

**Submission to the Advisory Council on Intellectual Property
in response to its Issues Paper**

**Implications of the Exclusion of Plant and
Animal Subject Matter from Innovation Patents**

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3 October 2002



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MELBOURNE**

Table of Contents

<i>Preface</i>	3
<i>Executive Summary</i>	4
1. INTRODUCTION	4
2. JUSTIFICATION FOR SECOND TIER SYSTEMS	4
3. INTELLECTUAL PROPERTY RIGHTS FOR PLANT AND ANIMAL SUBJECT MATTER	4
4. CONCLUSIONS FOR AUSTRALIA	5
<i>1. Introduction</i>	6
<i>2. Justification for Second Tier Patent Systems</i>	7
2.1 CHARACTERISTICS OF SECOND TIER PATENT PROTECTION	7
2.2 SUBJECT MATTER OF SECOND TIER PATENT SYSTEMS	8
2.3 EUROPEAN COMMUNITY UTILITY MODEL PROPOSAL	9
2.4 SUMMARY AND CONCLUSIONS	12
<i>3. Intellectual Property Rights for Plant and Animal Subject Matter</i>	12
3.1 ETHICAL ISSUES	12
3.2 LEGAL ISSUES	15
3.3 SUMMARY AND CONCLUSIONS	22
<i>4. Conclusions for Australia</i>	23

Preface

Australian innovation patents are not currently available for plants, animals or biological processes for the generation of plants and animals. The ACIP *Issues Paper* has sought submissions about whether this exclusion is justified.

IPRIA is not able to provide any empirical evidence on the economic or practical consequences of the exclusion of plant and animal subject matter, and so this submission is confined to a theoretical examination of the issue. This submission examines the justification for second tier patent protection in other countries, the subject matter for which such protection is commonly accorded, and the place of exclusions in these systems. This submission also examines the international practice of granting or excluding intellectual property rights for plant and animal subject matter. In our view, these analyses provide *indirect* assistance to answering the fundamental question of whether the Australian innovation patent should exclude plant and animal subject matter.

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Executive Summary

1. INTRODUCTION

Although plant and animal subject matter is capable of protection by standard patents, inclusion of this subject matter in the material protectable by innovation patents would be an *expansion* of the scope of intellectual property rights available – as innovators would be able to claim exclusive rights for innovations that would not meet the higher inventiveness threshold required for the grant of a standard patent. Thus a cautious approach must be taken to the issue of including plant and animal subject matter within the innovation patent regime, because such an expansion involves the creation of a wider intellectual property right than currently exists in Australia. It is not always in the public interest to provide exclusive rights over all types of inventions, as such rights may not be economically beneficial in some industry sectors.

2. JUSTIFICATION FOR SECOND TIER SYSTEMS

Many countries have introduced a second kind of intellectual property right for protecting technological innovation, in addition to the standard patent. The analysis of overseas jurisdictions has shown that the main rationale for providing second tier patent protection is to supplement an existing patent system by protecting innovations that would not satisfy the threshold of inventiveness required for standard patent protection. A secondary aim is to provide a procedure for granting protection in a short period of time, with decreased costs. The overall objective is to encourage innovation in the fields of technology to which second tier patent protection applies, in order to benefit society at large.

In some countries, the area of protected subject matter of second tier patents is identical to the patent system, while in other countries the range of protected subject matter is more narrow. Studies have shown that the main use of utility models in Europe has been in industrial sectors such as mechanical and electrical engineering, where there is a permanent need for innovation, especially for minor technical innovations. Even though most European countries have adopted some form of utility model protection, there seems to be general unwillingness to adopt a European Community-wide utility model. This may suggest that there is support for utility model protection when confined to traditional technical subject matter, but resistance against a wider scheme that would apply to all patentable subject matter.

3. INTELLECTUAL PROPERTY RIGHTS FOR PLANT AND ANIMAL SUBJECT MATTER

The patenting of plants and animals has raised a plethora of moral and ethical questions relating to animal rights, biodiversity, recognition of traditional knowledge and the commodification of life. In such a controversial area where so there has been so much public resistance to patenting, the legislature should bear the burden to prove that the benefits of the stimulation of innovation in this area outweigh the possible risks involved.

Most member countries of the Organisation for Economic Co-operation and Development (OECD), including the US and the European Union, allow for the patenting of plants and animals. In the European Community “plant varieties” are excluded from patentability under the European Patent Convention due to the existence of an alternative (*sui generis*) form of protection under the UPOV Convention and national Plant Variety Rights legislation. While the prohibition on dual protection under UPOV no longer exists, it still provides the underlying justification for why the patenting of certain plant subject matter is still prohibited in Europe. An additional justification for excluding plants from patent protection is that such protection would be contrary to ethics or morality. “Animal varieties” are treated in the same way as plant varieties in Europe, even though there is no *sui generis* intellectual property regime for protecting animals. It is hard to justify the exclusion of animal varieties from patenting, except for reasons of ethics and morality. In practice the European Patent Office construes the exception of “plant and animal varieties” narrowly, and shows a willingness to grant claims to plant and animal subject matter.

In Japan and the US, plants and animals constitute eligible patentable subject matter. In Canada, the patenting of plants and animals is currently unsettled. A clear position will emerge once the Supreme Court delivers its decision in the *Harvard Oncomouse* case and the Government responds to the Canadian Biotechnology Advisory Committee recommendations. The TRIPs Agreement allows member states to exclude plants and animals from patentability but provides that members must provide for the protection of plants either by patents or by an effective *sui generis* system.

4. CONCLUSIONS FOR AUSTRALIA

Australia’s current position of excluding plant and animal subject matter from innovation patents does not conform to international practice of exclusions, nor does it fit with the rationale of second tier protection. However, it is not enough to argue that there are no reasons to justify the *exclusion* of plant and animal subject matter. Where there is public resistance to the provision of intellectual rights over particular subject matters, the burden shifts to the legislature to prove that there are reasons to justify the *inclusion* of those subject matters within the realm of protection. Plants and animals, being higher order life forms, are examples of subject matters for which there is public resistance to patenting.

Australia must balance ethical, economic and other concerns in deciding whether it is desirable to grant *additional* intellectual property rights for plant and animal subject matter in order to stimulate further innovation and develop domestic skills in this sector. Empirical evidence is required on whether the current patent regime is operating effectively in this sector or whether increased intellectual property rights in the form of innovation patents are needed to stimulate greater investment in research, development and commercialisation of this subject matter. In the absence of evidence showing further intellectual property rights are required, the extension of the innovation patent to plant and animal subject matter should not occur.

1. Introduction

This submission will analyse the rationale for second tier patent systems in overseas jurisdictions and examine the place of exclusions in second tier systems. International practice with respect to granting or excluding intellectual property rights for plant and animal subject matter will be discussed generally, to determine whether first principles would justify the exclusion of such subject matter from second tier protection. This method of analysis is an indirect way to address the fundamental question of whether plant and animal subject matter should be excluded from protection by the innovation patent in Australia.

