Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Dear Ms Dennett,

Submission: Patent Amendment (Human Genes and Biological Materials) Bill 2010

In writing this submission, I commend Senator the Hon. Bill Heffernan for his long standing public advocacy on this issue.[1] The monopolisation of the human genome by corporate interests should be seen in an equivalent fashion to the major infrastructure issue of the moment, the National Broadband Network (NBN). As observed by Martin, our DNA is:

> like a book with 23 chapters-one for each of our 23 pairs of chromosomes, which make up the gene material (macromolecule) found in the nuclei of cells. Each chapter is divided into sections-genes. You have about 30,000 genes. A typical gene has about 10,000 letters (called 'nucleotides' or 'bases,' each of which can be one of four combinations…It is amazing to think that the entire 23-chapter book is coiled up in the DNA double-helix molecule in every cell of your body.[2]

To continue the analogy, the coiled up double-helix could well be considered nature's NBN. It is already laid down in every cell of our bodies and, has been there ever since we first appeared on Earth. It regulates how our bodies function, like a biological communications network, while variations in coding (wiring) give each individual person our unique characteristics. Yet, now corporations seek to 'enclose' various parts of our DNA, on the basis that they (the corporations) have developed methods to copy and extract parts of the chromosome.

So now, companies like Myriad and Genetic Technologies Ltd (GTL)[3] come along saying to various researchers 'you shall not have access to that gene, as we claim a patent monopoly over it'. It is much like Telstra asserting that it would not permit the NBN

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[1] *See for example*, Senator Heffernan's Second Reading Speech on the Bill, in Official Hansard (Senate) No. 4, 2010, Wednesday, 24 November 2010, Forty-Third Parliament, First Session—First Period, pp. 2100 – 2102, http://www.aph.gov.au/hansard/senate/dailys/ds241110.pdf as at 28 December 28, 2010.
[2] James Martin, *The Meaning of the 21st Century: A Vital Blueprint for Ensuring our Future*, Eden House Project Books, Random House Australia (Pty) Ltd, (2006), p.153.
[3] Various sources appear to refer to the company as 'Genetic Technologies', 'Genetic Technologies Limited' or from it own website 'Genetic Technologies Group' – See *Compressed Genetic Technologies brochure* http://www.gtglabs.com.au/images/stories/Compressed%20Genetic%20Technologies%20brochure.pdf as at 8 January 2011. I will refer to the company as GTL.

Company access to its copper wire phone network and series of exchanges. Unlike GTL however, Telstra and its precursor companies could at least claim to have built the copper network it was asserting exclusivity over. GTL and those like them cannot ever claim to have 'built' human DNA.

On this basis alone, I am opposed to any corporation (or individual, for that matter) gaining a monopoly over the BRCA 1 and BRCA 2 genes (or other genes). Furthermore, like Senator Heffernan, I welcome the judgment of the US Federal Court in *Association for Molecular Pathology, et al., v United States Patent and Trademark Office, et al.*,[4] (invalidating the breast cancer gene patent) however, acknowledge that it will be the subject of an appeal.[5] Additionally, if the cited *New York Times* article is any guide, the ruling is seen as perverse by a significant body of US jurisprudential opinion and is likely to be overturned.[6]

In my view though, it would be in the public interest for the *Molecular Pathology* case to be upheld. If this is ultimately not to be the case, then the US Congress should legislate to ensure the principles of Judge Sweet's ruling are enshrined in statute. In the Australian context, this means that the Bill as proposed by Senator Heffernan should stand, but that its ambit should also be extended. This can be done while ensuring that the amendments are in conformity with popular and professional expectations about how patent law should operate.

Recommendation 1: That Senator Heffernan's Bill should be enacted forthwith, with some minor amendments described below.

1. Historical perspectives

One of the least discussed aspects in this debate is the inherently political decision that is made when a patent is granted. Equally absent is any consideration of the historic social, political and economic pressures which gave birth to the *Statute of Monopolies*, as well as the political calculus which applied prior to that enactment, when the issue of *Letters Patent* and other offices and privileges was a matter of the Monarch's Prerogative. This history can tend to be lost as we look at the modern day bureaucratic process which is Intellectual Property (IP) Australia.

It suits GTL and others to ignore the complexities of this history. But this would be to miss the ebb of flow of the legal and political career of Sir Edward Coke. This jurist was largely responsible for the drafting of the *Statute of Monopolies* in 1623; a pragmatic

[4] *See* 09 Civ. 4515, Case 1:09-cv-04515-RWS Document 255 Filed 03/29/2010 http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf as at 30 March 2010
[5] For example *see* Andrew Pollack, *After Patent on Genes Is Invalidated, Taking Stock*, New York Times, Published: March 30, 2010, Published: March 30, 2010, Published: March 30, 2010, http://www.nytimes.com/2010/03/31/business/31gene.html?_r=1 as at December 29, 2010
[6] *See* ibid

position for someone who would write in his *Reports* just over a decade later that a monopoly could be "odious".[7] As Palombi says:

> (The *Reports*) contributed to the myth that Coke was in favour of free trade, which he was not. Coke was in favour of controlled or regulated trade and full employment. His reference to 'freedom of trade' was directed to the common law's distaste for restrictive and unfair trade practices that impeded employment, not to free trade in the modern sense.[8]

On this basis, I submit that there is a current impediment to scientific research, and indeed, life saving medicine itself, in the way gene patents are interpreted and enforced. In his speech to the Senate on this Bill, Senator Heffernan noted the concerns raised by eminent scientists like Professor Ian Frazer who said that:

> "restricting the use of a gene sequence could delay the development and testing of truly inventive and practical uses of the gene and its protein product for diagnosis and therapy"[9]

If Australia's scientists and researchers are not able to fully employ their talents and abilities to advance and improve therapeutic outcomes for patients, then we should seriously question whether the patent regime we have continues to serve our national interest? This is particularly in light of three clear objectives Coke had in sponsoring the enactment of the *Monopolies Act.* Parliament granted the King power to issue patents, but under the provisos that no patent would:

> be contrary to the law or mischievous to the state by raising prices of commodities at home or hurt of trade, or generally inconvenient.[10]

In light of this, I recommend that IP Australia become a division of the Australian Competition and Consumer Commission. Further, the regulator should be satisfied that the granting of a patent is not likely to lead to anti-competitive behaviour such as predatory pricing or price gouging. Concerns about competition were raised by both me and other submission writers to the Australian Law Reform Commission's (ALRC's) Discussion Paper on *Gene Patenting and Human Health* and, we recommended the issue be referred to the ACCC.[11]

Regrettably, the ALRC's response (having consulted with the ACCC) was weak and unimaginative. In particular, the ALRC seems to have been much too willing to accept a particularly narrow view from the ACCC, as to the appropriateness of the latter have

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[7] Lugi Palombi, *Gene Cartels: Biotech patents in the age of free trade,* Scribe, Melbourne, 2009, p.6
[8] Ibid
[9] *Hansard* above n 1, p.2101
[10] Palombi, above n 7, p.8
[11] *See* Australian Law Reform Commission, *Gene Patenting and Human Health (Discussion Paper 68),* Published on 16 March 2004, Commonwealth of Australia, pp.675-676 http://www.alrc.gov.au/sites/default/files/pdfs/publications/DP68.pdf as at 1 January 2011

regular liaison with health authorities and others, on the matter of gene patents.[12] I would hope that since the publication of the ALRC's final report *Genes and Integrity* in 2004, the ACCC may have had cause to reflect on its concerns that it would comprise its impartiality if it assumed anything beyond the role of a "complaint-driven regulator".[13]

While such concerns are reasonable to a point, you only have to look to other independent, statutory bodies such as the NSW Ombudsman for a precedent to see that a complaint handling body can successfully incorporate a number of other discrete oversight and reporting functions.[14] As such, it is always open to the Parliament to make IP Australia a division of the ACCC and, it need not follow that to have responsibilities beyond complaint handling compromises a body's independence.

