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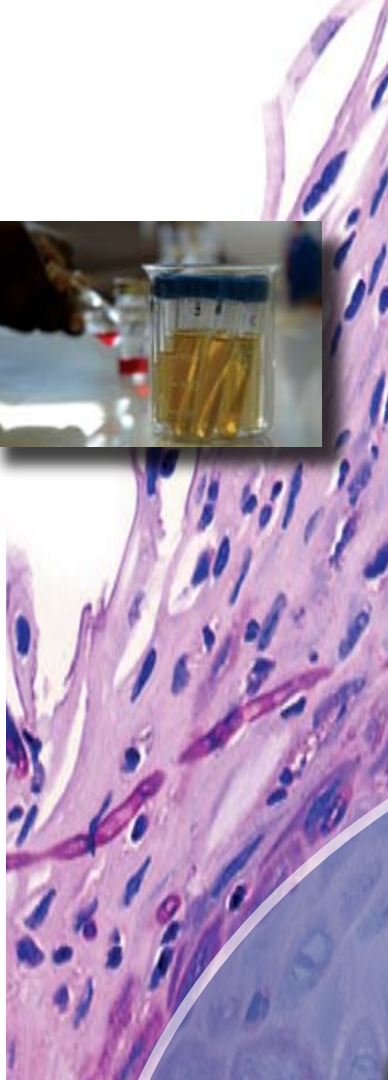
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We do
the **LAW**

Adams & Adams, the leading intellectual property law firm in Africa, is internationally known, with almost 100 years of successful practice. Adams & Adams has built up a patent corps which is not only formidable in size and capacity but has diversified legal and technical skills and expertise enabling it to deal expeditiously and effectively with all types of inventions.

The team has the technical expertise and patenting experience to advise clients regarding protecting and exploiting their Biotech inventions worldwide.



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GENERAL

This booklet is not intended to provide comprehensive or definitive guidance in biotech matters but is intended for general information.

Specialised advice on matters not dealt with in this booklet will be furnished on request.

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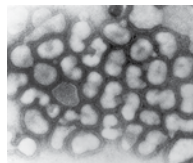
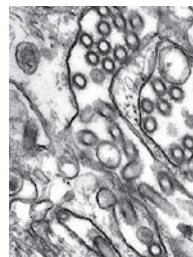
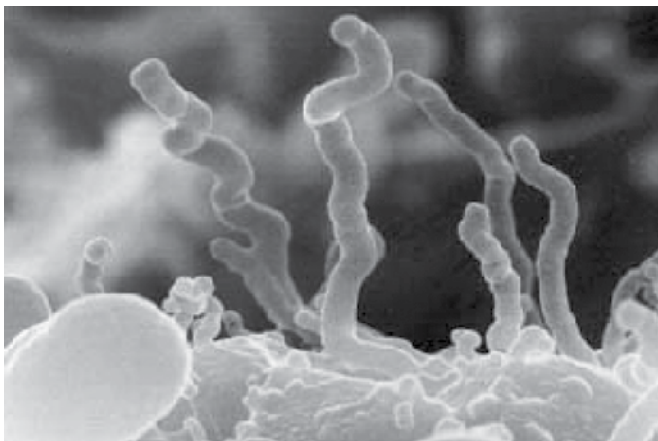
The Exploitation and Patenting of Biotech Inventions

The use and patenting of Biotech inventions in South Africa are governed and regulated by various laws, conventions and agreements which include the South African Patents Act, the South African National Biodiversity Act, the South African National Health Act, the South African Genetically Modified Organisms Act, the TRIP's Agreement, South African Indigenous Knowledge Laws and the Convention on Biological Diversity.

Many patent applications involving genetic engineering are concerned with the modification of a microbial host cell so that the host cell will manufacture a useful polypeptide in commercial quantities. Typically, this genetic engineering is performed by

inserting a DNA fragment coding for a desired polypeptide into a cloning vector, such as a plasmid, to obtain a "recombinant DNA molecule" with the expression of the inserted DNA fragment under the regulation of transcriptional and translational control elements and transforming the host cell with the recombinant plasmid construct.

Patenting of living organisms is unique for a number of reasons. Firstly, the invention itself is alive; secondly the invention can often reproduce itself; and thirdly it is often difficult for the invention to be adequately described for patent specification purposes, leading to the need for deposits of the invention in terms of the Budapest Treaty for patent purposes.





What is patentable in the Biotech Field

First, all biotech inventions must be novel, non-obvious and useful.

Secondly, since South Africa has a non-examining Patent Office, and since there is as yet no South African case law in this field, guidance is obtained from countries having examining Patent Offices and/or relevant case law in other countries. Particularly useful in this regard are the UK Patent Office and the European Patent Office ('EPO'), as their patent laws are similar to South Africa.

