
Mumbo jumbo: The patentability of biological materials in Australia

By Vaughan Barlow¹

1. Introduction

The *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) is currently being debated before the Australian parliament. The Bill seeks to ban the patenting of all biological material that is “identical or substantially identical to such materials as they exist in nature”. If passed, this legislation would represent a major shift in Australian patent law. It may also significantly jeopardize the biotechnology, pharmaceutical, medical and agricultural industries in Australia. This article therefore examines the current patentability of biological materials in Australia, charts the evolution of public debate surrounding this issue, sets out the proposed ban on patentable subject matter, and briefly discusses the ramifications of such a ban.

2. General requirements for patentable subject matter in Australia

To encompass patentable subject matter under Australian law, an invention must give rise to (1) an artificially created state of affairs that is (2) in a field of economic endeavour.² In making this assessment, the patent office or courts will not enquire into matters of ethics or social policy when determining questions of patentability.³ It follows that any biological material that is discovered in nature without any practical application is regarded as a "mere chemical curiosity" and not patentable subject matter.

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1. Vaughan is a legal practitioner admitted to the Supreme Court of New South Wales and a patent attorney registered to practice before the Australian Patent Office and the Intellectual Property Office of New Zealand. Vaughan is also a trade marks attorney registered to practice before the Australian Trade Marks Office. Vaughan practices with Pizzeys Patent and Trade Mark Attorneys: www.pizzeys.com.au;
 2. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (the “NRDC Case”);
 3. *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) 28 IPR 383;
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In order to satisfy the requirement for “an artificially created state of affairs”, patent claims encompassing naturally occurring biological materials must therefore distinguish that material from the form in which it already exists in nature. Hence, for example in relation to patenting genes, claiming “isolated” or “purified” nucleic acids or recombinant nucleic acids is allowable on the basis that the act of isolating, purifying or cloning satisfies the requirement that a patentable invention give rise to “an artificially created state of affairs”. The underlying rationale is that an isolated, purified or recombinant nucleic acid does not exist in nature, but rather, that nucleic acid only exists in nature in a different form, for example, as part of a chromosome. The act of isolating, purifying or cloning therefore creates the “artificially created state of affairs”. A similar rationale generally applies to claiming other naturally occurring biological materials such as isolated proteins, which may only exist in nature as part of a cell or organism. ⁴

In order to satisfy the requirement that there be “a field of economic endeavour”, a claimed nucleic acid or amino acid must have a function or putative function ascribed to it. Hence, for example, claiming of expression sequence tags (ESTs) is banned on the basis that ESTs do not constitute patentable subject matter for lack of “a field of economic endeavour”. A functional limitation must therefore be included in claims to naturally occurring nucleic acids, amino acids or other biological materials.

As a consequence, the allowable scope of claims for naturally occurring biological materials such as nucleic acids and amino acids generally includes the following:

1. Claims to fragments or complements of nucleic acids, or fragments of amino acids, are generally allowed provided that there is the same functional limitation ascribed as per the full length nucleic acid or amino acid;
2. Claims to nucleic acids or amino acids with a certain percentage identity to the full length nucleic acid or amino acid are allowed, again provided that there is the same functional limitation ascribed;

4. *Ranks Hovis McDougall Ltd's Application* (1976) AOJP 3915;

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3. There is no absolute rule on the level of percentage identity allowed. Some older patent office commentary states that as low as 60% identity is allowed. Claims with 70%-80% identity are reasonable to expect, provided again that the same functional limitation is ascribed;
 4. Claims involving nucleic acids or amino acids as part of a method of medical treatment for human beings are allowed.⁵

Under section 18(2) of the *Patents Act* (1990), there already exists a specific ban on patenting “human beings, and the biological processes for their generation”. This has been interpreted by the Australian patent office to include totipotent stem cells, but not pluripotent / multipotent stem cells, due to the difference in the potential of each of these cell types to create a human being.⁶ Accordingly, section 18(2) cannot be regarded as precluding *per se* the patentability of other biological materials that cannot of itself give rise to a human being.

