

PATENTABLE SUBJECT MATTER, *TRIPS* AND THE *EUROPEAN BIOTECHNOLOGY DIRECTIVE*: AUSTRALIA AND PATENTING HUMAN GENES

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I INTRODUCTION

This paper maintains that the word ‘inventions’ in art 27.1 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* 1994¹ (*TRIPS*) imposes an obligation on member countries to ensure that the subject matter of a patent application be scrutinised and not presumed. Article 27.1 of *TRIPS* provides that ‘[p]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application’. In other words, patentability involves satisfying a two-step test. Is the technological advance claimed in the patent application (a) an ‘invention’ (ie, patentable subject matter) and, if so, (b) is that ‘invention’ (i) novel, (ii) inventive and (iii) industrially applicable?

Article 27.1 of *TRIPS* mandates that patent protection be afforded only to ‘inventions whether products or process ... provided that they are new, involve an inventive step and are capable of industrial application’. Accordingly, all signatories to *TRIPS*, including Australia, have an obligation to ensure that their patent laws are consistent with this requirement.

The *European Biotechnology Directive* 98/44/EC² was passed by the European Parliament in 1998. Its passage was controversial at the time and remains so today. In July 2003 the European Commission referred Germany,

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1 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, opened for signature 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (entered into force 1 January 1995) (*TRIPS*).

2 Directive of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions, 98/44/EC, (6 July 1998), 13–21 (*European Biotechnology Directive*).

Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden to the Court of Justice of the European Communities for their failure to transform the Directive into their national patent laws by July 2002.

The question that this paper poses is whether Australia should follow the Europeans and provide specific legislative assistance to the biotechnology industry. Given the complete absence of any Australian court authority on point, this question is relevant to whether patents which claim isolated and purified genetic material are patentable subject matter within s 18 (1)(a) of the *Patents Act 1990* (Cth). The European solution to this uncertainty was to pass the *European Biotechnology Directive*. However, this paper suggests that the *Directive* may not be consistent with certain *TRIPS* obligations imposed upon member states. This creates a dilemma for Europe and may soon be an issue for the Court of Justice of the European Communities.

II THE EUROPEAN BIOTECHNOLOGY DIRECTIVE

The *European Biotechnology Directive* creates the presumption that biological inventions are patentable subject matter. Recital 18 of the *European Biotechnology Directive* implies that the 1998 patent laws of member countries inadequately dealt with biotechnological inventions. It states that, because

the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the Community and the Member States have a duty to respond adequately to this problem.³

Accordingly, the *Directive* mandates that 'Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive'⁴ so that '[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'.⁵

In response to the adoption of arts 1–11 of the *European Biotechnology Directive* by the United Kingdom ('UK'), the *Patents Act 1977* (UK) was amended in 2000. One amendment, s 76A,⁶ concerns biotechnological

3 *European Biotechnology Directive*, 98/44/EC, recital 18.

4 *European Biotechnology Directive*, 98/44/EC, art 1.1.

5 *European Biotechnology Directive*, 98/44/EC, art 3.2.

6 Section 76A of the *Patents (Amendment) Act 2000* (UK) states:

- (1) An invention shall not be considered unpatentable solely on the ground that it concerns -
 - (a) a product consisting of or containing biological material; or
 - (b) a process by which biological material is produced, processed or used.
- (2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.
- (3) The following are not patentable inventions -
 - (a) 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;

inventions.⁷ Consistent with the *Directive*, s 76A(2) creates the presumption that ‘biological material’⁸ that is ‘isolated from its natural environment or produced by means of a technical process’ is patentable subject matter.

