

PATENTING NEW LIFE FORMS: A DILEMMA IN BIOETHICS AND THE LAW

by

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Introduction

Two years ago Justice Michael Kirby wrote:

The dynamic forces of science and technology affect the definition of human rights. It could scarcely be otherwise in the last years of the twentieth century. Our time has seen many remarkable scientific and technological developments. They profoundly affect the individual, the social environment, the relationships of nation states and the planet. They reach out into space. The dreams of scientists of yesterday become the fascinating achievements of today and the prospects of tomorrow.¹

In this article the authors wish to consider an important and increasingly controversial legal aspect of one of the 'dynamic forces' of science and technology in the 1980's: genetic engineering. Two questions will be addressed in the ensuing pages: is it presently possible to patent the results of genetic engineering research on living organisms and is that position in law one which should be retained or altered in some way or other? It will be seen that the second question requires consideration not just of legal issues but of economic, moral and political issues as well.

The term 'living organisms' is a broad one, and encompasses all life forms from the single cell amoeba through to human beings, including bacteria, plants and all forms of animal and bird life. In the case of plants, the Plant Variety Rights Act 1987 (Cth) has introduced a system of registration of certain new plant varieties, granting certain exclusive rights to the registrant² but which rights are not as comprehensive as those rights provided for subject matter under the Patents Act 1952 (Cth). It is not therefore proposed in this article to deal with patentability of plants. A distinction will be made however, in the context of public policy considerations rather than as a matter of strict law, between 'lower' and 'higher' life forms. In the former category are placed bacteria and other micro organisms. In the latter category are placed all life forms which appear to be capable of thought including all animals and of course humans: this distinction is one by no means clearly defined but will serve well enough for present purposes.

A point of distinction is also made between the possibility of obtaining a patent for a process which leads to the creation of a living organism, and the possibility of patenting the living organism itself. The Patents Act 1952 refers to patents being granted in respect of

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1. The Hon. Mr Justice M.D. Kirby, *Human Rights - The Challenge of the New Technology*, (1986) 60 A.L.J. 170.
2. See sections 12, 13, 14.

'inventions', and this term is defined in s.6 as meaning 'any manner of new manufacture ...' In *Adhesives Pty Ltd v. Aktieselskabet Dansk Gaeringsindustria*³ the question was whether an improved process for manufacturing yeast could be the subject of a grant of patent. Evatt J. at first instance held that a patent for the process could be validly granted as it invoked a new principle which was embodied in a new method of manufacture which was an advance on previous knowledge and possessed great utility. His Honour rejected objections based on the specification for the process which are not relevant here. The decision of Evatt J. was affirmed by the Full High Court.⁴ In *American Cyanamid Co. v. Berk Pharmaceuticals Ltd*⁵ the action was for infringement of a patent for a method of producing the antibiotic tetracycline. The patent was for a process of production of the antibiotic different from existing procedures in that it evolved pure tetracycline rather than a contaminated version. Although the action for infringement was ultimately dismissed, Whitford J. held that the subject matter of the patent was an invention in terms of the Patents Act 1949 (UK). The difficulties experienced by the patentee concerned the specification and related matters rather than the substantial nature of the process as an invention. From these two cases it will be apparent that processes for creating living organisms are themselves patentable as inventions, subject to further compliance with the technical requirements of the Patents Act. It is with patentability of the living organisms themselves as the product of a process that the rest of this article is concerned. As there is no judicial authority and no statutory prescription on the matter in Australia, it will be necessary to turn to other jurisdictions for guidance. Before doing so however it may be useful to set out some background material.