The standard ‘intuitive’ response to this question is that the current exclusion of plant and animal subject matter is ‘illogical’, because that subject matter is already protected by standard patents and innovation patents are a lesser right than a standard patents. However, an important point to make is that although plant and animal subject matter is already capable of protection by standard patents, inclusion of this subject matter in the material protectable by innovation patents would be an *expansion* of the scope of intellectual property rights available – as innovators would be able to claim exclusive rights for innovations that would not meet the higher inventiveness threshold required for the grant of a standard patent. Thus a cautious approach must be taken to the issue of including plant and animal subject matter within the innovation patent regime, because such an expansion involves the creation of a wider intellectual property right than currently exists in Australia.

There also seems to be a perception that if standard patents protect a certain class of subject matter, then it logically follows that innovation patents should protect the same subject matter. The underlying assumption seems to be that because intellectual property rights promote innovation, *more* intellectual property rights must be better. However, it is not always in the public interest to provide exclusive rights over all types of innovations. Indeed, it may be that in some industry sectors the granting of exclusive rights for a lower level of inventiveness than a standard patent is not economically beneficial or pro-competitive for that particular sector. It should be noted that this submission does not purport to provide empirical evidence as to whether second tier protection is or is not economically beneficially to the industry sector concerned with plants and animals. Instead, this submission purports to provides an *indirect* assessment of whether such subject matter should be excluded through a theoretical examination of the rationale of the law. Direct empirical evidence of the situation in the plant and animal industry sector could either justify the exclusion of plant and animal subject matter from the innovation patent or warrant the inclusion of plant and animal subject within the innovation patent.

2. Justification for Second Tier Patent Systems

This section will analyse the justification for second tier patent systems in overseas jurisdictions, in order to gain an insight into the reasons *why* such systems were developed and *what* their current use is today. In particular, this section will focus on the characteristics of second tier patent protection, the subject matter which is commonly accorded protection, and the place of exclusions in such a system.

2.1 CHARACTERISTICS OF SECOND TIER PATENT PROTECTION

Second tier patent protection exists in 48 countries¹ around the world with differing requirements and conditions. This type of protection is known by a variety of names in different countries, and includes “utility”, “innovation”, “short term” and “petty” patents.² Neither the United States,³ the United Kingdom⁴ nor the European Union offers protection for a utility model. Many European countries, however, have national laws for their protection.⁵

Second tier patent systems do not share the same international harmonisation as standard invention patents. In most countries that offer utility model patents, the main features that distinguish utility model patents from standard patents are the following:

- Lower cost of acquisition and maintenance
- Lower criteria of inventive step
- Quick and simple registration without substantive examination by the national patent office
- Shorter term of protection

In general, the rationale of second tier patent protection is to protect modest improvements in technical inventions that may not merit the cost of a patent application, and in so doing encourage innovation in the *fields of technology* to which second tier systems apply. These patents are particularly useful where the lifespan of the product is shorter than the time it takes to obtain a patent. In order to further accelerate the grant of

¹ Australia, Argentina, Armenia, Austria, Belarus, Belgium, Brazil, Bulgaria, China, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Malaysia, Mexico, Netherlands, OAPI, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan.

² Utility model protection exists in the following countries, under the following names: France, Certificat d'Utilite; Denmark, Brugsmode; Belgium, Brevet de Courte Duree/Octrooi van korte duur; German, Gebrauchsmuster; Spain, Modelo de Utilidad; Ireland, Short Term Patent; Italy, Brevetto per Modelli di Utilita; Netherlands, Zesjarig octrooi; Austria, Gebrauchsmuster; Portugal, Modelo de Utilidade and Finland, Nyttighetsmodellagen: G. Tritton et al, *Patents in Europe*, (2nd ed, 2002) 176.

³ In the US, standard patents for inventions are called "utility patents". This should not be confused with the utility model patents in Europe as the US has no utility model system.

⁴ Instead, the UK has argued for improved efficiency in the patent system.

⁵ Germany, Spain, France, Denmark, Portugal, Greece, Austria, Finland and Belgium have utility model protection while Luxembourg, Holland, Great Britain and Sweden have no utility model protection.

the IP right, most countries are dispensing with substantive examination for these patents. However, the protection conferred is less secure.⁶

2.2 SUBJECT MATTER OF SECOND TIER PATENT SYSTEMS

Patent law must define the classes of subject matter to which it accords protection. An examination of international practice demonstrates that the subject matter criterion for second tier patent systems varies between countries. The classes of subject matter in second tier systems are often more narrow than in the first tier systems. Utility model patents commonly accord protection to devices, tools, implements and utensils.⁷ The reasoning behind the restriction of protection to such articles is to protect modest improvements to a technical invention that has been developed by an inventor who may lack the resources to embark on full scale patenting.⁸ The narrow definition of protectable subject matter in some countries can be traced back to the first utility model patent in Germany in 1891, which was introduced to protect three dimensional products, or “models,” such as tools, implements, machinery or equipment that fulfilled a “configurational criteria”. The rationale underlying the introduction of utility model patents was to protect small, incremental improvements that were practical but did not represent a step forward in the art.⁹

Many European countries have adopted some form of registered right, which confers exclusive protection for technical inventions. Studies have shown that the main use of utility models in Europe has been in industrial sectors such as mechanical and electrical engineering, where there is a permanent need for innovation, especially for minor technical innovations.¹⁰

There is a disparity between European countries with respect to the *type* of subject matter that is protected by utility model systems. Some countries provide second tier rights over *all* patentable subject matter,¹¹ other countries restrict protection to shapes and configurations¹² and some countries exclude protection for processes and chemical or pharmaceutical products.¹³ At present, the levels of protection offered by member states differ widely, thereby hampering the level of competition and the movement of goods in the internal market.

⁶ Ladas & Parry: International Intellectual Property Lawyers, <<http://www.ladas.com/Patents/PatentPractice/PettyPatents/PettyP03.html>>.

⁷ Ladas & Parry: International Intellectual Property Lawyers, <<http://www.ladas.com/Patents/PatentPractice/PettyPatents/PettyP08.html>>.

⁸ W.R.Cornish, *Intellectual Property* (3rd ed, 1996).

⁹ Japan followed Germany's lead and introduced a similar system with a narrow definition of protectable subject matter, as did Brazil, Argentina, Mexico, Greece, Italy, Portugal and Spain. In 1990, the new *Utility Model Act* changed the criteria for protectable subject matter in Germany, such that everything that can be protected by a standard patent can also be protected by a utility model (with the exception of processes and methods).

¹⁰ European Patent Office, Vienna Sub-office, position at 8 January 1993, and survey of firms in Denmark, AIPPI Yearbook 1986, 1-4.

¹¹ Belgium, Denmark, France, Ireland.

¹² Finland, Greece, Italy and Portugal.

¹³ Austria and Germany.

