First published in *The UNE Law Journal*, volume 1, issue 1 (2004)
Published by The University of New England

ISSN: 1449-2199
UNE Law Journal online: http://tlc.une.edu.au/lawjournal/

RIDING ON A GEEP'S BACK: PREPARING AUSTRALIAN PATENT LAW FOR A DOMESTIC INDUSTRY SOURCED IN THE TRANSGENIC ANIMAL

Kathleen Conroy*

ABSTRACT

Australia's biotechnology sector includes a transgenic animal industry. The fate of and fallout from this industry is a function of Australia's patent law. In this paper, the pivotal role of the patent in the growth of a transgenic animal industry in Australia is considered, the need to renovate Australian patent law in light of this industry discussed and a means for effecting this renovation proposed.

I INTRODUCTION

A geep[1] is a sheep whose genome has been artificially amplified with the genes of a goat. It is a transgenic animal — an animal which carries in its germplasm DNA artificially introduced from a different species. Transgenic animals began a rise to prominence in the 1970s as a result of advances in recombinant DNA technology[2] and today offer profound opportunities for medicine, agriculture, aquaculture and environmental science.

Transgenic animals have begun to make their mark. They have, for example, accelerated study into human retinal disease,

---

* Solicitor, Yandell Wright Stell, Lawyers

1 A geep is a cross between a goat and a sheep. In this regard, see, for example, Thomas Magnani, 'Biotechnology and Medical Devices: 1. Patenting Lifeforms: a) Chimeras: The patentability of Human-Animal Chimeras' (1999) 14 *Berkeley Technology Law Journal* 443, 445.

2 DNA is the general short form for deoxyribonucleic acid, the genetic unit of a cell. Recombinant DNA technology is 'cut and paste' technology. It allows single genes to be cut from the genome of one organism and inserted into that of another.

traditionally hampered by the miniscule number of donor eyes available at the early stages of retinal illness and disorder.[3] Similarly, transgenesis in the aquaculture industry has been put forward as 'the only way to sustainably increase seafood production on a global scale'.[4]

The beneficial reach of the transgenic animal is indicated by the subject matter of transgenic related patent applications held by the Australian Intellectual Property Office ('AIPO'). These include a non-human transgenic animal for determining the effect of xenobiotics or steroids on the expression of particular human genes;[5] 'transgenic animals for xenotransplantation[6] with reduced antibody-mediated rejection';[7] and a transgenic mouse modified to show cognitive behaviour characteristic of a schizophrenic for the purpose of, inter alia, developing schizophrenia remedies and diagnostics.[8]

Scientists expect that future exploitation of the transgenic animal will yield more diagnostic capabilities and pharming[9] options,[10] greater productivity from livestock and fish, environmental life guards in the form of animals that can monitor for pollution and animals with increased resistance to their natural pathogens.[11]

Australian researchers are working in the two most vibrant areas of animal transgenesis — medicine and agriculture — and are

---

3 John G Flannery, 'Transgenic Animal Models for the Study of Inherited Retinal Dystrophies' (1999) 40 (2) *ILAR Journal Online* [1] <http://dels.nas.edu/ilar/jour_online.asp?jour_online> at 6 October 2003.

4 L Galli, Bureau of Rural Sciences, *Genetic modification in aquaculture – A review of potential benefits and risks* (2002) 14.

5 Australian patent application no. AU 200213660.

6 The transplantation of organs from non-human animals into humans.

7 Australian patent no. 727546.

8 Australian patent application no. AU 200194216.

9 'Pharming' refers to the production and then farming of transgenic animals for particular proteins. The practice began commercially with the sheep, Tracey (US patent no. 5,476,995), whose genes had been augmented with those of a human so that in her milk she expressed, inter alia, human insulin and the protein alpha-1-antitrypsin.

10 Thomas S Plazinski, et al, Department of Agriculture Fisheries and Forestry, *Agricultural Biotechnology: What is happening in Australia in 2000* (2000) <http://www.affa.gov.au/content/print.cfm?objectid=D2C48F86-BA1A-11A1-A2200060B0A06254&showdocs=all> at 8 September 2003.

11 Galli, above n 4, 14.

forming domestic and international alliances to commercially exploit local inventions relevant to the transgenic animal industry.[12] This positions Australia squarely within the biotechnology revolution, which, it is argued, is destined not just to improve existing industries but to replace them.[13]

Understandably, the Australian Federal Government ('the Government') is keen to secure the economic and social benefits offered by a robust domestic biotechnology industry (of which the Industry forms part)[14] and to this end has taken a number of active steps. It has, for example, introduced tax reforms and initiatives for biotechnology players in the form of research and development tax rebates and has eased restrictions on pooled development funds. These reforms facilitate the provision of cash flow for start up companies and encourage investment in the biotechnology sector, respectively.[15] It has, further, directly funded biotechnology research, allocating $40 million for spending between 2001 and 2004 to assist in the commercialisation of biotechnology research[16] and a further $30 million to a conglomerate headed by Meat Livestock Association and Australian Wool Innovation Limited for its sheep genomics program. Most recently, in the 2004 Federal Budget, the Government, inter alia, '[r]estore[d] … the CSIRO's

---

12 For comment in this regard, see, for example, Ernst and Young, Freehills and the Department of Industry, Science and Resources, *Australian Biotechnology Report 2001* (2001).

13 Jonathan West reported in Mike Steketee, 'Remove biotech barriers urgently', *The Australian* (Sydney), May 7 2004, 4. Jonathan West is an associate professor at the Harvard University Graduate School of Business Administration and spoke at the Future Summit 2004 held in Sydney in May 2004 – *Future Summit 2004 Creating a Better World.*

14 In this regard, see, for example, Biotechnology Australia, *Australian Biotechnology: A National Strategy* (2000) (hereinafter 'the National Strategy').

15 AusBiotech Ltd, *Growing Australian Biotechnology Through Improved Access to People and Capital: Updated Recommendations for Changes to Taxation, February 2003* (2003) 8–9.

16 For a list of industry incentives and support programs, see, for example, Ernst & Young, Freehills and the Department of Industry, Science and Resources, above n 12, 67–8.

three-year funding package, integrating it with the [Backing Australia's Ability] framework'.[17]

For its part, the biotechnology sector is looking to the science of transgenesis as a portal to continued economic viability while the Industry, in its turn, is looking to the patent.

Patents are the keystone to success for the Industry with patent law being the focus of an essential symbiotic relationship involving the Industry, its financiers and the public. However, while, the realisation of the respective aspirations of the Industry and the Government is a function of Australian patent law, Australia patent law is not ready for the transgenic animal.

Patenting in Australia is governed by the *Patents Act 1990* (Cth) ('the Act'). This paper details a proposal to ready the Act for the transgenic animal — the Act Solution. The thesis set down herein is that the transgenic animal demands the Act be updated and its potential to guard and guide exploited. In this, two arguments are assumed. First, that while the Government has favoured the players in the biotechnology sector, it has not ordained their immunisation against all forms of legal restraint.[18] Second, that neither the Industry or science can be the arbiters in matters involving transgenic science. At best, rather, self regulation will only be effective where it 'involves a tripartite approach between industry, consumers and government'.[19]

This paper, first, introduces the Act Solution by discussing the relationship between the Industry, the patent and the public. Second, it looks at the solution itself — its nature and the parameters within which it must function. The paper then sees the solution at work with discussion on the updating of the Act and the exploitation of its potential. The conclusion to this paper highlights areas of further legal study which warrant attention in a transgenic age.

---

17 Samantha Maiden, 'Science boosted by $5.3bn fund hike' *The Australian* (Sydney) 7 May 2004, 5.

18 For discussion in this regard, see, for example, Australian Law Reform Commission, *Gene Patenting and Human Health*, Issue Paper 27 (2003).

19 Commonwealth of Australia, *Consumer Protection in Electronic Commerce* (2000) 4.

II THE PATENT PROBLEM

The transgenic animal has set the Australian biotechnology industry on fire and the Australian public on guard. To meet its needs, the Industry is looking to the Act. To protect its interests, the public is looking to the Act. Both the Industry and the public are justified in making their respective calls, and the response they receive will determine the Industry's fate.

A *Background*

Australia was one of the first countries in the world to release a genetically modified organism into the environment.[20] Today, the Industry is primarily engaged in the areas of medical science and agriculture/aquaculture.[21]

Medical applications of transgenic science include the development of pigs whose organs would be more suitable for xenotransplantation than is presently the case;[22] the development of an osteoporosis 'mouse 'model' for diagnostic and therapeutic study *vis a vis* that affliction;[23] and more generally, gene silencing techniques in mammals to 'advance medical research and develop therapeutics'.[24]

Agriculture/aquaculture activities include study into the production of transgenically induced sterility in fish to minimise

---

[20] The organism was 'No Gall', a bacteria to prevent crown gall infection in fruit trees and woody plants. It was released in Australia in 1991.

[21] This reflects our biotechnology interests in general. In this regard, see, for example, Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347.