2. Background

The ever increasing skills of genetic engineers have led us to a point in evolution where the ordered world of Charles Darwin is in grave danger of becoming the Brave New World of Aldous Huxley. Australian and United States scientists lead the world in biotechnology, and geneticists who only a decade ago were still trying to master the alteration of simple organisms like bacteria through recombinant DNA are now engaged in altering the gene sequences of animals. Already, genes have been successfully implanted across animal species in experiments such as that conducted at the University of Ohio Animal Biotechnology Center to produce a giant mouse through insertion of rabbit genes and even human growth hormones. The mating of lion and tiger genes to produce 'ligers' and of zebra and donkey genes to produce 'zonkeys' by means of artificial techniques are experiments which are now well known. The next step of course is manipulation of the human gene pool itself and indeed work has already begun.

Later this year a proposal will be considered by the United States Congress biomedical ethics board to transfer into the blood cells of a child with an inherited genetic disorder a human gene capable of reversing the disorder. Such an experiment would be fundamentally different from the research work into alteration of animal genes because in this case the human patient would not be able to transmit the new gene to the next generation. Nonetheless, the difficulty with the experiment is that once the gene has been inserted into the patient there is no way it can be retrieved, whatever may go wrong. In any case, the borderline between correcting human genetic defects in a non-evolutionary way and total intervention in the human evolutionary cycle is one which scientists are expected to cross within the next decade notwithstanding apparently formidable technical problems - unless

3. (1936) 55 C.L.R. 523.

4. (1936) 55 C.L.R. 565.

5. [1976] R.P.C. 231.

they are legally prevented from doing so. Already there have been allegations from Professor Brunetto Chiarelli of the University of Florence that research has been conducted in the United States into producing hybrid humans by artificially matching female chimpanzee ova with human semen. According to Professor Chiarelli, such creatures could one day be used to provide transplant organs to human patients.

At the recent Royal Melbourne Institute of Technology centenary conference on future directions in technology, education and society⁶ Professor Carl Wood of the University of Melbourne called for a 'searching debate' on the ethics of genetic engineering, saying that scientists now stood on the threshold of discovering means to alter basic human traits such as intelligence and dependence on food. According to Professor Wood it is an 'awesome responsibility to want to change your own species' and he would be against doing so because there is not yet enough evidence that we would know the effects of what we might do. In the distant future however, Professor Wood said human genetics might be altered to allow the race to survive environmental changes produced by pollution. For example, new genes might be inserted to create the ability to survive an overheated world caused by destruction of the ozone layer or a toxic environment caused by burning of fossil fuels or even chemical disasters.

It is against this background of the realities and portents of biotechnology and genetic engineering that the authors now turn to the legal question of patents being issued for the products of such research. As previously stated, the position in the United Kingdom and the United States will be considered first.

3. Overseas Law On Patenting Living Organisms

In the United Kingdom s.1(3) of the Patents Act 1977 specifically prohibits the grant of patents with respect to animals or plants, as well as with respect to 'any essentially biological process for the production of animals or plants'. The provision however states that microbiological processes and the products of such processes are excluded from the Act. Presumably therefore these matters fall to be determined upon the usual criteria for the granting of a patent under the Act. With specific reference to plants the United Kingdom has the Plant Varieties and Seeds Act 1964, which protects new plant varieties but under a scheme outside the area of patents. The object of this Act, given effect in s.4, is to grant to the 'breeder' of any new variety of plant the exclusive right to sell the reproductive material subject to a scheme of compulsory licences.

In the United States of America the patents statute, 35 USCS 101, contains no specific prohibition against the patentability of living organisms of any type and it seems that such organisms can be patented subject to the usual provisions of the Act. The leading authority on this question in the U.S. is *Diamond v. Chakrabarty*⁷ which concerned *inter alia* an application for a patent of man-made, genetically engineered bacteria of undoubted utility in dealing with crude oil spillages and which did not occur in nature. The relevant statute, 35 USCS 101, provided for grant of a patent to a person who invents or discovers any new and useful 'manufacture' or 'composition of matter'. In a split decision, the U.S. Supreme Court decided 5:4 that a live, man-made micro-organism is patentable subject matter under 35 USCS 101. The majority was constituted by Burger C.J., Stewart, Blackman, Rehnquist and Stevens JJ.

