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The Attack of the Clones: Patent Law and Stem Cell Research

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This article considers the integral role played by patent law in respect of stem cell research. It highlights concerns about commercialisation, access to essential medicines and bioethics. The article maintains that there is a fundamental ambiguity in the Patents Act 1990 (Cth) as to whether stem cell research is patentable subject matter. There is a need to revise the legislation in light of the establishment of the National Stem Cell Centre and the passing of the Research Involving Embryos Act 2002 (Cth). The article raises concerns about the strong patent protection secured by the Wisconsin Alumni Research Foundation and Geron Corporation in respect of stem cell research in the United States. It contends that a number of legal reforms could safeguard access to stem cell lines, and resulting drugs and therapies. Finally, this article explores how ethical concerns are addressed within the framework of the European Biotechnology Directive. It examines the decision of the European Patent Office in relation to the so-called "Edinburgh patent", and the inquiry of the European Group on Ethics in Science and New Technologies into "The Ethical Aspects of Patenting Involving Human Stem Cells".

Introduction

> "It's as though, if this were 100 years ago it's as though someone said I own the stars in the sky. Or I own Nebraska because I got there first. These intellectual property holdings are the most dramatic in the history of science and they will govern the future of the technology for decades if not for the century": Glenn McGee, the University of Pennsylvania.[1]

In 2002 the Federal Government announced the establishment of a National Centre for Excellence in Biotechnology, specialising in stem cell research, based at the Monash Institute of Reproduction and Development. This program has been assigned A$46.5 million over five years, with joint funding provided by Biotechnology Australia and the Australian Research Council. The decision was a surprising one – for although Professor Alan Trounson and his team of scientists have a distinguished reputation, there had been great discord within the Howard Government over the ethics of stem cell research.

Among a number of factors, the Prime Minister John Howard was no doubt swayed by the economic potential of biotechnology in general, and stem cell research in particular. The National Centre offered a bullish forecast for the prospects of its research:

> "The field of stem cell research has excited significant investment globally because of its capacity for potential returns from all phases of research. The research and development plans for the Centre have the strong prospect of early, mid and long term returns. There is the clear prospect of licensing of new intellectual property, enhanced cell lines and research reagents, development of cell types for applications in

* The author is grateful to Mr Alex Bruce, Dr Dianne Nicol and Professor Brad Sherman for their feedback, and Elsa Gilchrist for her research assistance. This project has been supported by an Australian Research Council Grant to research "Gene Patents in Australia: Options for Reform"

[1] D Martin, "Cloning: The Four Letter Word", Background Briefing, Radio National, ABC, 10 February 2002: http://www.abc.net.au/rn/talks/bbing/stories/s478238.htm.

diagnostics and drug development, and the use of cell lines in tissue and organ engineering and repair."[2]

The National Centre will rely upon ES Cell International Pty Ltd to handle the commercialisation of its research. This company controls significant platform technology due to its intellectual property and know-how in the area of human embryonic stem cells and their directed differentiation. To realise its ambitions, the National Centre will have to grapple with strong patent protection in the United States, and scope for ethical objections to stem cell research in the European Union.

This article considers the instrumental role played by patent law in respect of stem cell research. It examines the relationship between commercialisation, access to essential medicines and bioethics. The article considers the establishment of the National Stem Cell Centre, and the ensuing parliamentary debate over the *Research Involving Embryos Act 2002* (Cth). It argues that the Federal Government will need to reform patent law if it intends to foster the commercialisation of stem cell research. The strong patent protection secured by the Wisconsin Alumni Research Foundation and Geron Corporation in respect of stem cell research in the United States is examined and a number of mechanisms to safeguard access to stem cell lines, and resulting drugs and therapies, is considered. The article then seeks to accommodate ethical concerns within the framework of the patent system. It examines the decision of the European Patent Office to the opposition proceedings taken against the "Edinburgh patent". It also considers the inquiry of the European Group on Ethics in Science and New Technologies into "The Ethical Aspects of Patenting Involving Human Stem Cells".

The mouse that roared: Research involving embryos

There has been much policy discussion about the ethical regulation of stem cell research.[3] In Australia, the House of Representatives Standing Committee on Legal and Constitutional Affairs has released its report entitled *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*.[4] The Senate Community Affairs Legislation Committee also produced a report entitled *Research Involving Embryos and the Prohibition of Human Cloning Bill 2002* (Cth).[5] There were a number of submissions which considered patent law and stem cell research. IP Australia put forward a submission which outlined its philosophy and practice in this particular area. There was a range of comments from Australian companies which were undertaking stem cell research. There were also a number of submissions which raised ethical objections to the patenting and commercialisation of stem cell research. Lamentably, there was little sustained discussion of intellectual property in the final parliamentary reports. Such issues were considered to be secondary and ancillary to regulation of stem cell research. Arguably, though, there needs to be a comprehensive discussion of patent law and stem cell research.

Patent Office

In 1990 Independent Senator and pro-life patriarch, Brian Harradine, introduced amendments into Parliament which became s 18(2) of the *Patents Act 1990* (Cth):

> "Human beings, and the biological processes for their generation are not patentable inventions."

At the time, the amendments were criticised for a lack of clarity. Democrat Senator Coulter queried:

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[2] Biotechnology Australia, "Centre for Stem Cells and Tissue Repair, Backing Australia's Ability: Biotechnology Centre of Excellence", *Fact Sheet*, 30 May 2002, p 4: http://www.biotechnology.gov.au/library/content_library/BA_FS_summary.pdf.

[3] J Casell, "Lengthening the Stem: Allowing Federal Funded Researchers to Derive Human Pluripotent Stem Cells from Embryos" (2001) 34 (3) *University of Michigan Journal of Law Reform* 547; A Bruce, "The Search For Truth And Freedom: Ethical Issues Surrounding Human Cloning and Stem Cell Research" (2002) 9 (3) JLM 323; D Nicol, D Chalmers and B Gogarty, "Regulating Biomedical Advances: Embryonic Stem Cell Research" (2002) 2 *Macquarie Law Journal* 31; and B Gogarty and D Nicol, "The UK's Cloning Laws, a View from the Antipodes" (2002) 9 (2) *Murdoch University Electronic Journal of Law*: http://www.murdoch.edu.au/elaw/issues/v9n2/gogarty92.html.

[4] House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (September 2001).

[5] Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002: Supplementary Report* (October 2002), p 178.

> "Where the amendment goes on to say 'the biological processes for their generation' – referring specifically to human beings – it begs the very question of which we need some clarification. What are the biological processes for the generation of human beings?"[6]

It is difficult to ascertain the scope of the excluded subject matter.

In its submission to the House of Representatives Standing Committee on Legal and Constitutional Affairs, IP Australia emphasised economic concerns related to the patenting of new technologies, and downplayed matters of ethics and social policy.[7] The organisation maintained that s 18(2) of the *Patents Act 1990* (Cth) prohibits human cloning, but not stem cell research:

> "It is the understanding of IP Australia that its practice in granting patents for inventions involving human genes, cell lines and tissue is consistent with the provisions of subsection 18(2) of the Act. This is premised on a widely accepted view that human genes, cell lines and tissues are not regarded as human beings, as distinct from foetuses and embryos which are regarded as human beings and hence are not patentable.
>
> However, while the applicability or otherwise of subsection 18(2) is reasonably straightforward in these instances, IP Australia also recognises there exists a grey area within which there is the potential for ambiguity concerning what constitutes a human being or a biological process for the generation of a human being.
>
> To date there has been no judicial consideration of subsection 18(2) and it remains unclear which inventions would be strictly caught by that provision. In the absence of any judicial consideration, IP Australia is required to give applicants the benefit of the doubt in relation to the patentability of inventions concerning human material."[8]

There is little scope for consideration of ethical concerns elsewhere in patent law jurisprudence. The prohibition against the patenting of methods of human treatment has been eroded in a series of Federal Court cases.[9] The generally inconvenient proviso has seldom been invoked by judges because of a suspicion that it would amount to ad hoc policy-making by the judiciary.[10] Schedule 1 of the *Patents Regulations 1991* (Cth) provides that patent documents to be filed must not contain material "contrary to morality or public order". However, there is no indication that such regulations have ever been applied by IP Australia.