[22] This work is currently being undertaken by Bresagen Limited in conjunction with Melbourne's St Vincent's Hospital. For a brief resume on BresGen Limited, see, Freehills and Ernst & Young, above n 12, 12.

[23] This work is being undertaken by the Garvan Institute through Aza Research Pty Limited, a drug development company founded in 1994 and now wholly owned by Garvan.

[24] Benitec Limited, 'Commercial Overview' [1] <http://www.benitec.com.au/about/commercial_overview.htm> at 1 November 2003. Gene silencing occurs when a gene is 'turned off'. It is an essential component of transgenic animal work allowing the function of genes to be determined, biological reactions moderated and footprints for disorders detailed.

the risks of feral transgenic populations establishing themselves in the wild;[25] the modification of sheep for 'improved wool production' and prawns for improved growth rate and to 'protect them from viral diseases';[26] and the modification of livestock to self-treat for parasites in livestock.[27]

In both its fields of endeavour, the Industry is hampered by Australia's isolation, the relatively small size of the local market and inadequate private expenditure on research and development.[28] In addition, its growth is impeded by two factors: cost and public acceptance.

A transgenic animal is prohibitively expensive to produce. Nenow estimates that a transgenic animal being produced for a pharmaceutical will likely cost an inventor up to $250 million from the inception of the idea to the realisation of a marketable product.[29] A large percentage of this cost is attributable to the number of patents attaching to the tools of the transgenic animal inventor's trade. This minefield, which must be traversed through licence agreements and like commercial negotiations, traditionally includes patents for: 'markers, promoters, means of transformation, the transformed cells, the [animals] that are transformed, the genes inserted [and] the method of modification of the genes'.[30] The extent of this impediment to the progress of

---

25 Galli, above n 4, 8–9.

26 Commonwealth Scientific Industrial Research Organisation, 'Biotechnology in the Livestock Industry' (2003) <http://www.csiro.au/pubgenesite/biotechLivestock/index.htm> at 30 May 2004.

27 This work is being undertaken by, inter alia, Genetic Technologies Limited (hereinafter 'GTG') in conjunction with Melbourne University. See, for example, Jonathan Holmes interview with Mervyn Jacobson (London, 4 August 2003) <http://www.abc.net.au/4corners/content/2003/20030811_patent/int_jacobson.htm> at 15 August 2003. Mervyn Jacobson is founder and Executive Director of GTG and was interviewed here for a *Four Corners* special on gene patents.

28 Ernst and Young, Freehills and the Department of Industry, Science and Resources, above n 12, 25.

29 Lydia Nenow, 'To Patent or not to Patent: The European Union's New Biotech Directive' (2001) 23 *Houston Journal of International Law* 569, 581.

30 Brian D Wright, 'International Crop Breeding in a World of Proprietary Technology' in V Santaniello et al (eds) *Agriculture and Intellectual*

the inventor is graphically illustrated with plant transgenic patents. There are between zero and 44 patents attaching to the product 'Golden Rice', the number varying with the country of analysis.[31]

Recent activity at both ends of the transgenic animal development chain thickens this morass. At the initial stage, GTG, for example, has enforced its 'junk DNA'[32] patents against researchers.[33] The fees being asked by GTG are, at least locally, nominal. There is a concern, though, that this signals 'the beginning of the end'. As stated by Dr Francis Collins,[34] 'even if the licensing fee seems modest today, what will it be tomorrow, will we begin a veritable gold rush here where lots of other patent holders … say well me too'.[35] At the other end of the production chain are new patented technologies arguably essential to Industry players if they are to remain competitive. These include Xenogen Corporation's biophotonic imaging system, which images tagged genes[36] allowing biological activity

---

Property Rights: Economic, Institutional and Implementation Issues in Biotechnology (2000) 127, 135.

31 William Lesser, 'Patents, Trade Secrets and Other Forms of Intellectual Property Rights' in Max F Rothschild and Scott Newman (eds), *Intellectual Property Rights in Animal Breeding and Genetics* (2002) 1, 11.

32 Junk DNA is non coding DNA, initially of little research interest and over which GTG has taken out patents internationally. Of note, and in a discovery which augurs well for GTG's coffers, junk DNA has recently come to fore as possibly '… the secret of human complexity' (Deborah Smith interview with John Mattick, in Deborah Smith, 'Junk DNA yields frozen mystery clue', *The Australian* (Sydney), 8–9 May 2004, 5. John Mattick is a Professor at the Institute for Molecular Bioscience at the University of Queensland).

33 Deborah Smith, 'DNA scientists happy to buy junk', *Sydney Morning Herald* (Sydney) 4 August 2003, 4. The University of Sydney was informed by GTG that it was infringing that company's patents with its biotechnology research and subsequently negotiated a 'peppercorn' licence fee of $1500 for use of GTG's junk DNA patents for the next 15 years.

34 Francis Collins is the Director of the National Human Genome Research Institute and was head of the International Human Genome Project.

35 Jonathan Holmes, above n 27.

36 Xenogen Corporation, 'Products, Services and Licences' (2003) [2] <http://www.xenogen.com/prodlic.html> at 8 September 2003.

to be tracked and imaged in real time *in vivo* 'at the molecular level'.[37]

The cost to the Industry of 'inventing' the transgenic animal cannot be immediately recouped. Transgenic animals will not be marketable before passing through rigorous food and/or drug testing (as the case may be). Further, most biotechnology companies will have an 'invention' that, even if legally adequate, will be a commercial failure or will be further delayed post testing in reaching the market place.[38]

The expense of transgenic activity has meant that, for example, very little fish transgenesis work is being undertaken despite fish transgenesis 'being likely to improve the profitability of aquaculture through reduced time to market and improved harvest quality'.[39] It has also meant that any biotechnology company involved in transgenesis would likely operate at a loss when starting up and for several years thereafter.[40]

The Industry will not be able to turn to the Government, at least in the immediate future, for relief and/or assistance in this regard with the Government presently favouring commercialisation over increased research and development dollars for private business.[41]

As for public opinion, the history of the genetic modification of animals in Australia indicates that the stance the public take on transgenic science will determine the viability of the Industry. In this regard, it is noted that, for example, early in the history of the Industry Australia ceased production on transgenic pigs modified for better weight gain and food conversion as a result of hostile community sentiment.[42] This view is supported by the National Farmers Federation ('the NFF'), which has stated that

---

37 Xenogen Corporation (2003) [1] <http://www.xenogen.com> at 8 September 2003.

38 Nenow, above n 29, 582.

39 Galli, above n 4, 8.

40 Projection from the assessment of our biotechnology sector in general. AusBiotech Ltd, above n 15 [8].

41 Maiden, above n 17.

42 Plazinski et al, above n 10, 10.

the uptake of transgenic products will depend on market demand.[43]

The Industry can turn to public awareness campaigns to overcome the hostile sentiment it can generate. As for the financial impediments to its growth, it has turned to its nemesis — the patent.

A patent is an official grant bestowing upon the grantee the exclusive right over the subject of the patent in a defined territory for, in the case of a standard patent, 20 years.[44] The right conferred is to 'exploit the invention and to authorise another person to exploit the invention'.[45]

The grant of a letter patent ensures a potential market. It, therefore, affords the Industry a means by which to bait the private sector for 'venture capital, collaborative arrangements, and new research and development leads'.[46] This bait is working. In 1998-99, for example, 'Australia invested some $980 million in venture capital'[47] and the patent is now ensconced as the 'cornerstone' for a biotechnology company if it wishes to 'establish a strong commercial position … in the market place'.[48]

---

43 Wendy Craik, 'The Issues Ahead' (Address to the Grain Industry Association of Victoria AGM, Melbourne, 25 August 2000) <http://www.nff.org.au/pages/speeches/speech_old/2000_giaagm.htm> at 7 October 2003.

44 The Act s 67. Under the Act, innovative patents, which grant protection for a period of 8 years (s 68), are not permitted for transgenic animals. The 20 year period is, therefore, the relevant time frame in this discussion.

45 The Act s 13. The definition of 'exploit' is set down in Schedule 1 to the Act. For a product, it empowers the patent holder to exclusively '(a)… make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things'. For a process, it empowers the patent holder to exclusively '(b)… use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use'.

46 Office of Technology Assessment Congress of the United States, *New Developments in Biotechnology: Patenting Life* (1989) 55.

47 Colin Adam, 'CSIRO Strategic Research Plan 2000–2001 to 2002-2003' [9] <http://www.csiro.au/reports/StrategicResearchPlan2000to2003/innovate.html> at 20 May 2003.