In delivering the majority judgment, Burger C.J. began by observing that, based upon prior authority, the courts should not read into patent laws restrictions which the legislature has not expressed and that by choosing expansive terms such as 'manufacture'

6. 12 May 1987.

7. (1980) 65 L Ed (2d) 144.

and 'composition of matter' the legislature had 'plainly contemplated that the patent laws would be given wide scope'.⁸ According to His Honour, the Act embodied the philosophy of Thomas Jefferson that 'ingenuity should receive a liberal encouragement'.⁹ Next, His Honour referred to material extrinsic to the Act in the form of the Committee reports accompanying the Act which indicate the intention of the legislature that the subject matter for patents 'include anything under the sun that is made by man'.¹⁰ His Honour noted however that the laws of nature and physical phenomena are not patentable saying:

Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none'.¹¹

His Honour went on to reject the conclusion which had been arrived at by the patent examiner that as 'products of nature' the Chakrabarty bacteria could not be patented, saying that the subject matter was not a hitherto unknown natural phenomenon discovered by the applicant but a non-naturally occurring manufacture or composition of matter, a 'product of human ingenuity',¹² a discovery 'not nature's handiwork but his own'.¹³

Having ruled that the bacteria was prima facie patentable, Burger CJ went on to dispose of two arguments which had been raised against that contention. The first was that the Plant Patent Act 1930 and the Plant Variety Protection Act 1970, both of which authorized protection for plants, evidenced an understanding by the legislature that the terms 'manufacture' and 'composition of matter' do not encompass living things: if they did, why would such acts be necessary? His Honour noted that prior to 1930 there was a belief that all plants, even those artificially bred, were products of nature not subject to patent protection, and that in any event plants were considered incapable of fulfilling the specification requirements of patent law. According to the Chief Justice, the 1930 Act was introduced to overcome these difficulties and no Member of Congress had said anything at the time about living things generally being excluded from patent protection save one whose views were directed at the Plants Act rather than the Patents Act. As to the 1970 Plant Act, His Honour observed that this related to sexually reproduced plants not coming under the 1930 Act. Although the 1970 Act excluded bacteria from plant variety protection (as does the Plant Variety Rights Act 1987 (Cth)), the Chief Justice said that legislative history gave no reason for this and it may have been due simply to the legislature agreeing with an earlier decision of the US Court of Customs and Patent Appeals¹⁴ wherein it was held that bacteria were not plants for the purposes of the 1930 Act. Alternatively His Honour said, the reason may have been that prior to 1970 the patents office had issued patents for bacteria. Indeed as early as 1873 the US Patent Office granted to Louis Pasteur a patent on a yeast.

The second argument dealt with by Burger CJ was that living organisms could not qualify as patentable subject matter until parliament expressly authorized such protection, since genetic technology was unforeseen when 35 USCS 101 was enacted. His Honour answered this by saying that congress had spoken on the subject of patents and it was the duty of the

8. *Ibid.* at 149.

9. *Ibid.* at 150, quoting 5 Writings of Thomas Jefferson at 75-76 (Washington ed 1871).

10. S. Rep No 1979, 82^d Cong, 2^d Sess 5 (1952);
H.R. Rep No 1923 82^d Cong, 2^d Sess 6 (1952).

11. *Supra* n.7 at 150.

12. *Ibid.*

13. *Ibid.* at 151.

14. *In re Arzberge* (1940) 112 F. 2^d 834.

