Biological Deposits: Strategic Considerations

Introduction

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. Therefore, a biological deposit is often made, usually with an International Depositary Authority (IDA) under the Budapest Treaty, to ensure that subject matter relating to biological material that is not publically available and/or which cannot be adequately described by other means, 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.

This briefing focusses on strategic aspects relating to biological deposits, including how it might be possible to remedy a deficiencies relating to biological deposits. A complementary briefing sets out what a biological deposit is, why a biological deposit may be needed and basic requirements for making a biological deposit.

Are there any disadvantages to making a biological deposit?

It is common to think about biological deposits in the context of the benefit they offer to the applicant, i.e. ensuring that an invention is sufficiently disclosed to the public where this might not otherwise be possible. However, the consequence that is sometimes overlooked is that a Budapest Treaty-compliant biological deposit will generally eventually become physically available to third parties on request, usually once the patent application has been published[1]. Therefore, where the public availability of a biological deposit represents an unacceptable disadvantage to a potential applicant, it may be preferable to keep specific biological material confidential and control access to the physical resource instead. In other words, a potential applicant may choose to protect a specific biological resource as a trade secret and/or through contracts such as materials transfer agreements (MTAs), rather than through the patent system.

Trade secrecy of course comes with risks that control of the trade secret may break down, so the balance has to be carefully weighed. However, it is not a given that patent protection is always the best route to follow in the case of a very valuable biological resource. Also, where the deposit merely exemplifies a broader principle underlying the invention, it may not always be necessary to make a biological deposit for patent purposes, as the requirement is that **the invention** be reproducible, not the exact material that any given deposit would represent. For example, if the invention lies in a given mutation and that mutation is documented and can be reliably made again, it may not be necessary to deposit germplasm that embodies it, whereas such a deposit could give competitors an advantage in trying to copy the invention.

Put another way, making a biological deposit for patent purposes can be thought of as a gamble. If the applicant wins and the patent is granted, they obtain the powerful time-limited monopoly right of a patent. However, if the applicant loses (i.e. is unable to obtain and maintain a patent), then assuming that publication of the patent application has occurred[2], the public can benefit from the invention when it might have otherwise stayed confidential. Similarly, the biological resource is publicly available after patent expiry whereas a trade secret is potentially indefinite, and if there are several deposits in a specification but not all of them are eventually covered in the granted claims, the un-claimed ones are also available without the restraint that the granted claims place on the claimed ones[3]. Although this principle applies to the patent process more generally, the applicant's loss is potentially greater where biological deposits are involved because third parties can obtain physical samples of the biological deposit, rather than having to re-develop the deposited biological material based on the written teaching of a patent document[4].

Can these disadvantages be mitigated?

To an extent, an applicant can mitigate the risk of such a loss at the EPO by making use of the "expert solution" provision[5]. This means that, as long as the necessary formal requirements are met, a biological sample can only be released to a nominated third party expert, not to the requester itself[6],[7], and usually only after publication of the patent application. At the EPO, and for PCT applications too, a valid request for expert solution will be indicated on the cover page of the published application.

Even with an expert solution request in place to limit access to the biological sample, biological samples can still be released to the public when the patent right is granted or from 20 years after filing if the patent right is refused or withdrawn (i.e. the point at which the patent would have expired if it had been granted). So even if expert solution has been asserted, abandoning a patent application after publication will not prevent the eventual public release of the biological sample.

The expert solution can generally be requested up until technical preparations for publication are complete but in practice it is much better to make the request on filing, either in a separate letter or as part of the request form[8]. Various other countries worldwide also have similar provisions so a similar approach can be adopted in PCT filings.

If it appears early on after filing that the prospect of obtaining commercially relevant patent protection is slim[9], then in some cases it may be worth considering withdrawing the application to prevent publication. That way, patent offices would not be in a position to authorise release of a biological sample and so it may

still be possible to protect the biological material as a trade secret.

At a practical level, there is also a financial cost involved in making a biological deposit[10]. Further, there may occasionally be national security or other legal requirements that need to be satisfied over and above routine safety protocols[11], in particular relating to pathogenic biological samples. In addition, it is of course necessary to physically transmit the biological sample to the depository. As such, making a biological deposit involves additional resource and can delay the filing of a patent application.

Thus, it is worth considering both the pros and the cons when deciding whether or not to pursue patent protection for subject matter relating to a biological deposit and whether or not to make a biological deposit for patent purposes at all.

