

Biological deposits for patenting purposes under the Budapest Treaty



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A patent confers a limited-term right to exclude other parties from using an invention, in exchange for a comprehensive description of the invention. The granted claims of a patent define the scope of the right that is conferred.

Patents are jurisdiction-specific – a patent granted in one jurisdiction does not (at least directly) confer rights in other jurisdictions. However, a number of international agreements establish provisions for patent protection, including the Paris Convention for the Protection of Industrial Property (Paris Convention)¹, the Patent Cooperation Treaty (PCT)², and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)³. There is variation in the particular requirements for obtaining patent protection among jurisdictions, even those that are signatories to the same international agreements. Nevertheless, in the great majority of jurisdictions, for a patent to be granted its claims must be considered novel and inventive over earlier publicly available information, and supported by disclosure associated with the patent.

With regard to support requirements for patent protection, generally, it is considered necessary that the associated disclosure is sufficient to enable a legally defined ‘skilled person’ to perform the invention across the full scope of the granted claims. Typically, disclosure that can be relied on for support purposes is in the form of written description presented in the patent specification and figures. However, for inventions involving biological material, it may be difficult to adequately characterise the biological material using written description alone.

Budapest Treaty deposits for patent support

Factors associated with the eligibility of particular forms of biotechnology for patent protection can be complex, and vary substantially among jurisdictions. That topic is not dealt with in

detail here – the reader is directed to Sigareva and O’Donnell⁴, Fitzgerald *et al.*^{5,6} and Kimura and Burton⁷ for exemplary articles dealing with patent eligibility of biotechnology. Nevertheless, in many jurisdictions it is permissible to obtain patent protection for naturally occurring biological material, including microorganisms, when isolated from the natural environment⁸. In others, notably the United States, although isolated naturally occurring biological material cannot be patented *per se*, inventions involving naturally occurring biological material (for example, the use of a microorganism for an industrial purpose) can be patent eligible, as can engineered material differing in a meaningful way from its natural counterpart⁸.

Questions of patent eligibility aside, where patent protection is sought for a biological invention there may be concerns around the degree to which written description of biological material required for the invention is adequate for support purposes⁹. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty)¹⁰ was developed in response to this issue. The Budapest Treaty is an international patent law treaty that was originally signed on 28 April 1977, and first entered into force on 9 August 1980. The World Intellectual Property Organization (WIPO) is responsible for administering the treaty. As of August 2019, there are 82 contracting parties to the Budapest Treaty.

In general terms, the Budapest Treaty establishes that a sample of a ‘microorganism’ deposited at a designated International Depository Authority (IDA) may be relied on for a patent application¹⁰. This enables a patent applicant to provide a deposit to meet support requirements, where associated written description alone is deemed insufficient to characterise the sample. Relevantly, the Budapest Treaty does not include any definition of the term microorganism. This has resulted in general practice that a deposit under the Treaty can be used to facilitate support for any biological material that an IDA will accept¹¹. Biological material that may be deposited includes, for example, cell cultures of unicellular and multicellular organisms, including bacterial, fungal, plant, animal, and human cells; viruses; nucleic acids and proteins; and embryos and seeds¹¹. Individual IDA’s generally have internal policies regarding sample types that will be accepted. A useful summary of this information is maintained by WIPO¹¹.

The Budapest Treaty includes provisions on conditions that must be followed for deposit and storage of biological material. Among these provisions, the treaty requires all IDAs to accept deposits on

the same terms for all depositors, to furnish samples of deposits to all entitled parties (and only these parties), and to store deposits for a minimum period. More particularly, the treaty specifies that parties entitled to receive a sample of a deposit include the depositor, anyone with the depositor's written authorisation, and any jurisdiction's intellectual property office that declares that it is handling a patent application associated with the deposit. Entitlement of other parties to samples of deposits may be defined by jurisdictional laws. For example, in the US any person can obtain a sample once the patent is granted, with the depository notifying the inventor when someone makes such a request. Additionally, the treaty requires deposits to be stored for at least thirty years, and at least five years from the most recent request for a sample¹¹.

Importantly, however, the Budapest Treaty does not include provisions as to when a deposit must be made in order for it to be relied on by a patent application; rather, timing requirements are dictated by jurisdictional law. Requirements can also vary among individual jurisdictions as to when and how the jurisdiction's patent office is to be alerted of a deposit associated with a patent application. Jurisdictional laws may further include provisions specifying circumstances in which a deposited biological sample should or must be provided to support a patent application¹⁰.

Practical considerations for Budapest Treaty deposits

Given the potentially critical role of Budapest Treaty deposits in providing patent support in relation to biological material, it is important for patent applicants and practitioners to consider whether a deposit should be made when pursuing patent protection for inventions involving biological material. It is also important to ensure that formal requirements are met to enable all relevant patent applications to validly rely on any biological deposit that is made.