There are no other existing specific bans on the patentability of any form of biological material under the *Patents Act* (1990). However, section 50 states that a patent application may be refused:

- (a) for an invention the use of which would be contrary to law; or
- (b) on the ground that the specification claims as an invention:
 - (i) a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients; or
 - (ii) a process producing such a substance by mere admixture.

Australian examination guidelines advise that some “inventions relating to stem cells derived from human embryos may be in breach of the *Prohibition of Cloning Act* (2002) and/or the *Research Involving Human Embryos Act* (2002)”⁷ which limit research on human embryonic

5. *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383; *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* [2000] FCA 316;

6. *Fertilitescentrum AB and Luminis Pty Ltd's Application* [2004] APO 19 (13 July 2004); *Woo-Suk Hwang* [2004] APO 24 (9 September 2004);

7. IP Australia *Australian Patent Office Manual of Practice and Procedure - Volume 2 – National* at para 2.9.5.1. http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm;

stem cells to excess “assisted reproductive technology” (ART) embryos.⁸ However, no other legislative bans on other biological materials would appear to be capable of enlivening section 50, which therefore seems restricted to affecting the patentability of human embryonic stem cells only, and not any other biological materials.

3. Australian Law Reform Commission Report on gene patenting

In 2004, the Australian Law Reform Commission (“ALRC”) published a paper entitled “*Genes and Ingenuity: Gene Patenting and Human Health*” (ALRC No. 99, 2004). The terms of reference given to the ALRC were to consider the impact of current patenting laws related to genes and genetic technologies on (1) research and its application and commercialisation, (2) the Australian biotechnology sector and (3) the cost-effective provision of healthcare in Australia.

The ALRC recommended that applications for genes be assessed on the same criteria as other inventions, but that a new general requirement be made for applicants to demonstrate “usefulness”, whereby there must be a “specific, substantial and credible use” which must be satisfied by an applicant on the balance of probabilities. In addition, the ALRC recommended the introduction of an experimental use exemption allowing study on the subject matter of a patented invention, consistent with the approach in Europe. In relation to the patentability of genes and genetic material, the ALRC “concluded that there are significant impediments to amending the *Patents Act* to exclude genetic materials from patentability. These include a long history of patenting such inventions, international treaty obligations, and a biotechnology industry dependent on patents and inventions.” The ALRC further recommended that “the *Patents Act* should *not* be amended to exclude genetic materials or technologies from patentability; or to provide a new medical treatment exclusion; or to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.” Accordingly, the patentability of biological materials, and in particular genes, was considered at the time of the ALRC report to have been settled.

8. The ART must be excess to the needs of a person or couple using an IVF program and its use must be licensed by the Embryo Research Licensing Committee of the National Health and Medical Research Council.

4. Australian Senate Inquiry into Gene Patents

Despite the findings of the ALRC in 2004, a vocal minority of lobbyists and politicians successfully convened a government senate inquiry in 2008 into the patenting of genes and genetic materials. The terms of reference for the senate inquiry were to consider “the impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form”, with particular reference to:

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
 - (i) the provision and costs of healthcare,
 - (ii) the provision of training and accreditation for healthcare professionals,
 - (iii) the progress in medical research, and
 - (iv) the health and wellbeing of the Australian people;
- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of any matters identified by the inquiry; and
- (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

The inquiry involved a series of public hearings that were designed, in part, to better inform senators of the technical legal and scientific issues involved in patenting of genes. By way of example, the following transcript of a discussion between senator Bill Heffernan and the Commissioner of Patents, Fatima Beattie, reveals some of the difficulty experienced by senators in understanding basic principles of genetic technologies:

Senator HEFFERNAN—I presume it is true that when a scientist merely isolates a human gene, all that happens is that that gene is removed from the human body.