2.3 EUROPEAN COMMUNITY UTILITY MODEL PROPOSAL

The European Commission is currently considering the introduction of a *Community Utility Model Convention* in order to harmonise the protection for utility model inventions in the European Community so that the rights are uniform and reciprocal. There have been many meetings and discussions throughout Europe on the desirability of the adoption of a community wide second tier protection system.

2.3.1 Max Planck Institute Model

In 1994, a working group of the Max Planck Institute (MPI) in Germany issued a discussion paper entitled *Proposal for a European Utility Model*.¹⁴ The proposal identified the following three objectives as essential for any European-wide utility model:¹⁵

- Lower costs than standard patents
- Quicker grant of an enforceable right than a standard patent
- Lower level of inventiveness than that required by a standard patent

The MPI recommended that the same subject matter protected under the patent system should be protected under the utility model, with the same exclusions applying (thus plant and animal “varieties” would be excluded).¹⁶ The proposal states that a departure from established notions in patent law regarding exclusions in a new European utility model would result in “grave confusion among patent examiners and judges”. Thus, there was a consensus among participants to adopt the wording of Article 52(2) of the European Patent Convention in the MPI proposal.

2.3.2 British Chartered Institute of Patent Agents Model

The British Chartered Institute of Patent Agents (CIPA) drafted a general proposal in response to the MPI proposal, in order to stimulate debate on the issue. One of the main points of divergence was that CIPA took a broader view than MPI and proposed that utility model protection be available for *all* subject matter, regardless of whether it would be patentable.¹⁷ Thus under the CIPA model, types of subject matter which are excluded from patentability for reasons of public policy, could be protected under the utility model. The reasoning was that a restriction on the scope of protectable subject matter of the utility model would limit its availability and defeat one of the main aims of the model, namely to capture inventions which are not currently patentable.

¹⁴ ‘Proposal of the Max-Planck Institute for a European Utility Model’ (1994) *IIC* 25(5) 700.

¹⁵ While the MPI proposed the creation of a unitary utility model right, it recommended that countries that had never had a utility style model should be allowed to opt out of enforcement of such a right.

¹⁶ Art. 3 of the MPI Proposal.

¹⁷ Chartered Institute of Patent Agents, *Second Tier Protection: Proposals and Discussion Paper* (CIPA, 1993), discussed in *Report and Proceedings of the Bocket Hall Symposium* CIPA 1994.

2.3.3 Brocket Hall Symposium on Second Tier Protection

Both the MPI and CIPA proposals were debated at the Brocket Hall Symposium on second tier protection in 1994. The restriction of the scope of subject matter by the MPI proposal was met with criticism. However, there were also concerns that the CIPA model would allow unexamined rights over material that should not be the subject of intellectual property protection due to public policy reasons. Interestingly, neither proposal suggested that subject matter should be confined to technical inventions, such as three-dimensional products as in the original German utility model. The MPI proposal specifically noted that access to utility model protection is *not* limited to inventions which appear in “three-dimensional form” nor are “methods” excluded from protection” under their proposal.

Overall, the British industry opposed the introduction of a European utility model while representatives of CIPA and the British Patent Office believed that such a model would benefit small and medium-sized firms.

2.3.4 International Association for the Protection of Intellectual Property

In 1994 and in 1995, the International Association for the Protection of Intellectual Property (AIPPI) examined the issue of a community utility model and tried to achieve consensus among participants on the subject matter of protection and the scope of the requirement of novelty. At both meetings, many countries displayed a hostile attitude towards the initiative. The participants did not concur on the requirements of the model and the resolution was not adopted.¹⁸ The special AIPPI committee on the harmonisation of the existing utility model protection systems has since been dissolved.

2.3.5 European Commission Green Paper and Proposed Directive

In July 1995, the European Commission released a *Green Paper* on the protection of utility models in the single market, inviting interested parties to comment on three main options.¹⁹ The options were a Directive to make all national laws consistent; a broader provision enabling protection of a utility model in one country to be recognised in another; and the creation of an overarching Community-wide utility model system. Only one third of the responses to the green paper were in favour of setting up a Community-wide utility model.²⁰ The majority of the responses rejected the model²¹ because a single right would be too costly²² and would not correspond to the real needs of industry.²³

¹⁸ AIPPI Council of Presidents Meeting, Harmonisation of the Existing Utility Model Protection Systems, (AIPPI, Oslo 1999).

¹⁹ European Commission, The Protection of Utility Models in the Single Market, Green Paper (1995) COM(95) 370 final.

²⁰ European Commission Staff Working Paper, Consultations on the Impact of the Community Utility Model in order to Update the Green Paper on the Protection of Utility Models in the Single Market (COM(95)370final), (Brussels, 2001) at 6.

²¹ European Commission, Consultations on the Impact of the Community Utility Model in order to Update the Green Paper on Protection by the Utility Model in the Internal Market, (Brussels, March 2001) at 6.

²² Regulation would require unanimity under Article 308 of the EC Treaty and thus could result in exorbitant costs.

In December 1997, the European Commission presented a proposal for a Directive on the protection of utility models.²⁴ It was subsequently amended to take into account comments of the European Parliament and re launched in 1999.²⁵ Under the proposed scheme, the criteria for a utility model would basically be the same as for a patent, except that the level of inventiveness required would be lower.²⁶

The proposal provided that utility models should be granted for *all* products and processes, apart from the following subject matter:²⁷

- Inventions, the exploitation of which would be contrary to public policy or morality;²⁸
- Inventions relating to biological material;
- Inventions relating to chemical or pharmaceutical substances or processes;
- Inventions involving computer programs.

In 2001, the European Commission published a Staff Working Paper inviting public comments on the introduction of a Community Utility Model, with a view to updating the 1995 *Green Paper*.²⁹ The results of a public consultation on the impact of such a model were reported in March 2002.³⁰ The consultation only received 47 responses, mainly from governments and ministries of Member States, professional associations and companies. Three-quarters of respondents opposed the introduction of a Community Utility Model due to concerns regarding the risk of decreasing competitiveness of EU companies, the risk of decreasing legal certainty, and the unsatisfactory criteria of the level of inventiveness. A further objection was the disproportionality of creating such a right at a Community level as utility models are predominantly used for national protection purposes. Most of these opponents sought to abandon any initiative on the model, while a number were in favour of a recommencement of work on the proposed Directive to harmonise national laws.

Consultations continue on the issue and as yet there is no community level utility model, though most of the European community member states provide national utility model protection.

²³ Protection by utility model is rarely sought in more than 3 to 5 Member States and never in the whole EU.

²⁴ <http://www.patent.gov.uk/about/press/releases/1998/europarl.pdf>

²⁵ http://www.europa.eu.int/comm/internal_market/en/indprop/model/utilityen.pdf

²⁶ Inventiveness would be satisfied if a product or process represents an advantage and, from the point of view of a skilled worker, is not very obviously derived from the state of the art.

