



Australian Senate

Submission by
Senator Heffernan to the
Senate Community Affairs
References Committee
regarding the proposed Gene
Patent Inquiry Report

Introduction

Recently a European study¹ of patent claims related to genes for 22 inherited diseases concluded that they generate a:

... high level of legal uncertainty that [means] either enormous risks are taken if genetic tests are performed without knowingly infringing a specific patent, or much time and energy goes into establishing patent landscapes and freedom-to-operate analyses or to efforts to use different techniques and methods that may eventually be below the state of the art that is clinically requested.

The same study, like the ALRC's *Genes and Ingenuity* Report, went on to suggest that a ban on the patenting of human genes was not necessary. However, I am not convinced on the basis of the evidence presented to this Committee that such an option is acceptable in the Australian context. Indeed the Committee cannot ignore the clear and compelling evidence from experts in the field of Australian medical science, economics and patent law and which is indicative, they say, of problems attributable to gene patents (and by default the Australian patent system and its administration).

While the scale of the problem remains unclear, I believe that a regulatory strategy has to be urgently devised that can respond to these problems. The evidence from Australian researchers in the field of patents and biotechnology suggests that Australian policy makers must develop a regulatory approach that is responsive to dangers of monopoly pricing and that ensures that scientific research in the public health field is kept as open as possible. It would be irresponsible to do otherwise. The study mentioned above shows that gene-based patents are concentrated in foreign hands. Australia's National Medicines Policy has as a key objective timely access to the medicines that Australians need, at a cost individuals and the community can afford.

It must be remembered that the trigger for this Inquiry was the threat of patent infringement litigation made, for a second time in six years, by the same company against publicly funded laboratories that were providing an essential diagnostic service in Australia. That the threat of litigation dissipated, again for a second time, and again only after an inquiry into gene patents was announced, is fortuitous but it does not bring the matter to a close. The events which led to this Inquiry are beyond dispute.

This submission provides an account of some of the problems caused by gene patents. Gene patents, however, are a product of the Australian patent system and therefore the *Patents Act, 1990* and the current administration of the Australian patent system are part of the problem. The proposed recommendations therefore address both gene patents and the Australian patent system.

Terms of Reference

On 11 November 2008 the Senate referred the following matter to the Community Affairs Committee² for inquiry and report by the last sitting day of 2009. The reporting date was subsequently extended to 18 March 2010.

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

- (i) the provision and costs of healthcare,
- (ii) the provision of training and accreditation for healthcare professionals,
- (iii) the progress in medical research, and
- (iv) the health and wellbeing of the Australian people;

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of any of the matters identified by the inquiry; and

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

¹ Huys I, Berthels N, Matthijs G and Van Overwalle G, 'Legal uncertainty in the area of genetic diagnostic testing' *Nature Biotechnology*, 27, 903-909 (1 October 2009).

² Following the restructuring of Senate Committees on 13 May 2009, the inquiry was continued by the Senate Community Affairs References Committee.

Executive Summary

This inquiry commenced in November 2008, following Senate support for a motion moved by me. The initial reporting date of “the last sitting day of 2009” was extended to 18 March 2010, due to the complexity of the subject matter and the extensive volume of submitted written material and oral presentations.

The Committee received 75 written submissions from a diverse range of organisations and individuals, including biotechnology interests, health/medical professional and consumer groups, research organisations and government agencies. Six public hearings were held between March and September 2009, three in Canberra, two in Melbourne and one in Sydney.

This submission is the culmination of a thorough analysis and consideration of the wealth of evidence provided to the Committee. It makes 18 recommendations (see pages 4-5) based on conclusions to the extensive evidence articulated in its three separate sections, summarised as follows.

Part 1- The Impact of Gene Patents

Australian patent monopoly 600650 - polypeptides of erythropoietin

Evidence before the Committee shows that monopolisation of erythropoietin medicines not only had a significant impact on healthcare costs, but exclusive commercial rights over the natural biological materials from which they were derived could have legally impeded competitive research for the development of new medicines.

Following a litigation six weeks before the patent was to expire, the UK House of Lords rejected the company’s claim that genetic sequencing of erythropoietin was the “inventive” step required by a patent claim. The UK Parliament’s belated determination, however, had no bearing on the patent’s impact in Australia, where restrictions on development of erythropoietin-based products put Australia at a competitive disadvantage, reliant on high-cost imports. The erythropoietin patent is therefore an example of the inadequacies of the current patent framework in terms of the impact on healthcare costs and potential restrictions to research and development, despite the House of Lords’ finding that sequencing of the natural biological component was not “inventive”.

Australian patent monopoly 624105 - hepatitis C diagnostics and vaccines

The awarding of a patent monopoly over purified hepatitis C polynucleotide and polypeptide had made it an infringement for anyone but the patent holder, US company Chiron, to develop or supply these materials between 1988 and 2008 – with significant adverse consequences.

An extraordinarily broad patent monopoly enabled the company to control diagnostics, vaccines and treatment for hepatitis C over this period, impeding competitive research and restricting healthcare. One outcome was that laboratories were forced to rely on a single hepatitis C test, which was ineffective and had far-reaching consequences not only for people at risk of the disease, but also for blood banks. Yet community-based agencies such as the Red Cross were reluctant to litigate, given the risks of taking on a large commercial interest.

Australian patent monopoly 686004 - BRCA 1

BRCA1 is one of two gene mutations indicating familial risk of breast and ovarian cancer. A commercial attempt in 2008 to monopolise testing for these mutations was a trigger for this inquiry.

International experience and compelling evidence presented to the Committee showed that the demand by Australian licensee GTL for public laboratories to cease testing for BRCA1 and BRCA2 posed a considerable risk of the tests becoming less affordable and accessible. While the company eventually withdrew its demands after months of negative publicity, there was nothing in the Australian patents system to protect the interests of the public laboratories and their patients.

Lessons from the BRCA1 and BRCA2 experience permeate this submission, given their significance to the terms of reference. The patents remain valid, along with the continual risk that they will be enforced.

Australian patent monopoly 2001265698, 2004200978 - epilepsy gene mutations

These patents effectively provide 20-year corporate ownership of the human genetic materials that encode, inter alia, proteins linked to a severe form of epilepsy. This section of the submission explains in detail the significant impact the granting of this patent is having on healthcare and patients outcomes in Australia, including widely reported restrictions to diagnostic testing. The patent remains in force until 2024.

What is common to all four of these patent monopolies and others is the absence of any controls in the Australian patent system able to protect the public interest from serious risks to the provision of a wide range of health services.

Part 2 - The Anatomy of a Gene Patent

This section analyses in technical terms the biographical, specification and claims components of patent monopoly 686004 (BRCA1) and explores the impacts in terms of the evidence presented.

Of particular relevance is the documented evidence of genetic and cancer scientists, whose professional views and experience provide an essential perspective in relation to the question of “inventive” step. This section also draws on a number of relevant legal case studies.

Part 3 - Patent Monopolies

This section explores patent monopolies in the context of the terms of reference and Australia’s patent system. It discusses in detail the exhaustive review of gene patent policy conducted from 2002 to 2004 by the Australian Law Reform Commission and why the review’s findings were inadequate and in any case unimplemented.

Also explored more generally is the historical bias and imbalance in gene patent policy towards legal and commercial interests – i.e. patent attorneys and the biotechnology companies they represent – at the expense of the Australian community, as shown in section 1. This is further borne out by a critique of IP Australia and the Australia Council on Intellectual Property.

Conclusion

As the recommendations over page demonstrate, after thorough scrutiny of the evidence in the context of the inquiry’s terms of reference, I remain deeply concerned about the inability of Australia’s current patent system to protect the public interest. The evidence is clear that structural and legislative change are critical to ensuring healthcare provision is not further compromised by an outdated gene patent system.

List of Proposed Recommendations

I request the Committee to consider making the following recommends to the Australian government. That the Australian government:

Part 1

- 1.1 Amend the *Patents Act, 1990* so that a condition to the grant of a patent monopoly be the public disclosure of information sufficient to enable, without undue experimentation:
 - (a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of grant, and,
 - (b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.
- 1.2 Amend the *Patents Act, 1990* so that a condition of the patent registration renewal be the public disclosure of information sufficient to enable, without undue experimentation:
 - (a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of renewal, and,
 - (b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.
- 1.3 Devise and implement a set of coherent and national policies to facilitate the exercise of Crown Use powers by Commonwealth and State agencies;
- 1.4 Devise and implement a set of coherent and national policies to facilitate compulsory licensing so that it will encourage the working of the invention in Australia;
- 1.5 Devise and implement an administrative licensing system to facilitate and regulate the conduct of experiments which will be exempt from patent infringement.
- 1.6 Amend the *Patents Act, 1990* so that an injunction cannot be granted if the effect is to restrict access to an essential service or product.

Part 2

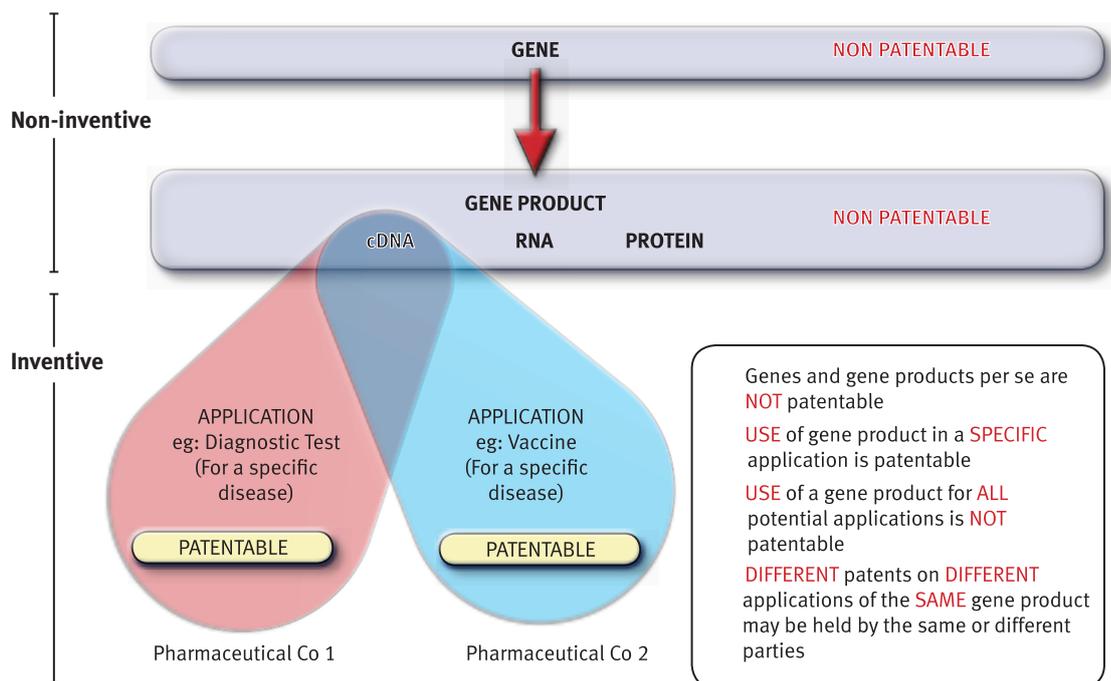
- 2.1 Amend the *Patents Act, 1990* to overrule *Rescare* and *Bristol Myers* in so far as the issue of patentable subject matter is concerned;
- 2.2 Amend the *Patents Act, 1990* to include a set of economic and social objectives;
- 2.3 Amend the *Patents Act, 1990* so that the patentability thresholds are consistent those economic and social objectives;
- 2.4 Amend the *Patents Act, 1990* to expressly prohibit the patenting of:
 - (a) biological materials that exist in nature, including their derivatives, however derived, and whether isolated or purified or not, and
 - (b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- 2.5 Require the Productivity Commission to monitor the impact on the Australian economy of the express prohibitions and present a report to the Australian government within 3 years of their taking effect.
- 2.6 Amend the *Patents Act, 1990* to insert general anti-avoidance provisions that give effect to a policy to strike down patents claims which are a blatant, artificial or contrived attempt to undermine the economic and social objectives set out in the legislation;
- 2.7 Amend the *Patents Act, 1990* so that patent claims define products, processes or methods that are (a) inventions within the full meaning of the Act, (b) novel, (c) contain an inventive step and (d) commercially practical and useful across the full breadth of the scope of the monopoly and not requiring undue experimentation based on the information disclosed in the patent specification;

2.8 Immediately have IP Australia establish a free and publicly accessible, user friendly and searchable database that will enable anyone to determine the effective legal boundaries of all patented technology in Australia and provide useful and meaningful statistics that will aid in the maintenance and development of economic and social policy in Australia.

Part 3

- 3.1 Immediately commission a broad and multidisciplinary Inquiry into the workings of the Australian patent system;
- 3.2 Immediately transfer to the Treasurer of Australia all responsibility for the administration and regulation of the Australian patent system;
- 3.3 Abolish ACIP forthwith and replace it with an independent, multidisciplinary and well-funded intellectual property regulator which will have the power to (a) audit IP Australia, patent attorneys and patent lawyers to ensure their compliance with Australia's patent law (b) investigate abuses of the Australian patent system (c) instigate civil and criminal proceedings in Australian courts against those that are alleged, on reasonable grounds and after a thorough investigation, to have abused the Australian patent system (d) oversee the regulation and discipline of patent attorneys, patent lawyers and patent bureaucrats and (e) provide regular advice and reports to the Australian government on the workings of the Australian patent system.
- 3.4 Immediately have IP Australia establish a patent transparency register that will:
 - (a) track and publish the patent portfolios of patent owners, especially those with large patent holdings; and
 - (b) develop databases in co-operation with user groups or other interested government agencies so that the degree of concentration of ownership of crucial technologies associated with that portfolio, and information about the licensing and assignment of those technologies are easily and publicly available.

Figure 1 Schematic of Express Prohibition as per recommendation 2.4(a)



Part 1 : The Impact of Gene Patents

Australian Patent Monopoly 600650

Polypeptides of Erythropoietin

Scope of the Patent Monopoly

Australian Patent Monopoly 600650 was granted on 23 August 1990, but its legal effect commenced on 11 December 1984 and ended on 24 April 2006 after a period of 21 years, 4 months and 13 days. The period of the patent monopoly, normally 20 years, was extended by IP Australia on the application of the patent holder.

The scope of the patent monopoly included:

1. Purified and isolated erythropoietin, a human protein, produced synthetically using a biotechnological process (claim 1), and
2. A purified and isolated DNA sequence encoding natural erythropoietin (claim 14).

Accordingly, the making, supplying or offering to make or supply purified or isolated erythropoietin, regardless of the biological process used to produce it, was an infringement of the patent monopoly. Therefore, by virtue of this patent monopoly, the patent holder, Kirin-Amgen, Inc, an US corporation based in Thousand Oaks, California, controlled the supply in Australia of this protein. It also controlled the “purified and isolated” DNA sequence encoding the protein, in other words, the human sourced genetic material that was identical or substantially identical to what existed in a human body.

The identity of both erythropoietin and the genetic material encoding erythropoietin in its natural and purified or isolated state was confirmed by the US District Court for the District of Massachusetts in *Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc* (1989) 11 USPQ2D 1466 where it was held:

... the overwhelming evidence, including Amgen's own admissions, establishes that [natural erythropoietin] and [recombinant erythropoietin] are the same product. The [erythropoietin] gene used to produce [recombinant erythropoietin] is the same [erythropoietin] gene as the human body uses to produce [natural erythropoietin]. The amino acid sequences of human [natural erythropoietin] and [recombinant erythropoietin] are identical. ... There are no known differences between the secondary structure of [recombinant erythropoietin] produced in a Chinese hamster cell and [erythropoietin] produced in a human kidney. Amgen's own scientists have concluded that by all criteria examined, [recombinant erythropoietin] is the “equivalent to the natural hormone.”

On the basis of this finding there can be no doubt that natural and purified erythropoietin are structurally, chemically and functionally identical. Likewise, the genetic material used in the biotechnological process to produce purified erythropoietin was identical to the corresponding genetic material in the human genome.

The legal effect of the patent monopoly was to grant exclusive control to Kirin-Amgen, Inc of the erythropoietin protein and the genetic material that encoded the protein in Australia for a period of 21 years 4 months and 13 days.

The Impact of the Patent Monopoly

The most immediate and significant impact of this patent monopoly was on the cost of the provision of healthcare in Australia.

The TGA approved recombinant human erythropoietin (rHuEPO) for the treatment of anaemia caused by chronic renal failure which is symptomatic and/or transfusion dependent. rHuEPO is prescribed to patients that suffer from chronic renal failure. rHuEPO is marketed in Australia under a number of trade marks as a pharmaceutical and has been funded by the Com-

monwealth under the Highly Specialised Drugs Program since its introduction in 1991. Accordingly, rHuEPO is available only through public and private hospitals having access to appropriate specialist facilities. Only medical practitioners who are affiliated with specialist hospital units are permitted to prescribe rHuEPO under the Pharmaceutical Benefits Scheme (PBS).

According to the Commonwealth Department of Health and Ageing the top 10 drugs on the Highly Specialised Drug List in 2001-02 were:

Table 1: Top 10 Most Costly Highly Specialised Drugs to the PBS in 2001-02

No	2001-02 Highly Specialised Drugs	Cost to PBS \$
1	Epoetin, Darbepoetin (rHuEPO)	56,353,409
2	Cyclosporin	28,037,171
3	Clozapine	23,935,695
4	Filgrastim	23,826,909
5	Lamivudine, Lamivudine & Zidovudine	20,834,599
6	Ribavirin & Interferon Alfa-2b	18,351,404
7	Stavudine	10,561,217
8	Mycophenolate Mofetil	10,164,617
9	Octreotide, Octreotide Acetate	9,934,563
10	Disodium Pamidronate	9,702,994

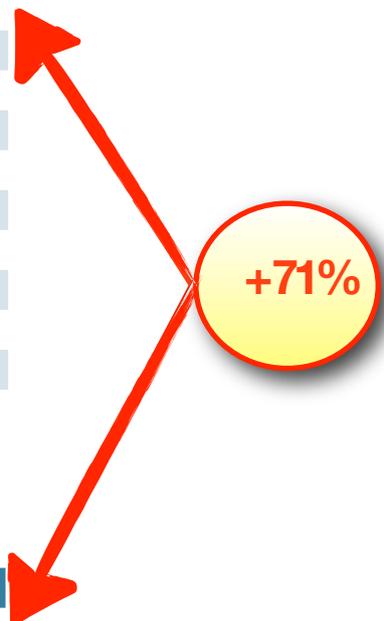
Source: Department of Health and Ageing: *Australian Statistics of Medicines*³

By 2006, the year the patent expired, that list was as follows:

Table 2: Top 10 Most Costly Highly Specialised Drugs to the PBS in 2006

No	2006 Highly Specialised Drugs	Cost to PBS \$
1	Epoetin alfa, Epoetin beta, Darbepoetin (rHuEPO)	96,112,295
2	Filgrastim, Pegfilgrastim	47,836,269
3	Clozapine	34,740,550
4	Ribavirin & Peginterferon Alpha-2a, Ribavirin & Peginterferon Alpha-2b	33,068,805
5	Tenofovir Disoproxil Fumarate, Tenofovir Disoproxil Fumarate with Emtricitabine	27,944,799
6	Lamivudine, Lamivudine and Ziovdine	18,128,824
7	Abacavir Sulfate, Abacavir Sulfate with Lamivudine, Abacavir Sulfate with Lamivudine and Zidovudine	17,348,015
8	Mycophenolate Mofetil	14,691,431
9	Cyclosporin	14,241,320
10	Tacrolimus	12,129,397

Source: Department of Health and Ageing: *Australian Statistics of Medicines*⁴



The combined total expenditure under the PBS for rHuEPO medicines in 1998, 1999, 2001-02, 2003, 2004, 2006 and 2007 (not included is 2000, 2005 and 2008) is \$ 481,079,704 or an average yearly expenditure of \$ 68,725,681. Extrapolating this average over the life of the patent, the total estimated cost to the PBS of rHuEPO drugs would have been somewhere in the order of \$1.5 billion.

³ Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pubs-asm.htm>

⁴ Ibid.

The control over the supply and price of rHuEPO medicines which Amgen was able to exert by effect of the patent monopoly is, however, only one of the impacts on the provision of healthcare in Australia. There were other consequences as well.

The scope of the patent monopoly was not only over rHuEPO as a medicine⁵, but over the actual protein itself⁶ in a purified form and derived from the human genome⁷. It also contained claims to derivative products such as antibodies⁸, biological components containing either the protein or gene or parts thereof, such as a cDNA⁹, 'host cells'¹⁰, plasmids¹¹, a single strand DNA sequence¹², and a genetically modified cell.¹³ It even contained claims to monkey erythropoietin¹⁴ and the monkey gene encoding the monkey erythropoietin.¹⁵

The exclusive right of exploitation provided to Amgen under s.13 *Patents Act, 1990* means that the making or supplying of any of these things, all of which were derivable from human or monkey biological materials using routine scientific techniques and methods as at the priority date of the patent (30 November 1984),¹⁶ were strictly prohibited without the express authority of Amgen. And although there is no evidence before the Committee that Australian scientists and researchers were directly inhibited by the patent for research purposes in making any of these components, my understanding is that they would have technically infringed the patent had they done so. Therefore, had Amgen chosen to, it could have sought to enjoin the use of these biological materials and products for any purposes, including research purposes. In addition, the absence of direct evidence to this effect does not mean that the patent did not have an adverse impact on medical and scientific research in this country. It follows that if the act of conducting research using these materials could have created a potential or actual liability under the *Patents Act, 1990*, then law abiding scientists may have been reluctant to undertake that research, or if they had, to make that research known publicly.¹⁷

Alternatively, Amgen could have allowed medical and scientific researchers access to these materials, but it could just as easily have imposed terms on that access, which in turn might have given Amgen a commercial advantage over the exploitation of the results of that research, particularly if the commercial application had the potential to undermine Amgen's business strategy. Whether it did or not is a matter of commercial confidence and as Amgen did not directly participate in this Inquiry it is impossible for the Committee to know precisely what has transpired. However, it is important to appreciate that Amgen held a virtual worldwide monopoly over erythropoietin until the UK House of Lords decision in *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] 1 All ER 667 held otherwise. That decision, however, came six weeks before the applicable European patent was due to expire and so it had very little impact on Amgen, but what the history of the litigation showed was Amgen's determination to maintain control over the worldwide manufacture, supply and distribution of the erythropoietin. It also provided an insight into what Amgen believed were the legal boundaries of the patent monopoly.

Dr Luigi Palombi, an expert in patent law and biotechnology at the Australian National University, explains the litigation in detail in his doctoral thesis entitled *The Patenting of Biological Materials in the Context of TRIPS*¹⁸ and in his book entitled *Gene Cartels: Biotech Patents in the Age of Free Trade (Gene Cartels)*¹⁹. Dr Palombi's study reveals that Amgen believed its technical contribution, the genetic sequence of the gene encoding erythropoietin, was the 'inventive step' which justified its

⁵ Claim 51 reads as follows: "A pharmaceutical composition comprising an effective amount of a polypeptide according to any one of claims 1, 16, 38 or 39, and a pharmaceutically acceptable diluent, adjuvant or carrier."

⁶ Claims 1-13, 16 and 38.

⁷ Claims 14, 17, 23-35 and 54.

⁸ Claims 48 and 49.

⁹ Claim 22.

¹⁰ Claims 15, 19, 21, 37.

¹¹ Claim 20 and 36.

¹² Claim 30.

¹³ Claims 40-44.

¹⁴ Claims 18 and 45.

¹⁵ Claim 18.

¹⁶ The relevant technical breakthrough was made by Prof Stanley Cohen and Dr Herbert Boyer in 1973. See Dr Luigi Palombi (Submission 4) Part 1 at pp 62-63 and Part 2 at pp 27-29.

¹⁷ This is not a farfetched scenario. The Committee was presented with evidence, some in camera, some during the public hearings and some in submissions, which showed, in the context of other areas of medical and scientific research, that medical and scientific researchers are not immune from the threat of patent litigation. More importantly, however, even if they were immune through some general legislative exemption, clinical applications of the materials or components coming within the scope of patent monopolies would not be.

¹⁸ Luigi Palombi, PhD Thesis UNSW, 2005 at pp 117-140 (http://cgkd.anu.edu.au/menus/PDFs/Palombi-PhD_Thesis.pdf)

¹⁹ Luigi Palombi, *Gene Cartels: Biotech Patents in the Age of Free Trade*, (Edward Elgar, Cheltenham UK, Northampton, MA, USA, 2009) at pp 265-270.

claim to a patent monopoly over *any* biotechnological method or process that would produce purified erythropoietin.²⁰ The UK House of Lords, however, disagreed. It held that such an interpretation was tantamount to a claim over the gene itself and this could not have been possible because the gene was a “discovery”.²¹ Their Lordships also held that Amgen could not patent erythropoietin, the human protein, even in a purified form, because it was not a “new”²² substance. Not only was it natural but it had already been extracted from the human body.²³ Thus the biotechnological process which had defined the use of the genetic material in a specific way to produce erythropoietin was critical to Amgen’s success. But Amgen failed to persuade the UK House of Lords. Their Lordships instead held that the defendant’s process used the genetic material differently to the way the process defined in Amgen’s patent did and therefore there was no infringement. In the end, although the entire patent was not invalidated, Amgen was unable to prevent the defendant from manufacturing and supplying erythropoietin in the UK. It also was unable to recover damages.

Importantly, the breadth of Amgen’s patent claims and the success it had enjoyed in related US patent litigation, gave rise to the general perception that Amgen’s patent was broad enough to cover all aspects of erythropoietin production. This combined with the market power it possessed would have made most scientists and researchers anywhere in the world think twice before embarking on a research strategy that was likely to offend Amgen.²⁴

Data from the Commonwealth Department of Health and Ageing’s *Australian Statistics of Medicines* indicate that erythropoietin was an extremely lucrative product for Amgen (and its licensees), so it is understandable that Amgen was determined to stop any non-licensed erythropoietin from entering the Australian market. Nevertheless, the principal issue in the related worldwide litigation was over whether the patent gave Amgen the right to prevent others using the human genetic material which encoded erythropoietin in any biological process. In other words, could Amgen prevent the production and supply of a generic competitive erythropoietin? The implications on the price of its product and profits were obvious.

In the United States, where Amgen’s original rHuEPO patents are still in force, the company sued F Hoffmann La Roche over the epoetin beta product marketed as Mircera.²⁵ According to an article entitled *Roche Infringes Amgen’s erythropoietin patents*, “There is a lot at stake for both parties, as the US erythropoietin market has annual sales of several billion US dollars”.²⁶ However, on 21 December 2009 Amgen halted the litigation when Roche agreed not to enter the US market with Mircera until 1 July 2014.²⁷ A condition of the settlement is as follows:

Except as allowed under any license agreement reached between the parties, Roche, its agents, servants, employees, counsel, and all persons and entities acting in concert therewith, are hereby permanently enjoined for the life of U.S. Patent No. 5,441,868, U.S. Patent No. 5,547,933, U.S. Patent No. 5,618,698, U.S. Patent No. 5,955,422 and U.S. Patent No. 5,756,349 from infringing said patents by the manufacture, importation, sale, offer for sale or non-exempt use of pegylated Epoetin beta (otherwise referred to as "MIR-CERA" or "CERA") in the United States.

What this has meant in Australia is that prior to 2006 local pharmaceutical companies which might have had the capacity to manufacture and supply purified erythropoietin locally to Australian hospitals were unable to do so. While they, like the defendants in the UK litigation, could have challenged the validity of Amgen’s Australian patent monopoly, this did not occur. Moreover, although the Commonwealth and the State Departments of Health had the power under s.163(1) *Patents Act*,

²⁰ Ibid at p 267-8.

²¹ *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and Others* [2005] 1 All ER 667 at paras 76-77.

²² Ibid at para 132.

²³ “In 1977 a team including Dr Takaji Miyake and Dr Eugene Goldwasser developed and published a protocol for purifying milligrams of EPO from large quantities of urine laboriously collected from patients suffering from aplastic anaemia: see Miyake et al, 252 J Biol Chem. 252 No 15, pp 5558-5564 (1977). Dr Goldwasser made some of this urinary EPO (“uEPO”) available to Dr Rodney Hewick of Cal Tech, who tried to sequence 26 residues at the N terminus. (The protein has 165 residues). This information was published by Sue and Sytkowski in 80 PNAS USA, pp 3651-3655 (1983) but two of the residues were incorrectly identified.” per Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and Others* [2005] 1 All ER 667 at para 5.

²⁴ Since 1989 there has been an enormous number of newspaper stories about Amgen’s patent litigation, particularly in the United States. The success which Amgen has enjoyed in the US has therefore received a great deal of publicity. See for example: http://www.bloomberg.com/apps/news?pid=conewsstory&tkr=RHHBYN:MM&sid=a_6dcOWfwZwl

²⁵ Mircera has been approved by the TGA in Australia. Approval was granted on 28 July 2009 (153801-153814). Roche Products Pty Ltd is the sponsor.

²⁶ Charlotte Harrison, ‘Roche Infringes Amgen’s erythropoietin patents’, *Nature Reviews Drugs Discovery*, 6, 948-949 (December 2007).

²⁷ Details of the settlement are available at: <http://www.patentdocs.org/2009/12/amgen-and-hoffmanlaroche-settle-mircera-litigation.html>

1990²⁸ to appoint an Australian manufacturer and supplier of erythropoietin to Australian hospitals, that power was never exercised.

Consequently, Australian scientists and researchers and Australian pharmaceutical companies have not developed a domestic capacity to manufacture rHuEPO. The consequence of this lack of capacity is that Australian hospitals are still reliant on imports of rHuEPO. Indeed, the lack of domestic know-how coupled with the fact that the no Amgen patent specification anywhere in the world contains sufficient information to enable the commercial production of erythropoietin without regulatory approval resulted in Mayne Pharma withdrawing from a joint project with Pliva, a Croatian pharmaceutical company, to produce rHuEPO due to higher than expected "clinical program costs".²⁹

However, there are three additional complicating factors.

Firstly, there is controversy in the medical community over the pharmacological performance of generic epoetin alfa³⁰, one of the three kinds of rHuEPO available under the PBS. Dr Simon Roger, a medical practitioner from the Renal Unit at Gosford Hospital, explained the problem in this way:

Can a biosimilar manufacturer produce a biosimilar that is similar enough to the original biopharmaceutical to be considered the same? We need robust risk benefit analyses and discussion to help direct the correct future approach. It will take time for substantial postmarketing safety data to fully persuade all stakeholders of the safety of biosimilars. Thus, their uptake may initially be slow until their safety/ efficacy track record materialises.³¹

Amgen enjoyed a 22 year patent monopoly in Australia for rHuEPO during which time it (and its licensees) received around \$1.5 billion from the Australian government for the provision of rHuEPO to Australian hospitals. Accordingly, I believe that generic drug manufacturers should have had access to information, experimental data and production specifications and that was provided to the Therapeutic Goods Administration by Amgen and/or its licensees in support of the regulatory approval process for the manufacture and supply of a generic form of rHuEPO immediately the relevant Australian patent expired.

Secondly, darbepoetin³² is the subject of an Australian patent application.³³ If granted, the patent monopoly will expire in 2026. This effectively doubles Amgen's patent monopoly on rHuEPO in Australia from 22 to 40 years.

Thirdly, epoetin beta is a close derivative of epoetin alfa, and while epoetin beta has different properties to epoetin alfa, Amgen argue that these "do not represent innovation". According to Amgen, all rHuEPO medicines "have the same mode of action" in that "they activate the EPO receptor" in the human body.³⁴ This raises the obvious question: what is so innovative about darbepoetin to warrant a further Australian patent monopoly?

I ask the Committee to note, using the data in the Table 3, that since becoming available on the Australian market in 2001 the cost of sales of darbepoetin, other than in that year, has vastly exceeded the combined cost of sales of epoetin alfa and epoetin beta.

²⁸ s.163 (1) Patents Act, 1990: "Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement: ..."

²⁹ Pliva Press Release 2 February 2006 (available at: http://www.pliva.com/en/edelivery/basic?news_id=1583&mshow=mod_news#mod_news)

³⁰ Roger, S D, 'Biosimilars: How similar or dissimilar are they?', *Nephrology* (2006) 11, 341-346.

³¹ Ibid at p 343.

³² For further information: Amgen Anaemia Advisory Group, 'Darbepoetin alfa: A new erythropoietic drug for treatment of renal anaemia', *Nephrology* (2002), 7, s173-s180.

³³ AU Patent Application No 2006295340. Should an Australian patent monopoly be granted, it will expire on 4 August 2026.

³⁴ Mr Daniel Whelan, Director of Nephrology Corporate Communications, Amgen, Inc as quoted by Manasee Wagh in *Biotech 360* (available at: <http://www.biotech360.com/biotechArticleDisplay.jsp?biotechArticleId=100002>)

Table 3: Cost of rHuEPO to the PBS in 1998, 1999, 2001, 2003, 2004-5, 2006 and 2007

Year	Cost of epoetin alfa	% change from previous year	Cost of darbepoetin	% change from previous year	Cost of epoetin beta	% change from previous year	Total
1998	31,375,913	N/A	N/A	N/A	N/A	N/A	31,375,913
1999	42,541,798	36	N/A	N/A	N/A	N/A	42,541,834
2001-02	52,662,695	24	2,690,714	N/A	N/A	N/A	55,353,433
2003	33,964,998	-36	41,755,878	1,452	N/A	N/A	75,720,876
2004-5	31,974,297	-6	52,365,271	25	N/A	N/A	84,339,568
2006	31,335,390	-2	64,461,220	23	315,685	N/A	96,112,295
2007	26,311,095	-16	64,024,641	-1	5,300,109	1,579	95,635,845
Total	250,166,186		225,297,724		5,615,794		481,079,704
Average	35,738,027		45,059,545		2,807,897		68,725,681

Source: Department of Health and Ageing: *Australian Statistics of Medicines*.³⁵

Legend: Highlighted (red) data indicates Amgen patent monopoly/patent monopoly application in force (the earliest expires in 2016 - extended from 2014 by IP Australia).