Court to interpret that language. The language was broad enough to include unknown developments and no ambiguity could be discerned. His Honour said:

A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. Mr Justice Douglas reminded that the inventions most benefiting mankind are those that 'push back the frontiers of chemistry, physics, and the like'. *Great A & P Tea Co v. Supermarket Corp.*, 340 US 147, 154, 95 L Ed 162, 71 S Ct 127 (1950) (concurring opinion). Congress employed broad general language in drafting 35 USCS 101 precisely because such inventions are often unforeseeable.¹⁵

In concluding his judgment, Burger C.J. stated his unwillingness to consider the numerous policy arguments which had been presented against allowing patent protection for living organisms. His Honour said:

These arguments are forcefully, even passionately presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates - that, with Hamlet, it is sometimes better 'to bear those ills we have than fly to others that we know not of'.

It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under 35 USCS 101. We disagree . . .

We are without competence to entertain these arguments - either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts . . . Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted.¹⁶

Some of the policy arguments presented to the Court in *Chakrabarty* will be canvassed later in this article.

In delivering the dissenting judgment in *Chakrabarty*, Brennan J (with whom White, Marshall and Powell JJ agreed) noted the attempt of patent law to reconcile the 'deepseated' American antipathy to monopolies with the need to encourage progress. His Honour took the view that:

Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.¹⁷

His Honour also took the view rejected by Burger CJ that the earlier Plant Acts (1930 and 1970) evidenced a parliamentary recognition that living organisms were not patentable. In particular, His Honour remained unconvinced that the 1970 Plant Act, in excluding

15. *Supra* n.7 at 154.

16. *Ibid.* at 155.

17. *Ibid.* at 156.

bacteria, did not evidence a belief by the legislature that bacteria, (and *ipso facto* living organisms), were not patentable. His Honour concluded by saying:

It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.¹⁸

The US Patent Office has already approved some 200 patent applications for micro-organisms and many times that figure are pending. As a direct consequence of the decision in *Chakrabarty* the US Patent Office ruled in April this year that animals produced by human intervention can be patented, although for the time being no patent will be given in respect of any human life form. It would be difficult to conceive of a patent being allowed for human life due to the requirement that the subject matter be new and not of nature, since human life and human beings are themselves so diverse in nature. More sinister possibilities arise however when consideration is given to patents on such humanoid, but not human, life forms as the future may produce.

4. Australian Law On Patenting Living Organisms

Unlike the Patents Act 1977 (UK), the Patents Act 1952 (Cth) as amended does not contain any specific exclusion relating to living organisms. The position in Australia therefore would at first glance be comparable to that in the U.S., where arguments addressed solely to the issue of statutory interpretation as in *Chakrabarty* could lead to a conclusion that living organisms can be patented in this country, the fact of their being alive having no legal significance. As previously noted, the Patents Act 1952 refers to 'any manner of new manufacture the subject of Letters Patent and grant of privilege within s.6 of the Statute of Monopolies'. However in *National Research Development Corporation v. Commissioner of Patents*¹⁹ the High Court disapproved of any attempt to conclusively define the nature of manufacture, saying in a joint judgment:

The truth is that any attempt to state the ambit of s.6 of the Statute of Monopolies by precisely defining 'manufacture' is bound to fail. The purpose of s.6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.²⁰

The approach to inventions considered by the High Court to be correct is illustrated in the following passage:

The inquiry which the definition demands is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the section. It is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose of the Statute of Monopolies. One may remark that although the Statute spoke of the inventor it nowhere spoke of the invention; all that is nowadays understood by the

18. *Ibid.* at 158.

19. (1959) 102 C.L.R. 252.

20. *Ibid.* at 271.

latter word as used in patent law it comprehended in 'new manufactures'. The word 'manufacture' finds a place in the present Act, not as a word intended to reduce a question of patentability to a question of verbal interpretation, but simply as the general title found in the Statute of Monopolies for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed. It is therefore a mistake, and a mistake likely to lead to an incorrect conclusion, to treat the question whether a given process or product is within the definition as if that question could be restated in the form: 'Is this a manner (or kind) of manufacture?' It is a mistake which tends to limit one's thinking by reference to the idea of making tangible goods by hand or by machine, because 'manufacture' as a word of everyday speech generally conveys that idea. The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s.6 of the Statute of Monopolies?'.²¹

It is apparent from the above that the Court would not be content with a limited exercise in statutory interpretation. Matters of policy would need to be addressed in order to determine whether living organisms are a 'proper subject' for patentability. This was not a question which needed to be considered in the *NRDC Case* and indeed it has not yet been the subject of any judicial determination in Australia.