IP Australia articulated its policy in relation to the patenting of human genes, tissues and cell lines as follows:

> "The practice of IP Australia is to grant patents on applications in respect of inventions involving human genes, tissues and cell lines, and non-human clones and cloning procedures, providing such inventions meet the statutory patentability requirements such as novelty, inventive merit, industrial application and adequate disclosure of the invention in the patent specification. (A human cell line is different from naturally occurring cells in the human body. It is capable of continuous propagation in an artificial environment by continual division of the cells, unlike naturally occurring cells which die after a limited number of divisions.)"[11]

The Patent Office reported:

> "To date IP Australia has granted 4 patents for cloning processes applicable to non-human mammals and routinely grants patents for both human and animal cell lines, DNA sequences and non-human animal varieties, provided these inventions meet the statutory requirements for patentability."

IP Australia observed:

> "It should be noted that the use of inventions such as human genes, cell lines and tissue would still be subject to other regulatory legislation."[12]

IP Australia wanted to stay above the fray of the policy dispute over stem cell research. This proved to be an institutionally wise decision, given the

[6] J Coulter, "Patents Bill 1990 (Cth), in Committee", Senate *Hansard*, 20 September 1990, p 2653.

[7] IP Australia, "House of Representatives Standing Committee on Legal and Constitutional Affairs Inquiry Into the Scientific, Ethical and Regulatory Aspects of Human Cloning", Submission 274, 2001, http://www.aph.gov.au/house/committee/laca/humancloning/sub274.pdf.

[8] IP Australia, n 7, p 4.

[9] *Bristol-Myers Squibb* v *FH Faulding* (2000) 46 IPR 553.

[10] *Bristol-Myers Squibb* v *FH Faulding* (2000) 46 IPR 553; *Welcome Real-Time SA* v *Catuity Inc* (2001) 51 IPR 327.

[11] IP Australia, n 7, p 4.

[12] IP Australia, n 7, p 5.

hysteria of the debate. However, IP Australia has not played an entirely neutral and impartial role. For instance, its interpretation of the "grey area" cast by the ambiguous s 18(2) of the *Patents Act 1990* (Cth) displays a particular moral judgment and purpose. There remains a need for the Federal Government to revise s 18(2) of the *Patents Act 1990* (Cth). The current provision is indeterminate. The nascent industry will find it difficult to secure investment if the underlying law is uncertain and ambiguous.[13] It would be unfair for research organisations to bear the cost of any legal challenges that would inevitably arise over the meaning of this clause of the *Patents Act 1990* (Cth).

Industry perspectives

In its inquiry into human cloning and stem cell research, the Andrews Committee interviewed Robert Klupacs, the chief executive officer of ES Cell International, the commercialisation centre of Alan Trounson's Melbourne Institute for Reproduction and Development.

Klupacs told the Committee that intellectual property was important for ES Cell International in terms of bargaining power. He observed that it placed the company in a position to trade for enabling technology with other stem cell research companies such as the Geron Corporation and the Roslin Institute:

> "The whole game in intellectual property development is to get as much as you can early to trade off with the other pieces you do not have. But if you have no tools to trade with you may as well give it up. The pharmaceutical area, as you know, is the most highly patented area in the world for exactly that reason. People like to get the monopoly to justify their investment, but more importantly it is to trade off intellectual property pieces of enabling technology so they can grow. If we do not move quickly and get access to intellectual property, particularly the regulation side, the gene side, our company will not survive, or we will be taken over, or someone else will just put us out of business. My investors do not want that to happen."[14]

Klupacs also foresaw that ES Cell International will be able to gain a commercial advantage in the future from using intellectual property to control downstream markets such as drug development and therapeutic development.

Klupacs observed that stem cell research would be advanced by a number of scientific teams of researchers – most notably, the Wisconsin group and the Roslin group. He expressed that view that it was unrealistic to expect that one company would be able to control access to such research:

> "We are not arrogant enough to think that we will ever know it all. A lot of discoveries need to be made by the scientific community, some of which we might get access to, some we will not. But we have taken the view internally that this needs to move very quickly, because ultimately it is about improving mankind, and we need to give it to as many people as possible. There are some smart people out there and serendipity will play a major role. If we sit on it and try to control it internally, all we are going to do is, firstly, piss off the scientific community and, secondly, not advance science. That is of no value to us."[15]

Klupacs was politic in noting that the company intended not to be as restrictive in its licensing as Geron Corporation. ES Cell International supplies its human embryonic stem cells to academic and commercial organisations under Material Transfer Agreements. Recipients grant ES Cell International a right of first refusal to negotiate exclusive licences for any discoveries made using ES Cell International's human embryonic cells.

In its inquiry into the stem cell legislation, the Senate Community Affairs Legislation Committee interviewed some of the other major corporate players in stem cell research in Australia.

Dr Christopher Juttner, executive director of Bresagen Ltd, explained that he had become convinced of the necessity for patent protection in the field of stem cell research. He said:

> "There needed to be protection to allow a period of time for an inventor to gain some recompense for the hundreds of millions of dollars they invest in development."[16]

[13] M Cook, "Fickle Fortunes of Biotech Biz", *The Weekend Australian*, 17 August 2002, p 26.

[14] House of Representatives, Standing Committee on Legal and Constitutional Affairs, "Public Hearing: Human Cloning", 11 May 2001, LCA 185-186.

[15] House of Representatives, Standing Committee on Legal and Constitutional Affairs, n 14.

[16] Senate, Community Affairs Legislation Committee, "Research Involving Embryos and Prohibition of Human Cloning Bill", 17 September 2002, CA 36-37.

Juttner elaborated on the position of Bresagen Ltd in relation to patent law and stem cell research:

> "Our own position about our embryonic stem cell lines is that within the US for any NIH-funded researcher we make those cells available at no cost, and we do not even get, because of the way NIH negotiated this, a right of first refusal to inventions that come from our lines. That was not our preferred position. Our preferred position is to make cells available for a small training fee of $5,000 and then to have a right of first refusal to negotiate on new IP, but with no guarantee or ownership built into that. We take that view because this is such a vast field. We are a small company. We are focused on one area. We cannot encompass everything. It is much better for us to have cells widely available. We are enthusiastic, indeed, to see comparative studies done between our cells and other people's cells. If they are not as good as other people's cells, the sooner we find out the better."[17]

Biotechnology Australia submitted to the Committee that one reason existing embryonic stem cell lines are insufficient for continued research and further development of therapies was that many existing stem cell lines are subject to patent protection, restricting researchers' freedom to operate. It identified that this inability to gain access to cell lines is likely to hamper scientists' work in this field.[18]

Dr Peter Mountford, the chief scientist of Stem Cell Sciences, argued:

> "SCS strongly opposes any commercial control and exploitation of such a fundamental biological resource as human stem cells. SCS supports the European Union's Ethics Group recommendation to prohibit patenting of unmodified human stem cells."[19]

Such a comment perhaps represents an effort by Mountford to distance himself from the controversy over the Edinburgh patent. Hugh Ilyine, general manager of Stem Cell Sciences, commented:

> "There has been a lot of difficulty with researchers getting access to the stem cell lines, I believe, for one reason or another. The second part is that the European approach is probably different from the US approach in the general philosophy of how things are done. There are of course recent recommendations to the European Union from the European Union ethics council, which has really come out to say that there should be no patenting of human stem cell lines. At the moment there is a patent which relates to stem cell coming out of the Wisconsin university under Professor Jamie Thompson. So the European position is looking to be different from that taken in the US. Then the question is: where does Stem Cell Sciences, as a company, wish to position itself? Our position is that we support the position in Europe as distinct from the position that is taken in the US."[20]

Stem Cell Sciences advocated the establishment of a National Stem Cell Bank, within an independent government organisation, to distribute human stem cell lines to researchers. This would be similar to the recent United Kingdom announcement to establish such a bank, operating independently of research institutions and commercial organisations.[21]

It is also worth mentioning that the pharmaceutical industry had a large stake in the debate over stem cell research. It heavily lobbied members of Federal Parliament to gain approval for the commercialisation of stem cell research.