III PATENTABLE SUBJECT MATTER AND NATURAL PHENOMENA

Recently, a panel of 13 judges of the Court of Justice of the European Communities heard *The Netherlands v European Parliament*.⁹ In response to a challenge to the validity of the *Directive*, the Court commented:

The biotechnological industry began to develop seriously after a decision by the US Supreme Court in 1980 that ‘a live, human-made micro-organism is patentable subject matter’ (*Diamond v Chakrabarty* 447 US 303 (1980)). That case concerned an invention of a human-made, genetically engineered bacterium capable of breaking down crude oil. The Supreme Court held (by a 5:4 majority) that the micro-organism constituted a ‘manufacture’ or ‘composition of matter’ within the meaning of the *Patent Act* 1952. (The wording derived unchanged from the first *Patent Act* 1793, authored by Thomas Jefferson.) The court noted that the committee reports accompanying the 1952 Act indicated that Congress intended statutory subject matter to ‘include anything under the sun that is made by man’.¹⁰

However, in this case the United States (‘US’) Supreme Court drew a very important distinction in the context of the human modified bacterium which was the subject of that case, and the conditions in s 101 of the *Patents Act* 35 USC (1952). The Court held that unless human intervention with respect to a natural phenomena, such as a bacterium, resulted in something with ‘markedly different characteristics to any found in nature’, the invention or discovery was not a ‘new and useful composition of matter’ within the meaning of s 101 and was therefore not patentable subject matter.¹¹

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- (b) processes for cloning human beings;
 - (c) processes for modifying the germ line genetic identity of human beings;
 - (d) uses of human embryos for industrial or commercial purposes;
 - (e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
 - (f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.

7 Biotechnological invention is defined to mean ‘an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used’.

8 Biological material is defined to mean ‘any material containing genetic information and capable of reproducing itself or being reproduced in a biological system’.

9 *The Netherlands v European Parliament* [2002] All ER (EC) [97].

10 Ibid [36].

11 *Diamond, Commissioner of Patents v Chakrabarty*, 447 US 303, 310 (1980) (‘*Diamond v Chakrabarty*’). The Court held:

The relevance of the distinction made by the Supreme Court seems to have been lost on the European Commission. In its final report to the European Parliament and the European Council, entitled *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*,¹² the Commission stated:

Article 5(2) of the *Directive* lays down that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, *even if the structure of that element is identical to that of a natural element*. ... The well-known distinction in patent law between a discovery and an invention thus applies fully in the field of biotechnology.¹³

With regard to the last sentence the Commission cited *Diamond v Charkrabarty*¹⁴ as authority. The Commission drew support for its argument by the use of the distinction between invention and discovery, explaining that:

As set out in recital 21 [of the *Directive*], the reasoning is that, to qualify for patentability, an element from the human body, including a sequence or partial sequence of a gene, must, for instance, be the result of technical processes which have identified, purified, characterised and multiplied it outside of the human body. *Such techniques cannot be found in nature*. Taken out of their natural context, elements isolated from the human body cannot be exploited on an industrial basis. They would show only natural properties which man alone, through genetic engineering, is capable of exploiting and inserting into a technical process.¹⁵

While ‘such techniques cannot be found in nature’ the ‘elements isolated from the human body’ are exactly as found in nature or practically so. The Commission’s rationale that the application of standard laboratory methodologies can transform an isolated human gene from a product of nature or ‘discovery’, into a product of man or ‘invention’ within *Diamond v Charkrabarty*, ignores the *ratio decidendi* of that case. In any event, the invention is not constituted by the techniques that ‘cannot be found in nature’. The subject of art 5(2) is not the patentability of these techniques, but the patentability of natural phenomena which, even if ‘taken out of their natural context’, carry the same or practically the same genetic information which they do within their natural context. It is this information – the genetic code for protein production – which remains the same or practically so. It is this genetic code which is valuable and must – because of what it is – remain true to nature.

Here, by contrast, the patentee has produced a new bacterium with *markedly different characteristics from any found in nature* and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under s 101: 310 (emphasis added).

12 Commission of The European Communities, *Development and Implications of Patent law in the Field of Biotechnology and Genetic Engineering*, Final Report, (2002) 545.

13 Ibid 17, [2] (emphasis added).

14 447 US 303 (1980).

15 Commission of The European Communities, above n 12, 17, [4] (emphasis added).

IV THE ISSUES

A The *European Biotechnology Directive* Violates Article 27.1 of *TRIPS*

Article 27.1 provides:

patents shall be available for *any inventions*, whether products or processes, *in all fields of technology*, provided that they are *new, involve an inventive step and are capable of industrial application*.¹⁶

In art 27.1 the word ‘inventions’ differentiates between things that are inventions and things that are not. In other words, the agreement sets up a patentable subject matter threshold. Furthermore, it distinguishes between inventions that are patentable and inventions that are not by requiring that patentable inventions be ‘new, involve an inventive step and be capable of industrial application’.