Furthermore, given other comments by Polombi, I think it is vitally important that IP Australia be placed within a new legislative framework which brings about changes in its overall emphasis, operation and perspective. In particular, Polombi observed that Coke believed patents were vital to English economic growth. Arguably, the engine of the Empire was fueled, at least in part, by inventions "pinched from others" as:

> letters patent…could be used to entice foreign artisans, craftsman and tradesman to come to England and bring with them their specialised knowledge to locals, so as to make the English economy more robust; and it is for this reason that for 250 years the phrase 'the true and first inventor' included the first to import a new technology to England.[15]

The concept of what a patent is and what rights it confers has been a political contrivance and a matter of economic and social convenience from its inception, regardless of whether it was granted by Monarchical/Executive fiat, or under the terms of the *Statute of Monopolies.*

Recommendation 2: That IP Australia should be broken up, with some staff being redeployed as a division of the ACCC and, that a determination must be made as to the likelihood of reduced competition, before a patent is issued.

For companies like GTL to claim that extracted or purified genes are unquestionably their property, over which they can claim, at least for a limited period, exclusive access due to

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[12] *See* Australian Law Reform Commission, *Genes and Integrity Report: Gene Patenting and Human Health,* Report 99, 2004, Commonwealth of Australia, p.580

[13] Ibid

[14] *See* generally the Ombudsman's homepage at http://www.ombo.nsw.gov.au/ as at 2 January 2011. I draw your attention to the range of guidelines, reports and factsheets, covering topics from complaint handling, employment related child protection, disability services and reviewable deaths. For a summary of functions and activities, refer to page 2 of the 2009 – 2010 *Annual Report – Highlights* at http://www.ombo.nsw.gov.au/publication/PDF/annualreport/09-10/AR_Ombo09_Oct10.pdf I acknowledge that my awareness of the NSW Ombudsman comes from working at the office as a complaints handler, though for the purposes of this submission all my comments are made in a personal capacity; they should in no way be taken as reflecting the views of any other person or agency.

[15] Polombi, above n 7, p.9

patentability should be challenged. Firstly, as a matter of history, Polombi observed that nineteenth century inventors generally went about their work without looking for a patent. Their "reward" came from public esteem, as the public saw discoveries made and lives saved. Grateful nations awarded Knighthoods and other honours, while the likes of Pasteur had a research institute named in his honour.[16]

While accepting that values may have changed during the 20th century and as we leave the first decade of the 21st century, it is important to ask about the consequences of such changes. In answering this question, we also need to ask whether the patent system itself has forsaken much of the socio-political elements which created it, in favour of a strictly *Laissez-faire*[17] approach, where only those corporations holding patent rights stand to benefit. This might be seen as somewhat ironic as corporate legal personality is a privilege granted by Parliament, in contemporary times by virtue of the corporations' law. Yet the populace that the Parliament allegedly represents appears to have little say, as to who owns and controls our DNA and, but for the current Bill, the Parliament has shown a marked reluctance to act.

Furthermore, the resistance that the Australian Parliament has put up to gene patents has been meek, when considering some of the findings contained in the November 2010 Senate Community Affairs References Committee[18] Report, *Gene Patents.* Most notably, the Committee stated that "there are few instances in Australia where enforcement of a gene patent has restricted medical research."[19] This statement is qualified in the very next sentence, with reference to the evidence from the Peter McCallam Cancer Centre.[20] My question to this inquiry is therefore: why wait for potential patent enforcement issues to emerge? Why not act now?

Is the jury *really* still out?

For someone like me, who has (at this stage in my life) a life long physical disability, the thought that the genetic and molecular sciences which could cure me would be hobbled by gene patent licence fees is unthinkable. Equally unthinkable is that the resulting therapeutic application of any research undertaken is so expensive, that few people can have access to it.

Yet, you only have to look to the unequivocal statement of Professor Bowtell of the McCallam Centre to see that GTL enforced their breast cancer gene patent with much hostility. This meant a collaborative venture with Myriad was "shut…down (because) Myriad was unable to move and that avenue completely collapsed."[21] It is noteworthy that aggressive enforcement has been a hallmark of GTL's modus operandi since the early 2000's. The Australian Broadcasting Corporation's (ABC's) *Four Corners* program aired a report in 2003 entitled '*Patently a Problem*'. In the broadcast, journalist Jonathan

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[16] *See* ibid., p. xi (Preface)
[17] *See Laissez-faire* http://en.wikipedia.org/wiki/Laissez-faire as at January 5, 2011
[18] Hereafter referred to as 'the Committee'.
[19] Senate Community Affairs References Committee, *Gene Patents*, 43rd Parliament, November 2010, Commonwealth of Australia, 2010, p.65
[20] *See* ibid
[21] Ibid., p.58

Holmes catalogued a range of concerns from a series of eminent scientists regarding GTL's patents and their enforcement methods. For example, the experience of Sequenom is instructive:

> JONATHAN HOLMES: At the Genetics Congress we approached Charles Cantor, chief scientific officer of Sequenom Inc., a company which makes high-throughput DNA sequencers. Last year, Sequenom paid A$1 million for a licence to GTG's patents. But Charles Cantor isn't complimentary about GTG's methods.
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> DR CHARLES CANTOR, CHIEF SCIENTIFIC OFFICER, SEQUENOM INC.: The amount of pressure they put on us to come to a conclusion one way or another was...in my personal experience, more than I've ever seen before. I mean, it was a very, very, um...high-pressure, short time, 'do it or else'...basically ultimatums. I mean, really, it was blackmail...
>
> JONATHAN HOLMES: That's a strong word to use.
>
> DR CHARLES CANTOR: Yeah, it is, but it was - it's blackmail. It's that sort of threat aspect - "We're going to take you to court and it's going to cost you so much money to defend yourself that you're better off just paying us what we're asking for and we'll go away and you'll never hear from us again."
>
> JONATHAN HOLMES: Sequenom decided to pay up.[22]

At common law, to put another in a position where they are fearful for their safety or wellbeing is considered assault.[23] Meanwhile, the payment of money to avoid court action could, under the 'high pressure' circumstances described, be characterised as extortion.[24] Furthermore, even if GTL's patents are arguably sound, it is to be wondered if their enforcement methodology bars them for seeking relief in the courts, as the clean hands doctrine requires parties to act in good faith and conscience, while not having "(taken) advantage of one's own wrong".[25]

Based on the evidence of Professor Bowtell cited earlier, as well as the comments of Dr. Cantor cited above, I believe it is arguable that GTL would be found to have breached the clean hands doctrine. While appreciating that for researchers, the prospect of litigation is

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[22] Australian Broadcasting Corporation, *Four Corners: Patently a Problem,* Broadcast 11 August 2003, http://www.abc.net.au/4corners/content/2003/transcripts/s922059.htm as at 27 April 2010

[23] **Assault** Any wilful attempt to threaten or inflict injury upon the person of another, when coupled with an apparent present ability so to do, and any intentional display of force such as would give the victim reason to fear or expect immediate bodily harm, constitutes an assault. An assault may be committed without actually touching, or striking, or doing bodily harm to the person of another – *See* Joseph R. Nolan and Jacqueline M. Nolan-Haley, *Black's Law Dictionary,* 6th edition, St. Paul, Minn., West Publishing Co., 1990, p.114

[24] **Extortion** The obtaining of property from another induced by wrongful use of actual or threatened force, violence, or fear, or under (colour) of official right - *See* ibid., p.585

[25] Ibid, p.250

a financially and emotionally devastating possibility, it is regrettable that the Australian Securities and Investment Commission (ASIC) has not to my knowledge taken a close look at the corporate conduct GTL and others, with regard to their enforcement of gene patents.

