



Australian Government

IP Australia

The Budapest Treaty and Australian Patents

Standard Patent Applications

The *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* was devised to enable applicants with inventions involving micro-organisms to comply with the requirement for repeatability and full description of biological materials by depositing a sample of the microorganism.

Depositable subject matter

The deposits are made at an International Depositary Authority (IDA) in accordance with the rules of the Treaty on or before the filing date of the complete patent application.

Since the Budapest Treaty came into effect, IDA's have accepted deposits for biological materials which do not fall within a literal interpretation of "microorganism".

The Treaty does not define what is meant by "microorganism" and deposits appear only limited by what a particular IDA is prepared to accept as a deposit under the Treaty.

The range of materials able to be deposited under the Budapest Treaty includes:

- cells, for example, bacteria, fungi, eucaryotic cell lines, plant spores;
- seeds that can be dried to a low moisture content and stored at -20°C (or lower);
- genetic vectors (such as plasmids or bacteriophage vectors or viruses)

containing a gene or DNA fragments;

- organisms used for expression of a gene (making the protein from the DNA). There are many types of expression systems: bacterial; yeast; viral; plant or animal cell cultures;
- yeast, algae, protozoa, eucaryotic cells, cell lines, hybridomas, viruses, plant tissue cells, spores, and hosts containing materials such as vectors, cell organelles, plasmids, DNA, RNA, genes and chromosomes;
- purified nucleic acids; or
- deposits of materials not readily classifiable as microorganisms, such as "naked" DNA, RNA, or plasmids, subject to the qualification given in the following paragraph.

International Depositary Authorities (IDA)

There are approximately thirty IDA's world wide, one of which is in Australia. IP Australia can provide a list of the IDAs in other countries on request. They are also listed in the "*Guide to the Deposit of Microorganisms under the Budapest Treaty*" by the World Intellectual Property Organization on http://www.wipo.int/aboutip/en/budapest/guide/part_ii/section_d/list_ida.htm

Currently, the Australian IDA is The National Measurement Institute (formerly the Australian



Australian Government

IP Australia

Government Analytical Laboratories) Port Melbourne, VIC
Phone (03) 9644 4888.

The National Measurement Institute will accept deposits of bacteria (including actinomycetes), yeasts and fungi, other than known human and animal pathogens, with a hazard categorisation no greater than W.H.O. Classification Risk Group 2, that can be preserved without significant change to their properties with the preservation techniques in use.

The National Measurement Institute will also accept nucleic acid preparations and phages under certain conditions but will not accept:

- microorganisms which require special attention to handling and preparation for storage;
- animal, plant, algal, and protozoal cultures; and
- viral, rickettsial and chlamydial agents;
- seeds (For information about IDAs that accept seed deposits see <http://wipo.int/treaties/en/registration/budapest/guide/>)

The written description

In addition to making a deposit of the inventive material under the Budapest Treaty, the applicant is required to provide as much descriptive information about the characteristics of the material as is possible at the time of making the application.

The type of information will vary with the nature of the material deposited and the invention. The following is a guide to the sort of information you should include in the patent specification:

- Microorganisms, per se:
 - species identification;
 - morphological details such as shape, size, stain ability, motility;
 - colony characteristics, for example, colour, shape, size, swarming and any distinguishing features in appearance, such as, shininess;
 - metabolic characteristics including substrate requirements, products or byproducts, isozyme characteristics;
 - genetic characteristics such as specific genes or mutations or variants of these (these may be characterised at either the nucleic acid or protein level); and
 - plasmids and phages (if any) in the microorganism together with relevant genetic characterisation.
- Viruses, plasmids, chromosomes, organelles, etc made as deposits within cells:
 - sufficient information to enable the cells to be cultured;
 - description of the method of isolation of the virus, etc., if it is necessary in order to repeat the invention; and
 - any identifying genetic or morphological characterisation known.
- Hybridomas;
 - the antigen used for immunisation;
 - the cells used and method of fusion; and
 - the criteria used for selection of the clone.
- Plant and animal cell lines:
 - clear description of the source of the



Australian Government

IP Australia

tissue;

- procedure used to immortalise the cell line;
- growth factors and nutrients required in the culture medium; and
- relevant genetic characteristics such as any foreign genes or chromosomes.

Full Description

A patent specification must describe the best method known to the applicant for performing the invention. It must also describe the invention in sufficient detail for a specialist in the particular technology to repeat the invention.

Best method of performance

Where the invention relates to a microorganism that has been deposited under the provisions of the Budapest Treaty, the deposit is often sufficient to satisfy the requirement for a best method of performance.

Repeatability

Similarly, repeatability is unlikely to be an issue where the invention relates to a microorganism that has been deposited under the provisions of the Budapest Treaty, because access to the deposited microorganism by a skilled third party enables the invention to be repeated.

Manner of Manufacture

An invention must also be useful, and where an invention relates to a microorganism or a Budapest Treaty Deposit, the patent specification must describe a specific use for the invention.

Patent specifications and the

Budapest Treaty

Deposits of "microorganisms" must be made at an IDA in accordance with the rules of the Treaty on or before the filing date of the complete patent application.