²⁷ Commission of the European Communities "Proposal for a European Parliament and Council Directive for the Protection of Inventions by Utility Model", Article 4 (Brussels, 1997).

²⁸ Provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all Member States. See section 3.2.2 for discussion regarding whether the public policy and morality exclusion could include plant and animal subject matter.

²⁹ European Union, <http://europa.eu.int/comm/internal_market/en/indprop/model/utlreport_en.pdf>.

³⁰ European Commission, Summary Report of Replies to the Questionnaire on the Impact of the Community Utility Model with a View to Updating the Green Paper on Protection by the Utility Model in the Internal Market, (Brussels, March 2002).

<http://www.europa.eu.int/comm/internal_market/en/indprop/model/utlreport_en.pdf>.

2.4 SUMMARY AND CONCLUSIONS

Second tier patent protection is widespread throughout the world. The analysis of overseas jurisdictions has shown that the main rationale for providing second tier patent protection is to supplement an existing patent system by protecting innovations that have a lower level of inventiveness than that required for standard patent protection. A secondary aim is to provide a procedure for granting protection in a short period of time, with decreased costs. The overall objective is to encourage innovation in the fields of technology to which second tier patent protection applies.

In some countries, the area of protected subject matter of second tier patents is identical to the patent system, while in other countries the scope of the subject matter is more narrow. Studies have shown that the main use of utility models in Europe has been in industrial sectors such as mechanical and electrical engineering, where there is a permanent need for innovation, especially for minor technical innovations. In Europe, despite many symposiums, working papers and proposals, there seems to be a general resistance to an expansion of second tier protection across Europe and disagreements between countries on the requirements of such protection, including the scope of protectable subject matter.

3. Intellectual Property Rights for Plant and Animal Subject Matter

This section will examine the rationale underlying the granting or denial of intellectual property rights for plant and animal subject matter.

3.1 ETHICAL ISSUES

3.1.1 Plant Subject Matter

The main ethical objections to allowing the patenting of plants are:³¹

- Life should not be regarded as a commodity and thus living organisms and living matter should not be patented;³²
- Genetic resources are our common heritage and a monopoly should not be granted over such resources³³
- Patents on biological inventions derived from plants and animals should not be granted without recognising traditional knowledge

³¹ Australian GeneEthics Network, Submission no. 71 to House of Representatives Standing Committee on Primary Industries and Regional Services Report on Primary Producer Access to Gene Technology, titled “Work in Progress, Proceed with Caution”, (2000) 11.

³² G.V.Overwalle, ‘Patent Protection for Plants: A Comparison of American and European Approaches’ (1999) 39 *J.L & Tech.* 143 at 150.

³³ C. Colston, *Principles of Intellectual Property Law*, (1999) 77.

In Australia, the requirements of novelty and inventive step can help to ensure that resources that form part of our common heritage are not patentable. Indeed, the House of Representatives Standing Committee on Primary Industries and Regional Services *Report on Primary Producer Access to Gene Technology* stated that the current practice in Australia of regarding the identification of genetic sequences as mere discoveries “meets some of the objections of those opposing patents on living organisms while still encouraging innovation”.³⁴ There is currently a considerable movement underway to formulate an international norm for protecting traditional knowledge and providing for equitable benefit sharing.³⁵

3.1.2 Animal Subject Matter

The main ethical objections to allowing the patenting of animals are:³⁶

- Interference with nature
- Devaluation of animal life
- Suffering of agricultural and laboratory animals.

The first objection, relating to interference with nature, encompasses the concern that the patenting of animals will lead to a decline in the genetic diversity in commercialised species. Animal patenting supporters note the possibility of this occurring but add that this development was already occurring with animal husbandry. A further response is that research and cryopreservation of DNA samples can aid in the improvement of the genetic diversity of endangered animals.

The second objection is that the value of animals would be undermined by patenting, due to a human-centred view of the world where all resources (including living things) exist for human exploitation. However, humans have ‘objectified’ animals for many thousands of years by treating animals as property to possess, and using them for such purposes as eating or trading.

The third objection derives from a fear that the issuance of patents on animals will contribute to the suffering of animals in both research and agricultural contexts. The creation of transgenic animals by the introduction of foreign genes could cause animal suffering. However, these technologies could also speed the development of preventions and cures for animal diseases. Another consideration is whether the potential for animal suffering could be outweighed by the possible benefits to mankind from the research.

³⁴ House of Representatives Standing Committee on Primary Industries and Regional Services Report on Primary Producer Access to Gene Technology, titled “Work in Progress, Proceed with Caution”, (2000) 109.

³⁵ See for example: Draft EC submission to WTO TRIPs Council, *Review of Article 27.3(b) of the TRIPs Agreement and the Relationship Between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore* (Working Document of the Commission Services, 2002), see also WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore at <<http://www.wipo.int/eng/meetings/2001/igc/index.htm>>.

³⁶ Animal Patents: The Legal, Economic and Social Issues. Ed. W.H.Lesser, Macmillan Publishers Ltd, 1989 New York. E.S. Van de Graaf, “Patent Law and Modern Biotechnology”, 1997 at 68.

In response to all of these concerns, many commentators argue that the patent law is not the appropriate realm to assess moral and public policy objections to scientific research. Instead, regulatory bodies should be used to control scientific, technical or medical practice and research due to ethical, health, safety and environmental concerns.³⁷ If an activity is deemed to be unacceptable, then the legislature has the power to make such an activity illegal rather than attempting to regulate and control it by way of patenting.³⁸ Indeed, patents only confer the right to prevent the activities of people other than the patentee and thus refusing to grant a patent would not provide the requisite control to prohibit further research and development.³⁹ An example of legislative control of scientific activity in Australia is found in the *Gene Technology Act 2000*, which provides a regulatory framework for managing gene technology in order to protect the health and safety of people and the environment.⁴⁰

The converse argument to the provision of legislative measures for regulation of research is that patents provide an incentive to research and development of new technology and thus the state cannot adopt a morally neutral stance about what kinds of inventions are protected by patent law.⁴¹ Instead, the state should define which inventions are morally repugnant and exclude such inventions from eligibility for patenting.⁴² A response to this argument is that patent examiners often do not possess the relevant expertise to make ethical decisions and such cases are often prolonged and clog up the patent examination process.⁴³

³⁷ C.Colston, *Principles of Intellectual Property Law*, Cavendish Publishing Ltd, London 1999.

³⁸ AIPPI Report, United Kingdom, Report Q 159 'The Need and Possible Means of Implementing the Convention on Biodiversity into Patent Laws'.

³⁹ W. R. Cornish, *Intellectual Property* (3rd ed, 1996) 195.

⁴⁰ Another example is in Europe, the European Commission's Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology, as mandated by Article 7 of the Directive on the Legal Protection of Biotechnological Inventions.

⁴¹ M. Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *AIPJ* 202.

⁴² W. R. Cornish, *Intellectual Property* (3rd ed, 1996) 195.

