Gene Patents and Patents granted over Biological Materials: *Their Impact on the Provision and Cost of Diagnostic Services and Medical and Scientific Research in Australia*

A Submission to the
Senate Community Affairs Committee
Inquiry into Gene Patents

Part One

Dr Luigi Palombi
Centre for the Governance of Knowledge & Development
The Regulatory Institutions Network

The Regulatory Institutions Network, The Australian National University, Canberra, ACT, 0200
(02) 6125 5465: 0400 606 263: luigi.palombi@anu.edu.au.

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Introduction

The purpose of Part One of this two part Submission is to inform the members of the *Senate Community Affairs Committee* of the relevant elements of patent law and the history of its development.

For nearly four hundred years patent monopolies have been lawfully granted to inventors, not as a reward for ingenuity but to encourage the disclosure and working of 'inventions', which as the word suggests are things that are human-made constructs, contraptions, machines, processes, devices, implements and so on. In broad terms, it has been the accepted wisdom that inventions of this kind contribute to the public good and to economic development.

At the same time it has also been the accepted wisdom that monopolies are not to be tolerated because they impose significant economic burdens and social costs on society and the economy.

An exception to this rule was made in the case of patents, but on strict conditions. The most important of these being that they only be granted in respect of things that are inventions.

This Inquiry will be considering this law in respect to one category of patents. That category, which for the sake of expediency shall be called 'gene patents', are patents that claim, as 'inventions', isolated biological materials; that is, biological materials that exist in nature but which have been isolated from their normal environments, either through a process of discovery or through some process of manufacture. Consequently, it is the 'isolation' of these materials which distinguishes them from their origins.

Isolated biological materials include human genes and proteins, their derivatives and components as well as such materials that are sourced from animals and other organisms, including bacteria and viruses.

Human genes and the proteins which they code for, however, are clearly not things which anyone invented. Indeed, it is ridiculous to suggest otherwise for they come within the class of things called 'natural phenomena'. Nonetheless, IP Australia has interpreted the law in Australia so as to justify the grant of gene patents which, because of the way the patents are defined, capture within the scope of the patent monopoly the exploitation of those natural phenomena in any way whatsoever. That said, the view of the law which IP Australia has adopted has not been the subject of review by an Australian court.

Additionally, gene patents almost always also claim as 'inventions' the medical and scientific use of the isolated biological materials to which they relate. Indeed, the assumption upon which these claims are drawn, sometimes speculative and sometimes simply plain obvious, is that knowledge of the isolated biological materials, which go to the core of the claimed 'inventions', are all that the educated reader of the patent needs to know in order to reproduce the inventions in all respects. As an example, one famous gene patent granted by IP Australia to Chiron Corporation not only claimed the isolated genetic material to the hepatitis C virus (HCV), but also the virus proteins and the use of the HCV viral materials (even to strains of HCV not even known at the time) in a vaccine that was capable of immunising a human being against HCV infection. That specific patent will be discussed in this Submission in some detail, but the Committee should note in the meantime that despite the fact that this patent was granted in 1992, one of the named inventors, a Dr Michael Houghton, wrote in the *Journal of Hepatology* in 1999, some 12 years after the original discovery that led to the patent, that: 'There is no vaccine for HCV'. This leads to the obvious question: why did IP Australia grant an Australian patent which gave Chiron a patent monopoly over a vaccine that did not exist?

Given that no Australian patent granted by IP Australia is guaranteed to be valid, the longer these patents remain untested, the longer they impact upon Australian society and the economy because the nature of the patent monopoly gives the patent owner the exclusive right to make, hire, use, sell, keep and import the invention in Australia for a period of 20 years.

It is therefore a matter of great importance that this Committee understand the origins of Australian patent law as well as understand the development of patent law in countries that the Australian legal system is related to. For just as gene patents have been granted in Australia, they have also been granted by the corresponding patent offices in those countries.

That this occurs is due to a policy which the patent offices of the United States, the European Union and Japan adopted in 1988 and which was followed by IP Australia. Some of the legal ramifications of this policy were recently considered by the Australian Law Reform Commission in its *Genes & Ingenuity* Report; however, for the reasons explained in this Submission the Committee is respectfully asked to ignore this Report.

Beyond the ALRC Inquiry (2002-2004) there has not been any multi-disciplinary review or investigation of the legal, economic or social impact of this policy. In fact, there has not even been a court decision in Australia with regard to its legality. Therefore, it is now incumbent upon this Committee to consider the impact which these gene patents have had, are having, and may have, on the healthcare system in Australia and whether it is necessary to legislatively address this policy.

Thus it is relevant that the Committee consider whether the *Patents Act, 1990* be amended so as to expressly prohibit the patenting of isolated biological materials that are identical or substantially identical to those materials as they exist in nature.

In this respect the patent system in Australia and how it has been and is being impacted upon by its relationship to patent systems in other countries is relevant to this Committee. Accordingly, the Committee's attention will be directed to a number of relevant international developments in which patents have played a significant role. These include:

(a) the European Commission's antitrust investigation into the use of the patent system in Europe to illegally suppress competition in generic medicines;

(b) the US Federal Trade Commission's legal action against pharmaceutical and generic drug makers for conspiring to illegally refrain from competition in generic medicines;

(c) reports concerning the inability of patent offices to undertake the examination of patent applications to suitable standards;

(d) reports and inquiries into the very high costs of patent litigation and the use of patent litigation, or its threat, as inducements in conduct that violates anti-competition laws;

and

(e) reports, investigations and inquiries that document how patent owners are using patents and patent systems, including the number of patents applied for and granted over what is essentially the same invention, to illegally suppress competition.

It is often said that without patents there would be nothing to encourage the investment of the millions of dollars needed to undertake risky research and development in new technologies. Apart from the fact that history shows that this is not true - that indeed some of the greatest inventions and medical and scientific breakthroughs have occurred regardless of patents – it

has been told so often by so many that it has become a truism. This Committee will undoubtedly become acquainted with this truism during the course of this Inquiry but the evidence, which is what this Committee must examine, will confirm that it is a myth.

What is not a myth is the propensity for patent owners, particularly multi-national corporations, to use their patents to control the use of leading-edge technologies for the sole purpose of maximising revenues. History shows that this level of control has led to the deliberate suppression of such technologies with the result that in times of international crisis or national emergency, national security has been jeopardised.

In the context of gene patents, the patent offices of the world (all of which earn revenue from the filing, grant and renewal of patents) have benefited greatly from the adoption of the patent policy in 1988 that created a fiction (that isolated biological materials are different from natural biological materials) for the express purpose of distinguishing things that have traditionally been excluded from patentability merely by this isolation. Needless to say, patent attorneys and patent lawyers have profited greatly from the growing patent domain. But there is a world of difference in the impact which such a policy has on technology exporting countries, like the US, the EU and Japan, against technology importing countries, like Australia, and that is something neither IP Australia nor the patent professions have taken into account. The effect of such a policy is multiplied when the so-called 'technology' is not an 'invention' but is natural phenomena that properly belongs in the public domain, free to be used for the common good.

Regardless, it would seem that the approach which led to this policy is under reconsideration, at least in the United States. Recently, the US patent office rejected a patent over a business method on the ground that it was not an invention. The decision has been upheld by the US Court of Appeals for the Federal Circuit and is now the subject of an application for leave to to appeal to the US Supreme Court. While it may be that this particular decision does not concern a gene patent, it nonetheless explores the principles that have their roots deeply embedded in the origins of patent law that exclude from patentability: 'laws of nature, natural phenomena, and abstract ideas'.

Therefore, it will be a matter for this Committee to examine the impact which the policy developed by the US, European and Japanese patent offices in 1988 and carried into effect by IP Australia has had on the Australian people and its economy and to intervene if, in its opinion, the patent law in Australia, for whatever reason, has been ignored, distorted or overruled.

This is also important in the context of Australia's obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). According to this agreement, which binds all countries that are members of the World Trade Organization (WTO), patents are to be granted only with respect to 'inventions'. Consequently, if, as this Submission maintains, isolated biological materials are not inventions, then the action of IP Australia in granting patent monopolies over such materials has exposed this country to potential international legal action.

Accordingly, the issue of whether isolated biological materials are, or should be, patentable subject matter is not an issue that can, nor should be, taken lightly because when patent laws transgress these inherent limitations, not only do the laws violate TRIPS but those that ignore or facilitate that violation are complicit in the economic and social costs which are inevitably and unnecessarily incurred by Australia and its people, economy, government and institutions.

1. The Australian Patent System

What is a patent monopoly and what can be the subject of a patent monopoly in Australia?

- An Australian 'patent' is a private monopoly right granted by the Australian Patent Office (now called IP Australia) in accordance with the AU Patents Act, 1990.
- The word 'patent' is defined in *AU Patents Act, 1990* to mean 'a standard patent or an innovation patent'. A ***standard patent***, being the typical kind of patent, provides a patent monopoly that has **a term of 20 years.** The patent monopoly provided by an *innovation patent*, however, has a term of only 8 years. There is more to the distinction than their duration, but for the purposes of this inquiry it is unnecessary to elaborate further as it is the *standard patent* which will occupy the attention of this Committee.

The subject matter must be an invention.

An invention is any manner of new manufacture that is not contrary to the law nor mischievous to the state by raising prices or commodities at home, or hurt of trade, or generally inconvenient

- **The legal boundary of the patent monopoly is defined by the 'claims' which are contained in the patent document**. The claims can number only one, but generally are more. The 'claims' define the 'invention' that is the subject of the patent monopoly. The legislative definition of 'invention' is:

> 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.

- According to the High Court of Australia [*National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269] this involves asking the question:

> Is what is defined in the claim(s) 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?

- Therefore the subject matter of a patent, namely an invention, must be a 'manner of new manufacture' and not be 'contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient'. This is the *primary* condition of patentability in Australia. Unless this condition of patentability is satisfied, the patent is invalid without any further consideration.
- However, if the primary condition is satisfied there are three further *secondary* conditions of patentability that *each* must satisfy in order for a patent to be valid. These are that the 'invention': (a) be novel; (b) contain an inventive step; and, (c) be industrially applicable.
- The first two of these three are only satisfied if the 'prior art' (i.e., relevant information that has been published or is publicly available before the earliest 'priority date' (i.e., the earliest filing date of the patent application)) does not disclose the invention (novelty) nor does not disclose enough information about the invention that would enable a person of ordinary skill in the relevant technology to consider the inventive step of the invention to be obvious (lack of inventive step).
- **Unless *all* patentability conditions are satisfied the patent is invalid *ab initio* (Latin: from the beginning).**
- A patent can also be invalid in as much as the conditions stipulated in section 40 *AU Patents Act, 1990* are not satisfied, namely, that (a) the invention is not fully described; (b)

the claim(s) is not clear and succinct and fairly based; and, (c) the claim(s) relates to more than one invention.

- No Australian patent is presumed to be valid as a matter of law. Section 20(1), *AU Patents Act, 1990* provides:

  > Nothing done under this Act … guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else.

- Moreover, section 20(2) provides that neither the Australian Patent Office nor any of its employees can be sued with respect to 'any act' under the *AU Patents Act, 1990*. This would include the granting of an invalid patent.

- Consequently, invalid patents are often granted by the Australian Patent Office and there is, at present, no legal or economic accountability for the consequences suffered by those detrimentally affected. Essentially, the Australian patent system (as does all others) relies on private litigation to resolve disputes over patent validity. This is an extremely inefficient and very expensive method which only works when the parties to the litigation have the commercial incentive, sophistication, lawyers and access to the millions of dollars needed to pursue the litigation to the highest appeal court.

- Invalidity of one or more claims does not necessarily render the whole patent invalid. Whether the whole patent is invalid will depend on the structure of the patent claims, and this will depend of the nature of the 'invention' and the skill of the patent attorney employed to draft the patent documentation.

No patent is guaranteed validity

IP Australia is immune from suit even if it grants an invalid patent

Invalidity of one or more claims does not necessarily render the whole patent invalid.

Brief History of Australian Patents Legislation

- The *AU Patents Act, 1990* (the current operating legislation) was preceded by the *AU Patents Act, 1952* which was preceded by the *AU Patents Act, 1903*.

- Prior to Federation in 1901 the Australian colonial governments had their own laws relating to patents. However, by virtue of section 51 (xviii) of the *Australian Constitution*, the 'power to make laws for the peace, order and good government of the Commonwealth' with respect to 'Copyrights, *patents of inventions* and designs, and trade marks' is exclusively vested in the Australian Parliament.

- The Australian colonies received their law from Great Britain. Through the effect of convention and law, the laws passed by the British Parliament and the interpretation of those laws by the British courts remained relevant to the development of law in Australia until 1986, when the *Australia Act* was passed by the Australian Parliament.

There remains a legislative link to the statutory beginnings of the modern 'patent' in Great Britain in that the *AU Patents Act, 1990* defines the word 'invention' 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'.

2. The British Patent System

- The *Statute of Monopolies, 1623* was a statute passed by the British Parliament in 1623. The principal objective of the law was to encourage economic development by declaring *all* monopolies (with some exceptions), including those established by virtue of the King's letters patent, illegal. Section 1 stipulated as follows:

> *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 … *[are] utterly void and of none effect*.

- The drafter of this legislation and its principal sponsor in the British Parliament was Sir Edward Coke, a noted lawyer, jurist, privy counsellor and parliamentarian. Coke believed that monopolies were contrary to the good governance of the economy and to the full employment of the people of Great Britain. Throughout his career he sought to strike down laws and regulations that permitted the capricious use of monopolies. Coke's contribution to the common law was significant. In one case, commonly referred to as *Dr Bonham's Case*, he held: 'when a statute was against the common right and reason, or repugnant, or impossible to be performed, the Common Law will control it and adjudge such Act to be void'. The effect was to hold parliament accountable to the judiciary – establishing one of the pillars of the separation of powers and an essential contribution to the evolution of the modern democratic state.

The principal objective of the *Statute of Monopolies, 1623* was to ban monopolies

An exception was made for letters patent that granted to the first and true inventor a monopoly of not more than 14 years in respect of a manner of new manufacture provided always that it was not unlawful nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient.

- There were, however, some exceptions to the prohibition of monopolies, such as the monopolies which the East India Company and the Virginia Company enjoyed with respect to the trade in specific commodities, and the monopoly of the Courts to grant certain warrants and of cities, towns and boroughs to regulate activities within their borders.
- Another exception was that provided in section 6. This allowed the King to issue letters patent for 'any manner of new manufactures' to 'the true and first inventor and inventors', provided that the monopoly did not extend beyond 14 years and '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'. Effectively, section 6 was the genesis of the modern patent systems of all common law countries including the United States, Canada, India, New Zealand, South Africa, Singapore and, of course, Australia. Indeed, until the 13 colonies of North America ceded from Great Britain to establish the United States of America under its Constitution in 1787, the laws of Great Britain provided the template for their own colonial legislatures, much like they did for the Australian colonies.

The Statute of Monopolies and its relevance to the patent laws of the United States of America

- Although the United States Congress passed the first *US Patents Act* in 1790 without specific reference to the *Statute of Monopolies, 1623*, it was the intent of the Congress that patent monopolies were only to be granted in the United States provided they

were not injurious to the economy or national security nor contrary to the best interests of its citizenry. Under section 1 of the *US Patents Act, 1790* not only was the patent monopoly restricted to 'any useful art, manufacture, engine, machine, or device, or any improvement therein', but petitions for the grant of patent monopolies were to be scrutinised by a high level executive committee consisting of Thomas Jefferson, the Secretary of State; Henry Knox, the Secretary of War and Edmund Randolph, the Attorney-General. That these men were delegated the responsibility of examining each and every petition for a US patent monopoly confirms that not only was the veracity of the inventor's claim to having 'invented' something patentable assessed, but, inevitably, so was its impact on the nation's economy, security and citizenry.

- Clearly the backlog in patent applications and the administrative burden placed on these three officeholders under this legislation was the reason why the *US Patents Act, 1793* removed the requirement that they examine each and every patent application, leaving it to private parties and the courts to resolve arguments about the validity of the patents. But that move produced an unforeseen consequence. It opened the patent-floodgates and after the many complaints about the low quality of a good number of the 10,000 patents that were granted between 1793 and 1836 was considered, it was decided that the removal of the requirement to scrutinise patent applications was detrimental to the country. So what was needed was some administrative body to scrutinise patent applications to ensure that the patents satisfied the patentability conditions under US patent law.

In 1836 the United States Patent Office was established in an attempt to stop the grant of patents over trivial inventions. Pre-grant examination by patent examiners provided a mechanism for vetting patent applications.

In 1883 the British Patent Office, established in 1852, was also required to undertake pre-grant examination of patent applications.

- Thus the *US Patents Act, 1836* saw two significant reforms. First was the establishment of the US Patent Office. Second was the reintroduction of pre-grant examination. Accordingly, pre-grant examination by the US Patent Office was expected to weed-out unmeritorious patents. Unfortunately the cost, which included the cost of employing a Commissioner of Patents and patent examiners and maintaining a patent office, was high; and while the US government underwrote the cost, the introduction of patent filing fees defrayed this cost.

- The establishment of the US Patent Office to assess applications for patent monopolies by reference only to compliance with certain technical patent thresholds had, however, unintended economic consequences. By 1890 the US Congress passed the *Sherman Antitrust Act* specifically to prohibit conduct designed to 'monopolize any part of the trade and commerce among the several States, or with foreign nations'. Despite the fact that this legislation has never been interpreted to apply to patent monopolies *per se*, it has been used to successfully prosecute corporations that have sought to gain an unfair advantage in the marketplace through the use of patent monopolies.

Establishment of a British Patent Office, 1852

- In Great Britain a proposal for the introduction of a US-style pre-grant examination was entertained in 1851 but rejected by the British Parliament in 1852. So although the British Patent Office was established in 1852, it was a library and repository for models of inventions.

British Royal Commission into the Workings of the British Patent Law, 1862-1864

- Within 10 years, however, the government of Lord Palmerston called a Royal Commission into the workings of the British patent system. It was conducted between 1862 and 1864 to investigate the proliferation of patents brought about by the 1852 legislation. There had been some considerable complaint that too many patent monopolies were being granted, many of which were of a 'trifling and frivolous nature'.
- Thomas Webster, a London barrister and drafter of the 1852 legislation, reminded the Commissioners that pre-grant examination had been a feature of the Bill which he drafted but was deleted through an amendment made to the Bill while it was before the House of Lords. He argued that this amendment had been a mistake because without pre-grant examination the British patent system was, in his opinion, 'not only useless, but positively mischievous'. According to Webster it encouraged a 'large class of speculators' against which 'almost all the objections' that had been made about the patent system arose. He pointed out that under the 1852 patents legislation, the two law officers who were duty bound to 'examine' petitions for letters patent had 'granted within a very short time, [patent monopolies] containing if not the same thing, so much of the same thing that one Patent would vitiate the other' and suggested that in the absence of a 'community of information' in regard to what was being patented, the patent system was flawed in that it was impossible to ensure that 'bad patents' were not granted. Clearly, Webster was in favour of extensive pre-grant examination being conducted by the British Patent Office for the reason that if inventors knew that such an examination would take place it would, as he said, 'stop a great number of Patents *in limine*' (Latin: at the threshold).
- Bennet Woodcroft, the Superintendent of Specifications at the British Patent Office, was, however, opposed to pre-grant examination of patents. Woodcroft referred to letters from his American counterpart, Justice Mason. He explained that pre-grant examination of patents would be very expensive and in support referred to one of the letters he had received from the US Commissioner of Patents to say that 'the Americans pay about £23,000 a year for preliminary examination and they are very much dissatisfied with it'. He not only described the US pre-grant examination of patents as 'very inadequate' but also 'a very cumbrous, unsatisfactory, and unfair mode' in the way it operated. He pointed out to the Committee that 'the system of preliminary examination has been tried and found wanting … in France, Austria, Sardinia and Belgium … and abandoned in each country'.
- Another concern raised before the Royal Commission was the cost of patent litigation. According to William Carpmael, a noted London patent agent with about forty years experience, patent litigation was 'very expensive'. He attributed the major cause of the increasing expense to the lack of a requirement on the patent owner to 'state with sufficient accuracy the precise point' in which the patent was infringed, and explained that often 'the defendant has not the slightest notion' until the opening of the case what the precise point of the complaint for the infringement against him was. Thomas Webster agreed, arguing that the 'greatest expense' of the proceedings arose from the 'bush-fighting' between

Evidence was presented to the Royal Commission into the British Patent Laws in 1862 that without pre-grant examination the British patent system was 'not only useless, but positively mischievous'.

the parties, where neither were compelled to disclose their case. In a related issue concerning the adequacy of the courts to deal with the factual and legal issues surrounding patent validity, Webster suggested that it would be better to 'get rid of the jury', with patent cases to be 'tried by one of the Judges of the superior courts' with the aid of scientific assessors. An American firm of patent attorneys, H & C Howson, who were observing the patent debate in Great Britain agreed with Webster and Carpmael. They reported that the British patent system encouraged '[the] indiscriminate and uncontrolled issue of patents … [with] no check upon the repeated patenting of similar inventions'. Worse still, the adjudication of the validity of British patents in the courts was 'so terrible an ordeal, that sooner than invite it, most ordinary mortals would be content to have their rights remain forever undefined and unrespected.'