Ethical objections

The Senate Community Affairs Legislation Committee report observed:

> "Although the current Bill does not directly address the issue of intellectual property rights in relation to human embryos and stem cells, this was an issue that was repeatedly raised during the course of this inquiry."[22]

Many submissions suggested that the regulation of embryonic stem cell research was being driven by the prospect of profits that could be derived under a patent. Those submissions claimed that the

[17] Senate, Community Affairs Legislation Committee, n 16.

[18] Biotechnology Australia, "Senate Community Affairs Legislation Inquiry into Research Involving Embryos and Prohibition of Human Cloning Bill", Submission 1263, 2002, p 7.

[19] Stem Cell Sciences, "Senate Community Affairs Legislation Inquiry into Research Involving Embryos and Prohibition of Human Cloning Bill", Submission 1263, 2002, p 2.

[20] Senate, Community Affairs Legislation Committee, "Research Involving Embryos and Prohibition of Human Cloning Bill", Senate Committee *Hansard*, 17 September 2002, CA 36.

[21] Senate, Community Affairs Legislation Committee, n 20.

[22] Senate, Community Affairs Legislation Committee, n 5, p 76.

potential for scientific and medical advances, which may also exist in adult stem cells, was secondary to the financial bounties that could be secured by asserting intellectual property rights that may only be claimed over embryonic stem cell lines.

In a prepared statement, Dr Warwick Neville, a research fellow of the Australian Catholic Bishops Conference, was critical of the emphasis upon commercialisation in the National Centre for Excellence in Biotechnology:

> "The Biotechnology Centre of Excellence's thrust for the commercialisation and commodification of life, with its concomitant entrepreneurial focus, does not take into account the literature which highlights that patenting in biomedicine does not enhance trust, among other things. Surveys have found that patenting has led to reductions in openness and data-sharing, delays in publication and tendencies to select research projects of short-term commercial interest."[23]

Neville cited with the approval the remarks of Canadian Professor Richard Gold that the intellectual property system skews research in biotechnology because it ignores ethical and social concerns.[24] He also discussed two alternative forms of regulation – consumer protection legislation[25] and anti-discrimination legislation.[26]

National Party Senator and ardent opponent of stem cell research, Ron Boswell, reflected:

> "This is a world of high finance, patents, trades and deals where monopolies on human genes are traded like football hero cards, only the stakes are much higher."[27]

Boswell argued that it was inappropriate for the Federal Government to provide public funds for a company with foreign ownership. He said:

> "We are being asked to underwrite the intellectual property portfolio of a foreign company dealing in embryo product, cloned or otherwise."[28]

Boswell has been busy scouring the ASIC records to work out the financial interests of the directors and the shareholders of ES Cell Australia. The purpose of this mission has been to find evidence of conflict of interest or commercial mismanagement. However, the accuracy of his allegations has been substantially challenged in the Senate Standing Committee on Privileges.[29]

Nonetheless, survey evidence suggests that a majority of Australians support the use of fetal tissue such as stem cells for medical research and treatment.[30] Such attitudes have remained stable over a long period of time. This community support is an important counterpoint to the ethical objections expressed in the inquiry.

Parliamentary responses

The Senate Community Affairs Legislation Committee considered the evidence proposed in relation to intellectual property and stem cell research. A supplementary report written by Democrat Senator Natasha Stott-Despoja, among others, advised:

> "We are sympathetic to many of the concerns raised concerning patents and intellectual property rights."

Senator Stott Despoja, in particular, has a long-standing interest in such matters and has introduced private members Bills seeking to prevent patenting of naturally occurring genetic material and gene sequences and other related genetic issues.

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[23] Community Affairs Legislation Committee, "Research Involving Embryos and Prohibition of Human Cloning Bill", Senate Committee *Hansard*, 26 September 2002, pp 215-216.

[24] R Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Georgetown University Press, Washington DC, 1996); R Gold, "Making Room: Reintegrating Basic Research, Health Policy and Ethics into Patent Law", in T A Caulfield, and B Williams-Jones (eds), *The Commercialization of Genetic Research: Ethical, Legal and Policy Issues* (Plenum Publishers, New York, 1999); and R Gold, "Biomedical Patents and Ethics: A Canadian Solution" (2000) 45 (2) *McGill Law Journal* 413.

[25] A Chalet, "Commercialisation and Misleading and Deceptive Conduct" (2002) 1 (5) *Biotechnology Law and Policy Reporter* 63.

[26] Neville mentioned Senator Natasha Stott Despoja's lapsed *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), and the ALRC and AHEC, *Protection of Human Genetic Information: Discussion Paper* (ALRC, Sydney, 2002).

[27] R Boswell, "Research Involving Embryos and Prohibition of Human Cloning Bill", Senate *Hansard*, 15 May 2002, p 1534.

[28] R Boswell, "Research Involving Embryos Bill 2002: Second Reading", Senate *Hansard*, 12 November 2002, p 5987.

[29] Senate Standing Committee on Privileges, "Persons Referred to in the Senate: Dr Geoffrey Vaughan, Dr Peter Jonson, Professor Brian Anderson", 110th Report, December 2002.

[30] J Kelley, M D R Evans and E Zanjani, "Moral Views on the Use of Foetal Tissue Depend on the Source of the Cells, Australia 1993-2000" (2002) 5 (3) *Australian Social Monitor* http://wff2.ecom.unimelb.edu.au/iaesrwww/sm/.

> "We do not favour, however, bringing patent and intellectual property amendments forward during debate on these Bills. Ad hoc changes to complex areas of law can create more problems than they solve, despite good intentions. Rather, we would prefer to see a considered approach that is well grounded in the challenges genetic sciences pose to lawmakers seeking to balance the interest of inventors and the community."[31]

The supplementary report noted that the review of issues relating to the protection of genetic information by the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) did not include stem cell science.[32] It concluded:

> "We believe it is appropriate that the ALRC and AHEC are given another reference to consider issues of patenting, intellectual property and stem cell science and that this reference should feed directly into the review of this legislation."[33]

In parliamentary debate, the Greens were concerned that patents related to stem cell research would limit research, and restrict access to therapeutic applications and drugs developed from stem cell lines. Senator Bob Brown commented:

> "You know, there's a big profit motivation behind some sections of the stem cell research, for example pharmaceutical research and so on, that area of science is driven by the profit motive and the big corporations and I'm very keen to see that we don't simply have exploitation of embryonic stem cells to line the pockets of those corporations, but rather that it be made sure that this is going to have a wide public benefit and that it's going to be a public benefit that's available to everybody."[34]

The Greens also proposed that the Commonwealth Government establish a national stem cell bank as a repository for stem cell lines from human embryos and adult stem cells.[35] It was envisaged that any holder of a licence issued under this legislation would be required to deposit stem cell lines into the national bank, and that any researcher approved for conducting research using human tissue would be permitted to use stem cell lines from the bank. The Greens hoped that a national stem cell bank would ensure that all research institutions would have access to the basic materials for developing applications from stem cell lines.

