# PATENTABLE SUBJECT MATTER AUSTRALIA

Patentable Subject Matter in Australia falls into two main categories:

- Is it a 'manner of new manufacture'?
- Is it excluded subject matter by law?

The failure of a claim to define a patentable invention will be a ground of refusal during examination, and a ground for revocation/cancellation.

## EXCLUDED SUBJECT MATTER

There are some subject matters that are excluded by Australian legislation from being part of patentable subject matter.

### BIOLOGICAL MATERIALS

Human beings and biological process for generation. Section 18(2) of the *Patents Act 1990* (Cth) (Australia) prohibits patents for human beings and biological processes for generation. This will include:

- Fertilised human ova and equivalents, zygotes, blastocysts, embryos, fetuses and totipotent human cells; and
- Methods of in vitro fertilisation, sperm injection, cloning, growing fertilised ova, introducing transgenes and donor genetic cytoplasmic material into fertilised ova, and methods of obtaining embryonic stem cells which include making an embryo.

However, not all biological material and processes is excluded as patentable subject matter. The following subjects may be patentable:

- a microorganism, protein, enatiomer or antibiotic in its isolated form;
- a recombinant, isolated or purified gene;
- a gene per se, provided the claim does not include within its scope the native chromosome of which the gene forms part.
- living organisms are patentable provided they are not in a naturally occurring state and they had been improved or altered.

Even within the regeneration of human beings, some subject matter has been held to be patentable including:

- cryopreservation of gametes;
- preimplantation genetic analysis of gametes, and
- determining the developmental progress or viability of a fertilised ovum, blastocyst or embryo, by analysis of culture or incubation media.

### CONTRARY TO LAW

Matters that are contrary to law are not patentable. Australia does not have a general contrary to public order provision like the EU. Objections are rare because it is limited to situations where the only use of the patent is an unlawful use. An unlawful use is a use that is a criminal act or which would be an offence under Australian law. For example, human cloning is contrary to *Human Cloning Act* (2002) and patents for human cloning would be contrary to law.

### INNOVATION PATENTS

Plants and animals and the biological process for the generation of plants and animals. Section 18(3) of the *Patents Act 1990* (Cth) Australia prohibits innovation patents for plants and animals and the biological process for the generation of plants and animals.

However, s 18(3) will not apply if the innovation patent is for a microbiological process or is a product of such process.

In addition, to excluding plants and animals, the same exclusions discussed above concerning human beings and the biological processes for the generation of human beings also applies to innovation patents.

## METHOD OF NEW MANUFACTURE

Under Australian patent law, the definition of 'invention' is not limited. It includes any manner of new manufacture. It is left to the courts to determine what is a 'manner of new manufacture' and, as such, what will be considered patentable subject matter in Australia.

The criteria applied by the courts is whether the invention results in an artificially created state of affairs and is economically useful (the NRDC case[1]). In some fields of innovation, such as methods of medical treatment, business methods and computer software the application of this criteria is still uncertain.

### METHODS OF MEDICAL TREATMENT

A method of medical treatment is patentable provided it is a an artificially created state of affairs and has economic utility. The following methods of medical treatment have been patented in Australia:

- cosmetic treatments, that is processes or methods for improving or changing the appearance of a part of the human body, having a commercial application;
- a process of curative treatment of the human body provided they have commercial application; and
- the administration of therapeutic drugs to humans.

### COMPUTER SOFTWARE

Computer processes of economic utility, source code and executable code are patentable subject matters.

**Mathematical algorithms.** Mathematical algorithms are patentable subject matter provided they are implemented in a useful way. If the algorithm results in some form of physical transformation, such as a new business method, then it will be patentable. However, an algorithm dealing with mathematical symbols and variables with no apparent purpose is not patentable.

#### Business methods

A business method that results in a useful, physical phenomenon or effect is patentable subject matter. Methods that claim a technical solution or technical advantage generally satisfy

[1] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252

these criteria, such as computerised accounting, monitoring, reporting or analysis systems.

Usually, the technological implementation satisfies the 'physical effect' requirement test if the implementation is directly involved in the operation of the method. However, the use of a computer to merely record information is unlikely to be patentable.

## STANDARD PATENTS

Table 1 -Fundamental bases for categories being considered unpatentable

| Historical category | Lack of practical utility | Non economic | Non man-made | Lack of novelty & inventiveness |
|---|---|---|---|---|
| Discoveries, ideas & theories | x | | x | |
| Laws of nature | x | | x | |
| Fine arts | x | x | | |
| Schemes, plans &methods of doing business | x | | x | |
| Mathematical algorithms with no practical implementation | x | | | |
| Printed matter characterised solely by the content | x | | | |
| Methods of treating humans | | x | x | |
| Living organisms | | | x | |
| Agricultural & other processes not producing/treating a man-made object | | | x | |
| Animals and plants and the biological processes for the generation of plants and animals | | OK standard patents<br><br>No innovation patents | | |
| Analogous uses | | | | x |
| Methods of testing, observation & measurement | | | | x |
| Working directions for operating a known product or process | | | | x |
| Collocations, kits & packages of known integers | | | | x |
| Foods or medicines that only exhibit known properties of the ingredients | | | | x |

