The attached submission has recently been made to the National Health and Medical Research Council Review of Commonwealth legislation concerning cloning and research into stem cells.

The submission, which deals essentially with disclosure of patent holdings, and other matters that relate to "conflicts of interest", may be of some relevance to the current inquiry.

Accordingly, although formally directed to the NHMRC Review, the same submission is offered to the Senate Committee inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

Yours sincerely

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Submission to: 2010 Legislation Review
Prohibition of Human Cloning for Reproduction Act 2002
Research Involving Human Embryos Act 2002

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Introduction

1. This submission has one object, and makes only one recommendation.

2. **Object**: The object is to detail briefly a significant legislative gap in the legislation under review, namely the failure of both pieces of legislation to require researchers to disclose all patent holdings, directorships, share-holdings and paid consultancies, so as to ensure transparency between their research and the funders and other stake-holders in it. In requiring public disclosure of patent and share holdings, as well as any directorships and paid consultancies, it will bring this regulatory regime into conformity with long-standing corporate statutory requirements in relation to conflicts of interests.[ii]

3. **Recommendation**: The recommendation is that, pursuant to statutory mandate, all researchers and clinicians who conduct research and or who engage in work that comes under either of these Acts must disclose all patent holdings (and patent applications), share-holdings, directorships and paid consultancies that relate directly or indirectly to their work under both of the Acts under review.[iii]

4. Our recommendation also is that the Licensing Committee be required to keep a register of these disclosures, and that they be included in that Committee's biannual report to Parliament.

Rationale

5. Two examples will be used to highlight and support the statutory requirement for a register of "disclosable interests."

6. First, it is common knowledge that scientific publications – local and international – require disclosure by authors of any conflict of interest in relation to the research or other material to be published. For example, the International Committee of Medical Journal Editors states in relation to biomedical publications that interests should be declared "whether or not the individual believes that the relationship affects his or her scientific judgment."[iv]

7. However, in a critical study published in the *Journal of Medical Ethics* in relation to the prevalence of required disclosure by authors in the prestigious journal *Nature*, S. Mayer from

GeneWatch UK found that two thirds of papers in which authors had patent applications or company affiliations that might be considered to be competing financial interests did not disclose them.[v]

8. Mayer noted that *Nature* asks the submitting author of a manuscript to make disclosure of (a) 'recent, present or anticipated employment by any organisation that may gain or lose financially through publication of the paper', (b) 'stocks or shares in companies that may gain or lose financially through publication', (c) 'consultation fees or other forms of remuneration from organisations that may gain or lose financially', (d) 'patents or patent applications whose value may be affected by publication.'

9. There is a further category noted by Mayer about which *Nature* requires disclosure from a submitting author: that relates to 'any undeclared competing financial interests that could embarrass you were they to become publicly known after your work was published.'

10. The final thing to note from Mayer's study is that "self-policing is not working.' Certainly, as a matter of regulatory principle, "self-regulation" is the least effective form. Next in effectiveness is "guidelines", such as those promulgated by the NHMRC over the years. But, as is well known, "guidelines" are essentially unenforceable. Hence our recommendation for (a) a statutory duty of disclosure and (b) a register of disclosable interests.

11. The second example is taken from the plethora of issues surrounding the fraudulent research of Dr Woo-Suk Hwang. It is a matter of public record that in 2004, Dr Hwang declared that he had isolated embryonic stem cells through somatic nuclear transfer and that he (and his colleagues at the Seoul National University) had generated a cell line. A number of other claims were also made. The claims were published in the prestigious journal *Science* in 2004 and 2005. Dr Hwang has also filed patent applications in Australia.

12. Dr Hwang was later exposed for scientific misconduct, fabrication of scientific evidence, and indicted on charges for fraud and embezzlement in relation to the mis-use of research funds. He was also accused of breach of various bioethics regulations in relation to his practices in obtaining human eggs from donors, including pressuring junior research assistants for them.

13. The point is made by others on the Hwang case about the failure of editors and others to scrutinise manuscripts for fraud, and on the failure of peer review to ensure the quality of publication.[vi]

14. It is certainly and clearly the case that many writers have warned, and done so for many years, of the risks when biomedical research, industry (and especially the pharmaceutical industry) and patents are in close proximity to each other. Indeed, something of a cottage industry has emerged which have documented the risks and failure of those who ignore such warnings.[vii]

Conclusion & Recommendation

15. Recently, the editor of the *Medical Journal of Australia*, Dr Van Der Weyden, reflected ruefully on the "hopelessly fragmented" approach in Australia to conflict of interest.[viii] He did so against the background of a French medical organisation that had taken action against nine doctors who had failed to disclose their relationships with drug and other medical industries. Dr Van Der Weyden also noted that regulators in the US "are moving to enforce mandatory disclosure of industry gifts and payments to doctors" and that this should occur on a public website.

16. The learned and esteemed editor of the MJA stated: "It is perhaps surprising that a profession which prides itself on ethical performance should continue to be plagued by lack of transparency in this one area. But history repeatedly attests to the lure of financial advantage."

