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The last taboo: patenting human beings

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This article considers the efforts of the Australian Law Reform Commission to clarify the meaning of section 18(2) of the Australian *Patents Act 1990* (Cth): '*Human beings and the biological processes for their generation are not patentable inventions.*' It provides a critique of the proposals of the Commission with respect to patent law and stem cell research. The Commission has recommended that IP Australia should develop examination guidelines to explain how the criteria for patentability apply to inventions involving stem cell technologies. It has advised the Australian Government that the practice code of the United Kingdom Patent Office (UKPO) would be a good model for such guidelines, with its distinction between totipotent and pluripotent stem cells. Arguably, though, there is a need to codify this proposal in a legislative directive, and not merely in examination guidelines. The Commission has been reluctant to take account of the ethical considerations with respect to patent law and stem cell research. There could be greater scope for such considerations, by the use of expert advisory boards, opposition proceedings and the requirement of informed consent. The Commission has put forward a number of general and specific recommendations to enhance access to patented stem cell technologies. It recommends the development of a research exemption, and the modernisation of compulsory licensing and crown use provisions. It also explores the establishment of a stem cell bank and the promulgation of guidelines by funding agencies. Such proposals to promote greater public access to stem cell research are to be welcomed.

Keywords: embryo, human being, patent law, pluripotent stem cell, totipotent cell

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1. Introduction

In Australia, there has been a strong emphasis on developing excellence in stem cell research in both the public and private sectors. In 2002, the Australian Government established the National Stem Cell Centre. It is a national endeavour with headquarters at the Monash University and will coordinate the research efforts of public and private sector institutions in a number of States and internationally. Furthermore, a number of Australian companies also feature in the international arena in the research and development of stem cell technologies, including ES Cell International, BresaGen, Norwood Abbey and Stem Cell Sciences. In spite of the promise of therapeutic benefits flowing from stem cell research, the industry remains relatively fragile and immature. Timothy Caulfield comments: '*Several factors are undoubtedly relevant to the creation of this sluggish environment, including political uncertainty and understandable ethical concern about research involving embryos and the use of cloning technology*' [1]. The Australian stem cell research firm, BresaGen, has entered into voluntary administration after suffering debts of $43.3 million [2,101].

There has been much parliamentary debate over patent law and stem cell research in Australia [3]. In response, the Attorney-General of Australia, Daryl Williams, provided a reference in December 2002 to the Australian Law Reform Commission

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to undertake an inquiry into gene patenting, with a particular focus on human health matters. The Attorney-General asked the Commission to consider the impact of gene and stem cell patents on the conduct of research, the Australian biotechnology sector, and the cost-effective provision of healthcare in Australia. He required the Commission to determine what changes, if any, may be required to address any problems identified in current laws and practices. The Commission released an issues paper on *Gene Patenting and Human Health* in July 2003 [4,102]. The paper canvassed a number of issues for consideration by scientific and research institutions, industry groups, the legal profession and the wider public. After further consultations with stakeholders, the Commission released a discussion paper on *Gene Patenting and Human Health* in February 2004 [5,103].

Chapter 16 of the discussion paper provides a review of the issues concerning patent law and stem cell research. It is a thorough, comprehensive report on a difficult, technical and refractory area of patent law. The Commission puts forward a proposal with respect to the development of examination guidelines for patent law and stem cell research:

> '*IP Australia should develop examination guidelines, consistent with the Patents Act 1990 (Cth), the Patents Regulations 1991 (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cell technologies. The examination guidelines should address, among other things, the patentability of inventions involving: (a) totipotent, pluripotent and multipotent cells; and (b) processes involving stem cell technologies*' [6].

The Commission recommends that the Australian Government provide broader access to patented inventions through measures such as research exemption, compulsory licensing and crown use. In addition, the Commission explores a number of specific mechanisms, such as stem cell banks and guidelines developed by funding agencies, which could be established to regulate access to stem cell technologies.

This article provides a critical evaluation of the proposals of the Commission in respect to patent law and stem cell research.

- The article argues that the administrative reforms proposed by the Commission do not go far enough. There is a need to express legislative changes to clarify the patentability of stem cell research. It is contended that there is a need to amend the *Patents Act* 1990 (Cth) to clarify whether inventions involving stem cell technologies constitute patentable subject matter.
- The article concurs with the Commission's proposal that IP Australia should develop examination guidelines to set out its examination practices with respect to inventions involving stem cell technologies. It considers three possible models: the guidelines of the European Group on New Technologies and Science, the practice notice of the United Kingdom Patent Office (UKPO) and the Weldon legislative rider to the *Consolidated Appropriations Act* 2004 (US). It is argued that the UK model is preferable.
- The article queries the exclusion of ethical considerations from the assessment of patent applications in respect of stem cell research. It puts forward the proposal of an informed consent requirement.
- The article supports the proposals of the Commission to facilitate access to stem cell technologies, such as the development of a research exemption, patent pooling, the use of compulsory licensing and the deployment of crown use provisions. It also considers the establishment of a stem cell bank and the development of guidelines by funding agencies. Such measures to facilitate access to stem cell technologies are to be applauded.

2. The myth of technology neutrality

In 1990, the Independent Senator, Brian Harradine, introduced amendments into the Australian Parliament which became subsection 18(2) of the *Patents Act* 1990 (Cth): '*Human beings and the biological processes for their generation are not patentable inventions.*' He sought to illustrate the intent of his amendments:

> '*Let me give an extreme example of a process which my amendment would prohibit. I refer to the techniques that may well be developed for cloning a human embryo at the four cell stage. That is an example, albeit an extreme one, of the type of technique or process which my amendment to this Bill would prohibit from being patentable*' [7].