⁴³ *Ibid.*

3.2 LEGAL ISSUES

3.2.1 European Patent Convention and UPOV

Plant Subject Matter

In the 1960's in Europe, patent law was considered unsuitable for protecting new plant varieties that were created using traditional breeding methods.⁴⁴ Although plant varieties were not considered suitable for patenting, it was recognised that there was a need to provide an alternative form of protection. Plant variety rights schemes were developed in some countries as well as the International Convention for the Protection of New Varieties of Plants (UPOV Convention)⁴⁵. The *Strasbourg Convention of 1963*⁴⁶ provides that Contracting States are not bound to provide patents for plant and animal varieties. In 1973, the European Patent Convention (EPC) was signed, creating a regional arrangement that allows patent protection to be obtained in 19 member states⁴⁷ by filing a single patent application at the European Patent Office (EPO). For legislative simplicity, the EPC⁴⁸ adopted the wording of the *Strasbourg Convention* and specifically excluded “plant varieties” from patentability since they are protected under the UPOV Convention⁴⁹ and national plant breeders’ rights laws.⁵⁰ At the time when these legislative instruments were developed, the potential importance of biotechnology could not have been foreseen.⁵¹

While the exclusion of “plant varieties” in article 53 of the EPC might seem to prohibit the patenting of plants in any form, the practice of the EPO has been to narrowly interpret this exclusionary provision as functioning to prevent conflict between patent and PVR

⁴⁴ The products of plant breeding were considered not to fulfil the patentability requirements of novelty, inventive step and disclosure due to certain practical aspects. The first practical aspect is that plant breeding depends on sexual reproduction, which is susceptible to genetic mutation according to Mendelian hereditary laws. The second consideration was that the development of a plant variety necessarily required testing at public testing lots, and thus the plants are publicly available at an early stage. Thirdly, new plant varieties are often distinct from another plant variety but without an improved characteristic and thus may not be considered “inventive” in the sense of patent law. E.S. Van de Graaf, *Patent Law and Modern Biotechnology* (1997) 81. Another objection that the products of plant breeding did not result from a creative process and could not be considered as inventions, as contemplated by patents law. G.V.Overwalle, ‘Patent Protection for Plants: A Comparison of American and European Approaches’ (1999) 39 *J.L & Tech.* 143 at 150.

⁴⁵ International Convention for the Protection of New Varieties of Plants, Dec.2, 1961, 33 U.S.T. 2703, 89 T.I.A.S. 100199.

⁴⁶ Council of Europe, <<http://conventions.coe.int/Treaty/EN/Treaties/Html/047.htm>>.

⁴⁷ Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom (19). Extension States (expected to become members in due course): Albania, Latvia, Lithuania, Romania, Slovenia, The Former Yugoslav Republic of Macedonia (6).

⁴⁸ EPC, Art. 53. The exclusion was originally formulated in the Strasbourg Harmonisation Convention of 1963, Art. 2.

⁴⁹ International Convention for the Protection of New Varieties of Plants, Dec.2, 1961, 33 U.S.T. 2703, 89 T.I.A.S. 100199.

⁵⁰ See, e.g. Decision G0001/98, *Novartis*.

⁵¹ G. Paterson, *European Patent System: The Law and Practice of the European Patent Convention*, (1992) 335.

systems.⁵² The EPO considers that the purpose of the EPC exclusion was that European patents should not be granted for subject matter under which patentability was excluded by the prohibition of dual protection under the UPOV Act.⁵³ Article 2 of the 1961/1972 and the 1978 UPOV Act bans state parties from providing protection both by means of a “special title of protection” and a patent, for the same botanical genus or species.⁵⁴ The Board of Appeal in *Novartis* noted that the preparatory documents of the EPC did not suggest that the EPC should exclude subject matter for which there was no plant variety right protection – indeed, the EPC and the 1961 UPOV Convention were intended to be *complementary*.⁵⁵ Thus the Board of Appeal held that a claim is in respect to plant varieties (and therefore should not be granted) only where the claimed subject matter is directed to plant varieties. Claims in which specific plant varieties are not individually claimed are not excluded from patentability. This examination practice is considered to be equally applicable to animal varieties. This approach has been adopted by the EPO Implementing Guidelines, which provide that an invention concerning plants and animals is patentable so long as the “technical feasibility” is not confined to a particular plant or animal variety.⁵⁶

The prevailing interpretation by the EPO seems to be that the provisions do not exclude claims for plants “*per se*” but only claims for “varieties” of plants. Transgenic plants can be patented, so long as they are not expressed in “plant variety” terms and the invention is not confined to the modification of a particular plant variety. There seems to be increasing awareness that plant variety rights are more equipped to protecting plants at the varietal level while patents are suited to protecting products of plant biotechnology.

Animal Subject Matter

Article 53 of the EPC also excludes “animal varieties” from patentability. There is no international system for the protection of animal varieties and no particular justification for treating plant varieties and animal varieties in the same way.⁵⁷ The preparatory

⁵² In *Ciba Geigy* (EPO T 49/83 – OJ 1984, 112) the EPO held that treated plants were capable of protection if the invention is not limited to a specific plant variety. This line of reasoning was not followed by the EPO in *Plant Genetic Systems*, where the EPO held that a plant becomes a plant variety when its genotype is altered by genetic engineering such that it satisfies the UPOV definition of stability, homogeneity and capability of propagation. In practical terms, if UPOV protection was available, then patent protection should not be granted. Thus the EPO held that it would not allow a claim that included plant varieties within its broad scope. This decision forced the EPO to change their practice of granting patents to genetically engineered plants. The Enlarged Board considered that the decision did not conflict with *Ciba Geigy* nor *Harvard Oncomouse* (T 1054/96). After much controversy, *Novartis* (G 0001/98, 20 December 1999, OJ EPO 2000, 111) appealed a test case relating to genetically modified plants and the Enlarged Board of Appeal held that a claim will *not* be excluded from patentability under the EPC where specific plant varieties are *not* individually claimed.

⁵³ *Novartis*, Decision T 1054/96 Technical Board of Appeal 3.3.4., at 3.6, 13 October 1997.

⁵⁴ This article was removed in the 1991 Act, such that dual protection by plant variety rights or patents is no longer prevented (in order to allow Japan and the United States to ratify the UPOV Convention). The allowance of dual protection opens the way for member states to allow patenting of animal and plant varieties. Of the 50 UPOV members, however, only 19 are signatories to the 1991 Act.

⁵⁵ *Novartis*, Decision T 1054/96 Technical Board of Appeal 3.3.4., at 3.6, 13 October 1997.

⁵⁶ Rule 23c(b). This rule was modified to incorporate the *Novartis* decision.

⁵⁷ W.R.Cornish, *Intellectual Property* (3rd ed, 1996) 191.

documents for the EPC do not refer to the purpose of excluding animal varieties from patentability.⁵⁸ It seems that animal varieties were excluded from patent protection under the EPC on ethical grounds, because there was no well-founded legal or economic reasoning for the exclusion and it does not seem to be in accordance with original intention of contracting states.