Highlighted (green) data indicates no Amgen patent monopoly/patent monopoly application in force

Highlighted (blue) data indicates F Hoffmann La Roche patent monopoly in force.

Note: F Hoffmann La Roche has three Australian patent monopolies over epoetin beta (199921581; 2000064299; 2002233230). The last of these expires on 8 December 2021. (IP Australia AusPat)

There probably are a number of reasons which might explain this shift, but clearly, there has been a sudden change in the prescribing habits of renal specialists from epoetin alfa to darbepoetin (and also epoetin beta). It is particularly important to understand why this has occurred especially as one medical study conducted in Australia suggests that there is no conclusive medical evidence to justify it. That study concluded: "most patients on haemodialysis received epoetin alfa and these patients tended to have better haematological parameters than patients receiving darbepoetin alfa".³⁶ It would also seem that the use of epoetin alfa, which is now available as a generic medicine, over darbepoetin and epoetin beta will significantly reduce the cost to the PBS of rHuEPO medicines and this must be a matter of great benefit to the Australian economy.

Australian Patent Monopoly 624105

NANBV Diagnostics and Vaccines

Scope of the Patent Monopoly

Australian Patent Monopoly 624105 was granted on 28 September 1992, but its legal effect commenced on 18 November 1988 and ended on 18 November 2008.

The scope of the original Australian patent monopoly included:

1. A purified HCV polynucleotide (claim 1),
2. Purified HCV (claim 10), and
3. A purified HCV polypeptide (claim 14).

The patent claims were amended in 1997 but the practical impact of the amendments were marginal.

Accordingly, the making, supplying or offering to make or supply purified or isolated hepatitis C virus nucleic acids and proteins, regardless of the biological process used to produce them, was an infringement of the Australian patent monopoly for 20 years.

³⁵ Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pubs-asm.htm>

³⁶ Pussel B A and Walker R, 'Australian haemodialysis patients on intravenous epoetin alpha or intravenous darbepoetin alpha: How do they compare?' *Nephrology* (2007), 12, 126-129.

There is no doubt whatsoever that the biological materials defined in the various claims in their original or amended form were identical or substantially identical to the hepatitis C virus (HCV), a naturally occurring microorganism. Indeed, so broad were the claims that the Australian patent monopoly not only covered any strain of HCV (and there are six different strains) but arguably covered any closely related virus that was causative of symptoms in humans and other higher order mammals (such as chimpanzees) that were consistent with hepatitis. This interpretation was confirmed by Dr Lynn Dalgarno, a molecular virologist at the Austin Research Institute in Victoria in an affidavit which was filed in Australian legal proceedings.³⁷ Dr Dalgarno said that the definition of HCV in the patent specification was "in terms of the disease which it causes"³⁸ and there were "prior to 1987, viruses other than hepatitis A, hepatitis B and hepatitis C, which were known to cause liver disease or hepatitis".³⁹ The example he gave of such a virus, other than those he mentioned, was dengue virus.⁴⁰

The legal effect of the patent monopoly was to grant exclusive control to Chiron Corporation, a US corporation based in Emeryville, California (Chiron), to the complete supply of HCV nucleic acids and proteins and their uses in *any* diagnostics, treatments, vaccines and therapies in Australia for a period of 20 years.⁴¹

Prior to the discovery of the causative agent of hepatitis C in 1987 by Chiron scientists working in collaboration with scientists at the Centers for Disease Control, a major US government agency, the transmission of non-A, non-B hepatitis (NANBH) through the blood supply in Australia was a major concern, as indeed it was in other countries. Many attempts, prior to its discovery, had been made to identify the causative agent of this disease in many countries. The label, NANBH, was coined because scientists had ruled out hepatitis A virus and hepatitis B virus as candidates, yet the hepatitis-like symptoms which patients developed after receiving contaminated blood or blood products (such as Factor VIII prescribed to patients with haemophilia), indicated that an unidentified agent, most likely a virus, was the culprit.

Once again, Dr Palombi's doctoral thesis,⁴² book⁴³ and submission⁴⁴ has brought much of the relevant history to the Committee's attention and will not be reproduced in this Submission, but what is clear is that the discovery of the causative agent of NANBH, subsequently called HCV, was a major medical breakthrough and those responsible for the discovery received many scientific awards and prizes. The discovery also led, almost immediately, to the development of diagnostic tests that would enable the rapid detection and elimination from the blood supply system of blood and blood products contaminated with HCV. However, while being hailed as a major medical achievement, I ask the Committee to accept that there are a number of relevant facts which must be discussed in this Submission because of the impact which this patent monopoly had, not only on the cost of the healthcare system in Australia, but also on the provision of accurate and reliable diagnostics across the full breadth of the Australian population.

Despite its misleading title, the patent monopoly was not only about the use of the HCV biological materials in a technology that would produce a diagnostic result, although that was certainly one aspect of it. Apart from the claims to the HCV biological materials, some of which have already been mentioned, were claims to the use of those materials in all manner of medical and scientific applications and products, including an HCV vaccine. However, despite the discovery of HCV and the disclosure of its genetic and amino acid sequences more than 20 years ago, there still is no HCV vaccine. Yet, in 1992 IP Australia granted Chiron a patent monopoly which gave it absolute and unfettered control on anything related to HCV and, specifically, an HCV vaccine. The award of this extraordinarily broad patent monopoly, made solely on the basis of the identification of the causative agent, its isolation and its characterisation, was of questionable legality. And although it has expired, its impact provides us with useful insights into the potential impact of other gene patents in the future.

This should be particularly relevant to the Committee because gene patents can so easily overreach, with unintended consequences on medical and scientific research. I ask the Committee to take note of what Prof Baruch Blumberg, awarded the Nobel Prize in Physiology and Medicine in 1976 for his work on hepatitis B, said this about this patent monopoly in 1994:

I have reviewed Chiron's Australian Patent No. 624105 for the purposes of these proceedings. In my opinion, the claims in this patent are very broad. These claims represent a view in scientific thought, i.e., that knowledge of the nucleotide sequence of the virus genome, let alone part of it, tells one all that needs to be known about the functions of the proteins produced by the virus and hence all that needs to be known about the virus ... Based on the unusually broad nature of the patent, if I were a research director for anti-

³⁷ *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Others Federal Court of Australia*, NSW District Registry, Action No: G106/1994

³⁸ Affidavit of Dr Lynn Dalgarno at para 9.4.

³⁹ *Ibid* at para 9.5.

⁴⁰ *Ibid*.

⁴¹ There are other Australian patents related to HCV. As a result the period of exclusivity which Chiron Corporation held exceeded 20 years.

⁴² *Op cit* 18 at pp 145-188.

⁴³ *Op cit* 19 at pp 245, 248-49, 283-293, 312, 314-315.

⁴⁴ Dr Luigi Palombi (Submission 4) Part 2 at pp 1-23.

virals and had the option of working on several viruses, the existence of this patent would weigh against my deciding to undertake HCV research. A company, or even an academic laboratory, might well be deterred from conducting research on HCV because the patent is, in effect, intimidating. With the patent as it stands, any investigator, particularly in commercial laboratories (where much of the work on hepatitis has been done) would have to seriously consider that Chiron would bring an action against them if they attempted any commercialization of anything related to HCV.⁴⁵

Prof Blumberg's opinion highlights how the misapplication of a fundamental principle of patent law, designed to preserve the scientific commons, can impact on scientific and medical research, particularly as is the case today when so much of that research is undertaken, even by universities, with a commercial objective in mind.

As an aside, the point which Prof Blumberg makes should cause the Committee to question the practical effectiveness of a general 'research exemption' as a means of overcoming some of problems caused by gene patents. It is important to appreciate how the role which the commercial imperative plays in academic institutions makes drawing the dividing line between 'pure research' and 'applied research' an extremely difficult thing to do.

The Impact of the Patent Monopoly

The most immediate and significant impact of this patent monopoly was on the cost of the provision of healthcare in Australia. This was not, however, the only impact. Other impacts, included the deterrent effect on medical and scientific research related to HCV diagnostics, treatments, therapies and vaccines. What the Committee, in my opinion, has been unable to assess, is the extent to which it happened. Another was the impact that erroneous HCV diagnostic tests results had on the blood donor population in Australia. A relevant fact is that only 3% of Australians donate blood⁴⁶ and so anything which negatively impacts on this very small population will have a serious impact on the amount of blood and blood products available. Thus the permanent loss of blood donors caused by an ambiguous or positive HCV antibody test result was a serious issue at the time. Fortunately, the subsequent development of nucleic acid tests, or genetic testing, has reduced the possibility to almost zero, but in the early to late 1990s this was not yet an option.

The ask the Committee to accept that HCV "has been Australia's most commonly notified infectious disease"⁴⁷ for more than a decade and that it is "a major public health problem in Australia". In 2005 it was estimated that 242,000 Australians had been exposed to the virus and 16,000 new infections occurred annually.⁴⁸ The seriousness of HCV infection in Australia prompted the Communicable Diseases Network Australia to establish the Hepatitis C Surveillance Committee (HCSC) in 1998. A review paper providing details of the outcomes of the first two years of the work of HCSC described the situation:

There are a number of aspects of hepatitis C infection that have presented challenges to surveillance activities. First, detection of incident cases of infection is difficult because less than 10 per cent of people who are exposed to the virus develop symptoms of acute hepatitis, and an even smaller proportion seek medical advice. New infection can also be detected serologically, but requires serial testing of individuals within a limited time period, to determine that antibodies have developed. Second, because hepatitis C infection in Australia is strongly associated with the illegal and socially stigmatised practice of injecting drug use, it is difficult to undertake monitoring of a large group of people who are at risk of infection. Finally, the long (over decades) and variable time course of chronic infection complicates the assessment of outcomes such as liver failure and hepatocellular carcinoma (HCC).⁴⁹

According to the Department of Health and Ageing's National Hepatitis C Strategy 2005-2008, by 2020 "projections of the number of people living with hepatitis C are likely to be between 321,000 and 836,000, depending on future patterns of injecting drug use".⁵⁰ The same report stated:

Conservative estimates of direct and indirect costs of hepatitis C to the community in 1996-97 amount to \$107.5 million for people with existing infections, with estimated lifetime costs rising by \$46.6 million for

⁴⁵ Affidavit of Prof Baruch S. Blumberg at paras 5.1 and 5.2.

⁴⁶ "While one in three people will need blood at some time in their lives, only one in 30 actually give it." per The Hon Paul McLeay MP, NSW Legislative Assembly, Hansard, 24 October 2006 (Matter of Public Importance: Australian Red Cross and Blood Donations).

⁴⁷ General Practitioners and Hepatitis C Guide (available at: <http://www.hepc.org.au/documents/GPs-720KB.pdf>)

⁴⁸ National Hepatitis C Strategy 2005-2008 at p 4 (Department of Health and Ageing: available at <http://www.health.vic.gov.au/hiv aids/hepatitisc.pdf>)

⁴⁹ Spencer J, Dore G, Robotin M, Correll P, Kaldor J Outcomes from the first two years of the Australian hepatitis surveillance strategy Communicable Diseases Intelligence (2002) 26 (1) 14-22.

⁵⁰ Op cit 48.

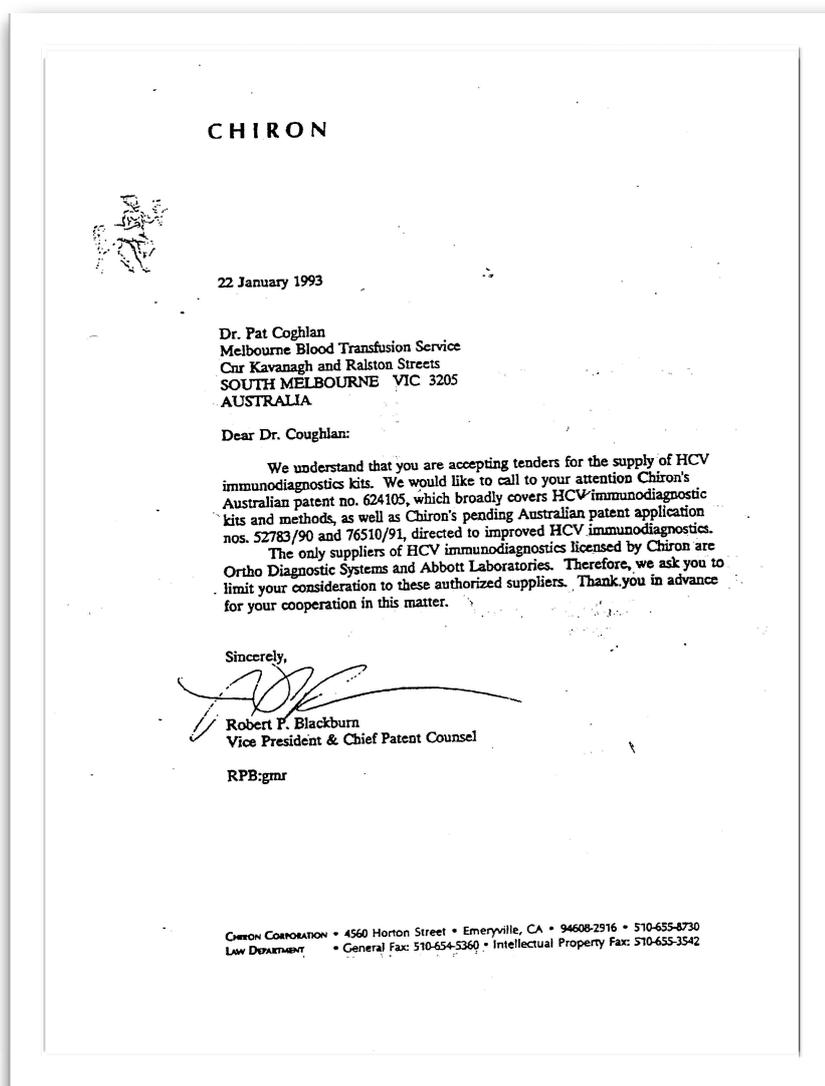
every 1000 new infections. With high numbers of existing and new infections, hepatitis C will continue to have serious implications for Australia's health care system for many years.⁵¹

Thus the extent to which this patent monopoly impeded access to HCV biological materials or interfered with their use in the development of diagnostics, treatments, vaccines and therapies in Australia until it expired in November 2008 is relevant to this Inquiry.

The Committee has previously investigated and reported on *Hepatitis C and the blood supply in Australia*.⁵²

A critical component of Australia's healthcare system is the supply of non-contaminated whole human blood and its components. This patent monopoly impacted greatly on that aspect of Australia's healthcare system by dramatically driving up the cost of blood screening to the Australian Red Cross and laboratories, clinics and hospitals that dealt with human body samples.

This commenced in 1990 with the sale of the first generation HCV antibody diagnostic tests which were supplied in Australia under license from Chiron.⁵³ The main supplier of Chiron licensed HCV antibody diagnostic tests were Abbott Laboratories and Ortho Diagnostics (a subsidiary of Johnson & Johnson).



According to an article published in the *Medical Journal of Australia* in 1998, "the first generation anti-HCV testing ... for reagents alone, [cost] about \$1.7 million in 1990 to screen 250,000 donations, using an assay that was only 70% sensitive".⁵⁴ That cost was significantly higher than the cost for comparable antibody tests.

The reliability of the first-generation Chiron licensed HCV antibody tests was also an issue at the time, as the passage from the MJA article suggests. In its previous report on *Hepatitis C and the blood supply in Australia* the Committee noted:

Initial screening of donors revealed a higher rate of positive test results than would be anticipated given the rate of clinical post-transfusion hepatitis. For example, the ARCBS stated that, 'in the first phase, 70 per cent of the people who reacted on the test were false positive; so they did not have HCV at all'. There was also very little knowledge about the significance of a positive test result in terms of the risk of developing significant liver disease or of infectivity to contacts in everyday life.⁵⁵

Murex Diagnostics Australia Pty Ltd (Murex) began to supply an HCV antibody diagnostic test soon thereafter at a price

⁵¹ Ibid at p 9.

⁵² Senate Committee Report, Community Affairs References Committee Hepatitis C and the blood supply in Australia (June 2004) available at: <http://www.hepc.org.au/documents/04HepC-blood-supply-800KB.pdf>

⁵³ Ibid at p 34 para 2.88.

⁵⁴ Moaven L J 'Should we be screening blood donors for hepatitis G virus? The case for screening', *Medical Journal of Australia* (1998) 169, 373-374 (available at: <http://www.mja.com.au/public/issues/oct5/moaven/moaven.html>)

⁵⁵ Op cit 50 at p 33 para 2.87.

of \$1.50/test less than the price charged by Abbott and Ortho. The entry by Murex into the Australian market introduced a level of competition which brought about a positive result for the Australian Red Cross and other laboratories which were performing blood screening in that they were able to acquire a commercial test at a lower price than charged by Chiron's licensees. By November 1992 Murex had succeeded in winning tenders to supply HCV antibody diagnostic tests to the Australian Red Cross in NSW and Tasmania.⁵⁶

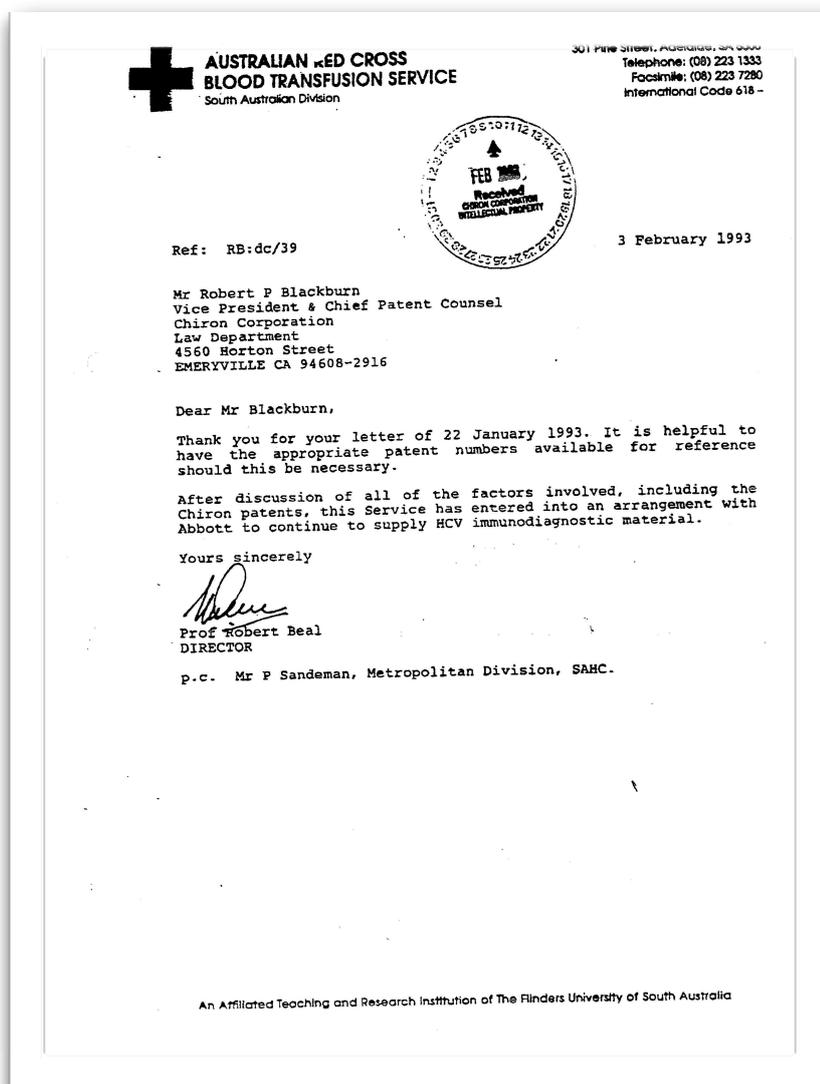
Murex's HCV antibody test was initially supplied by its UK associate, Murex Diagnostics Ltd (Murex UK). The Murex HCV antibody test had been developed by Murex scientists using biological materials from HCV strain 1b. Chiron-licensed HCV antibody tests, however, used biological materials from HCV strain 1a. This difference was important because the genome of HCV varied sufficiently between strains such that HCV antibody test performance was effected as a result.⁵⁷ Test performance was also effected by the selection of viral proteins as well as by the processes used to synthesise them. So there were a number of variables that affected HCV antibody diagnostic performance.

These variability issues, however, did not deter Mr Robert Blackburn, Chiron Chief Patent Counsel, from writing directly to the Melbourne Blood Transfusion Service advising it of the existence of Australian Patent 624105.

Continuing variability issues and the associated risk of misdiagnosis, particularly in the case of blood donors, eventually prompted the Hepatitis C Task Force, established by the NH&MRC, to recommend in its report⁵⁸ that Australian research laboratories "be encouraged to undertake full nucleotide sequence studies on Australian strains of hepatitis C virus". A problem in implementing this recommendation, however, was the patent monopoly which gave only Chiron (or those with Chiron's authority) the exclusive rights over the possession, supply, manufacture and use of *any* purified HCV biological materials as defined in claims 1, 10 and 14. The concern on the part of the blood banks and other testing laboratories, in light of the letter which Chiron had already sent to the Melbourne Blood Transfusion Service, was that Chiron could have sued them for patent infringement if they trespassed on Chiron's exclusive patent rights.

For blood banks and other diagnostic laboratories who could ill afford to become entangled in expensive patent litigation, compliance with Chiron's demands was the only alternative.

Indeed, by early 1994 Chiron had become embroiled in patent litigation with Murex. Murex filed suit in the Federal Court of Australia seeking revocation of the patent monopoly. Chiron, in turn, filed a counterclaim for infringement. While the patent litigation created an opportunity for a judicial review, it also sent a message into the marketplace that Chiron would not hesitate to assert its patent rights. Corresponding patent litigation against Murex UK and others, which had commenced in the UK and Europe in 1992, only served to reinforced that message. The result was that



⁵⁶ Dr Luigi Palombi (Submission 4) Part 2 at p 15 and Schedule B1 attaching memo from Abbott to Chiron, 25 November 1992

⁵⁷ Ibid at pp 19-22.

⁵⁸ Report On The Epidemiology, Natural History And Control Of Hepatitis C, Hepatitis C Task Force, National Health and Medical Research Council (November 1993).

HCV diagnostic research and development was effectively hamstrung in Australia by effect of this patent monopoly.

In the meantime, concerns over the reliability of Chiron licensed HCV antibody tests persisted beyond the first-generation diagnostic tests. By 1995 third-generation HCV antibody diagnostic tests had been released. Significantly, the viral proteins used in the those tests remained sourced from HCV strain 1a despite the Hepatitis C Task Force's Report concluding that the predominant HCV strains in Australia were HCV 1 and HCV 3.⁵⁹

In 2 October 1995 the following letter entitled *A positive hepatitis C enzyme immunoassay antibody test in a low risk population: what does it mean?* was published in the *Medical Journal of Australia*⁶⁰ in which the authors argue:

The introduction of screening of all blood donations for antibodies to the hepatitis C virus (anti-HCV) by enzyme immunoassay (EIA) has reduced the number of cases of post transfusion hepatitis C. Current third generation EIAs typically include antigens from the structural region (capsid) as well as one or more antigens from the non-structural region of the virus (NS3, NS4 or NS5). Such assays are highly reliable among individuals with risk factors for or symptoms and signs of hepatitis C virus infection, *but the false positive rate remains a significant problem when a low risk population (such as blood donors) is screened....A definitive diagnosis cannot be made from a positive anti-HCV EIA test result in a healthy asymptomatic individual with no risk factors for HCV infection and a normal ALT*" (emphasis in original affidavit of Dr Locarnini).⁶¹

Dr Stephen Locarnini, the Director of the Victorian Infectious Diseases Reference Laboratory (VIDRL) then located at the Fairfield Infectious Disease Hospital in Melbourne, swore an affidavit in 1996 (filed in the *Murex v Chiron* patent revocation proceedings) in which he told the Court that "[b]lood banks in Australia and elsewhere are losing blood donors permanently".⁶² The significance of this loss Australian blood banks was explained:

The fact that third generation anti-HCV test kits are giving such results is really saying something: it means in a low risk group such as blood donors, the present generation anti-HCV tests are detecting something other than HCV and giving false positive results in up to 75% of cases. It has been five years since the first anti-HCV test kits were first used in Australia and the manufacturers of these kits have not yet produced a kit which is as sensitive and specific as the test kits for HIV. This is clearly unsatisfactory.⁶³

The impact on the health and wellbeing of the Australian community was summarised by Dr Locarnini:

A positive diagnosis drastically affects peoples lives. Once people are labelled HCV positive, their blood is lost to the community if they are a blood donor; they are referred to a liver clinic; their private lives are affected; their relationships are affected; their insurance policies are affected; their quality of life is affected. In the case of a false positive, this to me is unacceptable and a great deal of research must be undertaken to encourage improvement in the specificity of these tests.⁶⁴

And the solution was reasonably simple. The problem was that Chiron and its Australian licensees simply chose to do nothing. According to Dr Locarnini, "the sensitivity of these tests can be improved if the kit manufacturers would include reagents from genotypes other than from strains HCV 1a and 1b."⁶⁵

Summary

This evidence proves conclusively that Chiron's patent monopoly over the HCV biological materials impeded the development of diagnostic tests that were necessary for the continued health and wellbeing of the Australian people. Besides the cost of the Chiron licensed HCV antibody diagnostic tests, which were significantly higher than they would have been if there had been competition in the provision of alternative HCV antibody diagnostic tests⁶⁶, Chiron and its licensees failed to adequately meet the needs of the Australian community. And blaming Chiron's management for ignoring repeated calls for the supply of tailor-made HCV antibody diagnostic test which were better suited to Australia's population is certainly no excuse. On balance I ask the the Committee to accept that the Australian patent system was incapable of remedying the situation.

⁵⁹ Dr Luigi Palombi (Submission 4) Part 2 at p 19.

⁶⁰ *Medical Journal of Australia*, Vol 163 (2 October 1995).

⁶¹ Affidavit of Dr Stephen Locarnini #2 at para 5; Dr Luigi Palombi (Submission 4) Part 2 at p 19-20.

⁶² *Ibid* at para 8.

⁶³ *Ibid*.

⁶⁴ *Ibid* at para 10.

⁶⁵ *Ibid* at para 14.

⁶⁶ Dr Locarnini appeared on ABC TV's *Lateline* in August 1994. He said that the initial cost of a Chiron licensed HCV antibody diagnostic test was \$14/sample. The cost of a comparable hepatitis B virus test was \$1.50/sample. There was no difference in the technological platform between the two tests. The only difference was in the biological materials inserted in the tests.

I ask the Committee to note the following:

1. IP Australia elected not to intervene in the Federal Court of Australia revocation proceedings in *Murex v Chiron*;⁶⁷
2. IP Australia failed to oppose Chiron's request to amend its patent claims;⁶⁸
3. IP Australia failed to re-examine the patent monopoly even though it had probable cause based on evidence filed in *Murex v Chiron*;⁶⁹ (the Committee has been advised that IP Australia even failed to appoint a watching brief during the course of the *Murex v Chiron* trial (June - August 1996)).
4. IP Australia failed to re-examine the patent even though it had probable cause after the European Patent Office revoked the very same claims which IP Australia accepted as amendments in 1997;⁷⁰
5. The State Departments of Health and the Commonwealth Department of Health and Ageing failed to exercise powers available to them under the *Patents Act*;⁷¹
6. The *Murex v Chiron* litigation was resolved on a commercial-in-confidence basis after a 9 week trial in the Federal Court of Australia on 28 August 1996. Only one published judgement was handed down by Justice Burchett during the trial. That dealt with an allegation that Chiron had improperly interfered with the administration of justice in the UK trial of *Chiron v Murex* in 1993 through the appointment of Prof Sidney Brenner (an expert appointed by the court to assist Justice Aldous (as he was then)) to the scientific advisory board of a company on which the chairman of Chiron's board was directly involved;⁷² and,
7. During the period in which the *Murex v Chiron* litigation was before the Federal Court of Australia (March 1994-August 1996) the issue of 'manner of manufacture' was raised by Murex and, therefore, evidence germane to the issue was presented to Justice Burchett. During the trial, senior counsel for Chiron and Murex presented arguments on this issue and cross-examined leading Australian scientists, such as Prof John Shine, Prof Sir Gustov Nossal, Dr Locarnini and Dr Dalgarno, who gave evidence with respect to various aspects of the relevant Australian science. IP Australia was therefore aware that these proceedings provided an opportunity to have judicial guidance on the issue of 'manner of manufacture' in respect to the patenting of isolated biological materials. Despite this opportunity, not only did IP Australia not participate in any way in these proceedings but the Deputy-Commissioner of Patents, Mr David Herald, handed down a decision in an Opposition concerning Australian Patent Monopoly 600650 (discussed at length in Part 3).

Australian Patent Monopoly 686004

In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene

Scope of the Patent Monopoly

Australian Patent Monopoly 686004 was granted on 11 June 1998, but its legal effect commenced on 11 August 1995 and will end on 11 August 2015.

The scope of the Australian patent monopoly includes:

1. An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19 (claim 1);
2. A preparation of polypeptides substantially free of other proteins, said polypeptides being a mutant or polymorphic BRCA 1 polypeptide compared to the BRCA 1 polypeptide having amino acid sequence set forth in SEQ ID No:2 which is obtainable by expression of a nucleotide coding sequence derived from the nucleotide sequence set forth in SEQ ID No:1 by incorporation of one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19; (claim 10), and

⁶⁷ s.139(2)(b) *Patents Act, 1990*.

⁶⁸ s.104(1) *Patents Act, 1990*.

⁶⁹ s.101A *Patents Act, 1990*.

⁷⁰ Dr Luigi Palombi (Submission 4) Part 2 at p 23.

⁷¹ s.163(1) *Patents Act, 1990*.

⁷² Dr Luigi Palombi (Submission 4) Part 2 at Schedule C.

Accordingly, the making, supplying or offering to make or supply isolated nucleic acids which code for mutant or polymorphic BRCA1 polypeptides and purified mutant or polymorphic BRCA1 polypeptides, regardless of the biological process used to produce them or their use, is an infringement of the Australian patent monopoly.

There is no doubt whatsoever that the biological materials defined in claims 1 to 3 (nucleic acids) and claims 10-13 (proteins) are identical or substantially identical to the corresponding biological materials in the human body. This has been confirmed in evidence presented to the Committee by Ass Prof Judy Kirk, Director of the Familial Cancer Service at the Westmead Millennium Institute for Medical Research in NSW:

... These families have an inherited fault in a gene which puts them at an incredibly high risk of developing breast and ovarian cancer, and prostate cancer in men. The two genes that we test in these families are known as BRCA 1, the breast cancer gene, and BRCA 2. ... We all have these genes. They are normal, good genes that work usually to control cell growth. These are genes that we all have and these sequences are in every human being. They are normally involved in cell growth, and most of us in this room will have a slight variation in the sequence of those genes. We will not all have an identical BRCA1 gene. But some of us, not very many of us, will have a fault or a mutation that is big enough to cause a problem with the protein that that gene makes. Those are the people who are at very high risk of cancer.⁷³

In Part 2 of this submission this gene patent is examined in detail and so there is no need to go into any more detail about the scope of the patent monopoly other than to point out that this specific patent monopoly is concerned only with mutations to the BRCA 1 human gene. There are other patents that deal with other aspects of the BRCA 1 and BRCA 2 gene. Needless to say, the same issues arise in respect to each of these other patents as arise in the discussion concerning this patent.

That said, the ownership of these patents is not identical, though in each case Myriad Genetics, Inc a US corporation based in Salt Lake City, Utah, is one of the co-owners of the Australian patent monopolies which effectively give Myriad Genetics and its partners control over the human gene mutations which occur in human BRCA 1 and BRCA 2 genes and the proteins which they encode.

The Impact of the Patent Monopoly

The most immediate and significant impact of this patent monopoly, had it not been for the decision on the part of the exclusive Australian licensee not to enforce its Australian patent monopoly, would have been on the cost of healthcare in Australia. In addition, it would have adversely impacted on the provision of much needed pre and post-diagnosis counselling and treatment for breast and ovarian cancer in women and prostate cancer in men.⁷⁴ It is also reasonably foreseeable that the private cost of BRCA 1 and BRCA 2 gene testing would have increased substantially during the balance of the patent monopoly.

I ask the Committee to accept that it is also likely that had there not been such a significant and adverse public and political reaction in 2002 and 2008, the exclusive Australian licensee, Genetic Technologies Ltd (GTL), a publicly listed Australian company based in Melbourne, would have enforced its Australian patent rights. That on two separate occasions GTL withdrew its threat of litigation may mean that the impact of these Australian patent monopolies was not felt, but there is no guarantee that Myriad may not seek to enforce its patent rights at some stage before 2016, when the last of the four relevant patent monopolies expire.

Therefore, I suggest that the Committee not be lulled into a false sense of security. It may be a case of 'once bitten twice shy' but the Committee cannot ignore GTL's conduct. The point must clearly be made that it was only after the ALRC inquiry into gene patents was announced that GTL withdrew its threat of litigation the first time. That decision, although costly to GTL, was a strategic withdrawal. It had the effect of taking the media spotlight both off GTL and the subject of 'gene patents' during the period of the ALRC's inquiry into gene patents. I ask the Committee to note that after the ALRC recommended not to impose a ban on gene patenting⁷⁵ and with no immediate government reaction to the ALRC's *Gene and Ingenuity* Report, indicating to GTL's management that, perhaps, the dust had settled on the issue of 'gene patents', GTL made a second attempt to enforce its Australian patent monopoly rights. That this occurred after GTL had made a public statement in 2003 about the gift of its patent rights to the Australian people, leads me to suggest that the Committee ask: what is to stop GTL renegeing on that 'gift' a second time? There is no legally binding agreement between GTL and the Australian government to this effect. Moreover, even if there was it would not bind Myriad, the primary patent rights holder.

⁷³ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 50.

⁷⁴ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 122.

⁷⁵ ALRC *Gene and Ingenuity Report*, Recommendation 7-1 (2004).