48 LB Farrell 'Corporate Intellectual Property Management' in GD McLean et al (eds) (1997) *Commercialisation of Transgenic Crops: Risk, Benefit and*

Benefits from a patent flow both ways. One commercially successful pharmed calf, for example, can produce up to US $300 million in pharmaceuticals. In 1998 alone, the supply of human therapeutic proteins from recombinant proteins was worth US $12 billion. This beneficial effect to the Industry backer is not a trade secret. As noted by Sellers, a biotechnology company's stock market success is directly linked to its patent portfolio.[49] This has been evidenced locally with the rise and rise of GTG, which tripled its share price between May and August 2003.[50]

The relationship between the inventor and financier in the biotechnological age is a strong but not traditional one. Historically, the patent encoded a covenant to encourage inventors but was also charged with ensuring that the grant of a patent did not come at a cost to the public greater than that warranted by the nature of the patented invention. This is evident in the rationale of the patent, which seeks to promote invention on the grounds of common benefit. More specifically, the Industrial Property Advisory Committee[51] noted that 'we should seek to modify the Australian patent laws … so as to maximise the social benefits and minimise the social costs to Australians'.[52] While the grant of a letter patent is not predicated upon public purpose, it is, therefore, 'conditioned by public purpose'.[53]

This conditioning generates a tension in patent law that traditionally has been maintained in two ways. First, patent law

---

Trade Considerations. Proceedings of a workshop, Canberra, 11–13 March, 1997, 201, 215.

49 M Sellers, 'Patenting Nonnaturally Occurring, Man-Made Life: A Practical look at the Economic, Environmental and Ethical Challenges Facing Animal Patents' (1994) *Arkansas Law Review* 269, 284.

50 Jonathan Holmes, ABC Television, 'Patently a Problem' *Four Corners*, 11 August 2003, 2 <http://www.abc.net.au/4corners/content/2003/transcripts/s922059.htm> at 15 August 2003.

51 The Industrial Property Advisory Committee was charged with bringing Australia's patent legislation into the 1990s.

52 Butterworths, *Patents, Trade Mark & Related Rights*, vol 1 (at 90) ¶5195.

53 *Mercoid Corporation v Mid-Continent Investment Company* (1994) 320 US 661 at 666 per Justice Douglas in Miranda Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 209.

encodes a number of exemptions and restrictions, fettering the power of the patent holder. These include: a research exemption;[54] a compulsory licence provision;[55] and a public policy provision.[56] Second, the inventor is obligated to disclose the 'secret' of his or her invention to society in the patent application.[57]

B *The Problem with the Act*

The Industry is attracting the private sector dollar, the private sector is profiting and the public are being given the opportunity of inventions unprecedented in the benefit they can bestow. Arguably, then, the meeting of the transgenic animal, patent and public in Australia has been a successful one negativing calls for patent law or other reform in the face of the transgenic animal invention.

The Government has adopted this view: 'Australian patents legislation is sufficiently flexible to accommodate the patenting of new and emerging technologies'.[58]

The Government's view is supportable on a least four significant grounds.

First, it is unlikely that any attack on the patentability of a transgenic animal would be upheld on the basis of transgenesis alone. This is indicated by *National Research Development Corp v Commissioner of Patents*[59] ('*NRDC*') wherein the High Court reasoned that 'manufacture' must be interpreted broadly because invention necessarily constituted an 'excitingly unpredictable'

---

54 The research exemption allows non-commercial research to be conducted without fear of patent infringement proceedings.

55 The compulsory licence provision affords the public a means of ensuring the patent, which ties up the market place with its monopoly right, is actually exploited.

56 This allows a patent to be denied on public policy grounds.

57 The rationale is that disclosure will allow members of the public to improve on an invention, thus encouraging further innovation which, in the first instance, augments society's body of knowledge and, in the second, becomes itself a block of knowledge upon which society can build for its betterment.

58 Ernst & Young, Freehills and the Department of Industry, Science and Resources, above n 12, 30.

59 (1959) 102 CLR 252.

pursuit.[60] As van Caenegem notes, the *NRDC* finding in practical terms reads that patentability is a question 'to be addressed with an open mind … [with] patents [to] evolve in line with changes in scientific knowledge as well as economic development'[61] leaving the door open for the transgenic animal patent.

Second, initial fears over the ability of an inventor to meet disclosure requirements have been overcome by flexibility on the part of the Australian Patent Office and scientific advance itself. The Australian Patents Office will, for example, accept transgenic animal patents in any reasonable format while improved transgenic methods have made it more likely that a disclosure of the steps leading to a transgenic animal invention can be copied to produce the desired result.

Third, the Industry will benefit from recent changes effected to our patent law through the *Patents Amendment Act 2001* (Cth) ('the Amendment Act'). Prior to the Amendment Act, the inventor would be given the benefit of any doubt where there was a question over whether an invention satisfied the requirements of 'novelty' and 'inventive step'. This allowed for the granting of broad and questionable patents, particularly detrimental on two grounds. First, the Industry is downstream[62] and, second, biotechnology patents are particularly expensive to oppose with the cost likely to run over many years[63] so that where a transgenic animal inventor has been unfairly deprived of access to some upstream requirement the inventor will likely not be in a position to exploit the possibilities of the opposition regime encoded in the Act. Post the Amendment Act, where there is doubt as regards novelty or inventive step the question will be decided on a 'balance of probabilities' test this raising the threshold for inventiveness thus decreasing the opportunity for applicants of broad patents to receive protection under the Act.

---

60 Ibid 271. *NRDC* was a landmark decision with the High Court allowing a patent to cover a process involving known chemicals but used in a previously unknown way. The decision turned on the meaning of 'method of manufacture', a fundamental requirement for patentability.

61 W van Caenegem, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 41, 42.

62 See generally Nicol and Nielsen, above n 21.

63 Wright, above n 30, 135; Holmes, above n 27, 6.

Four, the Industry is surrounded by a regulatory regime designed to keep it in check and protect the public. Significant legislation in this regard includes the *Therapeutic Goods Act 1989* (Cth), the *Food Standards Australia New Zealand Act 1991* (Cth) and the *Gene Technology Act 2000* (Cth) ('the Gene Act'). In particular, the Gene Act has as its object:

> to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with [genetically modified organisms].[64]

The view of the Act as adequate is, though, problematic in the eyes of both the inventor and the public.

As for the inventor, transgenic animal patent grants are not in parity with grants to inventors in other fields of endeavour. This is exemplified in s 123 of the Act, which deals with innocent infringement. Section 123(2) states:

> If patented products, *marked so as to indicate that they are patented in Australia*, were sold or used in the patent area to a substantial extent before the date of the infringement, the defendant is to be taken to have been aware of the existence of the patent unless the contrary is established (emphasis added).

Transgenic animals cannot be 'marked so as to indicate' their patent status. The transgenic animal inventor, is therefore, denied the benefit of this provision. This is particularly deleterious as:

> [t]he inability to enforce a patent because of lack of clarity in the pertinent laws … may result in the diminishing or complete elimination of a company's incentive to invest in the development of new products and processes.[65]

As to the public, transgenic animals will likely come at a price to the public greater than that permitted by the patent covenant.

---

[64] Section 3. The Gene Act achieves its objective through the Office of the Gene Technology Regulator (hereinafter 'the OGTR') established under the Gene Act Part 3. The OGTR sets all regulations for the commercial and research use of transgenic animals and plants.

[65] Nenow, above n 29, 582.

This is indicated by the effect of patents with transgenic plants. Not only have transgenic plant patents increased prices resulting in the delayed dispersion of the protected good,[66] they have been exploited by companies to gain a dangerous level of control within the agricultural sector. The US seed giant Monsanto Corp is particularly implicated here. Monsanto developed technology to control against pests and weeds without the use of pesticides or herbicides but through encoding traits in seeds. By patenting its technology and establishing a vertical monopoly in the seed industry, Monsanto was able, by year 2000, to set itself in a position to control 80% of the US cotton industry. Many see this as an untenable position on the basis that were a pathogen to evolve resistance to the Monsanto encoded trait the US cotton crop would be decimated.[67]

Other concerns with the transgenic animal relate directly to the environment and health.

Health concerns include the possibility that consumption of meat or milk from a transgenic animal will spark an allergic reaction where previously none was had. This reaction can arise by virtue of the transgene itself or a biochemical process which the transgene has alerted in the modified animal.

Environmental concerns include the inherent potential in the transgenic animal to spark an outbreak of gene pollution — the contamination of a non-modified life form by its erstwhile counterpart. This danger has been illustrated by Purdue University scientists Muir and Howard. Muir and Howard, in a computer simulated model, set 60 medaka fish genetically modified for enhanced growth and juvenile weakness[68] into a

---

66 William Lesser and Martha Mutschler, 'Lessons from the Patenting of Plants' in Max F Rothschild and Scott Newman (eds) *Intellectual Property Rights in Animal Breeding and Genetics* (2002) 103, 116.