However, during the parliamentary debate at the time, it was pointed out that the meaning of '*human beings and the biological processes for their generation*' was unclear and uncertain [8]. It was difficult to ascertain the scope of the excluded subject matter. Nonetheless, the amendments were passed by a careless Parliament.

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 [9]. The organisation maintained that subsection 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 fetuses 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' [10].

The Patent Office reported: '*To date IP Australia has granted four 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*' [10]. 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*' [11].

The Commission was not inclined to propose amendments to the *Patents Act* 1990 (Cth) that would expressly address the patentability of inventions involving stem cell technologies. It maintains that a specific provision dealing with stem-cell research would offend the principle that the patent legislation should be technology-neutral:

'*The requirements for patentability in the Patents Act are nearly all technology-neutral and are therefore capable of adapting to new technologies as they arise. Technology-specific exceptions to the requirements for patentability impact on the flexibility of the current statutory framework. Further, such provisions may conflict with Australia's obligations under the Agreement on Trade-Related Intellectual Property Rights* [The TRIPs Agreement]. *The express exclusion of inventions involving stem cell technologies is also likely to have an adverse effect on research in this burgeoning field. Moreover, the emergent state of stem cell science and the uncertainty about its potential applications must be borne in mind. A specific provision in the Patents Act relating to the patentability of inventions involving stem cell technologies is unlikely to be sufficiently flexible to adapt to future scientific developments*' [12].

This appeal to the principle of technological neutrality is not persuasive. Patent regimes inevitably have a clause dealing with the limits of patenting, usually dealing with human beings. The Commission suggests that such provisions may conflict with Australia's obligations under the TRIPs Agreement, in particular article 27(1), which emphasises non-discrimination between technologies. Such a view is based upon an over-conservative reading of the World Trade Organisation decision in the Canada Patent Protection case [13,14]. Arguably, Article 27(1) of the TRIPs Agreement should be read subject to Articles 27(2) and (3), which provide latitude for governments to exclude particular technologies from the scope of patentability.

There remains a need for the Federal Government to revise subsection 18(2) of the *Patents Act* 1990 (Cth). The current provision is a legislative aporia; it is a mystery that it is difficult to decode. The Commission should seize the opportunity to offer a legislative solution. Problems could arise with respect to the judicial interpretation of subsection 18(2), if the ambiguity of the provision is left unresolved. It is possible that a court could read the provision narrowly and conclude that stem cell technologies were not patentable subject matter in the jurisdiction of Australia.

The decision of the Supreme Court of Canada in *Harvard College v Commissioner of Patents* illustrates the need for the legislature to explicitly address the patentability of higher life forms [15]. In this case, the majority of the Supreme Court of Canada held that patents should not be granted in respect to higher life forms, such as the transgenic animal (for example, the Harvard oncomouse) in the absence of any explicit legislative directive. Justice Bastarche commented:

'*Patenting higher life forms would involve a radical departure from the traditional patent regime. Moreover, the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues. If higher life forms are to be patentable, it must be under the clear and unequivocal direction of Parliament*' [16].

Following this decision, it seems that the majority of the Supreme Court has strong ethical objections to patents being granted with respect to higher life forms. It is arguable that judges trained in a civil tradition might take a narrower view of patents being granted in relation to stem cell research. As a result, the Canadian Government would need to provide an express legislative direction in relation to the patentability of biological inventions, including stem cell research and genetic inventions [17].

In dissent, Justice Binnie considered the legislative proposal of the Canadian Biotechnology Advisory Committee that '*No patent shall be granted on human bodies at any stage of development*' [17,18]. His Honour noted that such an amendment would '*apply only to entire human bodies from the zygote to an adult body; DNA sequences, gametes, stem and other cells or organs will remain patentable*' [17,18]. Justice Binnie maintains that the patent regimen should apply to higher life forms. He proceeds to make a number of pertinent observations about patent law and stem cell research:

'*Parliament may wish to regulate outside the framework of the Patent Act the creation and use of "higher life forms" (however Parliament chooses to define "higher" life forms) in many ways: ethics boards could be set up to consider "higher life form" patentability on a case-by-case basis, including any patent applications on human genetic material; animal rights legislation might require that all transgenic animal varieties be "engineered" to alleviate or mitigate pain from experimentation; a policy of balancing the potential alleviation of human suffering*

against animal suffering might be added. Patents on human genetic material, including stem cell research and cloning, might include a provision to exempt all research from patent infringement or specify compulsory licences for such research' [19].

Justice Binnie argued that parliament had addressed ethical concerns surrounding higher life forms through other regulatory regimes, for example, he observed that the Parliament was considering at the time *An Act Respecting Assisted Human Reproduction and Related Research Bill* 2002 (Canada). The legislation has since been passed in 2004 after further legislative debate [104].

In light of the controversial decision in relation to the Harvard oncomouse, there seems to be very limited scope for therapeutic patents to be granted regarding stem cell research in Canada [20]. Significantly, patents could only be granted in relation to lower life forms [21,105]. If stem cell products were perceived to be within the definition of a human being, they would fall foul of the prohibition against higher life forms. However, patents could still be granted in relation to processes related to the stem cell line, but patents could not be granted in relation to methods of human treatment. Moreover, the usual requirements of novelty, obviousness and utility would have to be met. Finally, there could be the potential for ethical objections to be raised in a court case, especially before the Supreme Court of Canada [22].