The Committee has received submissions from parents of patients,⁷⁶ doctors,⁷⁷ patient advocacy associations,⁷⁸ cancer support groups,⁷⁹ professional medical associations,⁸⁰ medical research organisations,⁸¹ patent attorneys⁸², legal and patent attorney representative associations,⁸³ academics,⁸⁴ pharmaceutical companies,⁸⁵ pharmaceutical and biotechnology industry organisations,⁸⁶ the biotechnology industry,⁸⁷ government agencies⁸⁸ and departments,⁸⁹ State governments,⁹⁰ parliamentarians⁹¹ and the public at large⁹² and a great deal of these have focused on the breast and ovarian cancer gene patents which are sometimes called the 'Myriad patents'. It would seem that these patent monopolies, indeed the manner in which Myriad has sought to apply the exclusive rights all over the world, has caught the attention of the public in ways that other gene patents, although just as important, have not.

The trigger for this Inquiry was the letter that was sent to public laboratories performing BRCA 1 and BRCA 2 gene testing on 7 July 2008.

The doctors who received this letter took the threat seriously. So did the Department of Health and Ageing and the corresponding State health authorities. The Australian Competition and Consumer Commission was prompted by the Australian government, on the basis of this letter, to investigate the legality of GTL's conduct in the context of the *Trade Practices Act, 1975*. This was a serious threat made by a company which had been advised by its patent attorneys that it had the *Patents Act, 1990* on its side. This was neither an invitation to the negotiating table nor, as Mr Slattery, a patent attorney and former partner of the firm Davies Collison Cave, put it to us during his evidence, "a warning shot, perhaps fired over the bows".⁹³ Mr Slattery explained that this letter is typical of the tactics used by patent holders for the purpose of securing a "negotiated

⁷⁶ Dr Belinda Coyte Submission 55)

⁷⁷ Dr G K Sutherland (Submission 2), Dr Anne Rowan (Submission 3), Ass Prof Judy Kirk (Submission 9), Prof Jenny Leary (Submission 39) and Dr Deepak Gill (Submission 68).

⁷⁸ Breast Cancer Action Group NSW (Submission 30), Cancer Voices NSW (Submission 48) and MADGE (Submission 63),

⁷⁹ Breast Cancer Network Australia (Submission 48) and the Australian Marfan Association (Submission 52),

⁸⁰ Australian Medical Association (Submission 7), Human Genetics Society of Australasia (Submission 33), National Coalition of Public Pathology (Submission 40), Royal College of Surgeons (Submission 41), Medical Technology Association of Australia (Submission 43), Royal College of Pathologists of Australasia (Submission 49), Cancer Council of Australia (Submission 50) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (Submission 58).

⁸¹ Walter & Eliza Hall Institute of Medical Research (Submission 26) and the Peter McCallum Cancer Centre (Submission 28).

⁸² Davies Collison Cave (Submission 27) and F B Rice & Co (Submission 34).

⁸³ Institute of Patent and Trade Mark Attorneys of Australia (Submission 31), Intellectual Property Committee of the Business Law Section of the Law Council of Australia (Submission 57) and the Chartered Institute of Patent Attorneys (Submission 74).

⁸⁴ Dr Charles Lawson (Submission 5), Dr Luigi Palombi (Submission 4), Prof Dennis and Mrs Rhona Haskell (Submission 11), Emeritus Prof Jan Wahlstrom (Submission 13), Prof Mark Willcox (Submission 15), Profs Sarnoff, Kahn and Andrews (Submission 17), Dr Hazel Moir (Submission 20), Ms Naomi Hawkins (Submission 22), Prof Dianne Nicol and Dr Jane Nielsen (Submission 23), Intellectual Property Research Institute of Australia (Submission 36), Prof Andrew Christie (Submission 38), Dr Mathew Rimmer (Submission 45), Dr Ben Saul (Submission 46) and the Centre for the Governance of Knowledge and Development, Australian National University (Submission 60).

⁸⁵ Johnson & Johnson Family of Companies (Submission 44), Pfizer Australia (Submission 51) and CSL Limited (Submission 71).

⁸⁶ Medicines Australia (Submission 21), Biotechnology Industry Organization (Submission 29) and AusBiotech (Submission 75).

⁸⁷ Genetic Technologies Ltd (Submission 24), Xenome Limited (Submission 70),

⁸⁸ NH&MRC (Submission 12), Australian Law Reform Commission (Submission 18), IP Australia (Submission 19), Office of the Gene Technology Regulator (Submission 32), Swedish National Council of Bioethics (Submission 37),

⁸⁹ Department of Health and Ageing (Submission 62),

⁹⁰ Western Australian Government (Submission 14), South Australian Government (Submission 16), Tasmanian Government (Submission 53), New South Wales Government (Submission 54) and the Victorian Government (Submission 61)

⁹¹ The Hon Michael Such MP (SA) (Submission 10), Ms Melissa Parke MP (WA) Submission 69)

⁹² Mr Michael Partington (Submission 1), Ms Bee Winfield (Submission 6), Mr David Bath (Submission 25), Country Womens Association NSW (Submission 35), Ms Anna George (Submission 42), Ms Trish Carey (Submission 56), Mr Adam Johnston (Submission 59), Ms Alison Wylie (Submission 64), Ms Tracey Skippings (Submission 66) and Mr Paul Bourne (Submission 73).

⁹³ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 29.

licence agreement".⁹⁴ Although the Committee has no reason to doubt that, on the face of this letter it is clear that GTL was not offering to negotiate a licence on this occasion. Quite the contrary, the sole objective was to secure, for itself, a complete monopoly on all BRCA 1 and 2 gene testing in Australia for which it would earn \$15 million a year⁹⁵ until 2016 (\$120 million). This, after all, is the situation in the United States where Myriad Genetics is the exclusive provider of BRCA 1 and BRCA 2 gene testing.⁹⁶

07/07 2008 09:14 FAX 61 3 84127040 GTG MELBOURNE 002



7th July, 2008

Professor Ruth Salom,
SA Pathology,
P.O. Box 14,
Rundle Mall,
Adelaide SA 5000

Dear Professor Salom,

RE: Infringement of Exclusive Rights

I am writing to notify you that Genetic Technologies Limited (Genetic Technologies) is seeking to enforce its intellectual property rights with regard to offering diagnostic testing of the *BRCA1* and *BRCA2* genes for suspected cases of hereditary breast and ovarian cancer syndrome in Australia and New Zealand.

In the interests of avoiding costly and time consuming litigation, Genetic Technologies proposes a commercial solution whereby Genetic Technologies will perform all of SA Pathology's future *BRCA1* and *BRCA2* testing requirements as settlement of all SA Pathology's past and prospective infringement of our exclusive patent rights.

In October 2002, Genetic Technologies entered into a commercial agreement with Myriad Genetics, Inc., for an exclusive license to offer diagnostic testing of the *BRCA1* and *BRCA2* genes in Australia and New Zealand. Genetic Technologies has invested millions of dollars to both procure and to be in a position to exploit these exclusive rights. As a consequence, the dedicated and professional team at Genetic Technologies has established a world-class, rapid, high through-put, NATA / RCPA accredited molecular diagnostic laboratory.

As an organization working in the field of medical research and diagnostic testing, I am sure you would appreciate that the effective protection of intellectual property rights is fundamental to the continued investment in, and commercialisation of, medical research and technology in Australia. As a substantial investor in Australian biomedical research and technology, Genetic Technologies is greatly concerned by the ongoing infringement of its intellectual property rights. This situation is untenable and unacceptable to Genetic Technologies and our shareholders.

Genetic Technologies is the exclusive licensee from Myriad Genetics, Inc., of Australian Patents, including Patents No. 686004, 691958, 691331, and 773601 (the Patents), making us the exclusive holder of the right to offer diagnostic testing of the *BRCA1* and *BRCA2* genes in Australia. We are aware that SA Pathology is:

Genetic Technologies Limited • MFL 17 009 212 325 • 60-66 Hanover Street Fitzroy VIC 3065 Australia • Postal Address PO, Box 115 Fitzroy Victoria 3065 Australia • www.gtl.com.au
 Corporate Office • Phone +61 3 8415 1135 • Fax +61 3 9417 2987
 DNA Testing Laboratory • Phone +61 3 9415 7888 • Fax +61 3 9416 4076

⁹⁴ Ibid.

⁹⁵ Olga Galache, 'Biotech 'loses' royalties' *Herald Sun* Friday 7 August 2008 at p 57.

⁹⁶ Myriad Genetics and GTL issued a joint press release on 28 October 2002 announcing: "Myriad Genetics charges about US\$300 for limited BRCA gene test to US\$3000 for a full test on both BRCA 1 and BRCA 2 genes. Source: breastcancer.org (http://www.breastcancer.org/symptoms/testing/genetic/facility_cost.jsp)

Page Two of Two

- (a) using the methods and compositions claimed in the Patents; and
- (b) selling the results generated from using such methods and compositions.

We hereby request that SA Pathology, within 7 days of the date of this letter, provide confirmation in writing that it agrees to cease using the Patents and is willing to refer the performance of all *BRCAL* and *BRCAL2* testing to Genetic Technologies.

If SA Pathology is prepared to provide in writing the above undertaking within the specified timeframe, we confirm that:

- (a) Genetic Technologies will not seek to issue proceedings against SA Pathology;
- (b) Genetic Technologies will refrain from seeking any remedies in respect of any infringement that has occurred until the date of this letter; and
- (c) Genetic Technologies will offer reasonable transition arrangements necessary to ensure that there is no disruption to services. Specifically, under such transition arrangements, we would suggest that SA Pathology complete the testing of samples already in process and that future samples be sent to Genetic Technologies; and
- (d) Genetic Technologies will undertake to perform the *BRCAL* and *BRCAL2* testing to the same high quality and rapid turnaround time standards that it currently provides to its existing familial cancer clinic customers.

However, in the event that SA Pathology is not prepared to provide the requested undertaking in writing by Monday, the 14th of July, 2008, Genetic Technologies will then immediately proceed with legal action without further notice. Our lawyers have prepared a detailed Statement of Claim and are ready to file an Application with the Federal Court if necessary.

In summary, Genetic Technologies wishes to resolve the issues relating to its intellectual property amicably and we hope that you will constructively engage in discussions with us to resolve this matter on the basis that we propose above.

I will call you tomorrow, Tuesday July 8, 2008, to discuss this matter with you directly.

Yours sincerely,



Michael B Obanessian
Chief Executive Officer
Genetic Technologies Limited

The impact of the receipt of this letter on the Peter MacCallum Cancer Centre (PMCC) was explained in this exchange between Senator Moore and Prof Bowtell:

Senator MOORE—In terms of the process, what we have been told by the people who work from the legal perspective is that the original correspondence is often a shot across the bow — that was the term that they used. It was designed to attract your attention, which I am sure it did. The expectation was that after that it would lead to a form of negotiation and that was what they said is the standard practice in this field.

Prof. Bowtell—We tried to do that with GTG in terms of the research study. There was a subsequent tele-conference involving Myriad, GTG and us after the initial meeting that we had with them and it basically went nowhere.⁹⁷

But what was the legal basis of GTL's entitlement to receive \$120 million from the Australian healthcare system? The answer, it appears, was a negotiated settlement⁹⁸ with Myriad Genetics regarding the use of GTL's patent monopolies over 'non-coding' DNA⁹⁹ in return for which GTL received the exclusive rights for BRCA 1 and BRCA 2 testing in Australia and New Zealand.¹⁰⁰ While this alone does not cast a shadow over the propriety of that arrangement, I believe that it is relevant for this Committee to use this arrangement to draw attention to the fact that the subject matter of that settlement was the mutual rights to the use of each other's gene patents, both of which have been the subject of considerable scientific and political controversy at the time of their publication in Australia and the United States.¹⁰¹

Indeed, evidence presented to this Inquiry by Prof David Bowtell, Prof Stephen Fox and Dr Jillian Mitchell from the PMCC only serve to fuel that controversy because they advised us that these very same licensing arrangements had caused them to shelve an important piece of medical and scientific research that was to be conducted in Australia involving the BRCA 1 and BRCA 2 genes. The delay, apparently caused by some disagreement over which of these two companies had the right to give permission for the conduct of this research in Australia, was two years.¹⁰² Furthermore, now that permission has been given, the cost has tripled.¹⁰³

The following exchange between Profs Bowtell, Dr Mitchell and the Committee on this subject is illuminating.

CHAIR—Was there an explanation about why they 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.

Senator HEFFERNAN—You would not care to table that correspondence, would you?

Prof. Bowtell—A lot of that was verbal.

Dr Mitchell—The Department of Human Services holds a lot of that correspondence.

Prof. Bowtell—In fact, I think that that aggressive position was something that the people involved in GTG now regret because it really—

Senator HEFFERNAN—Was that in April this year or April last year?

Prof. Bowtell—That was at the start of 2008.

Senator BOYCE—As you quite rightly point out, it has impeded clinical work but it has not stopped it.

Prof. Bowtell—It impeded the research work substantially. It will potentially flow through to changing practice worldwide. The Canadian study was published in late 2007, I think, and that suggested that any woman with ovarian cancer should be offered this sort of testing. But it has not changed practice in the United States,

⁹⁷ Hansard, Senate Community Affairs Reference Committee, Tuesday 4 August 2009 at CA 121.

⁹⁸ Joint Myriad and GTL Press Release: 28 October 2002: announcing "the signing of a strategic alliance under which they will cross-license certain technologies related to the identification of non-coding DNA alterations and the assessment of inherited human diseases. Under the terms of the agreement, Myriad Genetics will receive a broad, non-exclusive license to Genetic Technologies' non-coding DNA analysis and mapping patents for all applications in human therapeutics and diagnostics. Genetic Technologies will become Myriad's exclusive marketing agent in Australia and New Zealand for its world-leading predictive medicine products for a range of important".

⁹⁹ GTL's non-coding DNA patents are over non-coding DNA in all genes in all multi-cellular species including humans, animals and plants and in many single-celled organisms.

¹⁰⁰ A copy of the Myriad and GTL license is available at:
<http://agreements.realdealdocs.com/Marketing-Agreement/Myriad-Genetic-Technologies-Marketing-an-871352/>

¹⁰¹ ABC TV Four Corners *Patently a Problem* [Aired: Monday 11 August 2003] (transcript available at:
http://www.abc.net.au/4corners/content/2003/20030811_patent/default.htm)

¹⁰² Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 115.

¹⁰³ *Ibid.*

Europe or Australia because any study like that needs to be replicated. There were some methodological issues with the way it was done. It was generally a very good study, but there were some methodological issues. Our study was in a position to really nail it absolutely once and for all because of the way that the study was constructed. *It was a study that could change practice worldwide and it has been set back two years, at least.* (Emphasis added)¹⁰⁴

What is perplexing, however, is why the PMCC, which simply wanted to conduct medical and scientific research involving human genes and the diagnosis of breast and ovarian cancer, was put in this invidious position? Why did these Australian scientists have to effectively seek permission from a foreign organisation in order to conduct medical research in Australia on a cancer which threatens the life of thousands of Australian women everyday?

The answer lies, it would appear, with IP Australia. It granted Myriad patent monopolies over the actual human BRCA 1 and BRCA 2 gene mutations, albeit in an isolated or purified form. Thus, any use of these biological materials is an infringement unless the PMCC, in this instance, has the proper authority to use them. And there lies another problem. The delay in the conduct of this medical and scientific research was caused by the inability of Myriad and GTL to come to an agreement over the conduct of this research and, possibly, the commercial control of its results.

Which in turn raises a further, but related, question: what is, or should be, the 'research exempt' status of the PMCC?

The Committee should appreciate, in my opinion, that research is increasingly undertaken with a commercial objective in mind, as Senator Humphries explored with Prof Bowtell.¹⁰⁵ Even these three dedicated scientists are probably required to do much of their research beneath a blanket of secrecy, so that in the event of some commercially exploitable result eventuating, they do no harm to its potential patenting through some statement made inadvertently at a scientific conference or alternatively published in a scientific paper. And this may have been a concern shared by both Myriad and GTL. Not only may they have wanted to avoid the possibility of a novelty-destroying disclosure being made by PMCC, but they may have wanted to exercise some degree of control, if not complete control, over the commercial exploitation of the results of that research. The Committee, in my opinion, must consider this scenario in view of submissions expressing the view that the long-term solution lies not in a ban on gene patents, but in a general research exemption. Indeed, this is precisely the approach that the ALRC¹⁰⁶ and IP Australia¹⁰⁷ have adopted and which is being actively pursued. The question, however, is this: how does any proposed research exemption work when a commercial partner, association or affiliation has an actual or potential legal interest in the results of that research? When and how would research conducted by the PMCC be designated 'pure' or 'commercial'?

In my opinion there is a problem with IP Australia's present research exemption proposal. According that proposal, an exemption should apply to "any act *on* a patented invention" done "solely for the purpose of ..." any one of a number of defined purposes but not if the "invention is used in, but is not the subject of, an experiment".¹⁰⁸ Apart from being very narrow because of the 'sole' purpose requirement, the exemption would not apply in clinical environments because of the express exclusion. Clearly, the assessment of a new BRCA diagnostic test means that the BRCA biological materials would need to be "used", since they are the "invention". The same problem would arise with all other gene patents.

Furthermore this exchange between Senator Moore and Prof Bowtell should be noted by the Committee:

Senator MOORE—You explained the situation you had when you were looking at the ovarian cancer research. Would that have been fixed or helped by having the research exclusion clause that the law reform paper has recommended?

Prof. Bowtell—I do not think it would have actually. It was complicated because there was a commercial relationship between GTG and Myriad. That is what they were concerned about; they were concerned about breaching the commercial relationship that Myriad had with GTG.

Senator MOORE—GTG has the licence from Myriad?

Prof. Bowtell—Yes.

Senator MOORE—Myriad has the world patent and GTG are their licensed providers.

Prof. Bowtell—Yes.¹⁰⁹

¹⁰⁴ Ibid at CA 115-116.

¹⁰⁵ Ibid at CA 126

¹⁰⁶ ALRC (Submission 18) at p 2.

¹⁰⁷ IP Australia (Submission 19) at pp 3-4.

¹⁰⁸ IP Australia, *Experimental Use Consultation Paper* at p 5 para 9.

¹⁰⁹ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 118.

For these reasons I ask the the Committee not to be persuaded to the view that a research exemption as proposed by IP Australia is a viable long-term and permanent solution to the problems caused by gene patents.

Furthermore, aside from the adverse impact on conduct of medical and scientific research, the PMCC's evidence should have alerted the Committee to the potential adverse impact on the provision of clinical services and to medical and clinical training. In their evidence Prof Fox and Dr Mitchell told us that the very economic viability of PMCC's clinical services and its capacity to provide training across the board was threatened if the PMCC was unable to conduct BRCA 1 and BRCA 2 gene testing. Prof Fox said:

BRCA testing is a huge core of our laboratory department work. If you were to take that away, there is not a lot left. Training, education and provision of services and other tests become more difficult.¹¹⁰

The ripple effect would impede PMCC in the provision of other clinical services unrelated to BRCA gene testing, as this exchange between Senator Boyce and Dr Mitchell demonstrates:

Senator BOYCE—So it threatens the viability of your organisation?

Prof. Bowtell—Not just ours, many.

Dr Mitchell—It will also then limit the ability to offer genetic testing for much more rare genes, which is certainly not cost effective from a large company point of view, because you have expertise that you then piggyback on lesser things. I should say that although we stated in our submission that we felt that the gene sequence was not the right place for the patent, we then move on one step in saying that if it is accepted that that is where it is going to be because there is too much law invested in it already that cannot be changed—it is just a shame that we cannot think to change laws if they are not actually working very well—how do we move on?

The experience that we have had has certainly been very problematic and certainly with the way that the GTG was trying to link our research activities to shut down the thing that was most threatening to them, which was the diagnostic testing in the public arena. How do we then move on and make it accessible so that it is not a monopoly position?

One of the points that we made here is coming back to that licensing. Again I do not want to say that I have any understanding of the legalities of that. But can't we sort out the licensing so there is some form of greater good within the country to make something accessible? Yes, there might be some payment made to a company that holds the patent, but how can we do that in a way that then makes it accessible?

What we cannot have is this position where someone holds that ability to do a test.¹¹¹

And Prof Fox confirms it would seem that GTL would not have had the capacity to provide the same level of service as the PMCC and Australia's other public laboratories provided:

Prof. Fox—What is more scary from a clinical perspective is that had all the laboratories in Australia ceased and desisted, GTG would not have been able to do the work. They are just not set up to do that volume of tests.¹¹²

This is a critically important issue. Mrs Lynette Swinburne, and her colleagues Ms Michelle Marven, Ms Heather Drum and Mrs Kristi Smith are part of the Breast Cancer Network Australia (BCNA), Australia's peak body representing more than 37,000 Australian women and their families affected by breast cancer. They explained to the Committee the importance to their members of having (a) no discrimination on the basis of genetic information, (b) the need for quality genetic counselling services being an integral component of genetic testing services, (c) the availability of genetic tests results within a reasonable time, and (d) the importance of women from high-risk groups to have ready access to quality surveillance methods, affordable genetic counselling and timely testing services.¹¹³

Accordingly, had GTL enforced its patent monopoly rights, on the basis of what Prof Fox has advised, in my opinion the Committee must reasonably conclude that the requirements of the BCNA and its members would not have been satisfied.

Dr Mitchell's evidence highlighted a further adverse impact, namely, the high cost of the BRCA gene tests. She explained:

Despite the fact that the BRCA testing has been available from Myriad since the mid-1990s, the price has not gone down, it has gone up. That is despite the fact that the cost of reagents has gone down and the

¹¹⁰ Ibid at CA 116.

¹¹¹ Ibid at CA 116-117.

¹¹² Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 121.

¹¹³ Hansard, Senate Community Affairs References Committee, Monday 3 August 2009 at CA 82.

fact that we know that when we do those tests in-house they are a fraction of the cost that they were 10 or 15 years ago.¹¹⁴

And price is not merely a matter which impacts on diagnosis. In the future it will impact on treatment, as Dr Mitchell advised:

Senator HEFFERNAN—It is what you call the river of gold.

Dr Mitchell—The monopoly position certainly seems to be causing a problem. I basically want access to this information for our patients. It has to be for the greater good and the financial good as well for the country to have treatments targeted to the people who are going to most benefit from them. We know that treatments are expensive. *They are getting more expensive as more time and effort is put into developing them* (emphasis added).¹¹⁵

While on the subject of treatment, Prof Bruce Mann, President of the Clinical Oncological Society, predicted that the “genetics of either the patient or the cancer or both”¹¹⁶ will soon be critical to determining a patient’s specific treatment and Prof Oliver reinforced that prediction. He said that in the “next couple of decades the genetic sequence of ... a cancer will be the most important aspect of it, now that we can measure multiple genes, so the pattern of your cancer’s genes will tell you what type of cancer you have, what targeted treatments you should have and what the prognosis of the aggressiveness of the cancer is.”¹¹⁷

Finally, I draw to the Committee’s attention the same flawed “scientific thought”, as observed by Prof Blumberg in the context of the HCV patent monopoly, “that knowledge of the nucleotide sequence of the virus genome, let alone part of it, tells one all that needs to be known about the functions of the proteins produced by the virus and hence all that needs to be known about the virus”, has been applied in this case. The flaw was exposed by Prof Jenny Leary in her testimony to the Committee:

I would like to give you a very real example of my own experience in researching the BRCA1 and BRCA2 genes that led to a very definite clinical change in testing in this country. We would not have been able to do that if the patents had actually been enforced. We studied a mechanism of gene inactivation that could not be looked at using the standard methodologies that were being used by most of us at the time and also by the sole provider in America offering the tests for BRCA1 and BRCA2. So we took the stored DNA from the families we have seen over many, many years, referred to by Professor Kirk, that we have held and we were able to provide some robust evidence that the testing for this different type of mutation that we had not known about previously was warranted in the Australian context. That has immediately been translated into clinical practice in Australia, even before it was introduced into America. The sole provider in America did not introduce that testing for several years after we had proven that it was a worthwhile test to be undertaken in clinical practice here.¹¹⁸

Mrs Drum’s compelling story dramatically demonstrated the impact of this flawed logic. Indeed, as Mrs Drum speculated, her family’s “mutation could be a non-discovered component of BRCA 1 or 2”.¹¹⁹ This led Mrs Drum to pose this question: “if someone owns a patent to one gene and someone owns a patent to the other gene and it happens that those two genes are the ones that influence our family, will they ever talk?”¹²⁰

That is a very good question.

Summary

There is clearly a need for scientists to learn more about the genetic landscape of the BRCA 1 and BRCA 2 gene mutations and the genetic links to the cause of breast and ovarian cancer. No matter how thorough Myriad’s scientists thought they had been in 1994 when they made the initial discovery of the BRCA 1 gene mutations, they did not identify all of the relevant genetic mutations.

This evidence documents, but for the decision of GTL not to enforce the Myriad patents in Australia, the irreparable damage that could have been inflicted upon the Australian economy and its people. In Part 2 we explain why the *Patents Act, 1990* needs to be amended to overrule two Full Federal Court of Australia decisions, the effect of which prevents judges from con-

¹¹⁴ Ibid at CA 117.

¹¹⁵ Ibid.

¹¹⁶ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 7.

¹¹⁷ Ibid at CA 8.

¹¹⁸ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 52.

¹¹⁹ Hansard, Senate Community Affairs References Committee, Monday 3 August 2009 at CA 82.

¹²⁰ Ibid.

sidering issues of an ethical or moral dimension in the context of patent law. This evidence shows that there are compelling reasons for the Committee to adopt my proposed recommendation in the final report.

In my respectful submission it is necessary for the *Patents Act, 1990* to be amended so that injunctions cannot be granted if the effect would be to restrict or withhold an essential service or product. Indeed, we believe that the Crown Use powers currently contained in the *Patents Act, 1990* should be significantly strengthened and that a set of coherent national policies are developed to facilitate their more frequent employment by Commonwealth and State government agencies.

The two attempts by GTL to enforce its Australian patent rights failed, but even so, as we have heard from PMCC, important medical and scientific research was significantly and unnecessarily delayed as a result of the Myriad patents. Moreover, even though the PMCC's research is now proceeding, the Committee should note that those costs have tripled.

This evidence amply demonstrates that locking up naturally occurring phenomena (regardless of their physical state or context) in patent monopolies is undesirable for many reasons, the foremost being that medical and scientific progress will be hampered in the process. This is what Australia's leading scientists have explained to the Committee in the context of the patents over BRCA 1 and BRCA 2 human genes. It would be irresponsible, in my opinion, for the Committee to ignore the collective wisdom, power and force contained in that evidence.

Australian Patent Monopolies 2001265698 and 2004200978

2001265698-Mutations associated with epilepsy

Scope of the Patent Monopoly

Australian Patent Monopoly 2001265698 was granted on 3 September 2006, but its legal effect commenced on 20 June 2001 and will end on 20 June 2021.

The scope of the Australian patent monopoly includes:

1. An isolated mammalian DNA molecule encoding a mutant γ -aminobutyric acid (GABA) receptor subunit, wherein a mutation event selected from the group consisting of point mutations, deletions, insertions and rearrangements has occurred and said mutation event disrupts the functioning of an assembled GABA receptor, or an otherwise functional fragment or homologue thereof (claim 1);
2. An isolated mammalian polypeptide, said polypeptide being a mutant γ -aminobutyric acid (GABA) receptor subunit, wherein a mutation event selected from the group consisting of substitutions, deletions, truncations, insertions and rearrangements has occurred and said mutation event disrupts the functioning of an assembled GABA receptor, or an otherwise functional fragment or homologue thereof (claim 38);

2004200978-A diagnostic method for epilepsy

Scope of the Patent Monopoly

Australian Patent Monopoly 2004200978 was granted on 4 June 2006, but its legal effect commenced on 4 October 2004 and will end on 4 October 2024.

The scope of the Australian patent monopoly includes:

1. An isolated nucleic acid molecule encoding an altered SCN1A subunit of a mammalian voltage-gated sodium channel, wherein the alteration gives rise to an SMEI phenotype and has the sequence set forth in any one of SEQ ID NOS: 1-25 (claim 27);
2. An isolated polypeptide, said polypeptide being an altered SCN1A subunit of a mammalian voltage-gated sodium channel, wherein the polypeptide has the amino acid sequence set forth in any one of SEQ ID NOS: 26-48 (claim 35).

Summary of the Patent Monopolies

As a result Bionomics Ltd, an Australian corporation based in Adelaide, South Australia, is the owner of these Australian patent monopolies which effectively give it control over the human genetic material which encodes:

- (a) a mutant γ -aminobutyric acid (GABA) receptor subunit and the protein itself; and
- (b) an altered SCN1A subunit of a mammalian voltage-gated sodium channel protein and the protein itself.

The Impact of the Patent Monopolies

The most immediate and significant impact of this patent monopoly has been on the cost of healthcare in Australia. Also adversely impacted have been Australian doctors and hospitals which treat children with epilepsy.

Unfortunately, most of those who were in a position to give this Committee relevant information about the impact of these patent monopolies on the Australian healthcare system failed to make themselves available. Only one, Dr Deepak Gill, a paediatric neurologist at the Westmead Childrens' Hospital, was prepared to provide a written statement¹²¹. However, despite a specific invitation to attend a public hearing by this Committee he was unable to accept. He did not explain why not.

■ GENETIC TESTING

Sick babies denied treatment in DNA row

Julie Robotham
Medical Editor

BABIES with a severe form of epilepsy risk having their diagnosis delayed and their treatment compromised because of a company's patent on a key gene.

It is the first evidence that private intellectual property rights over human DNA are adversely affecting medical care.

Deepak Gill, head of neurology at the Children's Hospital at Westmead, said he would test at least 50 per cent more infants for the SCN1A gene – which would diagnose the disabling Dravet syndrome – if the hospital could conduct the test in-house.

But rights to the gene are controlled by the Melbourne-based

Genetic Technologies, which has already threatened to stop public hospitals testing for breast cancer gene mutations, and the hospital will not risk a similar problem.

Specialists are sending blood samples to Scotland, and only babies whose seizure patterns closely resemble Dravet syndrome are tested. This means children with slightly different symptoms may be treated with the wrong medicines for months, potentially retarding their development.

"It's frustrating that we can't get the test done readily," Dr Gill said. "If we could include it as part of the work-up, we could identify them early."

At present the diagnosis is often

delayed until the child is 12 to 18 months old. This is after the optimum time for treatment with strong drugs that are unsuitable for most babies with epilepsy but are used for infants with Dravets to control severe seizures that can damage the brain. Standard childhood epilepsy medications are ineffective with Dravets and may worsen it, Dr Gill said.

The situation comes amid growing concern among doctors and medical researchers over the ethics of granting private ownership to human DNA. A Senate inquiry announced this month will

Continued Page 4

Sick babies denied treatment in DNA row

From Page 1

investigate the effects of gene patenting on health-care.

SCN1A is the most important epilepsy gene discovered, Dr Gill said, and is abnormal in about 70 per cent of children with Dravet syndrome, which affects about one in 30,000 babies – almost 10 per cent of infant epilepsy cases.

About one in 20 children have a seizure when they develop a fever, though only a minority had epilepsy, Dr Gill said.

The Scottish laboratory conducts SCN1A testing for all of Britain. Dr Gill said the price of the test – about \$1800 – was similar to that offered by Genetic Technologies, but he had more confidence in the expertise of the Scottish laboratory, run by a paediatric neurologist.

Dr Gill said patenting the gene

"may have helped initially to define and produce the test, but in 2008 it's not helping kids right now to access the test".

John Christodoulou, director of the Western Sydney Genetics Program, based at the same hospital, said his laboratory could not risk SCN1A testing in case Genetic Technologies – which licenses the gene patent from an Adelaide biotechnology firm, Bionomics – later barred him from testing or imposed a prohibitive royalty.

Genetic Technologies caused an uproar last month when it threatened to sue hospitals that test for breast cancer genes. It is reviewing that position.

Mervyn Jacobson, a founding director of the company, said, "The question is, are public hospitals allowed to break the law

and breach patents granted by the Australian Government?"

While in principle the company would insist on its rights, in practice it would be prepared to negotiate, he said. "We don't need to necessarily enforce them against publicly funded institutions."

He was unaware of an earlier approach by Dr Christodoulou to ask how the company would view the establishment of public SCN1A testing, made to a previous management team.

Luigi Palombi, an intellectual law expert from the Australian National University, said legislation needed to be revised to prevent patenting of human genes.

"Why should these people have a patent over DNA, and over treatment?"

While I fully understand the severe time pressures which medical practitioners, especially specialists, are under it is regrettable that Dr Gill, who must have known about this Inquiry for many months, was unable to assist us further in our Inquiry. More to the point, given the subject matter of this Inquiry and the nature of the complaints Dr Gill reportedly made to Ms Julie Robotham, the medical editor and a senior journalist with the Sydney Morning Herald (published on 20 November 2008 entitled *Sick babies denied treatment in DNA row*) we find it is difficult to understand why neither he, his colleagues at Westmead nor the management at Westmead were more forthcoming.

The article has been reproduced in full on this page so that the seriousness of the allegations which it contains can be readily appreciated. Dr Gill, however, stated to us that he was "not aware of any evidence that the licensing of one laboratory to carry out the tests has had a significant negative impact on research in the field of SCN1A testing."¹²² Yet, the article quotes Dr Gill as saying that "it's frustrating that we can't get

¹²¹ Letter from Dr Deepak Gill (Submission 68).

¹²² Ibid at p 2 (emphasis added).

the test done readily” and “if we could include it as part of the work-up, we could identify them early”. The article also explains that the exclusive licensee, GTL, the same company which has the exclusive license for the BRCA 1 and BRCA 2 patent monopolies, charges about \$1,800 per test but the reason the testing was performed by a Scottish laboratory was not due to the cost, but due to the laboratory’s superior expertise. The article also makes the point that SCN1A gene testing, were it not for the patent monopoly, could be conducted “in-house” at Westmead. The obvious question is: how much healthcare cost would it save if Westmead was able to do so?

How does anyone reconcile Dr Gill’s statement with these allegations without his voluntary cooperation and that of his colleagues and his employer? How could the Committee get to the bottom of this story without the powers of investigation and interrogation? Clearly, the Committee could not, but this should not be cause to ignore the allegations made by Dr Gill and repeated in Ms Robotham’s article.