In parliamentary debate over the *Research Involving Embryos Act 2002* (Cth), the Democrats, as well as the Greens, moved to establish a process by which the ALRC and AHEC will review intellectual property and patenting considerations of stem cell science including stem cell products.[36] Senator Stott-Despoja of the Democrats called upon her fellow senators to support the amendment.[37] The Senate voted 43 in favour, and 26 against this motion. The Minister for Health and Ageing, Senator Kay Patterson, was among the supporters of the inquiry. She was, though, conscious that a comprehensive review of the issues would take some time.[38] In the wake of the political debate, the *Research Involving Embryos Act 2002* (Cth) was finally passed in December 2002. The inquiry into intellectual property and stem cell research is still in the process of being set up.

Summary

The parliamentary debate over the *Research Involving Embryos Act 2002* (Cth) failed to resolve outstanding issues in respect of patent law and stem cell research. In particular, it did not adequately address s 18(2) of the *Patents Act 1990* (Cth), which is indeterminate as to whether stem cell research is patentable subject matter. The National Stem Cell Centre will require greater legislative clarity as to whether stem cell research is patentable if it is to realise its commercialisation strategies. The decision of the Federal Government to hold an inquiry into intellectual property and stem cell

[31] Senate Community Affairs Legislation Committee, n 5, p 178.
[32] Senate Community Affairs Legislation Committee, n 5, p 178.
[33] Senate Community Affairs Legislation Committee, n 5, p 178.
[34] L Motram, "Stem Cell Bill Goes Before Senate", AM, ABC Radio, 11 November 2002, http://www.abc.net.au/am/s723473.htm.
[35] K Nettle, "Research Involving Embryos Bill 2002: Second Reading", Senate *Hansard,* 11 November 2002, p 5914; J Skatssoon, "Stem Cell IP Law Patently Unclear – Expert", Australian Associated Press, 11 November 2002.
[36] N Stott-Despoja, "Democrat Stem Cell IP Review", *Australian Democrats Press Release*, 12 November 2002; N Stott-Despoja, "Democrat Win on Stem Cell IP Review", *Australian Democrats Press Release*, 12 November 2002; and N Stott-Despoja, "Stem Cell Bank On Track", *Australian Democrats Press Release*, 13 November 2002.
[37] N Stott-Despoja, "Research Involving Embryos Bill 2002: Second Reading", Senate *Hansard*, 12 November 2002, p 6043.
[38] K Patterson, "Prohibition of Cloning Bill 2002: Second Reading", Senate *Hansard*, 12 November 2002, p 6045.

research is to be welcomed. There is a diversity of views as to what is an ideal competitive regime for patent law and stem cell research in the context of Australia. ES Cell International stresses the importance of intellectual property in terms of bargaining and licensing. Bresagen Ltd supports an approach that is modelled upon the United States law. Stem Cell Sciences favours the position in the European Union. Against such commercial views, there remain a number of critics who are concerned about the possible negative consequences of patenting in biomedicine. For instance, the Australian Catholic Bishops Conference was concerned that patent law could have a detrimental impact upon research and publication among scientists. Such conflicting views will need to be taken into account in the inquiry into intellectual property and stem cell research.

An 800-Pound Gorilla: Geron Corporation

In 2001, the United States President George W Bush declared that future stem cell research would be confined to existing stem cells:

> "As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made."[39]

The decision of the President had the inadvertent effect of increasing the value of existing patents in respect of stem cell research. By refusing to allow taxpayers' money to finance the creation of new cell lines in this country, he reduced the chances that scientists would derive and patent cells that might challenge the dominance of existing players in the field. Eisenberg noted:

> "What constrains the monopoly power of a patent holder is the prospect of new technology being developed that will make it unnecessary to deal with them. The President's decision limits that threat."[40]

The University of Wisconsin was the main beneficiary of this decision, because it held extensive patents in respect of primate and human embryonic stem cell research. In November 1998, Dr James Thomson of the University of Wisconsin first isolated and cultivated pluripotent human embryonic stem cells. His team established five unmodified human embryonic stem cell lines. Through the Wisconsin Alumni Research Foundation (WARF), he filed a patent on 26 June 1998. After overcoming initial doubts from the patent examiners,[41] Thomson was issued on 13 March 2001 with US Patent No 6,200,806, with the title "Primate Embryonic Stem Cells". The patent broadly covers both the method of isolating human embryonic stem cells and the five unmodified stem cell lines themselves. The technology transfer unit, WARF, is proud of its intellectual property holdings.[42]

Prompted by a moratorium on federal funding of human embryonic stem cell research, WARF licensed the patent to the private firm Geron Corporation in return for research funding. Under a first licence agreement, WARF granted to Geron exclusive rights to develop and commercialise the unmodified stem cell lines isolated by Dr James Thomson into six specific modified stem cell lines – relating to liver, muscle, nerve, pancreas, blood and bone cells. The Foundation retained the right to distribute its unmodified stem cell lines to the academic research community.

On 13 August 2001 WARF filed a lawsuit against Geron, contesting the company's rights to additional human embryonic stem cell types.[43] This legal action was prompted, in part, by government pressure and media scrutiny. As Rai and Eisenberg observed:

[39] President George W Bush, "Remarks on Stem Cell Research", The White House, 9 August 2001, http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html.

[40] S G Stolberg, "Patent Laws May Determine Shape of Stem Cell Research", *The New York Times*, Washington Report, 16 August 2001.

[41] A Regelado, and M Louis, "Ethical Concerns Block Patents of Useful Embryonic Advances", *The Wall Street Journal*, 20 August 2001.

[42] M Penn, "Agency's Aggressive Patent Management Protects Public, Professors", *On Wisconsin*, The University of Wisconsin – Madison, 15 May 2002.

[43] *Wisconsin Alumni Research Foundation* v *Geron Corp* (2002) Case No 01-C-0459-C

> "Exclusive licenses on research tools with potentially broad applications threaten to throttle scientific progress by limiting the number of players in a developing field."[44]

On 26 July 2001 Geron exercised an option contained in the first licence to claim 12 additional stem cell types.[45] WARF argued that the option had expired a week earlier and that the use of the option could be denied at WARF discretion. The dispute was settled out of court.[46] On 9 January 2002 WARF and Geron signed a new licence that gives Geron:

- exclusive rights to develop therapeutic and diagnostic products from three types of human embryonic stem cells (nerve, cardiac muscle and pancreas cells);
- non-exclusive rights to develop therapeutic and diagnostic products from three further human embryonic stem cell types (blood, cartilage and bone cells);
- non-exclusive rights to develop research products in six human embryonic stem cell types.

Furthermore, WARF and Geron agreed to grant research rights to existing human embryonic stem cells patents and patent filings to academic and governmental researchers without royalties or fees.