GTL and others, including the Johnson Family of Companies and Medicines Australia submitted to the Committee that patent protection was essential to overcome the uncertainties and costs of long term research, which may or may not lead to a commercial product.[26]

While this is defendable to a point, the question of when firm's protection of their own corporate interest in profit is detrimental to the wider public interest is my focus. Certainly, the tactics employed by GTL lead me to question the sincerity of many corporate leaders when they claim to put great emphasis on 'corporate social responsibility', 'triple entry book-keeping' and 'being responsible corporate citizens'.[27] When it comes to the exploitation of gene technology, it would seem than any consideration apart from profit comes a very poor second, if it is in the race at all. Indeed, to paraphrase a famous industrialist "Corporate social responsibility is more or less bunk".[28] But, perhaps this is not altogether bad, if we accept something of the Tullberg papers discussed briefly at footnote 27.

While not seeking to start a debate about economics or sociology, I think it is important to look at corporate conduct from a business and economic standpoint; corporations exist to benefit their shareholders and, claims of other social imperatives are speculative at best. Parliaments, governments and the judiciary exist so that wider public and community interests can be served, as well as to bring the kind of constitutional 'peace, order and good governance' which both private commercial and public interests require, to allow both to prosper together in a democracy. One would not be compelled to make

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[26] *See* Senate Community Affairs References Committee, n 19, pp.50-52

[27] *See* for example, ACCSR: Australian Centre for Corporate Social Responsibility http://www.accsr.com.au/ as at 8 January 2011; however, by the same token see authors such as Birgitta S. Tullberg and Jan Tullberg, *On Human Altruism*: *The Discrepancy between Normative and Factual Conclusions*, Oikos, Vol. 75, No. 2 (Mar., 1996), pp. 327-329, Published by: Blackwell Publishing on behalf of Nordic Society Oikos, http://www.jstor.org/stable/3546259 Accessed: 07/01/2011 21:36; also *see* Jan Tullberg, *On Indirect Reciprocity: The Distinction between Reciprocity and Altruism, and a Comment on Suicide Terrorism*, American Journal of Economics and Sociology, Vol. 63, No. 5 (Nov., 2004), pp. 1193-1212, Published by: American Journal of Economics and Sociology, Inc. http://www.jstor.org/stable/3488071 Accessed: 07/01/2011 22:10. Human altruism and establishing a case for it in the first place, would appear to be far more complex than you might imagine. Moreover in *On Indirect Reciprocity*, Tullberg suggests at pp.1193-1194 that:

> There should be a strict separation between reciprocity and altruism, instead of using the term "indirect reciprocity" as a wide gray zone. Real indirect reciprocity, i.e., reciprocal reputation and institutionalized reciprocity, is socially valuable. Altruism, sometimes presented as indirect reciprocity, is more of an obstacle than an asset to a democratic society.

[28] Quote adapted from Henry Ford's original quote to the *Chicago Tribune* in 1916. The founder of the Ford Motor Company said: "History is more or less bunk. It's tradition. We don't want tradition. We want to live in the present, and the only history that is worth a tinker's damn is the history that we make today." *The Phrase Finder* http://www.phrases.org.uk/meanings/182100.html as at 7 January 2011

such statements of "the obvious" unless I was concerned that this vital balance was not being maintained in the gene patents debate.

A number of elements drive me to this conclusion. Firstly, there are the tactics employed by GTL outlined above. Add to this, the reluctance of the then New Zealand Science Minister to say anything definitive to *Four Corners* about the impact of GTL patents. This passage is revealing:

> JONATHAN HOLMES: My understanding is that GTG has suggested to the New Zealand health system that an appropriate licence fee would be $10 million up-front and $2 million thereafter.
>
> PETE HODGSON, NZ MINISTER FOR SCIENCE: Let me make sure that my body language gives nothing away on that. That is part of the constraint that I'm under because we now have a legal issue.
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> JONATHAN HOLMES: Are you being advised that these particular patents are challengeable?
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> PETE HODGSON: I'm being advised to shut up on that question.
>
> JONATHAN HOLMES: But you couldn't sustain going on doing those tests if you were having to pay those kinds of licence fees, could you?
>
> PETE HODGSON: I don't want to comment.
>
> JONATHAN HOLMES: Apart from those guarded comments by the Minister of Science, no-one from the universities or from the health system here in New Zealand has been allowed to comment to Four Corners. But there's no doubt that there's real concern. The sums of money being talked about could jeopardise the entire genetic testing system here. And it's not just New Zealanders who are worried about that.[29]

Let us reflect on history for a moment longer. As discussed earlier, letters patent were privileges first granted by the King, then by the King-in-Parliament via the *Statute of Monopolies*. The same is true of any company's Corporate Seal and grant of legal personality; these are privileges granted by the King-in-Parliament via legislation. Noted Austrian economist, the late Murray N. Rothbard observed that Lord Coke supported widespread government regulation of industry, so long as this was controlled by Parliament, and not a Royal Prerogative power.[30]

While contemporary economic theory would scoff at many of Coke's views, he was quite prepared to legislate for the benefit of the Empire, "personally (favouring) the monopoly

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[29] Australian Broadcasting Corporation, above n 22

[30] *See* Murray N. Rothbard, *The Alleged Liberalism of Sir Edward Coke*, Mises Daily*:* Thursday, September 16, 2010 http://mises.org/daily/4677 as at 11 January 2011

Russia, Virginia, and East India Companies".[31] Contrast this with the nervous Pete Hodgson; there was a day when Parliament knew it was sovereign and, granted legal privileges on terms it saw fit, in line with the policy objectives it set. Today, if Mr. Hodgson is any guide, Ministers of the Crown dare not say too much, even on matters of grave public importance, for fear their Governments will be sued by the corporate entities created by Parliament. It was then Australian Prime Minister John Howard who jibed several years back that then Opposition Leader Kim Beazley didn't have 'the ticker' to be Prime Minister.[32] I contend that Parliaments, Westminster or otherwise around the western world, will have lost their 'ticker', authority and relevance if they continue to let human DNA be patented by corporations, uncontested.

Recommendation 3: That this inquiry refers any issues of corporate misconduct regarding the enforcement of gene patents to ASIC, or other relevant law enforcement bodies.

Recommendation 4: That this inquiry reflect on how the relationship between corporate interests and Parliament have changed over time and, how elements of these changes may be doing significant damage to the standing of Parliament.

Possibilities for reform

You will recall that I wrote earlier in this submission, of life long disability. Various forms of technology, including stem cell technology, offer me and millions of others a real chance of life without impairment. Critical to many technologies, is the individual tailoring of therapies for the needs of each patient.[33] To achieve this, ready access will often be required to an individual's DNA, to run tests and/or grow replacement organs and tissues which will be accepted by a recipient's body.[34]

This inquiry needs to consider the consequences of expensive gene patents either shutting down research, as indicated by Professor Bowtell, or making medical tests, diagnosis and timely treatment unaffordable for many people. For example, in the *Molecular Pathology* case, pages 13 to 15 of the Opinion outline the circumstances of a number of American female claimants. These women, despite having medical advice indicating they should be screened for the BCA1 or BCA2 genetic mutation, were either not insured or

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[31] Ibid

[32] For example, *see* Australian Associated Press (AAP), *PM gets personal: Beazley's got no ticker* October 13, 2005 - 4:04PM, http://www.smh.com.au/news/national/pm-gets-personal-beazleys-got-no-ticker/2005/10/13/1128796640367.html as at 11 January 2011

[33] For example, *see* Science Daily, *Type 1 Diabetes: Grow Your Own Transplant? Human Testes Cells Turned Into Insulin-Producing Islet Cells*, 13 December 2010 http://www.sciencedaily.com/releases/2010/12/101212121739.htm as at 11 January 2011

[34] Technology already exists that allows us to grow organs in laboratories. For example, *see* PBS, *Alan Alda in Scientific American Frontiers: The Bionic Body – Web Features – The Body Shop* http://www.pbs.org/saf/1107/features/body.htm as at 11 January 2011. I also cited this research in my submission to the Senate Community Affairs Committee's 2006 inquiry into the *Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006* (Response to the Lockhart Review), p.13 http://www.aph.gov.au/Senate/committee/clac_ctte/completed_inquiries/2004-07/leg_response_lockhart_review/submissions/sub53.pdf as at 13 January 2011

their insurance companies had declined their claims for cover. Therefore, treatment did not proceed.[35]