Of the complaints made about the British patent system in the mid-19th century, one was that patent litigation was expensive and inefficient.

Another was the number of 'trival and frivolous patents'.

Yet another was the inability of patent examiners to assess novelty and inventiveness

British Free Trade Policies and Criticism of Patent Laws in Great Britain and Continental Europe, 1850-1875

- British scepticism of patent monopolies had been growing since the 1830s - a time when 'free trade' was considered to be in the best interests of the British economy. Increasingly patents were perceived to be trade barriers, akin to tariffs, which imposed additional (and unnecessary) burdens on domestic manufacture. Indeed by 1869, so convinced was the government of The Netherlands of the benefits of free trade that it repealed the country's first patent law which was first enacted in 1817. Moreover, Switzerland continued to refuse to enact such a law. [See Schiff, Eric (1971), *Industrialization without National Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907*, Princeton, New Jersey, US: Princeton University Press]

- Between 1850 and 1873 serious consideration was given to abolishing British patent monopolies. In February 1851 *The Economist* critiqued the British patent system:

> The privileges granted to inventors by patent laws are prohibitions on other men, and the history of inventions accordingly teems with accounts of trifling improvements patented, that have put a stop, for a long period, to other similar and much greater improvements. It teems also with accounts of improvements carried into effect the instant some patents had expired. The privileges have stifled more inventions than they promoted, and have cause more brilliant schemes to be put aside than they the want of them could ever have induced men to conceal. Every patent is a prohibition against improvements in a particular direction, except by the patentee, for a certain number of years; and, however, beneficial that may be to him who receives the privilege, the community cannot be benefited by it …. On all inventors it is especially a prohibition to exercise their faculties; and in proportion as they are more numerous than one, it is an impediment to the general advancement, with which it is the duty of the Legislature not to interfere, and which the claimers of privileges pretend at least to have at heart.

- Indeed successive British governments held Inquiries into the

British patent system. The last of these, in 1871, saw the appointment of a House of Commons Select Committee [*HC Deb 07 March 1871 vol 204 cc1512-34*]. The Committee took evidence from people in all sectors of industry, the legal and patent professions, inventors and trade associations. The result, in 1872, was a Bill to Amend the Patent Law the effect of which was to: (a) reduce the patent term from 14 years to 7 years; (b) provide for a much stricter pre-grant examination of patent applications; (c) enable the revocation of patents not worked within two years and (d) permit the compulsory licensing of all patents.

- The Bill, however, lapsed as the government of William Gladstone (British Prime Minister, 1868-1874) became concerned to deal with the effects of a major economic recession which began in early 1873.

By 1873 serious consideraton was being given to the repeal of patent laws throughout Europe. The Netherlands repealed its patent law in 1869, the newly unified Germany had not enacted a national patent law and Switzerland was refusing to do so.

In the UK a Parliamentary Select Committee had recommended reducing the patent term from 14 to 7 years and the ability to compulsorily license all patents.

- As it turn out, the Franco-Prussian War of 1870-71 not only cost William Gladstone the British election in 1874, but, having triggered a deep and long worldwide recession, as the recession's effects deepened so the call for free trade vanished. As protectionist policies regained popularity with governments across Europe the tariff reductions which had occurred since the 1830s, mainly as a result of various 'free trade' agreements that Great Britain had negotiated with its trading partners, evaporated. Notably, so did the idea of abolishing patent monopolies.

A Unified Germany: The New Economic Threat to Great Britain and Protectionism, 1871-1914

- The Conservative government of Benjamin Disraeli (British Prime Minister 1868, 1874-1880) introduced a Bill into the British Parliament in 1875 and 1876 to amend the British patent system. What is interesting is that although Lord Granville (a Liberal who had served in the government of William Gladstone) was of the opinion 'that there are evils "inherent in the nature of the Patent Law" which no legislation but legislation to abolish patents will succeed in removing', he was not complaining that the Bill 'did not propose the total abolition of the Patent Laws' because, he said, 'I am ready to admit that … public opinion is not yet ripe for such a measure'. What is even more interesting is that the sponsor of the Bill, The Lord Chancellor (Hugh Cairns PC QC), admitted in the House of Lords that he had 'never been a strong-advocate for patents', nonetheless he believed that it was 'desirable that the public should discriminate between the principles of a Patent Law and those inconveniences and anomalies which exist in the working of it … [which] in place of going to the abolition of our Patent Laws, are rather to be treated as arguments for the modification and amendment'. Finally he said:

> I will not speculate as to what may happen in the course of 100 years. The country may come round to the opinion that it could do without a Patent Law, and *I should look forward to such a state of things with considerable complacency*. But what we have to do in the present day is to see what we can do to improve the system which exists, and which by this Bill we are not going to overthrow. (Emphasis added) [HL Deb 26 February 1875 vol 222 cc916-41]

- Clearly, leading political and legal figures in Great Britain at that time were ambivalent towards patent monopolies which, in their opinions, had not been shown to be positive inducers of economic growth. But something made them hesitate in abolishing patents. Was it merely public opinion, as they say, or were they concerned to ensure that the British economy was not vulnerable to competition from Germany?

- It must be remembered that it would have been known to the Disraeli government that Germany's first Chancellor, Otto von Bismarck, was consulting with senior German industrialists to develop the country's first national patent law. Working in close consultation with Werner Ernst Siemens (a co-founder of Siemens AG), Bismarck not only sought to establish a German patent system but he also ensured that it would protect German industry. Tariffs may have been the blunt instrument of protectionism, but for Bismarck and Siemens patent monopolies were far more subtle. That this was a view held by Siemens is evident from a speech he made in 1876. He said:

> "Today [German] industry is developing rapidly; and as a result monopolization of inventions and abuse of rights will inevitably expose large segments of industry to serious injury. The government must protect industry against these dangers. *From abroad another danger may arise. Inventive work is far more developed in England, United States and France than in Germany.* … . New legislation will lead to a substantial increase of foreign patentees. We shall experience a wave of foreign – particularly American – patent applications. These patents will not be taken out in order to protect industrial plants established or to be established in Germany; *they will be taken out to monopolize production abroad.* These articles will be imported into this country. Such a danger must be met. It is not enough to provide that foreign patentees be required to submit evidence that they have established a plant in Germany. Such evidence may be mere shadow; they can merely keep a small domestic production going to maintain their patents." (Emphasis added)

The incentive to retain patent systems after 1873 was the protectionist policies that were fueled by a world economic recession and a uniquely American view that patents induced innovation and economic development.

- This Committee should note the words that have been highlighted because his words are as relevant today as they were in 1876. It is through the control on the use of leading-edge technology, which patent monopolies enable, that is posed the greatest economic threat to the host (or target) nation.

- Perhaps it may have been better for Germany to have followed the example of The Netherlands which repealed its patent law in 1869, but as a result of the diplomatic efforts made by the United States in 1873 at the world's first international patent conference held in Vienna, Germany did not have the same incentive to do so. So having committed to maintaining a patent system, Bismarck enacted a German patent law that would minimise the threat that Siemens spoke of.

- Undoubtedly, the German Reichstag's decision to pass the first national patent law in 1877 brought to an end Great Britain's 'free trade' foreign policy.

- Not only that, in what ultimately was a tit-for-tat response, between 1877 and 1880 the Disraeli

government continued to pursue a policy of maintaining British patent laws.

- Ultimately, the British Parliament passed a new and comprehensive patent law in 1883, but ironically it was the re-elected government of William Gladstone, returned in 1880, which sponsored this law. By 1883 even the Liberals (who had spoken in favour of the complete abolition of the British patent system before 1874) accepted that the British patent system had to stay if for no other reason than to protect Great Britain's economy from Germany.

Reform of British Patent Laws, and Protectionism

The decision to retain the British patent system was in response to the threat posed by German industrialisation.

In 1883 the first comprehensive patents law in British legal history deliberately made it difficult to get patents, particularly if the patentee was foreign.

Compulsory licensing was intended to ensure that British patents were not used to suppress industrialisation within Great Britain.

- Even so, certain features which the *UK Patents, Designs and Trade Marks Act, 1883* introduced into the British patent system showed that Gladstone's government was not going to make it easy for anyone, particularly foreigners, to obtain a patent monopoly. These features were:

  (a) Pre-grant patent examination: the British Patent Office, first established by the *UK Patent Law Amendment Act, 1852,* went from being essentially a patent library to being an office which scrutinised patent applications. This was supposed to prevent the grant of patent monopolies with respect to innovations that were not inventions;

  (b) Opposition: any interested party could 'oppose' the grant of a patent before grant by the British Patent Office. This enabled the market, so to speak, to self-regulate through the *opposition* process. The idea was that competitors would actively monitor each other's technological developments and so would augment the examination conducted by the patent examiners employed by the British Patent Office. This was to give British manufacturers the ability to supply information to the British Patent Office;

  (c) Definition of 'invention': for the first time the word was defined in a specific patent statute 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'. Accordingly, patentable subject matter was restricted to a specific class of innovation – one that was both a 'manner of new manufacture' and not illegal or injurious to the British economy;

  (d)Compulsory Licensing: Anyone in Britain could apply for a 'compulsory license' if the 'invention' was being manufactured 'exclusively or mainly outside' of the Great Britain or if the 'reasonable requirements of the public' with respect to its availability were not being met or if any person was 'prevented from working or using to the best advantage' that invention. The compulsory licenses were granted by the British Board of Trade 'on such terms [as the Board] may deem just'.

- Thus, under the 1883 legislation the British Patent Office was no longer a mere repository of patent information but was required to assess the effects of British patents on the British economy.

British and US Patent Systems Diverge – Misuse of Patent Laws and Antitrust

- While both the US and the UK had established patent offices, it would be fair to say that by 1890, when the *Sherman Antitrust Act* became law in the US, the US Patent Office's only role was to assess patent applications without reference to economic issues, whereas the British Patent Office did more – it was required to consider the economic effects of patents as well. Essentially, the economic effect of US patents on the US economy was a matter for the US Department of Justice, not the US Patent Office, whereas in Britain it was a matter for both the British Board of Trade and the British Patent Office. So although both patent systems had their genesis in section 6, *Statute of Monopolies, 1623*, by the turn of the 20th century they had diverged in this very significant way.

The British patent system was always designed expressly to take into account the economic effects of British patents in Great Britain, whereas by the mid-19th century in America that role had been relegated to antitrust laws.

- This philosophical divergence between the British and American patent systems continued to widen. By 1907 the British Parliament had replaced the 1883 legislation with the *Patents & Designs Act* - significantly strengthening Britain's economic shield in the process. Unlike the 1883 legislation, which gave the power to revoke exclusively to the courts, for the first time the British Patent Office was provided with the power to revoke a British patent, after a four year threshold, on the grounds that the patented article or process was 'manufactured or carried on exclusively or mainly outside' the UK. This was in addition to the fact that applications for compulsory licenses could continue to be made to the British Board of Trade, which was now also given the power to revoke the patent as an option to the grant of a compulsory licence. The new legislation thus provided a twofold defence to the British economy. While the working of a patent by a patent owner exclusively outside of the UK was retained as a ground upon which to seek relief, jurisdiction was transferred from the British Board of Trade to the British Patent Office at the same time as the applicable relief was not solely a compulsory licence but included the option of revocation. Moreover, while the ability to petition for a compulsory license or revocation was carried over from the 1883 legislation, the British Board of Trade was now required to refer an application to a court which would then decide whether to grant a compulsory licence or revoke the patent.

Impact of this Divergence on Australian Patent Law

- This divergence between US and British patent systems is also relevant to Australian patent law because, almost unquestioningly, **the new Australian Parliament not only modelled the *Patents Act, 1903 (Cth)* on the *UK Patents, Designs and Trade Marks Act, 1883* (*as it was amended in 1902)* but the Australian Parliament took its lead from London and amended the 1903 legislation to stay in step with subsequent developments in British patent law.**
- According to David Fulton, a British patent law commentator of the day, the patent legislation in 1902 and 1907 restored the 'original intention of the Statute of Monopolies', one that saw patents 'not granted to inventors as a reward for being ingenious, but for the purpose of introducing new manufactures into the country and to create increased employment for the working classes'.
- It is commonplace for people to believe that patents were and are a reward for inventors' ingenuity and it is important to appreciate the fact

that this is not now nor has it ever been the case. It may well be a side effect of patents that inventors may receive higher than normal prices for their inventions, but that was not, as Fulton emphasised, the principal purpose of patent monopolies.

True Purpose of Patent Law: Incentive for Industrialisation, Not to Reward Ingenuity

- The true purpose of the British patent system was always economic and while Fulton was right to point out that patent monopolies were designed to act as inducements for domestic industrial development, he acknowledged that whether they actually did so depended on how patentees chose to exercise their patent monopoly rights. As Fulton said:

> It is equally indisputable that, under the conditions existing before the coming into force of the present Act, many a patent granted to a foreigner, so far from being an encouragement to native industry, was a positive fetter upon the wrists of those who would otherwise have found profitable employment had working in this country been made compulsory.

It is commonplace for people to believe that patents were (and are) a reward for inventors' ingenuity. This is not now nor has it ever been the case.

The true purpose of the British patent system was always economic and while patent monopolies were designed to act as inducements for domestic industrial development, whether they actually did so depended on how patentees chose to exercise their patent monopoly rights.

- Fulton's view was also shared by Lloyd George (British Prime Minister (1916 - 22)) who, while the President of the British Board of Trade, introduced the 1907 patent legislation in the British Parliament. During the Bill's reading in the House of Commons, George emphasised that the object of the legislation was to 'combat the evil' created by the 'abuse' of the British patent system by foreign owners of British patents (and by this he meant mainly German chemical companies that had cartelised world chemical production). George's complaint was not only directed to their use of British patent monopolies so as to suppress chemical production in Great Britain but how, in 'covering all possible combinations [of chemicals]', they were used to restrict research and development as well. Kenneth Swan QC (a well respected British barrister who would chair a Parliamentary Committee of Inquiry into the British patent system in 1945) also shared these concerns. Writing in 1908, Swan believed that '[l]atter-day commercial methods have ... shown that in the hands of unscrupulous proprietors a British patent can be turned to great profit for the patentee without a corresponding benefit to the public.'

Calibrating the Patent System

- Thus, what Fulton, George and Swan understood was how important it was to get the balance right between the incentive which patent monopolies supposedly gave to domestic industrial development and the cost and effect which those monopolies imposed on the economy as a whole. If the patent system was out of balance, so that little regard was paid to the negative effects of patent monopolies, then rather than inducing economic growth patent monopolies could (and did) suppress it.
- Even worse, the patent system could be (and was) used by foreign interests to subjugate the host country's economic development.

German suppression of British and US industrialisation using Patents: Chemicals, Medicines and World War I

- Unfortunately, the *UK Patents &*

Designs Act, 1907 came a little too late to provide the British economy with any meaningful protection against German industry, which in 30 years had become the leader in chemical and electrical technologies. What was unforeseen was a war which brought the German and British Empires into military conflict only 7 years later. Even neutral countries, such as the US, suffered as a result. US textile manufacturers had come to rely on new and leading-edge artificial dyes, such as alizarine, that were manufactured in Germany and imported into the US; but with a wartime embargo on German exports in place, this became impossible. Suddenly, the US Congress realised that patents had undermined, not promoted, US industrialisation, the US economy and US national security. Of course, German chemical companies had patented these artificial dyes (which were then the product of leading-edge technological processes) in the US, a country that permitted the patenting of chemical substances and medicines (something which could not be done in Germany). Using their US patent monopolies over chemical substances, German companies ensured that the US remained an export market for their dyes and medicines by suppressing their manufacture in the US. Accordingly, essential know-how and expertise over chemical production remained in Germany. Shrewdly, much of the information disclosed in the US patents by German inventors was not only insufficient to permit large scale commercial production, but in some instances was so misleading as to be dangerous to human life. Indeed, even when passing pre-grant examination, these patents provided very little scope for any meaningful technological transfer to the US.

It is important to get the balance right between the incentive which patent monopolies may provide industrial development and the cost and effect which those monopolies imposed on the economy as a whole. If the patent system is out of balance, then rather than inducing economic growth patent monopolies will suppress it.

- Beyond artificial dyes, however, were medicines. The analgesic, Aspirin, and the anti-syphilitic, Salvarsan, were considered to be the miracle drugs of the day. Their production and availability in most countries, however, was tightly controlled by German companies through the patent monopolies which the host countries had granted. In February 1917 this situation prompted Dr F E Stewart, a noted American pharmacist, to write to the government of US President Woodrow Wilson stating:

> It becomes evident that [US] patent law as now interpreted and applied does not promote progress in the arts of chemistry, pharmacy and drug therapeutics as carried on in the United States; in fact it is a very serious hindrance … to science … because it does not stimulate original research on the part of would-be inventors in this country. Neither does it build up United States industries.

- The UK was in similar dire straits. In this extraordinary situation, the reinforcement of the compulsory licensing provisions under the *UK Patents & Designs Act, 1907* to even include revocation as an option proved to be ineffective. **The British and American patent systems, being the only ones that permitted the patenting of *all* inventions (including chemicals and medicines), had unwittingly undermined their own ability to developing crucial know-how and industrial capacity in leading-edge technological fields.**

- Of course extraordinary events prompted extraordinary responses. For instance, as reported in *The Australian* on 17 September 1915,

the Australian Prime Minister, William (Billy) Hughes, announced that the Commonwealth of Australia had compulsory licensed Henry Shmith and George Nicholas to manufacture and sell Aspirin. According to Hughes the Australian-made version of Aspirin was 'purer' than the German and the 'conditions of the license' ensured that the drug should 'comply strictly with the requirements of the British *Pharmacopœia'*, and that the conditions of manufacture and the price at which Aspirin would be sold should be 'satisfactory to the Attorney-General'. The Australian version used the trade mark Aspro, and through the marketing of this medicine by Alfred Nicholas sales of Aspro were eventually made to the UK, South Africa, Belgium, Egypt and by 1935 to France. This generous move by Hughes established one of Australia's most important pharmaceutical companies.

- The US and British governments both passed their own legislations entitled: *Trading with the Enemy Act*. The US legislation passed in 1917 and, despite the fact that WWI had ended, in 1919 nearly 10,000 patents were seized under this legislation, including approximately 100 patents that related to radio technologies alone. While the confiscated radio patents were sold to the US Navy Department for nominal sums, by far the largest single beneficiary of these patents was The Chemical Foundation, Inc. This Foundation, which acted essentially as a trustee for the US government, then used these US patents, confiscated from German chemical companies such as Bayer, to establish a chemical production capacity in the US. Indeed, many US pharmaceutical giants owe their very beginnings to this policy.
- The British Parliament went further and in 1919 passed amendments to the *UK Patents & Designs Act, 1907* that expressly excluded chemical products as patentable subject matter.
- What WWI had demonstrated to British and American policymakers was that patents were not innocuous instruments which only acted as stimuli and rewards for inventions. Moreover, it was a matter of national economic interest and security that a country had a practical capacity to produce leading-edge technologies, regardless of which country was the originator of these technologies.

What WWI demonstrated to British and American policymakers was that patents were not innocuous instruments that acted as stimuli for inventions.

The national economic interest and security demanded that at all times their countries possessed a practical capacity to produce leading-edge technologies.