The case provides a cautionary warning of the need for legislatures to explicitly define the limits of patentable subject matter in relation to higher life forms.

3. Complex subject matter

The Commission considered the practice of the Patent Office at IP Australia in dealing with applications for patents in respect of stem cell technologies.

In its submission to the issues paper of the Commission, IP Australia indicated its approach when determining whether subsection 18(2) of the *Patents Act* 1990 (Cth) is applicable to a particular invention. It observed:

'*What constitutes a 'human being' according to s 18(2) is currently a very grey area, as no clear guidance on this has yet been provided by the courts. Although IP Australia's position will no doubt change as the technology evolves, the organisation's current interpretation is that anything which has an inherent capability to mature and become a human being should be excluded. According to this, the more complex the subject matter, the more likely it is to be excluded. Human genes, cells, tissues, ovum and sperm are generally considered patentable. However, complexities arise for subject matter such as fertilised ovum, stem cells, fetuses, genetically modified animals containing human genes and humans treated with animal tissue*' [23].

The present policy of IP Australia is to refer applications claiming stem cell technologies to a supervising examiner and then to a Deputy Commissioner. The Commission notes:

'*It is unclear from IP Australia manual or submissions made by IP Australia to relevant government inquiries on this issue, exactly how Australian patent law is applied to inventions involving stem cells, particularly human embryonic stem* [ES] *cells*' [12].

Obviously, the current practice of IP Australia is inadequate; its rule of thumb that complex subject matter is not patentable is both vague and imprecise. Thus, there is undoubtedly a compelling need to develop comprehensive examination guidelines in the field.

There have been concerns expressed by research organisations and companies about the examination of patents with respect to stem cell technologies. In consultations, the National Stem Cell Centre commented that patent applications were typically allocated to a patent examiner with a background that is related to the technology involved in the invention [24], and it noted that there were variations in the level of skills of Australian patent examiners. BresaGen commented that patent examiners may not have an adequate understanding of stem cell technologies [25]. It suggested that this could be the result of both a lack of resources within IP Australia and a lack of training of Australian patent examiners.

The Commission proposes that IP Australia should develop examination guidelines to explain how the criteria for patentability apply to inventions involving stem cells: '*It would assist potential applicants in understanding the scope of patent protection available under Australian law if IP Australia's approach with respect to inventions resulting from stem cell research were more clearly articulated*' [12]. The Commission comments:

'*The ALRC recognises that uncertainty currently exists about the types of inventions involving stem cells that may be patentable under Australian law. The ALRC's preliminary view is, therefore, that IP Australia should develop clear examination guidelines setting out the types of inventions involving stem cell technologies that it regards as patentable and, to the extent that any inventions involving stem cell technologies may not be patentable, the basis on which patent protection may not be available'* [12].

The Commission recommends that IP Australia should consult with the National Health and Medical Research Council (NHMRC) and other relevant stakeholders before adopting any guidelines in final form. It advises that IP Australia should also obtain the assistance and advice from the panel of experts. Furthermore, the Commission notes that the guidelines should be consistent with the *Patents Act*, *Patent Regulations* and existing case law.

The Commission considers the approach of the European Group on Ethics in Science and New Technologies towards patent law and stem cell research. On 7 May 2002, the European Group on Ethics in Science and New Technologies released its opinion (number 16) on the '*Ethical aspects of patenting involving human stem cells*' [26,27]. After deliberating upon such evidence, the majority of the Group was of the opinion that isolated stem cells that have not been modified do not, as a product, fulfil the legal requirements to be seen as patentable, especially with regard to industrial applications [28]. In addition, such isolated cells are so similar 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 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 Commission was sensitive to the criticism that the distinction between unmodified and modified stem cells is not grounded in patent law [29]. It observed:

'*The EU Stem Cell Report does not explain why, as a general matter, isolated human biological material may constitute a patentable invention under European law but an isolated stem cell line requires an additional step–that is, further modification–in order to be patentable. It appears that the distinction between modified and unmodified stem cells lines is a response to concerns about access to patented stem cell technologies and the effect of broad claims in stem cell patents. The ALRC considers that it is preferable to address issues relating to the exploitation of stem cell technologies directly*' [6].

As a result, the Commission was unwilling to follow the example of the European Union. Instead, the Commission recommends that IP Australia should develop Stem Cell Examination Guidelines along the lines of the Practice Note issued by the UKPO. It observes:

'*In developing the proposed Stem Cell Examination Guidelines, the distinctions drawn by the UK Patent Office between totipotent and pluripotent cells may provide a helpful way to approach the application of s 18(2) of the Patents Act to inventions involving embryonic stem cell technologies*' [6].

In April 2003, the UKPO issued a Practice Note disclosing the general approach to patent applications, claiming stem cells derived from human embryos and processes involving human ES cells [30,106]. The Practice Note indicates that each patent application will be assessed on its merits but goes onto provide as follows:

'*Processes for obtaining stem cells from human embryos are not patentable because the Patents Act 1977 (UK) provides that uses of embryos for industrial or commercial purposes are not patentable inventions; ''human totipotent cells'' are not patentable because they have the potential to develop into an entire human body and the human body at its various stages of its formation and development is excluded from patentability under the Patents Act 1977 (UK); and "human embryonic pluripotent stem cells" will be patentable if such inventions satisfy the statutory criteria for patentability because such stem cells do not have the potential to develop into an entire human body*' [30,106].