67 Wright, above n 30, 132.

68 The encoding for juvenile weakness was to simulate the effect that organisms bred domestically and modified for growth may be weaker and less adaptable in the wild than their non transgenic counterparts.

wild population of 60,000. The population was extinct in 40 generations.[69]

There is nothing in the Act to prevent the realisation of the above dangers and outcomes. Nor are they militated against in Australia's legal regime. The OGTR, for example, regulates the release of genetically modified organisms through a regime of controlled separation. This regime, though, is 'counterproductive for the management of productive ecosystems'.[70] This is illustrated by a study of the European experience with Atlantic salmon farms:

> Hundreds of millions of salmon in cages have fouled the sea around their pens, spread diseases and sea lice to wild salmon, and led to large numbers of escaped fish. Runaway domesticated salmon have begun interbreeding with wild salmon, a development that could lead to a new hybrid that is far less capable of making the heroic spawning and feeding journeys that are the hallmark of the Atlantic salmon.[71]

To the extent that the public are dissatisfied with the patenting of transgenic animals, it will not, as seen above, accept them. In failing to amend the Act in light of the transgenic animal, the Government is, therefore, jeopardising both the Industry and its goal of a strong domestic biotechnology sector. Moreover, if it loses the Industry, Australia will lose the benefits which a vibrant transgenic animal sector can bestow. These benefits include increased foreign investment and cheaper goods and services where those goods and services derive from local transgenic animal inventions. In addition, it is likely that if Australia has no Industry where such an industry becomes an international norm, she will suffer 'substantial [economic] losses'.[72]

---

69 W M Muir, R D Howard and Sarah P Otto, 'Fitness Components and Ecological Risk of Transgenic Release: A Model Using Japanese Medaka (*Orysias latipes*)' (2001) 158 *The American Naturalist* 1.

70 Sima Williamson, David Brunckhorst & Gerard Kelly, *Reinventing the Common: Cross-boundary farming for a Sustainable Future* (2003) 12–3.

71 Fen Montaigne, 'Everybody loves Atlantic Salmon. Here's the Catch' (2003) *National Geographic* 104, 106.

72 Stephen Cauchi, 'GM's growing pains', *Sydney Morning Herald* (Sydney), 25-26 October 2003, 39, citing a 2003 report of the Australian Bureau of Agricultural and Resource Economics.

Patent law is at the centre of a symbiotic relationship between the Industry, the Industry's financial backers and the public, all of which parties must be 'on side' if the Australian economy is to set itself upon a geep's back. To be ready for its pivotal role, the Act requires amendment. This amendment, arguably, should involve technical changes and a creativity with the Act's provisions, which, in turn, must be encoded by reference to the milieu within which they are to work.

III SOLVING THE PROBLEM

The international position on the patenting of transgenic animals traverses the available range. Such patents are banned in South Africa,[73] China,[74] Brazil[75] and Argentina.[76] The USA has resisted all attempts to stop the transgenic juggernaut. The EU has trod a middle line — such patents are not barred but legislation includes a provision designed to guard against the excesses of transgenic invention and exploitation.[77]

While Australia's small local market demands that she be cognisant of the foreign law on transgenic animals and alert to the concerns from which foreign law was born, the most effective response to the Industry will be sourced in Australian conditions. There are three reasons for this.

First, considerations relevant overseas are only indicative of Australia's concerns. Unlike farmers in the US, for example, those in Australia have not called for a farmer's exemption,[78] but,

---

73 Section 25(4)(b) South African Patents Act No. 57 of 1978 (as amended) cited in A Blattman et al in 'Global Intellectual Property: International Developments in Animal Patents,' in Max F Rothschild and Scott Newman (eds) *Intellectual Property Rights in Animal Breeding and Genetics* (2002) 1, 11.

74 Article 25(4) The Patent Law of the People's Republic of China in Blattman, above n 73, 81.

75 Industrial Property Law No. 9.279/96 Article 10 in Blattman, above n 73, 82.

76 Articles 6(g) and 7(b) of Law No. 24.481 on Patents and Utility Models (as amended by Law No. 24.572) in Blattman, above n 73, 82.

77 For discussion in this regard, see Amending the Act Pt 1 below.

78 A farmer's exemption is a provision that farmers are not answerable to a patentee for the use of a patented product in the normal course of

rather, are especially concerned to ensure that transgenic and non-transgenic products be able to co-exist in one locale. Specifically, the NFF believes it should embrace the opportunity of biotechnology advances but:

> firmly advocates that farmers should retain the opportunity to adopt the method of production best suited to their business needs, be that GM, conventional or organic or any combination of these methods.[79]

Second, Australia has a distinctive environment. For example, while the co-existence of modified and non-modified animals on a single farm or within a region may generally be unrealistic in Europe, this is not necessarily the case in Australia due to its larger 'farm sizes and [the greater] distances between farms'.[80] Similarly, Australia must be particularly vigilant *vis-a-vis* her transgenic interests as: her landscape is already 'low

---

conducting a farming business. The US farmers were concerned that market imperatives would force them to carry only animals 'enhanced' for desirable traits thereby increasing establishment and restocking costs. They were also concerned that any increased cost could not be recovered on sale as a marked disparity between transgenic end product and 'organic' end product would likely not be tolerated by the market. Arguably, at least to a certain extent, the farmer's fear is unfounded. Market imperatives will, for example, limit the patentee (or its licensee) in any charge it can impose. Lesser and Mutschler note that while animal patents will raise prices, '(i) competition within the sector; and (ii) the sector profitability' will contribute to determine any price effects with, for example, 'the high-margin pharma sector [being able to] sustain greater price increases than low-margin live-stock operations' (Lesser and Mutschler, above n 66, 115).

79 National Farmers' Federation, *Biotechnology Position Statement* (March 2003), 2. Other concerns of Australian farmers include the likelihood of incurring liability for gene pollution and the likelihood of infringing transgenic patents and thus becoming liable to a patentee regardless of an inability to prevent such infringement. For detailed discussion in relation to liability issues in light of transgenic science in this country, see, Science and Economic Policy Branch, Australian Government Department of Agriculture, Fisheries and Forestry, *Liability Issues Associated with GM Crops in Australia* (2003) <http://www.affa.gov.au/corporate_docs/publications/pdf/innovation/liability_issues_paper_final.pdf> at 4 October 2003. As for innocent infringement, see below, Amending the Act Pt 1.

80 J Glover, Bureau of Rural Sciences, *Gene flow study: Implications for GM crop release in Australia* (2002) 10.

productivity';[81] her annual cost of land degradation is already high, estimated at $2 billion annually;[82] 37 per cent of her broadacre farms have a negative farm cash income (as at 2002–03);[83] and Australia is a centre of biodiversity.

Three, Australian law imposes distinctive obligations. Australia enforces, for example, a duty to prevent the economic loss which can emanate from a farmer's produce.[84]

However, neither Australia's distinctive position nor the transgenic animal itself can give rise to any radical reform of the Act. As noted by Professor Weisbrot[85] following the release of the findings of the Australian Law Reform Commission ('ALRC') inquiry in gene patents and health:[86]

> Australia is tied into international agreements on intellectual property and seeks international investment in our R & D industries, so we must try to work within the contours of the existing [patent] system.[87]

Rather, her response to the transgenic animal, it is proposed, should be to update the Act technically and exploit its potential.

---

81 Sima Williamson, David Brunckhorst & Gerard Kelly, *Reinventing the Common: Cross-boundary farming for a Sustainable Future* (2003) 9.

82 Ibid 10.

83 Australian Bureau of Agricultural and Resource Economics, *Australian Farms Survey Report 2003* (2003) (7). Available at <http://www.grdc.com.au/bookshop/docs/ABARE_FarmSurveyReport.pdf> at 30 May 2004. As the Report notes (at 9), the industry types comprising the broadacre sector are: wheat and other crops, mixed livestock-crops, sheep, beef and sheep-beef industries.

84 This was established in *Perre v Apand Pty Limited* (1999) 198 CLR 180. Apand supplied infected seeds to the Sparnons. A subsequent outbreak of bacterial wilt on the Sparnons' land attributable to the Apand seed prevented the appellants from exporting their potato produce to Western Australia. The High Court held that Apand was liable for the economic loss which the appellant suffered through the lost export opportunity.

85 David Weisbrot is President of the Australian Law Reform Commission.

86 Australian Law Reform Commission Discussion Paper, *Gene Patenting and Human Health* (Discussion Paper 68), (2004) (hereinafter 'DP 68').

87 Australian Law Reform Commission, *ALRC inquiry reveals confusion, anxiety over gene patents*, Media Release, 4 March 2004, <http://www.alrc.gov.au/media/2004/mr0403.htm>[8] at 28 March 2004.

Updating the Act calls for responsiveness to transgenic science. Responsiveness is Government practice. In 2002, for example, in recognition of the collegiate requirements of scientific researchers, a general 'grace period' was introduced into the Act so that where the inventor or someone authorised by the inventor publicises or uses an invention within 12 months prior to a patent application for that invention being lodged, the disclosure will not affect the prior art base for novelty and inventive step.[88]

Exploiting the potential of the Act involves using the provisions of the Act to achieve an end unrelated to 'inventiveness'. Its rationale is that a patent act can be more than a piece of enabling legislation. This is not a novel concept. Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS'),[89] for example, permits Governments to act through their respective patent laws to militate against the commercialisation of an invention if, once exploited, that invention would bring harm or offence.[90] In fact, the rationale has been with patent law throughout its history. The inception of modern patent law in the United Kingdom was motivated by a desire to keep profitable industry. Similarly, and in reverse, India, like the USA and Sweden before it, has refused to

---

88 Novelty and inventive step were, prior to this amendment, not made out where there had been local disclosure of the invention. Without these features being made out, the invention could not satisfy the inventiveness requirement necessary for the grant of a patent so that the application for the disclosed invention was rejected. This was seen as deleterious as it discouraged the discussion of ideas between researchers and denied patentability to an otherwise valid invention even where the disclosure had been accidental. The amendment in this regard was a recommendation of the Intellectual Property and Competition Review Committee. For discussion as regards this amendment, see, for example, Ann L Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' [2002] 24 *European Intellectual Property Review* 475.