Until a Court or Parliament rules otherwise it will be possible to patent living organisms in Australia due to the practice adopted by the Commissioner of Patents. This practice is expressed in the following terms:

The criteria to be met before an application concerned with living organisms will be accepted are precisely the same as those for any other application, i.e. no distinction is to be made solely on the basis that a claimed product or process is, or contains or uses, a living organism. High life forms will not be treated any differently from lower forms such as micro-organisms.

The only criterion having particular significance in relation to living organisms is the requirement of s.40 of the Patents Act concerning a full description of the best method of performing the invention. In this regard it should be noted that disclosure of a method of performing the invention, i.e. producing the new organism, which by repetition will again produce the organism, is required.²²

Thus, so long as a living organism is new, involves an inventive step, is useful (not in the sense of commercial viability but in the sense that the result can be achieved by others) and proper specifications for it are supplied the Commissioner will issue a patent for it.

The issue of patentability of a living organism had earlier required the attention of the Assistant Commissioner in *Rank Hovis McDougall Ltd's Application*,²³ where claims were allowed for specific variants of a new strain of micro-organism known as *tusarium graniearum* useful in producing edible protein. The basic organism itself occurred in nature and was thus not novel, however the variants could be produced only by human intervention. The Assistant Commissioner took the view that the fact that they were alive was no bar to their being patented:

In respect of the invention claimed by claim 2, what has 'the inventor' done? What contribution has he made? He has discovered a naturally occurring micro-organism

21. *Ibid.* at 269.

22. (1980) 50 A.O.J.P. 1162.

23. (1976) 46 A.O.J.P. 3915.

and, by altering its conditions of growth, he has changed its morphological characteristics. If that is all that he has done, he has made no useful contribution to the art. On the other hand, I think the situation is quite different if, in producing the variant by some man controlled microbiological process, he has produced a new micro-organism which has improved or altered useful properties. To suggest that a patent should be not granted for such an invention would in my opinion hardly accord with the views clearly expressed in the decision in *National Research Development Corp v. Commissioner of Patents*. An objection that a claim to a new micro-organism, being something living, is not a manner of manufacture is based, in my opinion, on too restricted a view of the meaning of manufacture in section 6 of the Statute of Monopolies.²⁴

It may well be some time before the Courts in Australia are called upon to determine the issue of patentability of living organisms, since the Commissioner's practice means that no application will be rejected on the ground only that the subject is alive and thus no dissatisfied applicant will take that issue to judicial determination. Some cases involving disputes over specifications may provide important opportunities for expression of *obiter dicta* on the matter, however final adjudication will probably need to await a claim for infringement of a patent already granted wherein the defendant will object to its validity in the first place. In the meantime it may be that Parliament will intervene in an attempt to resolve the matter at least in the case of 'higher' life forms.

5. Policy Pros and Cons

To many biologists genetic engineering represents one of the most important scientific breakthroughs in history, giving humans the ability to guide evolution in a way nature never could. Environmentalists see the technology as resulting in the gradual extinction of natural species in favour of genetically altered animals that could spread disease, ruin crops, and disrupt the food chain. To those in industry, biotechnology is a potentially profitable means of developing new products so long as they are protected by the laws of intellectual property. To the Church genetic engineering is yet another body blow to already besieged beliefs in a world full of agnostics.