I appreciate that Prof Warwick Anderson, CEO of the National Health and Medical Research Council¹²³ (NH&MRC) wrote to the Committee about the SCN1A gene but his response failed to address the specific concerns which were brought to this Committee’s attention by Dr Palombi in his submission and which were addressed in Ms Robotham’s article.¹²⁴ Instead, Prof Anderson simply referred the Committee back to the NH&MRC’s submission to the ALRC’s inquiry made in 2003 stating:

While NHMRC is not aware of any specific examples where patenting practices have had a negative impact on research in Australia, NHMRC supports the proposal from the Australian Government’s Advisory Council on Intellectual Property that research be exempt from provisions imposed by gene patents in Australia.

This, in light of the evidence received during the course of the Inquiry and documented in this submission, is a remarkable admission. The evidence presented to this Committee shows that gene patents have seriously and detrimentally impacted the provision of clinical and medical services in this country for more than 20 years, and while this kind of investigation may have been outside of the NH&MRC’s purview, as Australia’s peak medical and scientific research funding body it would be reasonable to expect that having *some* knowledge of the impact of gene patents on medical and scientific research would not have been. How is it possible for the NH&MRC not to have been aware of the need for research to overcome the problems associated with the poor performance of the Chiron licensed HCV antibody diagnostic tests? How is it possible for the NH&MRC not to have been aware of the situation faced by the PMCC over its BRCA 1 and BRCA 2 research? How is it possible for the NH&MRC not to have been aware of the research demands of scientists at Westmead over the SCN1A gene? There is clearly a problem here. Either the NH&MRC has not sought this information out or it has not been brought to its attention. Whichever way, I ask this Committee to conclude, as being unreliable, the NH&MRC’s statement that “patenting practices have [not] had a negative impact on research in Australia”.

Another aspect worthy of note comes from the evidence presented by Dr Palombi in which he documents the more salient parts of the history of the research which led to the patent monopolies.¹²⁵ His evidence shows that the Australian public purse has not only supplied critical research funds to the responsible universities and the scientific teams which conducted the research, but it also has provided funds to the company which holds the patent monopolies to undertake the development of the very diagnostic tests which are also the subject of the patent monopolies. It is now the case, that the Australian taxpayers, having made a substantial contribution to the funding of this important research, are being deprived, by decisions made by the patent holder and GTL, the exclusive licensee, of the benefits of this research, namely, reasonable access to an important diagnostic test.

The ALRC, IP Australia, Crown Use, Compulsory Licensing and Research Exemptions

The ALRC’s *Genes and Ingenuity* Report

The Committee has been invited by a number of submissions to follow the path set out in the ALRC’s *Genes and Ingenuity* Report. However, I ask the Committee to conclude that this is no longer appropriate in the Australian context. Apart from the evidence presented during this Inquiry which should have convinced the Committee of the seriousness of the problems created by gene patents, the evidence also shows that even had the ALRC’s recommendations been implemented in full, the threat posed by GTL in 2008 would not have been adequately met. **Thus a new path must be forged.**

IP Australia

The Committee has been advised that the problems caused by gene patents is not due to the Australian patent system or its administration. IP Australia believes that “the current system appears to be functioning effectively in achieving its concurrent objectives of encouraging innovation, promoting diffusion of information, and providing access to and transfer of technologies”. The urge the Committee not to agree. Indeed, in light of the evidence presented to this Inquiry, the Committee

¹²³ Letter from the NH&MRC (Submission 12a).

¹²⁴ Dr Luigi Palombi (Submission 4) Part 2 at pp 44-51.

¹²⁵ Ibid at pp 47-48.

should come to the view that IP Australia is both ill equipped and incapable of properly regulating intellectual property rights in this country. **Thus a new regulatory system for managing intellectual property with an independent and multidisciplinary team at the helm must be urgently devised and installed.**

Crown Use

The Committee has been advised that Crown Use provisions are an adequate safeguard to meet the needs of the Australian economy and the Australian people, yet no evidence was presented to this Inquiry which demonstrated the exercise of the current powers when appropriate. **Thus a set of coherent and national policies must be devised and implemented that will facilitate the exercise of those powers.**

Compulsory Licensing

The Committee has been advised that Crown Use provisions is an adequate safeguard to meet the needs of the Australian economy and the Australian people, yet the only evidence of the use of those powers in the 107-year history of the Australian patent system was that provided by IP Australian in response to a question on notice by Senator Boyce. IP Australia advised us that there have only been three applications for a compulsory license and none succeeded. The Committee was also advised by Dr Charles Lawson in his submission¹²⁶ that “in its present form the compulsory licensing provisions ... are effectively a barrier to the working of inventions in Australia”. I urge the Committee to agree. **Thus a new approach to compulsory licensing must be found and implemented.**

Research Exemption

The Committee has been advised that the insertion of an express research exemption will significantly address the concerns of those who oppose gene patents because they will protect medical and scientific researchers from the threat of patent infringement. I urge this Committee, for the reasons already explained, to disagree. **An express research exemption may be useful if it has broad application, but it will not be a substitute for the proper maintenance of the patent system by ensuring that patent monopolies are only granted for inventions of a very high standard.**

Part 1 Recommendations

Therefore I ask the Committee to recommend to the Australian government that it do the following:

- 1.1 Amend the *Patents Act, 1990* so that a condition to the grant of a patent monopoly be the public disclosure of information sufficient to enable, without undue experimentation:
 - (a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of grant, and,
 - (b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.
- 1.2 Amend the *Patents Act, 1990* so that a condition of the renewal of the patent term be the public disclosure of information sufficient to enable, without undue experimentation:
 - (a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of renewal, and,
 - (b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.
- 1.3 Devise and implement a set of coherent and national policies to facilitate the exercise of Crown Use powers by Commonwealth and State agencies;
- 1.4 Devise and implement a set of coherent and national policies to facilitate compulsory licensing so that it will encourage the working of the invention in Australia;
- 1.5 Devise and implement an administrative licensing system to facilitate and regulate the conduct of experiments which will be exempt from patent infringement;
- 1.6 Amend the *Patents Act, 1990* so that an injunction cannot be granted if the effect is to restrict access to an essential service or product.

¹²⁶ Dr Charles Lawson (Submission 5).

Part 2: The Anatomy of a Gene Patent

The Structure of Patent Monopolies

A gene patent, like all patents, is comprised of three components:

1. The **biographical**. This provides information such as the title of the patent monopoly; the date of publication; the date of the filing of the complete specification; the name of the inventors and the name of the patent applicant.
2. The **specification**. This contains information about the 'invention' and includes the state of knowledge as it was before the invention; the problems which were existing at that time; a detailed description of the 'invention' and how it was conceived and applied in a practical and useful way by the inventor; the problems existing before the invention was made that the 'invention' overcomes; the practical uses to which the invention can be put; details of experiments leading to the 'invention' or the manner of its construction. If there is specific terminology, this is also defined in the specification.
3. The **claims**. These define, in the patentees words, the legal boundary of the patent monopoly. There must be at least one claim but generally there are more than one. The first claim, however, is usually the broadest. The remaining claims can be dependent on or independent of the first claim. The claims are very important because what is not claimed is disclaimed. And while the claims can be narrower than 'invention' disclosed in the specification, they are not permitted to be broader.

Australian Patent Monopoly 686004

The Biographical

In Figure 1 (on the next page) is the biographical data provided by AusPat, IP Australia's searchable patent database. The title is: "In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene". It confirms that the 20 year patent monopoly commenced on 11 August 1995 and expires on 11 August 2015 and provides the identity of the inventors and the patent holders, the principal being Myriad Genetics, Inc (Myriad), a US corporation based in Salt Lake City, Utah.

Application Details

1995033212 : In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene

Bibliographic data

Application details

Australian application number	33212/95	Patent application type	Standard	Serial number	686004
Application status	SEALED	Paid to date	2008-08-11	First IPC Mark	C12N 15/09 (2006.01)
Currently under opposition	No	Proceeding type(s)			
Invention title	In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene				
Inventor(s)	Shattuck-Eidens, Donna M ; Simard, Jacques ; Emi, Mitsuru ; Nakamura, Yusuke ; Durocher, Francine				
Agent name	Shelston IP	Address for legal service	Level 21 60 Margaret Street SYDNEY NSW 2000		
Filing date	1995-08-11	Australian OPI date	1996-03-07	OPI published in journal	1996-04-26
Effective date of patent	1995-08-11	Expiry date	2015-08-11		
Additional/Divisional application number		Additional/Divisional relationship			

Applicant details

Applicant	Myriad Genetics, Inc.	Applicant address	390 Wakara Way Salt Lake City UT 84108 United States Of America
Applicant	Centre De Recherche Du Chul	Applicant address	2705 Laurier Boulevard Sainte-Foy Quebec G1V 4G2 Canada
Applicant	Cancer Institute	Applicant address	1-31-1 Kami-Ikebukuro Toshimo-ku Tokyo 170 Japan
Old name(s)			

Figure 1: Biographical Data: Source IP Australia, AusPat, Access date: 4 August 2008.

The Specification

Figure 2 is the first page of the patent specification. The specification consists of 184 pages, which includes 66 pages of nucleic acid and amino acid sequences relating to human gene BRCA 1.

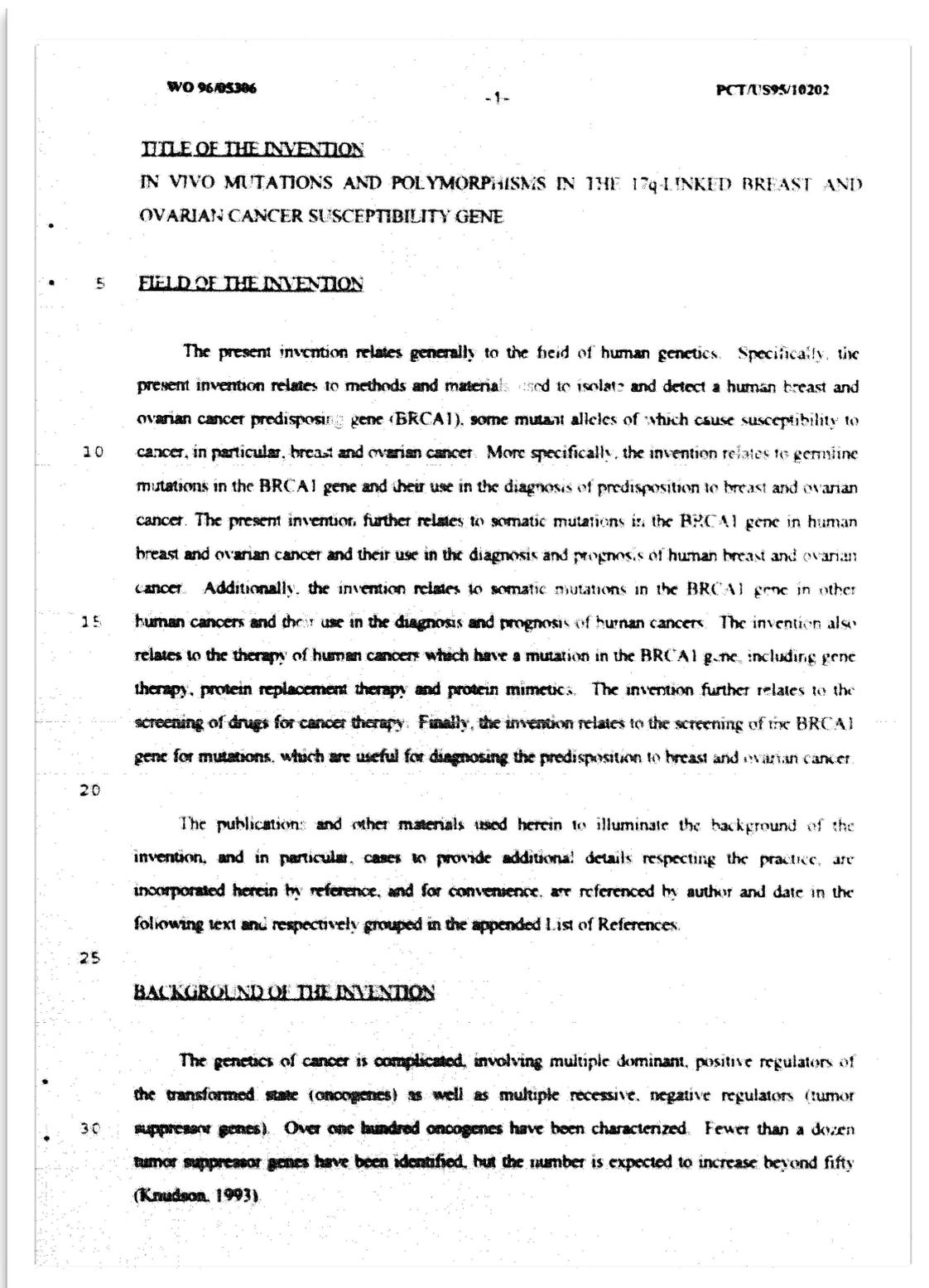


Figure 2: Page 1 of the Specification in Patent Monopoly 686004

-120-

CTG AAA CTT CTC AAC CAG AAG AAA GGG CCT TCA CAG TGT CCT TTA TGT	311
Leu Lys Leu Leu Asn Gln Lys Lys Gly Pro Ser Gln Cys Pro Leu Cys	
50 55 60	
AAG AAT GAT ATA ACC AAA AGG AGC CTA CAA GAA AGT ACG AGA TTT AGT	359
Lys Asn Asp Ile Thr Lys Arg Ser Leu Gln Glu Ser Thr Arg Phe Ser	
65 70 75 80	
CAA CTT GTT GAA GAG CTA TTG AAA ATC ATT TGT GCT TTT CAG CTT GAC	407
Gln Leu Val Glu Glu Leu Leu Lys Ile Ile Cys Ala Phe Gln Leu Asp	
85 90 95	
ACA GGT TTG GAG TAT GCA AAC AGC TAT AAT TTT GCA AAA AAG GAA AAT	455
Thr Gly Leu Glu Tyr Ala Asn Ser Tyr Asn Phe Ala Lys Lys Glu Asn	
100 105 110	
AAC TCT CCT GAA CAT CTA AAA GAT GAA GTT TCT ATC ATC CAA AGT ATG	503
Asn Ser Pro Glu His Leu Lys Asp Glu Val Ser Ile Ile Gln Ser Met	
115 120 125	
GGC TAC AGA AAC CGT GCC AAA AGA CTT CTA CAG AGT GAA CCC GAA AAT	551
Gly Tyr Arg Asn Arg Ala Lys Arg Leu Leu Gln Ser Glu Pro Glu Asn	
130 135 140	
CCT TCC TTG CAG GAA ACC AGT CTC AGT GTC CAA CTC TCT AAC CTT GGA	599
Pro Ser Leu Gln Glu Thr Ser Leu Ser Val Gln Leu Ser Asn Leu Gly	
145 150 155 160	
ACT GTG AGA ACT CTG AGG ACA AAG CAG CCG ATA CAA CCT CAA AAG ACG	647
Thr Val Arg Thr Leu Arg Thr Lys Gln Arg Ile Gln Pro Gln Lys Thr	
165 170 175	
TCT GTC TAC ATT GAA TTG GGA TCT GAT TCT TCT GAA GAT ACC GTT AAT	695
Ser Val Tyr Ile Glu Leu Gly Ser Asp Ser Ser Glu Asp Thr Val Asn	
180 185 190	
AAG GCA ACT TAT TCC AGT GTG GGA GAT CAA GAA TTG TTA CAA ATC ACC	743
Lys Ala Thr Tyr Cys Ser Val Gly Asp Gln Glu Leu Leu Gln Ile Thr	
195 200 205	
CCT CAA GGA ACC AGG GAT GAA ATC AGT TTG GAT TCT GCA AAA AAG GCT	751
Pro Gln Gly Thr Arg Asp Glu Ile Ser Leu Asp Ser Ala Lys Lys Ala	
210 215 220	
GCT TGT GAA TTT TCT GAG ACC GAT GTA ACA AAT ACT GAA CAT CAT CAA	839
Ala Cys Glu Phe Ser Glu Thr Asp Val Thr Asn Thr Glu His His Gln	
225 230 235 240	
CCC AGT AAT AAT GAT TTG AAC ACC ACT GAG AAG CGT GCA GCT GAG AGG	887
Pro Ser Asn Asn Asp Leu Asn Thr Thr Glu Lys Arg Ala Ala Glu Arg	
245 250 255	
CAT CCA GAA AAG TAT CAG GGT AGT TCT GTT TCA AAC TTG CAT GTG GAG	935
His Pro Glu Lys Tyr Gln Gly Ser Ser Val Ser Asn Leu His Val Glu	
260 265 270	

Figure 3 contains a part of the nucleic acid sequence and the amino acid sequence of SEQ ID NO 1 defined as "[t]he coding sequence for a BRCA 1 polypeptide".

None of the sequence data were conceived or modified by a human. It is, what US President Clinton and British Prime Minister Blair referred to as "raw fundamental data on the human genome"¹²⁷.

¹²⁷ Joint Statement of President Clinton and Prime Minister Blair, Office of the Press Secretary, 14 March 2000 (<http://clinton4.nara.gov/WH/EOP/OSTP/html/00314.html>)

The Claims

There are 30 claims in this patent. Figure 5, on the next page, contains the first 7 claims. The remaining claims define various **methods** such as: (a) methods of “producing a mutant or polymorphic BRCA 1 polypeptide” (claims 8 and 9); (b) methods for “diagnosing a predisposition for breast or ovarian cancer in a human subject” (claims 17, 19-30) and (c) methods for “diagnosing a breast and ovarian lesion of a human subject for neoplasia associated with the BRCA 1 gene locus” (claim 18); **purified BRCA 1 polypeptide** (claims 10-14) and the **use of a BRCA 1 polypeptide** in antibody production (claims 15 and 16).

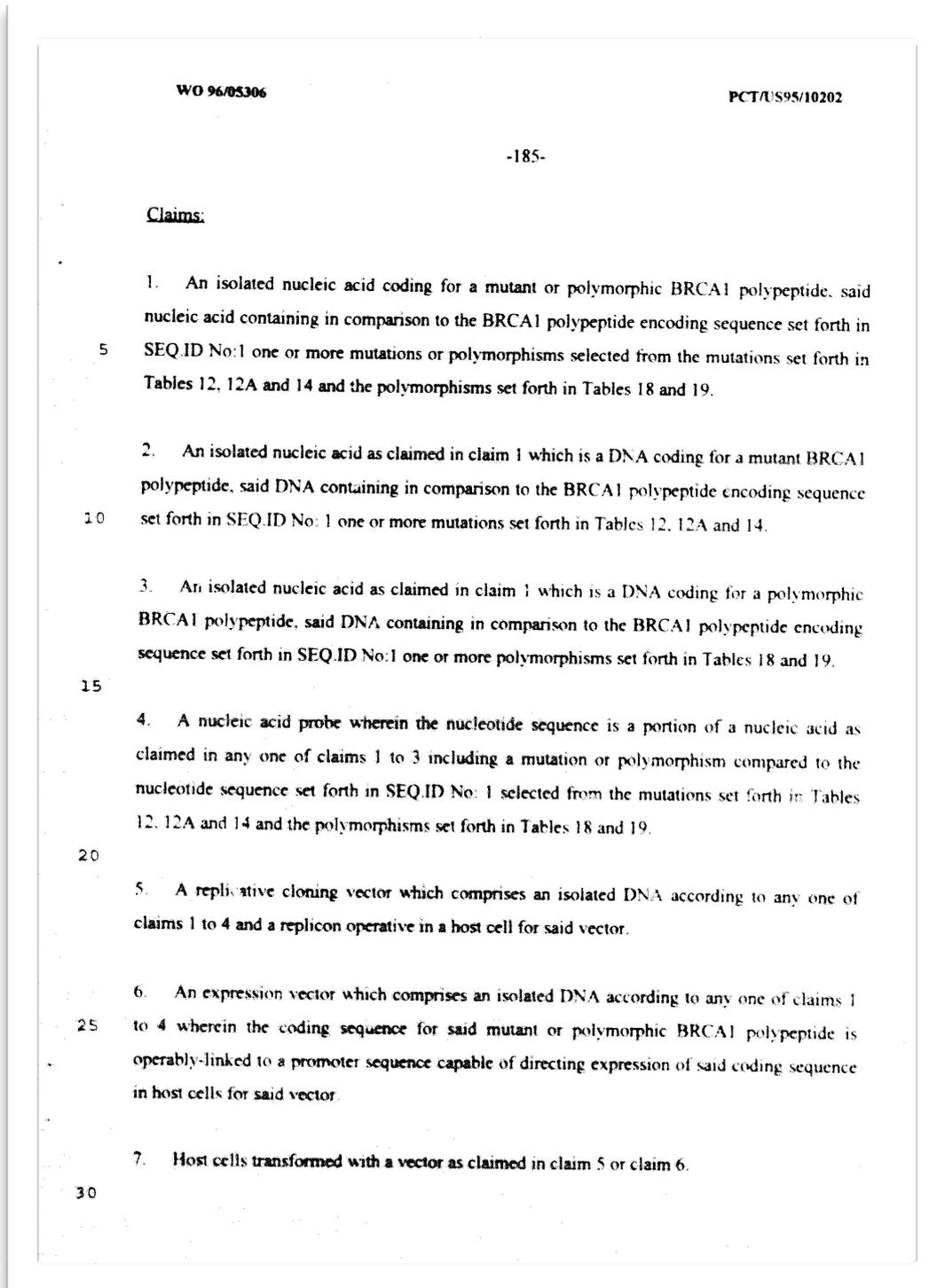


Figure 5: Claims 1 to 7

The Legal Issues

Nucleic Acid Product Claims

Claims 1-3 are *per se* product claims to isolated biological materials, namely, the human gene BRCA 1. Regardless of how they are obtained or made, once the nucleic acids that correspond with the sequence in SEQ ID NO 1 are 'isolated' it is an infringement to *do* anything with them.¹²⁸ So it does not matter how they are used. Literally any use, indeed, even possession of these isolated biological materials for use, will amount to infringement. The only qualification is that they be 'isolated'. Beyond their *being outside of the human body*, these biological materials are identical or substantially identical to their corresponding equivalents in the human body. The inventors named in the patent monopoly document did not conceive, design or modify any of the DNA which defines these isolated biological materials.

Amino Acid Product Claims

Claims 10-13 are *per se* product claims to purified proteins which are coded for by the isolated nucleic acids of claims 1-3. These are related to the nucleic acids that correspond to the sequence in SEQ ID NO 1.

Genetic Blueprints

A good way to think of the relationship between these two kinds of biological materials is to think of claims 1 to 3 as the engineering blueprints and claims 10-13 as the physical embodiment of the blueprints. There is a relationship between these two biological materials although they are different to each other. Both are natural, but one is 'isolated' while the other is 'purified'. Otherwise they are identical or substantially identical to how they exist inside the human body.

Invention or Discovery?

A number of submissions have referred variously to "gene technology", "gene technology patents", "gene-based technologies", "genetic technologies" and "biotechnological inventions"¹²⁹, which is all very well, but these terms are only confusing in this context.

The Committee has been advised that the BRCA 1 human gene is natural.¹³⁰ It exists in all humans.¹³¹ That some people have mutations in this gene that predispose them to breast and ovarian cancer is also natural.¹³² Accordingly, it must be the case that neither the BRCA 1 human gene nor the mutations to this gene nor the genetic sequence of the gene or the amino acid sequence of the proteins that are coded for by the gene (including any mutations) can be patentable. I ask the Committee to accept that a naturally occurring phenomenon cannot be patented in Australia as the law stands at present.¹³³ As Justice Heerey said in *Rescare*: "[taxol] is a naturally-occurring compound and thus is itself unpatentable"¹³⁴.

The Committee should understand that the isolation of the BRCA 1 human gene does not change what it is or the genetic

¹²⁸ s.13 Patents Act, 1990. The word 'exploit' is defined in Schedule 1 of the Act. According to that definition infringement of a product claim occurs when you "make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things".

¹²⁹ ALRC (Submission 18); Medicines Australia (Submission 21); Biotechnology Industry Organization (Submission 29); Pfizer Australia (Submission 51); Intellectual Property Committee of the Business Law Section of the Law Council of Australia (Submission 57);

¹³⁰ Peter MacCallum Cancer Centre (Submission 28); Royal College of Pathologists of Australasia (Submission 49); Ass Prof Amor, Hansard, Senate Community Affairs References Committee, Monday 3 August 2009, CA 51; Dr Jillian Mitchell, Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009, CA 105; Prof Jenny Leary, Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009, CA 51; Ass Prof Judy Kirk, Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009, CA 50; Prof Sir John Sulston cited by Dr Luigi Palombi, Hansard, Senate Community Affairs References Committee, Monday 14 September 2009, CA 10; Prof Ian Frazer cited by Dr Luigi Palombi, Hansard, Senate Community Affairs References Committee, Monday 14 September 2009, CA 50; Dr Graeme Suthers cited by Dr Luigi Palombi, Hansard, Senate Community Affairs References Committee, Monday 14 September 2009, CA 10.

¹³¹ Ass Prof Judy Kirk, Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009, CA 50; Dr Graeme Suthers cited by Dr Luigi Palombi, Hansard, Senate Community Affairs References Committee, Monday 14 September 2009, CA 10.

¹³² *Ibid.*

¹³³ Dr Luigi Palombi (Submission 4); IP Australia (Submission 19); Institute of Patent and Trade Mark Attorneys of Australia (Submission 31); Johnson & Johnson (Submission 44)

¹³⁴ *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (1998) 41 IPR 467 at 477.

information it contains. It merely changes its physical state by removing it from the human body.¹³⁵ And while, in my opinion, the Committee should appreciate that much time and money may have been expended in the search for the BRCA 1 gene (and some of the mutations linked to breast and ovarian cancer), the end result of that search was more knowledge about the human body and a cause of human illness. Information of this kind is not an invention.

Indeed, as the BRCA 1 gene has always been part of humanity neither it nor the proteins that it codes for are 'new'. The UK House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] 1 All ER 667 made that point when considering the validity of a European patent granted over the human protein erythropoietin. Lord Hoffmann held:

Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and ground-breaking process for making EPO and its analogues, they were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new.¹³⁶

This was the point made by the Australian Assistant Commissioner of Patents *In the Matter of a Patent Application by Ranks Hovis McDougall Ltd* [1976] AOJP 3915 (*Ranks Hovis McDougall*) decided almost 20 years earlier when he cited Lord Willburforce¹³⁷ in support of his decision to reject a patent application for a naturally occurring microorganism which had been "isolated from a soil sample".¹³⁸

Even in the United States, Justices Breyer, Souter and Stevens of the US Supreme Court have held that it is a principle of US patent law which "finds its roots in both English and American law" that excludes from patent protection "laws of nature, natural phenomena and abstract ideas". The rationale for the principle, they explain, "does not lie in any claim that 'laws of nature' are obvious, or that their discovery is easy, or that they are not useful ... [T]o the contrary research into such matters may be costly and time consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race ... [but] the reason for the exclusion is that sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts'".¹³⁹

In other words, patent law draws a line. Either there is an 'invention' or there is not. And a human gene, even one isolated from the human body or a protein synthesised in an artificial environment using a novel process, is not an 'invention'.

The Committee has received submissions and heard evidence from the medical and scientific community and also from IP Australia, government, industry, research institutions and representative organisations, but I urge the Committee to accept the evidence of the scientific and medical community on this issue, which is that DNA derived from a natural source is not something that anyone invented. Likewise, a purified protein derived from a natural source, even though synthesised artificially is not something that anyone invented. Thus an isolated or purified biological material which is identical or substantially identical to what exists in nature is not an invention. The characterisation of a naturally occurring biological material is a mere discovery.

In support of this conclusion I direct the Committee's attention to the following evidence, which was not contradicted.

Dr Jillian Mitchell testified:

The DNA is part of what we are. The basis of our submission is that we cannot understand how we can patent something that is part of us. Just discovering the genetic sequence is not innovative; it is just using technology as we increase our understanding about what that sequence is. What is innovative and what is important is how you then use that information.¹⁴⁰

Dr Ronan testified:

[Genes] are absolutely fundamental components of the human body; they simply should not be subject to patenting laws.¹⁴¹

Prof Judy Kirk testified:

¹³⁵ Dr Luigi Palombi (Submission 4); Prof Sir John Sulston cited by Dr Luigi Palombi, Hansard, Senate Community Affairs References Committee, Monday 14 September 2009, CA 10; Prof Ian Frazer cited by Dr Luigi Palombi, Hansard, Senate Community Affairs References Committee, Monday 14 September 2009, CA 50.

¹³⁶ *Kirin-Amgen Inc v Hoechst Marion Roussel and Others* [2005] 1 All ER 667 at para 132.

¹³⁷ "The priceless strain, being something living, found in nature, cannot be patented: the prosaic process, as applied to the strain, is capable of protection." per Lord Willburforce in *American Cyanamid (Dann's) Patent* (1971) RPC 425 at 448.

¹³⁸ *In the Matter of a Patent Application by Ranks Hovis McDougall Ltd* [1976] AOJP 3915 at p 3916.

¹³⁹ *Laboratory Corporation of America Holdings v Metabolite Laboratories Inc.* 126 S. Ct. 2921 (2006).

¹⁴⁰ Dr Jillian Mitchell, Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 105.

¹⁴¹ Dr Anne Ronan, Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 54.

We all have these genes. They are normal, good genes that work usually to control cell growth. These are genes that we all have and these sequences are in every human being. They are normally involved in cell growth, and most of us in this room will have a slight variation in the sequence of those genes. We will not all have an identical BRCA1 gene. But some of us, not very many of us, will have a fault or a mutation that is big enough to cause a problem with the protein that that gene makes. Those are the people who are at very high risk of cancer. ... Although these two genes were discovered—they were not invented but they were discovered—as the result of a culmination of work done by many publicly and privately funded researchers around the world, in the end we find that these two genes seem to be owned by an American company, Myriad Genetics.¹⁴²

Prof Bruce Mann testified:

I think the idea of an 'invention' would be a way of industrialising the testing—a new chip that has a clever way of rapidly testing for the sequence, that is better than what anyone else has, so the results can come back in three days rather than in three weeks. That would be a genuine invention and that clearly should be subject to a patent and commercialisation. But the sequence of genetic material on that chip, or whatever it is, is what I would have a problem with. I think it comes back to the idea of a threshold.¹⁴³

Application and Use Claims

These are claims to products and methods which make use of the isolated nucleic acid products (defined in claims 1 to 3) or the purified protein products (defined in claims 10-13).

The ask the Committee to accept that these are capable of being “gene-based technologies” and “genetic technologies”.

The patent in question contains claims to 8 broad categories:

1. Nucleic acid probes (claim 4);
2. Replicative cloning vectors (claim 5);
3. Expression cloning vectors (claim 6);
4. Host cells transformed with cloning vectors (claim 7);
5. Methods of producing a “mutant or polymorphic” protein using host cells and containing an expression vector (claim 8 and 9);
6. The use of a purified BRCA 1 “mutant or polymorphic protein” to induce the production of an antibody (claims 15-16);
7. A fused protein made up of various purified proteins defined in claims 10-12 (claim 14); and
8. Methods for “diagnosing a predisposition for breast and ovarian cancer in a human subject” which relies on identifying a “germline alteration in the BRCA 1 gene sequence” (claims 17-30).

The legal issues are twofold:

First, even if the claim is to a “gene-based technology” which meets the first part of the ‘manner of manufacture’ threshold, the question is this: is it ethically, socially or morally appropriate for patenting?

Secondly, if the answer to the first question is in the affirmative: is the “gene-based technology” sufficiently novel, inventive, fully described and fairly based so that it merits the award of a patent monopoly?

These are discrete questions. The first concerns ‘manner of manufacture’ or ‘invention’ threshold, while the second concerns the degree of innovation of an ‘invention’ and the quality of the disclosure.

The first is problematic according to the submissions filed by Dr Moir, the ALRC, ACIP and IP Australia and supported by the oral evidence given by Prof Christie. Indeed, the reluctance of IP Australia and the Australian courts, in recent times, to apply this part of the ‘manner of manufacture’ threshold is one of the reasons given in the ALRC Report, *Genes and Ingenuity: Gene patenting and human health* (ALRC 99, 2004) for its recommendation to review of the ‘manner of manufacture’ threshold. That review is currently being conducted by ACIP under the chair of Prof Christie, but in view of the scope of this Inquiry we will address this issue as well.

Methods of treatment and diagnosis of human illness

¹⁴² Ass Prof Judy Kirk, Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 50.

¹⁴³ Prof Bruce Mann, Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 12.

The Committee should note that both TRIPS and AUSFTA permit Australia to expressly “exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals ...”¹⁴⁴.

The Committee should also note that until 1994 “morality was a legitimate basis for the exclusion of medical methods from patentability”¹⁴⁵ under Australian patent law. However, that changed when Justice Gummow (then a judge of the Federal Court¹⁴⁶) held otherwise in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119 (*Rescare*). At issue was a method for the treatment of sleep apnoea.

On appeal to the Full Federal Court, Justices Lockhart and Wilcox concurred. Justice Sheppard, however, dissented.¹⁴⁷

Justice Lockhart observed that “the Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990 Act, but the limit of the exclusion was s. 18(2), namely: “human beings, and the biological processes for their generation, are not patentable inventions”¹⁴⁸. Justice Wilcox agreed, noting that “Parliament has never excluded a method of human medical treatment from patentability or the definition of “invention”; not even in the recent statute, the Patents Act 1990, that revised Australian patent law and made a specific provision (s.18(2)) dealing with the patentability of human beings and the biological processes for their generation”¹⁴⁹. His Honour explained, “that in the face of apparently deliberate decisions by Parliament not to build this particular exclusion into its legislation, courts should be hesitant to introduce the exclusion by reference to those very general principles.¹⁵⁰” Accordingly, they held that a method for the treatment of sleep apnoea was a ‘manner of manufacture’, satisfying *all* aspects of the test of inherent patentability as provided by s.18(1)(a) *Patents Act, 1990*.

