

BIOTECHNOLOGY AND THE LAW: CO-OPERATION NATIONALLY AND INTERNATIONALLY

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There is a growing awareness in Australia that current laws are inadequate to protect the increasing industrial application of biotechnology. To overcome these difficulties there is a need for co-operation both nationally and internationally. The Biological Control Act 1984 (Cth) and the Patents Amendment Act 1984 (Cth) are indicative of a trend towards this end.

The Biological Control Act 1984 (Cth) involves co-operation between the Commonwealth and the States to overcome gaps in the Commonwealth's power, while the Patents Amendment Act 1984 (Cth) involves international co-operation under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures 1977. Whereas the Patents Amendment Act 1984 (Cth) extends and secures the patent protection available for biotechnological inventions, the Biological Control Act 1984 (Cth) aims to protect certain scientific endeavours from undue interference from the law itself.

1 THE BIOLOGICAL CONTROL ACT 1984 (CTH)

In 1980, the CSIRO released a biological control agent against *Echium*, a noxious weed more commonly known as Paterson's Curse or, to those who regard it as a boon, Salvation Jane. An action for private nuisance was commenced in the High Court¹ where an interim injunction was granted. The matter was subsequently referred to the Supreme Court of South Australia. There, the parties agreed to discontinue court proceedings, with CSIRO agreeing to halt its program subject to the proviso that it was at liberty to apply to have the injunction set aside or varied.²

This result was helpful to the apiarists and dry land graziers who potentially stood to lose about \$1.8 million per year if the program proceeded.³ However, it was far from helpful to the rest of the agricultural sector who had spent large amounts of money attempting to control the plant, but had nevertheless seen their livestock and crop productivity drop as a result of it. Indeed, it has been estimated that agriculture would benefit, in time, by up to \$35 million annually if the weed were eradicated.⁴ The problem is that

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¹ *Ronald MacPerry, John William Hincks, Stephen John Victor and Paul Griffiths v Commonwealth Scientific and Industrial Research Organization* (unreported judgment of Stephen J No 9 of 1980).

² Industries Assistance Commission. Draft Report on Biological Control of *Echium* Species (including Paterson's Curse/Salvation Jane). AGPS 1985 esp at p 1.2.

³ *Ibid* Summary (1).

⁴ *Ibid*.

the law of private nuisance is concerned with the loss likely to be suffered by a plaintiff. It can by its very nature pay little regard, if any, to such policy questions as to where the wider public good actually lies.

The success of the apiarists had two consequences. First, it threatened to shelve a number of useful biological control programs, even though these were likely to be more effective, and less costly and environmentally damaging, than chemical controls. Secondly, it increased the risk of impatient persons "abating" a pest by resorting to their own controls, as happened in Gippsland where someone released a blackberry rust.⁵ Such amateur attempts at biological control pose a danger to the economy and to the environment. This is especially so, where the control is not specific in what it attacks and the target organism is, or is closely related to, commercially valuable crops or animals.

Against this background and after close collaboration between the Commonwealth and State Governments through the Australian Agricultural Council, the Commonwealth Parliament enacted the Biological Control Act 1984 (Cth). The purpose of the Act is to create a mechanism to resolve conflicts of interest over biological control programs which concern the control of either weeds or pests which are a danger to public health or to the environment. In an attempt to accomplish this the Act has set up a comprehensive procedural mechanism by which biological control programs may be authorised if they are in the public interest, having regard to the relevant economic, social and biological factors. This process which is made up of provisions for the obtaining of public comment, the holding of inquiries and the review of the decision-making process by the Administrative Appeals Tribunal, is set out in the figure below. It is initiated by either an individual's application, or a recommendation from the Australian Agricultural Council, to the Biological Control Authority which has been established under the Act.⁶

These procedures only apply to programs which have been voluntarily submitted to the Authority.⁷ However, their width has been criticised by people involved with biological control, as being potentially a hindrance to such programs because of the costs of advertising and representation it may impose on bodies such as the CSIRO.⁸

Once the procedures have been concluded, the Act ensures that programs that have been authorised will not as a general rule be subject to legal proceedings for an injunction or damages.