(Modified from IP Australia)

# 可专利客体
# 澳大利亚

在澳大利亚，可专利客体分为两类：

- 是否是新型制造方式？
- 是否是被法律排除在外的客体？

未能正确定义专利发明的权利要求是实质审查中的驳回理由之一，也是撤销理由之一。

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被法律排除在外的客体

澳大利亚的立法将某些客体排除在可专利客体之外。

### 生物材料

人体和衍生过程。澳大利亚专利法第 18 条第 2 款禁止人体和衍生过程作为可专利客体。其中包括：

- 受精的卵细胞和对等物；受精卵；胚泡；胚胎；胎儿；人体干细胞；
- 体外受精方式；射精；克隆；培育受精的卵细胞；将转基因和捐献遗传基因物质注入受精的卵细胞；获取包括创造胚胎在内的胚胎干细胞的方法。

但是，不是所有的生物材料和程序都被排除在可专利客体外。以下是可专利客体：

- 微生物；蛋白；对映体或分离的抗生素；
- 重组体，分离的或提纯基因；
- 基因本身，前提是权利要求不包括由该基因组成的染色体；
- 活体有机体，前提是不是自然形成，经提高或改造。

即使是人体再生，一些客体也可作为专利客体，这其中包括：

- 低温贮藏的生殖细胞；
- 植入子宫前生殖细胞的遗传分析；
- 通过分析培养基或【微】培养决定受精卵，胚泡或干细胞的发育进度和活性

### 违反法律

违法的客体是不可被授予专利的。与欧洲不同，澳大利亚没有一个总的违反公共秩序的法条。由于专利的唯一使用目的是违法使用才会遭到反对，所以反对很少。违法使用是指用于违法犯罪，或触犯澳大利亚法律的使用。比如，人体克隆为人体克隆法所禁止，专利用于人体克隆是违法的。

### 创新专利

动植物和衍生动植物的生物进程。专利法第 18 条第 3 款禁止创新专利用于动植物和衍生动植物的生物进程。

但是，如果创新专利是微生物学进程，或者是该进程的一个产物，专利法第 18 条第 3 款就不适用。

此外，关于创新专利的法条除了禁止动植物，也同样禁止人体和衍生过程。

## 新型制造方式

澳大利亚专利法就‘发明’这一概念不是定义死的，任何新型制造方式都可被囊括在内。最终由法院决定到底什么是‘新型制造方式’，以决定某客体是否符合澳大利亚可专利客体的要求。

法院采纳的标准是该发明是否是人造物，并具经济效用（来自 NRDC 案）[2]。在一些诸如医疗手段，商业方法，电脑软件的创新领域，该项标准是否使用仍未有定论。

### 医疗手段

医疗手段是可专利客体，前提是人工创造并有经济效用。以下医疗手段在澳大利亚是可专利客体：

- 整容医疗，即提高，改变人体部分外观外貌，商业上应用的进程或方法；
- 商业上应用的人体根治疗法
- 人体治疗用药

### 电脑软件

源代码，可执行代码，经济效用的计算机处理是可专利客体。

**数学算法**

数学算法可作为可专利客体，前提是此算法是有效用的。如果算法导致变化产生，例如产生了新的商业方法，则为可专利客体。但如果算法仅处理一些数学符号，变量，无实质目的，则不是可专利客体。

**商业方法**

产生实用，实质性变化或效应的商业方法是可专利客体。包含技术解决方案或技术优势的方法一般可满足上述条件，例如电子化会计，监控，报告或分析系统。

通常，如果实施直接作用于该方法的应用，则该技术实施满足‘实质性效应’的要求。但是，仅通过电脑记录信息不算是可专利范畴。

### 发明专利

**表 1 – 不可专利类别的基本依据**

| 历史范畴 | 缺乏实用性 | 无经济效用 | 非人工制造 | 缺乏创新性 |
|---|---|---|---|---|
| 发现，想法和理论 | X | | X | |
| 自然规律 | X | | X | |
| 艺术 | X | X | | |
| 经商的方案，计划和方法 | X | | X | |
| 无实用效能的数学算法 | X | | | |
| 特征仅限于其内容的印刷品 | X | | | |
| 治疗方法 | | X | X | |
| 活体 | | | X | |
| 农业&其他并未产生/治疗人造物的进程 | | | X | |
| 动植物和衍生动植物的生物进程 | | 可 发明专利<br><br>否 创新专利 | | |
| 类比使用 | | | | X |

[2] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

| | | | | |
|---|---|---|---|---|
| 试验，观察&测量方法 | | | | X |
| 操作已知产品或程序的工作指南 | | | | X |
| 已知整数的配置，装备&程序包 | | | | X |
| 仅展示已知成分属性的食品药品 | | | | X |

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