Justice Sheppard accepted there was no binding authority in Australia to the effect that “there cannot be a valid grant of a patent in respect of a method of treatment of the human body”¹⁵¹ but believed that the High Court in *NRDC*, on which, he said, sat “judges of great distinction”¹⁵², had held that whether such methods were patentable was a matter for a court to decide¹⁵³. That Parliament had not expressly banned patents over medical methods to treat humans was not indicative of an intent to restrict the court’s ability to assess inherent patentable subject matter nor was it indicative of permitting such patents. His Honour explained that it was “not going too far”¹⁵⁴ for a court to consider whether the grant of a patent was appropriate in circumstances where the exercise of a patent owner’s exclusive patent rights over the use of an invention “might mean the death or unnecessary suffering of countless people”¹⁵⁵. Having examined the technology and the human disease, which he described as “life-threatening”¹⁵⁶, his Honour held the patent claims to the treatment of this disease were not ‘manners of manufacture’.

Five years later, in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524 (*Bristol-Myers*) the Full Federal Court reinforced the approach taken by Justices Lockhart and Wilcox in *Rescare*. This time, however, the Full Court had to overturned the decision of Justice Heerey who, in following the reasoning of Justice Sheppard, invalidated a patent monopoly over a method for the administration of taxol on the ground that it was not a ‘manner of manufacture’.¹⁵⁷

Taxol was well known by this time; in fact, its chemotherapeutic activity was first discovered in 1977 but it was in 1994 that it was finally approved for use in the treatment of breast cancer. The patent monopolies in issue were ‘petty patents’,¹⁵⁸ namely, with a life of only six years and therefore were not standard patents with a life of 20 years. That aside, as the law was at the time, they were assessed on the same basis. Claim 1 was as follows:

¹⁴⁴ Article 27.3 TRIPS; Article 17.9.2(b) AUSFTA.

¹⁴⁵ Justine Pila, ‘Methods of Medical Treatment within Australian and United Kingdom Patent Laws’, [2001] *UNSWLJ* 30 at para 74.

¹⁴⁶ Justice Gummow was appointed to the High Court of Australia in April 1995.

¹⁴⁷ *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065.

¹⁴⁸ Justice Lockhart at para 77.

¹⁴⁹ Justice Wilcox at para 3.

¹⁵⁰ *Ibid*.

¹⁵¹ Justice Sheppard at para 42.

¹⁵² Justice Sheppard at paras 53.

¹⁵³ Justice Sheppard at paras 52-53.

¹⁵⁴ Justice Sheppard at para 58.

¹⁵⁵ *Ibid*.

¹⁵⁶ *Ibid*.

¹⁵⁷ *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (1998) 41 IPR 467.

¹⁵⁸ Petty patents were replaced with Innovation patents in 2001. Innovation patents have an 8 year life span and lower thresholds of patentability than apply to standard patents.

A method for treating cancer in a patient suffering therefrom including infusing from 135 to 175 mg/m² of taxol over a duration less than 6 hours wherein said method results in a reduction of hematological toxicity and neurotoxicity compared with infusing greater than 170 mg/m² of taxol over a duration of 24 hours.

It is important to appreciate that there was nothing new in taxol *per se* nor in its use as a chemotherapeutic drug. The key was (a) the length of time over which taxol was administered and (b) the actual dosage. Apparently, this new dosage regime provided some benefits to patients. So this drug regime was, at best, an incremental advance, not a medical breakthrough.

Justice Heerey concluded as follows:

At the priority date the material (taxol) had been known for many years. *It is a naturally-occurring compound and thus in itself unpatentable.* In the words of the specification, taxol had 'shown great promise as an anti-cancer drug' and 'been found to be an active agent against drug-refractory ovarian cancer' The properties which made taxol effective against cancer, that is to say its biological mechanism, were well known. They had been discussed in the articles referred to in the specification which were 'incorporated by reference as if reproduced in full below' Thus the specification is not merely a claim of a 'new use of an old substance' ... but a claim for the same use of an old substance.¹⁵⁹ (emphasis added)

Nonetheless, it was argued by the patent holder that this incremental development warranted the granting of a patent monopoly. Putting to one side whether this was the kind of innovation that the Minister had in mind as worthy of the grant of a patent monopoly when he addressed the Australian Parliament in 1989, the 'invention' as defined by claim 1 was not a product nor a process. It was not a medicine. It was not a process to make a medicine. It was a *method of treatment* for human cancer which involved the use of a known medicine for a known purpose. In the final analysis the petty patents were revoked on the ground that they lacked novelty, nevertheless, in my opinion, for the Committee to consider what the Full Court did with the issue of 'manner of manufacture'.

The Full Court, consisting of Chief Justice Black and Justices Lehane and Finklestein, was persuaded by "the clear preponderance of opinion at appellate level"¹⁶⁰. According to Chief Justice Black and Justice Lehane, "drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment was insurmountable problem"¹⁶¹, while Justice Finklestein took the view that it was "not the function of a court [to adjudicate] on an issue such as this ... [and] if public policy requires a different result, it is for the Parliament to amend the 1990 Act"¹⁶².

Therefore, by 2000 the Australian courts had effectively repealed the moral and ethical element of what had been a part of the 'manner of manufacture' threshold since 1624. And while the Committee may not be convinced that the Full Federal Court was correct in doing so, given the majority decisions in *Rescare* and *Bristol Myer*, I urge the Committee to consider, as an option, the express prohibition of the patenting of isolated biological materials which are identical or substantially identical to those that exist in nature.

Furthermore, I urge it to consider the possibility of an express prohibition of diagnostic, therapeutic and surgical methods for the treatment of humans.

There are a number of reasons for this:

First, the use of isolated biological materials in diagnostic tests, such as the kind claimed in claims 17 to 30 in this patent example, is no longer inventive. Ass Prof Amor, an Executive Member of the Human Genetics Society of Australasia told the Committee that using a biological material to make a useful diagnostic test was "not rocket science"¹⁶³. In his opinion "[a]ny student could design a [diagnostic] test"¹⁶⁴. His evidence was corroborated by Prof Mann, President of the Clinical Oncology Society of Australia who said: "with modern genetic technology, once you know what the sequence is, an honours student would be able to design a test to look for a mutation"¹⁶⁵. And in the absence of any evidence that qualified or contradicted these statements, I say that the Committee must accept their expert opinions.

Secondly, the Committee has been advised by IP Australia that the current patentability thresholds are too low and need recalibration. IP Australia explained that the current thrust of the seven consultative patent law reform papers, which it released in 2009, is designed to achieve this. Thus I ask the Committee to accept that Australia's patent system is inefficient and sub-optimal. That said, and in view of the recommendation by IP Australia to strengthen the patentability thresholds, particularly

¹⁵⁹ Ibid at p 477.

¹⁶⁰ *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524 at para 13.

¹⁶¹ Ibid.

¹⁶² Ibid, para 142.

¹⁶³ Hansard, Senate Community Affairs References Committee, Monday 3 August 2009 at CA 47

¹⁶⁴ Ibid.

¹⁶⁵ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 11

inventive step, and to bring them into line with the equivalent thresholds applied by Australia's trading nations, we must take into account recent patent law developments in the United States. Profs Sarnoff, Kahn and Andrews filed a supplementary submission in which they state:

As we had indicated, the recent U.S. Supreme Court case *KSR International, Inc. v. Teleflex Corp.*, "calls into serious question the validity of many of the genetic sequence and other natural products or phenomena claims issued by the [US Patent and Trade Mark Office]." This is because the Federal Circuit and the USPTO for decades had been applying a much more limited test of obviousness than was authorized by the law and binding precedents. Recently, the Federal Circuit recognized that *KSR* had "unambiguously discredited" the Federal Circuit's earlier holdings that had rejected an "obvious to try" approach to finding gene patents obvious. *Kubin*, slip op. at 13. Given the correct approach, the Federal Circuit held the claims invalid; there was sufficient motivation for skilled persons to isolate the cDNA sequences, given prior art knowledge of the importance of the protein and a reasonable expectation of success in doing so given that the methods of DNA isolation were conventional. *Id.* at 13-17. "Therefore, the claimed invention is 'the product not of innovation but of ordinary skill and common sense.' *KSR*, 550 U.S. at 421." *Id.* at 16. Similar motivations should exist for isolating the sequences claimed by many issued patents, and the reasoning of *Kubin* (known methods, a reason to apply them, and expected success makes the result obvious) also should extend to other reasons for isolating genetic sequences than a known important protein. Thus, many if not most issued gene patents are likely invalid for obviousness.¹⁶⁶

Accordingly, if the isolation of a gene does not meet the 'inventive step' threshold in the United States, it should not meet the equivalent threshold in Australia. Moreover, if the isolated product claims which we have considered in this example are invalid, then the mere application of those materials in obvious and non-inventive applications, such as in a diagnostic test, should equally not merit the grant of a patent monopoly.

Thirdly, an inquiry conducted by the United States Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) has concluded that:

1. Patents do not serve as a powerful incentive to conduct genetics research, to disclose genetic discoveries, or to invest in the development of genetic tests;
2. Sufficient incentives and funding for research and development [of genetic tests] already exist; and,
3. As such, the benefits of patents in the area of genetic testing are limited.¹⁶⁷

The SACGHS found that public funded research is the main driver of genetic research. This was confirmed by the Walter & Eliza Hall Institute of Medical Research (WEHIMR) which provided the Committee with information concerning its revenues in the 2009 year.¹⁶⁸ According to the WEHIMR, it received \$55 million from Australian and US government sources, while its "gross revenues" from "gene sequence patents" amount to a mere \$2.6 million.

Fourthly, the Committee cannot ignore the views of Justices Sheppard and Heerey which, in my opinion, persuasively describe the parliamentary intent behind the *Patents Act, 1990*. The insertion of s.18(2) is not, respectfully, suggestive of a general policy to remove the 'inherent patentability' limitation which had applied by virtue of the proviso in s.6 of the Statute of Monopolies. It must be remembered that s.18(2), the express prohibition to "[h]uman beings and the processes for the generation", was subsequently inserted into what became the *Patents Act, 1990* on the motion of Senator Harradine.¹⁶⁹ What s.18(2) did, and only did, was deny patentability to one class of invention. Nothing the Minister said in parliament during the second reading of the *Patents Bill, 1989* suggested that parliament wished to change the 'manner of manufacture' threshold. While it may be difficult for judges to make the kinds of assessments that Justices Sheppard and Heerey considered necessary, those difficulties do not absolve judges of the obligation to apply the law as parliament intended. Judges are required every day in other fields of law, such as family, defamation and criminal law, to deal with difficult and challenging issues of a moral or ethical nature and which involve subjective assessments which call upon them, as members of society, to put into effect their own perceptions of propriety in a societal context. As judges in these courts are quite capable of doing so, patent law should be no different.

Finally, there is no legal impediment to the Australian parliament expressly prohibiting the patenting of methods of medical treatment, diagnosis and surgery as applied to humans. Both TRIPS and the AUSFTA permit the express exclusion of patent monopolies over methods of medical treatment and diagnosis and the European scheme of patentability, which contains such an exclusion, has not been shown to be negatively impacted by it.

¹⁶⁶ Profs Sarnoff, Kahn and Andrews (Submission 17b).

¹⁶⁷ The SACGHS's final report is due to be published soon. However, on 8 October 2009 its chair, Dr James Evans, held a conference at which he discussed its key findings. For more details see <http://www.phgfoundation.org/print/news/4870/>

¹⁶⁸ Walter and Eliza Hall Institute of Medical Research (Submission 26a).

¹⁶⁹ ALRC Gene Patenting and Human Health Report at para 15.36.

In summary, the invite the Committee to conclude that a prohibition on the patenting of diagnostic, therapeutic and surgical methods for the treatment of humans would not be detrimental to the Australian economy nor its people.

Secondary patentability thresholds

In the present example there are 24 patent claims which relate to the application and uses of the isolated biological materials defined in claims 1-3 and claims 10-13. Those 24 patent claims can be broken up into 8 broad categories, one being to methods of “diagnosing a predisposition for breast and ovarian cancer in a human subject”. According to this category, which consists of 13 patent claims (claims 17-30), anyone that makes such a diagnostic test using those materials will infringe Australian Patent 686004.

These diagnostic method claims, however, do not disclose a new or non-obvious diagnostic platform technology. Any diagnostic method, old or new, falls within the scope of the patent monopoly so long as the objective of the diagnostic test is to *diagnose a predisposition for breast and ovarian cancer in a human subject*.

The Committee should accept the expert evidence of Profs Amor and Mann that there is nothing inventive in using the biological materials or the corresponding sequence information to make a diagnostic test. And while the disclosure of the genetic sequence information defined by claims 1-3 was not known at the priority date¹⁷⁰ of this patent monopoly, once this information was published, even at that time, the Committee should understand that the use of this information to make a diagnostic test was a matter of routine science. Indeed, the patent specification assumed this to be the case.

So what was the ‘inventive step’ of this invention? What was the advance in medical knowledge which this patent specification disclosed beyond the state of the art as at 12 August 1994? These are important questions because the value of the social contract, implicit in this patent monopoly, very much depends on the answers.

Clearly, the relevant advancement to medical knowledge was the discovery of a causal link between mutations in the BRCA 1 human gene and breast and ovarian cancer. That advance, however, was not an invention. It was not a ‘manner of manufacture’. It was medical knowledge about a cause of breast and ovarian cancer. And it was knowledge that was incremental to the discovery made by Prof Mary-Claire King from the University of California, Berkeley, in 1990 that this gene was located on human chromosome 17. It took Prof King 16 years to make that discovery. It took the scientists described in the patent monopoly as ‘inventors’ another 4 years to identify the BRCA 1 gene on chromosome 17. Such scientific knowledge cannot, however, be the basis of an award of a patent monopoly. For that to occur there must be an ‘invention’.

The question which follows on from this analysis is: should the discovery of a human gene (BRCA 1) and applied in a technology which is routine (diagnostic methods) to produce a new result (a diagnosis of a predisposition to breast and ovarian cancer) be sufficient to justify the award of a patent monopoly?

It seems apparent to me that if the answer to that question under the present ‘inventive step’ threshold is in the affirmative, then the value of the social contract to the Australian economy is well below what it should be. I therefore urge the Committee to accept that the ‘inventive step’ threshold should not permit a discovery (such as the isolation of a gene and the deduction of its function) and its use in a known or routine technology (such as a diagnostic method) to be the basis of the grant of a patent monopoly even if the end result (knowledge of a predisposition to breast cancer) is new. Not only must the end result be new but the underlying technology used to produce it must be both new and non-obvious. We are fortified in our view by developments in US patent law as explained by Profs Sarnoff, Kahn and Andrews.¹⁷¹

The Committee should note the Venturous Australia Report by the Review of the National Innovation System. The following recommendation was made to the Minister for Innovation, Industry, Science and Research, the Hon Kim Carr:

Patent law should be reviewed to ensure that the inventive steps required to qualify for patents are *considerable*, and that the resulting patents are well defined, so as to minimise litigation and maximise the scope for subsequent innovators.¹⁷² (emphasis added)

Inventive Uses of Isolated Biological Materials

I urge the Committee to agree with the Venturous Australia Report’s recommendation. Unless the inventive step threshold is raised considerably, patent monopolies will continue to be granted for trivial, elementary and obvious applications and uses of isolated or purified biological materials and these in turn may frustrate subsequent innovators and delay the development and commercialisation of incremental, but important, much needed improvements. It can also contribute to the creation of patent thickets around biological materials, which in the case of human genes may create serious obstacles for scientific and medical research in respect of the development of new treatments, diagnostics, vaccines and, hopefully, cures. Prof Ian Olver, an oncologist and CEO of Cancer Council Australia (CCA), explained the situation thus:

¹⁷⁰ The priority date is 12 August 1994 and is based on US patent application 08/289,221.

¹⁷¹ Profs Sarnoff, Kahn and Andrews (Submission 17b).

¹⁷² Venturous Australia Report, Recommendation 7.2.

... patent law was designed originally to protect inventions and innovations and not discoveries of things which already exist in nature, like genes. Our position is that we need to change the law to reflect what we regard as a common sense approach. The timing of this is absolutely critical since genes and their products are increasingly going to become the targets of new treatments for a range of diseases. If I stick to cancer, we are seeing a paradigm shift in cancer treatments towards targeted therapies—and the targets are genes and gene products. We are going to see hundreds more of these over the next decade, so a change now would protect us before the floodgates open.¹⁷³

Gene Patents in the Future

Obfuscation

Dr Kwang Lin, Associate Director of Intellectual Property Research Institute of Australia (IPRIA), an economist, told the Committee that this is “too new a technology” for there to be reliable data for a “policy” assessment. In his opinion, “[t]here is not enough prior research that will conclusively say that, if you increase patenting by x amount, society will be worse off by y amount, or vica versa, or that without gene patenting society will be in a terrible state.”¹⁷⁴ Yet, gene patents have been part of the patent landscape for over 20 years.

Dr Chris Dent, Senior Research Fellow at IPRIA, disclaimed having legal qualifications¹⁷⁵ and as such, Dr Dent is also not an expert in patent law. He told the Committee, however, that according to his “understanding” of patent law “[a] gene has to have another use outside of the human body”¹⁷⁶ before it has a “function”¹⁷⁷ which is considered sufficient for patenting. Yet, gene patents invariably claim any biological material as long as it has been ‘isolated’. These claims are not qualified by either “purpose” or “function”.

Dr Beth Webster, the Director of IPRIA, also an economist, told the Committee: “whether a discovery is part of a person is irrelevant, whether a discovery is God-given, such as resources, is irrelevant, whether a discovery constitutes an invention or not is also irrelevant and whether a discovery is medical or not is irrelevant”¹⁷⁸. Yet, the US Supreme Court has held on a number of occasions that “[p]atents cannot issue for the discovery of the phenomena of nature”¹⁷⁹ and the High Court of Australia has held that “it is a requirement of the [Patents] Act that an application shall be for a ‘patent’... and ‘patent’ is defined by s.6 to mean letters patent for an ‘invention’ ... [and] [i]nvention is defined to mean ‘any manner of new manufacture the subject of letters patent and grant of privilege within section six of the Statute of Monopolies.’”¹⁸⁰

Mr Richard Hamer, a partner of the law firm Allens Arthur Robinson, however, is an expert in patent law, “having practiced in the area of intellectual property law for about 25 years”¹⁸¹. He also told the Committee that he had “qualified in genetics”¹⁸². He came to the Committee as a member of the Intellectual Property Committee of the Law Council of Australia, a committee consisting of “leading barristers, solicitors and academic lawyers in the field of IP law”¹⁸³. Mr Hamer explained that “the issues that are being raised [in regard to gene patents] are really based on hindsight and that the position going forward is a different position to the position it was, and that is because the state of knowledge has changed”¹⁸⁴. He was clearly discussing the secondary threshold of ‘inventive step’ when he said “[w]hat is obvious now is not what was obvious 10 years ago”¹⁸⁵. Continuing, he said: “That is how it should be because that is the way the patent system works”¹⁸⁶. Finally, he said: “It is based on assessing inventions at the time that they are made”¹⁸⁷. In other words, no matter how bad things have been in the past, the future is going to be different. Indeed, Mr Hamer believes that patent law would see to it that patents are granted only if there is true invention. Yet, the Committee has been advised that only 1% of all patents are scrutinised by

¹⁷³ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 1.

¹⁷⁴ Hansard, Senate Community Affairs References Committee, Monday 3 August 2009 at CA 4.

¹⁷⁵ Ibid at CA 5.

¹⁷⁶ Ibid at CA 15.

¹⁷⁷ Ibid at CA 13.

¹⁷⁸ Ibid at CA 7.

¹⁷⁹ Profs Sarnoff, Kahn and Andrews (Submission 17) at pp 7-12.

¹⁸⁰ NRDC at p 260.

¹⁸¹ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 72.

¹⁸² Ibid.

¹⁸³ Ibid.

¹⁸⁴ Ibid at CA 73.

¹⁸⁵ Ibid.

¹⁸⁶ Ibid.

¹⁸⁷ Ibid.

Australian courts and even then only with respect to issues that are meet the objectives of the litigants. And if that is not bad enough, IP Australia is so concerned by the current standards applied by Australian courts with respect to these critical patentability thresholds, such as 'inventive step', 'fair basis' and 'full description', which it says are too low, that it has initiated a consultative process of law reform to re-calibrate them. With regard to gene patents specifically, he said: "[a]s a matter of principle you can get a patent for isolating something which has never been isolated before".¹⁸⁸ He continued: "The isolated compound is something that you can do something with - something that you cannot do when it is in the body".¹⁸⁹ Finally, that an isolated biological material "is also different chemically because it is separated from the other components".¹⁹⁰ Yet, the Committee has been informed by other medical and scientific expert evidence that an isolated biological material, such as the BRCA 1 gene, is the same 'chemically' in that the genetic sequence is identical or substantially identical to the corresponding gene in the human body.¹⁹¹ And while he may be correct to point out that once a gene has been isolated it can be used in ways that it could not be used while it was inside the human body, this point is quite misleading because the 'invention' is not defined by reference to what can be done with it, but by reference to what it is *in an isolated form*.

According to Australian patent law while a patent specification contains information germane to the grant of a patent monopoly, it is the patent claims which define the legal boundaries of the patent monopoly. Unless a 'purpose' or 'function' specifically qualifies the claim, the disclosure of a 'purpose' or 'function' in the patent specification has no bearing on the scope of that monopoly. It is all well and good, for example, that Myriad developed a genetic test for detecting BRCA 1 mutations using the discovery of the BRCA 1 gene, but that is not what claims 1 to 3 and 10-13 are about. They are specifically referring to the isolated human gene BRCA 1 and the proteins that it codes for. Therefore, I ask the Committee not to accept that the disclosure of one 'practical' application of the isolated BRCA1 gene and proteins in the patent specification justifies the grant of a patent monopoly over the actual isolated BRCA 1 gene and proteins themselves.

Patent Statistics and Trends

The ALRC's President, Prof Weisbrot, advised us that gene patents are "yesterday's battle" because the 20 year patent monopoly term for the early gene patents have or are about to expire. We were also told that these were "broad patents" reflected the state of the technology of the past. Therefore the "problems caused by patents granted over gene sequences" are "transient ones", he concluded. He also said that as a result of the Human Genome Project and "further rapid advances in sequencing technology", it would be "increasingly unlikely that a competent patent examiner would now approve an application for a patent rights over a pure gene sequence".¹⁹²

IP Australia has supported the ALRC's position by taking us to their patent filing statistics. According to IP Australia "post publication of the Human Genome Project in 2001, filing numbers for methods or processes ... have surged relative to the filings over the product patents for gene sequences per se",¹⁹³ IP Australia proffered an explanation:

This is not surprising because the increase in knowledge of the human genome would have meant patentability requirements for Inventive Step and Novelty became more difficult to satisfy. This trend also indicates that innovation efforts have shifted to downstream applications of gene sequences.

Yet, the Committee has been advised that the situation is not as simple as the ALRC or IP Australia suggest.

First, there is the evidence of Prof Ian Olver. He advised us that "in the next couple of decades"¹⁹⁴ cancer research and the development of diagnosis and treatments will be "determined by your genetic sequence".¹⁹⁵ He said that "the pattern of your cancer's genes will tell you what type of cancer you have, what targeted treatments you should have and what the prognosis of the aggressiveness of the cancer is"¹⁹⁶. According to Prof Olver, there has been a "paradigm shift in cancer treatment towards targeted therapies - and the targets are genes and gene products".¹⁹⁷ He stressed that "the timing of this [inquiry] is absolutely critical since genes and their products are increasingly going to become targets of new treatments for a range of diseases".¹⁹⁸

¹⁸⁸ Ibid at CA 76.

¹⁸⁹ Ibid.

¹⁹⁰ Ibid.

¹⁹¹ See also Dr Hazel Moir, Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009 at CA 7-8.

¹⁹² ALRC (Submission 18) at p 4.

¹⁹³ IP Australia (Submission 19) at p 26 para 7.10.

¹⁹⁴ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 8.

¹⁹⁵ Ibid.

¹⁹⁶ Ibid.

¹⁹⁷ Ibid at CA 1.

¹⁹⁸ Ibid.

His evidence implies that, regardless of what has happened in the past, the future will be different. Unless there is a change in the law to “protect us before the floodgates open”,¹⁹⁹ in his opinion both human and cancer genes are going to become increasingly the subject of patent monopolies. And by “protect”, what Prof Olver meant is explained by this exchange between Senators Heffernan, Williams and Prof Olver:

Senator HEFFERNAN—Lawyers are saying that this is the end of the iceberg and, in fact, we have had evidence like you have just given us that it is the tip of the iceberg.

Prof. Olver—Yes.

Senator WILLIAMS—We have some 23,500 or 25,000 genes in our body. If this is allowed to continue, we may see tens of thousands of patents taken out on genes when they are separated from the body. Would you say that it would lead to a hindrance to research, diagnosis et cetera in the future if this were to occur? I do not know how many patents have been taken out now. I hear of some 400. Looking to the future of medicine, control of diseases and treatment of diseases, we could see thousands of patents taken out on this. Would you agree with that?

Prof. Olver—I think the difficulty is that research depends on competition. So the competition to define a treatment that targets a gene is intense, because the rewards are enormous. That is what drives and has always driven some aspects of commercial research. We would actually be hindering that competition if we allowed monopolies on every gene product or gene sequence that someone discovered. It is also the case that a lot of the great discoveries in the past have not relied on commercial interests. So the whole human genome project, a current project to sequence cancers, is to put all that information in the public domain for the public good. That effort, which we are only just starting to exploit, is what will create the ability to find new treatments. So you make it widely available; you do not narrow it down so every company can have a monopoly and can only work on one gene.

Secondly, there is the empirical evidence presented by Dr Hazel Moir. She provided the Committee with data sourced from IP Australia’s database and an analysis of that data.²⁰⁰ This data confirmed that since the 1970s there had been some 42,326 patent applications in patent class C12N15 and of these 14,306 were granted. She says, however, that while the “volume appears to have peaked around 2001-02 ... [a]pplication numbers for 2008, 2007 and 2006 will almost certainly be revised upwards over time”. The reduction in volume, she suggests, could be due to the “volume of ‘inventions’ being produced, or applicants might now be trying to avoid this class”²⁰¹. She explained that “it should be remembered that this C12N15 class is not the only class in which gene and related patents may be found. It is merely the largest such class. Others are to be found in at least class C12Q/68.”²⁰²

Dr Moir’s evidence is also important because, although consistent with the data provided by IP Australia, she suggested that the cause for reduction in volume might not be for the reasons advanced by IP Australia or the ALRC. Indeed, she says there is a “lack of information on the ways in which granted monopolies are used in Australia” and this, in her opinion, “is a major problem for the development of sound policy.”²⁰³

Finally, there is the empirical evidence presented by Dr Luigi Palombi. Dr Palombi provided the Committee with data also sourced from IP Australia’s database. It was obtained on 16 February 2009 and showed that the total number of patents granted by IP Australia in classes C12N15 and C12Q1/68 amounted to 15,042.²⁰⁴ He also presented data from WIPO’s database (which records details of patent applications filed under the Patent Cooperation Treaty, 1970 (PCT)).²⁰⁵ This data showed that as at 12 September 2009 there were 13,818 pending patent applications containing at least one patent claim to an ‘isolated’ biological material. Dr Palombi also took us to an example of one of the more recent patent applications, namely, PCT/US2009/030998 entitled *Compositions and methods related to a human CD 19-specific chimeric antigen receptor* which, as the title suggests, seeks a patent monopoly over a human biological material, namely, a human CD 19-specific chimeric antigen receptor, in an isolated form.²⁰⁶ Claim 1 defines the invention:

An isolated human CD19-specific chimeric antigen receptor polypeptide (hCD19CAR) comprising an intracellular activation domain, a transmembrane domain and a heterologous extracellular human CD 19 binding domain.

¹⁹⁹ Ibid.

²⁰⁰ Dr Hazel Moir (Submission 20) at pp 35-39.

²⁰¹ Ibid at p 37.

²⁰² Ibid.

²⁰³ Ibid at p 39.

²⁰⁴ Dr Luigi Palombi (Submission 4) Part 2 at p ii.

²⁰⁵ Hansard, Senate Community Affairs References Committee, Monday 14 September 2009 at CA 2.

²⁰⁶ Ibid at CA 3.

Dr Palombi also took us to another PCT patent application, PCT/IL2008/001674 entitled *Novel protein*.²⁰⁷ Claim 1 of this patent application defined the invention:

An isolated polypeptide comprising an amino acid sequence of SEQ. ID. NO: 2 or SEQ. ID. NO: 4.

The same patent application also contained a claim to an isolated nucleic acid that coded for the protein defined in its claim 1.²⁰⁸

In summary, while the Committee was presented data to show that gene patent applications peaked in Australia in 2001-02, it has no way of knowing if this marks the beginnings of a permanent downward trend or is merely a temporary aberration. Apart from the evidence of Prof Olver and Dr Palombi, which is to the effect that gene patents will persist into the future in their thousands and will grow in number, the ALRC and IP Australia believe that the data indicates that gene patents are a diminishing problem. Dr Moir's evidence, however, suggests that there is not enough accurate patent data to predict what may happen and why,²⁰⁹ and we agree with her. Prof Drahos's study of 45 patent offices around the world and published in his book *The Global Governance of Knowledge (Global Governance)* supports her point.²¹⁰ He states:

One of the fundamental problems facing outsiders is a basic lack of information about the patent holdings of the few powerful beneficiaries of the system. Information about granted patents is public information, but it is not available in publicly useful ways that enable the forensic scrutiny of those patents by interested outsiders.²¹¹

Dr Moir's hypothesis, that the re-classification of patent applications may explain this reduction, requires further consideration because it seems plausible, in light of the evidence of Prof Drahos that the Australian patent system is capable of being gamed, for the reduction to be one consequence of such gaming. To illustrate, instead of a patent claiming an isolated biological material, it may be that the claim will be over an 'artifact', which for all intents and purposes, is equivalent to an isolated biological material but which will result in a different statistical classification of the patent application. Prof Drahos states:

Patent offices also understand better than anybody that it is patent attorneys who drive the gaming of the patent system. It is they who advise companies on patenting strategies. It is the patent agents who are the source of 'creative' claims-drafting that slips past the restrictions in law on patentable subject-matter. And it is they who make applications longer, with more and more claims. All the developed-country patent offices interviewed said that the complexity of applications had increased.²¹²

Patent Claiming Trends

It makes sense that if patent claims define the legal boundaries of the patent monopoly, patent attorneys and their clients will be inclined to seek the broadest scope permitted by the law. After all, that is what they are paid to do and so long as the claims remain within the law the validity of a patent monopoly will be upheld if and when it is challenged. That said, I urge the Committee to recognise the inherent weakness of the current Australian patent system which provides only one mechanism for the independent scrutiny of granted patents. That only 1% of Australian patents are scrutinised by the Australian courts means that the likelihood of the detection of illegal claiming is so small that the incentive to game the Australian system is, conversely, very high.

The consequences of this behaviour, however, can be very costly to the economy. For instance, on 28 November 2008 the European Competition Commissioner, Ms Neelie Kroes, made a public statement announcing the preliminary findings of a year long investigation undertaken by the European Commission into the patent practices of European pharmaceutical companies. She said: "[t]he worst example we found of this method was 1,300 separate patent filings, across the EU, for a single medicine"²¹³. The estimated cost to the European Community over 7 years is about \$4 billion.²¹⁴ In Australia, the patent which was at the centre of the decision in *Kiren Amgen*, namely, Australian Patent No 600650 entitled *Polypeptides of erythropoietin*, as we explained in Part 1 has made a significant contribution to the cost of healthcare in Australia as well as retarding this country's ability to manufacture and supply generic erythropoietin medicines to Australian hospitals and for the treatment of Australian renal patients.

²⁰⁷ Ibid at CA 4.

²⁰⁸ Ibid at CA 6.

²⁰⁹ Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009, CA 2.

²¹⁰ Peter Drahos *The Global Governance of Knowledge* (Cambridge University Press: Cambridge, UK: 2010)

²¹¹ Ibid at p 292.

²¹² Ibid at p 310.

²¹³ Dr Luigi Palombi (Submission 4) Part 1 at p 15.

²¹⁴ Ibid.

The economic incentive for large and sophisticated companies, such as pharmaceutical and biotechnology companies, that can afford to employ an international network of patent attorneys to game patent systems around the world is very high. And this explains why many past legislative attempts to control the breadth and number of patent monopolies have failed.

By way of example, in 1919 the UK Parliament amended the *Patents Act, 1907 (UK)* by imposing a ban on the patenting of chemical substances. This ban was designed to remedy a shortcoming in the British economy, namely, the lack of a domestic capacity to manufacture chemicals and medicines. World War I had exposed the UK to shortages of much needed chemicals and medicines and it was thought that the grant of broad patent claims over chemical substances secured by German chemical companies had enabled them to exert too much control over the British economy. Indeed, at that time it was not possible to obtain a German patent for chemical substances. So, the UK patent law was brought into line with German patent law. However, in 1947, after a two year inquiry into the British patent system, the committee appointed to undertake the inquiry recommended to the British government that the ban be repealed. One reason was as follows:

It has been pointed out that the limitation imposed by this sub-section has little practical value, and that it merely encourages the drafting of a specification to cover all conceivable methods of manufacture, so that, in effect, it is the substance itself and not the process of manufacture which is protected by the patent.²¹⁵

Although the Swan Committee, as it was known, was “impressed by the arguments ... advanced in support of the proposal for removing this limitation on the claiming of chemical substances”, its Final Report also recommended that claims “for a new substance” should not extend to “the same substance when found in nature”.²¹⁶ Accordingly, the *Patents Act, 1949 UK*, which repealed and replaced the *Patents Act, 1907 UK*, contained s.4(7). This provision read as follows:

Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature.

This example, although it may appear to be of an historical nature, is relevant to this inquiry for two reasons.