It follows that an alleged invention is only patentable if it satisfies a two-step test:

- (a) Is the alleged invention ‘an invention’? That is, is it patentable subject matter?
- (b) If yes:
 - (i) Is it new?
 - (ii) Does it involve an inventive step? and
 - (iii) Is it capable of industrial application?

If the answer to (a) is in the negative, it is not patentable subject matter and therefore considerations of (b) conditions are irrelevant.

If the answer to (a) is in the affirmative and the answer to *all* of the questions in (b) are also in the affirmative, then the alleged invention is patentable.

This two-step approach is the law in Australia. In *NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited*¹⁷ (‘*Philips*’) the High Court of Australia held that an alleged invention must first satisfy the definition of invention within s 18(1)(a) before it can be assessed for patentability under s 18(1)(b)–(d).¹⁸

The controversy in this case concerned the word ‘new’ in the definition of ‘invention’ – as in ‘manner of *new* manufacture’ – and whether this word required an assessment of ‘newness’ independently of and preliminary to an assessment of the inventive step condition of patentability in s 18(1)(b)(ii). The majority held that it did. The minority held that it did not. But, even though the minority disagreed about the purpose of the word ‘new’ in the definition of invention, they acknowledged that s 18(1)(a), being a condition of patentability that defined patentable subject matter to mean ‘a manner of manufacture’, was a relevant condition which was preliminary to the conditions of novelty and inventive step in s 18(1)(b). The minority’s objection was to the characterisation of the conditions in s 18(1)(b) to the word ‘new’ in the definition of ‘invention’. In the minority’s opinion, the definition of ‘invention’ went merely to patentable

16 *TRIPS*, art 27.1 (emphasis added).

17 (1995) 183 CLR 655.

18 *Ibid* 663, lines 3–12, 17, 26–33.

subject matter in s 18(1)(a) and the conditions of novelty and inventive step in s 18(1)(b) were exhaustive with respect to the word 'new'. The minority explained:

The result is that a patentable invention is a manner of manufacture which is, amongst other things, new in the sense that, when compared to the prior art base, it is novel and involves an inventive step. There is no additional requirement that it be new in some other sense, for that would defeat one of the purposes of the section.¹⁹

Accordingly, Australian patent law has in place a system of patentability which has both a threshold condition going to patentable subject matter or 'invention' (s 18(1)(a)) and subordinate conditions that go to patentability of the 'invention' (s 18(1)(b)–(d)).

Although the decision in *Philips* has been the subject of some critical discussion,²⁰ it remains the leading authority on this issue some eight years later and Federal Parliament has not seen fit to amend either the definition of 'invention' or s 18(1)(a) of the *Patents Act 1990* (Cth). Moreover, in its final report to the Commonwealth Attorney-General and Minister for Industry, Science and Resources in September 2000,²¹ the Intellectual Property and Competition Review Committee reported that it 'believe[s] that Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the "manner of manufacture" test' and recommended 'that this test be retained'.²²

This same test that applies in Australia with respect to s 18(1) of the *Patents Act 1990* (Cth)²³ also applies in the US with respect to ss 101, 102 and 103 of the *Patents Act 35 USC* (1952).²⁴

Under the US *Patents Act*, the word 'invention' is defined by s 100 to mean 'invention or discovery'. However, s 101 is expressed in terms of what a person can do in order to meet the 'invention' condition, namely to 'invent or discover ... a new and useful process, machine, manufacture or composition of matter'. The differences between s 101 of the *Patents Act 35 USC* (1952) and s 18(1)(a) *Patents Act 1990* (Cth) revolve around the use of the words (a) 'discovery' and (b) 'useful'.

19 Ibid 670, lines 35–40.

20 Miranda Duigan and Michael Dowling, 'Threshold Test of Manner of Manufacture in Australia – What Next?' (1998) 105 *Patent World* 26; Mary Padbury, 'Inventiveness Apart From Novelty and Inventive Step – The High Court Decisions of Manner of Manufacture in *Philips and Ramset*', (1998) 9 *Australian Intellectual Property Journal* 161.