A determinative issue for deposit under the Budapest Treaty is, of course, whether patent protection is to be sought in any jurisdiction that is a party to the treaty. Many jurisdictions of major economic significance are signatories to the Budapest Treaty, including Canada, China, France, Germany, India, Italy, Japan, the UK, and the USA. Accordingly, patent protection will frequently be sought in one or more jurisdictions in which it is appropriate to use the Budapest Treaty for biological sample deposit. While not the focus of this article, it is noted that in jurisdictions yet to accede to the Budapest Treaty, other jurisdiction-specific arrangements may be available for biological sample deposit.

Assuming that patent protection for a biological invention is to be sought in a Budapest Treaty jurisdiction, it remains necessary to decide, in all of the circumstances, whether submission of a biological sample is required or at least desirable. For the majority of signatory jurisdictions, legislation regarding the provision of biological samples simply specifies that a biological deposit may be used to assist with support of an application, where written description associated with the application is insufficient to enable the skilled person to carry out the invention. Relevantly, however, some jurisdictions have more prescriptive requirements for the availability of biological samples. For example, Australian legislation dictates that deposit of a culture of a microorganism is required 'if the invention is a microorganism' or 'if the invention involves the use, modification or cultivation of a microorganism which is not reasonably available to a person skilled in the art and if, without a sample of such microorganism, such person could not reasonably be expected to be able to perform the invention'.

Even in the absence of prescriptive requirements in a jurisdiction of interest, where biological material that is not otherwise well-characterised or accessible is required to perform an invention, the safest approach from a support perspective would typically be to arrange for submission of a sample of this material, to rely on if necessary. However, an important practical consideration for the deposit of biological samples is the associated expense. In this regard, IDA fees of ~US\$2000 per sample are typical for sample storage, as at the time of writing. Accordingly, the cost of sample deposit may represent a barrier to submission, particularly where large numbers of biological specimens are involved.

It will also be appreciated that where historically it may have been either impossible or unduly prohibitive in terms of time or cost to perform detailed analysis of biological material for patent support purposes, this may no longer be the case. With current technology, abundant biological information (e.g. nucleic acid and protein sequences; metabolite profiling; gene expression information) can be obtained comparatively quickly and cheaply, such that substantial characterisation of a range of biological samples may be feasible. Accordingly, in some cases, it may be desirable to perform detailed analysis to facilitate comprehensive written description of biological material for support purposes, rather than attend to sample submission. Notably, if an invention for which protection is to be sought has been developed in an academic research context, characterisation of associated biological samples may be desirable from a research publication perspective.

Where a decision is ultimately made to submit a biological deposit under the Budapest Treaty, timing issues will also need to be

appropriately managed. In most jurisdictions, for a biological sample to be relied on for a patent application a sample must have been submitted by either the filing date of the application itself (e.g. Canada; the UK), or the earliest priority date of the application (e.g. China; Germany). However, different requirements apply in some jurisdictions. For example, in the US the deadline for deposit of the biological material is at payment of the patent issue fee (although the US patent office strongly encourages the deposit to be made on or before the filing date of the application and any deposit made after the filing date can be subject to a requirement for evidence that what was deposited is what was disclosed and claimed). Furthermore, as noted previously, some jurisdictions specify other deadlines, such as for inclusion of filing receipt details obtained from an IDA in the patent application, or provision of these details to the jurisdiction's intellectual property office¹¹. Although specific formal requirements for Budapest Treaty submissions in signatory jurisdictions are helpfully summarised by WIPO¹¹, variation in these requirements substantially increases the complexity of ensuring that patent applications in all jurisdictions can validly rely on corresponding samples. It is therefore notable that greater harmonisation of formal requirements for reliance on Budapest Treaty deposits has recently been formally proposed (see AIPPI Standing Committee on Pharma and Biotechnology¹²). Such harmonisation could be advantageous for patent applicants and practitioners if successfully implemented.

Conclusions

A core principle of the patent system is the provision of exclusive rights to an invention for a limited term, in exchange for public disclosure that allows the invention to be performed. The deposit of biological samples under the Budapest Treaty provides a mechanism to disclose biological material that is required for an invention, where it may be difficult or impossible to characterise the material using written description alone. Although a substantial number of jurisdictions are signatories to the Budapest Treaty, including most of the world's major economies, many others are yet to accede to the treaty. Furthermore, specific requirements for reliance on Budapest Treaty deposits vary among signatories. When pursuing patent protection of biological inventions, applicants and practitioners should carefully consider whether sample deposit under the Budapest Treaty should be performed, and ensure that formal requirements are met for all applications to allow for any sample that is deposited to be validly relied on.

Conflicts of interest

The author declares no conflicts of interest.

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Biography

Tim Fitzgerald is a senior biotechnology patent attorney at IP Gateway, located in Brisbane, Australia. Tim is passionate about helping innovators protect their intellectual property, and has experience working with diverse clients – from those with extensive experience in IP matters and large commercial portfolios, through to those exploring IP protection for the first time. Before joining the IP profession, Tim spent 10 years as a research scientist, undertaking Honours and a PhD in plant molecular biology, then working for CSIRO. Tim's research was industry focussed, exploring quality and drought resistance traits in rice, and disease resistance in wheat. From his time as a researcher, Tim has published 20 peer-reviewed journal articles and book chapters, and is a named patent inventor himself.