If a patent application is definitely going to be filed and a deposit is definitely needed, some further mitigation tactics are as follows. Consider carefully:

- Exactly what to deposit – if the material is the result of an ongoing breeding or strain development programme, is an earlier generation of the germplasm good enough for enablement of a claim to germplasm that contains a trait without giving access to more developed generation that may have additional advantages? However, be careful with this approach as, for example, if the claim is going to be to a given strain, that exact strain will have to be deposited, and it could lead to issues with compliance with the USPTO's "best mode" requirement.
- How many deposits to make and cite in the application – if there are multiple strains but realistically only a few are likely to end up patented, is it in the applicant's interests to cite them all and allow them all to be accessed?
- Where to file patent applications and where/when to conduct commercial activity – there may be cases where it is safest to file only in jurisdictions that either: (a) do not generally permit release of samples until grant of a patent (for example Japan and the US); or (b) have an expert solution provision (see above). In these cases, it may also a useful precaution to file individually in those jurisdictions rather than via the PCT, to ensure control is maintained over the filing programme and the list of patent offices that third parties can approach to request release of a sample. In these cases, it will pay to check locally before filing exactly what any given jurisdiction's law is. If planned commercial products will contain replicable biological material, it may also be better not to place products on the market before the grant of a patent, to avoid copying taking place before an injunction can be obtained. This may also speak in favour of accelerating examination of some applications.

What can I do if I am unable to rely upon a biological deposit?

This scenario may arise because: (i) it is/was not possible to make a timely biological deposit[12]; (ii) a conscious decision has been/was taken not to file a biological deposit[13]; (iii) the need for a biological deposit before filing was simply not considered[14]; (iv) patent prosecution has developed in such a way that a biological deposit is now important for the sufficiency of the claimed invention[15]; and/or (v) a procedural deficiency prevents a biological deposit being relied upon[16]. Potential sufficiency issues may then be raised by the EPO or a third party, or noticed after filing by the owner of the patent right or their representative.

If it is known before filing a patent application that a biological deposit for undisclosed biological material is not being made, then other ways in which the biological material may be sufficiently disclosed in the patent application should be explored. For example, it may be possible to meet the EPO's sufficiency requirements by disclosing instead relevant genetic information in the patent application, for example the genetic sequence encompassing an inserted genetic sequence, or even the full genomic sequence of a microorganism. It may then be possible to argue that the skilled person would have been able to re-generate the new biological sample from publically available biological samples using gene editing techniques available at the filing date. At least at the EPO, it would however not be possible to validly add such genetic information after filing because this would almost certainly be held to add subject matter[17].

If an issue arises shortly after filing, it may still be possible to meet the deadline for providing certain missing information relating to a biological deposit and thus to rely at the EPO on a biological deposit that has been made before filing. If publication of the patent application has not occurred, it may also be an option to withdraw the application, if necessary make a (new) biological deposit, and re-file the application to remedy any deficiencies. In some cases, it may even also be possible to pursue this strategy after publication, by arguing that the original application was non-enabled and hence cannot take away novelty or inventive step of the new one. However, this would have to be weighed against the risk of additional prior art then becoming relevant.

Nonetheless, given that at the EPO it is necessary to take action relating to biological deposits upon filing (or relatively shortly thereafter), it is unfortunately sometimes the case that issues relating to biological deposits are spotted when it is too late to remedy the deficiency at the EPO[18]. However, even if a deposit receipt cannot be relied upon at the EPO, all is not necessarily lost.

For example, and subject to meeting other requirements of patentability, it may be an option to amend the patent case so that it is no longer necessary to rely upon a biological deposit. For example, if specific biological material referred to in the patent case is presented as a fall-back position in a dependent claim and/or not relevant to the claimed invention at all, then the reference to the biological material could simply be deleted or the claims broadened so that a reference to specific biological material is no longer necessary[19].

It may also be an option to argue that biological material referred to in a patent case is enabled in the absence of a valid deposit. For example, if it can be shown that the biological material was already publically available at the filing date (or if relied on, the priority date), then there is no need that a biological deposit be made specifically for the purposes of that patent right. Alternatively, it may be possible to show that the skilled person would have been able to re-generate the biological material from information in the application and their common general knowledge. This may be easier to do for more recent cases where more sophisticated gene editing techniques would have been available to the skilled person at the filing date. However, it would be necessary to be careful if taking such an approach to

ensure that there is no suggestion that the claimed invention was already known, or would have been obvious.

Thus, it is best to consider whether or not a biological deposit is made before filing a patent application and make sure all the requirements are met by the priority or filing date and all the relevant information is in the specification. Nevertheless, there may be some flexibility early on in the lifecycle of a patent application to mitigate any failure to meet requirements relating to deposit receipts, or to argue and/or amend around such an issue. However, given that the deposit requirement may be directly linked to the fundamental sufficiency of a case, it is an unfortunate reality that, in some cases, a failure to meet all of the biological deposit requirement upon filing will not be able to be remedied later on.

What about third parties?

As with any patent right at the EPO, where a claimed invention is not sufficiently disclosed at the filing date (or priority date, if priority is being relied upon), then this can be brought to the attention of the EPO in a pre-grant third party observation and/or a post-grant opposition. This could also be brought to the attention of a national court in a post-grant revocation action.

To be successful, the attacking party would need to show that the failure to meet the biological deposit requirements results in an insufficient disclosure of the claimed invention. Of course, depending on the facts of the case, the applicant or patentee may be able to defend against such an attack with arguments and/or amendments along the lines of those set out in the previous section. However, although the deposit requirements are largely procedural, failure to comply with them can lead to a substantive lack of enablement and therefore can validly be raised even in post-grant proceedings.