21 Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000).

22 Ibid 16.

23 *Philips* (1995) 183 CLR 655, [8]–[9]:

The primary focus of inquiry should, as we have indicated, be upon the opening words ('a patentable invention is an invention that') of that sub-section which impose a threshold requirement which must be satisfied before one reaches that contained in the body of para (a). The effect of those opening words of s 18(1) is that the primary or threshold requirement of a 'patentable invention' is that it be an 'invention'.

24 35 USC s 101 (patentable subject matter); 102 (novelty); 103 (obviousness). See introductory section in Donald L Zuhn, Jr, 'DNA Patentability: Shutting The Door To The Utility Requirement' (2001) 34 *John Marshall Law Review* 973 for an explanation of the test applied by United States' Courts.

The *Patents Act 1990* (Cth) defines ‘invention’ to mean ‘any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*, and includes an alleged invention’.²⁵

In addition, it defines ‘exploit’ – which is a reference to the exclusive right granted to a patentee – by reference to the word ‘invention’:

exploit, in relation to an invention, includes:

(a) where the invention is a product – make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or

(b) where the invention is a method or process – use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.²⁶

Although not exhaustive, the word ‘exploit’ specifically refers to three indicia of invention, namely ‘a product’, ‘a process’ and ‘a method’. This association between ‘invention’ and ‘exploit’ is made by the words ‘in relation to an invention’ and in (b) ‘where an invention is’. This type of association is also made in art 27.1 of *TRIPS* by the words ‘any inventions whether products or process’.²⁷

Section 6 of the *Statute of Monopolies*²⁸ does not refer to the discoverer of ‘any manner of new manufactures’ in the model of the *Patents Act 1990* (Cth). Nor does it refer specifically to the utility of such manufactures, although it has been suggested that the concept of utility is captured by the words ‘manner of ... manufacture’.²⁹

At first glance it appears as if there is a significant difference between Australian and US patent law concerning the condition of patentable subject matter. However, the proviso in s 101 of the *Patents Act 35 USC* (1952) requiring a ‘new and useful process, machine, manufacture or composition of matter’, has the effect of restricting the ambit of discoveries to a specific form. This restriction renders s 101 of the *Patents Act 35 USC* (1952) consistent with

25 *Patents Act 1990* (Cth) sch 1.

26 *Patents Act 1990* (Cth) sch 1.

27 *TRIPS*, art 27.1.

28 Section 6 of the *Statute of Monopolies 1623* (Imp) 21 Jac I, c 3 provides:

That any Declaration before-mentioned shall not extend to any Letters Patents and Grants of Privilege for the Term of Fourteen Years or under, hereafter to be made, of the sole Working or Making of any Manner of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the Time of Making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient: The said Fourteen Years to be accounted from the Date of the first Letters Patents, or Grant of such Privilege hereafter to be made, but that the same shall be of such Force as they should be, if this Act had never been made, and of none other.

29 ‘The industrial capability requirement arises from the reference to s 6 of the *Statute of Monopolies* and the words “manner of ... manufacture”’: Industrial Property Advisory Committee, Parliament of Australia, *Patents, Innovation and Competition in Australia*, Report to the Minister for Science and Technology (1984) 40.

s 18(1)(a) *Patents Act 1990* (Cth), because the word ‘discovery’ means no more than an activity accepted by the courts in Australia and the UK as coming within the definition of ‘invention’ in the context of both the Australian Patents Acts of 1903, 1952 and 1990, and the *Patents Act 1977* (UK). The specific exclusion of discoveries in s 1(2)(a) of the latter Act has been interpreted as meaning ‘pure discoveries’ by Whitford J in *Genentech Inc’s Patent*: ‘[i]t is trite law that you cannot patent a discovery, but if on the basis of that discovery you can tell people how it can be usefully employed, then a patentable invention may result’.³⁰

The problems with the distinction between invention and discovery for establishing an effective and simple criterion for patentable subject matter has been long recognised by the courts in Australia and the UK. This point was made in 1959 by the High Court in *National Research Development Corporation v Commissioner of Patents*³¹ when it stated:

The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. There may indeed be a discovery without invention – either because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of ‘manufacture’. But where a person finds out that a useful result may be produced by doing something which has not been done by that procedure before, his claim for a patent is not validly answered by telling him that although there was ingenuity in his discovery that the materials used in the process would produce the useful result no ingenuity was involved in showing how the discovery, once it had been made, might be applied. The fallacy lies in dividing up the process that he puts forward as his invention. It is the whole process that must be considered; and he need not show more than one inventive step in the advance which he has made beyond the prior limits of the relevant art.³²

Accordingly, the definition of invention in the context in which it appears in art 27.1 of *TRIPS*, art 52 *European Patent Convention*, s 1(1) of the *Patents Act 1977* (UK) and the Dictionary in sch 1 of the *Patents Act 1990* (Cth), does not mean that all discoveries cannot be inventions. It means that discovery and invention are not mutually exclusive. In certain circumstances even discoveries can be inventions and s 101 of the *Patents Act 35 USC* (1952) simply provides a codified formula.

What this analysis suggests is that the schemes of patentability in Australia, Europe, the UK and the US as mandated by art 27.1 of *TRIPS* have a patentable subject matter threshold that must be satisfied as part of the assessment of patentability. Whilst the distinction between discovery and invention as mutually exclusive concepts is not helpful to the analysis of patentable subject matter, this does not mean that the word ‘invention’ is meaningless so that anything can be patentable if it satisfies the conditions of novelty, inventive step and industrial application. One thing is clear: not everything under the sun is patentable subject matter.

30 *Genentech Inc’s Patent* [1987] RPC 553, 566 (Whitford J); See also *Gale’s Application* [1991] RPC 305.

31 (1959) 102 CLR 252.

32 *Ibid* 264.

*Diamond v Chakrabarty*³³ is clear and convincing authority that natural phenomena such as viruses and genes, and their component proteins, can never meet the patentable subject matter threshold – not because the identification of such natural phenomena are pure discoveries, but because even if ‘isolated and purified’, they remain products of nature. They do not have markedly different characteristics from any found in nature.

The *Directive*, however, mandates that the patent laws of member countries presume that ‘biological material’ be an ‘invention’. It therefore elevates biotechnological inventions above the status of other types of technology. Compliance with the *Directive* requires member countries to change their pre-1998 patent laws so that ‘biotechnological inventions’ are not required to be scrutinised for compliance with question (a). The only relevant considerations for patentability of such applications are that they comply with the patentability conditions considered by the questions in (b).

Article 27.1 of *TRIPS* does not allow special treatment to be afforded to specific technologies. It requires that member states enact laws that require only ‘inventions’ to be considered for patentability equally and consistently across ‘all fields of technology’. By distinguishing ‘biotechnological inventions’ so that ‘biological material’ is presumed to be an ‘invention’, the requirement upon member states to amend their patent laws in accordance with the *Directive* constitutes a direct violation of art 27.1 of *TRIPS*.

B Research Incentives and the *European Biotechnology Directive*

The rationale underpinning the *Directive* is that:

the patent system provides insufficient incentive for encouraging research into the production of biotechnological medicines which are needed to combat rare or ‘orphan’ diseases, [and] the Community and the Member States have a duty to respond adequately to this problem.³⁴

However, such reasoning employs questionable logic. One needs to look no further than the US to see that even in the absence of such a presumption under US patent law, the biotechnology industry has continued to grow. In fact, so much so that US biotechnology companies are now acquiring ownership or control of biotechnology companies in Europe.³⁵

Moreover, even with this legislative presumption in place since 1998, investment in the biotechnology industry sector in Europe has been in decline. The causes of this decline have been the subject of a recent European Commission Report entitled, *Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee Life Sciences and Biotechnology – A Strategy for Europe Progress*

33 447 US 303 (1980).

34 Recital 18 of the *European Biotechnology Directive*, 98/44/EC.

35 For example, in April 2003, Chiron Corporation, a US biotechnology company, announced its takeover of PowderJect Pharmaceuticals, a European biotechnology company. See also Andrew Scott, ‘Tough Times for European Biotech’ (2003) 17(15) *The Scientist* 52.