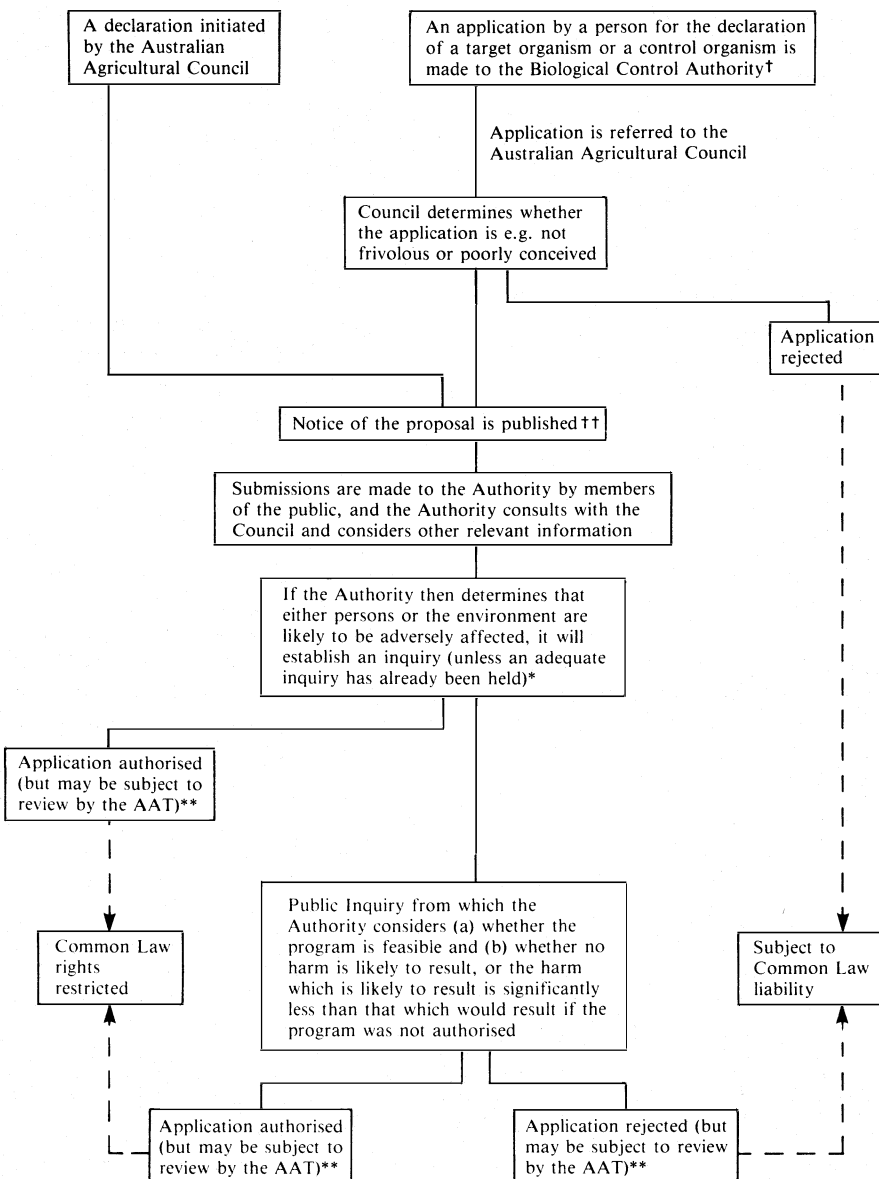
Nevertheless, the Act does not grant an absolute immunity, and there is one clear circumstance in which it expressly permits an action for damages

⁵ Commonwealth of Australia House of Representatives Parliamentary Debates Hansard 23 August 1984 at p 209 (E Cameron).

⁶ Biological Control Act 1984 (Cth) s 8. The Authority is at present constituted by the Commonwealth Minister for Primary Industry. After 1 April 1985, it shall be designated to be constituted by either the Commonwealth Minister or a relevant Minister from any of the participating States.