Firstly, quite apart from being one example of how a legitimate economic policy was undermined by the collective actions of British patent agents (as they are known), the Committee has noted that the *Patents Act, 1949 UK* became the template for the *Patents Act, 1952*, in Australia. And while this is unlikely to occur today between the UK and Australia, in the context of the international community of the WTO it may. The point being that Australian policymakers must be aware of the economic and social consequences which flow on from the harmonisation of patent law. And given that the Committee has been told about how patent law is an instrument of economic policy I urge the Committee to reinforce recommendation 7.3 of the Venturous Australia Report, namely: “It should make the same transition as competition policy did in the 1980s and 90s to being managed as such”.²¹⁷ In other words, a more multidisciplinary approach to the development of patent law must be adopted. The current approach is excessively legalistic and myopic and, as a result, is incapable of adequately assessing the economic and social impact of changes to Australian patent law. This must also mean that patent law be brought primarily within the responsibilities of the Treasurer.

Secondly, there are parallels between chemical substances and isolated biological materials. Those parallels have been brought to the Committee’s attention by IP Australia in defence of its stated policy on the patenting of such materials. I would suggest that the Committee may readily see the associations but, in the present context, what is particularly germane is the insertion of s.4(7) into the *Patents Act UK 1949*. Although biotechnology in 1949 was not what it is today, it appears that the Swan Committee was keen to avoid the possibility, in recommending the repeal of the ban on the patenting of chemical substances, of inadvertently permitting the grant of patents over chemicals that were the same as those “found in nature”. This suggests that this Committee must take great care to ensure that Australian patent law does not transgress on the great scientific commons which is, as the US Supreme Court has held, “free to all men and reserved exclusively to none”.²¹⁸

A General Anti-Avoidance Provision

This example, is of course the tip of the iceberg. Prof Drahos has provided the Committee with other examples of this kind of patent drafting behaviour. His book, *Global Governance*, contains a plethora of patent claims which would convince any reasonable person of the nature of the problem. He elaborates:

Patent systems .. remain open to innovation in claiming formats. This openness has produced a variety of formats including Beauregard claims, function claims, Jepson claims, Lowry claims, Markush claims, means plus function claims, method claims, omnibus claims, product-by-process claims, signal claims, Swiss

²¹⁵ UK Board of Trade, K R Swan (1947), Patents and Designs Acts, Final Report of the Departmental Committee, 1946-47 [Cmd 7206] at p 21 para 93.

²¹⁶ Ibid at p 22 para 95.

²¹⁷ Venturous Australia Report at p 86.

²¹⁸ *Diamond v Chakrabarty* 447 US 303 (1980) at p 309 following *Parker v Flook*, 437 U.S. 584 (1978); *Gottschalk v Benson*, 409 U.S. 63, 67 (1972); *Funk Brothers Seed Co. v Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v Morse*, 15 How. 62, 112-121 (1854); *Le Roy v Tatham*, 14 How. 156, 175 (1853).

claims and use claims. What is available in terms of a claim-drafting strategy for any given invention will be affected by the technological area of invention, the guidelines that the patent office has developed for various claim formats and the court jurisprudence that has developed around the interpretation of claims.²¹⁹

Therefore, I hope that the Committee will accept my contention that the spirit and objective of the *Patents Act, 1990* should not be allowed to be undermined by such drafting practices. Much like the general anti-avoidance provisions in Part IVA of the *Income Tax Assessment Act, 1936*, designed to “give effect to a policy to strike down blatant, artificial or contrived arrangements, but not cast unnecessary inhibitions on normal commercial transactions by which taxpayers legitimately take advantage of opportunities available for the arrangement of their affairs”,²²⁰ an anti-avoidance provision in the *Patents Act, 1990* would seek to achieve the same balance. After all, Prof Drahos alerted us to the fact that “Swiss claims allow applicants to overcome restrictions on method of treatment claims”²²¹ and this is relevant in view of the recommendations contained in this Submission.

Part 2 Recommendations

Therefore I ask the Committee to recommend to the Australian government that it do the following:

- 2.1 Amend the *Patents Act, 1990* to overrule *Rescare* and *Bristol Myers* in so far as the issue of patentable subject matter is concerned;
- 2.2 Amend the *Patents Act, 1990* to include a set of economic and social objectives;
- 2.3 Amend the *Patents Act, 1990* so that the patentability thresholds are consistent those economic and social objectives;
- 2.4 Amend the *Patents Act, 1990* to expressly prohibit the patenting of:
 - (a) biological materials that exist in nature, including their derivatives, however derived, and whether isolated or purified or not, and
 - (b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- 2.5 Require the Productivity Commission to monitor the impact on the Australian economy of the express prohibitions and present a report to the Australian government within 3 years of their taking effect.
- 2.6 Amend the *Patents Act, 1990* to insert general anti-avoidance provisions that give effect to a policy to strike down patents claims which are a blatant, artificial or contrived attempt to undermine the economic and social objectives set out in the legislation;
- 2.7 Amend the *Patents Act, 1990* so that patent claims define products, processes or methods that are (a) inventions within the full meaning of the Act, (b) novel, (c) contain an inventive step and (d) commercially practical and useful across the full breadth of the scope of the monopoly and not requiring undue experimentation based on the information disclosed in the patent specification;
- 2.8 Instruct IP Australia to immediately establish a free and publicly accessible, user friendly and searchable database that will enable anyone to determine the effective legal boundaries of all patented technology in Australia and provide useful and meaningful statistics that will aid in the maintenance and development of economic and social policy in Australia.

²¹⁹ Op cit 217 at p 87.

²²⁰ Second reading speech by the Hon Mr John Howard, Treasurer, concerning the *Income Tax Laws Amendment Bill (No 2) 1981*.

²²¹ Op cit 217 at p 89.

Part 3: Patent Monopolies

The Australian Patent System

The Legislation

The system for the grant of national patents in Australia commenced with the passing of the *Patents Act, 1903*. The system was continued with the passing of the *Patents Act, 1952*. Currently, the Australian patent system operates under and by virtue of the *Patents Act, 1990*.

Patent Monopolies

A patent monopoly for a maximum period of 20 years²²² can be granted by the Commissioner of Patents.²²³

The subject matter of a patent monopoly, as defined in any patent claim²²⁴, must be a “manner of new manufacture within the meaning of section 6 of the Statute of Monopolies”.²²⁵ In other words, the patent claim must define an ‘invention’.²²⁶

According to the High Court of Australia²²⁷ the appropriate question in respect of the subject matter of a patent claim as follows: “Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the Statute of Monopolies?”

If the answer to this question is in the affirmative, then for the patent monopoly to be valid and enforceable, the invention must also meet the thresholds of novelty,²²⁸ inventive step²²⁹ and industrial application.²³⁰

Unless *all* four thresholds of patentability are satisfied the patent monopoly is invalid and unenforceable.

²²² s.67 Patents Act, 1990. The maximum term can be extended for a period of up to 5 years for pharmaceutical substances that are included in the Australian Register of Therapeutic Goods, s.70 Patents Act, 1990.

²²³ s.61 Patents Act, 1990. The Commissioner of Patents (Ms Fatima Beattie) is an officer of IP Australia and reports to the Director-General of IP Australia (Mr Philip Noonan). The Director-General in turn reports to Senator, the Hon, Mr Kim Carr, Minister for Innovation, Industry, Science and Research.

²²⁴ A patent claim is that which defines the boundaries of the scope of the patent monopoly. Anything that anyone does in Australia which comes within the scope of the patent monopoly will infringe the patent monopoly.

²²⁵ s.18(1)(a) Patents Act, 1990. The Statute of Monopolies was passed by the English Parliament in 1624. The Act (s.1) banned all monopolies except those expressly permitted, one being (s.6): “That any Declaration before-mentioned shall not extend to any Letters Patents and Grants of Privilege for the Term of Fourteen Years or under, hereafter to be made, of the sole Working or Making of any Manner of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the Time of Making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient: The said Fourteen Years to be accounted from the Date of the first Letters Patents, or Grant of such Privilege hereafter to be made, but that the same shall be of such Force as they should be, if this Act had never been made, and of none other.”

²²⁶ The word ‘invention’ is defined in Schedule 1 Patents Act, 1990 to mean “any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.”

²²⁷ *National Research Development Corporation v The Commissioner of Patents* (1959) 102 CLR 252

²²⁸ s.7(1) and s.18(1)(b)(i) *Patents Act, 1990*.

²²⁹ s.7(2) and s.18(1)(b)(ii) *Patents Act, 1990*.

²³⁰ s.18(1)(c) *Patents Act, 1990*.

A patent monopoly gives the holder, or patentee, the right to exclusively exploit²³¹ within Australia the 'invention' defined in the patent claim or claims. The right of exploitation is property and can be transferred or licensed on an exclusive or non-exclusive basis²³². The holder of the exclusive license in Australia has the right to enforce the Australian patent monopoly in an Australian court as if it were the patentee.

However, no patent monopoly granted by the Commissioner of Patents is guaranteed to be valid.²³³ And the Commissioner of Patents is immune from any liability in respect of the grant of the patent monopoly.²³⁴

Nonetheless, once a patent monopoly has been granted it has effect of law unless it is revoked. A patent monopoly can be revoked by the Commissioner of Patents in certain limited circumstances but, more generally it is revoked by order of an Australian court. The jurisdiction of the Australian courts to revoke an Australian patent monopoly can be invoked by any person²³⁵. However, only a very small percentage of patent monopolies are challenged in the courts²³⁶ and fewer are revoked by them.²³⁷ A further reason for few challenges in Australia is that legal costs are paid by the losing party to the winning party. While the rule seeks to discourage frivolous litigation, a side effect is that it also reduces the likelihood of public groups being in a position to challenge potentially invalid patents.

IP Australia acknowledged the problem in its submission to the Review of the National Innovation System²³⁸ in which it explained:

One of the main issues associated with IP rights enforcement is the costs associated with taking enforcement actions. There is also a view within the small business community that litigation is about who has the greater financial resources rather than whether the IP right is valid or infringed. Such practices can lower confidence in the IP system and limit the benefits of IP protection to those who have large financial resources.²³⁹

Most patent revocation actions in Australia involve companies or organisations that are large, multinational and sophisticated and which are holders of many kinds of patent monopolies in Australia and around the world. Patent litigation involving these companies or organisations, more often than not, are part of a series involving the same parties or their local subsidiaries or affiliates in other countries.²⁴⁰ As a result, Australian courts are mostly exposed to legal arguments that are relevant to the interests of this class of litigant.

²³¹ The word 'exploit' is defined in *Schedule 1 Patents Act, 1990* to mean (a) in respect of an 'invention' that is 'a product', to "make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things"; and, (b) in respect of an invention that is 'a method or process', to "use the method or process or do any act mentioned [in (a)] in respect of a product resulting from such use."

²³² s.13(2) *Patents Act, 1990*.

²³³ s.20(1) *Patents Act, 1990*.

²³⁴ s.20(2) *Patents Act, 1990*.

²³⁵ s.138 *Patents Act, 1990*.

²³⁶ Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009 at CA16.

²³⁷ Patent litigation is expensive and only a small number of cases reach court. The challenger to a granted patent monopoly shares any benefits from having the patent declared invalid with all other innovators in the field, but bears the costs alone. In contrast the holder of a patent monopoly receives all the benefits of successful litigation. These asymmetries in the costs and benefits of patent litigation are a major reason why many weak-seeming patents remain unchallenged. These matters are touched on briefly in submissions by patent law experts from the Australian National University Prof Peter Drahos (Submission 60), Dr Luigi Palombi (Submission 4), Dr Hazel Moir (Submission 20) and Dr Matthew Rimmer (Submission 45). There is a reasonable empirical academic literature on this subject.

²³⁸ Review of the National innovation System commissioned by the Hon Mr Kim Carr, Minister for Innovation, Industry, Science and Research on 22 January 2008. The Venturous Australia Report was presented to the Minister on 29 August 2008.

²³⁹ IP Australia (Submission 537 to the Review of the National Innovation System) at p 40.

²⁴⁰ Examples from the past 10 years are: *Aktiebolaget Hassel v Alphapharm* [1999] FCA 628; *ICI Chemicals Polymers v Lubrizol* [1999] FCA 1417; *Bristol-Myers Squibb Co v F H Faulding* [2000] FCA 316; *Emory University v Biochem Pharma* [2000] FCA 37; *Advanced Building Systems v Ramset Fasteners* [2001] FCA 1098; *Welcome Real-Time SA v Catuity Inc* [2001] FCA 445; *Abbott Laboratories v Corbridge Group* [2001] FCA 810; *E I Dupont de Nemours v ICI PLC* [2002] FCA 230; *Merck Inc v Arrow Pharmaceuticals* [2003] FCA 1344; *Novartis AG v Bausch Lomb (Australia)* [2004] FCA 835; *Eli Lilly v Pfizer* [2005] FCA 67; *Hexal Australia v Roche Therapeutics* [2005] FCA 1218; *Ranbaxy Australia v Warner-Lambert* [2006] FCA 1787; *Pharmacia Italia SpA v Mayne Pharma* [2006] FCA 305; *Conor Medsystems v University of British Columbia* [2006] FCA 32; *Roche Therapeutics v GenRx* [2007] FCA 83; *CSR Limited v Rockwool International A/S* [2007] FCA 1258; *Alphapharm v H Lundbeck A/S* [2008] FCA 55; *Alphapharm v Wyeth* [2009] FCA 945; *Apotex v Les Laboratoires Servier* [2009] FCA 1019; and, *Medrad Inc v Alpine Medical* [2009] FCA 949.

A consequence, advises Prof Drahos, is that “relying on courts to reform the [Australian] patent system is fairly futile.”²⁴¹

Patent Law Reform

IPAC Report, 1984

The *Patents Act, 1990* was the product of a detailed review of Australia’s patent system conducted between 1979 and 1984 by the Industrial Property Advisory Committee (IPAC). The review was ordered in August 1979 by the then Minister for Productivity, the Hon Ian Macphee. According to Mr John Stonier, IPAC’s chairperson, it was the “first review of the Australian patent system from a predominantly economic perspective” and involved “over 40 formal meetings of the Committee”.²⁴²

The Committee comprised:

Mr John Stonier (chairperson), Manager of Patenting & Licensing, BHP Co Ltd.

Mr P A Smith (deputy chairperson), from 31 May 1984, Commissioner of Patents .

Mr F J Smith (deputy chairperson), until 19 January 1984, Commissioner of Patents.

Mr P A Grant (member), Officer-in-Charge, Commercial Group, CSIRO.

Prof D M Lamberton, Department of Economics, The University of Queensland.

Mr T F C Lawrence, Controller-General, Department of Productivity.

Mr D J Ryan, Patent Attorney, Davies & Collison.

Mr F J Smith, from 20 January 1984, Solicitor, Baker & McKenzie.

Mr D A Walsh, Solicitor, Mallesons.

The IPAC Report entitled *Patents, Innovation and Competition in Australia* was presented to the Hon Mr Barry Jones MP, Minister for Science and Technology, on 29 August 1984. On 1 June 1989 the *Patents Bill, 1989* was read a second time on the motion by the Hon Mr Jones MP, Minister for Science, Customs and Small Business. During his speech in support of the motion he made the following remarks:

1. The proposed patent law was a “complete redraft” of the patent legislation it “repeals and replaces”. It was “not merely a redraft” but “a thorough overhaul of the Patents Act with all its complexities”;
2. The proposed patent law had two main thrusts:
 - (a) to “implement a number of policy changes flowing from an expert report reviewing the Australian patent system from an economic perspective”, and
 - (b) to “bring the language and structure of the Act down to earth, so that mere mortals without law degrees have some chance of understanding what it is all about”;
3. The IPAC Report “contained a brief statement by economics professor Don Lamberston, dissenting from the majority’s findings on a number of issues” and that together with colleagues “Tom Mandeville and Jean Bishop from the University of Queensland ... had prepared a separate report [called] Economic Effects of the Australian Patent System ... [in which] they concluded that the economic costs of the patent system probably exceeded its benefits, but only after first acknowledging that the question was ‘ultimately a matter of judgment’”;
4. After the Government’s response to the IPAC Report was tabled in Parliament on 28 November 1986, the public was invited to comment;
5. Consistent with the “policy approach” which is to “optimise the net benefits arising from the operation of the patent system in the national interest to the extent possible consistent with international conventions ... we should seek to modify the Australian patent laws, adjusting the length, strength and breadth of patent rights so as to maximise the social benefits and to minimise the social costs to Australians”;
6. The proposed law “will make it harder to get a 16-year standard patent”.

In 1991 the *Patents Act, 1990* came into effect. While it did not include a provision to explain its objectives, the second reading speech (particularly points 2 and 5 above) indicate that the key objectives were economic and social:

- to optimise the net economic benefits for Australia consistent with international conventions; and
- to maximise the social benefits and minimise the social costs to Australians.

²⁴¹ Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009 at CA 16.

²⁴² Letter from Mr Stonier to The Hon Barry Jones, Minister for Science and Technology, 29 August 1984.

In short, the Australian Government recognised that these key objectives would not be met unless it was “harder to get a ... patent”.

The *Patents Act, 1990* was subsequently amended.

The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994

The first significant amendments, in 1994,²⁴³ were the result of Australia agreeing to join the World Trade Organization (WTO) on 1 January 1995. These were made necessary as a result of The Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS), one of the three international agreements mandatory for membership of the WTO. The most significant change required by TRIPS was that the standard patent term be extended from 16 years to 20 years.

IPCRC Report, 2000

The second significant amendments, in 2000²⁴⁴ and 2001,²⁴⁵ were the result of recommendations made by the Intellectual Property and Competition Review Committee (IPCRC) in its final report entitled *Review of Intellectual Property Legislation under the Competition Principles Agreement* and presented to the Hon Daryl Williams AM QC MP, the Attorney-General, and Senator the Hon Nicholas Minchin, Minister for Industry, Science and Resources in September 2000. The Australian Government did not, however, accept all of its recommendations.²⁴⁶

The IPCRC comprised:

Prof Henry Ergas (chairperson), Managing Director, The Network Economics Consulting Group Pty Ltd;

Prof Jill McKeough, Head of School, Faculty of Law, The University of New South Wales;

Mr John Stonier, Company Director and Consultant; and

Mr Andrew Bain (special advisor), Company Director of Natural Resources Consulting Pty Ltd.

The IPCRC was the second economic review of the patent system, but it was much broader than the first, the IPAC review, in that the scope of its inquiry included other forms of intellectual property.

Its terms of reference were:

- a. the determination, in the Competition Principles Agreement that legislation which restricts competition should be retained only if the benefits to the community as a whole outweigh the costs, and if the objectives of the legislation can only be achieved by restricting competition;
- b. the intentions and policies of the Government as expressed in statements made or authorised by responsible Ministers in relation to the legislation referred to in (1)(a), including amendments approved and announced but not yet enacted;
- c. the obligations under international treaties that relate to the subject matter of the legislation referred to in (1)(a) and of which Australia is a member country or may become a member country;
- d. the conclusions and recommendations in recent reviews affecting the legislation referred to in (1)(a) that have not yet been responded to by the Government, including, but not limited to:
 - i. the report of the National Competition Council entitled *Review of sections 51(2) and 51(3) of the Trade Practices Act 1974*;
 - ii. the report of the Copyright Law Review Committee entitled *Simplification of the Copyright Act 1968*;
- e. the views conveyed to it by any current review affecting the legislation referred to in (1)(a).

The IPCRC Report made a number of important observations about the “tension” between intellectual property policy and competition policy:

1. The “tensions arise because there is a cost to granting intellectual property rights”;
2. Intellectual property rights can be used by their holders to “unduly restrict the diffusion and use” of the results of creative effort;

²⁴³ *Patents (World Trade Organization Amendments) Act 1994*.

²⁴⁴ *Patents Amendment (Innovation Patents) Act 2000*.

²⁴⁵ *Patents Amendment Act 2001*.

²⁴⁶ See Budget Estimates 2004-2005 Attachment 1 to Answers to Questions by Senator Kim Carr, Hansard 31/5/04, Pages 125-126 (http://wopared.aph.gov.au/senate/committee/economics_ctte/estimates/bud_0405/industry/itr15.pdf).

3. Intellectual property right holders “almost always do charge some positive price” and consequently “the consumption of the existing output of investment in creative effort falls below that which, in the short term, would maximise social income”;
4. When intellectual property rights confer “monopoly power”, the right holders can use these rights to “further restrict diffusion below the level that maximises society’s gain from the stock of knowledge” which the subject of that right contributes to;
5. “Balancing between providing incentives to invest in innovation on the one hand, and for efficient diffusion of innovation on the other, is a central, perhaps crucial, element in the design of intellectual property laws”;
6. “It must also be recognised that the rights granted by intellectual property laws can be used for anti-competitive ends”; and
7. Thus, “Intellectual property rights should not therefore provide blanket immunity from the competition laws. Rather, the community’s interest in competitive markets needs to be protected by ensuring that abuse of those rights is prevented”.²⁴⁷

Specifically with regard to patents the IPCRC made four significant findings:

1. That the “inventive step” threshold of patentability was so low that it was “likely to lead to patents being granted too readily, imposing unnecessary costs on the Australian economy”. It recommended that the test for inventive step be raised so that it was “in line with that adopted by our major trading partners”;²⁴⁸
2. That “patenting gene sequences” was a “controversial area” with respect to which it “strongly” believed that “mere discoveries should continue to be excluded from patentable subject matter”. It recommended that “the Patent Office help ensure this outcome by requiring that granted patents disclose specific, substantial and credible uses” of gene sequences;
3. That “having appropriately high tests for patentability is not enough to ensure that the benefits to society of granted patents outweigh their costs”; and
4. That the quality of patent examination was too low. To remedy the situation, “rigorous examination” of patents was required to “help ensure that granted patents are strong and hence ultimately enforceable”. It recommended (a) that a higher burden of proof be placed on patent applicants and (b) that patent applicants have a “greater responsibility to disclose any prior art known to them up and until acceptance”.

Although it made no specific recommendations on the issue of discovery versus invention the IPCRC took the view that this was an important distinction, closely related to the central goals of patent policy:

Property rights in discoveries would therefore be costly to define and implement and could give rise to unreasonable barriers to potential competitors or to those who wished to use the ‘discovery’ in other fields of endeavour. It may also add very significant burdens on scientific communication.²⁴⁹

Australia and United States Free Trade Agreement, 2004

The third significant amendments, in 2004,²⁵⁰ were the result of the successful negotiation of a free trade agreement between Australia and the United States of America (AUSFTA).

Impact of TRIPS and AUSFTA on the ‘manner of new manufacture’ threshold of patentability

Australia’s accession to the WTO in 1995 and the signing in 2004 of the AUSFTA are important in the context of this inquiry. These international developments imposed obligations on Australia that did not exist when the *Patents Act, 1990* came into force in 1991.

Having reviewed the history of the legislation amending the Patents Act, 1990 and TRIPS and the AUSFTA I urge the Committee to adopt the view that the current ‘manner of manufacture’ threshold is consistent with Australia’s international obligations for the following reasons:

1. Neither the Patents (World Trade Organization Amendments) Act 1994 nor the US Free Trade Agreement Implementation Act 2004 amended the ‘manner of manufacture’ threshold specified in s.18(1)(a) or amended the definition of ‘invention’ in Schedule 1, *Patents Act, 1990*;

²⁴⁷ IPCRC Final Report, Review of Intellectual Property Legislation under the Competition Principles Agreement, pp 6-7.

²⁴⁸ Ibid at p 10.

²⁴⁹ Ibid at p 152.

²⁵⁰ US Free Trade Agreement Implementation Act 2004

2. The IPCRC Report specifically examined the 'manner of manufacture' threshold during its deliberations in 1999-2000 and recommended that the threshold be retained without amendment. The IPCRC concluded that "Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test" and the Australian Government accepted this recommendation without qualification;
3. Specifically, both article 27.1 TRIPS and clause 17.9.1 AUSFTA provide that patents be available for "any invention(s) ... in all fields of technology" provided that the invention is "new", involves an "inventive step", and is capable of or susceptible to "industrial application". In the Parliamentary Library Service's Current Issues Brief No 3 2004-5 entitled *Guide to copyright and patent law changes in the US Free Trade Agreement Implementation Bill 2004*²⁵¹ its author, Jacob Varghese, observed:

The drafters of the Bill seem to have felt that the current law already reflects the 'all fields of technology' element. This is an appropriate view, as that element is substantively congruent to Australia's 'manner of manufacture' test, as expressed, for example, in *CCOM v Jeijing*. Certainly, Australia has not received any complaint that its law on patentability does not comply with the TRIPs requirements, which uses very similar terms to AUSTFA including the phrase 'all fields of technology'.²⁵²

4. No complaint has been made by the United States Government to the Australian Government that the 'manner of manufacture' threshold contravenes the AUSFTA..

A number of submissions²⁵³ to this inquiry suggest that Australia's compliance with TRIPS and the AUSFTA would be compromised by an amendment to the *Patents Act, 1990*, which has the effect of limiting, restricting or prohibiting the patenting of biological materials that are identical or substantially identical to those that exist in nature. However, such an amendment would be consistent in principle with the 'manner of manufacture' threshold already supported by TRIPS and the AUSFTA, while clarifying a point of contention at the core of this debate: that the identification of a biological material derived (and thereby isolated) from a natural source (such as a human being) and the extraction of its protein sequence and the genetic sequence of the gene or genome which codes for that biological material is a 'mere discovery'.

I ask the Committee to note (a) that both TRIPS and the AUSFTA expressly require patents to be granted only for innovations that meet the threshold of 'invention' (as with TRIPS the word is not defined in the AUSFTA) and (b) that the patent laws of the United States and member countries of the European Patent Convention (EPC) contain provisions that are consistent with TRIPS and which contain thresholds on what is an 'invention' or patentable subject matter. The Committee has not been made aware of any suggestion that either the US patent law or the patent laws of member countries to the EPC do not comply with TRIPS.

The Committee has been advised that article 52(2) EPC expressly excludes from being 'inventions' any of the following things:

- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.

Accordingly, under the EPC's scheme of patentability something that is a discovery is not an 'invention' and therefore unpatentable.

I have already referred the Committee in Part 2 to the fundamental principle of US patent law that "excludes from patent protection ... laws of nature, natural phenomena and abstract ideas", which US law professors Joshua Sarnoff, Jonathon Kahn and Lori Andrews advised the Committee has been consistently upheld "over the past 150 years".²⁵⁴

The Committee has been further advised that the IPCRC, in final report, written five years after Australia joined the WTO, expressed a strong belief that "mere discoveries should continue to be *excluded* from patentable subject matter" (emphasis added).

²⁵¹ <http://www.aph.gov.au/library/Pubs/cib/2004-05/05cib03.pdf>

²⁵² *Ibid*, p 35.

²⁵³ ALRC (Submission 18), Department of Innovation Industry, Science and research and IP Australia (Submission 19), Medicines Australia (Submission 21), Davies Collison Cave (Submission 27), Institute of Patent and Trade Mark Attorneys of Australia (Submission 31), Pfizer Australia (Submission 51), Intellectual Property Committee of the Business Law Section of the Law Council of Australia (Submission 57), Chartered Institute of Patent Attorney's (Submission 74) and AusBiotech (Submission 75).

²⁵⁴ US Law Profs Sarnoff, Kahn and Andrews (Submission 17) at p 2.

Summary

I urge the Committee's to accept, *if* (on the basis of scientific evidence) an isolated biological material *that is identical or substantially identical to one that exists in nature* is but a *mere* discovery, an amendment to the *Patents Act, 1990* which makes this clear (and therefore prohibit their patenting) would not contravene either TRIPS or the AUSFTA. On the basis of my reading of the evidence and on the flexible nature of the TRIPS and AUSFTA standards I urge the Committee to conclude that it is open to the Australian Parliament to clarify the existing 'manner of manufacture' threshold in s.18(1)(a) *Patents Act, 1990*.

The Australian Law Reform Inquiry into Gene Patents 2002-2004

The Australian Law Reform Commission (ALRC) has informed the Committee of the inquiry it conducted into gene patents between 2002 and 2004.²⁵⁵ The ALRC presented its final report, entitled *Genes and Ingenuity: Gene patenting and human health* (ALRC 99, 2004), to the Hon Philip Ruddock MP, Attorney-General, on 29 June 2004. It is a highly detailed report consisting of 794 pages and 55 recommendations, the most relevant in the context this inquiry, being recommendations 6-1, 6-2, 6-3 and 7-1:

6-1 Patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

6-2 The responsible Minister should initiate an independent review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be 'generally inconvenient'.

6-3 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to:

- (a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;
- (b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use;
- (c) require the Commissioner of Patents to be satisfied on the balance of probabilities that the requirement of 'usefulness' is made out in order to accept an application for a standard patent or to certify an innovation patent; and
- (d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation.

7-1 The Patents Act 1990 (Cth) should not be amended:

- (a) to exclude genetic materials and technologies from patentable subject matter;
- (b) to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter; or
- (c) to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.

Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.

In contrast to IPAC's report in 1984 and IPCRC's report in 2000 which found the 'manner of manufacture' threshold satisfactory and relevant, the ALRC's report concluded there were "problems with the test".²⁵⁶ These had become "apparent during the course" of its inquiry.²⁵⁷ According to the ALRC "the key concept of 'manner of manufacture'" was based upon "a 380 year old English statute that has long since been repealed in the jurisdiction in which it was enacted"²⁵⁸ and which used "terms" that are "ambiguous and obscure"²⁵⁹. Specifically, the ALRC found that the term 'generally inconvenient'²⁶⁰ problematic because "Australian courts and IP Australia have been reluctant to rely on this proviso to deny patent protection to

²⁵⁵ ALRC (Submission 18).

²⁵⁶ ALRC Report 99, 2004 para 6.54.

²⁵⁷ Ibid.

²⁵⁸ Ibid, para 6.55.

²⁵⁹ Ibid, para 6.56.

²⁶⁰ The term appears in the proviso contained in s.6 of the Statute of Monopolies. See footnote 5.

particular inventions”²⁶¹, and that the “usefulness requirement” which it said “is an aspect of the manner of manufacture test” was “unclear”.²⁶²

The ALRC believed that gene patents had highlighted these particular problems. However, rather than addressing these in the *Patents Act, 1990*, the ALRC recommended that either the Intellectual Property Research Institute of Australia (IPRIA), or the Advisor Council on Intellectual Property (ACIP)²⁶³ undertake “an in-depth analysis of the way in which the manner of manufacture test has been applied to a broad range of inventions—not merely those involving genetic materials and technologies—and require consultations with a more diverse group of stakeholders”.²⁶⁴

However, I ask the Committee to note that the ALRC’s perspective is controversial even within its own ranks. Dr Vivien Santer, a member of the ALRC’s Advisory Committee, believes that the ALRC “did not present any real evidence that [the ‘manner of manufacture’ threshold] had in fact caused significant confusion to patent applicants or practitioners, or had resulted in other detriment”.²⁶⁵ Dr Santer has also countered the suggestion that it was redundant. In her opinion:

The test is well understood by patent attorneys, legal practitioners, the Patent Office and the courts, and the landmark NRDC decision ... is internationally known and respected. To introduce any new test would introduce great uncertainty which could not be resolved until at least one test case had been litigated, possibly up to the High Court. Such uncertainty would increase costs and would be greatly unfavorable to innovation.

She also states:

In my more than 23 years of professional practice as a patent attorney I have never had any difficulty in interpreting the manner of manufacture test and applying it to the cases I have dealt with. This is despite the fact that my practice has been in the field of biotechnology, which is at the cutting edge of scientific development and could be regarded as posing particular problems in assessing patentability.

ACIP Inquiry into patentable subject matter

Prof Andrew Christie’s submission²⁶⁶ included advice about ACIP’s review of the current ‘manner of manufacture’ threshold.²⁶⁷ Prof Christie, from the University of Melbourne, is a former director of IPRIA and chair of the ACIP review into the ‘manner of manufacture’ threshold, and an expert in patent law.

He advised the Committee that the Australian government had “failed to act on the recommendations” made by the ALRC in its report into gene patents “with the consequence that a range of stakeholders are rightly concerned about the way in which Australian patent law currently applies to genetic inventions”.²⁶⁸ He also spoke of “his hope” that the Inquiry “will ensure that those actions that should have been taken by the legislature in response to past inquiries will be taken as soon as possible”.²⁶⁹

While evidence presented shows that the Australian government did not respond to most of the ALRC’s recommendations for gene patent reform, recommendation 6.2 – “an independent review of the appropriateness and adequacy of the ‘manner of manufacture’ test as the threshold requirement for patentable subject matter” – is to some extent being addressed through an ongoing ACIP review of patentable subject matter.

Prof Christie explained to us that “the test for invention or patentable subject matter plays two roles. It plays the economic role and it plays the non-economic role - the social and moral role”²⁷⁰ and gave a brief description of the four options currently under consideration:

1. Do nothing and keep the ‘manner of manufacture’ threshold as it is presently worded. He would be “surprised” if this option was accepted but nonetheless it had to be recognised as “an option”;²⁷¹

²⁶¹ Op cit 255.

²⁶² Ibid.

²⁶³ Ibid, para 6.58.

²⁶⁴ Ibid, para 6.57.

²⁶⁵ Dr Vivien Santer (Submission to ACIP Review of Patentable Subject Matter, 17 September 2008).

²⁶⁶ Prof Andrew Christie (Submission 38).

²⁶⁷ Ibid, p 3 at para 2.2.

²⁶⁸ Ibid, pp 3-4 at para 2.3.

²⁶⁹ Ibid, p 4 at para 2.3.

²⁷⁰ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009, CA 69.

²⁷¹ Ibid.

2. "Clarify the language" of the test so as to "re-express the same concept" which is "most supported ... from the High Court's decision in the case of the National Research and Development Corporation";²⁷²
3. Replace "the test and do something that may result in our economic tests being done better";²⁷³ and
4. "Have no test whatsoever economically so that all the work done economically is done by novelty, inventive step and utility".²⁷⁴

Summary

In view of the evidence, I urge the Committee to conclude that whatever ACIP recommends regarding the 'manner of manufacture' threshold, Australian patent law must not permit the grant of patent monopolies over innovations that are not 'inventions'. The Committee should therefore be concerned by option 4, which implies that the appropriate threshold of invention would solely be achieved by the patentability thresholds of novelty, inventive step and industrial applicability. This contradicts the scheme of patentability provided by the EPC and US patent law and may, on the basis of the evidence, contravene the 'invention' threshold mandated by both TRIPS (article 27.1) and AUSFTA (clause 17.9.1).