In terms of the European Biotech directive, Biotech inventions are patentable if they concern:

- biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
- plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety; and
- a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

In terms of the European Biotech Directive, there are certain Biotech inventions which are not patentable.

European patents will not be granted for the following:

- processes for cloning human beings;
- processes for modifying the germ line genetic identity of humans;
- uses of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animals, and also animals resulting from such processes; and
- the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene.

In terms of the South African Patents Act, "any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or a product of such process" is not patentable.

Use of biotech inventions are regulated by the Biodiversity Act, the National Health Act and Genetically Modified Organisms Act.

Many biotech inventions are of

a non-living nature, e.g. genes, recombinant DNA molecules and metabolites such as proteins, but biotech inventions can involve living matter. Non-living biotech inventions can be considered chemical compounds expressed in a unique way, and are hence inherently patentable in terms of the South African Patents Act as well as the patent laws of most countries. In addition, micro-organisms such as bacteria and yeasts which have been modified by genetic engineering should be patentable in South Africa, if EPO developments are used as a guideline.

Patenting of biotech inventions involving living matter is more problematic. In the United States, patents to plants and animals *per se* have already been granted, and it would thus appear that there is currently no bar on patenting plant or animals in that country.

What does fall outside the scope of patentability in terms of the South African Patents Act are processes for modifying plants or animals by traditional breeding methods involving known crossing steps. The justification for this exclusion is that protection for certain types of new plant varieties obtained by traditional breeding methods is already provided for by Plant Breeders' Rights.

Patent applications for biotech inventions may be directed to, for example:

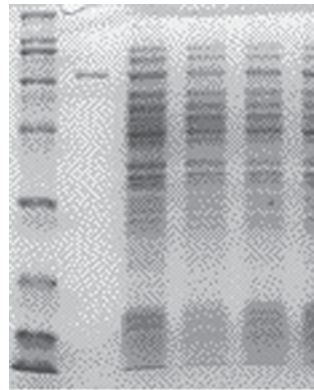
- Proteins, DNA, RNA, Amino

acid sequences

- Genes
- A process of genetically altering or otherwise inducing a single or multi-celled organism to:
 - Express an exogenous nucleotide sequence
 - Inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence
 - express a specific physiological characteristic not normally associated with that organism
- Cell fusion procedures yielding a cell line that expresses a specific protein (e.g. monoclonal antibody)
- Micro-organisms, cell lines
- DNA/RNA vectors
- Transgenic plants

The Patents Amendment Act and Patenting of Biotech Inventions in South Africa

This Act is intended to complement the South African National Biodiversity Act which came into force on 1 September 2004 (the parts of the Biodiversity Act dealing with traditional knowledge, bioprospecting, access and benefit sharing came into force on 1 January 2006). The Act introduces a requirement for applicants of patents to lodge a statement disclosing whether or not an invention is directly derived from an indigenous biological or indigenous



genetic resource, or is based on or derived from traditional knowledge or traditional use.

The disclosure requirement applies to all patent applications and not only to those involving indigenous biological or genetic resources and therefore all applicants for South African patents will be required to lodge such a statement.

The Patents Amendment Act is however not yet in force.

Bioinformatics

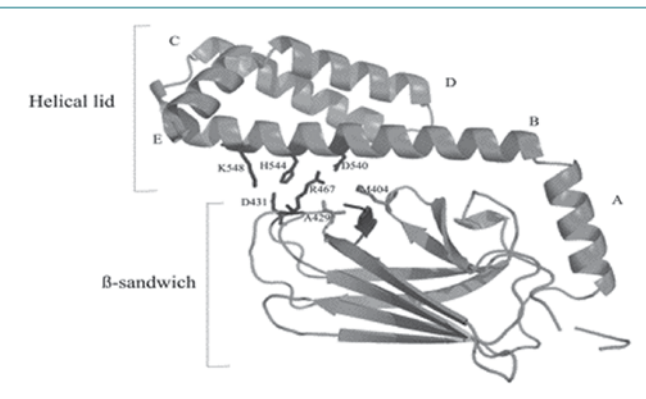
Bioinformatics presents numerous new and technologically-intensive opportunities. Establishing a proprietary position in this field may be critical to the success in this emerging sector. Bioinformatics covers various technology areas such as:

- computer software: databases, data management, algorithms, and modelling/prediction;
- engineering: arrays, high-

throughput screening devices, biochips, microfluidics, and instrumentation;

- gene discovery and function: high-throughput genetic sequencing, genetic linkage studies, genome sequencing and annotation, polymorphism, gene expression profiles, and micro-arrays;
- protein function: protein expression/modification databases, protein interaction maps, protein function prediction, and protein structure;
- cellular function: modelling metabolic pathways, cell signalling pathways, cell image databases, and microscopy imaging and data analysis; and
- drug design and development: computer aided drug design and molecular modelling, high-throughput screening, small-molecule compound libraries, clinical trial data analysis, pharmacogenomics, pharmacogenetics, and toxicology.

