SHOULD AUSTRALIAN INTELLECTUAL PROPERTY LAW PROTECT 'THE WAY THINGS WORK' OTHER THAN THROUGH STANDARD PATENTS?

Paper for the 1995 IPSA conference by Katrina Howard

INTRODUCTION

When I was invited to speak on this topic, my first reaction was to ask myself – "Do patents adequately protect the way things work?". It seems to me that it is only if they do not, that other protection – such as designs – is needed. After some reflection, I still thought that it was sensible to approach the debate as to whether designs should protect "the ways things work", by looking at the protection offered by patents, to see whether there was a gap which designs or some other protection needed to fill.

I was convinced that I should follow this course when I discovered that one of my co-speakers was a Commissioner reviewing the law of designs in Australia. The Australian Law Reform Commissioner Discussion Paper[1] released in August last year is full of proposals for reform, and I understand that these proposals are undergoing reforms themselves. So I am leaving this side of the debate to Professor Lahore.

WHAT IS A 'PATENTABLE INVENTION'?

The logical starting point is to look at what is a patentable invention[2].

"Invention" is a threshold question[3]. It has to be passed before other questions such as novelty and inventive step become significant[4]. The concept of "invention" may be

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[1] Discussion Paper 58 published August 1994.
[2] s. 18(1) Patents Act 1990.
[3] This requirement arises from the opening words of s. 18(1) Patents Act 1990.
[4] s. 18(1)(b)(c) & (d) Patents Act 1990.

broader than "manner of manufacture"[5]. Everyone here would be familiar with this term, and the handful of decisions which have considered it[6]. The question in each case is – is the alleged invention the proper subject of letters patent?[7]

The boundaries of inherent patentability are not defined. The Australian parliament has excluded only one category – "human beings, and the biological processes for their generation"[8]. This seems to be directed to in vitro fertilisation, although its scope may be wider. For example, does the exclusion of "human beings" include the human body, or parts of the body? If it does, does that mean legs and arms can be patented? And if it does, does it extend to internal parts of the body, which range from whole organs to genes and proteins?

By contract, the UK Patents Act makes seven specific categories of exclusions[9].

So, in Australia, it is up to our courts to give guidelines as to what is and what is not patentable.

As new technologies have emerged, the courts are being challenged on new fronts. Recently, Australian courts faced with difficult problems have come down on the side of patentability. The Full Federal Court has held that a method of medical treatment of a

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[5] In order for an "invention" to be a "patentable invention" it must be a "manner of manufacture within the meaning of section 6 of the Statute of Monopolies"; s. 18(1)(a) Patents Act 1990; s. 35(1)(a) Patents Act 1952.

[6] National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252; Commissioner of Patents v Microcell Ltd (1959) 102 CLR 232; N.V. Phillips Gloeilampenfabrieken v Mirabella International Pty Ltd (1993) 26 IPR 213; CCOM Pty Ltd v Jeijing Pty Ltd (1994) 28 IPR 481; Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) 28 IPR 383.

[7] NRDC case (supra) at page 269.

[8] s. 18(2) Patents Act 1990.

[9] The list of exceptions is contained in ss 1(2), 1(3) and 4(2) Patents Act, 1977 (UK):

1. A method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body.
2. A discovery, scientific theory or mathematical method.
3. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever.
4. A scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer.
5. The presentation of information.
6. Any invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour.
7. Any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such a process.

human being was patentable[10], and that a form of computer processing was patentable[11].

THE ISSUE OF PATENTABILITY OF GENES

What I want to talk about today, is whether genes (and gene products, such as proteins) are patentable. This has not been addressed by legislation in Australia[12]. Nor has it been addressed by the courts – yet! The patentability of genes has been raised in proceedings underway in the Federal Court[13], where an application has been made to revoke a patent concerning the hepatitis C virus. This will be the first biotechnology case to come before an Australian court. And the outcome will be very important to the biotechnology industry.

Patenting genes is also a very live topic overseas. The issue is before the Courts in the United Kingdom[14], and the European parliament has recently debated the matter. However, with the exception of France (where human genes cannot now be patented)[15], no country has introduced legislation.

