AND ADDRESS OF DEPOSITORY INSITUTE] in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure under the following accession numbers on the following dates:

[LIST ACCESSION NUMBER(S) AND DATE(S) OF DEPOSIT(S) AS PROVIDED BY THE DEPOSITORY]

The undersigned depositor hereby authorises [NAME AND ADDRESS OF APPLICANT OF THE PATENT RIGHT] to refer to the aforementioned deposited biological material in any patent application to be filed, and any patent applications deriving therefrom, and gives his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with the relevant patent legislation of the country in which the patent application is filed, e.g. European Patent Convention Rule 31 EPC, UK Patents Rules 2007, Rule 13(1) and Schedule 1, US Patent Rules 37 CFR 1.801-1.809, and generally

similar provisions mutatis mutandis for any other countries. This authorisation and this consent have been effective from the relevant deposit dates.

_____

[NAME AND ADDRESS OF DEPOSITOR AS INDICATED ON THE DEPSOIT CERTIFICATE]

Dated:_____

Annex B

Sample Text to Request Availability of Deposited Biological Material only to an Expert

In respect of all designated states to which such action is possible and to the extent that it is legally permissible under the law of the designated state, it is requested that a sample of the deposited biological material be made available only by the issue thereof to an independent expert, in accordance with the relevant Patent legislation, for example EPC Rule 32, UK Patent Rules 2007 (as amended) Rule 13(1) and Schedule 1 paragraphs 6 and 7, and generally similar provisions mutatis mutandis for any other designated state.

1. Examples of biological material include microorganisms, cell lines and genetic vectors.
2. Initially a request would be made to a patent office based on a patent or application for which it is responsible but this request is then transmitted to the depositary that has the material for the sample to be released to the requester.
3. A confidential deposit (such as a "safe deposit" made for central storage of a biological sample) cannot be relied upon for meeting the disclosure requirement for patent purposes because the deposit cannot be available to the public without the depositor's permission.
4. Generally an International Depositary Authority (IDA) under the Budapest Treaty. A list of Budapest Treaty depository institutions can be found here.
5. In full: "The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". See also Rule 31(1)(a) EPC.
6. A list of signatories of the Budapest Treaty can be found here. Most major patenting jurisdictions are members but note that, for example, Taiwan is not. The practical effect varies in light of local law and the availability of bilateral agreements. However, to rely on a deposit in non-Budapest Treat member countries, it may be necessary to make a deposit locally as well as under the Budapest Treaty, or to make a deposit in a country that has a separate bilateral agreement with the country in question, for example the UK, Japan or South Korea in respect of Taiwan. This will need to be planned in advance as shipping the biological material for deposit ahead of the filing date may not be simple owing to non-IP regulatory requirements.
7. In practice, it will be necessary to make a separate deposit at a local Depositary Authority or ensure that a deposit is made at an IDA that is recognised by the patent office of the country that is not party to the Budapest Treaty.
8. or priority date, if a claimed priority is to be valid in this respect.
9. See GL A-IV, 4.1 (final paragraph)
10. See Decision T 0107/09
11. For example, it should be considered whether or not a US priority application that is to be relied upon later at the EPO may need to refer to a biological deposit.
12. See Rule 31(1)(b) EPC
13. See Rule 31(1)(c) EPC
14. Rather, the necessary information has to be timely provided to the International Bureau (see Rule 13*bis* PCT).
15. Unless perhaps where a very specific relationship between legally independent entities exists (see T118/87 hn 2).
16. See Rule 31(1)(d) EPC
17. ibid
18. By showing that the applicant entity controls the depositor entity and hence has the right to rely on the deposit, or by requesting that the depositary changes the name of the depositor to match that of the applicant. Where the depositor was the inventor and the inventor is an employee of the applicant, it is also sometimes possible to argue that the deposit was made on behalf of the applicant.
19. Which means before the very initial priority filing if priority is claimed, so before filing of a US provisional application if the first filing is a US provisional application.
20. See sample declaration in Annex A of this briefing.
21. See, for example, Rule 32 EPC. At the EPO, the relevant box on the request form may be ticked to request expert solution. For a PCT, the sample text in Annex B of this briefing may be used.

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