Adams & Adams has a team of patent attorneys with the technical expertise to advise and assist you in obtaining intellectual property protection for your inventions in the emerging bioinformatics sector. These patent attorneys have extensive knowledge of intellectual property rights and include electronic/electrical engineers, chemists, biochemists, geneticists, microbiologists, etc.



Bioprospecting and Traditional Knowledge

South Africa is considered to be the third most biologically diverse country in the world. Are you aware of how the South African Biodiversity Act may affect your Biotech inventions?

The Biodiversity Act came into force on 1 September 2004. Chapter 6 and Section 105 came into force on 1 January 2006. Chapter 6 deals with bioprospecting, access and benefit sharing and Section 105 deals with the steps to be taken for persons who were already engaged in existing bioprospecting projects on 1 January 2006. What is of concern is that, to date, no regulations have been drafted for Chapter 6 and Section 105 and there is therefore uncertainty regarding the procedures that need to be followed to satisfy the requirements of the South African Biodiversity Act.

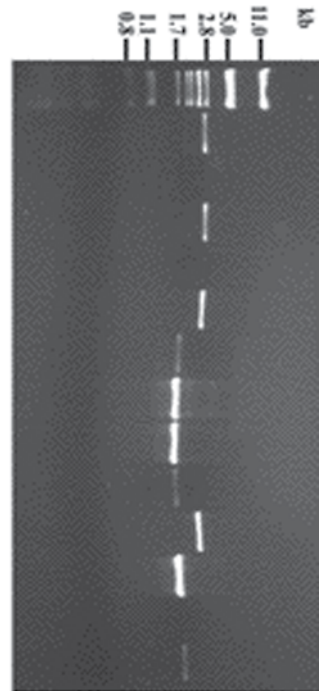
Chapter 6 of the Biodiversity Act regulates bioprospecting of genetic material and also provides for the fair and equitable sharing of benefits arising from bioprospecting of genetic material derived from indigenous biological resources. It also sets out the steps to be followed if traditional knowledge is associated with indigenous biological resources.

What is meant by bioprospecting in terms of the Biodiversity Act?

The Biodiversity Act specifies “bioprospecting”, in relation to indigenous biological resources, as meaning any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes:

- (a) the systematic research, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;
- (b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or
- (c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation.

The Biodiversity Act has extremely broad definitions relating to “indigenous biological resources”. The definitions include bioprospecting of genetic material derived from virtually any indigenous biological resources. The





Biodiversity Act specifically excludes the following:

- (a) genetic material of human origin;
- (b) any exotic animals, plants or organisms (but includes those genetically engineered with indigenous genetic material); and
- (c) resources listed in the International Treaty on plant genetic resources for food and agriculture.

In order to engage in bioprospecting in South Africa, one must obtain a permit from the South African Government. The permit will only be issued if a person or community providing access to the indigenous biological resource has consented to the terms and conditions of a Benefit Sharing

Agreement. A Material Transfer Agreement must also be entered into. If traditional knowledge is associated with the indigenous biological resource, a Benefit Sharing Agreement must be entered into with the traditional knowledge holders. Consent must be based on full disclosure of all relevant information including the intended use of the indigenous biological resource. This could be a problem if the bioprospectors wish to obtain patent rights in due course.

Without Regulations there is a lot of uncertainty as to what requirements have to be satisfied by bioprospectors and there are also many uncertainties and potential problems which may arise.

For further information, please contact us.

Plant Breeders' Rights

Do you have a new plant variety for which you require protection? You may then wish to consider obtaining Plant Breeders' Rights protection for your variety.

In order to be registrable, a plant must be named in the list of "kinds of plant" which is set out in the Plant Breeders' Rights Act. This list is varied from time to time. For example, the list currently includes as kinds of plants that are registrable:

Agricultural crops:

Kidney Bean, Castor Bean, Potato, Groundnuts, Oats, Soya Bean, Cotton, Sunflower, Barley, Rye Grass, Hops, Lucerne, Rice, Pearl Millet (Babala), Grain Sorghum, Wheat, and Grain Maize.