This raises vital issues of access and equity in a civilised society, particularly when it pertains to testing related to potentially life saving therapy. The ALRC, while noting "worldwide concern about the possible adverse consequences of existing patent laws…on the provision of healthcare,"[36] maintained the argument that patents were necessary for genetic testing, research and innovation to be economically viable.[37]

Again, while this may be defendable to a point, how many real, living people could die for the sake of the economic viability of a purely legal person: the corporation? It is to be remembered that the individual patients/claimants in the *Molecular Biology* case were not proceeding with treatment because they either could not afford to pay for the tests themselves, or their insurance companies had refused to pay. One line of argument may be that the market will determine who can pay, and those who cannot go without treatment; but not even Adam Smith's free market philosophy in *The Wealth of Nations* was meant for such an extreme interpretation. Mr. Smith also wrote a noted treatise on a *Theory of Moral Sentiments* in which he asserted that even the most lawless brute had some measure of concern in him for the fate of his fellow man.[38]

In the same work, Smith observed that doing justice with reverence and exactness to its requirements was the greatest virtue.[39] He proceeds to give the example of owing a man ten pounds and being sure to pay the exact amount on time, or when the other party calls in the debt. A preparedness to meet the demands of justice, however demanding, says Smith (even where a man's adherence to other virtues is questioned) makes a man "the most commendable, and the most to be depended upon".[40]

Patent holders like GTL would now doubt point to these comments and the discussion of theft not long thereafter,[41] but in the debate over genes, I submit that the questions over 'who owns what' and precisely 'who can demand payment for what' are issues which are not analogous to Smith's linear examples of owing someone ten pounds or having an item stolen from your house.[42] GTL could further point to the evidence the Committee received from the Law Council of Australia, who claimed that "scientists were generally

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[35] *See Association for Molecular Pathology*, above n 4, pp. 13-15
[36] Australian Law Reform Commission, above n 12, p.492
[37] *See* ibid., pp. 493-494
[38] *See* Adam Smith, *The Theory of Moral Sentiments*, Sixth Edition (1790), p.4, online edition © 2005 Salveo Marcelo Soares (apply only to edition, not to text), Published by MetaLibri, Sao Paulo May 15, 2006 http://www.ibiblio.org/ml/libri/s/SmithA_MoralSentiments_p.pdf as at 15 January 2011
[39] *See* ibid, p.156
[40] Ibid
[41] *See* ibid., pp. 156-157
[42] If anything, the latter example is greater use, because you can then draw the analogy that an individual's body as their home and, leave companies like GTL in the places of thieves in the night. They steal our DNA, extracting cDNA and, then claiming cDNA as their own property, seek a patent. If you accept as I do, that tissue samples taken from an individual's body should remain the legal property of that person, over which they should continue to have some form of control. This is not the generally accepted position at law, though there are some positive hints of change, which I will discuss later in this submission.

well informed about the patent system".[43] Equally, the corporation could make a case based around its own economic viability and its contribution to the Australian economy.[44] However, these assertions stand in notable contrast to the advice of Dr. Palombi, who told the Committee that when a gene patent is enforced "all hell breaks loose".[45] It is not in the national interest for "all hell to break loose". This is particularly in relation to medical research and advancement. Underlining this is the often doubtful awarding of patents, to what are described as purified parts of an extracted gene sequence. These extracted molecules of complimentary or copied DNA (i.e. cDNA) lack parts of DNA proper and rarely occur naturally.[46]

Therefore, while there might be some differences between cDNA and DNA, it is still highly doubtful that there is truly the degree of novelty to say that human labour has been mixed with nature to create a new thing. An analogy may be drawn with yeast and the process of fermentation which produces beer. As Polumbi notes, Pasteur's research did much to refine the process of fermentation. However, while Pasteur claimed the purified yeast process itself as an invention he never claimed to have invented the beer. This was despite that fact that the use of his purified yeast process meant beer "had a longer shelf life, could be transported without loss of quality and could be made all year round".[47] Potentially seeking to widen the ambit of his patent to include the beer itself, could have made Pasteur a wealthy man.

Polumbi speculates that Pasteur may well have been happy to publish his research and see brewers take it up with gusto, while neither being inclined to entrepreneurship or litigation. However, he also suggests that Pasteur's 'purified yeast' may not be patentable.[48] He highlights the 1931 US Supreme Court case of *American Fruit Growers v Brogdex*, where the Judges were asked to decide whether oranges became manufactured items (capable of being patented) when dipped in borax to increase their shelf life. Polombi observes that:

> (Justice) McReynolds made it clear that it was wrong to construe the invention as 'a combination of the natural fruit and a boric compound carried by the rind of the skin in an amount sufficient the fruit resistant to decay'. While it was correct to say that 'the complete article [in this form] is not found in nature', that fact alone did not make it 'an article of manufacture'. *Rather an indication of invention was whether the orange itself was, as a result of the process described in the patent, given a 'new or distinctive form, quality or property'. In this respect while the application of borax…resulted in the orange having a longer shelf life, in truth there was 'no change in the name, appearance, or general character of the fruit'.*[49] (my emphasis)

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[43] Senate References Committee, n 19, p.56
[44] *See* ibid., pp. 62-63
[45] Ibid., p.57
[46] *See* Australian Law Reform Commission, above n 11, p.140
[47] Polombi, above n 7, p.206
[48] *See* ibid., pp. 206-207
[49] Ibid., p.207

This case is compelling when applied to current patent disputes. Thus, it is hard to see on McReynolds reasoning, how GTL and others can justifiably claim patents over cDNA. Like the orange, cDNA retains the name, appearance and general character of DNA. It is noteworthy that Justice Sweet cites this case with approval in *Molecular Pathology.*[50]

His Honour also pointed to a series of related cases[51] before pointedly rejecting a submission from Myriad that purified substances could be patented. Justice Sweet argues the Myriad misread the opinion of the Learned Judge Hand in the *Parke-Davis,* as the dispute in that case turned on a products novelty, not its purity. As Sweet J observes:

> (Judge Hand) went on to conclude that the patented purified extract was not, in fact, different from the prior art "only in degree of purity," but rather was a different chemical substance from the prior art.[52]

Unfortunately, there has been some evidence to suggest that the U.S. Court of Appeals for the Federal Circuit has been prepared to depart from precedent. I do not intend to be drawn into a debate about the consequences of judges erring. Rather, one simply draws to your attention the relevant analysis from Polombi and, asks that you draw your own conclusion, particularly concerning the jurisprudential lapse of Judge Pauline Newman.[53]

On balance, it does not appear to be in the public interest to allow patents to apply to purified substances, or those which have undergone a degree of alteration, but are still basically the same item. However, quite the reverse seems to be happening. Referring to the submission of Senator the Hon. Bill Heffernan to the Committee, I note the 2008 letter from GTL to SA Pathology.[54] GTL was intent on making sure SA Pathology used GTL's testing kit and method. This did not appear to turn on the GTL method being of say, greater accuracy, or noticeably improved therapeutic methodology; the letter says quite clearly that enforcement was being proposed simply because:

> Genetic Technologies is the exclusive licensee from Myriad Genetics Inc., of Australian Patents…making us the exclusive holder of the right to offer diagnostic testing of the BRCA1 and BCRA 2 genes.[55]

While GTL claims SA Pathology infringed it methodology, it was prepared to settle the matter if SA Pathology referred their breast cancer tests to GTL.[56] To me, this reads like