The Rising Economic Threat of Technological Cartels Prior to WWII

- Throughout the 1920s, as US and British companies tried to develop large scale chemical production capacities, they soon realised that despite possessing the factories and patents once owned by German companies, without the associated know-how and practical and scientific expertise, which only the German's had, progress would be very slow. Exploiting the need for this knowledge, German industrialists were able to negotiate their way back into positions of influence within US and British corporations, either directly through share ownership or through strategic corporate relationships. For example, by 1926 Standard Oil had commenced a joint research project into the establishment of synthetic fuel production in the United States with I.G. Farbenindustrie A.G. (I.G. Farben) using catalytic hydrogenation research. [Incidentally, during WWII I.G. Farben's used the free labour supplied from Auschwitz to produce synthetic oil and rubber. It also owned patents over Zyklon B, the poison, manufactured by one of its subsidiaries, used in the Holocaust]

- Had it not been for the spectacular collapse of world capital markets in October 1929, the subsequent Depression and the rise of fascism in Europe during the 1930s, this process would have probably continued. However, the prolonged effects of the Depression and the remilitarisation of Germany made US and British policymakers wary of these corporate associations. On 29 April 1938 US President Roosevelt sent a message to the US Congress complaining that the 'concentration of private power without equal in history' was a threat to the United States. He asked that the US patent system be scrutinised because he believed that the concentration of corporate power was being exercised through the use of extensive patent portfolios that controlled leading-edge technologies. He wanted the US Congress to amend the patent law 'to prevent their use to suppress inventions and to create industrial monopolies'. Roosevelt struck out at the patentee's right to exclude the working of an invention by proposing that patented inventions should 'be made available for use by anyone upon payment of appropriate royalties'.
- However, with the US entering WWII, Roosevelt's attention turned to the defence of his country. Thus, his call for patent law reform faded as the US government instead turned to the *US Trading with the Enemy Act, 1917* to expedite its control, seizure and confiscation of German, Italian and Japanese owned patented technology. Once again the ownership of thousands of patents was transferred from foreign (enemy) nationals to US corporations. The British Parliament passed its own version of the *Trading with the Enemy Act, 1939*.
- While this action restored national security, Roosevelt left it to Thurman Arnold, an Assistant Attorney-General and head of the US Department of Justice's Antitrust Division (1938-1943), to unravel the cartels which had formed between US and German (and other foreign) corporations around various patent technologies.
- For example, in 1919 Sterling Drug, Inc acquired the plant, equipment, trade marks and patents owned by Farbenfabriken vorm. Friedr. Bayer & Co (Bayer Germany) in the US and confiscated by the US government. During the 1920s and 30s Sterling had become closely associated with I.G. Farben for the reasons already explained. Sterling and I.G. Farben came to Arnold's attention prior to WWII, but by 1941 as a result of his investigation into possible breaches of the *Sherman Antitrust Act, 1890*, Sterling, three of its subsidiaries and two of its most senior directors pleaded guilty, agreed to pay fines and gave written undertakings to break 'all contractual obligations with I.G. Farben' and to agree 'never again to promise any other drug manufacturer not to compete in foreign markets.'

Patents are supposed to contain information that teaches an ordinary skilled person how to make the invention. As the Americans learned in the 1920s this was often not true. On many occasions the information was deliberately misleading or so preliminary as to be practically useless.

3. Contemporary Problems and Issues with Patents.

- One of the longest and most lucrative cartels in history involved General Electric (GE) and Philips, which were the world's leading manufacturers of incandescent light bulbs (first invented around the same time by Joseph Swan in England and Thomas Edison in the US in 1878). They too were investigated for antitrust violations and by 1949, when the litigation between the Respondents and the US Department of Justice was finalised, nearly 70 years had passed since Edison's light bulb was first patented and around 33 years had passed since the last of the patents over key improvements had been granted. This meant that for over 50 years GE (in agreement with Philips) had, in the absence of a patent monopoly, used its market leadership, gained through patent monopolies, to illegally maintain and extend market control through various agreements and commercial devices deliberately designed to suppress competition.

The European Commission's Competition Commissioner, Neelie Kroes said: 'The worst example we found of [the use of patent monopolies to suppress generic medicines] was 1,300 separate patent filings, across the EU, for a single medicine'.

- Relevant to this Senate Inquiry are current events in Europe. Presently, the European Commission is undertaking a wide-ranging antitrust investigation of pharmaceutical companies into their alleged use of patents and patent litigation to inhibit competition.
- On 28 November 2008 the European Commission's Competition Commissioner, Neelie Kroes, held a press conference in Brussels in which she outlined the preliminary findings of a year long investigation. The Commission not only targeted established pharmaceutical giants but generic manufacturers, who had received some US$200 million from pharmaceutical companies for agreeing to withhold production of generic medicines as part of out-of-court patent litigation settlements. Apparently, 'patent clustering' is another tactic which has been used to create barriers to entry. In her statement, Kroes said: 'The worst example we found of this method was 1,300 separate patent filings, across the EU, for a single medicine'. Yet another tactic, which the Report noted, is the use of extensive patent litigation which when resolved usually went against the patentee - meaning that the patent, as granted by the EPO, was invalid in the first place. Consequently, even during the course of the patent litigation, which on average took three years, the patentee received an economic and benefit that it was not entitled to receive. Despite this, there is no mechanism currently in place that enables the authorities to recoup the economic value of the illegal patent monopoly from the patentee unless that conduct amounts to a breach of European antitrust laws, in which case, substantial fines and penalties can be imposed by the European Commission. According to Kroes, even so, the alleged illegal antitrust activity has cost EU governments about US$3,800 million to date. The investigation is continuing.
- What the European Commission's investigation demonstrates is that large multi-national corporations (which are usually also the owners of key patents over leading-edge technologies) have, in the absence of a strong regulatory and enforcement regime, a propensity to use their market power (and this may be exercised through patent and patent related litigation) in ways that are economically and socially damaging. It also demonstrates that despite the fact that 140 years have passed since the British Royal Commission into the workings of

the British patent system first heard complaints about the cost of patent litigation, and despite all of the measures introduced into various patent systems and court administrations around the world to reduce these costs and improve the efficiency of courts and patent administration since that time, the very same complaints are being aired today. As a result, not only has patent litigation been used, as Kroes alleges, for unlawful purposes, but the cost of patent litigation around the world (including in Australia) is itself an accessory to that illegality. On 15 February 2007 before the US House of Representatives Subcommittee on Courts, The Internet and Intellectual Property Committee on the Judiciary, Dr Mark Myers, a former Vice-President of Xerox Corporation, said in evidence:

> … [patent] litigation costs are escalating rapidly and proceedings are protracted. Surveys conducted periodically by the American Intellectual Property Law Association indicate that litigation costs, millions of dollars for each party in a case where the stakes are substantial, are increasing at double digit rates. At the same time the number of lawsuits in District Courts is increasing.

- However, the European Commission is not alone. On 27 January 2009 the US Federal Trade Commission and The State of California filed a complaint in the US Federal District Court for the Central District of California against three generic pharmaceutical manufacturers and Solvay Pharmaceuticals, Inc, the US subsidiary of the Belgium based Solvay SA. The complaint alleges that the generic manufacturers have violated the *Sherman Act, 1890* by agreeing to 'delay until 2015 the sale of the low-cost generic versions of AndroGel, a widely prescribed branded testosterone replacement drug, in exchange for substantial payments from Solvay'.
- The charges made in the Complaint arise from the agreement to settle patent litigation which Solvay had brought against the generic manufacturers for patent infringement and, in response to which, the generic manufacturers had cross-claimed to revoke the relevant Solvay patent (which was due to expire in 2020) on various grounds.

The European Commission's investigation demonstrates that large multi-national corporations (which are usually also the owners of key patents over leading-edge technologies) have, in the absence of a strong regulatory and enforcement regime, a propensity to use their market power (and this may be exercised through patent and patent related litigation) in ways that are economically and socially damaging.

- In this respect it is important for the Committee to understand that the grant of the patent under the *US Patents Act, 1952* (as it does under the *AU Patents Act, 1990*) comes without any conditions in respect of how a patentee may exercise their right of exploitation. Thus it seems, at first glance, impossible that the terms of a patent litigation settlement agreement, particularly when under US patent law a granted patent is presumed to be valid (not under Australian patent law), could constitute a breach of antitrust laws. After all, is not the patentee merely acting within its legitimate rights?
- However, the Complaint suggests otherwise. It alleges that how the patentee exercised its unconditional patent rights did constitute a contravention of antitrust laws. The Complaint asserts that the 'Defendants knew that if generic entry were to occur, Solvay's sales would plummet, as generic AndroGel would be priced dramatically lower than branded AndroGel' and so in settling the patent litigation protected its

revenue generated from the sale of this product in the US, which 'in the twelve months ending December 2007 … totalled … over $400 million.'

- The Complaint describes the impact to the economy and to the cost of healthcare in the US in these terms:

> Significant consumer savings can result when generic companies successfully challenge patents and enter [the market] prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the antidepressant drug Prozac resulted in generic entry 2 1/2 years before patent expiry and about $2.5 billion in estimated consumer savings. Another successful challenge invalidating patents covering the cancer drug Taxol resulted in generic entry over 18 years before patent expiry and estimated consumer savings of more than $3.5 billion.

The successful legal challenge which invalidated US patents covering the cancer drug Taxol resulted in generic entry over 18 years before patent expiry and produced estimated consumer savings of more than $US3.5 billion.

- Thus, by agreeing to settle the patent dispute, the challenge to the validity of Solvay's US patent was withdrawn. Accordingly, Solvay remains able to use its US patent monopoly to control the market (and price) for AndroGel in return for which Solvay agreed to: (a) allow the generic companies to enter the US market in 2015 and (b) provide them with 'substantial compensation'. In so doing, the Complaint alleges that '[r]ather than compete, [the Defendants] … agreed to cooperate on AndroGel and share in monopoly profits'.
- This example further demonstrates the propensity of patent owners (particularly pharmaceutical companies) to use their patent monopolies to thwart litigation that may, should it be successful, invalidate the patent that legitimises the patent monopoly. Furthermore, it demonstrates that private patent litigation is not an adequate check against the failure of patent offices to grant patents when they should not.
- What the bringing of the Complaint demonstrates is that even though the grant of a patent under US patent law may be unconditional, laws that protect the economy against illegal uncompetitive conduct, do impose conditions that limit or restrict the patentees how they exercises their patent rights in the US.
- Undoubtedly the Committee will read or hear during the course of this Inquiry that the problem is not the patent system but the way in which patentees exercise their patent rights. This example seems to support this. But the Committee must consider the possibility that a law that facilitates the kind of anticompetitive conduct complained in a systemic fashion suggests that the problem is indeed the patent system.
- As history shows, corporations accustomed to the above normal revenues generated by patent monopolies (usually over leading-edge technologies) have a significant propensity to play the patent system, both before and after the expiration of those patent monopolies, so as to maximise those revenues. Patentees do this by using their considerable economic and legal power to threaten, sue and prosecute alleged infringers (even though the validity of their patent monopolies may be questionable) through the courts. The cost and inconvenience of patent litigation is a considerable burden that only the most determined, wealthy and sophisticated defendants can legitimately bear. Thus, for the most

part, many patents of dubious validity remain on the patents register merely because there is no regulatory mechanism within the patent system, outside of the patent office itself, to test the validity of patents.

- Moreover, even when patents are invalidated as a result of private litigation, either wholly or partially, there is no penalty, civil or criminal, incurred by the patentee. Thus, at the present time, in the case of a patent which is invalidated, patentees retain the economic value of the patent monopoly *to which they were not entitled*. The lack of such penalties merely encourages, not deters, patentees to seek patent monopolies knowing that they are likely to be invalid or being recklessly indifferent to their validity.
- Furthermore, as both the European Commission and Federal Trade Commission examples demonstrate, the settlement of patent litigation usually demands that parties keep the terms of the settlement confidential. This lack of transparency makes it much more difficult for antitrust regulators to monitor this kind of illegal activity; thus encouraging, not deterring it. In this respect, the Committee should note that in order to undertake the antitrust investigation detailed above, the European Commission was required execute simultaneous raids on more than 40 pharmaceutical company headquarters and offices throughout the EU.
- This situation represents a serious failure in the antitrust regulatory regime only made worse by the fact that patent offices are finding it increasingly difficult to maintain acceptable patent pre-examination standards.

History shows that patentees accustomed to the above normal revenues generated by patent monopolies (usually over leading-edge technologies) have a significant propensity to play the patent system, both before and after the expiration of those patent monopolies, so as to maximise revenues.

Patent Office Efficiency: Reduced Productivity, Low Patent Examiner Morale and Low Patent Quality

- Beyond the issues of patent litigation costs and patent-antitrust related activity, it has been apparent for some time that patent offices (in virtually all major countries including Australia) are finding it increasingly problematic to complete pre-grant examination of patent applications to an acceptable standard. Consequently, there are growing concerns among patent administrators and antitrust regulators that patent quality across the world (not only in Australia) is falling, with the result that the number of invalid patents being granted by patent offices is rising. Dr Myers, also co-chair of the US National Academy of Sciences' four year study entitled 'The Patent System for the 21st Century', said in April 2004:

> Basically over the last fifty years there has been a significant and continuing strengthening of the patent processes within the United States and the world. You have had patenting extended to new technologies in the biotech area; patenting extended to technologies that previously were not subject to this form of intellectual property, such as software; the encouraging emergence of new players, universities and public research institutions; strengthening of the position of patent holders versus alleged infringers; relaxed antitrust constraints on patent use; and the extended reach of patenting upstream into scientific tools, materials, and discoveries. So this has been a fifty year period of greatly enhancing the

> patent system. But it has created strains. Patents are being more zealously sought and aggressively enforced, the volume is increasing, the cost is increasing, and the benefits of a patent stimulating innovation varies considerably across different parts of the industrial sector.

- According to a Report released in 2004 entitled 'Quality of Examination at the EPO' [as in the European Patent Office in Munich, Germany] prepared by the Staff Union of the European Patent Office (SUEPO), the EPO established a working group to investigate the 'strategic quality' of the EPO's patent examination standards. The Report stated:

> In the last couple of years, increasing concerns, not only of internal circles, that quality standards were seriously slipping, have led the Staff Representation to take a more pressing position in a number of publications.

"Patents are being more zealously sought and aggressively enforced, the volume is increasing, the cost is increasing, and the benefits of a patent stimulating innovation varies considerably across different parts of the industrial sector."

- One of the concerns raised was the EPO's reference to its 'clients' and 'products', which seemed 'particularly odd in view of the fact that the EPO is not even a public *utility* producing some vendible product or service'. It highlighted the fact that the EPO defined its products as 'granted patents'. Indeed, this is a criticism that can also be levelled at the Australian Patent Office, which seems to operate as a government 'business' with its own 'clients', 'products' and 'services' rather than providing an 'examination process' that achieves a 'balance between the monopoly right granted to the patentee and his contribution to the increase of technical knowledge'. But as the Report critiqued, the approach adopted by the EPO was inconsistent with the 'legal mandate … to ensure that patent applications meet the legal standards set out in the law'. Paraphrasing the Report, its main complaint was the unreasonable 'productivity' expectations for 'granting patents'. The Report concluded:

> … it should be clearly recognised that the EPO is not at the service of any "client", but is a public authority, whose decisions must be led solely by public interest. Staff should be given the necessary means to perform their tasks correctly, including a reasonable time allocation and appropriate initial and continuous training.

- The seriousness and extent of the problem is growing, as the European Community's Administrative Council's Report of November 2007 entitled 'Future Workload' shows. According to this Report the European Community is entertaining the 'outsourcing' of patent examination to 'Japan, China and others', if only so that the EPO can 'meet the challenges' of its 'future workload'. Citing statistics provided by the World Intellectual Property Organization (WIPO) in its 'World Patent Report 2007', the Report confirms that in 2005 'more than 1.6 million applications were filed worldwide'. It also noted that studies 'show that there is not only an ever-growing number of patent applications but also a steady increase in the complexity and volume of applications, as well as a growing number of claims filed.' Relevant to this inquiry is the finding that 'medical technology' was one of the 'four of the ten fastest-growing technologies between 1990 and 2003 before the EPO' and that between 2000 and 2006 there was an increase of almost 60% in worldwide international patent applications

filed through the Patent Cooperation Treaty.

- The reasons that the world's major patent offices have suffered a 'significant impact on the production' of patent monopolies, according to the Administrative Council's Report, are:

  > (a) the increasing growth of applications;
  >
  > (b) the complexity and volume of applications;
  >
  > (c) the shift towards technically more difficult fields; and
  >
  > (d) the steeply growing prior art.

- Naturally, the costs for patent offices are rising. The report confirms that the per unit costs at the EPO have 'substantially increased since 2004'. As these costs rise so does the pressure on patent offices to increase revenue, which is principally derived from patent filing and renewal fees. This will be particularly difficult to accomplish when there are calls for reductions in patent filing and renewal fees. Therefore, patent offices are being squeezed as the cost of examination rise while their revenues stagnate or fall.

The European Community's Administrative Council's Report of November 2007 entitled 'Future Workload' shows that the 'ever increasing workload' of patent examiners is producing 'growing backlogs and insufficient time and resources to examine applications with the necessary thoroughness.'

- Patent growth is not, however, a European-US phenomenon, but is being contributed to by patent applications filed in China, South Korea and India which, according to WIPO statistics in 2004, have increased by 27.9%, 27.3% and 23.6% respectively.

- According to the Report what this 'ever increasing workload' is producing is namely:

  > … growing backlogs and insufficient time and resources to examine applications with the *necessary* thoroughness. (emphasis added)

- With regards to the 'necessary thoroughness' of pre-grant patent examination, it is important to appreciate that the 'steeply growing prior art' is as much a contributor to patent office inefficiency as are the 'increasing growth of applications, the complexity and volume of applications [and] the shift towards technically more difficult fields'. This is because pre-grant examination is only as good as the ability of the patent examiners to access relevant data: namely, published scientific, medical and technical publications; patents; patent applications; trade and industry literature and other publicly accessible information that make up the 'prior art'. Therefore, the more complex the technology the more complex the prior art and the more difficult it is for a patent examiner to compare that prior art against what is claimed to be an 'invention'.

- It is worthy at this juncture to take stock of the situation today, given the controversy over patent monopolies that preoccupied a succession of British (and European) governments from the 1850s and the serious criticisms levelled at patent monopolies from both sides of politics in the period 1850 to 1876. Moreover, despite the extensive measures introduced to ameliorate the damage that patent monopolies inflicted upon the British economy, first introduced by the 1883 patents legislation and successively by the 1907 legislation and the amendments in 1919, today the same underlying problems exist. What this suggests, as the parliamentarians in the 1870s

suspected, is that the world's patent systems are irreparable and that the time has come for the abolition, in all their forms, of patent monopolies. It may be, as Lord Cairns (The Lord Chancellor in Disraeli's Conservative government) believed and as Lord Granville (a Liberal and noted British statesman) conceded in the House of Lords in 1875, that the time was not then right to abolish patent monopolies in Great Britain. But faced with the evidence which we have today, and after 140 years of concerted international effort effected through WIPO and its predecessor to harmonise patent laws, it should not be difficult for this Committee to take the initiative to do so. That it should do so is further reinforced by the international agreements that are in place, supposedly, to foster *free trade*. Indeed, given the World Trade Organization and the ideals which it represents, being antithetical to protectionism, that patents, which are instruments of protectionism, should be encouraged and fostered is an anomaly that can only be removed through their complete abolition.

Despite the attempt to ameliorate the negative effects of patent monopolies on the British economy, first introduced by the 1883 patents legislation and successively in 1902, 1907, 1919, 1932 and 1949, the same underlying problems that were complained of in 1862 exist today.

- In terms of the scope of this Senate Inquiry, which is directed specifically to patent monopolies granted over isolated biological materials and their effects on the provision of healthcare and medical and scientific research, the statement of Mr B. Samuelson, a British parliamentarian, on 7 March 1871 is as pertinent today as it was then. He said:

> The whole mischief of the Patent Laws had arisen from the interpretation given to the expression "new manufactures," which had been extended until they had been made to include any new invention *whatever*. [HC Deb 07 March 1871 vol 204 cc1512-34]

- As at 2009 tens of thousands of patents have been granted over isolated biological materials. Not only are these things not 'manners of new manufacture' (being an operative criterion in the current Australian patent legislation), but they are nothing more than natural phenomena that have been discovered and removed from their natural environments. Indeed, if one examines the rationale that has been used to justify the patenting of these biological materials (namely, their isolation), one immediately appreciates how the patent laws, nearly 140 later, remain open to the same criticism made by Samuelson in 1871.