Mrs Beattie—... Yes, they isolate it and they can clone it into a vector.

Senator HEFFERNAN—That is typical bureaucratic mumbo jumbo. Thanks very much for that.⁹

9. Official Committee Hansard, Senate, Community Affairs References Committee, *Gene Patents*, Tuesday 18 May 2010 at page CA 4;

Despite eight public hearings being held over a period of 17 months between March 2009 and August 2010, the Senate Committee concluded that “it is unable to provide a comprehensive report at this time”.¹⁰ The Senate Committee therefore did not make any recommendations on the patentability of genes and genetic technologies. The 2004 ALRC report therefore remains one of the most contemporary and thorough official government considerations on this issue.

5. The *Myriad* case

The New York District Court summary judgement decision in *Association for Molecular Pathology v United States Patent and Trade Mark Office*¹¹ (the “*Myriad Genetics Case*”), was viewed in Australia as fuelling the public debate on patenting of biological materials. However, many that propounded the *Myriad* decision as a sign of things to come in Australia failed to appreciate the legal nature of the decision, which has effect only in the Southern District of New York and is now under appeal by *Myriad* to the Court of Appeals for the Federal Circuit. Nevertheless, when counterpart litigation was commenced in the Australian Federal Court in June 2010 to invalidate Australian patent no. 686,004 owned by *Myriad Genetics, Inc.* and licensed to *Genetic Technologies Ltd*, the resulting voluntary surrender of AU 686,004 was widely regarded as a missed opportunity to finally achieve a binding court decision on the patentability of genes in Australia. To date, it remains the case that no Australian court has been required to determine whether or not genes or other biological materials constitute patentable subject matter, or whether or not a distinction should be made between different biological materials on the basis of inherent “informational” characteristics, as was the case in the *Myriad* decision.

6. The Advisory Council on Intellectual Property Report on Patentable Subject Matter

In 2008 the Advisory Council on Intellectual Property (ACIP) was asked by the Federal Government to undertake a review of patentable subject matter, including the patenting of

10. Senate, Community Affairs References Committee: *Report on inquiry into gene patents*, 26 August 2010;
11. No. 09-Civ-4515 (SDNY), handed down on 29 March 2010;

genetic materials. In its final report in December 2010,¹² the ACIP recommended essentially maintaining the present tests for patentable subject matter. However, the ACIP also recommended a general exclusion from patentability of “an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public”.¹³ In making this recommendation, the ACIP noted that “we do not expect a significant number of inventions to be excluded on this ground”.¹⁴

The ACIP explicitly recommended against providing a specific list of unpatentable subject matter on the basis that “[t]his mechanism lacks flexibility, because changes to technology or to Australian society’s values would require that the list of specific exclusions be updated. [Also]...some undesirable patents would be granted before the list could be revised. The mechanism could also work against the objectives of the patent system, because wholly preempting an area of technology from being patented would remove an incentive for any future innovation in that area”.¹⁵ Of particular significance, the ACIP also noted that “no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products.”¹⁶

The ACIP was therefore clear in its recommendation that there should be no specific exclusion from patentability of biological materials such as human genes and genetic products, preferring instead to recommend general exclusion criteria based on ethical considerations. These recommendations, insofar as they concern patentability of biological materials, correlate with those of the 2004 ALRC report.