In *American Cyanamid Co (Dann's) Patent*²⁵ Lord Diplock considered that it was consistent with the basic social policy underlying the patent system to treat the kind of research involved in the discovery of a strain of micro-organism from which a new and useful antibiotic could be prepared as an activity which entitled the person undertaking it to patent protection. The same might be said of the product of such research. The Supreme Court of the U.S. in *Chakrabarty* in allowing patentability of a micro-organism drew no distinction between that and a higher life form in point of law, though the following passage from the majority judgment illustrates concern:

The briefs present a gruesome parade of horrors. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life.²⁶

24. *Ibid.* at 3918.

25. [1971] R.P.C. 425.

26. *Supra* n.7 at 154, 155.

Most people would probably oppose patentability of any human life form, but short of that the difficulty is always where to draw the line. Section 1(3) of the Patents Act 1977 (U.K.) provides one answer although difficulties may occur in defining 'animals' which interestingly enough is not a term defined in the U.K. Act. The authors now propose to examine some of the policy arguments on each side of the patentability for living organisms case in order to ask, but perhaps not answer, whether the U.K. approach of confining patents to micro-organisms is the correct one.

The following principal arguments may be presented in favour of patentability of living organisms.

Firstly, useful advances have already been made in such diverse fields as medicine and pollution control through use of biotechnology and mankind has benefited as a result. Examples abound and can be found in areas such as production of interferon (a possible cancer suppressant) and genetic engineering of bacteria to deal with oil spills such as in *Chakrabarty*. The potential exists to further benefit mankind through genetic engineering which may reduce disease and also hunger, by making super-productive crops and farm animals. One of the most outspoken proponents of genetic engineering is Professor Bernard Davis, professor of bacterial physiology at Harvard Medical School, who says the technology has been yielding increasing benefits in medicine, agriculture and industry for six years. In Australia, Professor Carl Wood told a recent Symposium²⁷ that reproductive biology could offer a simpler and more effective way to improve human behaviour, for example to reduce the killing instinct or to improve metabolic processes so that people can survive on less food. Recent research in the United States has been directed at genetically altering animals to make them susceptible to human diseases so that new drugs may be tested on them. In terms of the necessity for patents it is argued that genetic engineering and biotechnology are unlikely to achieve their full promise without intellectual and financial input from the private sector which will not be forthcoming without some financial protection and reward at the end, such as patent monopolies.

According to Professor Wagner of the University of Ohio Animal Biotechnology Center, genetic engineering opens the prospect for large profits to be made by companies in the private sector but these companies will need encouragement for developmental costs in the form of patents on the end products of the research they fund.

This argument was rejected by the majority in *Chakrabarty*. Burger C.J. said:

Denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.²⁸

Nonetheless, His Honour did point out that patent laws do promote the progress of science by offering inventors exclusive rights as an incentive for their inventiveness in the hope that society may benefit through their efforts.

Secondly, patentability places biotechnological inventions in the public domain and precludes the secrecy which would attend an unprotected research environment. In this

27. R.M.I.T. Centenary Conference on Future Directions in Technology, Education and Society; 12 May 1987.

28. *Supra* n.7 at 155.

argument it is implicit that secrecy is to be avoided because society generally should be in a position to control biotechnological pursuits upon ethical grounds which cannot be trusted to self-regulation among the scientific community. As it is society which will have to bear the cost of biotechnological failures which produce harmful results, it is argued, then society has a right to know what is happening so that where necessary appropriate controls may be put in place.

Thirdly, patentability vests discoveries in the public domain and via compulsory licenses allows society to benefit from all discoveries, not just those which are seen to be economically viable at a given time.