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[50] *See Molecular Pathology,* above n 4, pp. 107-108
[51] *See* ibid., pp. 109-112
[52] Ibid., p.115
[53] *See* Polombi, n 7, pp. 213-216. In deciding the case of *Scripps* in 1991, Judge Newman claimed that should a process of manufacture be found patentable, the ambit of the patent was not confined to the specific product the process was claimed to produce, but applied to any instance of the process being used; *see in particular,* Polombi, n 7, p.214
[54] *See* Senator the Hon. Bill Heffernan, *Submission by Senator Heffernan to the Senate Community Affairs References Committee regarding the proposed Gene Patent Inquiry Report,* Australian Senate, pp. 20-21 http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents/submissions/Sub76.pdf as at 1 December 2010
[55] Ibid., p.20
[56] *See* ibid., p.21

a restraint of trade, rather than a genuine affront about SA Pathology's use of a unique process or product which added something the art of medical diagnosis. Given this, I endorse Senator Heffernan's call for higher standards to be applied before a patent is issued and, in particular, his emphasis that a patent not "restrict access to an essential service or product".[57]

Recommendation 5: That the inquiry endorse Senator Heffernan's submission to the Community Affairs References Committee investigation into Gene Patents

Recommendation 6: That the inquiry take particular note of, and endorse, the recommendations in Part 1 of Senator Heffernan's abovementioned submission

The urgent need for reform

It is quite clear that there is an urgent need for reform in the patent system. The first thing that needs to happen is the establishment of an independent authority to regulate the licence fees that patent holders can charge others for access to patented technologies. Examples such as the Independent Pricing and Regulatory Tribunal (IPART) in NSW[58] (which oversees the charges various public utilities can levy on the public) could be used as models for such a body. While IPART's rulings can be highly contentious, the process of seeking submissions, holding public hearings, as well as conducting other related research, provides a level of transparency about the setting of utility prices.

A similar form of accountability would be beneficial in the patent system. This matter is particularly urgent when you recall that the Peter McCallam Cancer Centre had to suspend BRCA 1 and BRCA 2 research.[59] What the Committee's report did not emphasis was a critical *Hansard* exchange drawn to my attention by Senator Heffernan's submission. While GTL may have been prepared to licence the Cancer Centre to continue it research, this came at a premium:

> **CHAIR**—Was there an explanation about why they (GTL) said no?
> **Prof. Bowtell**—They were extremely hostile about the fact that Peter Mac were continuing to do testing in the public domain. They offered to do it collaboratively.
> **Dr Mitchell**—For double price.
> **Prof. Bowtell**—For double price with GTG and on the condition that Peter Mac cease doing any clinical testing.[60]

Despite such testimony, the Committee continued to insist that "evidence of negative impacts caused by gene patents was relatively sparse".[61] I am left to wonder how much bigger the genetically modified 'Pink Elephant' in the room needs to be before Parliament will act. The Peter McCallam Centre was clearly told by GTL that its

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[57] Ibid., p.29
[58] *See* IPART's Home Page http://ipart.nsw.gov.au/welcome.asp as at 19 January 2011
[59] *See* Senate Community Affairs References Committee, above n 19, pp. 57-58
[60] Senator the Hon. Bill Heffernan, above n 54, p.22
[61] Senate Community Affairs References Committee, above n 19, p.64

clinicians had to cease providing clinical tests. The questions of medical ethics surrounding the disbanding of clinical tests and then, only restoring them under the auspicious of a third party who charges twice the price, could fill a textbook or two. It is nonetheless appropriate to ask whether a duty of care exists between the scientists and corporate executives of GTL[62] and the wider community, particularly patients who can no longer afford their medical tests.

Lord Atkin's famous discussion of the good neighbour principle in the case of *Donoghue v Stevenson*[63] is instructive as to the duty. That is:

> You must take all reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be – persons who are so clearly and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called into question.[64]

GTL and others would no doubt claim that I am pushing the bounds of neighbourliness and reasonableness to say their enforcement of a patent made them liable for a medical test being too expensive for some patients to afford. Equally, they might also point out that *Donoghue* relates to a very different facts situation; liability for a contaminated drink container.

In response, I argue that we are all neighbours. The Human Genome Project itself showed that each and every human on Earth shared over 99 percent of our DNA in common.[65] Further, via genetic markers, all peoples can trace common ancestors, as our forebears migrated across the globe.[66] Even if we accept that GTL owns legitimate patents,[67] there is the question of whether they are being reasonable stewards of their intellectual property? In assessing this question, an analogy might be drawn with real property. In the case of *Cambridge Water Co v Eastern Counties Leather Plc*[68] Lord Goff observed:

> (We) are concerned with the scope of liability in nuisance…The liability (is) kept under control by the principle of reasonable user – the principle of give and take between neighbouring occupiers of land, under which "those acts necessary for the common and ordinary use and occupation of land and houses may be

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[62] *See* Genetic Technologies Group http://www.gtglabs.com.au/about-us/directors as at 19 January 2011
[63] [1932] AC 562; [1933] All ER Rep 1 House of Lords
[64] Harold Luntz and David Hambly, *Torts: Cases and Commentary*, 4th edition, Butterworths, 1995, p.124
[65] *See Australian* Law Reform Commission, Essentially Yours: The Protection of Human Genetic Information in Australia - Report, Volume 1, ALRC Report No. 96, Commonwealth of Australia March 2003, p.120
[66] *See for example* James W. Zion, *Traditional Indian Law, The Intellectual Property Regime, and the Protection of Indigenous Genetic Materials*, International Institute for Indigenous Resource Management Roundtable, Denver, Colorado, June 4-5, 2001, p.9 http://www.iiirm.org/publications/Articles%20Reports%20Papers/Intellectual%20Property/Zion,%20Genetic%20Tradlaw2001-06-10.pdf as at 26 September 2006.
[67] I continue to be skeptical about the patents at law and, believe their award was not in the public interest.
[68] [1994] 2 AC 264; 1 All ER 53 House of Lords

> done, if conveniently done, without subjecting those who do them to an action"[69]

GTL has made quite clear by its conduct that it will not allow neighbours, be they scientists or infirmed people, access to "their" patented property. When the company is prepared to close clinical trials (or charge exorbitant fees to allow them to continue), there is little evidence of the give and take required of neighbours, nor the concern for fellow human beings referred to by Adam Smith.[70] I submit that GTL's moves to enforce patents have been unnecessarily combative and, show real potential to damage human health and retard the progress of science. As such, these are not the acts of a reasonable user of patented property, to paraphrase Lord Goff.[71]

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[69] Luntz and Hambly, above n 64, p.781

[70] Although, it is useful to remember that GTL is not a real person, just a legal abstraction.

[71] These may also be the acts of a legal abstraction which has unjustifiably enriched itself. *See* Nolan and Nolan-Haley, above n 23, pp. 1535-1536. GTL is obviously aware of the value being transferred to it in terms of gene patents otherwise it would not be taking action to enforce them, or seeking license fees. Given this, it is arguable in justice and equity that the company is aware (or should reasonably be aware) that it owes to those people who have provided the samples that permit its research, a return on their contribution; arguably holding the samples in an implied trust.

It is appreciated that such a line of reasoning runs into many problems, most notably those who oppose what they see as the 'commodification of the body'. Such objections seem quaint when you realise that our modern consumer society effectively commodified the body with everything from fad diets, cosmetic surgery, pornography and prostitution; all of which appeared well before genetic tests and therapies.