As with plant varieties, the EPO has construed the article narrowly, showing a willingness to grant patents for animals. Since there is no established system for protecting animal varieties, there is no established definition of what exactly constitutes an animal variety. Indeed, it has been noted in the first Board of Appeal decision dealing with the patentability of an animal (*Harvard Oncomouse* case) that the terminology of “animal varieties” has a different meaning in the three official languages.⁵⁹ This was used as an indication that the legislature intended to exclude patents on “animal varieties” rather than animals generally.

The Technical Board of Appeal of the EPO held that the expression “animal variety” refers to the lowest subdivision of species rather than something more general. Therefore, a claim for a mouse that was genetically manipulated to be sensitive to carcinogenic substances was not an animal variety and thus could be patentable under the EPC. It seems that the EPO transferred the reasoning applied in relation to plant varieties to animal varieties.⁶⁰ The Board addressed the concept of “ordre public” or “morality” by applying a balancing test which involves a “careful weighing up of the suffering of animals and possible risks to the environment on one hand, and the invention’s usefulness to mankind on the other”.⁶¹ The benefit of the Harvard Oncomouse invention to mankind in facilitating cancer research was found to outweigh possible animal suffering or environmental risks. Thus, the Harvard Oncomouse constituted patentable subject matter. Oppositions to this patent have been filed by many individuals, animal rights groups and church organisations, and are still yet to be resolved.

3.2.2 European Directive on the Legal Protection of Biotechnological Inventions

The objectives of the European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions (1998) are to clarify the distinction between what is patentable and what is not, to harmonise national patent laws in the EU, and to provide uniform legal interpretation of specific points in relation to the patenting of living materials.⁶² The Directive ensures the patentability of living matter (“biological material”) in general and establishes a narrow and specific exclusion in relation to plants and animals. The Directive provides that “plant and animal varieties and essentially biological processes for the production of plants or animals, including crossing or selection, are not patentable”.⁶³ Thus, parts of animal varieties or animals produced by a

⁵⁸ R. Nott, ‘Patent Protection for Plants and Animals’ (1992) 14(3) *EIPR* 79 at 82.

⁵⁹ In German the term could refer to an entire animal species whereas in English and French it would only refer to a subspecies. *Harvard/Oncomouse* [1990] O.J. EPO 476.

⁶⁰ W.R.Cornish, *Intellectual Property* (3rd ed, 1996) 193.

⁶¹ *Id* at 470.

⁶² Directive on the Legal Protection of Biotechnological Inventions (1998).

⁶³ Art. 4.

patented method such as genetic engineering can be patented in the EU. However, the Directive authorises EU Member States to *exclude* biotechnology inventions from patentability where their commercial exploitation conflicts with “ordre public” or morality. The Directive contains an illustrative list of examples of such inventions, which includes 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.

Plants and animals could also be excluded from patentability under the public policy and morality exception in the Directive. This exception is also included in the EPC in relation to standard patents⁶⁴ and has caused much debate (as mentioned above).⁶⁵ The EPO Guidelines interpret the public policy exception as a test of whether the public would consider the invention so abhorrent that the grant of patent rights would be inconceivable.⁶⁶

The Directive entered into force in July 1998 and was to be implemented by Member States by July 2000.⁶⁷ Although the Directive does not possess binding force on the EPO, it has an indirect effect on the practice under the EPC.

3.2.3 United States

Plant Subject Matter

The United States provides patent protection for “anything under the sun that is made by man” following the decision of *Diamond v. Chakrabarty*⁶⁸ in 1980 where the Supreme Court held that genetically altered bacteria constituted statutory subject matter. The Court further stated that when determining patentability, the relevant distinction is not between living and inanimate things, but whether living products could be seen as ‘human-made’ inventions. According to the Supreme Court, a determination of patentability based on public safety concerns should be left to the legislative sphere rather than the court system. While patents have been granted since 1930 in the United States for plants under the *Plant Patent Act*, until the *Chakrabarty* decision in 1980 the USPTO would not grant utility (ie standard) patents separate from the *Plant Patent Act* because it deemed products of nature not to be within the terms of the utility patent statute.

⁶⁴ Art. 53(a).

⁶⁵ These arguments against could apply equally to the analogous exclusion for utility model patents in the Proposed Utility Model Directive. The proposed Directive on utility models did not exclude plant and animal varieties, except such varieties that would be considered under the definition of “biological material”. The Directive does not provide a definition of “biological materials”. The European Commission justified their exclusion on the basis that such inventions call for a long period of preparation before being placed on the market and thus require patent protection. See European Commission, ‘Proposal for a European Parliament and Council Directive for the Protection of Inventions by Utility Model’ Part 5, Examination of the Provisions.

⁶⁶ Section C-IV, 3.1.

⁶⁷ Art. 15 of the Directive mandated the date of implementation. As of April 2001, the UK has implemented articles 1-11 and the implementation of articles 12-14 were expected and Denmark, Ireland and Finland have implemented the directive.

⁶⁸ *Diamond v. Chakrabarty* 447 U.S. 303 (1980).

The subsequent decision of *Ex parte Hibberd*⁶⁹ further extended the scope of patent protection in the US. The 1985 case of *Ex parte Hibberd* followed the *Chakrabarty* principle and held that US utility patents could be granted for genetically modified plants regardless of the protection available under the *Plant Patent Act of 1930* and the *Plant Variety Protection Act of 1970*. In 2001, the Supreme Court held that newly developed plant breeds (and thus sexually reproduced plants) are patentable subject matter, and that utility(standard) patents may be issued for plants.⁷⁰

Animal Subject Matter

The *Chakrabarty* decision provided the grounds for granting patents for higher life forms. In 1987, the Board of Appeal in *Ex parte Allen*⁷¹ considered animals to be patentable subject matter by holding that polyploid oysters were a non-naturally occurring manufacture or composition of matter and satisfied the criteria for proper subject matter. The court relied on the *Chakrabarty* decision and placed little emphasis on the ethical and moral objections to the granting of patents for living matter. Soon after the *Allen* decision, the USPTO issued an announcement that the US patents would be granted for “non-naturally occurring non-human multicellular living organisms including animals”.⁷² Subsequently, the USPTO issued a patent in 1988 to a transgenic mouse known as the Harvard Oncomouse. Although heated debates ensued concerning the patentability of an animal, the USPTO has accepted transgenic animals as patentable subject matter.

Public outrage surrounding animal patenting was evidenced in the 1989 Animal Legal Defence Fund challenge,⁷³ when animal and farmers rights groups argued that the USPTO did not possess the authority to issue the 1987 statement on the patentability of animals. The court held that the appellants lacked standing and rejected their arguments that the general public has an interest in limiting patentability by statute. The court did not address wider societal concerns regarding animal patenting but stated that the appellant’s action may not have the desired effect of preventing animal development research because excluding subject matter from patentability does not prohibit research or development on animals. The court noted that under the principles espoused by the *Chakrabarty* decision, the question in determining patentability is simply whether the “subject matter is made by man.”⁷⁴

⁶⁹ 227 USPQ 443.