In addition, the UKPO has concluded that the commercial exploitation of inventions involving human embryonic pluripotent stem cells is not, as a general matter, contrary to public policy or morality in the UK. The Practice Note states that, despite some opposition to embryo research in the UK, a number of reports have noted the enormous potential of stem cell research.

The question of the ethical difference between patenting totipotent cells and pluripotent stem cells might be asked. Totipotent cells have the capacity to form the placenta and other supporting tissue necessary for the development of an embryo *in utero*, as well as postembryonic tissues and organs. By contrast, pluripotent stem cells cannot themselves develop into a human being. However, they can develop into any of the three major tissue types: endoderm (interior gut lining), mesoderm (muscle, bone, blood), and ectoderm (epidermal tissues and nervous system). Thus, the scientific distinction between totipotent cells and pluripotent stem cells is a very important one. Totipotent cells should be excluded from patentable subject matter because they have the potential to come within the scope of the definition of a human being. By contrast, pluripotent stem cells could feasibly be included as patentable subject matter because they do not have the potential to form a human being.

The United States Patent and Trade Mark Office (USPTO) has long had a policy of banning human being and human embryo patents on the grounds that they would violate the 13th Amendment prohibiting slavery [31]. In July 2003, Congressman Dave Weldon, MD (Republican - Florida.) attached a rider to an appropriations bill that would prohibit patents on human organisms. The wording of the bill stated: '*None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism*'. Congressman Weldon commented on the intent of this bill:

'*Technology proceeds at a rapid rate, bringing great benefits to humankind, from treatments of disease to greater wealth and greater knowledge of our world. However, sometimes technology can be used to undermine what is meant to be human, including the exploitation of human nature for the purpose of financial gain. I recognize that there are many institutions. that have extensive patents on human genes* [and] *human stem cells. This would not affect any of those current, existing patents*' [32].

In November 2003, Sam Brownback (Republican - Kansas) put forward an alternative House rider to another appropriations bill in the Senate. It would ban patents on human beings and genetically engineered human embryos but includes the sentence that '*Nothing in this section shall be construed to affect claims directed to or encompassing cells, tissues, organs or other bodily components that are not themselves human organisms (including but not limited to, stem cells, stem cell lines, genes and living or synthetic organs).*' However, in the end, January 2004, Congress preferred the proposal of Congressman Weldon to that of Congressman Brownback [33].

There has been much debate whether this legislative rider will affect patents regarding ES cell research. The Director of the USPTO, James E Rogan, has maintained that the Weldon amendment as '*fully consistent with USPTO's policy on the non-patentability of human life-forms.*' He said the measure gave '*unequivocal congressional backing*' for a rule '*refusing to grant any patent containing a claim that encompasses any member of the species* Homo sapiens *at any stage of development*' [34].

However, policy-makers and industry have objected to the legislative rider being introduced into an omnibus spending bill, without the usual processes of committee hearings and public debate. There are fears that the legislative rider is part of a larger agenda by religious conservatives to discourage embryonic stem cell research. Michael Werner of the Biotechnology Industry Organisation comments: '*There may be situations that involve embryonic material that are not human beings and we don't want this language interpreted so broadly that those things are covered*' [32,35,107]. Sean Tipton from the Coalition for the Advancement of Medical Research observes:

> '*The legislative language is not as clear as [some people] would like to think it is. The language is still somewhat ambiguous as to what exactly is prohibited. Embryos? Or the products that come from embryos? If it's products, then it clearly will impact embryonic stem cell research*' [35,107].

He fears: '*It's possible that an ambitious US attorney could try to use* [the provision] *to go after a clinic or research firm that was trying to advance* [a disease cure]' [35,107].

Such complaints about the Weldon amendment are well-founded. The legislative rider suffers from the same problems that bedevil subsection 18(2) of the *Patents Act* 1990 (Cth). The language is vague and overly broad and fails to define 'human organisms'. It is a poor legislative model for a country like Australia.

4. A theatre of morality

The inquiry into *Gene Patenting and Human Health* considered whether Australian patent law should take ethical considerations into account in relation to stem cell technologies.

A few submissions to the inquiry into *Gene Patenting and Human Health* maintained that Australian patent law should take ethical considerations into account. Dr Warwick Neville of the Australian Catholic Bishops Conference submitted:

> '*Patent law and practice specifically and intellectual property law generally do not operate in a vacuum, isolated from either ethical principles or social policy. Ethical principles need to be incorporated into patent law and practice, especially with respect to genes and genetic material. In the formulation of those principles and in keeping with international human rights instruments and medical research protocols, there must be formal recognition and protection of the inherent and inviolable dignity of the human person. The commodification of human life is inimical to the recognition and protection of human dignity*' [36].

He concluded: '*It would be remarkable if, on the one hand, the Commonwealth Parliament has so recently enacted legislation* [the Research Involving Embryos Act 2002 and Prohibition of Human Cloning Act 2002] *which deals expressly with medical research involving embryos and stem cells and which includes reference to ethical considerations and on the other hand, patent law and patent office practice continue to exclude ethical considerations*' [36,23]. Another submission addressed the ethics of ES cell research generally and considered that future research on embryos should not be permitted.