The authors submit that what the previous two arguments ignore is that society will receive only such information as researchers decide to patent because it is commercially valuable or because it is sufficiently uncontroversial to allow into the public domain. What would be required to go further than that is a general system of monitoring and regulating scientific procedures which does not rely on voluntary disclosure, such as that suggested in the United States by the President's Commission for the Study of Ethical Problems in Medicine and Biochemical and Behavioural Research. That Commission argued that the design of such an oversight group should be guided by the following objectives:

- (a) The group should regard education as a primary responsibility.
- (b) The group should have roles both of general oversight and of leadership within the Federal Government.
- (c) The group should be capable of leading as well as reflecting public thinking on the important issues before it - serving as an intermediary between biomedical scientists and the public helping to translate and clarify the ideas and concerns for each other. The body would therefore need diverse membership.
- (d) The group should strive to operate from scientifically sound premises drawing on groups of scientists for advice.
- (e) The group should treat all the issues raised by genetic engineering, including laboratory and industrial safety, environmental hazards, agricultural and commercial opportunities and pitfalls, international ramifications, biomedical benefits and risks and social and ethical implications.
- (f) In so far as possible the oversight function should be separated from any sponsoring functions.²⁹

Such a body could play a useful role in alerting the legislature and the public to current developments but, in the absence of it being given extensive regulatory powers, it would not actually restrict sensitive research as technology always seems to advance many steps in front of the law. Nonetheless, as Professor Wood has said, the time may have come for a body such as the defunct Commission for the Future to take up the challenge of promoting education and debate on the religious, political, psychological and ethical, not to say legal, issues attending biotechnology.³⁰

The following principal arguments may be presented against allowing patentability of living organisms, at least under present arrangements.

Firstly, if living organisms are to be patentable, that is a decision which should be taken by the legislature rather than the Courts. There is sufficient doubt about the matter for the Courts to refuse patentability unless Parliament makes the position clear. Whilst this argument attracted the support of four members of the U.S. Supreme Court in *Chakrabarty*

29. Noted in J. Kerran, 'Science and the Law - Lessons from the Experience of legislating for the New Reproductive Technology', a paper presented to the 23rd Australian Legal Convention (Melbourne 1985).

30. *Supra* n.27.

it is submitted that it has little force in the Australian context. As a general rule, an Australian Court should not in interpreting a statute exclude from the operation of that statute things which were not known to Parliament at the time it was enacted if those things now fall within the words of the statute in their current meaning.³¹ The opposite of this proposition, *contemporanea expositio est optima et fortissima in lege*, was argued in *Chakrabarty* and rejected by the majority. Its use is now confined to very old statutes. The correct question is: would the legislature have intended the Act to encompass this subject-matter if it had been known when the Act was passed? The answer in the context of patents for living organisms can be found only in an examination of policy considerations, and here it should again be pointed out that the High Court in the *NRDC Case* have placed responsibility for finding the answer upon the shoulders of the judiciary. In a recent book Professor Weeramantry argues that the Anglo-Australian legal system, dominated by the adversarial notion of litigation, is not structured to be able to deal with scientific advances.³² His sentiments it will be recalled found the support of the majority in *Chakrabarty* and have been echoed by Justice Michael Kirby in the following terms:

Unless we can develop institutions that help the democratic arm of government or offer solutions to bioethical questions it will continue to fall to the unelected judiciary (and to a lesser extent the unelected bureaucracy) to weigh the public policies involved and provide the answers. A courtroom is a good venue for the resolution of factual disputes between parties where the issues are narrowly focused. It is an imperfect venue for the resolution of large philosophical quandaries based on ill-understood technological developments and restricted to the parties and their lawyers with little or no help from philosophers, theologians and the community.³³

Secondly, the risks involved in biotechnology are so great that such work is not to be encouraged through patentability of the results. The matter it is argued has gone far enough with patents for protection of processes. This is the 'parade of horrors' approach referred to in *Chakrabarty* but avoided by the majority in their belief that determination of policy was not their role.

In answer to this, commentators such as Professor Bernard Davis of Harvard Medical School state that the bulk of genetic engineering experiments are not dangerous. They use harmless organisms and produce harmless materials such as human insulin. According to Professor Davis, the power of biotechnologists is limited by nature's own 'self-policing' process, so that only very small bits of genetic material can be transferred (less than one part per thousand) between species. He concedes however that the future may unlock the secret of transferring larger amounts.