However, making GTL liable has even greater difficulties under Australian law because of the general reluctance of the High Court to recognise unjust enrichment in all but the most limited of circumstances. This is because drawing on the noted English precedent of *Barnes v Addy* (1874) LR 9 Ch App 244, Hugh Atkin writes that what is required is:

> (Most) often now referred to as 'knowing receipt', (which) applies where a third party receives an interest in trust property with notice that it is trust property and that it is being misapplied (Hugh Atkin, '*Knowing Receipt' Following Farah Constructions Pty Ltd v Say-Dee Pty Ltd*, Sydney Law Review, Vol 29: 713, p.716 http://sydney.edu.au/law/slr/slr29_4/Atkin.pdf as at 25 January 2011)

GTL can quite reasonably argue that it did not receive tissue or DNA sample in trust, or under contract. Such items tend to be in their own legal category and governed by two over-riding principles. The first is that there can be 'no property' in a human body, except for the purposes of an executor arranging for burial of the dead. The *Human Tissues Acts* also prevent the sale of human tissue and organs. Furthermore, advocates of a coherent body of principle around unjust enrichment in Australia seem to be in a state of constant reanalysis of allegedly inconsistently case law (*see for example*, Michael Bryan, *Essay: Peter Birks and Unjust Enrichment In Australia*, [2004] MULR 24, http://www.austlii.edu.au/au/journals/MULR/2004/24.html#fn78 as at 1 January 2011)

This is unfortunate because I see an attractive line of argument from Lord Atkin's 'good neighbour' principle, to our overwhelming genetic similarity (neighbourliness) as a species and, an implied duty on GTL and others to recognise a legal proximity to every person from whom they take a genetic sample (if not every person on Earth).

While writing a Masters Thesis (see Appendix 1: Adam Johnston, *How does the Common Law look at (a) the body and (b) property as it might relate to the body or body parts, cells or cellular information?*, A thesis submitted for the degree of Master of Laws of the University of New England, December 2010)

Giving validity to broad patent claims, where processes need not describe a unique product as their outcome, are part of the problem; at least until Justice Sweet called time with *Molecular Pathology.* As such, cDNA should be excluded from patentability, except where a tightly defined process leads to a substantially different end product. In my view, while a testing kit designed to detect a gene mutation for breast cancer is a product, this should never have given GTL any exclusive rights to the cDNA. After all, the testing kit would presumably rely on the cDNA being substantially unaltered, so that it could be determined with a reasonably degree of certainty, whether a person's real DNA showed a pre-disposition to breast cancer. Therefore, while GTL may well claim intellectual property over the kit, others should still be able to provide similar tests without fear of infringement and, the cDNA should be freely available itself, as the property of all.

Taking the property analogy one step further and, remembering that Martin likened our DNA to computer software,[72] why should we allow the *Lotus* menu of our very lives be monopolised by corporate entities? I use the *Lotus* example specifically, because in the case of *Lotus v Borland International*[73] the Lotus Company attempted to stop Borland using its spreadsheet software, but the court ruled that so long as Borland's 'spin-off' programs were sufficiently different from Lotus's code, there was no infringement of copyright.[74] This emphasises the need for DNA to be sufficiently modified before any legal monopoly is seriously considered valid.

Recommendation 7: That an IPART-like authority be established to regulate patent licence fees, with a mandate to place priority on the facilitation of research and, making such research clinically available as soon as practicable, while the ACCC being granted standing as Counsel Assisting the Tribunal.

Recommendation 8: That legislation specifically excludes complementary DNA, or cDNA, from patentability

Current regulatory failure

There are real questions over the utility and integrity of the patent system as we know it. Senator Heffernan's commentary on IP Australia is revealing. He relates part of the

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which tried to overcome the impediments against individuals owning their DNA, I found few jurists willing to bring together the classical liberal notions of personal liberty and private property, alongside the modern day reality of the valuable intellectual property found in genes. So long as this legal blind spot' continues, corporate and medical institutions will be able to profit from tissue and organ samples, while leaving those who provided the samples with no legal claim or return. Such a situation should be regarded as unconscionable, but even if research participants/patients are not remunerated in monetary terms, they should be granted access to a potentially life saving medical test, as an act of basic human decency.

[72] *See* Martin, above n 2, p.153

[73] 49 F.3d 807 (1st Cir. 1995)

[74] *See* ibid at 819. Also see the discussion generally in Robert P. Merges, *Locke for the Masses: Property Rights and the Products of Collective Creativity*, Hofstra Law Review, 5 January 2009 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1323408# as at 29 October 2009

contents of an article (and submission to the Committee) by Dr Charles Lawson of Griffith University. Dr Lawson wrote:

> IP Australia administers a number of Special Accounts established by written determination. Importantly, however, the full cost recovery by IP Australia from "customers" of its intellectual property services that are used to fund its operations are conducted through a Special Account. As a consequence, the Special Account acts as a standing appropriation of the amount credited to the account that is supplemented with any annually appropriated "national interest" and various other amounts for identified purposes .... However, the costs recovered from "customers" of intellectual property services also include a component of the costs of IP Australia's activity and another component related to other policy considerations.[75]

And if you missed the point, Senator Heffernan then says:

> In other words, IP Australia derives the bulk of its operating revenue from fees it receives from patent attorneys and their clients.[76]

This is an intolerable conflict, not dissimilar to the famous case of Dr Bonham. The College of Physicians insisted they held monopoly, by virtue of a Royal Charter, to license all medical practitioners in London and, similarly, to prescribe punishment if a doctor did not pay his dues to the College. Lord Coke, referred to earlier, was having none of this and in 1610, as Chief Justice of the Court of Common Pleas, he told the College:

> One cannot be Judge and attorney for any of the parties.[77]

Put another way, you cannot sit in judgment in situations where you stand to gain from the outcome. Yet, IP Australia awards patents, while also taking fees. Senator Heffernan highlights comments from Professor Peter Drahos, who writes of IP Australia:

> Questions of fundamental principle do not get raised. For example, biotech patent attorneys and patent offices have little incentive to ask whether, as a matter of legal principle, purified biological materials substantially identical to those that occur in nature actually do cross the threshold of 'invention' so as to be eligible for the grant of a patent. *Both parties have a financial incentive not to do so.* (my emphasis)

The last sentence shows that IP Australia is caught in the 'Bonham bind' and, that all its patents are potentially compromised by financial imperatives. Rulings on patentability must be given to a separate agency, which is clearly and fiercely independent, and does

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[75] Senator the Hon. Bill Heffernan, above n 54, p.68
[76] Ibid
[77] *Dr. Bonham's Case*, From Wikipedia, the free encyclopedia, http://en.wikipedia.org/wiki/Bonham's_Case as at 26 January 2011

not receive funds from patent applicants. Also, the basis of such rulings should be both transparent and capable of review. It is unacceptable that Australia lacks an auditing authority overseeing IP Australia,[78] or wider industry regulator.[79] This leaves intellectual property as a closed shop, administered by the 'patent attorney's club' who:

> (sit on) policy committees or advisory committees. These committees usually have a heavy representation from business and the patent attorney profession. If there is broader representation it is usually token. Insiders have little incentive to raise critical questions or issues in the development of patent office guidelines.[80]

For me, this explains a lot about what appeared to happen when I made a submission to the Australian Council on Intellectual Property's (ACIP's) report *Patents and Experimental Use.*[81] One was politely listened to when giving oral evidence and, my submission was duly recorded,[82] but nothing much happened. Perhaps, the irony is that ACIP concluded it had not found a scheme which protected patent rights while having "potential to (provide) broad solutions to the issue of experimental use".[83] Yet, the preferred model for experimental use it then preceded to draft[84] is notable for the four indicia of experimental use. To my mind, if these indicia are not answered prior to a patent being granted, then it shows how lax and flawed Australia's patent system really is.