⁷ *Ibid* s 52.

⁸ Carne P B and Whitten M J, "The Context of Biological Control Research in Australia" Unpublished paper presented at The Workshop following the International Congress of Entomology August 1984.

FIGURE: The authorisation processes under the Biological Control Act 1984

† These procedures are only excluded in cases of emergency s 30. But even emergency declarations are subject to review by the AAT s 56(1)(f).

†† While applications in respect of target organisms must be published in the Gazette and State newspaper s 17(1), applications in respect of control agents need only be published in the Gazette s 26(1).

* The Commission of Inquiry may be appointed under ss 19(1) and 28(1) of the Biological Control Act, or where appropriate the Industrial Assistance Act 1973 or Environment Protection (Impact of Proposals) Act 1974.

** Whether a particular decision is, or is not subject to review by the AAT, is governed by s 56(1) of the Act.

to be instituted against persons who have released an authorised biological control. This situation is where it was foreseeable that the control would move beyond the target organism and cause the damage which resulted.⁹ Liability will however be unlikely if the Authority has had regard to that risk, but nevertheless permitted the release to go ahead.¹⁰

In this situation, it might be possible for the Authority to make its authorisation subject to assistance being granted to the industries which have been adversely affected.¹¹ This could include monetary or other assistance which would offset the losses incurred through the release, or aid persons in reducing their dependence on the affected industry.¹² There appears to have been little consideration given to date to either the mechanics of this assistance or the sources of finance.

Assistance might also be given under the Rural Adjustment Scheme after the biological program has been implemented.¹³ Indeed, in the first inquiry to be held under the Act, which was a continuation of the Echium saga, the presiding Commissioner preferred to defer the question of assistance until after the implementation of the program, because of the uncertainties as to whether the extent of the harm would warrant assistance.¹⁴

However, the major problem with the Act is that it only applies to the Australian Capital Territory¹⁵ and to certain external territories which may be declared by the Minister to be subject to the Act.¹⁶ This is because of the limited constitutional powers of the Commonwealth Parliament in this area. Thus the Act will probably be impotent without complementary legislation being enacted in the States and Northern Territory. Organisms which are released as biological controls will simply not recognise State boundaries. Once a biological control moves into a jurisdiction without the protective umbrella of biological control legislation the full force of the common law will become available.

Despite this defect, the Act is important in that it is indicative of a process of co-operation between the Commonwealth and the States in this area. This approach overcomes gaps in Commonwealth power without the coercive overtones which are sometimes felt to arise, for example, by the use of conditions attached to grants under s 96 of the Constitution. Further, such a scheme is but an extension of the administrative co-operation which has existed between the Commonwealth and the States in the Australian Agricultural Council for about 50 years.

The full potential of this approach was recognised by Gibbs CJ in *Re Duncan, The Coal Industry Tribunal and Others; ex parte Australian Iron and Steel Pty Ltd*¹⁷ when his Honour said that there is:

⁹ Biological Control Act 1984 (Cth) ss 36(3) and 37(4).

¹⁰ *Ibid* ss 20(1)(e), 29(1)(d), 36(3)(c) and 37(4)(c).

¹¹ *Ibid* s 38(3)(b).

¹² Industries Assistance Commission *op cit* esp Ch 8.

¹³ *Ibid* pp 8.9-8.11.

¹⁴ *Ibid* pp 8.13 and 10.1.

¹⁵ See the Preamble to the Biological Control Act and the definition of "Territory" in s 2(1) of the Act.

¹⁶ Biological Control Act 1984 (Cth) s 4.

¹⁷ (1983) 49 ALR 19, 29.

no principle of constitutional law, that would prevent the Commonwealth and States from acting in co-operation, so that each, acting in its own field, supplies the deficiencies in the power of the other, and so that together they may achieve, subject to such limitations as those provided by s 92 of the Constitution, a uniform and complete legislative scheme.