Independent of attacking a patent right, and assuming that expert solution has not been asserted by an applicant, a third party can obtain a physical sample of deposited biological material mentioned in a patent document[20]. Thus, a third party looking to make use of biological material disclosed in a patent document[21] would not necessarily need to re-develop the deposited biological material from a written teaching.

Conclusions

If an invention relates to biological material that is not publically 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. By considering this requirement early on, an informed decision can be taken on whether or not a deposit is needed, as well as broader strategic questions surrounding the pros and cons of making a biological deposit and even whether to pursue protection through the patent system at all.

If a patent application is filed without meeting the necessary requirement relating to a biological deposit, there may be limited scope for mitigating the effects of such a failure. However, if the failure results in a fundamental insufficiency in the patent at the EPO, it will unfortunately often not be possible to remedy such deficiencies relating to biological deposits.

Although a biological deposit may allow an applicant to ensure that an invention is sufficiently disclosed, it also generally allows third parties to obtain physical access to the deposited biological material. There may be situations where such physical access for third parties is unacceptable, in which case protection of a specific biological resource through non-patent routes such as a trade secret and/or MTAs may be more appropriate. It may also be the case that after careful review, it is concluded that a specific deposit is not necessary for the sufficient disclosure of a particular invention and so patent protection may still be an option even if a specific deposit is not made. Where a biological deposit is being made, we also recommend routinely making use of "expert solution" provisions. There may also be reasons to choose the jurisdictions in which to file to minimise access to the deposit before grant or in the case that no patent is granted.

Footnotes

1. See, for example, Rule 33 EPC
2. Publication of an application usually occurs 18 months after the application has been filed, if all necessary formalities have been completed.
3. Note also that the EPO will routinely consider multiple deposited strains/lines each to represent a separate invention so it is likely that all but one will have to be restricted out and, depending on the number involved, it may be prohibitively expensive to protect all of the others in individual divisional applications.
4. At the EPO, a biological sample is generally available from publication of the patent application onwards. Although it is possible to get notification of requests for biological samples, and the requester will have to give an undertaking about what they will and will not do with the biological sample, policing this may be difficult, in particular if the requester takes the sample out of the jurisdiction of the country whose patent office authorised its release.
5. See, for example Rule 32 EPC; a similar provision is available in some other jurisdiction, including for PCT applications, but the details differ.
6. It is not clear to what extent it would be possible to police this if the nominated expert were to release the sample to a member of the wider public.
7. As long as the correct formalities are completed when making the biological deposit and/or filing the patent application, it is possible to be notified when third parties request biological samples from depositories. It is therefore possible to know who has at least initially requested the sample, and therefore might have an interest in the invention to which the deposit relates.
8. See sample text in Annex B of our complementary briefing.
9. For example, given comments in a pre-publication official action, such as the opinion that accompanies a European International Search Report.
10. USD 2,500 at the time of writing at the ATCC in the US, so potentially significant if multiple deposits are needed and also a significant fraction of the cost of many first-filings.
11. Deposits of cannabis seeds are also complex as we understand that US IDAs cannot accept those owing to US Federal restrictions even though some US State laws are more liberal; some depositaries elsewhere in the world can accept these seeds, including the NCIMB in Scotland, but a legal way has to be found to get them to these depositaries.
12. For example, if physical access to a biological sample was not possible at the time, but a patent application had to

nevertheless be filed in view of an upcoming disclosure.

13. For example, if public availability of biological material is commercially unacceptable.
14. For example, where the specific requirements of the EPO were not timely considered when filing a priority application or a PCT application, or patent protection is being pursued in a country that is not party to the Budapest Treaty (such as Taiwan) and a suitable biological deposit was not timely made specifically for that country as well as under the Budapest Treaty.
15. For example, where it has been necessary during prosecution to limit claims originally specifying a microorganism at a broad taxonomical level to a specific microorganism strain.
16. For example, if the applicant and depositor are not the same and the necessary declaration from the depositor to allow the applicant to rely on the deposit has not been timely furnished for the purposes of prosecution at the EPO.
17. See Article 123(2) EPC
18. For example, when entering the European regional phase. However, this will not necessarily the case elsewhere. For example, at the USTPO, it may be possible to rely upon a biological deposit made during patent prosecution.
19. For example, if a patent application claims a specific microbiological strain, but also shows that the invention would also work at a higher taxonomical level, then the higher taxonomical level may be able to be claimed instead.
20. For example, at the EPO, this form may be used.
21. For example for research purposes or once the patent has expired.

For more information, please contact:

Andrew Bentham — abentham@jakemp.com
Kapil Tuladhar — ktuladhar@jakemp.com
Ian MacLeod — imacleod@jakemp.com
Pamela Tuxworth — ptuxworth@jakemp.com