The bioethicist David Resnik has canvassed some of the complex ethical issues involved in the commercialisation of human stem cells [37]. He observes that the current stage of the debate involves a '*battle over property rights relating to human ES cells*' [37]. Resnik observes: '*The basic argument for property rights related to ES Cells is unabashedly capitalistic and utilitarian: property rights in ES cells should be granted in order to promote the progress of science, technology, medicine, business and industry*' [37]. He dismisses objections that patents should not be granted on stem cells and products because it would violate notions of human dignity and communal property: '*Treating these cells (and their products) is not inherently or intrinsically immoral*' [37]. Resnik concedes to some extent that patents in ES cells and related products could have an impact upon clinical care, research and healthcare. He recommends that '*patents relating to ES Cells should not be excessively broad*' and should state '*a clear, definite and plausible use for the invention*' [37]. Moreover, Resnik maintains that there should be mechanisms to allow access to patents on stem cells, such as a research exemption and compulsory licensing.

The dominant sentiment within the courts and the patent offices is that ethical considerations are necessarily extrinsic to patent law. As academic, Benjamin Enerson, has observed:

> '*The patent system should not become a theater for judging the morality of controversial inventions. The legislature can better address important moral problems because patent examiners and courts lack the ability to answer these difficult questions. Although patent examiners may hesitate to determine the morality of an invention, they do not officially endorse granting intellectual property protection to controversial inventions. Laws outside the patent system – and not patent law itself – should shape*

national policy regarding the morality of controversial inventions' [38].

Such sentiments have been echoed by patent offices. 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 [39].

Arguably, though, the patent system is not merely an instrument designed for the promotion of economic ends. Brad Sherman argues that patent law could be a regulatory mechanism for a number of non-economic ends:

'*While there is no denying the important role that patents play in macro-economic policy, there is no reason why the patent system, as a regulatory tool, should only be used in the pursuit of economic ends, nor any reason why 'external' factors such as the impact of technology on the environment or health should not fall within the core remit of the patent system. That is, there is no compelling reason why the various practices, rules and concepts that have been developed and fine-tuned over the last couple of centuries or so should only be used for economic ends*' [40].

Therefore, it should be possible to use the patent system to achieve other objectives, such as access to healthcare, the protection of the environment and the acknowledgement of indigenous knowledge.

In its report on gene patenting and human health, the Commission was reluctant to consider ethical considerations within the framework of the patent system. This was particularly evident in the context of patent law and stem cell research. The Commission refused to make any recomendations with respect to patent law and stem cell research:

'*Inventions involving embryonic stem cells may raise issues that are not raised by inventions involving adult stem cells. Objections to patenting inventions involving embryonic stem cells are often founded on ethical concerns about the conduct of research involving embryos and embryonic stem cells per se. As described above, regulation of embryo research is the subject of separate federal, state and territory laws, which themselves draw a delicate balance between competing interests, taking ethical considerations into account. In the ALRC's view, amendments to the Patents Act to address ethical concerns about the patenting of stem cells are not required at this stage as an additional layer of ethical consideration*' [41].

Arguably, though, ethical issues surrounding stem cell research cannot be so easily confined within the regulatory regime concerning the *Research Involving Embryos Act* 2002 (Cth) and *Prohibition of Human Cloning Act* 2002 (Cth) [42]. Such concerns will inevitably arise in other contexts, particularly in relation to the commercialisation of such research within the patent regime.

In its report, the Commission argued, somewhat unconvincingly, that existing provisions in the *Patents Act* 1990 (Cth) could be deployed to deal with ethical concerns:

'*Existing provisions in the Patents Act may be used in appropriate circumstances to reject patent applications claiming human embryonic stem cells or related processes. The Commissioner of Patents has a discretion to refuse a patent application claiming an invention whose use would be contrary to law. Since it is an offence under the Research Involving Human Embryos Act to use an excess ART* [assisted reproductive technology] *embryo without a licence from the NHMRC Licensing Committee (unless the use falls within a statutory exemption), inventions involving human embryonic stem cells lines that are derived from the use of an excess ART embryo without a licence or in breach of the conditions in any such licence, could fall within the 'contrary to law' provision in the Patents Act. Similar considerations could apply to inventions involving human embryonic stem cell lines derived from non-excess ART embryos. Further, as discussed in Chapter 7, the incorporation of the Statute of Monopolies into the definition of 'invention' in the Patents Act may provide a basis for excluding inventions that are 'generally inconvenient' from patentability under Australian law'* [43].

Arguably, the *'contrary to law'* and *'generally inconvenient'* provisions have become dead letters in Australian patent law. The discretion to refuse a patent application claiming an invention whose use would be *'contrary to law*' has been rarely invoked [44,45]. The Australian Patent Office Manual of Practice and Procedure seems to envisage that the '*contrary to law*' provision would deal with criminal acts [46,108]. It does not seem to contemplate the possibility of civil offences – such as the breach of a licence condition of the *Research Involving Human Embryos Act* 2002 (Cth). Similarly, the *'generally inconvenient*' proviso has seldom been invoked by the courts. In recent cases, the Federal Court has declined to rely upon the *'generally inconvenient'* proviso, in relation to methods of human treatment and business methods [47]. It is doubtful that the judiciary would show any more enthusiasm for such considerations in the context of stem cell technologies.