⁷⁰ *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 122 S.Ct. 593 (2001).

⁷¹ *Ex parte Allen*, 2 U.S.P.W.2d (BNA) 1425, 1425-27 (PTO Bd. Pat. App. & Inter. 1987).

⁷² Animal-Patentability, 1077 Official Gazette of USPTO 24 (1987).

⁷³ *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 924 (Fed. Cir. 1991).

⁷⁴ Id at 928, citing *Ex parte Allen*.

3.2.4 Canada

At present in Canada, there seems to be no common understanding regarding whether patent law extends to higher life forms. The Canadian Patent Office has consistently held the view that while the Canadian *Patent Act 1985* does not exclude plant and animal subject matter as such, the Act does not allow the patenting of higher life forms such as plants and animals.⁷⁵ The Government of Canada supports this interpretation.⁷⁶

However, in August 2000, the Federal Court of Appeal in the “Harvard Oncomouse” case, interpreted the definition of “invention” in the Act as including genetically modified, non-human mammals, and placed considerable reliance on the majority opinion of the United States Supreme Court in *Chakrabarty*.⁷⁷ The “Harvard Oncomouse” case has caused much controversy in Canada. The claim was filed by Harvard University in Canada in 1985 and it was rejected by the Canadian Patent Office in 1993, who held that the animal was made primarily by nature rather than humans. The Commissioner of Patents upheld the rejection in 1995, as did a federal trial court in 1998. A majority of the Canadian Federal Appeals Court reversed these decisions in August 2000 and approved the patent, stating that the patenting of animals was not prohibited by the Canadian Patent Act. The Federal Appeals Court held that there may be policy reasons against the patentability of higher life forms, however, such arguments are for Parliament and not the Courts. This decision set a new precedent, making higher life forms patentable in Canada.

However, the Canadian Federal Government has appealed to the Supreme Court of Canada, arguing that parliament is a more appropriate place to address such a complex question and emphasising the need for public dialogue on the patenting of higher life forms.⁷⁸ The government has recognised the issue as one of significant public interest and established the Canadian Biotechnology Advisory Committee in September 1999. The Committee was given a mandate to provide the government with policy advice on matters relating to biotechnology. The Committee released a report on the *Patenting of Higher Life Forms and Related Issues*⁷⁹ in June 2002, which recommended that higher life forms (seeds, plants and non-human animals) that meet the criteria in the Patent Act, should be patentable, subject to certain limits.⁸⁰ This is the interpretation that the Federal

⁷⁵ Manual of Patent Office Practice, Ch. 16, section 16.05 Living Matter and section 16.04 Examples of Non-Statutory Subject-Matter.

⁷⁶ See Industry Canada, ‘The Government Seeks Leave to Appeal the Federal Court of Appeal Decision on the Harvard Oncomouse Case to the Supreme Court,’ <http://strategis.ic.gc.ca/sc_mrksv/cipo/corp/corp_appeal-e.html>.

⁷⁷ *President and Fellows of Harvard College v. Commissioner of Patents [Respondent] and Canadian Environmental Law Association [Intervenor]* (2000) A-334-98.

⁷⁸ See Industry Canada, ‘The Government Seeks Leave to Appeal the Federal Court of Appeal Decision on the Harvard Oncomouse Case to the Supreme Court,’ <http://strategis.ic.gc.ca/sc_mrksv/cipo/corp/corp_appeal-e.html>.

⁷⁹ Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* (2002).

⁸⁰ Limits include exceptions for farmers, innocent bystanders (see *Monsanto Canada Inc. v. Schmeiser*) and research and experimental use.

Court of Appeal endorsed in the "Harvard Oncomouse" case. The Canadian government has not yet responded to this report.

The Supreme Court of Canada is currently considering the appeal by the government and is expected to release a decision soon.⁸¹ If the Supreme Court affirms the Federal Appeals Court decision and holds that higher life forms are patentable, the government could still impose limitations on their patentability through the parliamentary process, subject to Canada's international obligations.⁸² While the status of the patentability of transgenic organisms in Canada is currently undetermined, in view of the recommendations of the Biotechnology Advisory Committee and the Federal Court of Appeals decision, it is likely that this subject matter will be regarded as patentable in Canada soon.

3.2.5 Japan

Like the EPC and the European Directive, Japanese patent law excludes from patentability inventions that are contrary to public order or morality.⁸³ However, unlike the EPC and the Directive, the Japanese Patent Office (JPO) considers that morality and safety issues are irrelevant for the purposes of determining whether animals are eligible for patenting; rather these should be addressed by other legal measures.⁸⁴ Thus, in Japan, as in the US, animal and plant inventions constitute patentable subject matter.⁸⁵ Japanese patent law makes no distinction between plant and "varieties" and plants and animals themselves.

3.2.6 International Obligations under the TRIPs Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) mandates that member states must establish minimum standards of intellectual property protection, and includes the requirement that member states protect product and process inventions in all fields of technology.⁸⁶ However, the TRIPs Agreement permits members to exclude from patentability inventions which should be prohibited in order to "protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment".⁸⁷ The TRIPs Agreement also allows member states to exclude plants and animals from patentability but provides that members must provide for the protection of plants either by patents, an effective *sui generis* system, or by any combination thereof.⁸⁸ The obligation to provide some type of protection allows members to choose what kind of

⁸¹ *The Commissioner of Patents v. The President and Fellows of Harvard College* (FC) (Civil) (By Leave) (28155). The Supreme Court hearing was on May 21, 2002.

⁸² Under TRIPs and the North American Free Trade Agreement (NAFTA), countries may not discriminate between one technology and another.

⁸³ Japanese Patent Law, Law No. 121 of 1959, amended by Law No. 220, Article 32.

⁸⁴ A. Watanabe, 'Animal Patent Protection' (1994) 3 *Inst. Intell. Prop. Bull.* 140 at 144.

⁸⁵ In June 1993, JPO issued patent examination guidelines for living organisms, which specified that inventions relating to animals and methods for producing animals are eligible subject matter for patenting.

⁸⁶ Art. 27(1).

⁸⁷ Art. 27(3).27(2).

⁸⁸ Art. 27(3)(b).

protection to adopt. The TRIPs Agreement gives no guidance as to what is an “effective *sui generis* system” and there is no agreed interpretation of this term among WTO members.⁸⁹ This article of the TRIPs Agreement was modelled on the similar provision in the EPC (indeed, it was adopted due to pressure from EC member states and developing countries⁹⁰) but the exception goes beyond the EPC exclusion of plant and animal “varieties”. Australia has implemented the *Plant Breeders Right’s Act 1994* as an effective *sui generis* system in accordance with the TRIPs Agreement and the UPOV Convention 1991.