- The propensity for those that benefit the most from patent monopolies to employ patent attorneys to draft patent applications that inevitably (no matter what legislative mechanisms are put in place to stop this behaviour) extend to things that are not 'manners of new manufacture', demonstrates the futility of persevering any system of patent monopolies. Indeed, the playing of the patent system is so entrenched in the psyche of patent attorneys that this profession, which is skilled at word play, will exploit whatever loophole is inadvertently created in statutory language to obtain a patent monopoly for their clients, regardless of the spirit and intent of that legislation.

- In the context of this Inquiry it matters a great deal that the Danish Council of Bioethics, a body of independent scientists and ethicists who were charged with investigating the patenting of human genes in Denmark and the European Biotechnology Directive which facilitated this, stated in their 2004 report entitled *Patenting Human Genes and Stem Cells* that:

> The Council's principal objection to the wording of the directive was precisely that in reality it rubber-stamps the practice that has gradually evolved in the USA, Japan and Europe whereby, under certain conditions—which it turns out to be very hard to get a grasp on in practice—parts of the human body can nevertheless be patented.

And later:

> … it cannot be said with any reasonableness that a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body.

The playing of the patent system is so entrenched in the psyche of patent attorneys that this profession, which is skilled at word play, will exploit whatever loophole is inadvertently created in statutory language to obtain a patent monopoly for their clients, regardless of the spirit and intent of that legislation.

- To understand how this has come about we must first return to British patent history and go back to 1919 when the British Parliament passed amendments to the *UK Patents & Designs Act, 1907* for the express purpose of banning the patenting of chemical and medicinal products.

4. The Banning of Patents over Chemical and Medicinal Products and the Strengthening of Compulsory Licensing in 1919

- The response in the US and the UK (including Commonwealth countries) to the shortages of chemicals and medicines caused by the German embargo on the export of these goods during WWI, and exacerbated by the effect of German owned US and British (including Commonwealth countries) patents, differed significantly. Whilst the US government, through the power provided by the *US Trading with the Enemy Act, 1917,* simply confiscated German owned US patents and the plant and equipment of German chemical and pharmaceuticals companies situated on US territory (after military hostilities with Germany had ceased) and established the Chemical Foundation which then licensed US companies to create a US capacity for the domestic production of such goods, the British government took a slightly different approach. [Vaughan, F.W. (1919), 'Suppression and Non-Working of Patents, With Special Reference to the Dye and Chemical Industries', *The American Economic Review*, 9 (4), 693-700; Steen, K. (2001), 'Patents, Patriotism, and "Skilled in the Art": USA v The Chemical Foundation., 1923-1926', *Isis,* 92, 91-122]

By the end of WWI the US and British governments both recognised that foreign owned patents had been used to undermine their own domestic capacity for industrial production of, what were then, leading-edge technologies.

- In 1919 the British Parliament passed amendments to the *UK Patents & Designs Act, 1907*. Some of the amendments were in anticipation of the *Treaty of Versailles* which was in the process of being settled. Instead of the wholesale confiscation of German owned British patents, the British government decided to simply ban the patenting of chemical products, adopting the German approach which from its legislative inception in 1877 permitted patents on chemical processes but not on chemical products (which included medicines) themselves. It also further strengthened the compulsory licensing provisions first introduced in the 1883 patent legislation and subsequently reinforced in the 1907 patent legislation. Accordingly, if a foreign-owned British patent (of any kind) was not worked within the UK 'without undue delay', the British Patent Office was authorised to issue a 'license of right' on such terms as the Comptroller of Patents would 'think expedient'. Furthermore, the Comptroller could, if the foreign patentee was unable to demonstrate that it had sufficient capital in the UK to work the patent, grant an exclusive license to a British manufacturer or revoke the patent.
- With regard to patents over the processes for chemical products and substances intended for food or medicine, the British Patent Office was required to grant British manufacturers a license unless there were 'good reasons to the contrary'. The Comptroller of Patents was directed to take into account 'the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention'.
- These divergent approaches were reflective of differing views between US and British policymakers on the role of patents - a view that the US steadfastly maintained despite the apparent disastrous results during WWI. Equally, the British maintained their bias towards compulsory licensing despite the fact that WWI demonstrated that compulsory licensing, available since 1883, had done little or nothing to prevent the shortages of essential chemicals (leading-edge technologies) at a time of national emergency.

- That said, the US and British governments both recognised that foreign owned patents had been used to undermine their own domestic capacity for industrial production of, what were then, leading-edge technologies. That the US government took a more drastic approach to that taken by the British government is simply reflective, again, of a philosophical divergence. Either way both meant, by their actions, to encourage the establishment of a domestic production capacity of leading-edge technologies and goods that were essential to the national security of their countries; and confiscating foreign owned patents or ameliorating their effects, were seen as the first steps towards achieving their goal.

- When the British government appointed a Committee of Inquiry in 1930 to examine and report on how the 1919 amendments to the patents law had been operating, the Committee recommending the retention of both the ban on the patenting of chemical substances and the Comptroller's power to revoke patents. The Committee believed that foreign pharmaceutical patent owners were, as a result, more likely to grant licenses to British manufacturers on reasonable commercial terms. [UK Board of Trade, C. H. Sargant, (1931), *Report of the Departmental Committee on the Patents and Designs Acts and Practice of the Patent Office*, 1930-31 [Cmd 3829]

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- The Sargant Committee also recommended that the grounds of opposition and revocation be provided in the patents legislation and so, in 1932, amendments to this effect were made to the *UK Patents & Designs Act, 1907*.

- **Similarly, the Australian government of Joseph Lyons commissioned a Committee of Inquiry chaired by Sir George Knowles which, for reasons of conformity with Great Britain, recommended in 1935 that the Australian patent legislation be similarly amended.**

Patent Law Reform in Britain and Australia after WWII – Removal of the Ban on the Patenting of Chemicals

- With the end of World War II came a renewed interest in the British patent system. Why this was so when there were other more pressing issues confronting Great Britain in the wake of WWII is unclear, but one possibility might be the decision to establish the National Health Service (NHS), a revolutionary welfare scheme which guarantee healthcare to all Britons. That this is the reason is plausible given that under the NHS all prescription medicines were to dispensed free-of-charge and thus the price of patented medicines would be a major component of its budget.

- Accordingly, the British government recognised that a mechanism was needed to keep a lid on the price of patented medicines; and with patents being a cause of higher-than-normal prices, naturally attention was directed to the way the British patent system could be adjusted to ameliorate the potential for the NHS budget to blow-out. Thus, a Committee chaired by Sir Kenneth Swan QC (referred to earlier), was appointed to look into the British patent system and between 1945 and 1947 the Committee produced two interim reports and a final report.

- Surprisingly, the Committee recommended the repeal of the ban

on the patenting of chemical products which had been introduced in 1919. The Committee's decision, however, was not made on the basis that the ban had been shown to have produced deleterious effects on the British economy or that it had not achieved some level of success in encouraging the British production of chemicals and medicines. Rather, the reason was simply to do with the actions of patent agents (as they are known in the UK – and known in Australia and the US as patent attorneys) who, according to the Committee, had deliberately undermined the effectiveness of the ban by drafting patent claims so as to 'cover all conceivable methods of manufacture', producing the effect that 'the substance itself and not the process of manufacture' was the subject of the patent monopoly. Under those circumstances, maintaining the ban was a futile exercise.

By 1947 another Committee had concluded that British patent agents had deliberately undermined the effectiveness of the ban by drafting patent claims so as to 'cover all conceivable methods of manufacture', producing the effect that 'the substance itself and not the process of manufacture' was the subject of the patent monopoly.

- Therefore, the Committee turned its attention to the use of compulsory licensing as the chief price control mechanism for patented medicines. Swan had known how easy it was for registered trade marks to be associated with patent medicines so that, even after the patent had expired, the doctor or the patient would continue to make that association which would in turn influence them to choose the medicine to which the trade mark was applied. So in seeking to use compulsory licensing, the Committee knew that it needed to broaden its application. It warned that 'taken together, ... [the existing compulsory licensing provisions were] not adequate to prevent patents being used to the prejudice of the public interest.' [UK Board of Trade, K. R. Swan, (1946), *Patents and Designs Acts, Second Interim Report of the Departmental Committee*, 1945-46 [Cmd 6789], 10 (41)]

- In its final report the Committee made recommendations to the post-war British Government of Clement Atlee, many of which were accepted. The *UK Patents Act, 1949* was the result. The main aspects of this legislation, as needs concern this Senate Inquiry, were as follows:

  (a) <u>Substances found in nature not patentable</u>: Section 4(7) provided 'Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature';

  (b) <u>The compulsory licensing for medicines, food or surgical and curative devices made easier</u>: First, the British Patent Office was mandated to grant compulsory licenses 'to make, use, exercise and vend the invention as a food or medicine, or for the purposes of the production of food or medicine or as or as part of a surgical or curative device' so as to make them 'available to the public at *the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights'* (Emphasis added). Secondly, compulsory licences for these inventions could be applied for immediately upon the grant of a British patent. It was no longer necessary to wait four years before making an application;

  (c) <u>Heightened patent scrutiny in pre-grant examination and in opposition</u>: First, patent examiners were empowered to reject patent applications on the ground that the invention was for 'anything obviously contrary to well-established natural laws' or 'contrary to law or morality' or 'a

substance capable of being used as food or medicine' produced by mere admixture. Secondly, the British Patent Office was now able to consider the lack of an inventive step (otherwise known as 'obviousness') as a ground of opposition (under the 1932 amendments it was not);

(d) Ability for any person to bring an action for revocation in the courts: Until 1949 only persons who had an 'interest' in the patent or who had the 'fiat of the Attorney-General' could bring a patent revocation action in the courts. The idea was to encourage private litigants to create a secondary patent-vetting process through civil patent litigation; and

(e) Wider Crown Use Powers: First, government departments could, if it was 'contrary to the public interest' not to do so, disregard any patent monopoly. Secondly, a patent that was subject to Crown use could be revoked if the patentee 'without reasonable cause failed to comply with a government request's to make, use or exercise the invention for services to the government on reasonable terms'. Finally, in the event of a declared emergency, any patent could be used on such terms as the British government deemed 'necessary and appropriate' to meet the specific purposes of the emergency. The prescribed emergencies included: 'the maintenance of supplies and services essential to the life of the community'; 'securing a sufficiency of supplies and services essential to the well-being of the community'; 'promoting the productivity of industry, commerce and agriculture'; 'fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade'; and 'ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community'. The 'period of emergency' in operation at the time of the legislation was stipulated to end on 10 December 1950, but could be extended at any time, 'by Order in Council'.

- As in 1935 (when the Knowles Committee advised the Australian government over the amendments in 1932 to the *UK Patents & Designs Act, 1907*) the passage of the *UK Patents Act, 1949* prompted the Australian government to investigate the new legislation and report on whether the Australian patents legislation should be similarly amended. **In 1950 a Committee chaired by Sir Arthur Dean QC recommended to the government of Sir Robert Menzies that it follow suit. The result was the *AU Patent Act, 1952*.**

5. Patent Law Reform in Britain and Australia in the wake of the NHS in Britain and the PBS in Australia

- By 1950 a number of attempts had been made to establish what is called the Pharmaceutical Benefits Scheme (PBS). Before the end of WWII the first PBS Bills were introduced and debated in the Australian Parliament. The legislation was eventually passed but was controversial and led to a successful High Court challenge. In fact it was the government of Sir Robert Menzies that eventually introduced the operative legislation for the PBS as it is today. Earle Page, the Minister for Health, 'argued that the cost of health schemes in the UK and New Zealand made it an imperative that the Commonwealth do all it could to contain costs in Australia'. [Warwick Neville, PhD Thesis, ANU, 2007: Healing the Nation: Access to Medicines under the Pharmaceutical Benefits Scheme – The Jurisprudence from History, 256]

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- However, just as it was becoming clear in Great Britain that the *UK Patents Act, 1949* was failing to contain the impact of prescription medicines, which were mainly patented or trade marked, by 1952 it was understood in Australia that more than the *AU Patents Act, 1952* would be needed to contain the cost of the PBS to the Australian taxpayer. In the year ending June 1952 it was reported that the PBS had cost £6,699,002 and the cause of the budget blow-out, of between £2 and £4 million (based on estimates made in the 1940s), was the unexpected number of prescriptions for patented antibiotics.
- According to Dr Warwick Neville, Page advised the Australian Parliament that the 'provision of free drugs has proved the Achilles heel of other national health schemes'. Neville writes that Page reported:

> … in the UK, the initial estimate of providing medicaments for the first nine months was £12,700,000 in 1948-49. In 1952, the cost had risen to £43,600,000. In that year, a charge of 1s. per prescription was introduced, but still, the estimated cost of medicines under the NHS in the UK for 1952-53 was £40,000,000. At the inception of the New Zealand health scheme in 1941, it was estimated that the drug cost to the Government would not exceed £500,000 per annum. In 1945-46, the cost had passed £1,000,000. In 1953-54, the estimated cost of drugs in New Zealand was £3,200,000. [Neville, 266]

- By 1953 it was undeniable that even though significantly strengthened, the strategy of using the compulsory licensing of medical patents (introduced into the *UK Patents Act, 1949)* was an inadequate response to the market power of the pharmaceutical companies which, just as Swan had predicted in 1908, used both the positive association between patented and trade marked medicines and their relationship with the medical profession to neutralise the competitive effect of generic medicines.
- Clement Atlee's government, however, implemented the NHS before there was time to appreciate the just how bad the budget blow-outs would be. So the die was cast in the UK as a succession of British governments sought solutions to the growing size of the problem during the 1950s and 60s. Australia, at

least, was able to learn from Great Britain's mistake. It was under these circumstances that the *AU National Health Act, 1953* and the *AU Therapeutic Substances Act, 1953* were passed.

- Thus while Australia had the PBS in the UK, the Minister for Health appointed Prof Guillebaud to chair a Committee of Inquiry '[t]o review the present and prospective cost of the National Health Service; to suggest means, whether by modifications in organisation or otherwise, of ensuring the most effective control and efficient use of such Exchequer funds as may be made available; to advise how, in view of the burdens on the Exchequer, a rising charge upon it can be avoided while providing for the maintenance of an adequate Service; and to make recommendation.'

- The result was that in 1957 the Conservative government of Harold Macmillan introduced the Voluntary Price Regulation Scheme (which still operates today in an amended form as the Pharmaceutical Price Regulation Scheme). It was an attempt to induce the pharmaceutical companies to set reasonable prices by allowing new medicines a 3 year window during which there was no price control. After that time the price would be established between the Ministry of Health and the respective pharmaceutical company. The problem, as its name suggests, was that it was a voluntary scheme which the Association of the British Pharmaceutical Industry (ABPI) did not fully support. Consequently, in its first year of operation, as Judy Slinn noted in her study, while 'reductions in the prices of some 300 products had been made, the overall saving was, at some £400,000, well short of the £750,000 envisaged'. [Slinn, J (2005), Price Controls or Control through Prices? Regulating the Cost and Consumption of Prescription Pharmaceuticals in the UK, 1948-67, *Business History*, 47 (3), 352-366, 358]

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- In 1959 another Committee of Inquiry, this time chaired by Sir Henry Hinchcliffe, submitted a report on the 'Cost of Prescribing' to the UK Minister for Health. Hinchcliffe's report was the subject of some debate in the British Parliament mainly because the Committee attributed, in part, the rise in the cost of prescription medicines to the relationship between doctors and pharmaceutical companies. Dr Edith Summerskill MP, for instance, advised Parliament:

> 'The joke among doctors' wives today is that when they want to do shopping in town they leave their husbands to have lunch with a drug firm. The following invitation came to my notice last week. It says: "Bayer Products Ltd. have pleasure in inviting Dr. —to the showing of a new film-strip on rheumatoid arthritis. Any medical colleagues will also be welcome. At the Green Dragon, N.21, on Wednesday and Thursday, 8th July and 9th July. Cocktails, 12.45; Film. 1 p.m., lunch, 1.20 p.m." A doctor whom I know, who went to one of these shows —rather a cynical man— said, "We were expecting some pep pills at cocktail time." But no, there was an adequate supply of gin. The film was not a film at all, but a few cheap lantern slides. The lunchers were well supplied with wine, and another cynical doctor said, "The most important things given out were leaflets telling us what drugs to prescribe"—all made by the firm, to recompense it for the lunch.' [HC Deb, 15 July 1959, Vol 609, 419-548, 421.]

- By 1959 the cost to the NHS of prescribed medicines was over £70 million. [HC Deb, 15 July 1959, Vol 609, 419-548, 420]

Patent Law Reform in Europe and Edward Heath's push to have the UK join the European Economic Community in the 1960s collides with the NHS and the UK Department of Health

- By 1960 the European Economic Community (EEC) had already commenced a process of patent law reform in Europe. Under the stewardship of Kurt Haertel (a German patent lawyer who served as the President of the German Patent Office between 1963 and 1975), by 1963 his Committee had produced and published the first draft of what would become the European Patent Convention. [Oudemans, G. (1963), *The Draft European Patent Convention*, London, UK: Stevens & Sons Ltd; New York, US: Mathew Bender & Co. Inc.]

By 1959 the cost to the NHS of prescribed medicines was over £70 million.

- The key reform of Haertel's Committee was the establishment of a single unified European patent system administered through a single organisation. In addition however, and most importantly, were the proposals that no 'invention' should be banned from patentability (that is, subjected to technological discrimination) and that patents should have a maximum life of 20 years. Both of these proposals were incorporated into the draft convention.

The all too evident problem was that pharmaceutical companies were successfully minimising the effects of compulsory licensing.

- At the same time, the Macmillan government sought to have Great Britain join the EEC. The application, however, was rejected on the veto of France.
- By 1964 the Labour government of Harold Wilson had been elected into office and as a result joining the EEC was temporarily off the agenda, but the problem of what to do about the NHS budget was not. Fresh in government and keen to demonstrate a new approach to this issue, the Wilson government's Minister for Health, Kenneth Robinson, appointed Lord Sainsbury to chair yet another Committee of Inquiry into the NHS, this time specifically directed to the 'Relationship of the Pharmaceutical Industry with the National Health Service'.
- Clearly, the UK Ministry of Health remained keen to find ways to reduce the cost of prescription medicines and following on from the findings of the Hinchcliff Committee's report (that pharmaceutical companies were buying favours from doctors in order to sell medicines) the Wilson government decided to investigate the pharmaceutical industry and the manner in which it conducted its relationship with the NHS itself. The all too evident problem was that pharmaceutical companies were successfully minimising the effects of compulsory licensing.
- The Inquiry which Lord Sainsbury chaired was extensive. It commenced in 1965 and presented its report to the Minister in 1967. During the period of the Inquiry many submissions were filed and, naturally, the Association of the British Pharmaceutical Industry (ABPI) defended the interests of the pharmaceutical sector. In this respect, it is particularly relevant to know that during the Swan Committee's Inquiry into the British patent system only 20 years earlier, the ABPI (known then as the Wholesale Drug Trade Association) had argued against the compulsory licensing of medicines and for the lifting of the ban on the patenting of chemicals (which had been in operation since 1919). Thus, Swan's Committee was very well aware of the issues that concerned the British pharmaceutical industry when it made its recommendation to strengthen the compulsory licensing regime under British patent law.

Indeed, Swan's concession to the ABPI in recommending the removal of the ban on the patenting of medicines came, as we already know, because of the patenting strategies employed by the ABPI's members – strategies that undermined the effect of that ban. For this reason it cannot be said that the Swan Committee was against the idea of continuing the ban on patenting medicines; it simply accepted that there was no point in continuing it.

- Predictably, the Sainsbury Committee was, during the course of its Inquiry, reacquainted with the ABPI's views on patenting. However, in the intervening 20 years the ABPI's views happened to also dovetail with Haertel's draft of the European Patent Convention. This was significant, as it was to turn out, for now the Ministry's plan to reduce the NHS budget was on a collision course with those that had aspirations for Britain's membership of the EEC.

Lord Sainsbury's Committee rejected the argument calling for an extension of the British patent term from 16 to 20 years, expressing the view that the existing patent term was 'too long' and 'that the position could be met by a shorter period of complete protection.' With regard to the argument that to 'induce adequate research and development and innovation in the pharmaceutical industry' there was a need for strong patent laws, the Committee countered with the recommendation that 'a shorter period of monopoly for the patentee followed by a right to receive royalties under a licence of right' would suffice.