Scope of the patents

David Earp, Geron's vice president of intellectual property, discussed the intellectual property portfolio licensed to Geron by the Wisconsin Alumni Research Foundation:

> "Our patent portfolio includes issued US patents for primate and human embryonic stem (ES) cells and human embryonic germ (EG) cells, as well as over 50 patent applications pending around the world covering many aspects of human embryonic stem cell culture, production, differentiation and uses in cellular reprogramming."[47]

The United States Patent and Trade Mark Office adopted the position that purified and isolated stem cells are patentable subject matter.[48] The organisation has been criticised for granting broad patents in respect of stem cell research. Shulman observed:

> "Perhaps the biggest lesson of all, though, surrounds the chronic myopia of the US Patent and Trademark Office in awarding such needlessly all-encompassing patents as it has in this field."[49]

There has been a concern that the granting of broad patents to private companies would impair further research and development. There have been anxieties that patent holders could charge unreasonable fees for the use of their inventions – or block access altogether. Rai commented:

> "Control of embryonic stem cell research by the private sector may have significant justice-related consequences. As a general matter, the private sector focuses on medical research that is likely to recoup its costs in the marketplace. It does not necessarily focus on the severity of the disease in question. In the context of stem cell research, exclusive private funding is likely to mean that individuals who have severe diseases but not much in the way of market power will not have research directed towards them."[50]

However, the managing director of WARF, Carl Gulbrandsen, has sought to allay such fears:

> "I don't want people to see us as an 800-pound gorilla. We will work very hard with the government to make sure that there is access to this technology and that our patents are not an impediment to researchers."[51]

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[44] A Rai and R Eisenberg, "The Bayh-Dole Reform and the Progress of Biomedicine" (2002) 66 (1) *Law and Contemporary Problems* 19.

[45] For a full account of this dispute, see B Gratton, "The Wisconsin Alumni Research Foundation and Geron Corporation", in The European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, Opinion No 16, 7 May 2002, p 61.

[46] WARF and Geron Corporation, "WARF and Geron Resolve Lawsuit and Sign New License Agreement", *Press Release*, 9 January 2002.

[47] Geron Corporation, "Geron Reports Issuance of US Patent for Human Embryonic Stem Cells", Menlo Park, California, 13 March 2001.

[48] T Dickinson, "Statement of the Commissioner of Patents and Trademarks before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee", 12 January 1999.

[49] S Shulman, "Owning the Future: The Morphing Patent Problem", *Technology Review*, November 2001.

[50] A Rai, "Stem Cell Research: An NPR Special Report. A 'Virtual Roundtable' on Federal Funding", 2002, http://www.npr.org/programs/specials/stemcells/viewpoints.rai.html.

[51] Stolberg, n 40.

In an interview with *Background Briefing*, Professor Alan Trounson was uncertain as to whether the research at the Monash Institute for Reproduction and Development would be affected by the patents of Geron Corporation:

> "The patents are only being granted in the USA so they're not relevant at the present time in Europe or in Australia or Asia. But their patents are very broad and so we're a bit surprised they were granted for such widely known methodologies. But nevertheless they've been granted. So if we do commercialisation work in the USA we'll probably have to consider their position very closely. If they provide rights to people widely at a reasonable rate I don't think there's any difficulty with respect to it. If they make it extremely difficult and the cost very high, then I think there will be a general reaction, and the reaction will be to challenge the patents to see if they can be broken."[52]

However, the Professor has reason to show greater alarm. First of all, there is evidence that Geron Corporation has already filed patents in Australia. A search of the database of IP Australia reveals that the company has obtained patents in respect of stem cell research in this jurisdiction. Secondly, the research will be at least indirectly affected by the United States patents in terms of prior art. The recent reforms in the *Patent Amendment Act 2001* (Cth) have expanded the prior art base to include inventions created and information published overseas. Finally, the possible commercial exploitation of the stem cell research in the United States is necessarily limited by both the regulatory restrictions laid down by President Bush and the strong, broad patents held by Geron Corporation.

Glen McGee at the University of Pennsylvania recognises the threat that such patents will pose for Australian stem cell research:

> "America is going to be collecting the money for the toll bridge. American companies own essentially all the relevant intellectual property to create a stem cell line to keep it in culture for a long period of time using cells from mice, and to derive new kinds of cells from those stem lines after they're created. And it will be amazing to watch the patent battles that take place, as for example, the University of Wisconsin tries to sue the government of Australia for creating a lab that would produce a whole bunch of embryonic stem cell lines. And they will do exactly that. Can America collect in that way? Can we, as it were, own basic research? I don't know, and I hope not. I have yet to hear anyone from the Bush administration or Wisconsin Alumni Research Foundation or from any of the international companies involved or hospitals involved, anyone say, 'Yep we'll allow people to look at this stuff and develop devices and innovate.'"[53]

However, Geron Corporation and WARF would be exposed to counter-claims for patent invalidity. Rai has observed:

> "It is a very broad patent. Generally speaking, broad patents in the biotechnology area tend to be vulnerable. The claims in the patents cover stem cells in any primate species, from monkeys to man. The strategy has been to claim as broadly as possible and then see what sticks at the patent office. It can be risky."[54]

However, other commentators doubt whether the WARF's claims were susceptible to legal challenge. Todd Dickinson, the former United States Commissioner of Patents and Trade Marks, maintained:

> "All patents are presumed to be valid by law when they issue from the patent office. Going against them would require a strong challenge. I doubt that would happen. It would be a lot cheaper to take a license than to spend several million dollars trying to overturn the patent."[55]

There has been wider debate as to whether there should be administrative and legal reforms to restrict the scope of patents relating to stem cell research. In particular, there has been a push to apply stringently the threshold patent criteria of novelty, inventive step, utility and written description. Shulman argued:

> "The problem with broad patents on embryonic technology is clear: they wind up blocking the

[52] D Martin, "Cloning: The Four Letter Word", Background Briefing, Radio National, ABC, 10 February 2002, http://www.abc.net.au/rn/talks/bbing/stories/s478238.htm.

[53] Martin, n 52.

[54] J Gertzen, "Stem Cell Patents Put UW Agency in Spotlight", *Milwaukee Journal Sentinel*, 25 August 2001.

[55] Gertzen, n 54.

> path for other, more specific patents seeking to bring innovations to market. The patent office virtually needs to learn to distinguish between these kinds of embryonic research tools and marketable inventions more akin to the differentiated cells that perform specific jobs in the body."[56]

Meanwhile, van Overwalle doubted whether the limitation of patent claims will gain widespread acceptance.[57] He observed that research institutions and companies will be reluctant to change their commercial policy of seeking broad patents.

Research tools

On 5 September 2001, the National Institutes of Health signed an agreement with the WiCell Research Institute.[58] The memorandum of understanding covered both access to intellectual property and tangible property held by the WARF.

The parties agreed that Wisconsin patent rights are to be made available without cost for use in the biomedical research program subject to a number of conditions. First, the patent rights only may be used in certain programs in compliance with the law. Additionally, National Institutes of Health (NIH) researchers have to send a yearly notification saying that they are using the cells in accordance with the law. Secondly, WiCell agreed to allow the patent rights to be used in research programs involving other materials. Finally, the parties agreed that the Wisconsin patent rights may be used in public research to make patentable inventions, which themselves may eventually be the basis of commercial products that benefit human health. Essentially, the NIH did not allow "reach-through rights", whereby the owner of a certain material retains the ownership on any invention developed with this material.

In the agreement, the cells are considered as research tools, and inventors using them retain the rights to their own inventions, unless the cells are part of the final invention. The NIH is enthusiastic about dealing with access to embryonic stem cells in terms of "research tools":

> "The NIH urges all providers to make their cells available in accordance with its policy on access to research tools, 'Sharing of Biomedical Research Resources, Principles and Guidelines for Recipients of NIH Research Grants and Contracts'."[59]

The NIH maintain that the patents filed by the Wisconsin Alumni Research Foundation, Geron Corporation and other organisations will not inhibit studies into embryonic stem research. It emphasises that the issuance of patents on new inventions need not adversely affect continuing research, provided that the patent owners devise a licensing and sharing strategy to allow basic research to proceed.

WARF and ES Cell International have signed a licence agreement enabling ES Cell International to distribute its human embryonic stem cells worldwide for use in research.[60] This was the first licence agreement WARF has signed with a commercial provider listed on the National Institutes of Health Stem Cell Registry with lines approved by President Bush.