The Commission on Intellectual Property Rights has issued a report that recommends that developing countries should not provide patent protection for plants and animals but should consider different forms of *sui generis* systems due to restrictions that patents may place on the use of seed by farmers and researchers.⁹¹

Article 27.3(b) of the TRIPs Agreement provides that the potential for exclusion from patentability of plants and animals should be reviewed four years following the date that the TRIPs Agreement enters into force. The review is currently underway, and it is likely that some countries (mostly developing nations) will support maintaining or expanding this section while other countries (such as the United States) may campaign for a narrowing or elimination of the section.⁹²

3.3 SUMMARY AND CONCLUSIONS

The patenting of plants and animals has raised a plethora of moral and ethical questions relating to animal rights, biodiversity, recognition of traditional knowledge and the commodification of life. These objections are valid and should be addressed by the legislature. In such a controversial area where so there has been so much public resistance to patenting, the legislature should bear the burden to prove that the benefits of the stimulation of innovation in this area outweigh the possible risks involved. Indeed, under the EPC, Japanese patent law and the TRIPs Agreement, inventions can be excluded on the grounds of public policy or morality.

Most member countries of the Organisation for Economic Co-operation and Development (OECD), including the US and the European Union, allow for the patenting of plants and animals. In the European Community “plant varieties” are excluded from patentability under the EPC due to the existence of an alternative form of protection

⁸⁹ Interestingly, the Council and the Office of the Union of UPOV maintain that the UPOV Act is the only internationally recognised *sui generis* system for the protection of plant varieties. CEAS Consultants, The Relationship Between the Agreement on TRIPS and Biodiversity Related Issues (Report for DG Trade European Commission) at 25. <http://europa.eu.int/comm/trade/pdf/ceas_final.pdf>.

⁹⁰ F. Beier, G. Schricker [Eds], ‘From GATT to TRIPS – The Agreement on Trade Related Aspects of Intellectual Property Rights’ IIC Studies, vol. 18.

⁹¹ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, (London 2002).

⁹² The review has raised broader issues of the relationship between intellectual property rights under TRIPS and biodiversity under the Convention on Biodiversity. Australia has submitted a paper to the TRIPs Council on this issue in September 2001, see <http://www.dfat.gov.au/ip/trips_27b.doc>.

under the UPOV Convention and Plant Variety Rights legislation. While the prohibition on dual protection under the UPOV Convention no longer exists, it still provides the historical, underlying justification why the patenting of plants is prohibited. Animal varieties are treated in the same way even though there is no other means of patent protection for animals. It is hard to justify their exclusion from patenting, except for reasons of ethics and morality, as discussed above. In relation to standard patents, the EPO construes the exception of “plant and animal varieties” narrowly, and shows a willingness to grant claims to plant and animal subject matter.

In Japan and the US, plants and animals constitute eligible patentable subject matter. The US Supreme Court in the famous case of *Chakrabarty* held that the only question in determining patentability is simply whether the “subject matter is made by man”. In Canada, the patenting of plants and animals is currently unsettled. A clear position will emerge once the Supreme Court delivers its decision in the *Harvard Oncomouse* case and the Government responds to the Canadian Biotechnology Advisory Committee recommendations. The TRIPs Agreement allows member states to exclude plants and animals from patentability but provides that members must provide for the protection of plants either by patents or by an effective *sui generis* system.

4. Conclusions for Australia

The analysis of overseas jurisdictions has shown that the main justification for providing second tier patent protection is to supplement an existing patent system by providing fast and cheap protection of innovations that have a lower level of inventiveness than that required for standard patent protection. The aim is to stimulate innovation in the field of technology to which this protection applies. An examination of international practice demonstrates that the subject matter criterion for second tier patent systems varies considerably between countries. Some countries provide second tier rights over *all* patentable subject matter, other countries restrict protection to shapes and configurations, and some countries exclude protection for processes and chemical or pharmaceutical products. There is no overseas precedent to support the *exclusion* of specific subject matter from second tier patent systems. Australia’s current position of excluding plant and animal subject matter from innovation patents does not conform to international practice of exclusions, nor does it fit with the original rationale of second tier protection.

Intellectual property rights with respect to plant and animal subject matter have engendered controversy world wide. There is evidence of reluctance in Europe and Canada to grant intellectual property rights with respect to plant and animal subject matter. Even though most European countries have adopted some form of utility model protection, there seems to be general unwillingness to adopt a community-wide utility model. There were significant disparity in stakeholder views, some which may have been caused by disagreement as to the type of subject matter to which utility model protection should apply. This may suggest that there is support for utility model protection when confined to traditional technical subject matter, but resistance against a wider scheme that would apply to all patentable subject matter.

While the exclusion of plant and animal subject matter from the innovation patent in Australia may not be consistent with international practice, this should not lead to an automatic expansion of protected subject matter. Rather, the focus should be on examining whether the *inclusion* of this particular subject matter is appropriate and justified. It has been argued by one commentator that where the system of second tier patent protection has been confined to technical design then it meets its aim of protecting modest improvements; however, where the system is expanded to encompass *all* patentable subject matter the patent holder may be entitled to a claim that is so broad that the patent system may not be able to sustain it.⁹³ Thus a patent holder may be able to acquire extensive, unexamined protection for the first eight years, and thereafter acquire a standard patent for as much as he or she could justify.⁹⁴

In conclusion, it is not enough to argue that since there is not sufficient evidence of international practice to justify the *exclusion* of plant and animal subject matter, such subject matter should be included in the material to which the innovation patent regime applies. Where there is public resistance to the provision of intellectual rights over particular subject matters, the burden shifts to the legislature to prove that there are reasons to justify the *inclusion* of those subject matters within the realm of protection. Plants and animals, being higher order life forms, are examples of subject matters for which there is public resistance to patenting. It has been recognised in Europe that this issue should be addressed with caution due to the different societal values that come into play.⁹⁵ Australia must balance ethical, economic and other concerns in deciding whether to grant *additional* intellectual property rights for plant and animal subject matter.

The aim of second tier patent protection is to stimulate innovation *in particular industries*. The key question is whether there is evidence that the plant and animal industries are lacking innovation and require the availability of the innovation patent as an incentive for greater investment in research, development and commercialisation of plant and animal subject matter. This submission does not provide any empirical evidence of this type, but emphasises the importance of such evidence in the debate. In the absence of evidence showing further intellectual property rights are required, the extension of the innovation patent to plant and animal subject matter should not occur.

⁹³W.R.Cornish, *Intellectual Property* (3rd ed, 1996) 107.

⁹⁴Tootal [1994] *EIPR* 511.

⁹⁵Draft EC submission to WTO TRIPs Council, *Review of Article 27.3(b) of the TRIPs Agreement and the Relationship Between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore* (Working Document of the Commission Services, 2002) at 8.