- Apart from the political situation, there had been consolidation in the ownership and control of British pharmaceutical companies by foreign pharmaceutical companies, mainly from Switzerland and the United States. This, as Lord Sainsbury's Committee concluded, meant that the ABPI's views were no longer those of a British industry.
- The Sainsbury Committee noted that 'there was almost complete agreement' among the members of the ABPI that 'patent law should be strengthened by restraining the ability of the Government to intervene' and that medicines should not be 'treated differently from other products'. It also noted that the ABPI proposed 'the patenting of new uses for known compounds,' and the extension of the patent term to 20 years. Thus the scene was set. On the one side was the ABPI which was striving to strengthen patent protection for the pharmaceutical industry in the UK. On the other was the Sainsbury Committee which was determined to find a way to halt the runaway cost of the NHS.
- Understandably, the Sainsbury Committee dismissed the ABPI's submissions not only because its key objective was to find a way of keeping the price of medicines low, but because it was suspicious of an organisation which it considered no longer representative of British economic interests.
- Thus its Report rejected the ABPI's submission regarding the extension of the British patent term from 16 to 20 years, expressing the view that the existing patent term was 'too long' and 'that the position could be met by a shorter period of complete protection.' With regard to the ABPI's argument that to 'induce adequate research and development and innovation in the pharmaceutical industry' there was a need for strong patent laws, the Report countered with the recommendation that 'a shorter period of monopoly for the patentee followed by a right to receive royalties under a licence of right' would suffice. Not only that, the ABPI's criticism of compulsory licensing as having been 'little used' was dismissed as irrelevant by a Committee that blamed the British Patent Office's 'inefficient' administration, which 'seemed to have discouraged or delayed potential licensees', for its poor

utilisation. In fact, rather than recommending the repeal of compulsory licensing, the Report recommended the simplification of its administration so as to encourage more British companies to apply.

- That said, the Report by implication rejected key aspects of the draft European Patent Convention, namely the extension of the patent term of 16 to 20 years and the non-discriminatory treatment of inventions. Furthermore, it recommended that a system of non-exclusive patent licensing be developed. In its view, such a system would not only provide an adequate incentive for pharmaceutical research and development, but would also mitigate against the effect of high prices for patented medicines. [Lord Sainsbury (1967), *Relationship of the Pharmaceutical Industry with the National Health Services, 1965-1967*, [Cmd 3410]]

- The Report thus complicated the situation in terms of Britain joining the EEC. Although within the British Labour Party there remained a strong division of opinion on Britain's joining the EEC, it was becoming increasingly clear that the government did not want to make any decisions that could jeopardise its chances should the government decide to reapply. Therefore, the Wilson Government was in a bind. On the one hand the Ministry of Health wanted to reduce the NHS budget and the current patent laws made this impossible. On the other hand, if Britain were to reapply to join the EEC, its patent law would need to conform to the proposed European Patent Convention, and in this respect the Report's recommendations, if they were followed, would take British patent laws even further away from conformity with its European neighbours.

- The government's solution was to hold yet another Inquiry. This time one that investigated the British patent system in general terms, the idea being to move the debate about British patents away from their specific application to the pharmaceutical industry and the impact upon the NHS.

The Banks Committee Inquiry into the British Patent System, which was heavily influenced by patent lawyers and British patent agents, effectively sanitised the Sainsbury Committee's Report.

- This Inquiry had already been commissioned by the British government by the time the Sainsbury Committee's Report had been presented to the Minister, no doubt because drafts of the report had been made known to the government well beforehand. The chair of this Committee of Inquiry was M A L Banks, who had recently retired from the Board of British Petroleum. By July 1970, when the Banks Committee presented its report, Harold Wilson's government had been defeated in an election and the new Prime Minister was Edward Health. In spite of this change, there is no doubt that the Banks Committee's Report, presented in July 1970, found an appreciative government, especially as it had been Heath who had failed to secure Great Britain's membership of the EEC in 1960.

- The Banks Committee effectively sanitised the Sainsbury Committee's Report by seizing upon the Committee's concession that it was unable to deal with the British patent system beyond its terms of reference. It did this in three ways.

- First, it portrayed the British patent system as being out-of-step with the rest of the world with regard to 'the treatment accorded to drugs', by pointing out that the patent laws of 'the United States and most of Western European countries do not distinguish between drugs and other chemical substances.' This was quite misleading, of course, since Germany only allowed the patenting of chemical substances from 1968 and most other European countries still, at that time, continued to expressly prohibit patents over

medicines.

- Next, it dismissed the Sainsbury Committee's recommendations for streamlining the administrative processes to improve the effectiveness of compulsory licensing by arguing that whatever were the reasons behind compulsory licensing in 1947, it had 'not generally worked in the way in which it was intended'.
- Finally, it argued that the Government already had the ability to control the price of patented medicines by, first, invoking Crown Use powers that enabled it to use 'any patented medicine for the services of the Crown', secondly, imposing 'licenses of right' on patents and, thirdly, revoking patents on the ground that the patentee had failed to make the patented invention available for Government service upon reasonable terms.
- What the Banks Committee failed to spell out was that if (and when) the ABPI succeeded in destroying non-government compulsory licensing there would be nothing to stop the pharmaceutical industry neutralising the competitive effects of generic competition in the UK market place. That, of course, would be the price that had to be paid if Britain was to join the EEC. Thus, having laid the groundwork for a different approach, the Banks Committee made recommendations that suited both the ABPI and a thankful British government. They were: first, non-government compulsory licensing be abolished; secondly, 'pharmaceutical substances … continue to be patentable'; and thirdly, the term of a British patent be extended from 16 to 20 years.
- Accordingly, it was convenient for the British government to adopt a new patent philosophy – the pharmaceutical patent paradigm – one that said that without patents there would be no new medicines. Suddenly, and without explanation, the British patent system was now described officially as being necessary to encourage innovation and not about 'introducing new manufactures into the country and to create increased employment for the working classes.'
- Clearly, the British government was not alone in adopting this new philosophy. Haertel had managed to persuade the West German government of Kurt Kiesinger to accept the pharmaceutical-patent paradigm – one that he believed to be essential if the EEC was to be an economic and political equal to the United States; and it is important to recognise that EEC policymakers also believed the US to be its main trade competitor. For Haertel, who had risen through the ranks from patent attorney to President of the German Patent Office, a single European patent that applied throughout Europe just as a US patent applied throughout the US, was an imperative.
- Indeed, Haertel's original draft of the European Patent Convention provided for just that, but after ten years of international consultation and with a pressing need to meet the political compromises involved in expanding the EEC to include the UK, Ireland, Denmark and Norway, Haertel's vision of a single European-wide patent to be administered and enforced through two European-wide patent organisations (patent office and patent court) was turned into a patchwork of European patents. These patents would be granted by a European Patent Office (located in Munich) under the banner of a 'European patent', with national courts retaining the right to revoke that part of the European patent that applied in their country. This compromise, as unpalatable as

What the Banks Committee failed to spell out was that if (and when) the ABPI succeeded in destroying non-government compulsory licensing there would be nothing to stop the pharmaceutical industry neutralising the competitive effects of generic competition in the UK market place.

it was to Haertel, was finally accepted in 1973.

- What did not disappear from Haertel's original draft, however, was the prohibition on the technological discrimination of patentable inventions. This was one of the fundamental changes that the European Patent Convention would now impose on all members and, naturally, this suited the American and Swiss pharmaceutical companies who, since WWII, had demanded a level technological playing field. Consequently, article 52(1) of the European Patent Convention, 1973 expressly provides that patents must be granted for inventions 'in all fields of technology'.
- By 1978, when the European Patent Convention, 1973 came into effect, the pharmaceutical-patent paradigm was entrenched into the very fabric of the European patent system. No longer concerned about the petty squabbles over European trade, European politicians accepted that national patent laws that excluded pharmaceutical products as inventions were unnecessary. This was only the beginning of a wider and more aggressive offensive by the pharmaceutical industry (which would soon include the fledgling biotechnology industry) to ensure that the pharmaceutical-patent paradigm became a feature of the patent laws of all countries.
- Finally, with the passage of the *UK Patents Act, 1977*, the patent laws of the country that had given Australia its patent laws and guided the development of those laws, would no longer do so.
- The consequences of the adoption of this new patent philosophy is today obvious, as the antitrust investigation currently being undertaken by the European Commission into the pharmaceutical industry and its use of patents demonstrates (referred to earlier). In this regard it is important to appreciate that the problem is not merely a product of the aberrant behaviour of some elements within the pharmaceutical sector, but is the result of a change in policy at a governmental level – a policy which ignores the fact that patent monopolies were never intended to be rewards for innovation. Instead, what this policy has done is provide the patentees of leading-edge technologies with enormous economic power which can be used (and is being used) to suppress scientific and technical research (and thus reduce innovative competition) in the host country. The fact that generic medicines are not making it into the pharmaceutical market in Europe as rapidly as they should be, thus keeping the price of medicines artificially high, is directly related to the application of this economic power in this manner.

The consequences of the adoption of this new patent philosophy is today obvious, as the antitrust investigation currently being undertaken by the European Commission into the pharmaceutical industry and its use of patents demonstrate.

> Using a sample of medicines across 17 Member States that faced loss of exclusivity in the period 2000 to 2007 we found €14 billion in savings after generic entry, and that delays to entry cost consumers around € 3 billion on that sample. Neelie Kroes, European Commissioner for Competition Policy, 28 November 2008

- **Thus, as the Sainsbury Committee well understood, the broader the rights of patentees, the more difficult it is for any government to control the price of the goods over which the patent monopolies apply, either through the processes used to produce those goods or over the goods themselves.**
- **To the extent that there may be a need to provide an incentive to undertake research and development into new technologies the obvious solution, as that Committee proposed, may**

be to simply replace the patent monopoly with the non-exclusive licensing of all patented inventions.

6. The AU Patents Act 1952 and its reform during the 1980s and reccurring issues

- Great Britain severed its economic ties to the Commonwealth in 1973 as a consequence of joining the EEC. At about the same time Australians elected the Labor government of Gough Whitlam. Together these events weakened the links that had existed between Australia and Great Britain since Federation. In the few short years the government of Gough Whitlam (1972-1975) managed to capture a growing nationalism to facilitate the introduction of significant reforms that would subtly indicate that Australia was an independent nation and one that was in control of its own destiny.
- Thus by 1975 not only was the Federal Court of Australia established so as to provide an alternative court to the various State Supreme Courts, but the right of appeal from the High Court of Australia to the Privy Council was abolished. The High Court would now be the final court of appeal and this meant that it would no longer be possible for English jurists to influence the development of law in Australia. Moreover, the High Court became exclusively an appellate court leaving the Federal Court to deal with the development and interpretation of Federal law at first instance.
- However, it was during the government of Bob Hawke (1983-1991) that all formal legalities were completed so that Australia was truly an independent nation. The passing of the *Australia Act* in 1986 by both the British and Australian Parliaments and its assent by Elizabeth II were the final acts of Australia's independence.

'The Patents Bill 1989 is a complete redraft of the Patents Act 1952, which it repeals and replaces.'

- It was under these circumstances that the Industrial Property Advisory Committee (IPAC) presented to Barry Jones, as the Minister for Science, a report entitled *Patents, Innovation and Competition in Australia* in 1984. Acting on the basis of this report (a report originally commissioned by the Minister of Productivity in the government of Malcolm Fraser, Ian McPhee) the Minister began a process to reform Australia's patent legislation. By 1989 the *Patents Bill, 1989* was introduced to the Australian Parliament. During the Bill's second reading, the Minister said:

> The Patents Bill 1989 is a complete redraft of the Patents Act 1952, which it repeals and replaces. It has two main thrusts. First, it implements a number of policy changes flowing from an expert report reviewing the Australian patent system from an economic perspective. Second, it brings 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, at least in general terms. [HR, Hansard, 1 June 1989]

- However, the members of IPAC were not unanimous. There was disagreement with the patent lawyers, patent attorneys and patent bureaucrats on the one side and an economist on the other. The chair, John Stonier (then a patent licensing lawyer employed by BHP, and today an associate at Davies Collison Cave), Des Ryan (then a partner of patent attorney firm, Davies & Collison now known as Davies Collison Cave), David Walsh (then a partner of the law firm Mallesons), Frank Smith (the former Commissioner of Patents, subsequently joining the law firm Baker & McKenzie as a solicitor) and Pat Smith (then the

Commissioner of Patents) were understandably in favour of patent monopolies.

- Don Lamberton, a professor of economics from the University of Queensland, on the other hand, was very critical of the failure of the Committee to (a) apply 'economic criteria' consistently; (b) make 'full use of available empirical evidence', and (c) refer to the 'concept of social cost' without it ever being 'fully grasped'. In his dissent he dismissed 'the underlying idea … that more patent protection will ensure more innovation' as being 'little more than faith' noting that 'no amount of talk about individual patent successes nor about a future in which the Australian economy has magically become progressive, innovative-oriented, and competitive in a world scene, can hide the facts that Australia exports little in the way of manufactured goods and has few inventions for sale'.

'No amount of talk about individual patent successes nor about a future in which the Australian economy has magically become progressive, innovative-oriented, and competitive in a world scene, can hide the facts that Australia exports little in the way of manufactured goods and has few inventions for sale.'

- Specifically, Lamberton referred to the patent data which confirmed that '[m]ost patents are granted to overseas firms'.
- But Lamberton was not alone. Tom Mandeville and Jean Bishop (also economists from his university) had produced an earlier study entitled *Economic Effects of the Australian Patent System* ['Supporting Papers for Economic Effects of the Australian Patent System', AGPS, Canberra, April 1982] in which they joined him in concluding that the economic costs to the Australian economy of patent monopolies were probably greater than the benefits.
- The Minister's approach to these divergent views was to err on the side of the status quo. While he acknowledged that even IPAC 'did not wholeheartedly embrace the patent system', he noted that, 'it by no means rejected it'. More interesting, however, was the Minister's flippancy toward a system that he said some viewed as 'some kind of mysterious sacrament which has to be observed if we are to proceed along the path to economic heaven'. Clearly, the Minister was just as ambivalent about the benefits of patent monopolies in 1989 as was the Lord Chancellor of England in 1876 but, just as then, the Minister felt unable to make the decision to abolish patents because, as he said:

> Faced with conflicting opinions on economic questions, IPAC recognised that it is imperative that Australia continue to operate a patent system and to participate in the international patent system. [HR, Hansard, 1 June 1989]

- In the context of this Senate Inquiry it is absolutely critical that this Committee revisit the rationale expounded by the Minister, which was simply a regurgitation of the views of the patent lawyers and patent attorneys. This is what the Minister said:

> The policy approach to review and change should be to seek 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, having regard to the particular circumstances of the Australian economy. *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*.

More specifically this implies seeking-

to gain increased benefits for Australians by *fostering indigenous innovation*, and utilising the international patent system in development export markets to improve Australia's international competitive position;

to *reduce unnecessary social costs* including those resulting from undesirable anti-competitive conduct involving patents; and

to *improve the efficiency of the administration of the patent system* with consequent reduction of direct costs. …

One of the most important and constructive measures recommended by IPAC was *an adjustment of the standards of novelty and inventiveness required of standard patents*. Under the present law, standard patents are tested for novelty only against prior disclosures in Australia. Under the Bill, they are to be tested against disclosures in documentary form anywhere in the world. This change will make it harder to get a 16-year standard patent, but it will bring the requirement into line with similar requirements in most of Australia's trading partner countries. [HR, Hansard, 1 June 1989] (Emphasis added)

According to the World Intellectual Property Organization's (WIPO) World Patent Report 2008, the number of non-Australian resident patent filings rose from about 3,000 in 2000 to about 8,000 in 2006 while, during the same period, the number of Australian resident patent filings per GDP remained unchanged.

- So, if the objective of the *AU Patents Act, 1990*, the current legislation, was to 'maximise the social benefits and to minimise the social costs to Australians' by:

  (a) fostering indigenous innovation;

  (b) reducing unnecessary social costs;

  (c) improve the efficiency of the administration of the patent system; and

  (d) to make it harder to get a patent by strengthening the standards of novelty and inventiveness

  were are we today, nearly 20 years later?

- Rather than 'fostering indigenous innovation', just as Lamberton had noted in his dissent in 1984, the Australian patent system seems to operate mainly for the benefit of foreign patentees who are able to obtain patent monopolies in Australia in ever-increasing numbers. According to the World Intellectual Property Organization's (WIPO) report entitled *World Patent Report 2008,* the number of non-Australian resident patent filings rose from about 3,000 in 2000 to about 8,000 in 2006 while, during the same period, the number of Australian resident patent filings per GDP remained unchanged.

- As for 'reducing unnecessary social costs resulting from undesirable anti-competitive conduct involving patents' there are, as this submission will detail later, clear cases of foreign companies using Australian patents to massively increase 'social costs' by stifling competition in Australia.

- In terms of the efficiency of the patent system, not only is IP Australia finding it increasingly difficult to maintain satisfactory pre-grant examination standards (and this is also the case internationally), but the costs of patent litigation are as prohibitively expensive as they ever were.

- Furthermore, rather than making it 'harder' to get a patent monopoly, it is actually easier. According to the

Review of the National Innovation System conducted by an Expert Panel, *Venturous Australia*, chaired by Terry Cutler (an industry consultant and Board member of the CSIRO), 'the tests of non-obviousness and 'analogous use' have become much less stringent – as some have argued, to the point of vacuity'. In its report delivered to Kim Carr, the Minister for Innovation, Industry, Science and Research, on 29 August 2008 the panel warned that 'where intellectual property rights are too easily granted, and where they are ambiguously defined' there is 'mounting evidence that this is impeding rather than stimulating innovation'.

- Coming like an echo from the 19th century, yet another Committee made a recommendation to government to raise the patentability bar. The expert panel recommended that:

  > 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. [Recommendation 7.2]

- This submission asks the question: how many more times do we have to review the standards of novelty and inventiveness before we accept that the problem is systemic?

- **Clearly, patent attorneys and patent lawyers refuse to accept that there is a systemic problem, which is why the Cutler expert panel in the *Venturous Australia* Report has recommended that the government not rely so heavily on patent lawyers and patent attorneys in formulating innovation policy. In what is a clear rebuff to the dominance that these professions have enjoyed in the area of intellectual property in Australia, the report notes that 'it is imperative that IP policy 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.'**

- Beyond these issues, and despite one of the stated objective for introducing the Bill being to modernise the statutory language, as IPAC recommended, the definition of 'invention' that had existed in both the 1903 and 1952 legislation remained unaltered. Thus the reference to the Statute of Monopolies in the definition of 'invention' appears in the *AU Patents Act, 1990*.

7. The AU Patents Act, 1990 and the boundaries of patentable subject matter.

- It is a fundamental and irrevocable requirement of patent law (that has existed since the exception to the ban of all monopolies was made law in 1623 by effect of section 6 of the *Statute of Monopolies*) that patent monopolies must only be granted for 'manners of new manufacture', in other words, 'inventions'.
- Thus, patent monopolies are not to be granted for the discovery of natural phenomena. Nor are they to be granted for innovations that are essentially mental abstractions, such as mathematical formulae or algorithms, or theories which explain laws of nature, such as $E=mc^2$.
- Regardless of the modern tendency to see the creation of private monopolies, which patent monopolies are one of many, as the price that society must pay those who are creative, ingenious or artistic, this has never been the object of patent law.
- Our forefathers not only knew that scientific and technological progress is cumulative but that it is critical for human advancement that knowledge be shared. This has been acknowledged by the Cutler expert panel in the *Venturous Australia* Report: as 'new knowledge always builds on old knowledge, the property rights we have erected to encourage innovation can actually obstruct it'.
- One way in which our forefathers tried to encourage the transfer of this knowledge from artisans, such as the Venetian glass makers, to their own trades people was through incentives to migrate, which included the right to practice their skills exclusively for a short period of time in the new territory. This was common place throughout northern Italy from around the 13th century and was eventually adopted in other parts of Europe. Thus in 1623 when Lord Coke drafted the *Statute of Monopolies* and used the term 'manner of new manufacture' in the exception to the ban on *all* monopolies, he was contemplating a very specific kind of innovation.
- Inevitably, as science and technology progressed, inventions that were unimaginable to people who lived at that time, such as cars, trains and planes, were devised by ingenious people. New machines have also been invented that applied new forms of energy, such as the steam engine, the dynamo, the telephone, the light bulb, the radio, the television, the jet engine, the rocket engine and the nuclear reactor just to name a few. Of course there are countless other examples.

The expert panel in the *Venturous Australia* Report acknowledged that as 'new knowledge always builds on old knowledge, the property rights we have erected to encourage innovation can actually obstruct it'.