However, there are obvious limitations to the access to research tools scheme which has been set by the National Institutes of Health. The access regime suffers from many of the same problems that bedevil "research tools" in biomedical research.[61] There has been criticism, too, of the memorandum of understanding.[62] The way remains open for WARF and Geron Corporation to bring legal action

[56] S Shulman, "Owning the Future: The Morphing Patent Problem", *Technology Review*, November 2001.

[57] G van Overwalle, "Study on the Patenting of Inventions Related to Stem Cell Research", European Group on Ethics in Science and New Technologies to the European Commission, 30 December 2001, pp 88-90.

[58] United States Department of Health and Human Services, "Memorandum of Understanding Between the WiCell Research Institute and the Public Health Service", 5 September 2001, http://www.nih.gov/news/stemcell/WicellMOU.pdf.

[59] National Institutes of Health, "Update on Human Embryonic Stem Cells", 27 August 2001, http://www.nih.gov/news/stemcell/082701list.htm. Access to research tools policy can be found at: http://ott.od.nih.gov/NewPages/RTguide_final.html.

[60] Wisconsin Alumni Research Foundation, "Wisconsin Alumni Research Foundation and ES Cell International Sign License Agreement", *Press Release*, 26 April 2002.

[61] R Eisenberg, "Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?" in R Dreyfuss, H First and D Zimmerman (eds), *Expanding the Bounds of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford University Press, Oxford, 2001), p 223.

[62] A Leigler, "Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research", *Duke Law and Technology Review*, 16 October 2001, http://www.law.duke.edu/journals/dltr/articles/2001dltr0037.html.

for patent infringement against its rivals and competitors, outside of the licensing scheme. Some have advocated a reform of patent law to deal with stem cell research.[63] A research exemption would ensure that researchers could contemplate follow-on innovation, without the fear of litigation.[64] It would also clarify the operation of research tools in respect of stem cell research. The provision of compulsory licensing of patents should be encouraged where the access to diagnosis and treatment is blocked by misuse of patent rights.[65] This measure would ensure that the private rights of patent holders do not impinge upon the wider public interest.

Competition law

There could be scope for the intervention of competition law in relation to patent law and biotechnology.[66] In particular, there is hope that anti-trust law could allay the fears that have been expressed that Geron Corporation will become "an 800 pound gorilla", a veritable King Kong monopolist of the biotechnology field.

However, biotechnology companies have become alert to the potential threat of anti-trust action. They have taken steps to maintain good relationships with government regulators. In particular, David Earp, the Vice President of Intellectual Property at Geron Corporation, was involved in the round-table hearings held by the Federal Trade Commission in the United States. He repeatedly stressed that Geron Corporation is "a small biotechnology company", which does not warrant the rigorous application of antitrust law to its business activities.

First, Earp queried the legal status of reach-through licensing in the field of research tools because it involves the licensing company demanding royalties on the sale of a product not covered by their patent. He observed that it was difficult to determine market power in a dynamic market:

> "Ten years down the road though, if you're successful, if your product and your technology become very successful, you do now have marketing power, you do now have market power, that license agreement gets scrutinized at that time, the outcome might be very different. And I struggle with ... the analysis of whether there is an antitrust issue, and potentially maybe the patent misuse issue."[67]

Secondly, Earp was concerned that the company is vulnerable to patents held by competitors and rivals. He maintains that there is a need to overhaul the patent opposition system in the United States, along the lines of the European model. Thirdly, Earp argues that there needs to be clearer guidelines developed by the Department of Justice and the Federal Trade Commission on the application of anti-trust and patent misuse issues in the field of patent law and biotechnology. Such reforms, he believes, will enable greater investment, competition and access to technologies.

In light of this action, it would seem that Geron Corporation would be safe from antitrust action in the foreseeable future.[68]

Summary

In the United States, there are concerns that stem cell research will be monopolised by a small number of research institutions and commercial biotechnology companies which hold key patents in the field. A number of reforms could help guarantee access to stem cell research in the field, and therapies and drugs derived from this work. The scope of patent protection could be limited by the stringent application of patent criteria – such as novelty, inventive step, utility and written description. The research tools scheme set up by the National Institutes of Health could be supported by a research exemption to give third parties access to stem cell products and research tools. The use of compulsory licensing could enable parties to obtain

[63] Leigler, n 62.
[64] M O'Rourke, "Toward a Doctrine of Fair Use In Patent Law" (2000) 100 (5) *Columbia Law Review* 1177.
[65] D Gitter, "International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exemption" (2001) 76 *New York University Law Review* 1623.
[66] D Nicol and J Nielsen, "The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development" (2001) 23 (3) Syd LR 347; and C Lawson, "Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition" (2002) 30 *Federal Law Review* 97.
[67] Federal Trade Commission, "Competition and Intellectual Property Law and Policy in the Knowledge-based Economy: Business Perspectives on Patents – Biotech and Pharmaceuticals", 26 February 2002, http://www.ftc.gov/opp/intellect/020226trans.pdf.
[68] Leigler, n 62.

access to stem cell research without need for authorisation from the patent owners. Competition law could intervene in circumstances in which there were a misuse of market power.

A secular cloister: the ethics of stem cell research

One-time Swiss patent examiner, Albert Einstein, observed in his correspondence that the patent office was a "secular cloister".[69] This metaphor is an apt description. It helps evoke the insular attitude of patent administrations to matters of public policy.

Typically, patent offices seem to assume that ethical considerations are necessarily extrinsic to patent law. As Sherman and Bently observed:

> "One of the defining features of patent law, at least up until its encounter with biotechnology, was that it was treated as if it was hermetically sealed, closed off from external considerations. Modern patent law is characterised not only by its highly technical and specialised nature but also by its startling and marked isolation from matters cultural, political and ethical."[70]

IP Australia has baulked at taking into account ethical considerations in the examination of patent applications. The Australian Patent Office *Manual of Practice and Procedure* asserts that it is inappropriate for the patent office to deal with matters of ethics and social policy.[71] Similarly, the United States Patent and Trade Mark Office has been reluctant to take into account public order and morality. Famously, it avoided dealing such questions when Jeremy Rifkin put forward patent applications in respect of chimaeras.[72]

By contrast, the European Union makes explicit provision for opposition on the grounds of public order and morality under the European Biotechnology Directive. Article 6(1) provides:

> "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be contrary merely because it is prohibited by law or regulation."

Article 6(2) stipulates that certain particular inventions shall be considered to be unpatentable, including:

> "(a) processes for cloning human beings;
> (b) processes for modifying the germ line genetic identity of human beings;
> (c) uses of human embryos for industrial or commercial purposes;
> (d) 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."

Such ethical considerations were evident in the recent opposition proceedings against the Edinburgh patent. These concerns were also a feature of the inquiry of the European Group on Ethics in Science and New Technologies into "The Ethical Aspects of Patenting Involving Human Stem Cells".[73]

The Edinburgh Patent

The "Edinburgh" patent is European patent No EP 0695351, with the title "Isolation, selection and propagation of animal transgenic stem cells". The patent relates to an invention in the field of developmental biology. It describes a method of using genetic engineering to isolate stem cells – including embryonic stem cells – from more differentiated cells in a cell culture in order to obtain pure stem cell cultures. Holders of the patent are Austin Smith at the University of Edinburgh and Peter Mountford, chief scientific officer at the Stem Cell Sciences.[74]

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[69] Albert Einstein, Swiss Patent Office technical expert third class, fondly spoke of the patent office as "that secular cloister where I hatched my most beautiful ideas": A Einstein, "Letter to Michele Besso: 12 December 1919" in P Speziali (ed), *Michele Besso, Correspondence 1903-1955* (Hermann, Paris, 1972), pp 147-149.