The other justices agreed with the Chief Justice's approach, and Mason J in particular emphasised that:

[a] federal constitution . . . necessarily contemplates that there will be joint co-operative legislative action to deal with matters that lie beyond the powers of any single legislature.¹⁸

This is not to deny the many practical and political problems involved in developing an integrated system. Indeed, the Biological Control Act 1984 (Cth) itself bears witness to this, for while the States and the Northern Territory have agreed in principle to introduce complementary legislation, only one State, New South Wales, has made any substantial progress to that end.¹⁹ The other jurisdictions are involved in working out the precise wording of their legislation, some, it is understood, in the face of lobbying by persons whose interests may be affected by the passage of such legislation.

2 THE PATENTS AMENDMENT ACT 1984 (CTH)

Another aspect of this trend towards co-operation is the Commonwealth Parliament's increasing involvement with international arrangements concerning patents.²⁰ Currently, Australia is a party to the Paris Convention,²¹ Patent Co-operation Treaty²² and Strasbourg Agreement.²³ In addition, it is likely that Australia will accede to the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures sometime in 1986. These arrangements aim at improving the ability of patentees to obtain patent protection for their inventions in a number of countries.

There is nothing new in the granting of patent protection to "living" organisms. Ever since the days of Louis Pasteur when patents were granted for yeasts it has been possible to patent living organisms.²⁴ However the Budapest Treaty is concerned with the improvement of the patent protection available at present to micro-organisms in Australia²⁵ by minimising the cost

¹⁸ *Ibid* 36; see also Brennan J at 52 and Deane J at 59-60.

¹⁹ The NSW Bill was introduced into Parliament on 19 November 1985.

²⁰ See generally, OECD, *Biotechnology and Patent Protection. An International Review* OECD Paris 1985; and WIPO, *Industrial Property Protection of Biotechnology Inventions - Analysis of Certain Basic Issues* (Doc BIG/281) 1985.

²¹ Paris Convention for the Protection of Industrial Property 1883.

²² The Patent Co-operation Treaty 1970 provides that a person who complies with certain procedural formalities may gain protection in any member State designated in the application.

²³ Strasbourg Agreement concerning the International Patent Classification 1971.

²⁴ US Patent No 141,072 (1873). See Cooper 1 P, *Biotechnology and the Law* (1982) 2.5-2.6.

²⁵ The Patent Office in *Rank Hovis McDougall Ltd's Application* (1976) 46 AOJP 3915 acknowledged that patent protection was available to micro-organisms where the normal pre-conditions to the granting of a patent had been met.

of multiple patenting overseas.²⁶ Currently, 18 nations have either ratified or acceded to the Treaty, and they include such high-technology nations as the United States of America, United Kingdom, West Germany and Japan.²⁷ The need for effective protection is indicated by the growing number of applications for genetically engineered inventions. In Australia alone, the number of such applications rose from 44 in 1981, to 49 in 1982, to 67 in 1983.²⁸

The Patents Amendment Act 1984 (Cth) ensures that Australians will be able to take advantage of the Budapest Treaty. The Act achieves this by bringing Australian law into line with those countries where it is necessary to file a sample of the micro-organism. This overcomes the decision of the House of Lords in *American Cyanamid Co (Dann's) Patent*,²⁹ that held that there was no obligation on a patentee to furnish a sample which might be necessary to carry out the claimed process, even if the strain was only possessed by the patentee. The Patent Office in Australia had arrived at a similar conclusion.³⁰ The rule now is that a sample of the micro-organism must be deposited at a prescribed depository unless the micro-organism is reasonably available to persons skilled in the art.³¹ In this way the legislation ensures that a patentee will satisfy his debt of allowing effective access to his invention, in return for obtaining his monopoly of 16 years. The cost to the patentee of making this deposit will be off-set by the reduction in the cost of drafting patent specifications, for s 40(5) of the Act merely requires information on the micro-organism's characteristics and where it is located.