89 TRIPS forms annexure 1C to the Marrakesh Agreement, was concluded on 15 April, 1994, and entered into force on 1 January, 1995. It binds all members of the World Trade Organisation.

90 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or to avoid serious prejudice to the environment …'.

recognise patents so that she can, inter alia, develop a domestic pharmaceutical industry.[91]

More recently, Sherman argued that the legislature should exploit the Act to address the situation where biopiracy deprives 'access providers' of the opportunity to derive income from flora and fauna over which the access provider has been afforded rights under the draft Environment Protection and Biodiversity Conservation Amendment Regulations 2001.[92]

Eleven years ago, Reichman stated that:

> Governments adopt intellectual property laws in the belief that a privileged monopolistic domain operating on the margins of the free-market economy promotes long term cultural and technological progress better than a regime of unbridled competition.[93]

This statement underplays the role of 'big business' in shaping government policy in matters of intellectual property. It, however, identifies the quintessence of patent law — service. Patent law is born to serve. It serves governments in meeting macro-economic ends. It serves inventors in providing a means to recoup on investment. It serves the public as a means of guarding against the excesses of inventive endeavour and the unnecessary corrosion of the public's right to a free marketplace. The transgenic animal has upset this service quotient. The following two sections of this paper see the Act Solution at work to reset the same.

IV AMENDING THE ACT PT 1

This section, first, considers immediately pressing technical amendment to the Act in the areas of innocent infringement, time

---

91 Willem Pretorius, 'Trips and Developing Countries: How Level is the Playing Field' in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge Access and Development* (2002) 184.

92 Brad Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' (2003) 25 *European Intellectual Property Review* 301.

93 J H Reichman, 'Charting the collapse of the patent-copyright dichotomy: Premises for a restructured international intellectual property system' (1993) 13 *Cardozo Arts & Entertainment Law Journal* 475, 475.

and research in light of the transgenic animal invention. The issue of a public policy provision is then addressed, specifically, why any call to include a public policy provision in the Act should be resisted.

A *Innocent Infringement*

Innocent infringement is the infringement of a patent holder's rights where 'the defendant was not aware, and had no reason to believe, that a patent for the invention existed'.[94] It is a particularly relevant concept in light of transgenesis as a result of the possibility of gene flow, the natural movement of genes from one organism to another.[95]

The legal significance of gene flow in a transgenic world is illustrated in the widely cited Canadian case, *Monsanto Canada Inc. v Schmeiser*.[96] Monsanto had a patent for glyphosate resistant canola plants.[97] Glyphosate resistant canola plants were found to be growing on Schmeiser's farm and Monsanto prosecuted for patent infringement. Schmeiser argued that he should not be liable on three counts. First, he had not deliberately planted what in effect were patented seeds. Second, he had gained no benefit from growing canola from the patented seeds. Third, Monsanto had no right to enforce its patent as, by planting in the open, it had put itself in a position where its patent could be innocently infringed.

---

94 The Act s 123(1).

95 Gene flow makes it possible for a patented product to move from that product to another plant or animal (as the case may be). This movement will not extinguish the patent holder's rights so that the patent holder will have a claim over any new stock containing the displaced DNA. This right will subsist regardless of whether the patent holder owns the now transformed stock and regardless that the owner of the transformed stock could not have prevented the movement, or, indeed, been aware of its occurrence.

96 (2001) FCT 256, reported as (2001) 202 F.T.R. 78, 12 C.P.R. (4th) 204, [2001] F.C.J. No. 436 (QL).

97 Specifically, 'man made genetically engineered genes, and cells containing those genes which, when inserted in plants, in this case canola, make those plants resistant to glyphosate herbicides'. Canadian patent number 1,313,830.

The court disagreed. Specifically, it noted that: first, knowledge or intention is irrelevant to the fact of infringement; second, where the essence of a patented invention is used without permission, the patent holder's rights will be infringed regardless of whether any profit subsequently accrues to the infringing party; and third, the plaintiff, who had 'under[taken] a variety of measures designed to control the unwanted spread of canola containing their patented gene and cell',[98] had neither expressly or impliedly waived its claim.

Schmeiser's appeal of this decision was dismissed.[99]

As Sherman notes, were a Schmeiser incident to occur in Australia, it is equally unlikely that a defendant farmer could succeed.[100] This leaves the defendant's only hope in s 123(1) of the Act, whereby a court has a discretion to 'refuse to award damages'. This, though, is a tenuous hope as the exercise of this discretion is predicated upon

> the defendant satisfy[ing] the court that, at the date of the infringement, the defendant was not aware, and had no reason to believe, that a patent for the [infringed] invention existed'.[101]

It is suggested that once transgenic animal science takes hold in the Australian agricultural sector all potential plaintiffs will make known the presence of transgenic stock so as to receive the full benefit of the Act.

---

98 Above, n 3 per MacKay J.

99 *Percy Schmeiser & anor v Monsanto Canada Inc & anor.* 2002 FCA 309. On 21 May 2004 the Supreme Court of Canada ruled 5:4 in favour of Monsanto on an appeal by Schmeiser of the decision of the Federal Court of Appeal (Indexed as *Monsanto Canada Inc. v Schmeiser* 2004 SCC 34). The Supreme Court found that Monsanto's patent for glyphosate resistant canola plants was valid, although set aside the award for an account of profits set by the trial judge. In this latter regard, the Supreme Court stated that "[Schmeiser's] profits arose solely from qualities of their crop that cannot be attributed to the invention" (at 106 per McLachlin CJ and Fish J delivering the judgment of the majority).

100 Brad Sherman, 'Biological Inventions and the Problem of Passive Infringement' (2002) 13 *Australian Intellectual Property Journal* 146, 153.

101 The Act s 123(1).

On the basis of a farmer's high susceptibility to innocent and passive infringement, it is proposed that the Act be amended in relation to its infringement provisions in two regards.

First, it is proposed that s 123 of the Act be amended by the insertion of a provision that the court *must* refuse to award relief where the defendant has unwittingly infringed a patent as a consequence of gene flow.

Second, it is proposed that s 125 of the Act, which provides for the issuing of non-infringement declarations, be amended to allow for farmers to apply for what would amount to a non-infringement declaration in globo, so that the farmer need not fear unwittingly infringing a transgenic patent as a consequence of gene flow.

B *Time*

Patent monopolies are economically inefficient. They prevent competition thereby allowing the monopoly company to charge a premium for its patented product. The patent monopoly, however, also promotes efficiency by encouraging invention, the efficiency being a factor of the diversity of products which invention makes available in the marketplace. The patent system demands that these two dynamics, efficiency and inefficiency, be kept in balance. The link between monopoly and the efficiency quotient dictates this can only be achieved where an appropriate tenure is attached to the patent grant.[102]

The Act ordains that the appropriate term for a standard patent is 20 years[103] with provision for a 5 year extension to this term in the case of pharmaceutical patents.[104]

As Langinier and Moschini argue, the notion of a standard patent length is questionable on macro-economic grounds. Some innovations consume more resources in production than others while for resource light innovations (those which 'would have

---

[102] For discussion in this regard, see Corinne Langinier and Giancarlo Moschini, 'The Economics of Patents' in Rothschild and Newman, above n 31, 31.

[103] Section 67.

[104] Section 70.

been pursued even with a shorter patent period'),[105] a 20 year term produces an excess in inefficiency.[106]

The questionable nature of the theoretical underpinning of the standard term implies that a monopoly term should be varied where economic efficiency demands. There are two grounds for arguing that economic efficiency makes such a demand in the case of the transgenic animal.

First, it is likely that there will be a longer lag time between application and grant date for transgenic animals by virtue of their status as biotechnology inventions. Biotechnology patent applications, that is, are normally in the examination stage for up to 20% longer than other patent applications.[107] This reduces the effective monopoly time of the transgenic animal patent.

Second, transgenic animal patents may be effectively shorter due to food and therapeutic goods requirements which must be met before public release. This problem is likely to increase over time with the onset of gene stacking — the importation of more than one transgene into the target organism.

With gene stacking:

> [r]egulators will need to test for possible side-effects of individual genetic modifications and, at the same time, investigate the possibilities of negative effects from interaction of multiple modifications.[108]

Gene stacking is also indicated by the fundamental market imperative of cost effective production and the susceptibility of quality and yield to '[the] diverse array of complex

---

105 Above n 31, 38.

106 See Langinier and Moschini, above n 31 – the length of the monopoly is greater than that required to procure the efficiency of the invention.