Vegetable crops:

Onion, Garden Beet, Cauliflower, Cabbage, Turnip, Sweet Pepper, Cucumber, Pumpkin, Squash, Carrot, Lettuce, Tomato, Garden Bean, Pea, Sweet Corn, Popcorn, Watermelon, Spanspek (Sweet Melon), Eggfruit and Olive.

Fruit crops:

Citrus, Quince, Strawberry, Litchi, Apple, Mango, Banana, Granadilla, Avocado, Apricot, Sweet and Sour Cherry, Plum, Peach, Nectarine, Guava, Pear, Grape, Almond, Pecan Nut, Coffee, Tea and Macadamia Nut.

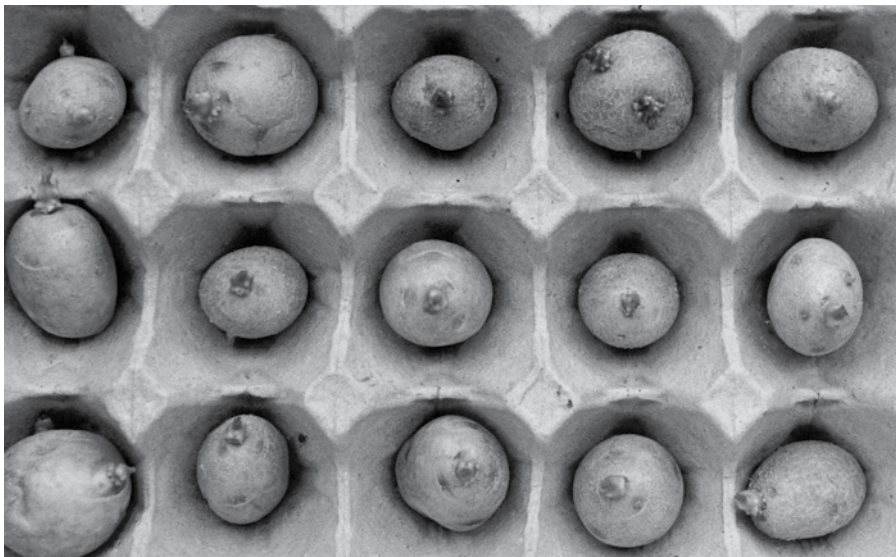
Ornamental crops:

Protea, Chrysanthemum, Carnation, Poinsettia, Freesia, Gladiolus, Geranium, Rose, African Violet, Lachenalia, Chinkerinchees, Brunia, Wax flower, Heath, Sword fern, Giant Panicum, Protea, Agapanthus, Michaelmas daisy, Fuchsia, Begonia, Ivy, Hibiscus and Oleander.

The above list is not exhaustive. Please let us know if you would like a copy of the most recent full list.

Effect of Plant Breeders' Rights

When Plant Breeders' Rights are granted, any person intending to undertake the production or reproduction, conditioning for the purpose of propagation, sale or any other form of marketing, importing, exporting, or stocking for any of these purposes of propagating material or harvested material (including plants) obtained through unauthorised use of propagating material of the variety protected, must obtain authority by way of a licence from the holder of the Plant Breeders' Rights. The holder of Plant Breeders' Rights thus has the sole right in South Africa to produce, sell, import, export, etc. the propagating or harvested material.



The Genetically Modified Organisms Act 15 of 1997

Matters connected with the use of genetically modified organisms are regulated by the Genetically Modified Organisms Act, as amended by the Biodiversity Act.

“Genetically Modified Organism” as defined by the Act includes an organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and “genetic modification” has a corresponding meaning.

In terms of this Act the Executive Council of Genetically Modified Organisms may require any applicant for a permit to use facilities for the development, production, use or application of genetically modified organisms, or to release such organisms into the environment, to submit to the council through the Registrar, an assessment of the risk and, where required, an assessment of the impact on the environment of such development, production, use, application or release as the case may be.

Furthermore, the applicant is required to submit notification of any intended change in the type of activities or release

involving genetic modification of organisms being undertaken at any facility for which approval was granted.

Guidelines to the Genetically Modified Organisms Act 15 of 1997 have been published which address the following aspects:

- Potential effects of GMOs
 - intended and unintended:
 - o phenotypic changes
 - o ecological effects
 - o human health and welfare
- Possible routes of dispersal of GMOs into the environment
- Risk assessment of GMOs
 - human health, food safety, environmental effects
 - classification of biological agents and GMOs as well as containment levels (physical and operational requirements for small-scale use)
 - basic laboratory procedures
 - reviewer’s checklists
 - guidelines for the Advisory Committee when considering proposals in terms of the GMO Act

If more information is required in respect of the genetically modified organisms Act, please contact us.