The following deposit details must be included in the patent specification before the application is first published:

1. The name of a prescribed depository institution from which samples of the microorganism can be obtained.
2. The file, accession or registration number of the deposit given by the institution.
3. All relevant information on the characteristics of the microorganism that are known at the filing date of the application.

Access to samples of the microorganism must also be available (under certain conditions) from the institution from the date of filing of the complete application.

Before the acceptance of a patent, where the applicant wishes to rely on the provisions of the Budapest Treaty, the applicant is also required to provide a copy of the receipt from the depository institution, which applies to the microorganism, and a translation (if required).

The Notice of Entitlement required before acceptance, also needs to indicate the applicant's right to rely on the deposit.

Access to samples

A sample of a biological material deposited under the Budapest Treaty can be obtained from the IDA under the rules of the Treaty. The procurement of such a sample requires the person requesting the sample to firstly obtain a certificate from the Commissioner of Patents authorising the release.



Australian Government

IP Australia

A request for the Commissioner's authorisation of release of the sample may be made on or after the date on which the patent application is first published and must be accompanied by an undertaking that the person requesting release:

- a) will not make that deposited biological material, or a culture derived from that biological material, available to another person; and
- b) will only use the sample either,
 - for *bona fide* experimental purposes,
 - for in relation to:
 - i. opposition proceedings for standard patents,
 - ii. an objection to an extension of term for a petty patent, or
 - iii. relevant proceedings in relation to the patent.

At any time before the first publication of the patent specification an applicant can notify the Commissioner of Patents that a sample of the deposited biological material is only to be released under certain conditions. In this case release will only be made to a specialist in the field nominated by the person making the request for the certification of release. The above limitations apply equally to this specialist who must have no interest in the invention.

Innovation Patent Applications

According to the *Australian Patents Act 1990* certain inventions are not patentable for the purposes of an innovation patent. Plants and animals, and the biological processes for the generation of plants or animals are not patentable subject matter for an innovation patent. In particular this includes:

- genetically modified whole plants, plants produced by cross-breeding of one strain with another strain, or selection of a plant from a range of plants;

- genetically modified whole animals (including human beings), animals produced by cross-breeding of one strain with another strain, or selection of an animal from a range of animals;
- seeds of plants, plant tissue cultures, or any matter that could give rise to a plant; or
- animal embryos or foetus, zygote, or any matter or group of cells, that could give rise to an animal.

Patentable subject matter for an innovation patent may include:

- microorganisms, for example bacteria, moulds, protozoans, fungi, yeasts, algae, and viruses, as these are not considered to be either plants or animals;
- processes which use a plant or animal, or part thereof, but which do not result in a plant or animal; and
- microbiological processes or products of such processes, for instance:
 - a) preparation of cheese, wine making, brewing and industrial processes involving the use of microorganisms such as microbial bleaching, leaching of ores using microorganisms;
 - b) the use of enzymes derived from microorganisms for the preparation of, for example cheese or, detergents comprising protease;
 - c) the use of yeast, fungi or moulds for the preparation of useful products, for example penicillin, enzymes, fermented meats, or industrial alcohol and the products produced by such use; or
 - d) the use of viruses in the preparation of



Australian Government

IP Australia

vaccines.

In the case of innovation applications involving microorganisms, each application must comply with the requirements for full description and repeatability as detailed above. These requirements can be fulfilled by depositing a sample of the microorganism under the Budapest Treaty provisions.

Example Standard Patent Applications

Application	Subject	Application	Subject
89929/91	Babesial protease antigen	44942/93	Herbicide resistance in plants.
26231/92	Antifungal agent.	45362/93	Recombinant herpesvirus of turkeys and uses thereof.
27111/92	Antitumor antibiotic.	58154/94	Cloning and expression of xylanase B.
27144/92	Microorganisms and a process for preparing 3 alpha, 7 alphadihydroxy-12-keto-5 beta-cholanic acid.	78996/94	BCRF 1 proteins as inhibitors of interferon - gamma.
28105/92	Chimeric antibody with specificity to human tumour antigen.	10712/95	Transcriptional regulatory sequences of carcinoembryonic antigen for expression targeting.
38365/93	Active principle based on avermectins, related strain and process for the preparation thereof, as well as veterinary composition containing it.	18388/95	Recombinant infectious bovine rhinotracheitis virus S-IBR-052 and uses thereof.
38539/93	Insecticide composition	20409/95	Inhibitor and anti-inhibitor monoclonal antibodies.
38581/93	Octahydronaphthalene	44661/96	Cloning and recombinant production of CRF receptors.
		67899/96	The use of homologous amdS genes as selectable markers.
		10371/97	Modification of starch synthesis in plants.
		17257/97	Parapoxviruses containing



Australian Government

IP Australia

foreign DNA, their
production and their use in
vaccines.

Seek professional advice

This sheet provides only basic information. Patent matters can involve complex legal issues and it may be in your best interests to consult a patent attorney, solicitor experienced in intellectual property matters, or your business adviser.

For a list of IP professionals, visit the IP Australia website www.ipaustralia.gov.au or search your local Yellow Pages Directory.

Disclaimer:

This information is intended to help the reader gain a basic understanding of some IP principles. It is not designed to provide legal, business or other relevant professional advice. IP Australia recommends that you seek independent legal, business or other relevant specialist advice.

© IP Australia 2008