'Invention' in the UK under s.1 *Patents Act, 1977 UK* (prior to the European Biotech Directive, 1998)

The Committee was advised²⁷⁵ that in *Genentech Inc's Patent* [1989] RPC 147 the UK Court of Appeal had cause to consider whether isolated human tissue plasminogen activator (t-PA), a protein produced in humans in very small amounts, was an 'invention' under s. 1 *Patents Act, 1977 (UK)* (as it applied prior to the European Biotechnology Directive²⁷⁶). The UK Court of Appeal held that it was not.

Given that this case is analogous with the current Australian inquiry into gene patents yet was resolved 20 years ago, I bring to the the Committee's attention, in full, the instructive findings of Lord Justice Mustill (as he was then) particularly in view of ACIP's option 4:

This suggestion of a need to identify the invention leads me to a part of the case which I found most perplexing. Most of the arguments have been concentrated on the three conditions precedent to the grant of a patent set out in paragraphs (a) to (c) of section 1(1) - and understandably so, given the shape of the old law. But this approach tends to mask a more fundamental requirement which must be satisfied before a patent can properly be granted, namely that the applicant has made an "invention".

In my judgment, this requirement emerges clearly from the opening words of section 1(1):

"A patent may be granted only for an invention in respect of which the following conditions are satisfied . . .".

Compliance with these four conditions turns an invention into a "patentable invention" (see the concluding words of section 1(1)).

Section 1(2) then goes on to exclude certain matters from the scope of "invention" -- not "patentable invention". To my mind this shows that question whether the claim discloses anything which can be described as an invention must be answered in the affirmative before compliance with paragraphs (a) to (d) becomes relevant: and the wording of Article 52 in all three languages is even more plainly to the same effect.

I am fortified in this view by the Guidelines for Examination in the EPO which, in paragraph 1.1 of Chapter IV, say:

"There are four basic requirements for patentability:

1. There must be an 'invention'.
2. The invention must be 'susceptible of industrial application'.

²⁷² Ibid.

²⁷³ Ibid.

²⁷⁴ Ibid.

²⁷⁵ Dr Luigi Palombi (Submission 4).

²⁷⁶ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions. Official Journal L 213, July 30, 1998, 13 - 21. The Directive came into force in all EPC member countries on 1 July 2000 and expressly provides in article 5.2: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." The Directive effectively overturns the decision in *Genentech Inc's Patent*.

3. The invention must be 'new'.
4. The invention must involve an 'inventive step'."

In paragraph 2.2 the Guidelines go on to point out that:

"It must also be borne in mind that the basic test of whether there is an invention within the meaning of Article 52(1) is separate and distinct from the questions whether the subject-matter is susceptible of industrial application, is new and involves an inventive step."

It might, at first sight, seem that this adds a wholly unnecessary complication, where paragraphs (a) to (c) do all that is necessary to define the permissible subject matter of the monopoly, and that it is absurd to speak of an invention which does not involve an inventive step -- as one must be ready to do, if the interpretation just suggested is sound. But this is not so, as the example of an amateur experimenter working alone will demonstrate. It must quite often happen that such a person will, through the exercise of imagination and ingenuity devise a useful product or process. By doing so, he will, in a real sense, have made an invention. But it will also quite often happen that, although he does not know it the same device may already have been invented and published by someone else: so that the experimenter's invention, though real enough, is not patentable, for want of novelty.

Also, although it may seem paradoxical, his invention may also fail as a patent, on the ground that it involves no inventive step: for the latter concept is artificial, in that it relates the "step" to the objectively prior art, rather than to the actual knowledge of the inventor before he takes that step. The inventor may have made what for him is a giant leap, and yet find that through prior art of which he was unaware, his invention must be treated as obvious.

Thus, although the objection to a patent on the ground that it monopolises something which is not an invention will very often overlap another potential objection -- and such an element of overlapping is nothing new in patent law -- it is none the less a separate element which, in the appropriate case, ought to be separately investigated.²⁷⁷

The ALRC Report's Recommendations

A number of submissions²⁷⁸ have urged the Committee to support the ALRC's recommendations. However, in view of evidence that only one of the ALRC's many recommendations has drawn a government response in six years, I urge the Committee to form the view that a different approach to reforming gene patent policy is required. Moreover, adoption of the ALRC recommendations would not have prevented the incident that triggered this inquiry: a (second) commercial attempt by Genetic Technologies Limited (GTL) to monopolise genetic tests for breast and ovarian cancer risk that are currently available in Australian public laboratories.²⁷⁹

As we have already mentioned in Part 1, the threat of patent litigation from the same company in 2002 was also the trigger for the Attorney General to instruct the ALRC to conduct its inquiry into gene patent policy. In 2003, as in 2008, GTL withdrew its claim -- on the pretext that public use of the BRCA1 and BRCA2 patents (for which the company was Australian licensee, not owner) was a "gift to Australia". Only the company's voluntary decision to withdraw the patent enforcement claims, on both occasions, enabled the tests for the BRCA1 and BRCA2 genes to remain in public hands. The absence of any legal protection puts Australian researchers, clinicians and patients at serious risk of being placed in a difficult situation -- and one that could recur at any time and could also apply to other a wide range of other medical applications.

Despite two threats to public tests for BRCA1 and BRCA2 genes over the past decade, it is evident that the ALRC remains as convinced today as it was in 2004 that the problems created by gene patents are "yesterday's battle".²⁸⁰ Prof Weisbrot, the ALRC's President, advised the Committee that "many or most of the problems caused by patents granted over gene sequences, or overly broad patents ... by overwhelmed Patent Offices around the world in the 1980s and early 1990s [are] ... coming towards their end (if they have not already been invalidated for other reasons) ... [and therefore] are transient ones."²⁸¹ While the ALRC acknowledged that there were "attractive arguments for the view that [naturally occurring biological materials] should not have been treated as patentable subject matter", it concluded that "the time for taking this approach ...

²⁷⁷ Genentech Inc's Patent [1989] RPC 147 at 262.

²⁷⁸ ALRC (Submission 18), Department of Innovation Industry, Science and research and IP Australia (Submission 19), Prof Dianne Nicol and Dr Jane Nielsen (Submission 23), Davies Collison Cave (Submission 27), Institute of Patent and Trade Mark Attorneys of Australia (Submission 31), Intellectual Property Committee of the Business Law Section of the Law Council of Australia (Submission 57); Victorian Government (Submission 61); Department of Health and Ageing (Submission 62).

²⁷⁹ Speech by Senator Heffernan, Hansard, Senate, 12 November 2008, pp 49-51 at p 50 Col 1.

²⁸⁰ ALRC (Submission 18)

²⁸¹ ALRC (Submission 18) at p 4.

has long since passed".²⁸² Prof Weisbrot's comments are consistent with those of a number of others individuals and agencies contributing to this inquiry – Pfizer Australia, Mr Trevor Davies, Counsellor for the Institute of Patent and Trade Mark Attorneys of Australia, Mrs Fatima Beattie, the Commissioner of Patents, Mr John Slattery, Consultant to Davies Collison Cave and Dr Chris Dent, Researcher.

Gene patents are not a transient problem

The ALRC's position was not supported by independent cancer and genetic scientists, including Cancer Council Australia Chief Executive Officer, Prof Ian Olver (a medical oncologist, researcher and bioethicist),²⁸³ who advised that, rather than yesterday's battle, "genes and their products are increasingly going to be the targets of new treatments". He told us: "We are going to see hundreds more of these [gene-based therapies] over the next decade, so a change now would protect us before the floodgates open." The concern about risks to the future of genetic technology was further supported by independent medical organisations, such as the Human Genetics Society of Australasia²⁸⁴ and the Royal College of Pathologists of Australasia,²⁸⁵ who also advised that genetic technology for diagnostics and treatment is in its infancy, therefore patent law reform is urgently required to reflect rapid technological changes and prevent a situation where retrospective action becomes impossible.

We also heard from Prof Bowtell at the PMCC who said:

... in the last issue *Nature Genetics*, which is probably the leading genetics journal in the world, there was a slew of papers about new genes that have been found using what are known as genome-wide association studies. ... We are coming into an era where lots of genes are actually being identified that work in concert to actually cause an outcome, like the risk of developing breast cancer, diabetes, stroke or something like that. If the patents for each of those genes are held by different companies then it is going to be extremely difficult to assemble a practical test to test for a particular condition.²⁸⁶

The following exchange between Senator Heffernan and Prof Bowtell corroborates the evidence of Prof Olver:

Senator HEFFERNAN—We received evidence earlier from some people—probably lawyers, I cannot remember—that this is not an issue because we are coming to the end of it and there is only a few of these things out there. But we are actually at the start of the journey not the end of the journey.

Prof. Bowtell—Absolutely. It is not going like this; it is going like this. The genes that we found in the first place were the easy mutations. These were the things that had a devastating impact and it was easy to see the track through a family. Those are the minority of people who develop disease. For the rest of us, it is the multiple genes. It is more like being dealt a hand of cards rather than being dealt a joker. That is for the majority of us.

We are just now, because the technology has changed, starting to find all these more common lower risk genes that work in concert and very much in relationship to the environment. With some of these genes, like Huntington's disease, it does not really matter what you do it is completely penetrant; that is, you will develop Huntington's disease if you carry that mutation.

For many of these other diseases, whether you develop breast cancer, cardio-vascular disease or Alzheimer's, it is probably very heavily influenced by the hand that you are dealt and the environment that you live in. That is the kind of thing that we have to prepare for. The number of genes that are important are increasing enormously.²⁸⁷

Summary

Throughout this inquiry, submitting agencies and individuals have tended to fall into one of two opposing camps: patent attorney and industry groups that reject the need for legislative (or any other significant) reform; and independent, not-for-profit clinician and patient groups concerned about short and long-term threats to the public interest if protection from gene patent monopolies is not mandated.

While the ALRC and the IP legal professions believe that gene patents are "yesterday's battle" this appears to be a predominantly legal perspective and one which is out of step with the prevailing views of independent clinician and patient groups

²⁸² ALRC Report 99, 2004 paras 6.51 and 6.52.

²⁸³ Hansard, Senate Community Affairs References Committee, Wednesday 5 August 2009 at CA 1.

²⁸⁴ Submission 33.

²⁸⁵ Submission 49.

²⁸⁶ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 117.

²⁸⁷ Ibid at p 118.

involved in genetic medicine and participating in this inquiry. It is also not supported, in my opinion, by the evidence presented to this Committee.

Arguably the most compelling pragmatic evidence in the context of these diverse views was the experience of Genetic Technologies Limited twice attempting to monopolise tests for BRCA1 and BRCA2 gene mutations by enforcing its Australian licence for the patents – which, under current arrangements, the company was able to pursue, despite the risks of reduced public access to the tests. This is a major concern and challenges the view that the current framework provides adequate protection.

Therefore I urge the Committee to support the need to find a workable, effective and permanent legislative solution to the problems caused by gene patents and one which, as IPCRC stated in its final report, balances the “tensions” between patent monopolies on one hand and competition policy on the other²⁸⁸ and which takes into account the social and moral dimension for Australia and its people.

Patent Policy in Australia

The Committee should understand that patentable subject matter or ‘invention’ is a prerequisite to the grant of a valid patent monopoly in Australia and that currently this prerequisite is defined by the ‘manner of manufacture’ threshold as explained by the High Court of Australia in *National Research Development Corporation v The Commissioner of Patents* (1959) 102 CLR 252 (NRDC).

The Committee should note the evidence from Prof Christie:

[T]he test for invention or patentable subject matter plays two roles. It plays the economic role and it plays the non-economic—the social and moral role.²⁸⁹

The Committee should understand that the genesis of the modern Anglo-American patent system is s.6 of the Statute of Monopolies, 1623.²⁹⁰ The words in s.1²⁹¹ of the Statute of Monopolies was the legislative recognition made nearly 400 years ago by the English parliament of an economic policy, and one that is still embraced today in the market-based economic system to which Australia belongs, namely that competition leads to market efficiencies.²⁹²

The exception to s.1 provided by s.6 is therefore critical to the balance required by the economic policy, as a patent monopoly is only granted to the extent that the threshold of ‘manner of manufacture’ (or ‘invention’ to use another word) is satisfied. As Prof Christie has confirmed, it has both an economic and a social/moral dimension. Therefore, only if the product of human ingenuity satisfies the ‘invention’ threshold in all respects and meets all other legislative requirements provided in the *Patents Act, 1990*, is a patent monopoly consistent with the general thrust of the policy. This, the Committee should understand, is what the IPCRC meant when it referred to the need to resolve the “tensions” between patent monopolies on the one hand and competition policy on the other.²⁹³

The report by the committee recently reviewing Australia’s National Innovation System emphasised that patent policy is fundamentally economic policy: “intellectual property policy is most fundamentally an aspect of economic policy.”²⁹⁴ In her submission to the Committee Dr Hazel Moir, suggested there has been such a reliance by successive Australian governments on the advice of intellectual property lawyers, patent attorneys and patent bureaucrats has led to patent policy being developed through “a legal rather than economic perspective”.²⁹⁵ The Venturous Australia Report also noted this and commented

²⁸⁸ IPCRC Final Report, Review of Intellectual Property Legislation under the Competition Principles Agreement, p 6.

²⁸⁹ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009, CA 67.

²⁹⁰ Luigi Palombi, *Gene Cartels: Biotech Patents in the Age of Free Trade*, (Edward Elgar, Cheltenham UK, Northampton, MA, USA, 2009) pp 8-16.

²⁹¹ “All monopolies and all commissions, grants, licenses, charters and letters patent theretofore made or granted or heretofore to be made or granted to any person or persons, bodies politic or corporate whatsoever, of or for the sole buying, selling, making or using of anything within this realm ... utterly void and of none effect.”

²⁹² *Patents Act, 1903*, *Patents Act, 1952* and *Patents Act, 1990* all incorporate reference to s.6 of the Statute of Monopolies, 1623.

²⁹³ “A fundamental principle in economic policy is that markets are efficient distributed allocative mechanisms. It is therefore better not to intervene in markets unless it can be clearly demonstrated that the benefits of doing so exceed the costs. This principle has been adopted, following the Hilmer review, into the Competition Principles Agreement between the Commonwealth and State and Territory Governments. This agreed policy—that a demonstrated case should be made for market intervention—also has the benefit of ensuring that public policy does not inadvertently favour narrow sectional interests.” Dr Hazel Moir (Submission 20) p 1. See also pp 5-9.

²⁹⁴ Venturous Australia Report - building strength in innovation at p.85 (<http://www.innovation.gov.au/innovationreview/Documents/NIS-review-web.pdf>).

²⁹⁵ *Ibid*.

that "IP policy [should] make the transition that competition policy made over a decade ago now, from a specialist policy area dominated by lawyers, to an important front of micro-economic reform."²⁹⁶ I urge the Committee to accept that there is considerable substance in this viewpoint. There is evidence that the membership of committees that have reviewed Australia's patent law are drawn strongly from the patent community.

This view is borne out of evidence, as follows.

The IPAC review of patents [1984]: Of the eight persons to serve on IPAC only one, Prof Lamberton, from the University of Queensland, was an economist. Six were patent lawyers, patent attorneys, patent executives or patent bureaucrats and Mr Lawrence was an engineer by qualification. Of these, Mr Desmond Ryan was a partner of the firm Davies Collison (now Davies Collison Cave), Mr FRanks Smith, the former Commissioner of Patents, was a member of the international law firm Baker & McKenzie and Mr David Walsh was a partner of the law firm Mallesons. Mr Stonier was then an employee of BHP, but subsequently became associated with the patent attorney firm Davies Collison. With regard to the IPAC report, Dr Moir directed the Committee to a relevant fact. Dr Moir stated:

While the IPAC report was billed as an economic assessment of Australia's patent system, the sole economist on the panel lodged a dissenting report, stating that "[t]his report does not live up to its claim to have adopted an economic perspective and to have applied economic criteria. ... It is constrained by the very 'haze of assumptions about rights and rewards for inventors, special pleading by those directly involved, and a plethora of legal procedures and criteria in the Patents Act' that it deplors." (IPAC 1984: 79-80) ²⁹⁷.

The IPCRC review of intellectual property and competition [2000]: Of the three persons to serve on IPCRC, only Dr Ergas was an economist. Prof McKeough and Mr Stonier were intellectual property lawyers.

The ALRC review of gene patents [2004]: The ALRC established a special advisory board to assist it in its inquiry into gene patents. Of the 23 members, nine were legally trained. The others were either scientists, administrators or academics. In other words almost 40% of the membership was made up of lawyers and patent attorneys. It was also brought to the attention of the Committee that the lawyers and patent attorneys were from larger law firms, firms that would often represent multinational clients seeking patents in Australia, including gene patents.²⁹⁸ Indeed, some had acted for Amgen and Chiron in legal proceedings which objected to or challenged the validity of Australian Patent Monopolies 600650 and 624105.

The ACIP review of patentable subject matter [current]: The chair of this review is Prof Andrew Christie, who is associated with patent attorney firm Davies Collison Cave. The current chair of ACIP, however, is Mr Leon Allen, a partner of Davies Collison Cave. Of the remaining eleven members Mr Adam Liberman and Mr Philip Mendes are lawyers, while Mr Michael Gilbert, Mr Graeme Huon, Dr Noel Chambers and Dr Tracie Ramsdale are employees or directors of organisations that have commercial interests in gene patents. This leaves Ass Prof Beth Webster, an economist and director of IPRIA and Prof Edwina Cornish, the Deputy Vice-Chancellor of Monash University.

Summary

This analysis shows that lawyers and patent attorneys have been disproportionately represented on the committees that have been established to reform the patent system. I urge the Committee to accept that this is a matter of concern. Patent law is expressly tied to public policy goals that demand a broad societal representation on key policy committees. As TRIPS makes clear WTO members can exclude from patentability inventions that threaten public order or morality, especially to protect human, animal or plant life or health or to avoid serious prejudice to the environment (See Article 27.2). Patent reform committees need a wide range of competencies in order to implement the public policy goals of the patent system. Scientific expertise of a public-regarding kind is critical to understanding the effects of the patent system. The evidence-based nature of any policy process is likely to be compromised or rendered incomplete if it is dominated by one group.²⁹⁹

²⁹⁶ Op cit 294.

²⁹⁷ Dr Hazel Moir (Submission 20) p 7.

²⁹⁸ As Dr Palombi advised, of the lawyers and patent attorneys, Dr Trevor Davies (a partner of Allens Arthur Robinson, a law firm which had acted for Chiron Corporation in proceedings to invalidate Australian Patent Monopoly 624105), Dr Bill Pickering (who acted for Chiron Corporation and drafted Australian Patent Monopoly 624,105 while being a partner of F B Rice & Co, a patent attorney firm), Dr Vivien Santer (a partner of the patent attorney firm Griffith Hack) and Mr John Stonier (a consultant with the patent attorney firm Davies Collison Cave). In fact Mr Stonier was the only person who had served on all three reviews. Justice Annabelle Bennett was also a member of the advisory board and although a Federal Court judge, had practised as a barrister almost exclusively in the field of intellectual property law and represented Amgen, Inc in proceedings concerning the validity of Australian Patent Monopoly 600650. Prof Andrew Christie, although an academic, was the inaugural holder of the Davies Collison Cave chair in intellectual property law at the University of Melbourne. Dr Palombi advised that he wrote to Prof Weisbrot at the time pointing out the possibility that these persons were not independent due to their association, or past association, with firms that had acted for companies that owned significant and important gene patents.

²⁹⁹ Prof Peter Drahos (Submission 60); Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009 at CA 14-15.

The Role of IP Australia and the Australian courts in developing patent policy

Prof Drahos advised the Committee that “relying on courts to reform the [Australian] patent system is fairly futile”.³⁰⁰ However, there is evidence that the Australian courts do participate in the reform of patent law when the opportunity arises. The question is: how effective are the courts in developing patent law that is consistent with meeting Australia’s economic and social/moral objectives?

I urge the Committee to accept that Australian courts have limited opportunities to participate in patent law reform, predominantly because few patents are litigated to the point of a court decision. Prof Drahos advised that, while in the United States fewer than 2% of patents are litigated³⁰¹, in Australia it was more likely to be fewer than 1%.³⁰² While there are a number of reasons for this, the outcome is that unless the courts get it right, the only mechanism for recourse, apart an appeals process, is the Federal Parliament.

As we have discovered in the course of this inquiry, the patent reform process is not only very slow, but it is also controlled by patent lawyers, patent attorneys and patent bureaucrats. Who dominates in the process is critical to this debate: the Committee was advised that, in the 20 or so years that IP Australia has been granting gene patents not once has an Australian court scrutinised the validity of a gene patent claim to ensure it meets the ‘manner of manufacture’ threshold. Thus the courts have not played a role in the development of patent policy with regard to this very important threshold. Consequently, IP Australia has continued to apply a policy that was developed in 1988 by the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Japanese Patent Office (JPO). The result is that some 15,000 patent monopolies over genes and proteins derived from human and non-human sources and the use of these biological materials³⁰³ have been granted in Australia over the past two decades.

This raises a key question in the context of this Inquiry: why, in an area of intense debate³⁰⁴ and with significant implications for the Australian economy, have the courts not played a role in clarifying patent law with respect to the patentability of isolated biological materials and their use?

A significant part of the answer lies in the fact that parties to patent litigation are free to decide what the contentious issues are between them. In patent litigation this can be quite complex because the validity of a patent monopoly is subject to challenge on any number of grounds³⁰⁵. One of these grounds can be “that the invention is not a patentable invention”³⁰⁶. This means that unless the ‘patentable invention’ meets all of the requirements of s.18 it must be revoked. As we know, s.18(1)(a) *Patents Act, 1990* is the provision which stipulates that a patentable invention must be a ‘manner of manufacture’. In the hypothetical case of a gene patent which contains a patent claim to a patentable invention defined as “an isolated human gene X” and another claim to “an purified protein Y coded for by human gene X” and which is challenged by a third party, if that party were to do so on the ground that these claims did not satisfy the ‘manner of manufacture’ threshold and succeeded, the court decision would establish a legally binding precedent that would guide IP Australia in the future. It would also have the effect of putting in doubt the validity of other patent monopolies that used the same formula to define a similar ‘invention’ to say gene A and protein B, which is the subject of another hypothetical patent monopoly. While the challenger and litigant in the patent litigation directly benefits, so does the Australian community because by effect of this court decision others will be forever free to use the information in the patent document and make the ‘invention’ freely, and the precedent it sets will be used by others in respect to other patent monopolies to determine the lawful boundaries of the scope of the monopoly.

However, as we have found, this is all a matter of chance. In the case of the hypothetical example we give, it has yet to happen in Australia. We have been advised and accept that to date no Australian court has handed down a decision regarding the ‘manner of manufacture’ threshold in the context of a gene patent claim to an isolated biological material that is identical or substantially identical to what exists in nature.

That said, both IP Australia³⁰⁷ and Dr Palombi³⁰⁸ brought *Kiren-Amgen Inc v Board of Regents of the University of Washington* [1995] EPOR 541 (*Kiren-Amgen*) to our attention. In this case, Mr David Herald, the Deputy Commissioner of Patents, in a patent opposition appeal ruled that two claims (claims 33 and 34) in a patent monopoly (Australian patent 600650) that defined the ‘invention’ as the genetic sequence of a human gene that codes for erythropoietin, a human hormone, was a

³⁰⁰ Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009 at CA16.

³⁰¹ Ibid.

³⁰² Ibid.

³⁰³ IP Australia (Submission 19).

³⁰⁴ The IPCRC Final Report at p. 10 refers to “the controversial area of patenting gene sequences”.

³⁰⁵ s.138(3) *Patents Act, 1990*.

³⁰⁶ s.138(3)(b) *Patents Act, 1990*.

³⁰⁷ IP Australia (Submission 19) p15 at para 4.16.

³⁰⁸ Dr Palombi (Submission 4, Part 2) pp 31-32.

patentable invention within the 'manner of manufacture' threshold. He accepted that the claims were "directed to molecules which have been deliberately changed from the naturally occurring form" and on that basis concluded: "an objection of manner of manufacture might arise if the claims were directed to a mere chemical curiosity; but that is plainly not the case with this invention." And while his decision legitimated IP Australia's policy on gene patents, it must be recognised that, first, it was an internal decision of IP Australia and not an independent review conducted by an Australian court and, secondly, that even though the decision was subsequently appealed to the Federal Court of Australia, the 'manner of manufacture' threshold was not raised by the parties and therefore did not form part of the two court decisions which subsequently followed on from it³⁰⁹. Had the parties in the two appeals to the Federal Court of Australia raised the issue of 'manner of manufacture' then perhaps the controversy over gene patents might have been resolved some years ago, but, as we have observed, it is a matter of chance and in this case the litigants were not prepared to raise it as an issue. Indeed, as Dr Palombi advised us, it was not even raised by them in the patent opposition in the first place. That it was raised at all, it would seem, was due entirely to the Deputy-Commissioner himself.

In my opinion, it is not for the Committee to speculate why the litigants took this approach, although it has been suggested that the challenging litigants were also patent applicants or the holders of patent monopolies in respect to other genes and proteins and therefore did not have the incentive to attack the validity of their competitor's gene patent for fear that it would have had obvious repercussions on the viability of their own patent portfolios either in Australia or elsewhere. Whatever the cause, it would seem that in Australia there has been some reticence on the part of patent litigants to challenge the validity of gene patents on the ground that the claims to isolated biological materials are not 'inventions' in accordance with s.18(1)(a) *Patents Act, 1990* and this fact is one of the reasons why, I would suggest, the Committee is now having to undertake this investigation in the absence of any judicial guidance on point.

So how have IP Australia and the Australian courts played their role with respect to other kinds of patent monopolies in the context of s.18(1)(a)?

The Committee should understand that other than through IP Australia in the first instance, and the Australian courts in the second and final instance, there is currently no alternative mechanism available to remove unmeritorious patent monopolies from the Patents Register. And making this even less likely is the "reluctance"³¹⁰ on the part of IP Australia and the Australian courts to deal with "matters of ethics or social policy"³¹¹. According to IP Australia's Examiners Manual, the instruction book which patent examiners refer to in implementing IP Australia's policy during their examination of patent applications, "it is for Parliament, not the courts or the Patent Office to decide whether matters of ethics or social policy are to have any impact on what is patentable"³¹². What this means, if this is a correct interpretation of the law, is that an important arm of the 'manner of manufacture' threshold is being overlooked during patent examination and, in the case of a granted patent monopoly, during revocation proceedings. Prof Christie explained to us that this situation is one of the reasons why the ACIP inquiry into patentable subject matter is considering other options to the current 'manner of manufacture' threshold.³¹³

Dr Moir referred us to the Full Federal Court of Australia decision in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, as a result of which methods of medical treatment, which up until then had been considered to be unpatentable under Australian patent law on social and moral grounds, were rendered patentable³¹⁴. She also referred us to the decision of the Federal Court of Australia decision in *Welcome Real-Time SA v Catuity Inc* (No 2) [2001] FCA 445 which permitted the patenting of a business method, effectively extending patentable subject matter into a field that had never before considered to be patentable in Australia³¹⁵. In doing so, Justice Heerey relied on a decision of the US Court of Appeals for the Federal Circuit (CAFC) in *State Street Bank & Trust Co v Signature Financial Group* 149 F 3d 1368 (1998) (*State Street*) saying that he had found it "persuasive"³¹⁶. The problem, however, is that having extended patentable subject matter in Australia on the basis of the CAFC decision, seven years later an *en banc* CAFC panel³¹⁷ decision in *In Re Bernard L Bilksi and Rand A Warsaw* 545 F 3d 943 (2008) (*Bilksi*) overruled that decision. Now the *Bilksi* decision has been appealed to the US Supreme Court, which heard oral argument on 9 November 2009, and while a decision from that august Court will provide a clearer patent boundary line for the United States, the point is that our courts are reforming our patent law not only on the basis of

³⁰⁹ *Kirin-Amgen, Inc v Genetics Institute No 3* [1998] FCA 740 (Federal Court); *Genetics Institute Inc v Kirin-Amgen, Inc* [1999] FCA 742 (Full Federal Court).

³¹⁰ IP Australia (Submission 19) p 16 at para 4.22.

³¹¹ *Ibid*, at para 4.23.

³¹² *Ibid*.

³¹³ Hansard, Senate Community Affairs References Committee, Tuesday 4 August 2009 at CA 66-67.

³¹⁴ See also Justine Pila, 'Methods of Medical Treatment within Australian and United Kingdom Patent Laws', [2001] *UNSWLJ* 30.

³¹⁵ *Ibid*.

³¹⁶ *Welcome Real-Time SA v Catuity Inc* (No 2) [2001] FCA 445 at para 129.

³¹⁷ *En banc* refers to a full sitting of all 12 CAFC judges.

what is happening in this country but also on the basis of what is happening overseas. It is worth repeating what Justice Heerey said:

In both countries, in similar commercial and technological environments, the law has to strike a balance between, on the one hand, the encouragement of true innovation by the grant of monopoly and, on the other, freedom of competition.³¹⁸

Various experts have explained to the Committee that striking the right balance in patent law is not a simple matter. To begin with the Australian economy is very different to the US economy. Next, judges generally are not experts in economics and must adjudicate on legal issues in an adversarial environment that is overwhelmingly legalist. Generally there is no economic evidence adduced beyond that relevant to the parties. In these circumstances a judge will find it difficult to come to an accurate assessment of where to strike *that* balance. Finally, the social and moral dimension which Prof Christie acknowledged to be part of the 'manner of manufacture' threshold, and with respect to which the Committee, in my opinion, should agree, is part of the equation. Thus, it is not simply a matter of economics, just as it is not simply a matter of patent law, in deciding where to draw the appropriate line and achieve the right balance for the Australian economy and its people. According to Dr Moir "it is hard to see how a country like Australia, where only 8% of patents are owned by Australian companies or individuals could benefit from a patent system".³¹⁹ This evidence Justice Heerey had in mind when he made his decision is unstated. Dr Moir's data (which comes from IP Australia) suggests that:

"With less than 2% of the OECD market, an Australian patent is not likely to create the incentive to invent for most overseas owners of Australian patents. I estimate that perhaps 3% of Australian patents might be induced and might deliver the potential social benefits with which to offset the costs that flow from all granted Australian patents."³²⁰

The Committee should accept the importance of 'striking' the right balance but, may I ask, how is that to happen on a day-to-day basis if there is no mechanism within the administration of patent law to do so other than through legislative intervention?

It seems reasonable to assume that IP Australia, the Australian government agency which is responsible for the grant of patents monopolies, bears the primary responsibility of ensuring that only patent monopolies which strictly comply with Australian patent law are granted in the first place. And as difficult as it might be for IP Australia to perform that role as the law stands at the present time, and as it has stood since 1903, the 'manner of manufacture' threshold requires an assessment that includes a social and moral component.

It would seem that the Australian Patent Office, which became the Australian Industrial Property Office in 1992 then IP Australia on 25 February 1998,³²¹ had been less reticent in the past. Indeed *NRDC* is a case in point. There the Commissioner of Patents had rejected a patent application for a horticultural process on the ground that it was not a 'manner of manufacture'. And while the High Court of Australia came to a different conclusion on that occasion, that decision did not stop the Australian Patent Office maintaining its vigilance and rejecting patent applications that strayed over the line.

An example of this is *In the Matter of a Patent Application by Ranks Hovis McDougall Ltd* [1976] AOJP 3915 (*Ranks Hovis McDougall*). The key elements of this decision for our purposes are:

1. **Isolation:** Claims 1 to 6 defined the invention to be a naturally occurring microorganism (a strain of fungus, called *Fusarium graminearum Swabe*). This organism, which lived naturally in the earth had been "isolated from a soil sample";³²²
2. **Practical application:** The 'invention' defined in claims 1 to 6 was not qualified by a specific use, although the patent specification stated that the microorganism "may be employed in known processes for the production of an edible protein containing substance";³²³ and,
3. **Artificial synthesis:** The specification stated that the microorganism defined in claims 1 to 6 could be "man made" by a "man controlled microbiological process".³²⁴

³¹⁸ Op cit 157.

³¹⁹ Dr Hazel Moir (Submission 20) at p 14.

³²⁰ Ibid.

³²¹ Charles Lawson, Managerialist influences on granting patents in Australia, (2008) 15 AJ Admin L, 70-99 at p73.

³²² *In the Matter of a Patent Application by Ranks Hovis McDougall Ltd* [1976] AOJP 3915 at p 3916.

³²³ Ibid.

³²⁴ Ibid at p 3918.

The Committee was advised by IP Australia and Mrs Beattie, the current Commissioner of Patents, that a human gene can be a 'manner of manufacture' and the subject of a patent monopoly under Australian patent law if (a) it is isolated; (b) a practical application disclosed and (c) it is capable of being produced synthetically.³²⁵

However, in the *Ranks Hovis McDougall* decision those three indicia did not satisfied the Assistant Commissioner of Patents that the 'isolated' microorganism was a 'manner of manufacture'. While he rejected the patent examiners reasoning, that being "something living"³²⁶ it could not qualify as a 'manner of manufacture', criticising his reasoning as "too restricted a view of the meaning of manner of manufacture in section 6 of the Statute of Monopolies"³²⁷, he was not persuaded that the microorganism, even when it was (a) isolated, (b) usefully employable in a process and (c) synthetically reproducible, was a 'manner of manufacture'.

Here are the parallels:

1. The microorganism lived naturally in the earth, just like a human gene is naturally a part of the human genome.
2. The microorganism had been discovered in the earth and isolated "in a soil sample", just like a human gene is discovered and isolated from the human body.
3. The microorganism had a practical use, just like a human gene can be usefully employed in a genetic test or a biological process.
4. The microorganism was capable of being reproduced in an artificial process, just like a human gene can be purified in an artificial process.

This is an important point because it undermines IP Australia's present rationale as it was explained to us by the Commissioner. While it is noted that the Assistant Commissioner in the *Ranks Hovis MaDougall* case rejected the patent application on a number of grounds, including novelty and fair basis, he also made a number of relevant observations that cast doubt over the rationale that IP Australia is currently employing to justify its position in regard to 'manner of manufacture'.