17. The issue of potential conflict of interest is compounded by the multi-national character of much research in this area. Professor Plomer comments:[ix]

... the legal and economic reality is that some [patent] applicants have already begun to bypass the EPO [European Patent Office] and position themselves strategically in potentially lucrative markets in Europe to secure patent protection on some foundational hESC inventions. When these patents are aligned to others in the international landscape, the emerging picture is of some emerging globally dominant patents with the potential to control the commercialisation of future advanced therapies.

18. While not a complete answer to the "lure of financial advantage", pursuant to legislation, a national register that records patent holdings (and applications), share-holdings, and directorships for those who research and work clinically in areas that come under the Acts under review, would be a significant step in the right direction.

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[ii] See, for example, *Ford's Principles of Corporations Law*, 13th Edition, (Sydney: LexisNexis Butterworths, 2007) Ch.9 "Conflicts of Interest and Special Cases." Beyond corporate law, there is a vast literature – academic and popular – which expresses differing but consistent concerns about the lure of *lucre* in its many forms. Among many places, see J. Kassirer MD, "Physicians' Financial Ties with the Pharmaceutical Industry," in *Conflicts of Interest: Challenges and Solutions in Business, Law, Medicine and Public Policy*, (eds. D. Moore et.al) (Cambridge: Cambridge University Press, 2005) 133-141; A. Caulfield & B. Williams-Jones (eds.), *The Commercialisation of Genetic Research: Ethical, Legal and Policy Issues*, (New York: Kluwer/Plenum Publishers, 1999); A. Plomer, "Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions," in *Embryonic Stemm Cell Patents: European Law and Ethics*, (eds. A. Plomer & P. Torremans) (Oxford: Oxford University Press, 2009) 173-202.
For the important and regularly ignored feminist perspective, see Donna Dickenson's essential study, *Property in the Body: Feminist Perspectives*, (Cambridge: Cambridge University Press, 2007), especially Ch.2 "Property, Objectification and Commodification," and Ch.3 "The Lady Vanishes: What's Missing from the Stem Cell Debate."

[iii] The requirements under ss.29 & 30 of the *Research Involving Human Embryos Act* in relation to disclosure requirements and confidential commercial information is not and would not be affected by the recommendation here in relation to patent holdings, share-holdings and directorships.

[iv] See International Committee of Medical Journal Editors: "Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication." 2004. Available at www.icmje.org

[v] S. Mayer, "Declaration of patent applications as financial interests: a survey of practice among authors of papers on molecular biology in *Nature*," (2006) 32 *Journal of Medical Ethics* 658-661.

[vi] See the detailed discussion in M. Rimmer, *Intellectual Property and Biotechnology: Biological Inventions*, (Cheltenham, UK: Edward Elgar, 2008) Ch.9 "Still life with stem cells: patent law and human embryos." In the same chapter, Rimmer also discusses the long-standing issues surrounding WARF patents. WARF is the acronym for Wisconsin Alumni Research Foundation, which foundation has long-held patents (which have proved to be hugely lucrative) in relation to 'primate embryonic stem cells.' The astonishing wealth generated to WARF has come, in large measure, from licensing its patents to Geron Corporation in return for research funding. Even more recently, see the ongoing contest to break up the WARF patents. "USPTO rejects WARF's stem cell patent claims" in www.news-medical.net/news (accessed 27th February 2011).

[vii] The following is a very select sample of such warnings: Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," (1 May 1998) 280 *Science* 698-701; D. Nelkin & L. Andrews, "Homo Economicus: Commercialisation of Body Tissue in the Age of Biotechnology," (1998) 28 *Hastings Center Report* 30-39; L. Knowles, "Property, Progeny, and Patents," (1999) 29 *Hastings Center Report* 38-40; D. Nicol & J. Nielsen, "The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development," (2001) 23 *Sydney Law Review*347-374; V. Sharpe, "Science, Bioethics and the Public Interest," (2002) 32 *Hastings Center Report* 23-26; A. Chalet, "Commercialisation and misleading and deceptive conduct," (2002) 1 *Biotechnology Law & Policy Reporter* 63-64; M. Angell & A. Relman, "Patents, profits & American Medicine: conflicts of interest in testing & marketing of new drugs," (2002) 131 *Daedalus* 102-111; R. Moynihan, I. Heath, D. Henry, "Selling sickness: the pharmaceutical industry and disease mongering," (2002) 324 *British Medical Journal* 886-891; D. Nicol, "Gene patents and access to genetic tests," (2003) 11 *Australian Health Law Bulletin* 73-78; M. Angell, *The Truth About the Drug Companies: How They Deceive Us and What to do About it*, (Melbourne: Scribe Publications, 2005); J. Kassirer, *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*, (New York: Oxford University Press, 2005); J. Avorn, *Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs*, (New York: Vintage Books, 2005); P. Mitchell, "Winds of change: growing demands for transparency in the relationship between doctors and the pharmaceutical industry," (2009) 191 *Australian Medical Journal* 272-275.

[viii] See "Confronting conflict of interest," (2009) 191 *Medical Journal of Australia* 241.

[ix] A. Plomer, "Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions," in *Embryonic Stem Cell Patents: European Law and Ethics*, (eds. A. Plomer & P. Torremans) (Oxford: Oxford University Press, 2009) at pp.198-199.