In the United States, the courts have upheld the validity of patents for genes[16]. But there is now great controversy as ownership of genes is seen as part of the "Right to Life" debate. A religious alliance of more than 80 groups is demanding an immediate moratorium on patents for genes and genetically altered life-forms until American Congress can debate the matter, and draw up legislation to specifically designate where the right to grant a patent stops.[17]

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[10] Anaesthetic Supplies v Rescare (supra).
[11] Ccom v Jeijing (supra).
[12] cf. s. 18(2) Patents Act 1990.
[13] Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Anor Proceedings No. G106 of 1994.
[14] Chiron Corp v Murex Diagnostics Ltd; Chiron Corp v Organon Teknika Ltd and Anor (1994) FSR 202, on appeal to the Court of Appeal; Biogen Inc v Medeva PLC (1995) FSR 4, on appeal to the House of Lords.
[15] The question of patentability of genes particularly affects France because of the work done there on mapping the human genome. L. 116,17 of the Intellectual Property Code was introduced to deal with this question on July 20, 1994. Under the new law "the human body, its parts and products and the knowledge of the partial or complete structure of a human gene may not, as such, be patented".
[16] See, for example, In re Bell 26 USPQ 2d. But note that the decision was made on the basis that the gene sequences in question were not obvious.
[17] 2 BL, A.M. 19/5/95, Peter Cave, Washington correspondent.

WHAT ARE GENES?

Before I go on, I shall give you a lesson in very basic genetics – I assure you that it is going to be very short!

Genes contain all of the information that controls the development and function of any organism, from bacteria and viruses, to human beings. As well as programming cells, genes copy themselves so that the programme can be passed on from generation to generation. This is the secret of life – how the characteristics of parents can be passed on to their children.

Genes are made of DNA[18]. Along the DNA is a sequence of chemicals[19]. The sequence is a code (the genetic code) – like letters in the alphabet – which is read by machinery in the cell. The reading takes place in two steps. A working copy of the region to be copied is made[20]. Then, the copy is translated into proteins[21]. Proteins therefore have a sequence of chemicals (amino acids) which correspond to the DNA sequence from which they are read. A region of DNA coding for one protein, is called a gene.

THE PRACTICAL PROBLEMS WITH PROTECTION FOR GENES

Millions of dollars are invested every year to identify the sequences of genes and proteins. If competitors were free to use those sequences, it is plain large sums of money would not continue to be invested.

Industry has looked to patents for protection. There are many different genes (and proteins) for which patent protection has been sought or would be wanted. These include:

1. genomes of bacteria or viruses, so that they can be detected and vaccines can be developed;

[18] Deoxyribonucleic acid.
[19] There are four chemicals – the bases called A (adenine), C (cytosine), G (guanine) and T (thymine).
[20] RNA (ribonucleic acid) – this is almost identical to the DNA but with U (uracil) substituted for T. This process is called "transcription".
[21] Polypeptides of varying length.

2. genes coding for valuable proteins such as insulin, interferon or growth hormones, for use in treatment, and

3. genes of plants, animals and yeasts, with a view to modifying those genes to cure defects or give advantages.

Indeed, there are many such patents granted or in the pipeline at the Australian Patent Office.

ARE SEQUENCES FOR GENES REGISTRABLE AS DESIGNS?

At this stage, some of you are probably asking yourselves – what have genes got to do with whether the Designs Act should protect functional designs?

It sounds ridiculous to suggest that the sequence of a gene or protein could in some way be registered as a design[22]. But is it? At first glance, a protein made by recombinant DNA technology would seem to be an "article of manufacture"[23]. And the case would be even stronger where the sequence had been manipulated. Genes and proteins do have features of shape and configuration. They are, to a large extent, dictated by the coding sequence[24]. Such features, however, are practically invisible and could not be "judged by the eye"[25]. But, could the coding sequence itself be considered a feature of configuration applicable to the gene or protein – in other words, the arrangement whereby the shape of the article is arrived at[26]? I raise this only as a matter of interest. There are other difficulties, such as whether the coding sequence would be excluded as a method or principle of construction[27], or because it is dictated solely by function[28].

I believe that if we are looking at the gap between patents and designs, we should include things which the current patent system does not cope with well. And if sequences for

[22] The possibility that a sequence of DNA or an amino acid sequence may be protected by design right in the IJK is discussed in "The Modern Law of Copyright and Designs" second edn, Vol 1 by Laddie H., Prescott P. and Vitoria M., Chapter 21, at pages 867-8.
[23] s. 4(1) Designs Act 1906. But note that if the sequence merely corresponds to that of the natural product, the gene or protein is unlikely to be an "article of manufacture".
[24] They are not dictated solely by the sequence, because the shape and configuration of the molecule will also be determined by what surrounds it.
[25] s. 4(1) Designs Act 1906.
[26] See Gramophone Company Ltd v Magazine Holder Co (1911) 28 RPC 221.
[27] s. 4(1) Designs Act 1906.
[28] s. 18(1) Designs Act 1906.

genes and proteins are beyond the limits of patentability, then there ought to be some other form of protection.