107 Daniel K N Johnson and Vittorio Santaniello, 'Biotechnology Inventions: What Can We Learn from Patents?' in V Santaniello et al (eds), *Agriculture and Intellectual Property Rights: Economic, Institutional and Implementation Issues in Biotechnology* (2000) 169, 193.

108 David Zilberman, Cherisa Yarkin and Amir Heiman, 'Knowledge Management and the Economics of Agricultural Biotechnology' in Santaniello, above n 30, 142.

environmental settings' within which 'agricultural production takes place'.[109]

For economic efficiency and in the interests of parity for transgenic animal inventors, one amendment to the Act is proposed. It is proposed that s 70 of the Act be amended so that the opportunity of time extension therein afforded to holders of pharmaceutical patents be enlarged to cover holders of transgenic animal patents. This amendment will require concomitant changes, including reference where appropriate, to Australia's Food Standards authority.

C *Research Exemption*

In Australia, 'there's been an unwritten convention that research — especially into fatal diseases like cystic fibrosis — is exempt from the demands for licence fees from patent holders'[110] where no commercial value attaches to the research. The enforcing by GTG of its junk DNA patents means that this is no longer the case.

GTG's commercial view of its patents has benefits — it allows GTG to fund its own research and other work thereby 'bringing new technology to a marketplace which can save lives'.[111]

The case against losing the research exemption is, however, strong.

First, the dismantling of the unwritten exemption regime will push universities into the hands of the private sector. This may serve to 'distract the university's research effort away from work on the intellectual commons in favour of secret research to benefit only the private funder',[112] with, at the same time, the work of the universities becoming 'progressively more

---

109 Ibid.

110 Jonathan Holmes, ABC Television, 'Patently a Problem' *Four Corners*, 11 August 2003, 2 <http://www.abc.net.au/4corners/content/2003/transcripts/s922059.htm> at 15 August 2003.

111 Holmes, above n 27.

112 Peter Drahos and John Braithwaite, *Information Feudalism Who Owns the Knowledge Economy?* (2002) 188–189.

subservient to the priorities of the rich'.[113] This adverse result is indicated by the course of industrial endeavour in the area of plant transgenics. Little work is being done on those diseases which predominantly affect developing countries because, it is argued, developing countries will not be able to pay the price necessary to recoup the research and development costs necessarily paid out to assay diseases and develop treatments for any targeted affliction.[114]

Second, the absence of a research exemption will increase the already expensive exercise of inventing in relation to transgenic animals.

Third, the absence of a research exemption contradicts the rationale of patent law. Patent law demands disclosure of the patented invention in the patent application. Disclosure is a trade off for the monopoly grant: it affords the public an opportunity to build on inventions and thereby improve society's lot. With biotechnology patents, this building will be achieved only through fundamental research, there being a particularly strong link between scientific research and biotechnology inventions.[115] To enforce the biotechnology patent against the research community is, therefore, to put a caveat on actual disclosure. Such a caveat has never been contemplated by patent law.

In light of the above, one amendment to the Act is proposed. It is proposed that the Act be amended by the insertion therein of a provision which affords to researchers an exemption where the research work entails study on or related to transgenic science.[116]

D *Public Policy*

For many, an essential amendment to the Act as a result of transgenic science is a public policy provision along the lines of

---

[113] Ibid.

[114] For discussion in this regard, see, for example, Jean O Lanjouw, 'A New Global Patent Regime for Diseases: U.S. and International Legal Issues' (2002) 16 *Harvard Journal of Law & Technology* 85.

[115] See, for example, Gustav J Nossal and Ross L Coppel, *Reshaping Life: Key issues in genetic engineering* (3rd ed, 2002) 177.

[116] An alternative to an encoded exemption is an 'experimental use' defence as proposed in relation to gene patents in DP 68. The ALRC's paper can be consulted in this regard.

Article 6 of European Directive 98/44 on the Legal Protection of Biotechnological Inventions ('the Biotech Directive').[117] This Article is analogous to Article 53(a) of the European Patent Convention and dictates as unpatentable inventions which jeopardise 'public security … the physical integrity of individuals [or] … the environment'[118] or 'processes and products of processes that cause animals to suffer 'without any substantial medical benefit to man or animal'.[119]

There are strong grounds for arguing that such a provision should be inserted in the Act, such arguments finding basis in any one or more of religion, the environment, ethics, social worth and the law.[120] The language in these arguments can be coloured and it is not unrealistic to posit that these responses are, at least in part, the product of a mythology which has consistently associated transformed animals with horror. However, the arguments are not unfounded in toto, as evident from the points raised earlier in this paper. In fact they are often meritorious at heart in that they seek to strike a balance between the conflicting concerns of the public and the needs of the inventor in light of an invention both dangerous and beneficial. Further, they cannot be disregarded as the product of biotechnophobes.

---

117 For discussion in this regard, see, for example, Duncan Curley and Andrew Sharples, 'Patenting Biotechnology in Europe: The Ethical Debate Moves On' Opinion [2002] *European Intellectual Property Reports* 565. The Biotech Directive allowed the patenting of higher life forms.

118 As noted by Curley and Sharples, this is the definition of the term *order publique* laid down in the *Oncomouse* case (European Patent Office Reports Case T19/90) and now accepted in European patent law. Curley and Sharples, above n 117, 566.

119 The Biotech Directive, Article 6, para 2(d).

120 There is ample literature in each of these regards. With religion, the argument generally notes that only God can 'own' life or play with its form. With the environment, the concerns reflect those detailed in this paper. With ethics, the arguments are sourced in topics ranging from the value hierarchy on life forms which transgenesis appears to impose to the more perennial pain being inflicted on the transformed animals. Social worth notes, for example, the pressure placed on farming communities. The legalist notes that the provision would enunciate the covenant between the public and the patent giver.

Those who have expressed some reservations about transgenic science include Professor Sir Gustav Nossal[121] and Professor Ross Coppel,[122] who have mooted that, in face of the biotechnology revolution in general, patent law be altered to allow for 'some sort of hiatus while the technology is assessed for societal effects beyond the area of product safety'.[123] More directly, since the World Trade Organisation's Third Ministerial Conference,[124] 'concerned scientists' have been calling for a step back with the number of concerned scientists having grown from 144 at the conference to 658 presently. This call has taken the form of an open letter, which presently reads:

> We … call for the immediate suspension of all environmental releases of GM crops and products, both commercially and in open field trials, for at least 5 years; for patents on living processes, organisms, seeds, cell lines and genes to be revoked and banned; and for a comprehensive public enquiry into the future of agriculture and food security for all.[125]

However, there are several arguments that militate against the insertion of a public policy provision in the Act.

First, such a provision fails to discriminate between the exploitation of the technology and the fact of the technology, seeming to argue that the latter will always either be offensive or non-offensive.[126] This is an untenable position. Both the

---

[121] Gustav Nossal is a former director of The Walter and Eliza Hall Institute of Medical Research, Melbourne. He has chaired, amongst other things, the Strategic Advisory Group of Experts of the Vaccines and Biologicals Programme of the World Health Organization (Nossal and Coppel, above n 115, back cover).

[122] Ross Coppel is Professor of Microbiology at Monash University (Nossal and Coppel, above n 115, back cover).

[123] Nossal and Coppel, above n 115, 198.

[124] Seattle; 30 November – 2 December 1999.

[125] Full text available at <http://www.i-sis.org.uk/list.php> at 8 September 2003.

[126] This view is not uncommon. See, for example, Francis Fukuyama *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2002) 182 wherein it is argued that in light of inventions such as the transgenic animal, we 'discriminate between those technological advances that promote human flourishing and those that pose a threat to human dignity and well being' with only the former being eligible for patent protection.

purgatory and the promise of transgenic science are inherent in every transgenic animal. For example, the same salmon that if transgenic and enclosed may lead to environmental degradation will also take pressure off marine waters, particularly important as 'sixty to seventy percent of the world's marine fisheries are threatened by over-fishing'.[127]

Second, as Gitter notes, '[m]orality is a exceedingly complex standard to implement as a criterion of patentability'.[128] Should, for example, a 'public abhorrence' test be used to determine the issue, as in *Re Lubrizol Genetics Inc*[129] and *Hormone Relaxin,*[130] or is an 'unacceptable' test, as applied by the European Patent Office to the patent application for the Harvard Onco-mouse and as applied in *Greenpeace Ltd v Plant Genetic Systems N.V.,* [131] more appropriate? Again, is it appropriate (or possible) to apply a test to a potential bad? Given the complexity of transgenic inventions, is a test referrable to public sentiment suitable at all? Notably, even the members of the EU seem to agree that the 'protection' afforded through Article 6 is cosmetic at best.[132]

Third, to encode an *ordre publique* provision is to ask patent law to assess the purpose to which the patent is put. This is not a function of patent law. This was made clear by the European Court of Justice when called on by the Dutch Government to annul the Biotech Directive. Here, the Netherlands Government was, in effect, 'question[ing] the ethical basis of patenting biotechnology'.[133] In rejecting the Dutch, the European Court of

---

127 Galli, above n 4, 5.

128 Donna M Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (2001) 19 *Berkeley Journal of International Law* 1, 21.

129 1990 O.J. E.P.O. 71 (Opp. Div.) concerning the validity of a patent for a hybrid transgenic plant and the method for its production. Discussed in Gitter, above n 128.