- In time it became accepted that even a new process that could be used to make an existing thing could also be an invention. For example chemical processes that could use coal tar to make artificial dyes that were almost identical to natural dyes were eventually accepted to be 'inventions'. Another example were chemical processes that changed the molecular structure of naturally occurring compounds so that they could be safely used as medicines.
- As science and technology has progressed so patent law has had to face up to this challenge. Thus the term 'manner of new manufacture' has been interpreted by the courts in ways that have kept up with the times.
- In this respect, in 1959 the High Court of Australia handed down a decision in the case of *National Research Development Corporation v Commissioner of Patents* (1959)

102 CLR 252 (*NRDC*) that has long been accepted in Australia (and in other common law jurisdictions) as expressing sound principles that aid the law in meeting this challenge, and numerous scholarly articles have been written about it. But the reason why it was an important decision is that it held that a method of using known chemicals (which were herbicides) to produce a new effect (which was horticultural, namely, it killed weeds but not the crops over which the herbicide was sprayed) was patentable subject matter – it was an invention. This technology presented a challenge for patent law. The Commissioner of Patents had ruled that it was not a technology that was an invention because it was a horticultural process. The High Court, however, decided otherwise.

- The controversy revolved around the fact that the end result of this method or process was not a physical product. While the result of the use of this method was measurable and visibly apparent, it was not something one could touch. The challenge for the High Court was to decided whether such a result was nevertheless a 'product' because, as the Court acknowledged: 'if there were nothing that could properly be called a 'product' of the process, even an ingenious new departure would be outside the limits of patentability.'
- The Court found, however, that there was a 'product' in the form of the effect achieved by the combining of these known herbicides. It was this effect which it held was a *new* and *vendible* and *useful* product. According to the Court a process was a patentable invention, even if it was agricultural or horticultural in nature, because the *end result* of the process was the achievement of *an effect on the production of crops that was unprecedented*. The Court held:

> The effect produced by the appellant's method exhibits the two essential qualities upon which 'product' and 'vendible' seem designed to insist. It is a 'product' because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic; for it provides a remarkable advantage, indeed to the lay mind a sensational advantage, for one of the most elemental activities by which man has served his material needs, the cultivation of the soil for the production of its fruits.

IP Australia has interpreted NRDC as authority for supporting the patenting of isolated or purified human genes and other genomes. However, this interpretation has yet to be tested in an Australian court.

- Certainly, IP Australia (the Australian Patent Office) has interpreted *NRDC* as authority for supporting the patenting of isolated or purified human genes and other genomes. However, this interpretation has yet to be tested in an Australian court and the High Court's own statement in *NRDC* that 'however advantageously man may alter the conditions of growth, the fruit is still not produced by his action' suggests that it did not mean to extend the boundary of patentable subject matter to include isolated or purified biological materials even if produced by technical processes. Yet, as the Australian Law Reform Commission (ALRC) noted in its report entitled *Gene Patents and Human Health*, some academics support IP Australia's interpretation. The report stated:

> Dr Dianne Nicol has suggested that inventions involving genetic materials and technologies appear to satisfy the *NRDC* requirements because

> genetic research and treatments are commercial in nature and have value in an economic sense, both directly through the activities of the Australian biotechnology industry and indirectly through the ability of such technology to alleviate disease.

- **It follows that biotechnology has provided the law with yet another challenge for where to draw the line. Is it the case, as IP Australia and some academics contend, that isolated biological materials such as human genes that have been removed from the human body and purified through some technical process are, or should be, considered to be inventions?**
- However, after conducting its review of patent law and its interaction with biotechnology, the ALRC's report failed to make any meaningful recommendations with regard to what the law should be. Apart from noting that it had been the practice in some overseas jurisdictions to allow the patenting of isolated biological materials, and that this had produced some questionable results, it recommended that patent law not be changed in Australia. That said, the ALRC was somewhat critical in its report about the definition of 'invention'. It stated:

> The test for patentable subject matter may nevertheless warrant reform. The manner of manufacture test was considered in 1984 by the IPAC Report and in 2000 by the IPCRC, and was endorsed on both occasions. Yet it has become apparent during the course of this Inquiry that there are problems with the test. [para 6.54]

- The principal cause of its criticism lay in the language used in s.6 of the *Statute of Monopolies*, specifically, the proviso that excludes from patentability an invention that is 'contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient'. The problem of what to do with these words, the report says, has been compounded by the Australian Federal Court which has been 'reluctant' to apply these words 'to deny patent protection to particular inventions'. Thus the ALRC recommended that:

> 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'.

- Such a review is currently being conducted by IPAC's successor, the Advisory Committee for Intellectual Property (ACIP).

The ALRC's report is so riddled with inaccuracies with a pro-patent bias that it is unreliable.

8. The ALRC Gene Patent and Human Health Report .

- Unfortunately, the ALRC's report is fundamentally flawed in a number of respects, both as to procedural fairness and substantively on matters of law. Consequently, the report is so riddled with a pro-patent bias that it is *unsafe* and must be ignored by this Committee in the context of this Inquiry.

Procedural Unfairness

- Clearly, the independence of the ALRC demanded that the Advisory Committee, appointed to assist the ALRC on patent law and biotechnology, be made up of experts who would provide the ALRC and, ultimately, the Attorney-General with a *balanced* view. Regrettably, this was not the case in this instance. Indeed, it is fair to say that no one on the Advisory Committee who professed an expertise in patent law was of the view that isolated biological materials should not be patentable. That they acted for, or had acted for, or were, or had been associated with organisations that derived income from companies that had a vested interest gene patents, the very subject of the Inquiry, should have disqualified them from any involvement whatsoever.

The independence of the ALRC demanded that the Advisory Committee, appointed to assist the ALRC on patent law and biotechnology, be made up of experts who would provide the ALRC and, ultimately, the Attorney-General with a balanced view. Regrettably, this was not the case. in this instance.

- The Advisory Committee, appointed by the ALRC was made up of the following (those with patent law expertise or who directly involved in gene patents are highlighted in blue and underlined):

Associate Professor Ian Anderson, Deputy Director, Centre for the Study of Health and Society, University of Melbourne
Justice Annabelle Bennett, Federal Court of Australia
Dr Kerry Breen, Chair, Australian Health Ethics Committee of the National Health & Medical Research Council
Professor Don Chalmers, Head, University of Tasmania Law School
Professor Andrew Christie, Intellectual Property Research Institute of Australia, University of Melbourne
Dr Trevor Davies, Partner, Allens Arthur Robinson
Dr Carina Dennis, Australasia Correspondent, *Nature*
Professor Paul Greenfield, Senior Deputy Vice-Chancellor, University of Queensland
Dr Eric Haan, Head, South Australian Clinical Genetics Service and Chair of the Human Genetics Society of Australasia
Dr Jane Hall, Director, Centre for Health Economics Research and Evaluation, University of Technology, Sydney
Ms Helen Hopkins, Executive Director, Consumers Health Forum
Professor John Mattick, Director, Institute of Molecular Bioscience, University of Queensland
Dr Dianne Nicol, University of Tasmania Law School
Professor Alan Pettigrew, CEO, National Health & Medical Research Council
Dr Bill Pickering, Partner, Blake Dawson Waldron
Dr Deborah Rathjen, CEO, Bionomics Ltd
Dr Vivien Santer, Principal, Griffith Hack
Professor Vicky Sara, CEO, Australian Research Council
Professor Sue Serjeanston, Executive Secretary, Australian Academy of Science

Professor Brad Sherman, Director, Centre for Intellectual Property Research, Griffith University
Mr John Stonier, Davies Collison Cave
Professor Ron Trent, Head, Department of Molecular & Clinical Genetics, Royal Prince Alfred Hospital and University of Sydney
Mr Guy Wilmington, Manager–Scientific & Technical Affairs, Medicines Australia

- Thus, Dr Pickering, Dr Santer, Mr Stonier and Dr Davies were patent law professionals whose firms acted for companies that owned or had significant interests in patents over isolated human genes or other biological materials. Indeed, Dr Pickering was the patent attorney that filed Australian patent applications for Chiron Corporation (Chiron) in the late 1980s over the hepatitis C virus genome and its proteins and Dr Davies's firm, Allens Arthur Robinson, acted for Chiron in litigation that challenged the validity of one of those patents in the 1990s. Moreover, Mr Stonier is the same person who chaired IPAC and which led to the report referred to earlier - a report that was favourably disposed toward the patent system.
- Justice Annabelle Bennett QC, although no longer practising as a barrister at the time, did, while she was a barrister, act for a number of large multinational pharmaceutical and biotechnology companies, one of which was F Hoffmann La Roche AG - a company that had substantial interests in patents over isolated biological materials. Justice Bennett also acted for Kirin-Amgen, Inc, one of the world's largest biotechnology companies with respect to its patenting of erythropoietin, a human hormone.

Erythropoietin

It is a protein that is produced naturally by the human body to regulate red blood cell production.

For more information:

http://en.wikipedia.org/wiki/Erythropoetin

Principles of fairness and the interests of justice demanded that those associated with the ALRC be untainted in respect to any issue over which the ALRC had been asked by the Attorney-General to specifically advise him on.

- Dr Rathjen was, and still is, the CEO of an Australian company that has patent applications and granted patents for various human genes and other biological materials.
- The remaining members of the Committee were either scientists, academics, journalists or administrators who, except for Dr Nicol, Prof Christie and Prof Sherman, had no prior expertise in patent law.
- Indeed, Dr Nicol, Prof Christie and Prof Sherman (being patent law academics) had, prior to their joining the Committee, expressed the view that the patenting of biological materials was within the legal boundaries of patentable subject matter in Australia. Prof Christie even going so far as to suggest in an academic paper that the patentable subject matter threshold was so low that even the formulae $E=mc^2$ was patentable subject matter. [Christie, A (2002) 'Business Method patents and Beyond: Why E=mc2 is inherently patentable (at least in the US and Australia)'] And it is also to be noted that Prof Christie's chair at the University of Melbourne was funded by Davies Collison Cave, the patent attorney firm to which Mr Stonier, another member of the Committee, was associated (being the same firm that had played a role in the IPAC Report some 20 years earlier).
- With regard to the scientists on the Committee Prof Mattick was named as an inventor on a number of patent applications, one dating back to 1988 that involved a method for the production of proteins. Furthermore, that same patent application (bearing international publication number W0 88/08430) was prepared by the patent attorney firm F B Rice & Co, which just so happened to be the firm that Dr Pickering, also a member of the Committee, was a partner when he prepared the patent applications for Chiron in 1989. Finally, Prof Mattick gave evidence

as an expert for Kirin-Amgen, Inc as part of an opposition that concerned an application to patent isolated erythropoietin in Australia.

- In respect to conflicts of interests that may arise in similar situations, it is useful for the Committee to be referred to the decision taken by the Judicial Committee of the UK House of Lords to vitiate a previous decision concerning an application to extradite General Pinochet which was made while one of Lord's was a member of Amnesty International – an organisation that had publicly supported the application but which was not a party to the proceedings. There the House of Lords held:

> The principle that a judge was automatically disqualified from hearing a matter in his own cause was not restricted to cases in which he had a pecuniary interest in the outcome, but also applied to cases where the judges decision would lead to the promotion of a cause in which the judge was involved together with one of the parties. [*R v Bow Street Metropolitan Stipendiary Magistrate and others, ex parte Pinochet Ugarte (No 2)* [1999] 1 All ER 577]

- It follows from what their Lords said that principles of fairness and the interests of justice require complete independence and although it cannot be said that the ALRC Advisory Committee was judicial, nonetheless, it was part of a process which, if it was to have any credibility, demanded that those associated with it be untainted in respect to any issue over which the ALRC had been asked by the Attorney-General to specifically advise him on.
- Whether they were actually motivated by, or acted upon, any bias is irrelevant. What mattered was that there be an apprehension of bias.

Substantively on Matters of Law

A misrepresentation of the state of patent law in the US

- The ALRC report referred to US patent law on the issue of patentable subject matter so as to provide information on developments of patent law in other countries. In doing so it grossly misrepresented the state of US patent law.
- For instance, at paras 6.39 and 6.40 the report discusses the US Supreme Court decision in *Diamond v Chakrabarty* 447 US 303 (1980). It states that this case was the first case to support the patenting of biological material in the US and that it laid the foundation for the patenting 'of a range of biological material, including whole organisms, genes, proteins, and cell lines'. This is a particularly one sided view which happens to agree with the views of those that support the patenting of biological materials and ignored the literature from US patent law academics and other scholarly organisations that questioned the relevance of the decision with regard to the patenting of isolated biological materials, which is what human genes in the context of the ALRC inquiry was about. For example, Prof Rebecca Eisenberg, an American law professor, observed that the US Supreme Court in *Chakrabarty* 'did not reach the issue of whether naturally-occurring microorganisms that have been newly isolated or purified also fall within the ambit of "manufactures" or "compositions of matter"'. [Eisenberg, R. S. (1987), 'Proprietary Rights and the Norms of Science in Biotechnology Research', *The Yale Law Journal*, 97 (2), 177-231.]
- This is very relevant because in most instances the only point of distinction between a human gene (or the protein that it codes for) that is the subject of a patent monopoly and the human gene (or protein) in the human body is that one is isolated from the human body while the other remains *in situ*.
- This is far removed from the

Hepatitis C Virus

Is a naturally occuring virus which causes hepatitis C. Hepatitis is the inflammation of the liver.

For more information:

http://en.wikipedia.org/wiki/Hepatitis_C_Virus

Insulin

It is a protein (hormone) produced naturally by the human body and enables cells to absorb glucose from the blood.

For more information:

http://en.wikipedia.org/wiki/Insulin

Insulin-like growth factors 1 & 2

It is a protein produced naturally by the human body and stimulates cell growth.

For more information:

http://en.wikipedia.org/wiki/Insulin-like_growth_factor_1

genetically modified bacterium that was the subject of the patent which the US Supreme Court consider in *Chakrabarty*. Sure enough, in *Chakrabarty* the US Supreme Court held as patentable 'anything under the sun made by man', but the Chief Justice went further and was quite specific about the kinds of human intervention necessary to transform a product of nature into a product of man.

- The invention in US 3,813,316, entitled *'Microorganism having multiple compatible degradative energy-generating plasmids and preparations thereof'*, granted on 28 May 1974, was a genetically modified bacterium. Although it was derived from nature, the Court found that, unlike the natural bacterium from which it was derived, it contained 'two stable energy-generating plasmids, each of which provided a separate hydrocarbon degradative pathway', which the natural bacterium did not contain. Dr Chakrabarty's insertion of these two plasmids, through the use of what was then a leading-edge molecular biological technique, was held by the Chief Justice to result in something 'made by man' because: 'the patentee has produced a *new* bacterium with *markedly different characteristics from any found in nature* and one having the potential for significant utility.' (emphasis added)
- Undoubtedly, this genetically modified bacterium was artificial in some degree. Undoubtedly, it was derived from nature. Undoubtedly, it had a commercial and industrial application and, undoubtedly, it was valuable. However what actually convinced the US Supreme Court that it was a new 'composition of matter' was that it displayed 'markedly different characteristics from any found in nature'. Indeed the biological function that it performed had no natural precedence. For the first time ever, a microorganism was capable of degrading crude oil. The Chief Justice emphasised that this was a significant degree of artificiality – one that so changed the microorganism that it could no longer be said to be a product of nature.
- The Chief Justice considered three characteristics about Chakrabarty's bacterium to be crucial: the level of human intervention, the end result (its function) that was unprecedented in nature and the significant utility that this function had.
- In the first instance, the artificial bacterium in *Chakrabarty* was *significantly modified* when compared to any natural microorganism, not just the bacterium in issue. The human intervention involved the genetic modification of a natural bacterium through the insertion of two plasmids that were not found in any naturally occurring microorganism.

The genetically modified microorganism was not merely 'isolated' from its natural environment, nor purified through a process of manufacture.

- In the second instance, the microorganism displayed *markedly different characteristics from any found in nature*; namely, it degraded crude oil. There was no naturally occurring microorganism or anything that came close that performed this function. The Court's emphasis here was not on the artificial bacterium performing a new function in comparison to the natural bacterium, but on the artificial bacterium performing a function different from *any* found in nature. It did more than simply *replicate or reproduce* an identical substance or thing already produced in nature, such as insulin, human growth factor, hepatitis C virus, erythropoietin, human tissue plasminogen activator or Factor VIII: C.
- Finally, the microorganism's ability to degrade crude oil had the *potential for significant utility* that

Human Growth Hormone

It is a protein (hormone) produced naturally by the human body and stimulates cell growth.

For more information

http://en.wikipedia.org/wiki/Growth_hormone

Factor VIII

It is a protein produced naturally by the human body and facilitates blood clotting.

For more information:

http://en.wikipedia.org/wiki/Factor_VIII

was directly attributable to its new characteristics – characteristics that were alien to nature.

- Only in satisfying all three criteria did the US Supreme Court rule that Chakrabarty's genetically modified bacterium was something that was patentable *subject matter*. Of course to be a patentable invention Chakrabarty's invention had to also satisfy the secondary conditions of patentability: namely novelty, obviousness and written description. Thus the US Supreme Court emphasised that it was the *new* characteristics per se which possessed the potential for *significant* utility, not simply the *artificiality* of the bacterium per se that proved decisive. What was crucial in this process of transformation was the degree of human intervention, which was significant, and how that directly contributed to its *new* function of degrading crude oil. The microorganism was not merely 'isolated' from its natural environment, nor purified through a process of manufacture.

What actually convinced the US Supreme Court that the genetically modified organism was a new 'composition of matter' which was capable of being an 'invention' under US patent law was that it displayed 'markedly different characteristics from any found in nature'. It degraded crude oil.

- Moreover, it has long been accepted in the US that making something that already exists, through the use of an inventive process, does not justify the grant of a patent over that thing. In *Cochrane v Badische Anilin & Soda Fabrik* (*BASF*) 111 US 293 (1884) the US Supreme Court held that 'artificial alizarin', a chemical dye that was identical to alizarin, a natural dye made from the Madder plant, was not patentable subject matter regardless of the fact that the artificial version was the result of a technical and artificial process. The Court held:

> '[c]alling it artificial alizarin 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 alizarin, a well known substance.

- Thus it has never been lawful under US patent law to claim as 'inventions' products that are identical to those that exist in nature, such as proteins that already exist naturally, even though they were the product of a technical process.
- Yet the impression which the reader of the report is left with is that Australia would be out of step with the US if it did amend the *AU Patents Act, 1990* to expressly prohibit the patenting of isolated biological materials that are identical or substantially identical to naturally occurring materials. At para 6.52 the report states:

> However, the time for taking this approach to the patenting of products and materials has long since passed. For decades, naturally occurring chemicals have been regarded by patent offices in many jurisdictions as patentable subject matter, when they are isolated and purified.

A misrepresentation of the state of patent law in Europe

- In 1998 the *Directive on the Legal Protection of Biotechnology Inventions* (Biotech Directive) was passed by the European Parliament. It then became incumbent on countries that are members of the European Union (EU) to transform the Biotech Directive into their national patent laws. Quite rightly, the ALRC report at para 6.38 confirms that the Biotech Directive provides that isolated biological materials derived from human and other sources are patentable subject matter under the *European Patent*

Convention.

- Unfortunately, what the ALRC report failed to point out is that the Biotech Directive required all EU countries to adopt the Biotech Directive by July 2000, yet amid enormous controversy in Europe, by that date, of the 15 countries which then made up the EU, only 7 had complied. The 8 that had not included Italy, France, Germany, Belgium and The Netherlands.
- Failure to mention the dissention over the Biotech Directive among EU countries was a significant omission.
- Furthermore, the ALRC's report failed to mention that of the countries that had complied, such as Denmark, the government had commissioned the Danish Council of Ethics to investigate and report on the Biotech Directive. Despite the fact that the Danish Council of Bioethics had yet to publish its report by the time that ALRC had completed its inquiry, the ALRC should have known about it and thus should have mentioned it.
- In this respect it is important for this Committee to know that the Danish Council of Bioethics' Report was critical of the rationale employed by the Biotech Directive to justify the distinction between a product of nature and a product of mankind. Indeed, the Report completely rejected the idea that the mere isolation of a human gene could be a sufficient act to distinguish it from a human gene that exists in the human body. According to the Danish Council of Bioethics, the idea that 'a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body' was 'unreasonable'.

