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Australian Patents for Biological Inventions

This fact sheet provides information on the patentability of micro organisms, cell lines, hybridomas, related biological materials and their use, and genetically manipulated organisms.

Standard Patent Applications

Patentable subject matter

The range of patentable inventions for standard patent applications which involve microorganisms, cell lines and microbiological or biotechnological processes includes:

- bacteria and other procaryotes, fungi (inc. yeast), algae, protozoa, plasmids, viruses, prions;
- cell lines, cell organelles, hybridomas, viruses;
- genetic vectors and expression systems;
- apparatus or processes for enzymology or microbiology;
- compositions of microorganisms or enzymes;
- propagating, preserving or maintaining microorganisms;
- mutation or genetic engineering;
- fermentation or enzyme using processes to;

- synthesise a desired chemical compound or composition;
- measuring or testing processes involving enzymes or microorganisms;
- processes using enzymes or microorganisms to liberate, separate, purify or clean; and
- the use of microorganisms to produce food or beverages.

Standard patent protection can also be obtained for inventions involving:

- genotypically or phenotypically modified living organisms. For example, genetically modified bacteria, plants and non-human organisms. Patenting of plant varieties is described in our fact sheet *Australian Patents for Plants*;
- DNA, RNA, chromosomes and genes (including human DNA and genes); and
- products of such DNA, RNA and genes including polypeptides and proteins.

The range of patentable inventions involving genetic manipulation found in Australian standard patent applications includes:

- synthetic genes or DNA sequences;
- mutant forms and fragments of gene sequences;



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- the DNA coding sequence for a gene;
- the protein expressed by the gene;
- vectors (such as plasmids or bacteriophage vectors or viruses) containing the gene;
- methods of transformation using the gene;
- host cells carrying the gene;
- higher plants/animals carrying the gene;
- organisms for expression of the gene (making the protein from the DNA); and
- general recombinant DNA methods such as PCR and novel expression systems.

"Human beings, and the biological processes for their generation" are not patentable, as they are specifically excluded under subsection 18(2) of the *Patents Act 1990*.

Although standard patents can be obtained for biological material such as microorganisms, nucleic acids, peptides and organelles, this material is only patentable if it has been isolated from its natural environment, or has been synthetically or recombinantly produced.

For example, DNA or genes in the human body are not patentable, however, a DNA or gene sequence which has been isolated from the human may be patentable.

Patent specifications must also describe a specific use for biological material. For example, if the invention relates to a gene, the specification must disclose a specific use for the gene such as its use in the diagnosis or treatment of a specific disease or its use in a specific enzymatic reaction or industrial process.

Standard Patents

A standard patent is granted for an invention that is a new idea which provides a practical solution to a technological problem. In this context, a standard patent would only be granted for subject matter which meets all the following tests:

- involves the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from the natural source material. (A patent cannot be granted for a mere discovery of biological material);
- is new in the sense of not previously being publicly available. That is, a patent cannot be granted for materials in their naturally occurring state or for materials which have previously been made publicly available;
- is inventive when compared to the prior art;
- has been fully described in the sense that sufficient information is provided to allow the technologist to make the product or perform the process without having to resort to invention; and
- has a demonstrated use. The use to which the invention is to be put, for example, for the treatment of human diseases such as cancer or multiple sclerosis, must also be fully described. This means that there must be an actual use for an invention rather than speculation as to future uses.

The written description

The specification must include a full description of the microorganism, hybridoma, enzyme or transgenic material (including the organisms in which the transgenic products are expressed), and their use, as well as the best method of performing the invention known to the



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applicant.

Where the invention is a microorganism, enzyme or related material or a specific method to produce or use these materials, there should be sufficient details in the specification for a specialist in the field to identify and repeat the invention.

Applicants can have difficulty in satisfying the requirement to reproduce or repeat the invention and to fully describe biological materials such as microorganisms. To enable an applicant to meet these requirements applicants may choose to deposit the biological material under the provisions of the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". This Treaty was devised to enable applicants to describe their invention.

Deposits of microorganisms must be made at an International Depository Authority (IDA) in accordance with the rules of the Treaty on or before the filing date of the complete patent application. For more information on the Budapest Treaty see the information sheet *The Budapest Treaty and Australian Patents*. Full description of the microorganism includes the full morphological, biochemical and taxonomic characteristics of the organism known to the applicant.

Where the invention is a plant or animal product or a specific method to produce such a product, there should be sufficient details in the specification for a specialist in the field to identify and repeat the invention (e.g. an isolated gene or a specific method to produce a transgenic product).

There must be sufficient clear information to enable the specialist to perform the

invention without conducting lots of experimentation or resorting to invention to discover the conditions necessary for performance of the invention.

Applicants should be wary of subjective descriptive characteristics (e.g. for plants — robust, tall, extensive, bright; or for microorganisms — large, small, distinctive colonies, etc.). If there is no point of reference or objective standard, these terms will be meaningless.

Best method of performance

In order to satisfy full description requirements for an invention involving:

- newly discovered and isolated Microorganisms;
- a process involving microorganisms; or
- products of microorganisms;
- genetically modified organisms, including animals and plants.

In addition to the broad description of the invention, all specific steps required to reproduce the microorganism, to carry out the processes or prepare the products must be disclosed in the specification. There may be a number of ways to achieve the desired result but the best way of obtaining the invented product or performing the invented process, must be described in detail.

Repeatability

A patent monopoly is granted in return for a full written description of an invention. Such a description is required to ensure that other people are able to make a product or repeat a process once the patent has expired. A specialist in the particular technology must be able to repeat the process or reproduce the product from the directions given in the



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written description.