Furthermore, the Commission recognises that the Patent Office is not well-equipped to deal with the ethical considerations associated with new technologies such as stem cell research. It notes: *'Patent offices and examiners have no special authority in philosophical or moral matters*' [49]. The Commission recommended that the Patent Office should establish a panel of experts to provide advice regarding scientific and legal issues associated with new classes of technology [50]. However, it advised that the Government should not establish a new ethics advisory body in IP Australia to assess the possible social and ethical implications of patents:

'*Given that IP Australia examines more than 16,000 patent applications each year and that only a small*

proportion of these applications can be expected to have contentious social or ethical implications, ethics assessment of all patent applications seems unlikely to be the most efficient or effective form of regulation. Reform to permit inventions to be excluded from patentability based on the advice or determinations of patent examiners or some new ethics advisery body would thus have uncertain consequences for the efficiency of the patent system' [51].

Arguably, the Patent Office should not be sequestered away from such concerns. It should contemplate establishing a committee of independent experts to evaluate ethical considerations which arise in patent applications. It should seek to include public policy considerations, such as ethical considerations, in an assessment of patent applications. It should introduce an opposition process which would allow interest groups to voice their concerns, in a similar way to the European Union.

Furthermore, the Commission should consider introducing additional requirements for the grant of a patent, for example, through the incorporation of an informed consent requirement. Geertrui van Overwalle of Leiden University has written extensively about this topic as part of her report for the European Group on Ethics in Science and New Technologies [52]. She observes that the need to obtain informed consent could be made a mandatory requirement with respect to patent law:

'*Ethical concerns regarding the patenting of inventions based on biological material of human origin or using such material, can be taken care of within patent law or can be cured in other laws by introducing a supplementary provision, prescribing that the person from whose body the material is taken must have had an opportunity of expressing free and informed consent to possible patenting. Such a provision can be issued by a government and carries an obligation to comply. Non-compliance may result in a regulatory penalty. It might be argued in this respect that non compliance, in the case of the non-existence of an informed consent, results in the nullity of the patent involved'* [53].

Alternatively, van Overwalle explores the option of a voluntary code of conduct: '*If it appears undesirable to implement the informed consent requirement through legal action, the establishment of informed consent concerning patent matters through voluntary codes of conduct might be considered*' [53]. She stipulates the elements of such a code, including guidelines with regard to informed consent, the establishment of an advisory board, and the development of ethical rules and disciplinary action.

Of course, patent offices are resistant to the addition of a requirement of informed consent in relation to patent law. They argue that, in practical terms, requiring informed consent in the context of patenting would be difficult if not impossible to administer. However, such objections are overstated. They also betray a certain anxiety about dealing with ethical concerns about patents. Patent offices already have to undertake wide-ranging searches of prior art to determine novelty and inventive step. It would be no more onerous for patent examiners to check that patent applicants have obtained informed consent with respect to genetic material. Indeed, it would be good practice for patent offices to ensure that patents are not granted to parties who have not followed proper ethical practices under other regulations.

5. Strictly philosophical inquiry

Finally, the Commission considered concerns that stem cell patents may impede further research and development, particularly if the patent holders licence such patents exclusively or on restricted terms [3]. The Commission was unclear whether there were particular problems in Australia over access to stem cell technologies:

'*Licences over stem cell patents and other collaborative arrangements relating to the development of stem cell technologies have also been reported in connection with Australian commercial entities. For example, a 2003 report published by Invest Australia indicated that three Australian entities – BresaGen, ES Cell International and Stem Cell Sciences – had entered into agreements with organisations based in the United States and Japan pursuant to which intellectual property rights would be licensed for use in human embryonic stem cell research and the development of human embryonic stem cell therapies. However, the extent to which access to stem cell technologies is being restricted, particularly outside Australia, is unclear'* [54,55].

Nonetheless, the Commission took such concerns seriously and proposed both general and specific mechanisms to facilitate access to stem cell technologies [56]. It recommends that the Australian Government provide a number of general reforms to patent law with respect to research exemption, patent pooling, compulsory licensing and crown use. It also considers other possible mechanisms – such as stem cell banks and guidelines developed by funding agencies.

The Commission has proposed that the Australian Government should recognise a defence for experimental and research use to facilitate access to both genetic technologies and stem cell research:

'*The ALRC has concluded that it is desirable to remove uncertainty about the existence and scope of an experimental use defence in Australian law. Such a reform received broad support in submissions. The existing uncertainty is unhelpful to the research community and commercial organisations. It has the potential to lead to underinvestment in basic research and hinder innovation because researchers are concerned that their activities may lead to legal action by patent holders*' [57].

The Commission rejects the narrow, procrustean view of the research exemption adopted by the United States Court of Appeals in *Madey v Duke University*, which held that the defence was limited to actions performed '*for amusement, to satisfy idle curiosity or for strictly philosophical inquiry*' [58]. It maintains that a statutory defence should be broadly based and resemble the law of the UK and other member states of the European Union. It notes: '*Moreover, basing a new defence on the European Union model would promote harmonisation of Australian patent law with the law of a major trading bloc and would give Australian courts the benefit of considering European case law in applying the new provisions*' [59].

The Commission also considered whether patent pools, patent clearing-houses or collective rights organisations might also help address difficulties in obtaining access to patented genetic materials and technologies [60]. Members of the USPTO have published a paper on whether patent pools are a solution to the problem of access in respect of biotechnology patents [61,109]. They define a '*patent pool*' as an '*agreement between two or more patent owners to license one or more of their patents to one another or third parties*' [61]. David Resnik is a champion of such a scheme: '*Industry leaders and scientists could choose the path of enlightened self-interest by forming a biotechnology patent pool*' [62,110].