[70] B Sherman and L Bently, "The Question of Patenting Life", in S Maniatis (ed), *Intellectual Property and Ethics* (Sweet & Maxwell, London, 1998), p 111.

[71] Australian Patent Office, *Manual of Practice and Procedure*, November 1999, Pt 8.1.

[72] D Dickson, "Legal Fight Looms over Patent Bid on Human/ Animal Chimaeras" (1998) 392 *Nature* 423; and E Chick, "Biotech Critic Tries to Sew Up Research On Chimaeras" (2003) 421 *Nature* 4.

[73] The European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, Opinion No 16, 7 May 2002.

[74] There is already an Australian patent (No AU678233) which appears to be similar to the one in Europe. Vivienne Thom, Commissioner of Patents at IP Australia, said that the Australian patent was sealed in 1997 without opposition.

The granting by the European Patent Office of this patent to the University of Edinburgh in December 1999 led to fierce protests and triggered a major public debate on the patenting of stem cell technology.

Greenpeace staged dramatic protests against this particular patent at the European Patent Office in Munich, Germany.[75] The spokesperson for the group, Christopher Then, declared: "The EPO is selling out the right to use animals, plants and humans to the genetic engineering industry."[76] Ninety activists managed to shut down the EPO by bricking up the main entrance and the basement garage. Climbers hoisted a banner reading, "Stop breeding human beings. No patents on life!"[77] Greenpeace dismissed the apologies of the EPO: "Apologies, promises, and cosmetic corrections are not enough."[78] Christopher Then emphasised: "The patenting of human beings is not the result of the EPO's carelessness – it's a cold-blooded policy."[79]

The patent was opposed by 14 parties, demanding that it be revoked. Ten of the opponents took part in the hearing. The Governments of Germany, Italy and The Netherlands, and the German branch of Greenpeace, were among the parties that have lodged oppositions to the patent. The opponents alleged, among other things, that the "Edinburgh" patent contravened Art 53 (a) of the *European Patent Convention* (EPC), which precluded the patenting of inventions whose exploitation would be contrary to "ordre public" or morality.

The disputed part of the Edinburgh patent was claim 48, which related to a "method of preparing a transgenic animal". Although the practical examples mention mice, the scope of the patent had the potential to encompass humans. The description of the patent mentions that

> "in the context of this invention, the term 'animal cell' is intended to embrace all animal cells, especially of mammalian species, including human cells".

Edinburgh University, the patent proprietor, has made it clear that it never intended the patent to cover creation of genetically altered humans. It therefore requested that the patent be limited. In a statement, Dr Peter Mountford denied any intention to patent or develop technologies for human genetic engineering:

> "The techniques described in this patent represent a significant advance in the culture of stem cells, making available populations of specific types of stem cells for numerous research and clinical applications. While we at Stem Cell Sciences are delighted to be at the forefront of this exciting technology, we are however concerned that our techniques may have been misunderstood."[80]

After a three-day public hearing at the European Patent Office, the Opposition Division decided that the Edinburgh patent should be maintained in an amended form as introduced by the patent proprietor during the oral proceedings.[81] It no longer includes human or animal embryonic stem cells, but still covers modified human and animal stem cells other than embryonic stem cells.

The Opposition Division took the view that the granted patent failed to comply with the requirements of Arts 83 and 53(a) in conjunction with r 23d(c) of the *European Patent Convention* (EPC). Article 83 stipulates that the invention must be disclosed in a manner sufficiently clear and complete for it to be carried out by an expert in the relevant field. Rule 23d(c) provides that uses of human embryos for industrial and commercial purposes are excluded from patentability.

The Opposition Division referred to its earlier communication, issued on 14 April 2000, stating that the subject-matter of the patent had never included the cloning of humans or animals. Long before the end of the opposition period, the patent proprietor had also voluntarily limited the patent to exclude human germ-line intervention.

The Opposition Division emphasised that it was bound in its decisions by the EPC and the applicable international and European law, including the EU Biotechnology Directive. These, and not national

[75] AFP, "Greenpeace Paralyses Patent Office in 'Human Clone' Protest", Munich, Germany, 22 February 2000.
[76] AFP, n 75.
[77] AFP, n 75.
[78] AFP, n 75.
[79] AFP, n 75.

[80] A Salleh, "A Patent Mistake", ABC Science Online, 23 February 2000, http://www.abc.net.au/science/news/stories/s102681.htm.
[81] European Patent Office, "'Edinburgh' Patent Limited after European Patent Office Opposition Hearing", *Press Release*, Munich, 24 July 2002.

law – such as the German Law on the Protection of Embryos – are the basis for the decision.

The European Patent Office had been severely embarrassed by the granting of such a broad patent in the first place. The incident suggested that its examiners had been lax in the scrutiny of their specifications. Nicol commented:

> "I don't think there was any way they could have missed it. It seems bizarre that the applicants in this case would even try and get the claim through given how controversial it is. It's unusual for a patent to be accepted when it's obviously invalid. And where there is a grey area, a patent office is required to give the applicant the benefit of the doubt."[82]

The European Patent Office declared that the decision was a vindication of the institution:

> "In the 'Edinburgh' case, the opposition procedure, anchored in the EPC, has once again proved its worth as an effective and transparent means of reviewing patents granted by the EPO."[83]

The parties will have an opportunity to contest the outcome of the hearing by instituting second-instance proceedings before one of the EPO's Technical Boards of Appeal. The written statement of the reasons for the Opposition Division's decision will be issued in the coming months.

The Edinburgh patent prompted the European Parliament to pass a resolution condemning the cloning of human beings.[84] First, it stressed that it was

> "deeply shocked at the granting of a patent to the University of Edinburgh, which includes a technique for the genetic modification of the germ line of human embryos and of the embryos themselves, a patent on isolation, selection, and propagation of animal and transgenic stem cells, which could be used for the cloning of human beings".

Secondly, it undertook "to file without delay an objection to patent number EP 695351 if legally possible, and calls on the other institutions of the European Union and Member State governments to do likewise". Thirdly, it

> "demands a review of the operations of the EPO to ensure that it becomes publicly accountable in the exercise of its functions, and to amend its operating rules to provide for it revoking a patent on its own initiative".

In the wake of the furore, Edinburgh University sought to revise its international application[85] published under the *Patent Co-operation Treaty* (PCT). A number of the claims in the specifications have been amended, so that "transgenic animal" becomes "transgenic non-human animal".[86] Such changes have been hastily hand-written in the margins by Daniel Fitzpatrick, a patent attorney from the firm Philips, Ormonde and Fitzpatrick.[87] Obviously, Edinburgh University wanted to avoid any repetition of public controversy with its PCT application.

European Group on Ethics in Science and New Technologies

On Tuesday 7 May 2002, the European Group on Ethics in Science and New Technologies released its opinion No 16 on the "Ethical aspects of patenting involving human stem cells".[88] The study aims to define the conditions and the limits of patenting of stem cells, not only in relation to ethical considerations but also in the relevant processes securing ethical evaluations.

The Group carried out its research as part of a wider evaluation of the ethical aspects of biotechnology required by the *European Union Directive on the Legal Protection of Biotechnological Inventions 1998*. It elaborated upon its prior research into the ethical aspects of stem cell research and cloning, as well as patenting

[82] Salleh, n 80.

[83] European Patent Office Press Release, n 81.

[84] European Parliament Resolution on the Decision by the European Patent Office With Regard to Patent No EP 695351 Granted on 8 December 1999 (Document BS-0288, issued on 30 March 2000, Official Journal EC-L- 29 December 2000, 378/95).