Each technological area has its own standard of repeatability and this must be taken into consideration when assessing repeatability of an invention. The issue when considering repeatability is not the numerical probability of achieving the specified result, but whether the result can be reproduced to a practical level acceptable to the person skilled in that particular technology.

In a case involving the 'Scarlet Queen Elizabeth' rose, the method of production was a chance genetic mutation. It has been estimated that the chance of such a variety occurring is 1 in 100,000,000. IP Australia would consider the process essentially unrepeatable and would not grant such a patent. Repeatability is not likely to be an issue where the description of an invention, such as a novel organism, relies on a deposit made under the Budapest Treaty, because access to the deposited microorganism by a skilled third party enables the invention to be repeated.

The issue of repeatability is best considered through the following examples:

(i) *Mutagenesis* — With our increased understanding of molecular inheritance of, for example, plant and animal characteristics, breeders now have an armoury of techniques to make mutational events occur more frequently — irradiation, drugs that alter the genetic coding for the characters, and sometimes manipulation of the genes for the characters themselves. The use of these techniques means that repeatability is sometimes an issue. The description would need to clearly identify the organisms used, the type and amount of mutagenic agent, and how the organism was treated and how the mutants were

subsequently identified and recovered. Provided the inventor gives sufficient clear instructions for the specialist to follow and repeat the invention, then this may be acceptable.

(ii) *Genetic engineering* — A more common approach has been through genetic engineering where genes are taken from one quite unrelated organism and put into a second.

This approach permits not only the accurate introduction of characteristics into plants but also the introduction of characteristics from unrelated species — impossible by the normal routes of sexual propagation. The description requires additional details about the genes used, such as for example, the sequence of the gene used to transform the organism. Repeatability is rarely an issue in genetic engineering inventions, provided the invention is fully described.

Patenting microorganisms and other biological materials

Patent claims to inventions relating to microorganisms may be directed to the microorganism itself, its products or processes involving the microorganism. The claims must be fairly based on a full description of the invention in the body of the specification.

The specific details required in a description of a new microorganism or related invention will vary depending on the nature of the particular invention claimed and must include information enabling the repeatability of the invention. The following is intended only as a guide to the applicant and is not an all-inclusive list of the sort of information needed.



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Processes involving microorganisms, cell lines, hybridomas, etc.

When the invention lies in a process, such as fermentation, which makes use of a microorganism, the description of the invention should provide details including the source of the particular organism used for the process, as well as its required nutrient and culture conditions.

New microorganisms, cell lines, hybridomas, etc.

If the invention is a microorganism per se, such as a bacterium or fungus, or a new cell line, etc, as much as is known of its features should be described. This may include:

- the taxonomic description;
- morphological characteristics such as shape, size, stain ability, motility, etc;
- 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, etc; and
- genetic characterisation of any known genes relevant to the use or the characterisation of the organisation or the inventive concept. The characterisation may be at the level of gene sequence, function or restriction pattern

Products of microorganisms, cell lines, hybridomas, etc.

A microbial product, such as a novel antibiotic, is best characterised by its structure. However, as this is not always

known, the product may be defined in terms of the organism from which it is produced and/or by the physical or chemical characteristics that are known and which are sufficient to distinguish it from other known compounds. Such information may be UV or IR absorption spectra, NMR spectrum, elemental analysis, molecular weight, melting point, solubility characteristics and HPLC analysis.

In all the above cases a deposit made under the Budapest Treaty may assist in fully describing the invention.

Transgenic plants and animals

The characteristics of the gene introduced into the organisms must be described (preferably including the complete sequence of the gene) as well as the best method of transformation, regeneration and selection of the transformed materials, e.g. protoplast, pollen or embryo. The parent strains or the source of the host material must also be fully described and readily available to the public.

Mutant plants and animals

The parent strains must be fully described and readily available to the public. The method of mutagenesis (e.g. chemical or UV radiation) and the method of selecting or obtaining the mutant organisms must be disclosed. Finally, there must be a full written description of the mutant produced. A deposit made under the Budapest Treaty may assist in this regard.

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



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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:
 - (i) preparation of cheese, wine making, brewing and industrial processes involving the use of microorganisms such as microbial bleaching, leaching of ores using microorganisms;
 - (ii) the use of enzymes derived from microorganisms for the preparation of, for example cheese or, detergents comprising protease;

(iii) 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

(iv) the use of viruses in the preparation of 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.

Examples of Standard Patent Applications

Application	Subject
13186/92	Bioleaching of cobalt and copper containing pyritic concentrates.
21122/92	Method for the rapid determination of the microorganism content of liquids and fluid solutions, and apparatus for implementing this method.
30088/92	Tumour associated monoclonal antibody 88BV59.
35853/93	Biochemical purification of simvastatin.
37166/93	Method for producing a microorganism which is natural enemy to a nematode.
62066/94	New Bacillus Thuringensis strains and their insecticidal proteins.
13703/92	Gene construct for transgenic fish.
26766/92	Transgenic plants.
81063/91	Enhanced implantation, development and maintenance of



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- embryos using leukaemia inhibitory factor.
- 19530/92 Genetic sequences encoding flavonoid pathway enzymes.
- 34025/93 Pseudorabies virus (PRV) polynucleotides and their use for preparing virus resistant eukaryotic cells.
- 36303/93 Transgenic wheat.
- 51356/93 Transgenic animal models for neurodegenerative disease.
- 80226/94 A novel cruciferous plant having a high carotene content.

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.

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