According to the Danish Council of Bioethics, the idea that 'a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body' is 'unreasonable'.

- Even today, 11 years later, the Biotech Directive remains, according to Christoph Ann, a Professor of Law at the Munich Technical University, 'highly controversial, both ethically and politically; not only in Germany but throughout Europe and in most parts of the world'. [Ann, C (2006) Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It', *German Law Journal*, 7 (3), 279-291]
- Professor Ann explains that the Biotech Directive 'triggered', in the *Bundestag* and among legal scholars, 'a lengthy and extremely controversial discussion' which was only resolved in Germany in 2005 when the German Parliament finally conceded to the demands of the European Commission. Even so, argues Ann, the transposition into German patent law technically did not comply. The German patent law, *Paragraph 1a Sec. 4 PatG*, included a stipulation that for an isolated human gene to be patentable subject matter the patentee had to show the application of that gene in 'at least one application'. Thus, says Ann, '[w]ithout such disclosure a human gene sequence is not patentable under German Patent Law'.
- While Ann is critical of *Paragraph 1a Sec. 4 PatG* because he argues it creates a disparity between German and European patent law, it is relevant that the Committee which is undertaking this Senate Inquiry understand that it is by no means the accepted position in Europe that isolated biological materials *per se* (that is, without qualification) should be patentable subject matter.
- It is also worth noting that France and Italy have followed the German legislative example.

A misrepresentation to the effect that Australia would be out of step with the rest of the world

- At para 6.53 the ALRC's report states: 'the ALRC considers that a new approach to the patentability of

genetic materials is not warranted at this stage in the development of the patent system' and it gave a number of reasons, the first being, that do to so 'would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions'.

- This statement is misleading. There is no 'accepted international practice with respect to [the patenting of] genetic inventions' that has been legally verified. Apart from the disparity in the patent law between European countries, all of which are members of the EU as well as the European Patent Convention with regard to 'genetic inventions', it is not necessarily the case that the patenting of isolated biological materials is lawful in the United States. Moreover, there are a number of countries, such as Argentina, that expressly exclude the patenting of biological materials that exist in nature or are substantially identical thereto.

Erythropoietin

It is a protein that is produced naturally by the human body to regulate red blood cell production.

For more information:

http://en.wikipedia.org/wiki/Erythropoetin

"The overwhelming evidence, including Amgen's own admissions, establishes that human erythropoietin (uEPO) and isolated erythropoietin (rEPO) are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO. The amino acid sequences of human uEPO and rEPO are identical."

- While it is true that the patent offices of the United States, Europe and Japan agreed among themselves in 1988 that they would permit patents that claimed isolated biological materials as inventions and published a memorandum to this effect and have since granted such patents, this does not mean that the patents are valid. Indeed there is presently considerable controversy in the United States among intellectual property law academics and practitioners over the validity of these very patents.

A misrepresentation on the state of patent law in Australia

- At para 6.33 the ALRC refers to the decision of David Herald, a Deputy Commissioner of Patents (of the Australian Patent Office), *Kirin-Amgen Inc v Board of Regents of the University of Washington* (1995).
- The parties were represented by Dr Bennett, Dr Santer and Dr Pickering (who were all subsequently to be appointed members of the ALRC's Advisory Committee). Kirin-Amgen was represented by Dr A Bennett (now Justice Bennett of the Federal Court), instructed by Mr I Ernst (patent attorney of Shelston Waters, Sydney) and Mr G Cox (patent attorney). The Board of Regents was represented by Dr J Emmerson, instructed by Dr V Santer (patent attorney of Griffith Hack & Co, Melbourne). Genetics Institute, another Opponent, was represented by Dr W Pickering (patent attorney of F B Rice & Co).
- The invention (which was the subject of the patent application filed by Kirin-Amgen) was to erythropoietin in an isolated and purified form. Erythropoietin is a protein which is produced naturally in humans.
- In all other material respects the erythropoietin, as produced in the human body and as isolated and purified, is identical. This fact had been confirmed in 1989 in patent proceedings before a US Federal District Court which held:

> …the overwhelming evidence, including Amgen's own admissions, establishes that human erythropoietin (uEPO) and isolated erythropoietin (rEPO) are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO. The amino acid sequences of human uEPO and rEPO are identical. [*Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc* (1989) 13 U.S.P.Q.2D 1737]

Amino acid sequence

Is the order in which amino acids lie in the chain in proteins.

Proteins consist of amino acid chains.

For more information:

http://en.wikipedia.org/wiki/Amino_acid_sequence

- However, either because he was ill-

informed or because he ignored this US court decision (published some 6 years earlier), Herald erroneously concluded that isolated and purified erythropoietin had 'been deliberately changed from the naturally occurring form' and so was patentable subject matter under s.18(1) *AU Patents Act, 1990* because it was 'directed to artificially created states of affairs'.

- That finding was incredible in view of the fact that recombinantly made erythropoietin was according to the patent owner, Kirin-Amgen, identical to the erythropoietin made by the human body.
- In effect, the Opponents had conceded this issue so it really did not matter what Herald thought about the legal limits applicable to the *primary* patentability threshold of patentable subject matter. This may seem strange given that this was an issue that was open for them to contest, especially as no Australian court had made any ruling, but when it is appreciated that both Opponents had their own patent applications pending for essentially the same kinds of inventions, it becomes easy to see why they had chosen not to do so.

The Deputy-Commissioner of Patents handed down a decision on the issue of 'manner of new manufacture' knowing that the issue 'not [been] directly argued' by the parties in the Opposition.

- Indeed, the Grounds of Opposition were limited to <u>three issues</u>. Namely: (a) was the invention obvious?; (b) was the invention novel?; and, (c) did the claims that defined the invention comply with requirements of s.40 (in other words was the definition of the invention clear and succinct and fairly based on the information disclosed in the patent)? These are all *secondary* patentability thresholds.
- Nonetheless, Herald handed down a decision on the issue of 'manner of new manufacture' knowing that it had 'not [been] directly argued'. Precisely why he did so is unknown for he did not proffer any explanation. The problem, however, is that (a) the parties never raised patentable subject matter as an issue; (b) no evidence was filed by the parties which was relevant to that issue (probably explaining the error he made in thinking that the erythropoietin 'molecules' which were the subject of the patent had been 'deliberately changed' when in fact they were identical); (c) there was no legal argument by the parties with respect to that issue; and, (d) regardless, he had no jurisdiction in the absence of the parties raising it as an issue.
- The ALRC, however, simply ignored these points in its report, leaving it open for the reader to deduce that this decision was legitimate when it was, in fact, nothing of the kind. It was highly irregular and it is relevant for this Committee to understand why Herald, a Deputy Commissioner of the Australian Patent Office, would deliberately set about trying to establish a legal precedent without having any right at law to do so.
- Furthermore, it is relevant for this Committee to understand why the ALRC would choose to ignore this irregularity.

9. International Developments in Patent Law and their effect on the development of Australian Patent Law.

Events leading to the establishment of the World Intellectual Property Organization

- Although Australia was merely a collection of colonies in 1873, an event occurred in August of that year which was to play a role in the development of its patent (and copyright and trade mark) law as it progressed into Federation and beyond. That event was the first international intellectual property convention and it occurred during the Weltausstellung (German: *International Exhibition*) which was held in Vienna between May and September. Then within the Austro-Hungarian Empire, which was formed only a few years earlier in 1867 (and survived until end of WWI), Vienna was the site chosen by the Emperor, Franz Joseph I, to proudly display the grandeur of his vast empire to the world. It was, in effect, a world trade fair and it was one of many that preceded and superseded it during the 19th century. Importantly for Franz Joseph, the International Exhibition was the first in which German was spoken as the official language.
- These grand international exhibitions, which had started in Paris a little after the French Revolution, were held in London and Paris mainly, but by 1873 it was Vienna's turn. After that, in 1876 it was Philadelphia and even Melbourne and Sydney hosted this event in 1879 and 1880 respectively. The last great international trade fair was held in Paris in 1937.
- In the context of these grand affairs the first international intellectual property convention took place. Although it was hosted by the Austro-Hungarian government, it was the United States which had first raised the possibility of this event being held in diplomatic communications. Specifically, the United States government was alarmed at the prospect of European governments taking their lead from The Netherlands and repealing their patent laws. Naturally, it was well aware of the negative attitudes towards patents which prevailed in Great Britain (and other countries) at the time and that neither the newly unified Germany nor Switzerland had enacted national patent laws. Moreover, of the European countries and states which had enacted patent laws, nearly all followed the French example which excluded patents over medicines and food and other technologies. This was at odds with the American approach which perceived these laws that protected the right of the ingenious and the creative to receive fair compensation for their contribution to social and economic development, as essential to a new world order – one that was democratic in nature.
- Indeed the American approach to patents at the time is best summed up in a book published by H & C Howson, US patent attorneys, in 1872. They wrote:

  > Our Patent Laws are, undoubtedly, the most truly liberal of any. They more clearly than any other recognize the truths that productive industry is the basis of natural wealth and power; that such industry will flourish in proportion as it is made a secure course of individual profit; that true invention is intellectual production of the most beneficial kind, and that, therefore true policy, which is always just, demands that it shall be made, as far as possible, a secure source of individual profit.

- It must be remembered that the world in the 1870s was not predisposed to democracy as it is

today. Apart from the fact that women were excluded from the electoral process, the very idea that everyday working people would have the right to vote was anathema except in the United States.

- Understandably, American perceptions of individual freedoms and rights were strongly regarded, defended and promoted. American people were beginning to show the world that a new democratic country could industrialise and become a serious competitor to the manufacturers in Great Britain, Germany and France. Therefore, the protection of American intellectual property was seen as sacrosanct and countries that did not follow suit were portrayed as free-riding on the intellectual genius which American entrepreneurship encouraged.
- Ironically, it was an attempt by a US congressman in December 1872 to stop American participation at the Weltausstellung that sparked the idea of an international intellectual property convention. Congressman Shellabarger objected to a proposal that the US government contribute $100,000 towards the cost of the US exhibition. He was prompted to rise to his feet by an article that had been published in *Scientific American,* whereby the 'substance and effect', he said, showed 'that both the law of Austria and the practice of that Government [was] such as that the exhibition of any of the inventions of our country there will result practically in a surrender of those inventions.' In other words, the public display of American ingenuity in Vienna would destroy the ability of the American inventor from seeking patent protection throughout the Austro-Hungarian Empire.
- The reaction of the US government was to complain to the Austro-Hungarian government about the state of these laws. Naturally, with the prospect of the US withdrawing from participation, the Austro-Hungarian government passed legislation to specifically protect exhibitors from the effect of this patent law. But it also led to a suggestion by the US government, which the Austro-Hungarian government accepted, that it host an international intellectual property convention. In accepting the invitation on behalf of the United States, Columbus Delano, US Secretary of the Interior, wrote on 29 May 1873 to the Austro-Hungarian government stating that while he believed the meeting would be, 'of the very greatest importance … if the American [patent] system can be properly presented before that Congress, discreetly and cautiously sustained with facts and figures, I feel confident that the best results can be expected.'

In 1872 the United States government was alarmed at the prospect of European governments taking their lead from The Netherlands and repealing their patent laws. Naturally, it was well aware of the negative attitudes towards patents which prevailed in Great Britain (and other countries) at the time and that neither the newly unified Germany nor Switzerland had enacted national patent laws. Moreover, of the European countries and states which had enacted patent laws, nearly all followed the French example which excluded patents over medicines and food.

- US President Ulysses Grant appointed the Assistant Commissioner of Patents, John Marshall Thacher (who was to serve as the US Commissioner of Patents in 1874-75), to head the US delegation. Thacher's objective was, according to a report of the events published by *Scientific American* on 6 September 1873, 'to discuss the propriety of establishing a uniform patent law in Europe … and also to suggest, to the several governments, the general principles and features which such a law ought to embrace'.
- Thacher's mission was made easier by the presence of other delegates whose views aligned with his.

Naturally, coming from the patent community these delegates were sympathetic towards patent monopolies and so at the end of the meeting a predictable resolution was passed that called upon their governments to accept: 'the protection of inventions should be guaranteed by the laws of all civilized nations under the condition of a complete publication of the same.'

- The Vienna meeting in 1873 was a watershed in the history of the patents. It provided the stimulus for the drafting of the world's first international patent, trade mark and copyright treaty, the *Paris Convention for the Protection of Industrial Property of 1883* (known as the Paris Convention), which by 1893 had led to the formation of United International Bureau for the Protection of Intellectual Property, BIRPI. For members of the Paris Union, signatories to the Paris Convention, the Bureau, headquartered in Berne, remained the principal route through which intellectual property would be discussed and administered internationally. Eventually the *Convention Establishing the World Intellectual Property Organization* (WIPO) was signed in Stockholm on 14 July 1967 and in 1974, in accordance with that Convention, the BIRPI became the WIPO, headquartered in Geneva. The current head of WIPO is an Australian, Dr Francis Gurry.

The US objective was, according to a report of the events published by Scientific American on 6 September 1873, 'to discuss the propriety of establishing a uniform patent law in Europe … and also to suggest, to the several governments, the general principles and features which such a law ought to embrace'.

- Today WIPO is an agency of the United Nations and administers a variety of international agreements and conventions regarding intellectual property. One of these is the *Patent Cooperation Treaty, 1970* which facilitates the filing of patent applications throughout the world. As such WIPO is an important source of data regarding patents.

- That said, and as has already been explained, even after Federation and despite having its own diplomatic status, until the early 1970s Australian patent law and policy was very much shaped by attitudes and policies in London.

The Agreement on Trade Related Aspects of Intellectual Property

- By the 1980s the attitude of the US Government of President Reagan towards WIPO had deteriorated sufficiently that it was actively seeking an alternative. The multilateral nature of the WIPO, particularly as it was a UN agency by this time, was seen by US companies such as Pfizer to be frustrating US attempts to promote US-style intellectual property standards and their enforcement in developing countries. Developing countries had become increasingly important to the US economic strategy in that they provided US corporations with cheap labour and higher profit margins. Together with intellectual property laws, US corporations were able to control product access to their own internal market and those markets which had intellectual property laws of a similar standard. However, this was very difficult in countries which did not, and the majority of countries (particularly low labour cost countries) fell into this category. This approach, of course, was similarly being copied by the EEC and Japan.

- Critical to the success of this strategy was the repatriation of royalty revenues earned through the licensing of intellectual property to companies that were either subsidiaries of the multinational parent companies headquartered in the US, Europe and Japan or associated to them as third party suppliers of various components or as assemblers, distributors and suppliers.

- Accordingly, while the GATT was not the right place, it was the only place in which to raise this issue outside of WIPO, an organisation which, as ANU Professors Peter Drahos and John Braithwaite, confirmed 'was no longer a forum that could be trusted to deliver the standards' being demanded by the US, Europe and Japan [Drahos, Peter with Braithwaite, John (2002), *Information Feudalism*, London UK: Earthscan Publications Ltd, 111]

- Unfortunately, the GATT, which was the only agreement through which the post-WWII aspirations for free trade could be pursued, was not a suitable vehicle because intellectual property laws had been deliberately excluded from the two agreements that were signed at Bretton Woods in July 1944. Thus, in order to protect the balance of payments of countries in which the owners of leading-edge technologies reported their revenues, it was imperative that all forms of intellectual property become part of world trade discussions and so in the 1970s Japan raised the issue of the counterfeiting of trade marked and copyrighted goods in the GATT. This had nothing to do with patent law, but as the GATT secretariat eventually placed the issue of counterfeiting on the agenda, the US, EEC and Japanese trade negotiators were able to have the agenda broadened to include patents as well.

- By 1984 all aspects of intellectual property were on the agenda for the next round of the GATT which was to be held in Uruguay.

- The vehicle used to progress this further was the draft of the *Agreement on Trade Related Aspects of Intellectual Property* (TRIPS). When the TRIPS negotiations opened in March 1987, the chief US negotiator blamed the 'deficiencies in protection of intellectual property rights' as the cause of a distortion of the 'trade in goods'. It was the firm view of the US that 'the entire trading system as a whole will benefit from eliminating trade distortions resulting from lack of adequate and effective protection of intellectual property rights'.

- The reaction of developing countries, many of whom were worried that bringing intellectual property law enforcement within the GATT would inhibit their right to economic self determination, was guarded. They believed that the Paris Convention provided flexibility and that WIPO, which administered this and other intellectual property treaties, was the appropriate body to facilitate all international discussion concerning intellectual property. In their view the GATT talks, which were mandated by the Uruguay Ministerial Council, were narrowly confined to trade-related aspects of intellectual property law, not to the wholesale harmonisation and enforcement of these laws. The Brazilian TRIPS negotiator complained:

The multilateral nature of the WIPO, particularly as it was a UN agency by this time, was seen by US companies such as Pfizer to be frustrating US attempts to promote US-style intellectual property standards and their enforcement in developing countries.

> For more than 500 years, the main objective of the protection of IPRs has been the promotion of industrial creativity *to the benefit of a country's social and economic development*. Each State, therefore, recognises IPRs according to well-defined public interests. This basic orientation guides, for instance, the system established by the Paris Convention. It also explains and justifies the differences which naturally exist between various national laws dealing with the subject.

Australia's role in the TRIPS negotiations and the Impact of TRIPS on Australia

- Australia played a significant role in these negotiations which commenced in 1987 and ended in 1994. Having quickly aligned itself with US, EEC and Japan, the Australian TRIPS negotiators tried to mediate between the two sides. Why they did so, given that Australia was not a leading-edge technology producing country of any significance (in fact on the basis of the patent statistics it was a significant net importer of leading-edge technology), is a matter of speculation. Indeed, according to the IPAC Report, between 1979 and 1984 over 90% of Australian patents had been granted to foreigners (incidentally, according to WIPO, today that figure is even higher). Even more puzzling is why they persisted with this strategy when in 1989, only two years after the start of the TRIPS negotiations, the relevant Minister, Barry Jones, explained in the Australian Parliament that the objective of the proposed new patent law, which he had introduced and which was drafted to take into account the IPAC 1984 report, was:

  > … adjusting the length, strength and breadth of patent rights so as to maximise the social benefits and to minimise the social costs to Australians.

- Whether the Minister appreciated that Australia's TRIPS negotiators were in favour of an international agreement that directly contradicted this statement is a matter of speculation; but, objectively, one must consider the possibility that, given that he would not deliberately mislead parliament, he did not. However, it would have been apparent to those advising the Minister that once TRIPS was a reality it would be impossible for Australian policymakers to adjust 'the length, strength and breadth of patent rights' in Australia to the degree required to '*maximise* the social benefits and to *minimise* the social costs to Australians'.

- Of even greater concern is why Australia's TRIPS negotiators supported the specific drafts of the TRIPS agreement, which were put forward by the EEC and the US, in light of an economic study that concluded that 'the benefit/cost ratio of the patent system in Australia is negative, or at the very best, in balance'. It must be emphasised that although the IPAC Report recommended retaining the patent system it did so with a caveat, namely, that 'there is considerable economic justification for policy action' to modify patent laws so as to:

  > …[provide for] stricter examination … reducing the length of the term and the scope of patent monopolies, and by action to deal with undesirable restrictive practices in patent licensing.

For more than 500 years, the main objective of the protection of IPRs has been the promotion of industrial creativity *to the benefit of a country's social and economic development.*

- Instead, under TRIPS, which came into effect in Australia on 1 January 1995, the exact opposite result was achieved. First, the length of the patent term was increased from 16 years by 4 years and fixed at 20 years. Secondly, it would no longer be possible for patent laws to discriminate against specific technologies. Thirdly, the ability of government to use compulsory licensing was restricted. Fourthly, to the extent that pre-grant patent examination was made stricter, a series of court decisions reduced the effectiveness of the threshold for 'inventive step', according to the National Innovation Study, *Venturous Australia*, 'to the point of vacuity'. Finally, the Australian Federal Court in two Full Court decisions interpreted Australia's accession to TRIPS as an indication of a new policy that no longer

required IP Australia nor the courts to enforce the proviso in section 6 of the Statute of Monopolies, namely, that patents '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'.