7. The *Patent Amendment (Human Genes and Biological Materials) Bill (2010)*

Despite the 2004 ALRC report recommending against a ban on patenting of genes, and despite the Senate Committee failing to make any recommendations on the patentability of genes and genetic technologies, and despite the 2010 ACIP report explicitly recommending

12. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010;

13. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010, page 18;

14. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010, page 18;

15. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010, page 14;

16. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010, page 14;

against the introduction of specific exclusions for patentability, and despite no Australian court ever having provided any *obiter dicta* or *ratio decidendi* on the patentability of biological materials, a group of senators recently introduced into both houses of the Australian parliament the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010). The Bill has yet to be passed into law by the Australian parliament. Among other proposed changes, the Bill seeks to amend section 18 of the *Patents Act* (1990) as follows (shown in strikethrough for proposed deleted text and underline for proposed added text):

- (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:
 - (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
 - (b) when compared with the prior art base as it existed before the priority date of that claim:
 - (i) is novel; and
 - (ii) involves an inventive step; and
 - (c) is useful;

.....
- ~~(2) Human beings, and the biological processes for their generation, are not patentable inventions.~~
- (2) The following are not patentable inventions:
 - (a) human beings, and the biological processes for their generation; and
 - (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

.....
- (5) In this section:
biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.

The proposed ban on patenting of biological materials under section 18(2) is therefore far broader than the current ban, which is limited to “human beings and the biological processes for their generation”. Proposed section 18(2)(b) bans from patentability all biological materials that are “identical or substantially identical” to those existing in nature. The breadth of this proposed ban therefore also goes well beyond any recommendation made by the ALRC, the ACIP or even the decision in the *Myriad* case, given that no distinction is made on the basis of inherent “informational” characteristics of a biological material.

The legal definitional problems associated with the proposed language of section 18(2)(b) are numerous, and include (1) defining the scope of a “biological material”, (2) defining the scope of a “component or derivative” of a biological material, (3) defining the scope of “substantially identical” and (4) defining the scope of “such materials as they exist in nature”.

In relation to defining the scope of the term “biological material”, some assistance is provided under section 18(5) which proposes a non-exhaustive inclusive definition including DNA, RNA, proteins, cells and fluids. Accordingly, it appears that any biological material from any naturally occurring biological system is proposed to be banned from patentability. This would of course include just not human biological material, but any biological material from any animal, plant, bacteria, virus, yeast, coral, etc that is naturally occurring. In addition, the molecules encompassed by any “biological material” must presumably be read to include not only DNA, RNA, proteins, cells and fluids, but any molecule whatsoever that naturally occurs in a biological system. Anti-cancer compounds such as taxol, isolated from the Pacific Yew tree, would therefore be banned from patentability. Also, the ability to patent autologous cell therapies, the precise aim of which is to replicate biological material from a patient in need, would be jeopardized. Moreover, the term “fluid” under section 18(5) must presumably be limited to fluids found naturally in biological systems, rather than including any fluid whatsoever. In any case, this would include not just blood, plasma, serum, lymph, saliva, urine, sperm, venom, etc, but conceivably also water, which is arguably the most fundamental of all biological fluids.

The term “component or derivative” of a biological material even further broadens the scope of the ban on biological materials. On a literal interpretation, a “component” of a “biological material” (specifically defined as including DNA, RNA and proteins) arguably encompasses, for example, any one or more single nucleic acid residues or single amino acid residues. It is therefore difficult to know where to reasonably draw the line on the scope of the term “component”. Equally problematic, the term “derivative” is commonly defined as a compound or molecule that is derived from a similar compound or molecule by some chemical or physical process. The term “derivative” can also be used for compounds that can at least theoretically be formed from a known precursor compound. Hence, it is difficult to know whether a “derivative” of a biological material, which may for example be a chemically

altered amino acid that does not exist in nature (due to the artificial chemical or physical process applied to produce it), would nevertheless still fall within the proposed banned subject matter.

In relation to defining the term “substantially identical”, it is noteworthy that section 44 of the Australian *Trade Marks Act* (1995) bars registration of a trade mark that is “substantially identical” with a prior filed trade mark.¹⁷ Although the term “substantially identical” has therefore been subject to at least 15 years of interpretation in relation to Australian trade mark law, it is nevertheless difficult to see how any significant interpretive benefit may be translated over to issues of “biological material” as proposed under section 18(2) of the *Patent Act* (1990). Indeed, use of the term “substantially identical” would almost certainly result in prolonged and potentially expensive interpretation during patent office or court proceedings.