The real question in any case is whether denying patentability to living organisms will limit biotechnological research. In the opinion of the authors it will not, for the reasons expressed earlier in this article. Furthermore, it is often only long after a discovery and perhaps the granting of a patent that detrimental effects of a discovery originally thought to be only useful are themselves discovered, e.g. depletion of the ozone layer by hydrocarbon sprays. Denying patents will not stop this, because it will not stop the research in the first place.

Thirdly, it is morally wrong to grant proprietary rights over any life form because it is morally wrong to engage in biotechnology and genetic engineering. Biotechnology companies would obtain ownership of a life form and such exploitation of nature should

31. *Lake Macquarie S.C. v. Abedare C.C.* (1969) 123 C.L.R. 327.

32. C.G. Weeramantry, *The Slumbering Sentinels: Law and Human Rights in the Wake of Technology*, (1983).

33. E. Nichols and T. Hogan (eds), *Making Babies: The Test Tube and Christian Ethics*, (1984).

not be permitted. Few perhaps would disagree in the case of 'higher' life, many perhaps would disagree in the case of bacteria which could improve the conditions in which higher life exists. Dr Ricketson points out that we generally draw a dividing line between human life and all lesser life forms. If we can own and destroy an animal at will, he asks, why not acknowledge the right to make a particular type of animal by genetic engineering?³⁴ As stated earlier in this article the difficulty is where to draw the line. The 'human versus others' species test may be totally inapplicable to a genetically engineered creature looking non-humanoid yet possessing unmistakable human characteristics such as rationality and ability to choose. Few would doubt that animals are intelligent, some would say they have rights which should be protected in the same way as human rights. Nonetheless, it is submitted that it would be absurd to deny patentability of micro-organisms on these grounds.

Fourthly, current patent laws are ill-equipped to cope with the difficulties of description of a 'patentable' living organism. This, it is submitted, is no answer to the central question. If one agrees that living organisms should be capable of being patented, the 'specification' requirements can always be tailored appropriately. An attempt has already been made through the 1984 amendments to s.40, Patents Act.

6. Conclusion

The issue of patentability of living organisms is a complex one with deep entrenchment on both sides. Whilst it may be settled in the U.S., the Congress not having acted to overturn *Chakrabarty*, Australia remains in a position to benefit from overseas experience and formulate a position, judicially or legislatively, in a fully-informed manner. In the short-term it would be perhaps acceptable for Parliament to amend the Patents Act so as to deny patents for intelligent life forms, and perhaps even for procedures producing such life forms, in line with s.1(3) Patents Act 1977 (U.K.). This would be subject to the difficulties of definition, and it may be that 'animals' is the best word which can be found at which to draw the line. In the longer term it might be possible to remove living organisms altogether from the scope of patent protection and place them under some new legislative scheme which may or may not allow for some higher life forms to be the subject of proprietary rights if, after an extensive period of investigation, that is thought desirable. It is submitted that no change is necessary, nor should one be made to the *status quo* in the case of micro-organisms.

There is no doubt that this is an area in which to date the law has largely ignored scientific developments. It might be as well to heed the warning given by Justice Michael Kirby about the dangers of the law failing to keep up with science:

My chief point is a simple one. Science and technology are advancing rapidly. If democracy is to be more than a myth and a shibboleth in the age of mature science and technology and more than a triannual [sic] visit to a polling booth, we need a new institutional response. Otherwise, we must simply resign ourselves to being taken where the scientists 'and the technologists' imagination leads. That path may involve nothing less than the demise of the rule of law as we know it. It is for our society to decide whether there is an alternative or whether the dilemmas posed by modern science and technology, particularly in the field of bioethics, are just too painful, technical, complicated, sensitive and controversial for our institutions of government.³⁵

34. S. Ricketson, *The Law of Intellectual Property in Australia*, (1984).

35. M. Kirby, *Reform the Law*, (1983).