THE LEGAL PROBLEMS WITH PATENTS FOR GENES (AND PROTEINS)

The problems in patenting genes – public policy questions aside – are complex legal ones.

Briefly, identifying a sequence of DNA can take much time and tremendous effort. And many obstacles may need to be overcome. A different set of steps may be required for every sequence. But, in many cases, the techniques are not new, and the nuances in a particular combination of steps will not involve an inventive step.

This problem has been recognised by the Court of Appeal in the UK. In Biogen v Medeva, a case which concerned the identification of the sequence of the hepatitis B virus[29], Hobhouse LJ said:

> The problem for the Plaintiffs in drafting their claim was that they knew that they could not make any claim to a process. They had not, on any view, claimed any process. But they could not do this and had simply to claim the invention of products independently of the process by which they are produced.

Even if the method for identifying a sequence does not involve an inventive step (and all the other requirements for patentability are satisfied), this would, at best, justify a patent for the method. But once the sequence is obtained, the method is almost always redundant. And, a patent for the method will be of no use.

Whether or not the method itself was inventive, to determine whether there is a patentable invention, the questions which need to be asked are: Was the product of that method inventive? Or is the application of the product of that method inventive?

Was the product of the method inventive?

The product of the method is a sequence of DNA (or protein). This sequence is something which already exists in nature. On one view, the identification of a sequence of DNA

[29] Biogen v Medeva, supra at p. 137. See also Genentech's patent (1989) RPC 147, at p. 227 per Purchas LJ, and at p. 262, 274-5 per Mustill J. this was the first genetic engineering case to come before the UK courts.

(without anything further, such as genetic manipulation) is merely a discovery. It is therefore not patentable, because discoveries alone are not inventions[30].

Is the application of the product of that method inventive?

The types of claims in patents for genes include applications of the sequence in: recombinant DNA molecules (ie recombined DNA molecules containing an insert of DNA), purified or isolated molecules, vectors for expressing the protein of interest, methods for producing the protein using recombinant DNA techniques, the protein encoded by the specific DNA sequence, diagnostic kits, vaccines, pharmaceutical compositions and other forms of treatment. These applications are generally obvious and do not involve an inventive step.

In Genentech's patent[31], the three Lord Justices each took a different view as to whether claims of this type were to a patentable invention[32].

In Biogen v Medeva[33], the Court of Appeal wanted to hear submissions as to whether claims in the form "a recombinant DNA molecule having certain characteristics", were to inventions at all, but a decision was made not to argue the point[34].

The Court also asked: "if the methods used by the inventor are all within the common general knowledge of those skilled in the art and there is nothing novel about the selection or combination of the methods used, what is inventive about the invention? If there was a discovery, was there something more involved which was patentable?"[35]

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[30] See, for example, Lane-Fox v Kensington & Knightsbridge Electric Lighting Co (Ltd) (1892) 9 RPC 413 at 416, per Lindley J.

[31] Genentech's patent, supra.

[32] Note that discoveries are specifically excluded by s. 72(1)(a) Patents Act 1977 and the decision involved the construction of that section. Mustill LJ thought that the merit of the discovery per se ought to be left out of account in assessing the obviousness of the invention. To secure a patent the discoverer must take a further, non-obvious step by way of turning it to practical account. Dillon LJ disagreed, citing the example of making a new chemical compound and discovering it has therapeutic value. This may not be a good analogy because the inventive step may reside in selecting the chemical compound for testing. Purchas LJ adopted an intermediate course. He agreed that a patent ought not to be impeached merely because the invention was preceded by a discovery where making the discovery was the only remarkable part of the transaction. But he held that a broad and speculative claim which sought to monopolise future discoveries should be regarded as an attempt to monopolise the use of the discovery as such.

[33] Biogen v Medeva, supra.

[34] Mr Peter Prescott, QC, pers comm.

[35] Biogen v Medeva, supra, pages 26-27.