The Act then proceeds to provide the foundations upon which a depository can be established. This institution, in compliance with the Treaty, will have the special expertise and equipment that is necessary for the receiving, handling and storage of micro-organisms. It is likely that these matters, together with the availability of new deposits when the original ceases to be viable and the question of who is entitled to access to the deposit, will be provided for by the regulations which will be made under the Act.³²

Australian patentees, by depositing samples of micro-organisms at the Australian depository, will have satisfied the deposit requirements of each contracting country to the Treaty, and thereby saved themselves the need to repeat this costly and complex procedure.³³ In addition, Australians will have access through this depository to strains that have been deposited overseas by foreign patentees.³⁴

²⁶ WIPO, Records of the Budapest Diplomatic Conference for the Conclusion of a Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1980, 483.

²⁷ WIPO, *Industrial Property* Vol 24 (1985) 16, 163, 235 and 321.

²⁸ Statistics derived by The Hon Barry Jones from Patent Office survey entitled Genetic Engineering — Patent Trends and Developments 1983 — see Commonwealth of Australia House of Representatives Parliamentary Debates Hansard 28 March 1984 897.

²⁹ [1971] RPC 425.

³⁰ *Rank Hovis McDougall Ltd's Application supra* n 25.

³¹ Patents Act 1952 (Cth) s 40(3).

³² *Ibid* s 177(ae).

³³ See Article 3 of the Treaty, and the definition of "prescribed depository institution" in s 6 of the Patents Act 1952 (Cth).

³⁴ Commonwealth of Australia House of Representatives Parliamentary Debates Hansard 28 March 1984 899 (Barry Jones).

There is much, however, that has been left untouched by both the Treaty and the Act. In particular, the making of a deposit does not necessarily satisfy all the requirements of registration in member countries to the Treaty. Whether those requirements have been met will depend upon the domestic law of each of those countries. This creates problems for a patentee where there exists a conflict between the requirements of Australian law and that of another member country. For example, such a conflict may well exist between Australian law and the domestic law of West Germany whose Federal Supreme Court requires, in addition to the deposit, a specification which discloses a reproducible method of manufacture.³⁵ This, as was seen earlier, is in marked contrast to the limited amount of information required under the Australian Act. This might nevertheless be reconsidered in the light of Germany's accession to the Treaty.

Further problems arise out of the general application of patent law to living organisms.

There is the difficulty of the Patent Office being able to determine whether there is a real and practical difference between one micro-organism and another, especially since micro-organisms have a tendency to change in genetic characteristics as time progresses. The depositary's power, under the Treaty, to request the renewal of a deposit will generally arise only when the micro-organism has lost its viability.³⁶ The other side of the coin relates to the means by which the Patents Office will determine how wide claims can be, since the existence of special biological and chemical languages, together with the broad classifications of organisms, may lead to the use of broad definitions in patent claims. Further, the comparatively lower cost of obtaining a licence may deter interested persons from challenging the validity of such patents in the courts.³⁷

3 CONCLUSION

Both the Biological Control Act 1984 (Cth) and the Patents Amendment Act 1984 (Cth) indicate the Commonwealth Parliament's concern to solve the problems arising out of the industrial application of biotechnology. The constitutional constraints on the Parliament have meant that national and international co-operation has emerged as a favoured approach.

Although this approach shows potential for the future, it does have a number of practical and political difficulties. These are exemplified by the fact that, at the time of writing, no State has enacted complementary biological control legislation and no regulations have been made which would enable Australia to accede to the Budapest Treaty. It is to be hoped that these particular problems will be overcome and that this will lead to further and more effective co-operation both domestically and internationally.

³⁵ *In re Koninklijke Nederlandsche Gist — en Spiritusfabriek N.V. (Baker's Yeast) decision* (1975) 611C 207 and affirmed in the *Bakterienkonzentrat (Concentrate of Micro-organisms) decision* (1981) GRUZ 263.

³⁶ Budapest Treaty Article 6.

³⁷ Thomas P, "Patents for Genetic Engineering Inventions", in Department of Science and Technology, *Genetic Engineering: Commercial Opportunities in Australia*, Proceedings of a Symposium held in Sydney 18-20 November 1981. AGPS 1982 194-195.