In relation to defining the scope of the phrase “such materials as they exist in nature”, it is presumably necessary to attempt to define what biological material is naturally occurring and what is artificial. This brings into focus a temporal question: from what point in time can a biological material be said to exist in nature? For example, Australian farmers have for several years now grown genetically modified cotton. This cotton clearly exists in nature, but is it now naturally occurring? Similar enquiries can be applied to a wide array of biological materials that may have been developed through human intervention and therefore could be considered artificial, but which have since melded into the environment and have existed there for a long period of time. For example, how does one differentiate between the human intervention involved in artificially creating genetically modified cotton versus the breeding of animals and crops to suit human needs over thousands of years? At what point in time, or through what type of human intervention, can we differentiate between biological material that “exists in nature” and that which does not? Such issues are particularly pertinent for agriculture, where it is arguable that the continued release of genetically modified crops or animals for widespread use by farmers changes what defines “existing in nature” on a continual basis.

17. Registration is only barred if the substantially identical or deceptively similar trade mark is sought to be registered in respect of similar goods or closely related services;

It is therefore clear that not only would the proposed ban on patenting of biological materials significantly change the scope of patentable subject matter in Australia, but the particular language proposed is overly broad, problematic and confusing.

8. Conclusion: Ramifications of the proposed bans on patentable subject matter

It is immediately apparent that if passed into law, the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) would have a profound affect on the biotechnology, pharmaceutical, medical and agricultural industries in Australia. Despite the recognized expertise of the ALRC, its recommendation that the *Patents Act* should not be amended to exclude genetic materials or technologies from patentability appears to have been ignored. In addition, the significant impediments to amending the *Patents Act* to exclude genetic materials from patentability, including “a long history of patenting such inventions, international treaty obligations, and a biotechnology industry dependent on patents and inventions”, has also been ignored. Moreover, the approach taken goes directly against recommendations made by ACIP that a specific list of unpatentable subject matter should not be provided, and that “no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products.”¹⁸

From a legal perspective, it is important to note that Australia is a signatory to the Trade Related Aspects of Intellectual Property (TRIPS) agreement. Article (Art) 27(1) of TRIPS obliges member countries to make patents “available for any inventions, whether products or processes, in all fields of technology...”.¹⁹ An exception to this requirement is found in Art 27(2) which permits members to “exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health...”. In addition, Art 27(3)(a) allows exclusion of “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”, and Art 27(3)(b) allows exclusion of “plants and animals

18. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010, page 14;

19. Article 27(1) TRIPs, which further requires that such patents are “new, involve an inventive step and are capable of industrial application”.

other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”.

Although the exclusions to patentability under Art 27(2) and 27(3) of TRIPS are therefore potentially broad, it appears clear that the proposed exclusions under the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) are even broader. For example, the proposed Australian Bill clearly excludes patenting of micro-organisms, but Art 27(3)(b) of TRIPS disallows such exclusion. While it is conceivable that exclusion of micro-organisms may be allowable under Art 27(2), this remains far from clear. Proponents of the amendments to section 18(2) argue that TRIPS would not be contravened because the banned subject matter would not qualify as an “invention” and therefore would not be subject to Art 27.

In addition to Australia’s potential contravention of its obligations under TRIPS, the commercial reality of banning from patentability all biological material that exists in nature could result in the biotechnology, pharmaceutical, medical and agricultural industries withdrawing investment in Australia. As a consequence, there is the potential for future difficulty in accessing medicines and associated problems in the provision of healthcare. This possible lack of investment could arise not only because of diminished returns on investments through a lack of patent rights, but also because of the remaining significant costs in obtaining regulatory approval.

Patent applicants seeking to claim biological materials in Australia are therefore strongly urged to closely monitor the progress of the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) through the Australian parliament.