[85] A Smith and P Mountford, "Isolation, Selection, and Propagation of Animal Transgenic Stem Cells", WO94/24274.

[86] For instance, Claim 40 has been revised to "a transgenic [non-human] animal which includes a source of cells suitable for the isolation and/ or propagation of stem cells by a method according to any one of claims 1 to 37". Similar modifications appear in Claims 41, 42, 43, and 53.

[87] Dr Dianne Nicol of the University of Tasmania shared this anecdote.

[88] The European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, Opinion No 16, 7 May 2002.

inventions involving human elements.[89] The Group organised a round table in 20 November 2001 with members of the European Parliament, jurists, philosophers, scientists, and representatives of industry, religious groups, and patent associations. It also commissioned a number of expert studies.[90]

After deliberating upon such evidence, the majority of the Group was of the opinion that isolated stem cells which have not been modified do not, as product, fulfil the legal requirements to be seen as patentable, especially with regard to industrial applications.[91] In addition, such isolated cells are so close to the human body, to the fetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body. When unmodified stem cell lines are established, they can hardly be considered as a patentable product. Such unmodified stem cell lines do not have, indeed, a specific use but a very large range of potential undescribed uses. Therefore, to patent such unmodified stem cell lines would also result in broadly framed patents.

The Group maintained that only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application, fulfil the legal requirements for patentability.[92] As to the patentability of processes involving human stem cells, whatever their source, there is no specific ethical obstacle, insofar as they fulfil the requirements of patentability – the criteria of novelty, inventive step and industrial application.

Some commentators have been critical of this key recommendation, claiming that the distinction between unmodified and modified stem cells is not grounded in patent law. A patenting consultant Stephen Crespi argued:

> "In the end the EGE report has, in my view, side-stepped the most difficult questions and has settled for devising its own patentability criteria, of which the key opinion is that only stem cells that have been modified by in vitro treatment or genetic modification can be considered fit subject-matter for patents."[93]

He considered that a case has not been made out that human stem cells should be treated any differently from genes, cell lines and other products of natural derivation.

The Group also made a number of other important recommendations to address the social and economic consequences of applying the patent system to stem cell research.[94] Inspired by the Stem Cell Bank being set up in the United Kingdom, the Group called for the creation of a European Union Registry of unmodified human stem cell lines.[95] Its aim would be to ensure transparency and facilitate access by the research community to the needed biological material for further research. Additionally, the Group stressed the importance of informed consent.[96] It insisted that, when donated cells become part of a patent application, donors should be informed of the possibility of patenting and entitled to refuse such a use. However, it maintained that donors should only be entitled to justified compensation. The Group also envisaged that there would be a need to make ethical evaluations in the course of the examination of particular patent applications.[97] It argued that it was

[89] The European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, Opinion No 8, 25 September 1996; the European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Cloning Techniques*, Opinion No 9, 28 May 1997; the European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Research Involving the Use of Human Embryo in the Context of the 5th Framework Programme*, Opinion No 12, 23 November 1998; and the European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Human Stem Cell Research and Use*, Opinion No 15, 2000.

[90] See D Kelves, "A History of Patenting Life in the United States with Comparative Attention to Canada and Europe", European Group on Ethics in Science and New Technologies to the European Commission, 12 January 2002; G van Overwalle, "Study on the Patenting of Inventions Related to Stem Cell Research", European Group on Ethics in Science and New Technologies to the European Commission, 30 December 2001.

[91] The European Group on Ethics in Science and New Technologies to the European Commission, n 73, p 16.

[92] The European Group on Ethics in Science and New Technologies to the European Commission, n 73, p 16.

[93] R S Crespi, "Patenting and Ethics: A Dubious Connection" (2001/2002) 5 (3) *Bio-Science Law Review* 71.

[94] van Overwalle, n 90.

[95] The European Group on Ethics in Science and New Technologies to the European Commission, n 74, p 18.

[96] The European Group on Ethics in Science and New Technologies to the European Commission, n 74, p 17.

[97] The European Group on Ethics in Science and New Technologies to the European Commission, n 74, p 18.

desirable that the European Patent Office and patent offices elsewhere set up advisory panels of independent experts to undertake the ethical evaluation of patent applications.

However, there was a strong dissent from Professor Gunter Virt who objected to the patenting of processes and products using material resulting from destroyed human embryos:

> "Human embryonic stem cells and also embryonic stem cell lines are excluded from patentability because we cannot get embryonic stem cell lines without destroying an embryo and that means without use of embryos. This use as material contradicts the dignity of an embryo as a human being with the derived right to life."[98]

Such comments have been echoed by opponents of stem cell research. Donald Bruce, a spokesman for the European Churches Working Group on Bioethics, argues that the patenting of differentiated cells should be banned as well because they are as close to being "body parts" as stem cells themselves: "That's the one thing you mustn't patent, because that's what you want to use in patients."[99] These objections will doubtless be reiterated in future opposition proceedings to patents relating to stem cell research.

Summary

In its report, the European Group on Ethics in Science and New Technologies provides a blueprint for the reform of patent law. The majority opinion maintains that unmodified stem cell lines should not be patentable, but that modified stem cell lines should be patentable. This distinction should help draw the right balance between the economic interest of research institutions and biotechnology companies in securing investment in research and development, and the wider social concern in enabling access to essential medicines and pharmaceutical drugs. The dispute over the Edinburgh patent demonstrates that ethical considerations about patents are inescapable. The proposal to establish a committee of experts to consider social issues which arise in patent applications is a sensible response.[100] Such measures would help accommodate ethical concerns within the framework of the patent system.

Conclusion

If it is to realise its ambitions for the National Stem Cell Centre, the Federal Government needs to amend the *Patents Act 1990* (Cth). At present, s 18(2) of the *Patents Act 1990* (Cth) is fundamentally ambiguous. The Government must act to provide a clear directive as to whether stem cell research is patentable under the *Patents Act 1990* (Cth), and, if so, to what extent protection should be granted. In particular, it must determine whether unmodified and modified stem cells will be patentable. Such reforms are necessary to foster the commercialisation of stem cell research. In addition, the Government has to resolve whether a stem cell bank will be established. Such a decision will have a critical bearing upon the operation of research institutions and commercial biotechnology companies in Australia.

The government also needs to ensure that the granting of patents in respect of stem cell research will not impair research and development in the field, or prevent equitable access to therapies and drugs derived from this work. The scope of patent protection for stem cell research could be limited by the strict application of patent criteria. The government would be well advised to a create a research exemption to give third parties access to stem cell products and research tools. It should also modernise the compulsory licensing provisions of the *Patents Act 1990* (Cth) to enable parties to obtain access to stem cell research without need for authorisation from the patent owners. The government needs to address fears that the field of stem cell research will be monopolised by a small number of commercial biotechnology companies. It must open intellectual property law to oversight under competition law.

The government must also consider patent law and stem cell research within the prism of the debate over the ethics of patenting life forms. It should seek to include public policy considerations – such as ethical considerations – in an assessment

[98] The European Group on Ethics in Science and New Technologies to the European Commission, n 74, p 19.

[99] A Coghlan, "Say No To Stem Cell Patents", *New Scientist*, 18 May 2002, p 5.

[100] The European Group on Ethics in Science and New Technologies to the European Commission, n 73, p 18; see also Ontario State Government, "Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare", *Draft Report to the Provinces and the Territories*, January 2002, p 50.

of patent applications. The government should transform the patent administration from a "secular cloister" to a more worldly regulator. It should introduce an opposition process which would allow interest groups to voice their concerns, along the lines of the European Union. It should contemplate establishing a committee of independent experts to evaluate ethical considerations which arise in patent applications. Such reforms would ensure a greater harmony between the regulation of stem cell research and the intellectual property regime.