Furthermore, IP Australia's guidelines should be transformed into more robust regulatory instruments which are capable of disallowance by Parliament and review by the judiciary. As was observed pointedly by then Victorian Attorney General, the Hon. Rob Hulls, at the Centenary Sitting of the High Court of Australia:

> In our defence of the rule of the law, we must also be alert to, and alarmed by, attempts to bypass judicial scrutiny, whether it be via privative clauses or the more insidious trend towards unenforceable guidelines. In my view, any suggestion that an Executive's "non-binding guidelines" be accepted as authoritative is dangerous terrain. Yet it is increasingly the case that we are asked the accept the legitimacy of such guidelines, whether it be in Industrial

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[78] *See* the Hon. Bill Heffernan, above n 54, p.70
[79] *See* ibid
[80] Ibid, p.69 (quoting Professor Drahos)
[81] Australian Council on Intellectual Property, *Patents and Experimental Use*, Commonwealth of Australia, October 2005, http://www.acip.gov.au/library/ACIP%20Patents%20&%20Experimental%20Use%20final%20report%20FINAL.pdf as at 26 January 2011
[82] *See generally,* Adam Johnston, *A Submission In Response to the Australian Law Reform Commission's Discussion Paper 68 and The Advisory Council on Intellectual Property's Issues Paper on Patents and Experimental Use*, 2004, http://www.acip.gov.au/expusesubs/Adam%20Johnston.pdf as at 26 January 2011
[83] Australian Council on Intellectual Property, above n 81, p.68
[84] *See* ibid, p.71

> Relations, decisions concerning grants of Legal Aid, or more poignantly in the immigration area.[85]

Nothing I have read gives me much to feel confident about, in either IP Australia or the ACIP. Therefore, ACIP's insistence in 2005 that Australia must meet its 'obligations' under the Trade Related Aspects of Intellectual Property (TRIPS) Agreement[86] and the Committee's slavish repetition of something similar in its 2010 report,[87] are conclusions which are most distressing. It would appear to me that international comity in IP law is a 'sickening race to the bottom', where I can patent almost anything; probably including that poor orange dipped in borax in *American Fruit Growers.*

Recommendation 9: That IP Australia be reformed, so that decisions regarding patent applications are clearly separated from the receipt of filling fees

Recommendation 10: That IP Australia's "guidelines" be transformed into Regulations which must be tabled, as subordinate legislation, in Parliament

International law

This insistence that TRPS and like documents must be observed, cannot go unchallenged. International law[88] is not a body of binding principle or enforceable law, as we traditionally understand it. It is a body of agreed norms which sovereign states agree to look to when doing business with each other, but critically, one sovereign nation cannot generally bind another to international law. Perhaps, the best current example is the United States refusal to become a signatory to the charter establishing the International Criminal Court. Therefore, former judge the Hon. Dr Ken Chrispin has written:

> (The) International Criminal Court lacks jurisdiction to try Americans, and while British and Australia troops could be tried for any offences committed during the conduct of (a) war, there is no general offence of military aggression with which official could be charged.[89]

Thus, no state can be bound to a treaty or similar covenant without its consent, because at the intersection of diplomacy and politics:

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[85] The Hon Rob Hulls, Ceremonial - Special Sitting at Melbourne - Centenary of High Court of Australia [2003] HCATrans 406 (6 October 2003), available at http://www.austlii.edu.au/cgibin/disp.pl/au/other/HCATrans/2003/406.html as at 27 January 2011. Also, see my paper, *Ethics: A Ruse by Any Other Name?*, pp. 11-30 http://www.health.gov.au/internet/main/publishing.nsf/Content/eHealth2-010/$FILE/010_Adam%20Johnston%20pt2_31-12-09.doc as at 27 January 2011, where I previously raised questions over secretive, specialist institutional ethics committees, run on the basis of 'guidelines'.

[86] *See* Australian Council on Intellectual Property, above n 81, pp. 20-25

[87] *See* Senate References Committee, n 19, pp. 90-93

[88] I would prefer it to be called international *lore*, lore being "the body of knowledge, esp. of a traditional, anecdotal, or popular nature, on a particular subject". *See* Dictionary.com http://dictionary.reference.com/browse/lore as at 27 January 2011

[89] Ken Crispin, *The Quest for Justice,* Scribe Publications Pty Ltd, 2010, pp. 260-261

> (It) is perfectly possible that a state may decide to forgo legality in favour of self-interest, expediency or 'humanity', as with the Iraqi invasion of Kuwait and the NATO bombing of Serbia during the Kosovo crisis.[90]

Additionally, the general rule is that a treaty's terms do not become enforceable in the domestic law of a country until incorporated into an Act of Parliament. This is certainly the proper and accepted course of events; and I endorse the reservations of the late Sir Harry Gibbs, when he spoke to the Samuel Griffiths Society in 2003 about the implications of the *Teoh* case. In that case, the High Court had concluded the where the Executive Government had ratified a treaty there was a reasonable expectation that Departments of State would apply a treaty's provisions as part of public policy.[91] The learned former Chief Justice of the High Court noted that given the multitude of broadly worded document ratified by Australia, the effect of the application of the *Teoh* ratio was one of great uncertainty.[92]

Later in his address, Sir Harry critically observed that:

> (The) English-speaking countries of the common law world have set a standard of liberty and democracy which most other countries have failed to attain. (Yet some) argue that globalisation, as it is called, is a reason why Australia should make its law conform to international standards. The facts that trade has been liberalised, and communication and travel accelerated, do not mean that we should attempt to bring our law into harmony with those of every country with which we trade and communicate and to which we travel, except, perhaps, so far as is necessary to facilitate trade, travel and communication. Perhaps the hankering for international norms indicates a lack of faith in our inherited institutions---a failing of post-modern attitudes.[93]

In the debate over gene patents, successive parliaments, politicians, judges, and the executive (in the form of IP Australia) have failed us all – miserably. We have watched our genetic heritage become a saleable commodity (where everyone except the donor is rewarded), and our organs and tissue samples become "someone else's property" in hospital and research laboratories around the world. We have watched as corporations close down life-saving clinical research that affects real people, the quality and *longevity* of life. In the face of this, alleged "obligations" under the TRIPS or other agreements should always be seen as sacrificial, particularly where the health or welfare of our domestic population is potentially compromised by their observance. As such, I recommend that the Bill proposed by Senator Heffernan include a clause specifying that the enactment should be read as supplanting the terms of any international instrument.

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[90] Martin Dixon, *Textbook on International Law*, 4th ed., Blackstone Press Limited, London, United Kingdom, 2000, p.3

[91] *See* Sir Harry Gibbs, *Chapter Seven: Teoh: Some Reflections*, Proceedings of the Fifteenth Conference of The Samuel Griffith Society, Stamford Plaza Adelaide Hotel, North Terrace, Adelaide, 23--25 May, 2003 Copyright 2003 by The Samuel Griffith Society. All rights reserved, http://www.samuelgriffith.org.au/papers/html/volume15/v15chap7.html as at 27 January 2011

[92] *See* ibid

[93] Ibid

Recommendation 11: That the proposed legislation specifically provide that its terms over-ride all applicable international instruments

Independent oversight

The Australian public needs an Independent Oversight Authority[94] (IOA) to maintain a public register of tissue samples, which is inclusive of the ability to trace a sample back to the patient who provided it; thus allowing the patient/research participant to claim an ongoing interest in their sample.[95] My accompanying thesis is based on the premise that this is not only possible but desirable. If I can own a car, a house, or any other inanimate piece of property[96] within my means, why can't I own myself? One of the key policy reasons identified in the famous case of *Moore v Regents of the University of California*[97] was that to do so would be to inhibit science.[98]

But this argument is spurious, as pointed out by Justice Mosk in a dissenting ruling in the same judgment. His Honour said:

> (It) does not follow that the researcher who obtains (tissue) must necessarily remain ignorant of any limitations on its use: by means of appropriate recordkeeping, the researcher can be assured that the source of the material has consented to his proposed use of it, and hence that such use is not a conversion. To achieve this end the originator of the tissue sample first determines the extent of the source's informed consent to its use -- e.g., for research only, or for public but academic use, or for specific or general commercial purposes; he then enters this information in the record of the tissue sample, and the record accompanies the sample into the hands of any researcher who thereafter undertakes to work with it…As the Court of Appeal correctly observed, any claim to the contrary 'is dubious in light of the meticulous care and planning necessary in serious modern medical research.[99]

Justice Mosk was obviously keenly aware that the leukaemia patient in the case (Mr Moore) had been exploited by his doctor for profit. While Mr Moore's spleen had been