130 1995 O.J. E.P.O. 388 (Opp. Div.) concerning the validity of a patent for a DNA fragment encoding a protein produced by pregnant women. Discussed in Gitter, above n 128.

131 T356/93-3.3.3, 1995 O.J. E.P.O. 545 (Technical Bd. Of App.) concerning the validity of a patent for cells transformed to be resistant to a particular herbicide and seeds and plants derived from those cells. Discussed in Gitter, above n 128.

132 See generally Gitter, above n 128.

133 Curley and Sharples, above n 117, 565.

Justice observed 'patent law was not the appropriate framework for [the] regulation of research or the use in society of patented products'.[134]

Finally, the body of social opinion in Australia, though at times vocal, may be less adverse to the transgenic animal industry than any 'Death by DNA' media reports imply. In a 1999 national survey conducted by Biotechnology Australia, consumers ranked the importance to them of various food issues. The result saw the genetic modification of food in any form coming in at only fourth behind food poisoning, pesticide use and the tampering of foods during manufacture.[135] Similarly, little objection has been raised in the media to the application of transgenic science in the area of medicine.

Regardless of the desirability of doing so, not all possible amendments to Australian patent law in light of the transgenic animal can be catered for in the Act. Consider, for example, the compulsory licensing provision encoded therein at s 133. It is widely noted that, at least in relation to the biotechnology industry, this provision is inadequate. This is particularly deleterious to the Industry given the aforementioned patent minefield which the transgenic animal inventor must traverse — if a licence cannot be procured from just one patentee in this patent morass the inventor will be stymied before he or she begins. As Ergas notes, though, this should be dealt with outside the Act on two grounds. First, a compulsory licensing system may result in efficiency loss by 'undermin[ing] socially desirable price discrimination'. Second, the compulsory licence is not optimal in the fact of the voluntary licence. With voluntary licences there is flexibility in relation to 'the creation of sublicences, the sharing of information between the two parties and the extension of the licence term'.[136]

---

134 Ibid 569.

135 See Craik, above n 43.

136 Henry Ergas *Treatment of unilateral refusals and compulsory licensing in Australia.* A paper presented to the Federal Trade Commission/Department of Justice Hearings on Antitrust and Intellectual Property Law and Policy in the Knowledge-Based Economy 22 May, 2002, Washington DC <http://www.necg.com.au/pappub/papers-ergas-compulsory-licenses-may02.pdf> at 8 September 2003.

At the same time, the amendments detailed above do not begin to intimate an exhaustive list of the surgery required to the Act to satisfy the demands of the Act Solution. This is indicated by the rejection of the public policy provision. While it may be out of order to encode for such a provision, the Act's covenant with the public and the Industry's need to cultivate public acceptance insist that the effects that a public policy provision attempts to guard against be catered for in the Act. This is the province of Act exploitation, to which this paper now turns.

V EXPLOITING THE ACT

This section justifies an exploitation response to the Industry and considers the same at work in reference to: genetic use restriction technologies ('terminator genes'); germplasm variety and the fate of the world's developing countries. In this, the rationale is that described by Evans and Fitzgerald in relation to contract law in the digital age, namely:

> [w]hile we acknowledge that industry norms will drive … commerce, there is a need for legislative direction in the interests of fairness of exchange … far from resiling from public regulation, governments need to assert the power of the legislature in defence of the individual welfare of citizens and that of society in general.[137]

A *Terminator Genes*

Terminator technology provides a means to block the natural perpetuation of a species, affected organisms destroying their progeny in the second generation. The terminator effect can be achieved in a number of ways. At its simplest, it is brought about by the artificial manipulation of a natural sequence of biochemical events wherein genes turn on and off in response to particular inducer and repressor proteins, respectively. The sequence culminates in the activation of a toxin gene with the toxin produced killing the embryo of a mature seed pre harvest.

---

[137] Gail E Evans and Brian F Fitzgerald, 'Information Transactions Under UCC Article 2B: The Ascendancy of Freedom of Contract in the Digital Millennium' (1998) 21 *University of NSW Law Journal* 404, 409.

Terminator technology was developed by the US Department of Agriculture and the American Delta and Pine Land Company[138] for the purpose of avoiding the likelihood of 'accidental reseeding, escape of the crop plant to areas outside the area of cultivation or germination of stored seed'.[139]

Terminator science is particularly attractive to a seed supplier. It negates the need to instigate monitoring procedures against unlicensed use and the need to prosecute for infringement, both of which activities significantly increase the expense associated with amassing and maintaining an effective intellectual property portfolio.

Terminator genes can be remarkably beneficial. This is immediately evident from crop science. Male sterility in maize, sorghum, rice and sunflower, for example, has facilitated the process of annually 'crossing genetically dissimilar genotypes' thereby allowing additional annual output to the tune of '90 million tons of food production … [which] additional output enables us to spare approximately 34 million ha for the cultivation of other crops'.[140]

Further, as argued by Srinivasan and Thirtle, the incentive offered by terminator technology to agricultural research in the form of captured returns will likely give rise to a 'doubling' in 'private sector research investment in new plant varieties', with, in time, this leading to 'improved seed supply … result[ing in] substantially higher yields for those farmers with access and purchasing power'.[141] This reflects the view of industry player Monsanto, which company argues that:

> [t]he need for companies to protect and gain a return on their investments in agricultural innovation is real … Without this return we would no longer be able to

---

[138] See Patricia Lucia Cantuaria Marin, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems and Biopartnerships* (2002) 63.

[139] US patent no. 5,723,765.

[140] S S Virmani and M Ilyas-Ahmed, 'Environment-Sensitive Genic Male Sterility (EGMS) in Crops' (2001) 72 *Advances in Agronomy* 139, 139–40.

[141] C S Srinivasan and Colin Thirtle, 'Terminator technology: the economic benefits of sterile seeds', *id21 society & economy* [4] <http://www.id21.org/society/s1ccs1g1.html> at 30 May 2004.

> continue developing new products growers have said they want.[142]

As for the animal world, the CSIRO is hoping to use terminator technology to reduce the presence of carp in Australian territorial waters.[143] When used in this way, terminator technology facilitates a variant form of the practice whereby species are introduced to an environmental to control pest populations. This practice, while dangerous, is both common and recognised as beneficial. At the same time, the ability to 'silence' genes, which rests at the heart of terminator technology, is being used extensively in medical transgenic work, including, most recently, to facilitate study into Alzheimer's disease, depression and addiction.

Despite the above, there have been international moves to ban patents over terminator technology, either simpliciter or to the extent that the technology forms a part of an invention the subject of a patent application. Section 14(2) of India's *Protection of Plant Varieties and Farmers Rights Bill*, for example, stated:

> no variety shall be registered under this Act if such variety contains any gene or gene sequence involving any technology including terminator technology which is injurious to life or health of human beings, animals or plants.

As this provision implies, such legislation is motivated by ethical, environmental and health concerns.

The ethical argument is that, if used in the Monsanto manner, terminator genes see the destruction of life forms purely on the basis of cutting overheads.

---

[142] Bob Shapiro, Monsanto CEO, in A Salleh, 'Terminator Gene Technology Scrapped' (1999) *The Lab, News in Science* [10] <http://www.abc.net.au/science/news/stories/s56887.htm> at 8 September 2003. In response to public criticism, Monsanto announced in 1999 that it would not commercialise 'terminator technology'. This should be read narrowly as a decision not to sell seeds impregnated with a terminator gene to farmers in the short term.

[143] Galli, above n 4, 14. For discussion in relation to sterility and pest control, see, for example, Rachel Nowak, 'Silencing the pests' *New Scientist* March 2003, 25.

The environmental argument, in as much as it relates to animals, is that the movement of genes encoded with terminator technology may lead to the decimation of non-transgenic stock. This concern has been expressed most vocally in relation to fish transgenesis and runs thus: the terminator fish are modified for both termination and some other feature such as increased size. The size modification makes the modified fish the more attractive mate in the wild. Though the target of mating activity, the progeny of the modified fish are sterile. Because the majority of the mating produces sterile progeny, the non-modified population become increasingly less self generating to the point of no return. More generally, there is the view that 'maintaining the status quo by a series of technological fixes is a practice that will ultimately fail'.[144]

The health concern is sourced in the biological processes necessary to produce the terminator effect with, in plants, this effect being achieved by the production of toxins in the seed.

There are also economic reasons for prohibiting the use of terminator genes. Enhancing seeds with terminator genes forces farmers to continually restock through a particular seed supplier, which both increases the cost of farming and hands control of crop supply to the entity holding the relevant patent.