Firstly, in terms its 'isolation', the Assistant Commissioner said:

... [a]s the organism was isolated from a soil sample, there may, at best been a discovery. *No invention was involved in the mere discovery, or the mere identification, or the mere isolation* by an unsuspecting method, of something that occurs in nature (British Thomson-Houston Company Ltd (1925) 42 PRC 180 at 207). As Lord Wilberforce said in American Cyanamid (Dann's) patent (1971) RPC 425 at 448:

The isolation of the strain represents the effective result of the research effort of the applicant: the process thereafter to be applied, though appearing elaborate to the layman, is in scientific terms simple and probably routine. The priceless strain, being something living, found in nature, cannot be patented: the prosaic process, as applied to the strain, is capable of protection. (emphasis added)³²⁸

In referring to Lord Wilberforce's judgment the Commissioner was clearly drawing a distinction between a claim to the microorganism in question, which was not 'an invention', and the process for its manufacture, which was.

Secondly, in terms of the significance of its 'isolation' he said:

In respect of the invention claimed ... what has 'the inventor' done? What contribution has he made? He has discovered a naturally occurring microorganism and, by altering its conditions of growth, he has changed its morphological characteristics. *If that is all he has done, he has made no useful contribution to the art* (emphasis added).³²⁹

Thirdly, with regards to its potential as a 'manner of manufacture' he said that the threshold would be reached:

if producing the variant [of the naturally occurring microorganism] by some man controlled microbiological process, he has produced a new microorganism which has *improved or altered useful properties* (emphasis added).³³⁰

³²⁵ IP Australia (submission 19) at p 18 para 4.28. See also the evidence of Mrs Fatima Beattie, the Commissioner of Patents, Hansard, Senate Community Affairs Committee, Thursday 19 March 2009, CA 11; Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009, CA 27.

³²⁶ Op cit 322 at 3918.

³²⁷ Ibid.

³²⁸ Ibid.

³²⁹ Ibid.

³³⁰ Ibid.

That statement is the hub of the issue because it is only when the isolated biological material has “improved or useful altered properties” that there is a proper basis for distinguishing it from what exists in nature. The importance of the point being that the distinction is not in its mere isolation. Nor is it, in its practical application in that form. Nor is it, in its reproduction in some artificial process in that form. In other words, the isolated biological material itself must have been so altered by human intervention or by a process of human intervention that it can no longer be said to be a naturally occurring biological material. And that is precisely the approach which the US Supreme Court adopted in *Diamond v Chakrabarty* 447 US 303 (1980). There the Court held that a genetically engineered bacterium which degraded crude oil was so “markedly different from any found in nature and one having the potential for significant utility”³³¹ that it could no longer be said to be “nature’s handiwork”.³³²

Unfortunately, the Assistant Commissioner’s decision was not appealed to the Federal Court of Australia³³³ so the Committee did not have the benefit of a judicial opinion. However, in 1988 the Australian Patent Office, as IP Australia was then known, adopted a policy with regard to the patenting of isolated biological materials which was contrary to the law as it had been interpreted in the *Ranks Hovis McDougall* decision and it did so without any support from the Australian courts. In defence of this new policy, the only Australian decision that IP Australia has been able to cite is the Deputy-Commissioner’s own decision in *Kiren-Amgen* - a decision which did not even mention *Ranks Hovis McDougall* and which is puzzling given that the ‘isolated’ human erythropoietin gene in *Kiren-Amgen* is analogous to the ‘isolated’ micrororganism in *Ranks Hovis McDougall*.

It is therefore relevant to this inquiry, in my opinion, for the Committee to understand (a) why there was a change in policy at the Australian Patent Office in 1988 away from that expressed in the the *Ranks Hovis McDougall* decision in 1976 and (b) why the *Kiren-Amgen* decision in 1995 failed to address the issue.

IP Australia did provide the Committee with two old patent documents in its possession. These patent documents, one being a patent application dated 8 May 1919 entitled “Improvements in dye-stuff producing processes, and products thereof”³³⁴, and the other being a patent application dated 19 July 1923 entitled “A product obtainable from the mammalian pancreas, the related glands of fishes, and other sources, useful in the treatment of diabetes mellitus, and a method of preparing it” were produced for the hearing on 20 August 2009. According to the present Commissioner, these two examples showed that since the 1920s “Australia’s patent system has regarded as inventions *substances isolated from nature, both flora and fauna, for which a practical use has been identified*”³³⁵. She testified as follows:

By way of actual examples I provide in evidence: a patent granted in 1920 for substances isolated from Australian flora for use in dyeing wool, cotton et cetera; and a patent granted in 1924 for a substance isolated from mammalian pancreas or glands of fishes and other sources which relieves the cardinal symptoms and signs of diabetes. In both of these examples a patent was granted over *the isolated substance* and the method of isolation. Neither patent extends to the substance in its natural state, namely the she-oak or the bovine pancreas, from which the substances were derived respectively (emphasis added).³³⁶

We have italicised the words “the isolated substance” because it is these words, we believe, which go to the heart of the problem when it comes to gene patents. We have already given our reasons earlier in this submission, but to recap, it suffices to state that the scope of a gene patent monopoly covers isolated genes and the proteins which they code for. The scope also extends to the use of these biological materials in other ways, such as in diagnostics and treatments, but for the moment we are not concerned about these ‘use’ claims. Our focus, as would have been well understood by the present Commissioner and IP Australia on 20 August 2009, was on the product claims - claims to isolated biological materials per se. This is why, it seems to us, the present Commissioner brought these two old patent documents to our attention - to convince us that the patenting of isolated biological materials has been going on for over 70 years and to negate the criticism leveled against IP Australia for pursuing a policy that permits the grant of patent monopolies over isolated biological materials which are identical or substantially identical to what exists in nature. Her purpose was reinforced by her statement that “neither [the 1920 nor 1924] patent” granted a patent monopoly over the “substance in its natural state”. In my opinion her intent was to convince the Committee that an isolated biological material was different to a biological material as it exists in nature and this difference, provided a practical use could be found for the biological material, was enough to make it patentable subject matter and had been the case since at least 1920. In her opinion “chemical inventions such as isolated human gene sequences for which a practical use id identified have not been treated differently because they are derived from the human body”³³⁷.

³³¹ *Diamond v Chakrabarty* 447 US 303 (1980) at p 310.

³³² *Ibid.*

³³³ Until then the High Court of Australia was a court of original jurisdiction for appeals from a decision of the Commissioner of Patents.

³³⁴ IP Australia (Submission 19f)

³³⁵ Hansard, Senate Community Affairs References Committee, Thursday 20 August 2009, CA 27 (emphasis added).

³³⁶ *Ibid.*

³³⁷ *Ibid.*

However, for the following reasons we have found this evidence convoluted at best and misleading at worst.

Firstly, the Assistant Commissioner's decision in *Ranks Hovis McDougall*, contradicts the current rationale employed by IP Australia but this difference was not addressed in her evidence. As already explained the *Ranks Hovis McDougall* decision involved a claim to an isolated fungus (being identical or substantially identical to what existed in nature) was held not to be a 'manner of manufacture'.

Secondly, product claims to isolated biological materials are generally not qualified by the use to which they may be put. When the present Commissioner spoke of a "practical use" being "identified" she was not referring to the scope of the patent monopoly being restricted or confined to that specific biological material and used in the manner specified. Certainly this information may have been provided in the patent specification, but the scope of the patent monopoly, as defined by the claims (which is what defines the 'invention'), covered the isolated biological material per se. Therefore, any use whatsoever of that material will interfere with the patent monopoly. An example of a product claim to an isolated biological material per se is contained in Australian Patent No 686,004 which is entitled "In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene" and was granted in 1996. The patent monopoly is currently in force and expires on 11 August 2015.³³⁸ Claim 1 is as follows:

An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

This, in short, is a claim to gene mutations to the human gene BRCA 1. It is a per se product claim. There is no practical use qualification. In fact there are no qualifications of any sort. The 'invention', if there is one, is defined by claim 1 as the mutations to the BRCA 1 human gene in an isolated form (as defined by the gene and amino acid sequences referred to in the claim). In this context, the present Commissioner's evidence, which emphasised IP Australia's requirement for a practical use to be "identified" before it could be considered to be patentable subject matter, was confusing. True it was that the patent specification identified the use of these mutations in a genetic test, but that was not the point. The scope of the patent monopoly was not confined to that practical use. If it were, then one could understand the point, but clearly this was not the case.

Thirdly, IP Australia relied on the *Kiren-Amgen* decision in support of its policy. However, not only did Mr Herald, the Deputy-Commissioner, not refer to the Assistant Commissioner's decision in *Ranks Hovis McDougall* and distinguish it on the facts or explain it away on a point of law, but the issue of 'manner of manufacture' was not even before him. This meant that the parties in the Opposition, over which he was adjudicating, had not produced any evidence upon which he could come to an informed decision on the issue. Thus when Mr Herald held, relying as he did on a statement in the patent specification to the effect that the claims were "directed to molecules which have been deliberately changed from the naturally occurring form", there was not a shred of evidence to verify this to be the case. This is an important consideration for the Committee in light of the criticism of Mr Herald's reasoning by Dr Palombi. In his Submission (Part 2) Dr Palombi described patent litigation in the United States concerning the US equivalent of the patent which was before Mr Herald. He wrote:

The Massachusetts litigation then proceeded to produce findings of fact that confirmed that both the human Epo gene and the corresponding protein in the isolated and purified forms that were claimed as 'inventions' were identical to the naturally occurring human Epo gene and its corresponding protein. On 5 May 1989 Federal Magistrate Saris held:

... the overwhelming evidence, including Amgen's own admissions, establishes that [natural erythropoietin] and [recombinant erythropoietin] are the same product. The [erythropoietin] gene used to produce [recombinant erythropoietin] is the same [erythropoietin] gene as the human body uses to produce [natural erythropoietin]. The amino acid sequences of human [natural erythropoietin] and [recombinant erythropoietin] are identical. ... There are no known differences between the secondary structure of [recombinant erythropoietin] produced in a Chinese hamster cell and [erythropoietin] produced in a human kidney. Amgen's own scientists have concluded that by all criteria examined, [recombinant erythropoietin] is the "equivalent to the natural hormone." [Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (1989) 11 USPQ2D 1466].³³⁹

Therefore this US Court held that there was no difference in either the human gene that coded for the human protein erythropoietin or the human protein erythropoietin no matter how it was made, whether by the human body or by biological processes. I urge the Committee to accept that Mr Herald must have been aware of this decision given that it was decided six years earlier, yet IP Australia elected not to explain why, and on what evidentiary basis, Mr Herald accepted the statement of the patentee that "the human gene had been deliberately changed". Not to put too fine a point on this, but if the Commissioner's decision in *Ranks Hovis McDougall* was a correct application of the High Court of Australia's decision in *NRDC*, and

³³⁸ For details see Dr Luigi Palombi (Submission 4, Part 2) at pp 36-43.

³³⁹ Ibid, pp at 24-35 at p 27.

there is nothing before the Committee to suggest otherwise, it would appear that as the human gene for erythropoietin and the protein which it coded for, either inside or outside the human body, were “identical” then claims 33 and 34 of Australia Patent No 600,650 could not have satisfied the ‘manner of manufacture’ threshold.

Finally, I take the Committee to the patents granted in 1920 and 1924 which Mrs Beattie asserts show that patents “over the isolated substance”, which were isolated biological materials, have been an accepted practice in Australia for decades.

The **first patent** was about a process from which vegetable dye was extracted from various “trees, shrubs, or plants”. The process described in the patent application was said to be different to the kinds already employed either in or “outside Australia” as at the priority date. Indeed, the extraction of natural dyes from plant material had been carried out for thousands of years. Yet, on the basis of the so-called ‘new’ process, the patent specification asserted that certain colours could be obtained from certain plants, e.g., a brown natural dye was extracted from the “Native Cherry” while a yellow natural dye was extracted from the “Yellow Kalma Tree”. Putting to one side the issue of whether there was actually anything inventive at all disclosed in this application, given what was already known about the extraction of vegetable dyes from plant materials, and focusing only on the issue of ‘manner of manufacture’, the Committee should not, in my opinion, accept that claim 1 is analogous to the kinds of claims to isolated genes and proteins like the claim discussed earlier over the mutations to BRCA 1. Claim 1 was as follows:

Improved dye-stuff consisting of the product obtained by the treatment with a solution of soda and lime in water, of vegetation divided into small parts, substantially as described.

Thus it was not, I would urge the Committee to accept, a claim to an isolated biological material *per se*.

First, the patent monopoly was over an ‘improved dye-stuff’ (a colouring agent) not the vegetable material *per se*.

Secondly, the patent monopoly was qualified by the process used to produce the ‘improved dye-stuff’, thus it was a product-by-process claim, which is significantly narrower in scope.

The **second patent** was about a medicament for the treatment for diabetes mellitus in humans. Claim 1 was as follows:

A product containing in concentrated form a substance necessary to normal carbohydrate metabolism.

This patent undoubtedly describes one of the major breakthroughs of medical science in the 20th century. Indeed, Dr Banting, one of the named inventors, and Prof Macleod, his colleague at the University of Toronto in Canada were awarded the Nobel prize in 1923. Dr Banting was also knighted for his services in 1937. There is also no doubt that the “substance” of claim 1 was, in the context of the patent specification, “the active anti-diabetic principle or hormone” or insulin as we know it today. That it was “concentrated” meant it was “free or practically free from toxic substances”. For all intents and purposes, the patent monopoly defined by claim 1 was to a medicament *containing* purified insulin (the impure form extracted from mammalian animals and cartilaginous fishes) that “restores to the body a normal metabolism of carbohydrates, fats and proteins”. Certainly the patent contained a claim to a product *per se*, but it was not a claim to isolated or purified insulin.

Thus, I would urge the Committee’s to conclude that neither of these two patents could fairly be said to support IP Australia’s policy with regard to the patenting of isolated biological materials and certainly have little or nothing to do with the issue of gene patents - patents which include claims to the nucleic acids (DNA or RNA) and amino acid sequences (proteins), which are informational not physical.

However, even if the Committee were to assume that claim 1 of the second patent was a claim to isolated insulin (which it is not), returning to the Assistant Commissioner’s decision in *Ranks Hovis McDougall* we fail to see how it could have satisfied the ‘manner of manufacture’ threshold. First, the “substance” was extracted from “mammalian animals and cartilaginous fishes” while the “microorganism” was extracted from “a soil sample”. In other words, both were ‘discovered’ from the natural environment. Secondly, the process used to extract the “substance” was, in the words used by the Assistant Commissioner: “by an unsuspecting method ..[of] something that occurs in nature”. Finally, the “active anti-diabetic principle or hormone” was a naturally occurring substance just as were the “microorganism” and its “mutants” and “variants”.

There is no doubt that Drs Banting, Best and Collip, the inventors named in the second patent, developed a new process that produced a pure form of the naturally occurring substance which was subsequently called ‘insulin’³⁴⁰, but they did not invent that substance. And as the noted English jurist Lord Willburforce held in *American Cyanamid* (1971): “The priceless strain, being something living, found in nature, cannot be patented: the prosaic process, as applied to the strain, is capable of protection.” Applying this reasoning, which seems entirely appropriate, they were entitled to a patent monopoly for that process but they were not entitled to a patent monopoly for purified insulin.

A famous example applying similar reasoning from the United States is discussed by Dr Palombi in his book.³⁴¹ It involved a

³⁴⁰ The name ‘insulin’ was suggested by Sir Sharpley Schafer. See the Nobel prize presentation speech of 1923 made by Professor J. Sjöquist (http://nobelprize.org/nobel_prizes/medicine/laureates/1923/press.html)

³⁴¹ Op cit 19 at pp 211-213.

process for the production of a synthetic dye which was chemically identical or substantially identical to a natural dye, alizarin, which was extracted from the madder plant. The artificial alizarin was, however, much cheaper. The chemical processes used to manufacture artificial alizarine were simultaneously invented by the famous English chemist Sir William Henry Perkin and German chemists Charles Graebe and Charles Liebermann employed by Badische Anilin and Soda Fabrik (BASF) in 1869. They were, however, slightly different. BASF was able to secure a US patent to one of the two processes, but then applied and was granted a second US patent that covered "artificial alizarine, produced ... by any other method which produces a like result". BASF's objective was to stop the import into the US of any artificial alizarin even though it was produced using the Perkin's method. The US Supreme Court, however, revoked the patent claim to artificial alizarin in *Cochrane v BASF* 111 US 293 (1884). In doing so Justice Blatchford noted that artificial alizarin "besides having the same composition, had also the same properties as vegetable alizarine [and] ... that [c]loth printed with mordants dye exactly alike with both coloring matters." In other words, even though it was synthetic produced using a new process, according to Justice Blatchford "it was an old article"³⁴² because it was indistinguishable from natural alizarin. Justice Blatchford concluded:

While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction to being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially for the first time from anthracine, if it was set forth as alizarine, a well known substance.³⁴³

This finally brings me to pose this question: what motivated the Australian Patent Office, as it was in 1988, without the benefit of any Australian court decision on point and without any public consultation, to adopt a policy which emanated from overseas and which was of doubtful legal validity in Australia?

An article by Dr Charles Lawson³⁴⁴, senior lecturer in law at the Australian Centre for Intellectual Property in Agriculture at the Griffith University, entitled *Managerialist influences on granting patents in Australia*³⁴⁵, provides a useful insight into the internal workings of IP Australia and may explain why. He writes:

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.

In other words, IP Australia derives the bulk of its operating revenue from fees it receives from patent attorneys and their clients. Therefore:

1. IP Australia's revenue grows commensurately with the number of patent applications it processes, the number of patent monopolies it grants and the number of granted patents which are renewed.
2. IP Australia has a direct financial relationship with the users of the Australian patent system, namely, Australian patent attorneys and their clients. The Committee should note that 92% of all Australian patent monopolies are granted to foreign corporations, organisations and individuals.³⁴⁶

But how can IP Australia act as the patent gatekeeper in Australia when it earns most of its operating revenue from fees it derives from Australian patent attorneys and their foreign based clients? As Prof Drahos puts it:

The cosy networked relationship between the professional bodies that represent patent agents and patent offices makes the implementation of an enforcement pyramid by a patent office not very likely.³⁴⁷

Indeed, Australia's consolidated revenue might be adversely impacted if the operating budget of the Australian Taxation Office was derived from fees charged to Australian tax accountants, tax lawyers, tax agents and their clients.

Both the question and the analogy are appropriate for two reasons.

³⁴² *Cochrane v BASF* 111 US 293 (1884) at 311.

³⁴³ *Ibid.*

³⁴⁴ Dr Charles Lawson (Submission 5).

³⁴⁵ Charles Lawson, *Managerialist influences on granting patents in Australia*, (2008) 15 AJ Admin L, 70-99.

³⁴⁶ Dr Hazel Moir (Submission 20) at p 14.

³⁴⁷ Prof Peter Drahos (Submission 60); see also Chapter 11, 'The Global Governance of Knowledge: Patent Offices and Their Clients' in Peter Drahos *The Global Governance of Knowledge* (Cambridge University Press: Cambridge, UK: 2010) at p 460.

First, **patent quality**:

The Hon Mr Barry Jones MP, Minister for Science, Customs and Small Business, made it clear during the second reading speech of the *Patents Bill, 1989*, the precursor to the current *Patents Act, 1990*, that one of the main objectives of the new law was to “make it harder to get a ... patent”³⁴⁸ monopoly. He also said that “we should seek to modify the Australian patents laws, adjusting the length, strength and breadth of patents rights so as to *maximise the social benefits and to minimise the social costs to Australians*”³⁴⁹. In other words, when IP Australia grants patent monopolies for innovations that do not meet the patentability thresholds, greater economic and social costs are imposed on the Australian economy and the Australian people.

Today IP Australia admits that “Australia’s patentability standards are set at a level that is lower than the standards set in countries who are our major trading partners”. In March 2009 it released a consultancy paper entitled *Getting the Balance Right*, in which it attributed the cause to a number of deficiencies in Australia’s patent law and its administration. According to that paper, “these differences potentially upset the balance between the patent system and competition” because they “allow the grant of broader patents in Australian than elsewhere, and they allow the grant of patents that may disclose less information about the inventions that they claim than is disclosed elsewhere”. The effect is to reduce “access to follow-on innovation for Australian innovators and the advantages that flow to Australian consumers from access to information about new technology and competition in the Australia marketplace”.³⁵⁰

That consultation was, however, one of six that IP Australia released during 2009 which concerned the Australian patent system. In November and December it released two consultations papers in which it set out a series of possible reforms.

It therefore seems likely that the *Patents Act, 1990*, 20 years after it was passed into law, has yet to achieve its stated objective. To make matters worse, during this time IP Australia seems to have done little to ensure that the ‘manner of manufacture’ threshold has been rigorously applied. Not surprisingly, the resulting explosion of patents has created “patent thickets”, which IP Australia readily admits “are most likely to occur in complex technologies and in jurisdictions where patent thresholds are low”.³⁵¹ And what does IP Australia say are the consequences of patent thickets?

Patent thickets impede the effective functioning of the patent system in that they increase the complexity of identifying where there is freedom to operate and gaining access to patented technologies and act as a disincentive to engage in innovation within and around the scope of the thicket.³⁵²

While I acknowledge that IP Australia is finally taking the issue of patent law reform in hand, it cannot go unnoticed that this activity has occurred suddenly, coinciding with the commencement of this inquiry, and in what seems to be a case of urgency. Yet, one of the reforms which IP Australia is now proposing was made by the IPCRC in its final report in 2000.³⁵³ Why has it taken ten years for IP Australia to act? It is possible that Prof Drahos provides a plausible explanation. He writes in his submission:

Patent offices typically have 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. Rather, the focus is on productive efficiency, on making it easier, cheaper and faster to obtain patents. 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.³⁵⁴

Second, the **social contract**:

It must be recognised that the social contract, that is the bargain between the inventor on the one hand and the Australian people on the other, must be such that the Australian economy has more to gain than lose by entering into that contract. At the present time the terms of that contract, although set by the *Patents Act, 1990*, are negotiated *only* by IP Australia. The Committee should understand from IP Australia’s submissions and evidence that the “quid pro quo that forms the basis of the patent system” is as follows:

³⁴⁸ Hansard, House of Representatives, Thursday 1 June 1989: Second Reading Patents Bill, 1989.

³⁴⁹ Ibid (emphasis added).

³⁵⁰ Getting the Balance Right: Towards a Stronger and More Efficient IP Rights System, IP Australia Consultation Paper, March 2009 at p 3.

³⁵¹ Ibid, at p 10.

³⁵² Ibid.

³⁵³ Ibid, Para 34, Footnote 22, p. 10

³⁵⁴ Peter Drahos *The Global Governance of Knowledge* (Cambridge University Press: Cambridge, UK: 2010) at p 294.

The patentee is given a time limited monopoly in exchange for public disclosure of their invention and detailed information about how to make and use the invention.³⁵⁵

Therefore, IP Australia says:

To justify the grant of a patent what is required is not merely knowledge about an invention but information that would enable a skilled reader to carry it out successfully without undue experimentation.³⁵⁶

Yet, there is currently no audit mechanism in place to ensure that IP Australia is performing its assigned task efficiently and lawfully. Neither is there an independent IP industry regulator to ensure that Australia's patent laws and patent system are sufficiently rigorous and properly calibrated so that the right 'balance' is achieved. The only other organisation which currently plays a role is ACIP - a committee that is dominated by patent attorneys, lawyers and commercial users of the Australian patent system.

I bring to the Committee's attention that in April 2009 the chair of ACIP, Mr Leon Allen, himself a partner of the patent attorney firm Davies Collison Cave, was quoted in an article that was critical of IP Australia for engaging in the process of patent law reform. Under the headline "Planned reforms anger Australian patent attorneys"³⁵⁷ the article begins as follows:

IP Australia's proposed reforms to the country's patent system are poorly thought through, partly unnecessary and will increase prosecution costs for businesses, say lawyers.

The reference to Mr Allen is as follows:

These changes will create a lot of uncertainty, according to Leon Allen, another partner of Davies Collison Cave in Melbourne and the chair of the Australian Council on Intellectual Property (ACIP). "Compliance costs will be high, particularly for Australian applicants," he told Managing IP. Allen also questioned whether the changes are necessary in the first place, as did Wayne Condon, a partner and patent litigation specialist for Griffith Hack in Melbourne. "We need to be careful that we are not playing around with something that doesn't need fixing," Condon said.

The Committee should note that Davies Collison Cave is a firm that has directly played a role in every significant review of Australia's patent system. First there is IPAC in which Mr Desmond Ryan, as a partner of the firm, was a member. Next there was IPCRC in which Mr John Stonier, as a consultant to the firm, was a member. Next was the Advisory Committee of the ALRC's review of gene patents on which Prof Andrew Christie, as the Davies Collison Cave Professor of Intellectual Property Law, participated as a member as did Mr Stonier in his capacity as a consultant to the firm. Finally, there is ACIP on which Prof Christie has been a past member and which is currently chaired by Mr Allen. Of course, Davies Collison Cave is not the only firm to have played a major role, but it has played an outstanding role in the past 30 years.

In light of this evidence it should be clear to the Committee why Prof Drahos and Drs Moir and Palombi believe that there are insufficient checks and balances in the Australian patent system and how this situation has contributed to the current imbalance. Prof Drahos and Dr Moir consider that Australian patent attorneys, like patent attorneys in other countries, have incentives to 'game' the system. That is, they seek to exploit weaknesses and loopholes in patent legislation to gain patent monopolies which run counter to the spirit of the legislation.

The Committee has been advised that the Australian courts, through the revocation of patents, provide a check and balance, but it must be remembered that the Australian courts have the opportunity to review less than 1% of all granted Australian patent monopolies. Therefore, about 99% of patent monopolies go untested under the current system of review. It is undeniable that for the vast majority of patent monopolies there is no effective system of check and balance and in this scenario it is entirely plausible that IP Australia would, over time, become vulnerable to inappropriate influence. According to Prof Drahos "[t]he problem lies in the absence of moral consensus about gaming behaviour that costs the public dearly in terms of access to essentials like medicines, and more in ignorance on the part of politicians, policy makers and the general public about the true costs of this gaming behaviour. Things might be different, of course, if these groups understood that the patent system has become a globally networked system of private taxation".³⁵⁸

Unfortunately, the problem is not confined to 'gaming'. The Australian courts, on the basis of the evidence presented to this Inquiry, must also accept a share of the responsibility because of their reluctance to deal with the moral, ethical and social aspect of the 'manner of manufacture' threshold. For instance, Dr Moir³⁵⁹ brought the Full Federal Court of Australia decision

³⁵⁵ Getting the Balance Right: Towards a Stronger and More Efficient IP Rights System, IP Australia Consultation Paper, March 2009 at p 6.

³⁵⁶ Ibid.

³⁵⁷ Managing IP Australia - Weekly News - 3 April 2009 (<http://www.managingip.com/Popups/PrintArticle.aspx?ArticleID=2174647&issueID=71511&categoryID=>)

³⁵⁸ Ibid.

³⁵⁹ Dr Hazel Moir (Submission 20) at p 33.

in *Grant v The Commissioner of Patents* [2006] FCA 120 to the Committee's attention. In their decision, Justices Heerey, Kiefel and Bennett held:

Nor is the Court in a position to determine the balance between social cost and public benefit. Parliament has already made that judgment, as its predecessor did in 1623, by rewarding innovation with a time-limited monopoly.

But that is precisely the point is it not? The Australian parliament retained the 'manner of manufacture' threshold in the *Patents Act, 1990* and therefore it (not the courts) determined that the grant of a "time-limited monopoly" would only be justified so long as the social benefits exceeded the social costs. This result, after all, was one of the *primary* objectives of the legislation as the responsible Minister advised the Parliament of the day. But instead of handing down decisions that are consistent with that policy, the Australian courts have systematically watered down the 'manner of manufacture' threshold thereby contributing to the current imbalance and undermining it as Dr Moir has argued in her submission.

According to IP Australia the Australian courts have watered down other aspects of other patentability thresholds. For instance, IP Australia is critical of a series of court decisions³⁶⁰ because they have weakened the disclosure³⁶¹ requirement as well as the fair basis³⁶² requirement with the result that "there is a notable difference between the full description and fair basis requirement in Australia and requirements in the US, Europe and Japan".³⁶³ Another example raised by IP Australia is the "date at which the description should be met, and whether the description can be amended to include new matter after a patent application is filed". IP Australia cites the Full Federal Court of Australia decision in *Pfizer Overseas Pharmaceuticals v Eli Lilly and Company* [2005] FCAFC 224 and explains that by effect of this decision "it appears that a failure to fully describe the invention or to include the best method of performing the invention can be rectified up to at least grant of the patent and hence those requirements so not need to be met at the time of filing".³⁶⁴ What are the consequences? Again IP Australia explains:

Lower Australian standards may allow a patentee to obtain protection for an invention that they had not fully realised or described at the time of filing. They can also contribute to uncertainty for the public and competitors who may not be given the full details of an invention until well after the patent specification has been filed and published. Furthermore, innovation suffers from the delay in innovators being provided with sufficient information to commence follow-on innovations and understand the detail of new technologies.³⁶⁵

There are other examples given by IP Australia which we need not itemise in this submission. The point has been well made.

Conclusion

During the course of this inquiry a significant number of submissions have urged the Committee not to make recommendations which would tamper with the Australian patent system and to leave it to the existing agencies responsible for its administration to undertake the necessary fine tuning to re-calibrate it. I urge the Committee to disagree particularly when many of the proponents of this view are part of the patent community.

I urge the Committee on the basis of the overwhelming evidence presented in this inquiry, much of it coming from IP Australia itself, to accept that the Australian patent system is out of balance and in need of a radical overhaul. IP Australia's belated attempt to address the causes of this imbalance are admirable, but the Committee should be skeptical that the process will be adequate. Nor should the Committee be convinced that IP Australia is best placed to lead that process. It would appear that the causes of the imbalance which have been identified by IP Australia in its consultancy papers released in 2009 needed fixing years ago. In any event, the corrective proposals which have now been suggested³⁶⁶ amount, I urge the Committee to find, to no more than tinkering around the edges. The real problems are subcutaneous and deeply imbedded in the system's structure. The remedy will not be found, in my respectful submission, within the current patent system. In my opinion it is necessary to understand what those problems are, establish economic and social objectives and milestones that meet Australia's needs and design a system that will achieve those objectives and milestones efficiently, cost effectively and equitably (if that is possible).

³⁶⁰ *Kimberley-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1; *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* [2004] HCA 58; *Pfizer Overseas Pharmaceuticals v Eli Lilly and Company* [2005] FCAFC 224.

³⁶¹ Getting the Balance Right: Towards a Stronger and More Efficient IP Rights System, IP Australia Consultation Paper, March 2009 at p 7 paras 14-15.

³⁶² *Ibid* at p 7 para 16.

³⁶³ *Ibid* at p 7 para 17.

³⁶⁴ *Ibid* at p 8 para 20.

³⁶⁵ *Ibid* at p 8 para 22.

³⁶⁶ IP Australia Reports November and December 2009.

IP Australia's defence of a foreign sourced patent policy which has promoted the patenting of isolated biological materials, particularly human and non-human genes, and which in all probability is contrary to Australian patent law, has been puzzling. Its failure to address the *Ranks Hovis McDougall* decision while seeking to rely on the *Kiren-Amgen* decision was unfortunate, as was its continued reference to the requirement of "a practical use" in conferring patentability on a *per se* product claim. Based on the evidence presented to the Committee, it seems to me that the core of the problem is the grant of patent monopolies as *per se* product claims. Finally, its reference on two 1920s patents as examples to defend its current policy was unhelpful. In our view, IP Australia has not displayed an even-handed approach to considering both the costs and the benefits to different parties in its extension of patentable subject matter to what many scientists consider to be mere discoveries.³⁶⁷

The ALRC undertook a two year inquiry into gene patents. At the end of that inquiry it released a detailed report. That was six years ago. Yet, having made 55 recommendations for changes to the existing patent system (although not one was actually directed to the subject matter of the inquiry) only one has been acted upon - the ACIP inquiry into the 'manner of manufacture' threshold. That in itself is an issue because ACIP, in my opinion, lacks the necessary degree of independence to be regarded as a reliable source of advice to the Australian government. There is an obvious conflict of interest present between the majority of those that sit on ACIP and the administration of patent law. If there is any doubt about this then the article published in April 2009 in *Managing Intellectual Property*, a periodical read by patent attorneys, patent lawyers and patent bureaucrats around the world, should dispel that doubt.

Part 3 Recommendations

Therefore I ask the Committee to recommend to the Australian government that it do the following:

- 3.1 Immediately commission a broad and multidisciplinary Inquiry into the workings of the Australian patent system;
- 3.2 Immediately transfer to the Treasurer of Australia all responsibility for the administration and regulation of the Australian patent system;
- 3.3 Abolish ACIP forthwith and replace it with an independent, multidisciplinary and well-funded intellectual property regulator which will have the power to (a) audit IP Australia, patent attorneys and patent lawyers to ensure their compliance with Australia's patent law (b) investigate abuses of the Australian patent system (c) instigate civil and criminal proceedings in Australian courts against those that are alleged, on reasonable grounds and after a thorough investigation, to have abused the Australian patent system (d) oversee the regulation and discipline of patent attorneys, patent lawyers and patent bureaucrats and (e) provide regular advice and reports to the Australian government on the workings of the Australian patent system.
- 3.4 Immediately have IP Australia establish a patent transparency register that will:
 - (a) track and publish the patent portfolios of patent owners, especially those with large patent holdings; and
 - (b) develop databases in co-operation with user groups or other interested government agencies so that the degree of concentration of ownership of crucial technologies associated with that portfolio, and information about the licensing and assignment of those technologies are easily and publicly available.

³⁶⁷ There can be a number of causes which may explain this pro-IPRs bias. According to Ms Anna George (Submission 42) these include "lack of transparency in the system; strong corporate and legal vested interests; over-emphasis on trade-related factors; a general ignorance of the role and consequences of IPRs across whole-of-government decision making process, the media and public in general; and, also lack of sufficient parliamentary scrutiny."