The Court stated that: "Many of these questions are similar to those raised by the patent in the Genentech case and are fundamental to the validity of claims to patents of this type in this field". They noted that counsel for the Defendants questioned whether the claims were directed to any invention at all, however "he appeared to concede in argument, as a matter of law, he could not succeed on that ground before us". The Court stated that it felt "some difficulty about the concession" and emphasised that in view of the concession, its decision did not rest upon their Lordship's views as to whether there was an invention[36].

This judgement strongly suggests that claims to genes and gene products are open to challenge on the ground that they do not claim an invention at all.[37]

POLICY QUESTIONS

Apart from the legal issues, there may be public policy grounds for excluding genes from patent protection. There are avenues for the Court to take account of public policy in determining whether there should be patents for genes (and gene products)[38]. But I do not wish to enter the moral debate[39].

THE NEED FOR REFORM

It is my view that there needs to be some sort of legislative reform to make sure that there are rights given to those who are first to identify the sequence of a gene or protein.

In this area, the lawyers have not kept up with the scientists. The problems in patenting genes (and gene products) have been recognised since at least 1989[40], when Mustill LJ, in Genentech's patent, flew a flag for the legislature. He said[41]:

[36] Biogen v Medeva, supra, page 27.
[37] Leave has been granted to appeal to the House of Lords, where this issue may well be explored.
[38] Policy considerations could be taken into account either (a) in determining the threshold question of "invention"; or (b) in determining whether patents for genes were "generally inconvenient" within the meaning of section 6 of the Statute of Monopolies.
[39] See Genentech's patent, supra, per Mustill LJ at pages 259, 261 and 287.
[40] Genentech's patent, supra.
[41] Genentech's patent, supra, at pages 259-260. See also page 274.

> It may be that the explosively new technology with which we are concerned has exposed some deep flaws even in the current regime: but if this is so, any necessary repairs must be affected by the legislature, not by the courts.

In Europe, legislative reforms have been contemplated. But on March 1st this year, the European parliament (after seven years of discussion) rejected a directive that would have granted legal protection to patents on human genes, proteins and cells[42]. Many such patents have already been granted[43]. And companies will still be able to apply for patents for genes and gene products through the individual patent offices of member countries. But the lack of the Directive means that their patents could vary a lot from country to country.

A SOLUTION?

What then, is the solution? Because of the problems with "invention" and "inventive step", petty patents (as well as standard patents) are not the way to go. Nor do designs seem appropriate – even if they did apply to purely functional designs.

The possibility of copyright in sequences has been canvassed in the UK[44]. But even if a sequence were an "original literary work"[45], the major drawback seems to be the term of protection. Another problem is the reciprocal copyright laws in other countries.

One solution would be to create a new limited form of right, like the separate protection given to plant varieties[46], that I will call a "Sequencing Right"[47]. This would give protection to those who are first to sequence DNA or a protein.

It could be similar to copyright protection. So, for example, it should not prevent others from using the same (or closely similar) sequence where they have independently identified the sequence.

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[42] Amended Proposal for a Council Directive on the legal protection of biotechnological inventions, 16 December 1992. The limitation is that they must not have been obtained in such a way that they could be linked to a specific individual. The directive would also have allowed patents on "transgenic" animals and on plants.
[43] Directive, ibid, page 7.
[44] See "The Modern Law of Copyright and Designs", supra, Chapter 21, especially page 869.
[45] s. 32 Copyright Act, 1968. Note that it might be objected that the sequence cannot be original because it is copied from nature. This would not apply to manipulated sequences.
[46] Plant Breeder's Rights Act 1994.
[47] A term coined by David Catterns QC.

Of course, many questions would need to be answered. Such as:

1. What if you only sequence part of a gene or protein?

2. Would protection extend to the same gene in other species?

3. How far could the sequence be varied, and still be protected?

4. What would constitute infringement? For a start, it would have to cover DNA to protein and vice versa. But how much of the sequence would have to be copied? It may only be a very small portion because a long sequence can be obtained by using a short sequence as a “probe”.

The most important question is whether such legislation would be retrospective? What is going to happen to all of the patents which have been granted or applied for in Australia?

Reform needs to be looked at soon. Because what will happen to all of the patents for genes and proteins (and the industry itself) if, in the near future, they are found by the courts not able to be patented?

No doubt the introduction of special protection for genes and proteins would spark a big ethical and moral debate. But