*Report and Future Orientations*³⁶ ('*Report*'). Released in March 2003, the *Report* stated that:

European biotechnology lags behind the US in terms of patents and collaborative R&D projects and this principal competitor of ours has a dominant lead in innovative activities, while a rapid decline in GMO field research has been reported in the EU over the last four years. This raises the risk of failing to meet the objective of the *Lisbon* process in the area of life sciences and biotechnology. Decisive action is now needed in a number of areas identified in this report.³⁷

The European Commission identified that one of the causes of this lag was that investment in research and development in biotechnology in Europe was significantly less than in the US. It estimated the gap to be €124 billion³⁸ and reported that since 1994 the gap has doubled. Other causes included the lack of a coordinated approach to research and development between member states, the fragmentation of the pharmaceutical and biotechnology markets within Europe, an insufficient level of risk capital available to biotechnology, and the lack of a unitary European patent system. Finally, the *Report* suggested that failure to transpose the *Directive* into law by all member states is 'hampering the development of biotechnology in Europe in comparison to our competitors'.³⁹ However, the *Report* provides no evidence to support this assertion.

The *Report* confirms that if the European biotechnology industry is to be internationally competitive it must address a number of issues, not merely the patentability of biological materials. The problems facing the biotechnology industry discussed in the *Report* relate more to the fragmented political and economic policies between member states than to specific issues regarding biotechnological inventions. Arguably though, the very reason why the US is better able to compete than Europe is because, unlike Europe, it has had a single unified political, legal and economic system in place for more than two hundred years.

C The Validity of the *European Biotechnology Directive*

The validity of the *Directive* is open to challenge in the Court of Justice of the European Communities. In the case of *The Netherlands v European Parliament*⁴⁰ such a challenge was made. This challenge was not, however, based upon the *Directive*'s conflict with art 27.1 of *TRIPS*. It was argued that the *Directive* was removing the rights of member states to exclude from patentability 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes' as provided by art 27(3)(b) of *TRIPS*. The point at issue, then, was that the *Directive* was inconsistent with art 27(3)(b) of *TRIPS*.

36 European Commission, *Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee Life Sciences and Biotechnology – A Strategy for Europe Progress Report and Future Orientations* (2003) 96.

37 *Ibid* 3.

38 *Ibid* 9.

39 *Ibid* 15.

40 (Case C-377/98) [2002] All ER (EC) [97].

The Court, however, held that in narrowing the scope of excludable patentable subject matter, the *European Biotechnology Directive* was not inconsistent with *TRIPS* because the European Community was merely exercising an option provided by art 27 (3)(b) of *TRIPS*, and not therefore acting contrary to an obligation imposed.

However, as art 27.1 of *TRIPS* does impose a specific obligation, it follows that the Court's conclusion that 'the Community legislative framework itself is not illegal'⁴¹ is questionable.

V CONCLUSION

Whether isolated genetic materials should be considered inventions within the meaning of the word as defined in the *Patents Act 1990* (Cth), or within the meaning of the word in art 27.1 of *TRIPS* is debateable. This paper argues that they should not. If Australia were to adopt a *Directive*-style solution to this debate, this paper suggests that it could well contravene Australia's international obligations. Importantly though, it would provide biotechnology with a significant advantage over all other technologies. This is not desirable. The patentability conditions must be applied equally. Fundamentally, this issue brings into question the appropriateness of the patent system as a vehicle of intellectual property protection for isolated genetic materials.

Professor Eisenberg from the University of Michigan has argued that the patent system was created for 'a bricks and mortar world'. The system has inherent and logical limitations when transposed into the seemingly unlimited expansion of patentable subject matter. She suggests that:

At some point, we may need intellectual property rights that permit the creators of information products to capture the value of the information itself in order to motivate socially valuable investments. But if we have arrived at that point, then we need to look beyond the patent system for a suitable model.⁴²

This paper suggests that this point was reached sometime ago and that the *Biotechnology Directive* patch to the biotechnology hole in the patent system is not the solution.

41 Ibid [229].

42 Rebecca S Eisenberg, 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49(3) *Emory Law Journal* 783.