The Commission recognised that '*some participants in the Australian biotechnology sector may find the negotiation of patent licences to be problematic*' [63]. The law reform body, though, was not inclined to make proposals specifically aimed at regulating gene patenting licensing practices. It recommended that such matters should be taken up by an industry body: '*The ALRC believes that a representative industry body should consider the feasibility of establishing patent pools or patent clearing-houses over particular types of patented genetic materials or technologies*' [64].

There was some debate in the inquiry as to whether patent pools could have anticompetitive effects in the marketplace. The Australian Competition and Consumer Commission submitted: '*While pooling and cross-licensing can be pro-competitive, there is also the potential for arrangements to be used for blatant price fixing or market sharing agreements among competitors without any possible pro-competitive justifications*' [65]. It suggested that patent pools would be less likely to raise competition concerns if they combined complementary patents, did not restrict access to the technology by third parties, and did not facilitate the sharing of commercially sensitive information of competitors in downstream markets.

The Commission has also proposed a number of amendments to the existing compulsory licensing regime in the *Patents Act* 1990 (Cth) [66]. It recommended that the Commonwealth should amend the *Patents Act* 1990 (Cth) to insert the competition-based test as an additional ground for the grant of a compulsory licence. Such measures are to be welcomed because they modernise the anachronistic currently in place. The analysis of the impact of patents upon competition could have particular relevance in the emerging field of stem cell research. Glenn McGee and Elizabeth Banger consider the dynamic nature of the marketplace:

> '*It is difficult to know what implications stem cell patents will have for the conduct or cost of clinical trials or therapy using derivative technologies. It may be months or years before hES research yields therapies ready for human clinical trials and still longer before it is clear what research might have been initiated if there had not been excessive cost or restriction attached. It is, however, clear that patents will have an effect both in the short-term development of research programs under US funding and in the longer term as the research area evolves. Small companies may elect to sell their patents or even their entire research endeavor, to larger life science companies or to pharmaceutical corporations, which have thus far been reluctant to talk about investing in hES research. And some stem cell research and education programs will no doubt never begin or never achieve leadership, as a result of the new paradigm in which whole categories of basic research are open from their very beginnings to protection as intellectual property*' [67].

The provision of compulsory licensing would be useful in the future, for example, if a company abuses its dominant market position against rival research organisations in the field of stem cell research. Such measures would also be relevant in circumstances where access to treatments and diagnosis were blocked by misuse of patent rights.

The Commission has promoted the use or acquisition of patented technologies pursuant to the Crown use provisions in the *Patents Act* 1990 (Cth) [68]. It recommends that the Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act* 1990 (Cth) for the purposes of promoting human health. Similarly, the Commission advises that the Commonwealth Department of Health and Ageing should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health. It advises that the Commonwealth should amend the *Patents Act* 1990 (Cth) to clarify that, for the purposes of the Crown use provisions, an invention is exploited '*for the services of the Commonwealth or the State*' if the exploitation of the invention is for the provision of healthcare services or products to members of the public. Furthermore, it suggests that the Commonwealth should amend the *Patents Act* 1990 (Cth) to ensure that when a patent is exploited or acquired under the Crown use, or Crown acquisition provisions of the *Patents Act* 1990 (Cth), the Crown must pay remuneration or compensation.

The Commission has considered whether the establishment of an Australian stem cell bank would help facilitate and regulate access to stem cell lines by researchers.

There has been support for stem cell bank in Australia from both industry and political parties. 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. Senator Kerry Nettle commented:

'*If all citizens are to benefit from the output of stem cell research involving human embryos, then government needs to moderate market forces and no one should be permitted to patent stem cell lines. To ensure this happens, the Greens propose that the Commonwealth government establish a national stem cell bank as a repository for stem cell lines from human embryos and adult stem cells. We envisage 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. At the very least, a national stem cell bank ensures that all research institutions, in particular publicly funded institutions, will have access to the basic materials for developing applications from stem cell lines*' [69,70].

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.

The UK Stem Cell Bank provides a model for such a facility [111]. The Director, Glyn Stacey comments that the Bank seeks to promote wider use of cells and to facilitate the possibility of new discoveries whilst protecting depositor intellectual property rights [71]. The Bank has issued guidelines regarding terms and conditions for deposition and access of human stem cell lines. It provides an overview of the treatment of intellectual property interests:

'*Depositors of stem cell lines may have interests in the materials (e.g., intellectual property, confidential know-how) which they will wish to see protected and, in donating their cell lines, may wish to impose certain terms and conditions for distribution and subsequent use. The Bank will release cell lines to users provided they have obtained the 'freedom to use' directly from the originator of the cell line and have also secured approval for the intended research from the Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines.*

It is not the intention that the Bank will take any direct interest in IP embodied in deposited cell lines or become involved in the negotiations between depositor and user. It is the intention that material transfer agreements will be required between depositor and Bank and user and Bank (respectively Material Deposition Agreement and Material Access Agreement) and that a use licence will be required by the user from the depositor (owner) of the cell line' [72].

The Bank envisages that there will be a Materials Use Licence negotiated between the accessor and the depositor. It observes: '*Since Materials Use Licences will be negotiated between depositors and accessors on a case by case basis a model agreement cannot be provided*' [73]. Nonetheless, the Bank provides advice as to the terms of such a Materials Use Licence. It recommends a number of terms, including reasonable financial terms for the licence, only upfront fees for commercial users and a revenue share on products in line with industry standards.