The benefits of terminator technology argue that a terminator technology ban is inappropriate. Two factors argue, though, that some action is required. First, the aforementioned dangers of the technology. Second, the precautionary principle,[145] to which Australia is committed and which, as Esmaeili notes, is encoded in s 56 of the Gene Act.[146]

---

144 Nossal and Coppel, above n 115, 76.

145 This principle states that 'where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'. (*Rio Declaration on the Environment and Development*, United Nations Conference on Environment and Development, Rio De Janeiro, 3–14 June 1992.)

146 Hossein Esmaeili, 'Regulating Agricultural Biotechnology in International Law, with a Specific 'Reference to Australian Law' (Paper presented at the 7th ICABR International Conference on Public Goods and Public Policy for Agricultural Biotechnology, Ravello (Italy), June 29 to July 3, 2003) 15.

In light of the above, it is proposed that a provision be inserted in the Act whereby the exploitation of terminator technology is tied to a compulsory licence revocable upon evidence that such exploitation has resulted in either compulsory back to base restocking or the degradation of the environment beyond that caused by traditional agricultural practices.

B *Biodiversity*

Biodiversity underpins International Environment Law. Biodiversity the term refers to diversity within and among species. Biodiversity the logic refers to the need to maintain an exotic germplasm base. This need arises as '[a] wide pool of diversity … keeps evolutionary options open', particularly important where we have 'variations in the physical components of the biosphere, such as climate changes.[147]

The need for biodiversity has motivated projects such as the Consultative Group on International Agricultural Research ('CGIAR') and the Germ Enhancement of Maize (GEM) Project. CGIAR is an international body sponsored by, inter alia, the World Bank and the United Nations Development Programme and seeks to preserve biodiversity through the establishment, ex situ, of plant genetic resources.[148] The GEM Project was designed to elevate both the quality and quantity of the American corn hybrid germplasm base.[149]

On the one hand, transgenesis supports diversity. It allows a person skilled in the art to import variety into any genus. The variety comes from the transgene and the scope, at least to the

---

147 Guide to the Convention on Biodiversity (opened for signature in the Earth Summit, Brazil,1992) in Marin, above n 138, 95.

148 For discussion on CGIAR, see, for example, Michael Blakeney, 'Access to Biological Resources: Domestic and International Development and Issues' (1998) Vol 5 (3) *E Law - Murdoch University Electronic Journal of Law* <http://www.murdoch.edu.au/elaw/indices/author/25.html> at 8 September 2003 and Michael Blakeney, 'Agricultural Research: Intellectual Property and the CGIAR System' in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (2002) 108.

149 For discussion on GEM, see, for example, Linda M Pollack, 'The History and Success of the Public-Private Project on Germplasm Enhancement of Maize' (2003) 78 Ad*vances in Agronomy* 45.

novice, appears endless. However, the power to vary is conducive to a reduced germplasm base. This deleterious result is excited by both commercial imperatives and natural forces. Commercial imperatives operate primarily in relation to agriculture and biopharming stock. It is a phenomenon sourced in market economics and states that producers will favour what the market requires. Natural forces are implicated where, inter alia, the transgenic change has made for a more attractive mate.

On the basis that commercial and natural forces will overall diminish germplasm variety, one exploitation strategy for the Act and a concomitant technical amendment are here proposed.

It is proposed that a provision be inserted in the Act which passes to the Patent Office the power to exclude a particular animal breed from patentability from time to time to the extent that the animal has been declared in appropriate regulations to the Act. A model in this regard is found in s 42 of the *Plant Breeder's Rights Act (1994)* Cth ('the Plant Breeder's Act'). Section 42 prevents a breeder from obtaining a plant breeder's right over taxons so nominated in the regulations. The nomination for the regulations will only be made on the recommendation of the Plant Breeder's Rights Advisory Committee established by s 63 of the Plant Breeder's Act.

Second, it is proposed that a provision be inserted in the Act establishing an advisory committee with functions and powers analogous to the Plant Breeder's Rights Advisory Committee.

C *International Stewardship*

Thus far, the exploitation model has been used to protect. Exploitation can also enable, and in this regard the plight of the world's undeveloped and developing countries warrant attention. These countries can particularly benefit from transgenic animal work. Micronutrient deficiency, for example, is prevalent in the developing world[150] while pharming can produce micronutrients cheaply on a huge scale.

---

[150] See generally in this regard, Robin D Graham, Ross M Welch and Howarth E Bouis, 'Addressing Micronutrient Malnutrition Through Enhancing the Nutritional Quality of Staple Foods: Principles, Perspectives and Knowledge Gaps' (2000) *Advances in Agronomy* 77.

The world's poorer countries have not benefited from transgenic technology, animal or plant. Moreover, to the extent that the needs of these countries have been attended to, their treatment has been inequitable with, as Pretorius notes, higher comparative price being charged in the developing country than in the developed country for pharmaceuticals and treatments. The price captures a smaller market but maximises the return for the company releasing the product, typically a drug.[151]

This position is unacceptable on any of three grounds.

First, developing countries have frequently been the source of the transgene upon which a production entity has developed its product.[152] Second, international obligations demand that the needs of the world's poorer countries be attended to. This position characterised the Brundtland Report[153] and underlies concepts such as environmental technology transfers.[154] Third, developing countries will be denied the opportunity of building domestic industry in the manner enjoyed by, for example, India and the USA before it with TRIPS making it a requirement that developing countries who are members of the World Trade Organisation honour patent laws.[155]

---

151 Pretorius above n 91, 189.

152 In this regard, see, for example, Marin, above n 138, 101ff.

153 The Brundtland Report (Our Common Future) made by the World Commission on Environment and Development and published in 1987.

154 Technology transfer requirements call on signatory to a convention to share information and/or technology with developing nations so that the developing world can both 'leap frog' to developed status and do so in an environmentally sound manner. Such calls are seen in, for example, Article 3 of the Convention on Long Range Transboundary Air Pollution (Geneva), *UKTS57* (1983) (in force 16 March 1983) – contracting parties are here called upon to 'facilitate the exchange of technology to reduce nitrogen oxide emissions by exchanging existing technology and information and promoting technical assistance and industrial co-operation.' For more general discussion on technology transfer, see, for example, M Townsend, 'The International Transfer of Environmental Technology' (1993) *Environmental and Planning Law Journal* 164.

155 For discussion in this regard generally, see, for example, Peter Drahos with John Braithwaite, *Information Feudalism Who Owns the Knowledge Economy?* (2002).

Several exploitation methods present themselves in this regard. Lanjouw,[156] for example, proposes a system whereby on making a patent application the applicant warrants that should the application be accepted the applicant will not prosecute where infringement occurs in a designated developed country — 'the Mechanism'. This paper, proposes two further exploitation options.

First, it is proposed that the research exemption to be encoded in the Act continues to apply after commercialisation of a transgenic animal invention where and to the extent that the research targets a requirement specific to a developing country. Any income from that application would accrue to the researching body. This mutant form of market segmentation deal[157] will reduce significantly transgenic animal research costs thereby freeing researchers from the strictures of Industry financiers thus the necessity of conducting research primarily to meet the needs of developed countries.

Second, and in accordance with the sentiment of DP 68, it is proposed that s 168 of the Act be amended to allow the Commonwealth to make an agreement with a foreign country to exploit an invention without infringement to assist a foreign country in meeting its health needs.[158]

VI CONCLUSION

Following the release of DP 68, Prof Weisbrot commented that:

> [w]hile we have avoided some of the worst difficulties experienced in the US and Europe [in relation to genetic patents], we have to get the systems in place now to ensure a calm, balanced and flexible approach is

---

[156] Lanjouw, above n 114.

[157] The terminology here is that of Wright, above n 30, 137, who therein proposed a market segmentation deal involving technology providers and developing countries.

[158] Presently, s 168 permits such agreement to assist a foreign country to meet its defence needs. In this regard, see, also, DP 68 as to the Crown use provisions of the Act.

> taken to patents on genetic materials and technologies.[159]

In the spirit of this view, this paper has argued, firstly, that such an imperative exists in the face of the transgenic animal, secondly, that the Government has a pivotal role to play in the establishment of appropriate systems, and, finally, that the Government's role would be best fulfilled by technical amendments to the Act together with a review of the Act's function.

In conclusion, it is proposed that to more fully prepare for the Industry, debate be had on:

- the implication of transgenic science for animal breeders;
- establishing an effective national compulsory licensing system;
- ways to improve the controlled separation approach to the release of transgenic animals;
- the adequacy of addressing indigenous rights over germplasm outside the Act; and
- the insurance and like needs of our farming sector in a transgenic age.

It is hoped that such debate together with the legislative renovation herein discussed will result in a patent system which allows for the responsible growth of the Industry and for an Act, perhaps dysfunctional, but sufficient to launch Australia into the biotechnological age.

First published in *The UNE Law Journal*, volume 1, issue 1 (2004)
Published by The University of New England

ISSN: 1449-2199
UNE Law Journal online: http://tlc.une.edu.au/lawjournal/

[159] Above, n 87 [3].