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[94] *See* Adam Johnston, above n 82, p.3

[95] *See* Australian Law Reform Commission, above n 65, p.533

[96] Not to mention animate property, like livestock

[97] *See* Louisiana State University's (LSU's) Law Centre, *Fiduciary Duty of Researchers - the Spleen Case - Moore v. Regents of University of California, 793 P.2d 479 (Cal. 1990)*, Case Compliments of Versuslaw, © 1998 VersusLaw Inc., http://biotech.law.lsu.edu/cases/consent/Moore_v_Regents.htm at 5 August 2009

[98] *See* ibid at 64 where, writing for the majority, His Honour Panelli, J., said: *No court, however, has ever in a reported decision imposed conversion liability for the use of human cells in medical research. While that fact does not end our inquiry, it raises a flag of caution. In effect, what Moore is asking us to do is to impose a tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research. To impose such a duty, which would affect medical research of importance to all of society, implicates policy concerns far removed from the traditional, two-party ownership disputes in which the law of conversion arose. Invoking a tort theory originally used to determine whether the loser or the finder of a horse had the better title, Moore claims ownership of the results of socially important medical research, including the genetic code for chemicals that regulate the functions of every human being's immune system.*

[99] Ibid at 204 (Mosk J.); Also *see* Adam Johnston, above n 71, p.86

removed for therapeutic purposes, his physician then cultured a cell line from the spleen, before taking out a highly valuable patent. Mr Moore was not told of this, and only found out about it when he had his lawyer conduct a patent search.[100] In response, Justice Mosk's words say it all:

> Above all, at the time of its excision (Mr Moore) at least had the right to do with his own tissue whatever the defendants did with it : i.e., he could have contracted with researchers and pharmaceutical companies to develop and exploit the vast commercial potential of his tissue and its products. Defendants certainly believe that their right…is a significant property right, as they have demonstrated by their deliberate concealment from Moore of the true value of his tissue, their efforts to obtain a patent on the Mo cell line, their contractual agreements to exploit this material, their exclusion of Moore from any participation in the profits, and their vigorous (defence) of this lawsuit. The Court of Appeal summed up the point by observing that "Defendants' position that plaintiff cannot own his tissue, but that they can, is fraught with irony." It is also legally untenable. As noted above, the majority cite no case holding that an individual's right to develop and exploit the commercial potential of his own tissue is not a right of sufficient worth or dignity to be deemed a (protectable) property interest. In the absence of such authority -- or of legislation to the same effect -- the right falls within the traditionally broad concept of property in our law.[101]

Justice Mosk clearly believed Moore's property rights in his own tissue should be legally recognised. To a certain extent, the cases of *Hecht v Superior Court of Los Angeles County (Kane),*[102] *Yearworth and others v North Bristol NHS Trust*[103] and *Kate Jane Bazley v Wesley Monash IVF Pty Ltd*[104] all take nervous steps in the right direction.[105]

My own attempt to resolve such issues led me to try and find parallels between Lockean property principles and, the finding in *Mabo v Queensland (No. 2)*[106] that Native Title remained in place (to an extent) after English settlement of Australia. *Mabo* acknowledged that the proper characterisation of Crown Title at settlement should have been radical (which allowed acknowledgement of pre-existing claims), instead of absolute title.[107] I see no reason why every person should not hold a similar Mabo-type title in their tissues and organs, which exists alongside patents and other interests.[108] In

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[100] *See* Rebecca Skloot, *Taking the Least of You*, New York Times Magazine, Published: April 16, 2006, p.7 http://www.nytimes.com/2006/04/16/magazine/16tissue.html as at 6 December 2006; Also *see* Adam Johnston, above n 71, pp. 99-100

[101] Louisiana State University's (LSU's) Law Centre, above n 97, at 182 (Mosk J)

[102] (1993) 20 Cal Rptr 2d 275

[103] Court of Appeal, [2010] QB 1

[104] [2010] QSC 118

[105] See the discussion of these cases in Adam Johnston, above n 71, pp. 102-109

[106] (1992) 175 CLR 1

[107] *See* for example Samantha Hepburn, *Feudal Tenure and Native Title: Revising an Enduring Fiction*, Sydney Law Review, Vol. 3, [2005] http://www.austlii.edu.au/au/journals/SydLRev/2005/3.html at 23 February 2008

[108] *See* discussion in Adam Johnston, above n 71, pp. 67-73

establishing the public registry, I would also require the IOA to undertake audits of hospitals, universities and other facilities maintaining tissue banks. This would be to ensure that researchers conduct the 'consensual pedigree cheek' that Mosk believed was essential in a well planned and well organised, robust scientific study.

Recommendation 12: That an Independent Oversight Authority should be established, with the responsibility to:

(a) maintain a public register of tissue samples and;

(b) ensure that all researchers are required to properly inform themselves (and duly record) the 'consensual pedigree' of all samples they hold

Conclusion

In conclusion, I again take an opportunity to commend Senator Heffernan for introducing the *Patent Amendment (Human Genes and Biological Materials) Bill 2010.* My submission has been an attempt to show where the Bill's scope can, and should, be expanded.

Ultimately, genetic technology represents the best chance for people who are currently sick and disabled to have a life not blighted by infirmity. I find it odd then, that so much public policy is still directed at either accepting or "normalising" chronic illness or disability[109] It is time for a change in policy; we must make genetic technology accessible so that:

> In 100 years (no-one experiences) experience any form of disability, and for the phrase to have completely fallen into disuse. Furthermore, it is my view that between 2010 and 2020 we should be able to do for the amelioration of disability, what President John F. Kennedy did for the achievement of manned flight to the Moon. At the beginning of the 1960's many may have seen Kennedy's pronouncement of a manned moon landing "before this decade is out" as fanciful. But by the end of the decade, Western ingenuity had put Neil Armstrong and Buzz Aldrin on the Moon and brought them safely back home again.
>
> I suggest that the analogy with space exploration is that those disability advocates, who have pre-supposed that disabilities are indefinite (and therefore, insurance essential), are similar to those who thought a Moon landing was impossible. They appear to have settled for dependence and taxpayer funded 'charity' ahead of cures; and it is not as if science isn't showing us advances towards curing many debilitating disabilities almost daily.23 In these circumstances, why are we settling for what is virtually the re-institutionalisation of disability as a focus for mandated public insurance, rather than aiming to insure that disability is eliminated from the human condition?

[109] *See* generally my submission (No. 4) to the Senate Legal and Constitutional Affairs Committee *Inquiry into the Disability Discrimination and Other Human Rights Legislation Amendment Bill 2008* http://www.aph.gov.au/Senate/committee/legcon_ctte/disability_discrimination/submissions.htm as at 30 January 2011.

> Again, the space flight analogy should cause us to focus on the question: what are we aiming for and, are our sights high enough? My personal answer is: no. If the kind of money that an insurance scheme would truly require (or even part of it) was diverted to research and development we could have a realistic hope for many cures by 2020.[110]

It offends me that the law does not recognise any capacity for me, and others, to own ourselves. Rather, it wants to understand me (and have me accept my identity) as someone with a disability. In other words, the law specifically denies people a form of dominion over themselves, which would give many of us real power to determine our own future; particularly in relation to our health and resulting quality of life.[111]

It is time to demand better.

Yours faithfully,

Adam Johnston

30 January 2011

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[110] *See* my Second Submission to the Productivity Commission's Inquiry into Disability Care and Support, pp. 6-7 http://uat.pc.gov.au/__data/assets/pdf_file/0016/100726/sub0186.pdf as at 30 January 2011

[111] *See* for example Adam Johnston , *Who owns you?* On Line Opinion, posted Monday, 18 October 2010 http://www.onlineopinion.com.au/view.asp?article=11109 as at 30 January 2011; also see Adam Johnston, *Reserving the right to protect our genetic code*, The Punch, http://www.thepunch.com.au/articles/reserving-the-right-to-protect-our-genetic-code/ as at 30 January 2011