The UK Stem Cell Bank illustrates that this model is not the tough regulator of the marketplace that the Australian Greens imagine it is. The Bank has no powers to compel parties to provide access to stem cell lines. Of course, much will depend upon the content of the contractual agreements between various parties. Nonetheless, the Bank plays an important role as a fair broker between parties to encourage the sharing and exchange of stem cell lines at reasonable prices. It is a model that would be worth emulating in the context of Australia.

The Commission proposes conferring responsibility on the Australian Research Council (ARC) and the NHMRC to consider the potential exercise of any patent rights that may arise from research involving human stem cell lines conducted by Australian entities. In the past, the ARC and the NHMRC have taken the position that they do not wish to hold a stake in direct ownership of intellectual property nor do they intend to benefit directly from commercial outcomes of the research funded through their financial support. Arguably, though, there is a need for greater government involvement in intellectual property management in respect to collaborations between the private sector and the public sector. The Commission recommends that the ARC and NHMRC be required to develop guidelines and principles for researchers that would ensure the public interest in the commercial exploitation of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies.

Rebecca Eisenberg and Arti Rai comment upon the creative role played by the National Institutes of Health (NIH) in relation to access to intellectual property: '*On a number of occasions, NIH has been able to use hortatory strategies to convince academic institutions to act collectively to keep basic research information in the public domain*' [74]. For example, they observe that the NIH played an instrumental role in securing access to patents to ES cells held by the Wisconsin Alumni Research Foundation [75,112]. Eisenberg and Rai comment: '*There is growing evidence that NIH may require authority beyond the bully pulpit to ensure continuing compliance with these norms in the future*' [74]. The authors conclude argue that funding agencies should have greater

discretion in imposing restrictions on patenting by the recipients of government funding: '*We believe that the time is ripe to alter the Bayh-Dole Act to give funding agencies more latitude in guiding patenting and licensing activities of their grantees*' [74,112].

Similarly, in the Report on Intellectual Property Rights and Genetics, William Cornish, Margaret Llewelyn and Mike Adcock submit that the UK Department of Health needs to play a more active role in relation to gene patents: '*The Department needs to develop a coherent policy for both the receipt and the provision of patented material*' [76]. It notes that it is clear that the Department of Health will be directly affected by the patenting of genetic material. The impact of these patents will be twofold. The report recommends that the Department of Health should instigate a robust central policy for '*licensing in*', designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use. It should adopt a balanced approach for '*licensing out*', particularly over the question of exclusivity, and where appropriate the Department should provide model agreements for use by hubs and Trusts.

The ARC and NHMRC should consider the models of the NIH and the UK Department of Health in developing guidelines to secure access to stem cell research.

6. Expert opinion and conclusion

The Commission has sought to dispel uncertainty and confusion over the patentability of stem cells under the *Patents Act* 1990 (Cth). It has to sought to elucidate the meaning of subsection 18(2) of the *Patents Act* 1990 (Cth), which provides: '*Human beings and the biological processes for their generation are not patentable inventions.*' The Commission has recommended that IP Australia should develop examination guidelines to explain how the criteria for patentability apply to inventions involving stem cell technologies. It has advised the Australian Government that the Practice Note of the UKPO would be a good model for such guidelines, with its distinction between totipotent and pluripotent stem cells. However, there remains dissonance between the legislative direction contained in subsection 18(2) of the *Patents Act* 1990 (Cth) and the examination guidelines. Arguably, a court could take a narrow reading of the legislative provision and repudiate any guidelines of the Patent Office. Therefore, it is necessary that the Commission should go further and revise subsection 18(2) of the *Patents Act* 1990 (Cth). The distinction contained in the UK Practice Note should be codified in a legislative form. The Australian Government should seize this opportunity to clarify the outer limits of patentable subject matter with respect to human beings and stem cell research.

In the Discussion Paper, the Commission was unwilling to address ethical considerations about patents regarding stem cell technologies. It maintained that such concerns were better addressed by other regulatory mechanisms, such as the *Research Involving Embryos Act* 2002 (Cth), and the *Prohibition Of Human Cloning Act* 2002 (Cth). It is disappointing that the Commission has taken such a dour approach to dealing with ethical considerations about patents regarding stem cell technologies. There are greater possibilities for synergies between the regulatory regimes. The government should contemplate establishing a committee of independent experts to evaluate ethical considerations which arise in patent applications. It should seek to include public policy considerations – such as ethical considerations, in an assessment of patent applications. The government should introduce an opposition process which would allow interest groups to voice their concerns, along the lines of the European Union. It should also make the grant of a patents, regarding stem cell technologies, conditional upon evidence of informed consent. Such reforms would provide an integrated approach to the regulation of stem cell research.

The Commission has proposed a number of general and specific measures to ensure that the granting of patents, with respect to stem cell research, will not impair research and development in the field or prevent equitable access to therapies and drugs derived from this work. Such initiatives are to be welcomed as timely and judicious reforms to the patent system. The Commission supports the legislative recognition of broad-based research exemption, in line with the European Union. It recommends the modernisation of provisions dealing with compulsory licensing and crown use to allow for greater recognition of public interest in access to healthcare. The Commission contemplates the establishment of a stem cell bank to facilitate access to stem cell lines. It also explores whether funding agencies should develop principles and guidelines to govern access to stem cell research. Such measures will create a niche for Australian research institutions and companies to flourish in the field of stem cell research. It will also help allay fears that the promising area of therapeutic research will be monopolised by a small number of commercial biotechnology companies.

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