- As a result Australia's patent law in 2009 is simply incapable of meeting the objectives which Barry Jones, the sponsor of the current legislation, expressly promised the Australian Parliament and the Australian people it would in 1989. To be frank, Australia's patent law and the economic policies which supposedly justify it should be the subject of a major multi-disciplinary and multi-expert review - one that takes into account the empirical evidence and *the views of a range of stakeholders*, not one that ignores the evidence and only takes into account the views of patent lawyers and patent attorneys (and indirectly the views of their clients which are mainly foreign multi-national corporations). Regardless of the existing international agreements that apply to Australia at the present time, this Committee should consider calling for a wide ranging Inquiry to investigate the Australian patent system and its relevance to the Australian economy in the 21st century.
- Although TRIPS was not yet a reality when the *AU Patents Act, 1990* became law, the TRIPS negotiations had been going for 3 years. The first draft of what was to become TRIPS was not circulated by the EEC until 29 March 1990, nine months after the Minister made his speech in the Australian Parliament about the legislation's objectives; but even so, the Minister must have had a hunch that perhaps those objectives may ultimately have be incompatible with TRIPS.
- Thus, even if the Minister did not deliberately mislead Parliament when the *Patents Bill, 1989* was read a second time in the House of Representatives on 1 June 1989, the fact remains that there had never before (nor since) been a major multi-disciplinary review of the effect of patent monopolies on the Australian economy. The simple truth is that the reviews of patent laws which have taken place to date have either been instigated in response to amendments to UK patent laws (as occurred in 1935 and 1950) or conducted by Committees controlled or unduly influenced by patent lawyers and patent attorneys (as occurred in 1984, 2000 and 2004).

According to the IPAC Report, between 1979 and 1984 over 90% of Australian patents had been granted to foreigners

Australia's patent law and the economic policies which supposedly justify it should be the subject of a major multi-disciplinary and multi-expert review - one that takes into account the empirical evidence and *the views of a range of stakeholders*, not one that ignores the evidence and only takes into account the views of patent lawyers and patent attorneys (and indirectly the views of their clients which are mainly foreign multi-national corporations).

10. Patentable Subject Matter

- Andrew Christie, the first holder of the Davies Collison Cave Chair of Intellectual Property Law at the University of Melbourne, subscribes to the view that Australian patent law has a very broad definition of patentable subject matter. So broad, in fact, that just about anything is capable of being made the subject of a patent monopoly. In his paper entitled *Business Method Patents and Beyond: Why E=mc2 is inherently patentable (at least in the U.S. and Australia)* Christie asserts that the 'truism of patent law throughout the world that abstract concepts such as "the laws of nature, physical phenomena and abstract ideas" are not inherently patentable' is 'not true'. He argues that patent law in the US and Australia did away with these antiquated notions long ago. In support, he specifically relies on 'the practice of the Patent Offices' in these countries and 'to the decisions of the[ir] courts, in relation to computer programs, mathematical algorithms and business methods.'

It is argued by proponents of gene patents that the 'truism of patent law throughout the world that abstract concepts such as "the laws of nature, physical phenomena and abstract ideas" are not inherently patentable' is 'not true'.

- Specifically, Christie relies on a decision of the US Court of Appeals for the Federal Circuit (CAFC), an appellate US Federal Court vested with exclusive jurisdiction over appeals from US Federal District Courts concerning patent law, to support his argument. The decision is *State Street Bank v Signature Financial Group* 149 F.3d 1368 (Fed. Cir. 1998), and according to Christie, the CAFC held that an algorithm which had been '"reduced to some type of practical application" so as to produce "a concrete, tangible and useful result"', thus being something that was "limited to a practical application in the technological arts", was "within the category of inherently patentable subject matter".
- This kind of reasoning, as was employed by the CAFC in *State Street,* was not new nor confined to the technology in issue nor an idiosyncratic example of US jurisprudence and so, perhaps, Christie's hypothesis is not so far fetched. Rather, the reasoning was quite commonplace in some quarters of intellectual property and although not universally accepted, the European Patent Office's administrative appellate bodies, the Technical Board of Appeals, had championed it since the early 1980s. Even the Patents Court and the Court of Appeal in the UK had, on occasion, displayed some sympathy towards it, especially when the invention in the patent in issue came within one of the categories of things that were expressly excluded by the European Patent Convention as 'inventions'. Such things include discoveries, computer programs, mental acts and business methods. So whether the invention in issue was the discovery of a human gene as the cause of human illness, but which was isolated and used in a diagnostic (which was not new), or a device which was itself not novel, but which when incorporating a computer chip performed a function in accordance with a computer program (the computer program being the only thing that was new), the question became: is the invention *as a whole* something excluded from the definition of 'invention'?
- Although *State Street* was a US court decision it was, according to Christie, good law in Australia because an Australian Federal Court judge, Justice Heerey, had applied its reasoning in an Australian case, namely, *Welcome Real-Time SA v*

Catuity Inc [2001] FCA 445. Thus, concludes Christie, 'the law in Australia is the same as the law in the US – namely, claimed subject matter is not inherently unpatentable merely because it concerns a method of doing business'.

- Without going into the facts or the merits of either *State Street* or *Welcome Real-Time*, the reason why this Committee should be wary of the kind of analysis undertaken by Christie and the recent tendency of Australian courts to look to the United States for guidance with respect to patent law, is that the state of the patent law in the US regarding patentable subject matter is highly controversial and far from being settled. Moreover, it would seem that the kind of reasoning employed in *State Street* and, on some occasions, by other courts and tribunals in other parts of the world, is not only wrong but it displays a particular view of patent law which seeks to expand the scope of patentable subject matter to the point where, as Christie asserts, literally anything can be regarded as capable of being patentable subject matter.

"Whether a claim is drawn to patent-eligible subject matter ... is a threshold inquiry, and any claim of an application failing the requirements ... must be rejected even if it meets all of the other legal requirements of patentability."

Chief Judge Michel of the US Court of Appeals for the Federal Circuit, *In re Bilski*, October 2008

- Indeed, it must be brought to the Committee's attention that only recently an *en banc* panel of the CAFC, that is the CAFC consisting of the full complement of all 12 judges, held by 10:2 that *State Street* had been wrongly decided (although according to the Michel CJ it was an 11:1 decision against the patenting of the claim to the business method in issue [see webcast at http://www.wcl.american.edu/pijip/webcast.cfm#]). Not that this decision necessarily settles the law in the US. The claim in question, *In re Bilski*, is now the subject of an application to appeal to the US Supreme Court. Should the US Supreme Court accept the application it will probably be another 12 months, at least, before we will know how the issue is to be resolved at a judicial level, and even then it is quite possible that the US Congress may amend the *US Patents Act, 1952* (the operative legislation) in response to that decision.

- That possibility aside, it is instructive for this Committee to be taken through the en banc decision in *Bilski*. It does not involve biotechnology nor gene patents, but a business method. Irrespective of the subject matter, the decision is helpful because it demonstrates just how important (and relevant) are the statutory limits imposed on patentable subject matter.

- The decision consists of 132 pages so it will be necessary to abridge its reasoning. The invention in issue was 'a method of hedging risk in the field of commodities trading'. That is how Michel CJ described it. There was no doubt that it was artificial, useful, valuable and had an industrial or commercial application. Even so, the US Patent Office had rejected the patent application on the ground that it was not an invention within s.101 *US Patents Act, 1952*. According to the patent examiner, 'the invention is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application, therefore, the invention is not directed to the technological arts'. The US Board of Patent Appeals upheld the rejection. The patent applicant then appealed to the CAFC.

- Almost immediately, at page 4 of the judgment, Michel CJ confirmed that patentable subject matter is the primary threshold of patentability. He stated:

> Whether a claim is drawn to patent-eligible subject matter under § 101 is a threshold inquiry, and any claim of an application failing the requirements of § 101 must be rejected *even if it meets all of the other legal requirements of patentability*. (Emphasis added)

- In further reinforcing the relevance of this threshold in the context of the subject matter, being a method or process, the Chief Judge said:

> Specifically, the [US Supreme] Court has held that a claim is not a patent-eligible "process" if it claims "laws of nature, natural phenomena, [or] abstract ideas." … Such fundamental principles are "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none."

"The English practice in 1793, imported into the American statutes, explicitly recognized a limit on patentable subject matter."

Judges Dyk and Linn of the US Court of Appeals for the Federal Circuit, *In re Bilski*, October 2008

- The Chief Judge summarised the issue before the Court as 'whether Applicants are seeking to claim a fundamental principle (such as an abstract idea) or a mental process'. In other words, said the Chief Judge, '[t]he question before us then is whether Applicants' claim recites a fundamental principle and, if so, whether it would pre-empt substantially *all* uses of that fundamental principle if allowed'. (Emphasis added)
- Two judges of the majority (Dyk and Linn JJ) wrote a separate judgment in which they affirmed:

> The English practice in 1793, imported into the American statutes, explicitly recognized *a limit on patentable subject matter*. As the Supreme Court recounted in Graham v. John Deere, the English concern about limiting the allowable scope of patents arose from an aversion to the odious Crown practice of granting patents on particular types of businesses to court favorites. 383 U.S. 1, 5 (1966). (Emphasis added)

- Ultimately, the en banc CAFC also rejected the patent application.
- But what is particularly troubling about Christie's argument, an argument that is often made by proponents of this kind of approach to patentable subject matter, is that it ignores the most fundamental requirement of patent law: that a patent should only be granted in respect to something that is inherently an 'invention' – the primary threshold of patentability. Whether the definition of 'invention' be the current Australian definition in the *AU Patents Act, 1990* or the definition in s.101 of the *US Patents Act, 1952* or some other definition which applies a series of exclusions to what is not an 'invention', such as does the European Patent Convention, the fact remains that there are things that have never been and can never be 'inventions' and this has been acknowledge by the highest courts of appeal in Australia, the US and the UK.
- At its most basic level, this is the issue that concerns this Committee in terms of isolated or purified biological materials which are identical or substantially identical to those that exist in nature, and not only does the *AU Patents Act, 1990* refer back to section 6 of the *Statute of Monopolies*, but the High Court of Australia has provided guidance on what the relevant parameters are in terms of patentable subject matter. Accordingly, it is relevant that at no time has the High Court of Australia endorsed the argument subscribed to by Christie (and others). It is simply nonsensical and it has no merit whatsoever.

- As the Chief Judge in *Bilksi* said: the issue is whether a patentee has defined the invention in such a way that the patent monopoly, should it be granted, includes 'a fundamental principle [which]… pre-empt[s] substantially *all* uses of that fundamental principle'. If that is the issue, then a patent which defines the invention to be an isolated biological material will, by definition, 'pre-empt substantially *all* uses of' that biological material because incorporated into the very essence of that biological material are 'fundamental principles' in the form of the nucleic acid (if it is a gene) or the amino acid sequence (if it is a protein), neither of which were invented by anyone.

TRIPS and Patentable Subject Matter

- Although TRIPS expressly imposes an obligation on WTO member countries to have patent laws (as well as other intellectual property laws) that conform to stipulated parameters, thus making it impossible for countries like Australia to use patent laws so as to '*maximise* the social benefits and to *minimise* the social costs to Australians' in the manner that Barry Jones explained in 1989, it does nonetheless provide that patents be granted only in respect of 'inventions'.
- Article 27.1 TRIPS states:

  > … patents shall be available for *any inventions*, whether products or processes, in all fields of technology, *provided* that they are *new*, involve *an inventive step* and are *capable of industrial application*. … [and] *patents shall be available* and patent rights enjoyable *without discrimination as to* the place of invention, *the field of technology* and whether products are imported or locally produced.

- The language of art. 27.1 TRIPS is virtually identical to the language of art. 52.1 European Patent Convention (EPC), an international agreement which was originally drafted by Kurt Haertel in 1963. [Haertel was instrumental in persuading the West German government (as it was then) to remove the ban, which had existed since 1877, on the patenting of chemical substances. Thus his vision to eliminate all technological discrimination went from being a mere European condition to a condition that today applies in all countries that are members of the WTO.]
- Thus art. 52.1 EPC and art 27.1 TRIPS are inextricably linked. That said, the conditions of patentability which are encapsulated in both of these provisions are identical to those that have existed in all common law jurisdictions, linked through history and jurisprudence, to section 6 of the *Statute of Monopolies, 1623*. Those conditions, as has already been stated, mean that a patent can only be granted in respect to something that is:

  (a) an invention, — **primary condition**

  and then only if *that* invention is:

  (b) novel, and
  (c) involves an inventive step, and
  (d) is industrially applicable.

  } **secondary conditions**

- As the Chief Justice confirmed in *Bilksi,* regardless of whether the subject matter of a patent meets the secondary conditions, unless it meets the primary condition, the patent is invalid.
- This is also the law in the UK (post-EPC under the *UK Patents Act, 1977*) as well as in Australia. Two appellate court decisions confirm this. The first, *Genentech Inc's Patent* [1989] RPC 147 (*Genentech*) is a decision of the UK Court of Appeal which involved a patent application that claimed an isolated human protein, the corresponding human gene and a biotechnological process that used the genetic sequence of the human gene to synthesised the protein in a isolated

and pure form. The second, *NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited* (1995) 183 CLR 655 (*Philips*) is a decision of the High Court of Australia which involved a patent for a light bulb that used a specific component.

- In the context of this Inquiry into patents that claim, as inventions, isolated biological materials and the biotechnological processes for their synthesis, it is critical that this Committee not be persuaded by submissions that use the argument made by Christie. Furthermore, the Committee should accept that the common heard phrase that 'anything under the sun made by man is patentable subject matter', often bandied about, out of context, by proponents of gene patents is not to be interpreted literally. That phrase was originally made by PJ Federico, a US patent law academic in 1951 and referred to favourably by the US Supreme Court in 1980 in *Diamond v Chakrabarty*, and although the Court upheld the validity of the patent over a genetically modified organism (GMO), it did so only because that GMO performed a useful function that was *unknown* to nature, namely, it degraded crude oil.

Tissue Plasminogen Activator (t-PA)

It is a protein that is produced naturally by the human body to dissolve blood clots.

For more information:

http://en.wikipedia.org/wiki/Tissue_plasminogen_activator

"Claims 1 to 6 all refer to the final protein product in one form or another and prepared by one method or another. In my judgment these are not inventions …"

Lord Justice Purchas

- The Court did not hold that *any* level of human intervention was sufficient to transform a product of nature into a product of mankind. Rather, it emphasised that the level of human involvement needed in that process of transformation had to be *significant*. Moreover, the Court it did not repudiate the long held caveat against the patenting of 'laws of nature, physical phenomena and abstract ideas'; in fact, it reemphasised it.
- What this means is that the mere act of isolating a human gene from its natural environment is not sufficient to justify the private appropriation of that genetic material and the removal from, what the US Supreme Court in *Funk Brothers Seed Co v Kalo Inoculant Co* 333 US 127 (1948) (*Funk Bros*) held to be, the body of knowledge that is 'free to all men and reserved exclusively to none'.
- Indeed, even deducing the function of a specific human gene or using the gene in a biotechnological process does not warrant the private appropriation of either the gene or the product of that process, whether the product be a protein in a purified form, or information which can be used in the prognosis of a disease or a biological reaction. Judicial support for this position is also to be found in post-EPC British patent law jurisprudence. For instance, the UK Court of Appeal in *Genentech* held that a patent which claimed a patent monopoly over the human gene which coded for the protein tissue plasminogen activator (t-PA), the use of that human gene in biotechnological processes and the product of those biotechnological processes, purified t-PA, was invalid. In so doing the Court held that the claim which defined the patent monopoly to be over 'recombinant human tissue plasminogen activator essentially free of other protein of human origin' was not valid because it was directed to something that was not an 'invention' within s.1(1) *UK Patents Act, 1977* (which was equivalent to art. 52(1) EPC) being expressly excluded by effect of s. 1(2)(a), namely, that it was 'a discovery'. Lord Justice Purchas held:

> Claims 1 to 6 all refer to the final protein product in one form or another and prepared by one method or another. In my judgment these are not inventions …

- Accordingly, as isolated and

purified biological materials do not qualify as 'inventions' within the meaning of that word in TRIPS, it would not be a contravention of Australia's obligations under TRIPS for the Australian Parliament to pass legislation to expressly exclude isolated biological materials from patentability.

Isolated or Purified Biological Materials

- The United States Patent and Trademark Office (USPTO) provides guidance as to the meaning of the term 'biological materials'. There is a requirement to make a deposit of biological materials which are to be made the subject of a US patent. In this context, the USPTO states [http://www.uspto.gov/web/offices/pac/mpep/documents/2400_2403.htm]:

> The term *biological material* shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and *other non-living material existing in and reproducible from a living cell* may be deposited by deposit of the host cell capable of reproducing the non-living material. (Emphasis added)

The term 'isolated biological material' means biological material that has been removed from its natural environment, whether that environment be a human being, an animal, a plant, a virus or some other organism.

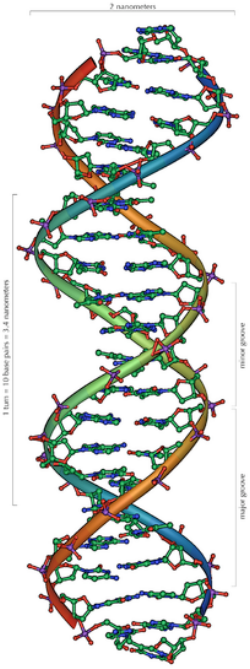
- On this basis DNA or RNA, generally called 'nucleic acids' (nucleotides), and proteins (polypeptides) come within the definition of 'biological materials'.
- The term 'isolated biological material' means biological material that has been removed from its natural environment, whether that environment be a human being, an animal, a plant, a virus or some other organism.
- The 'purified biological materials' means biological materials from which all (or nearly all) extraneous material has been removed.

Biotechnological Processes

- There are many kinds of biological processes used to manufacture products, one of the oldest, going back to 6,000 BC, is used in the brewing of beer. Thus the use biological processes is not new. However, as human knowledge has increased and a deeper understanding of our world has been achieved, those processes have been modified, improved and, in some cases, new ones developed.

The UK Court of Appeal in *Genentech Inc's Patent* held that a patent which claimed a patent monopoly over the human gene which coded for the protein tissue plasminogen activator (t-PA), the use of that human gene in biotechnological processes and the product of those biotechnological processes, purified t-PA, was invalid.

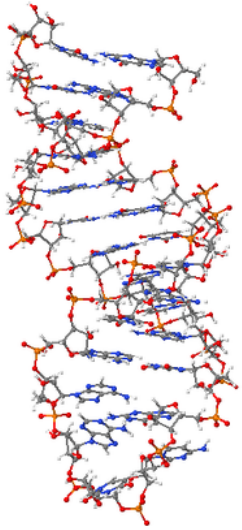
- Louis Pasteur, the famous French chemist and microbiologist, was granted two US patents over an improved beer making process. The first, US 135,245, was granted on 28 January 1873. Entitled 'Improvement in Brewing Beer and Ale', in one and a half pages it provided details of a process that improved 'the capacity of unchangebleness' of beer and enabled it to be 'transported without detriment or deterioration'. He was also granted a second US patent, US 141,072, on 22 July 1873. Entitled 'Improvement in the Manufacture of Beer and Yeast', in a little over two pages it provided details of a process and drawings of an 'apparatus' which, when used together, would: 'eliminate and prevent the multiplication [of] … microscopic organisms … in "brewers" yeast, worts, and beer'. According to Pasteur, it was 'pernicious germs' that were responsible for 'changing the condition of the product'. In other words, microbes caused beer brewed using traditional methods to



spoil. His process involved the heating and cooling of the 'wort' and the use of 'pure alcohol yeast', thereby destroying the microbes and producing a beer that could be 'preserved without the aid of ice' and 'made in hot as well as cold climates, as summer as in winter.' Indeed, modern beer manufacturers and consumers must be grateful to Pasteur.

- One hundred years later, Stanley Cohen, an associate professor of medicine at Stanford University, and Herbert Boyer, a biochemist at the University of California, San Francisco, discovered that it was possible to cut DNA from the genome of one organism and splice it into the genome of another (called a plasmid) and have that plasmid produce the protein (consisting of amino acids) coded by that recombined DNA. Their discovery, like Pasteur's discovery of 'pernicious germs', was so revolutionary that it forever changed scientific thinking, contributing to a body of knowledge that finally enabled scientists to adapt nature's processes to the manufacture of biological materials in vast quantities and with a purity that was hitherto thought impossible. They were acknowledged as inventors on a US patent, US 4,237,224, granted on 2 December 1980 entitled 'Process For Producing Biologically Functional Molecular Chimeras'.

In 1973 Stanley Cohen, an associate professor of medicine at Stanford University, and Herbert Boyer, a biochemist at the University of California, San Francisco, discovered that it was possible to cut DNA from the genome of one organism and splice it into the genome of another (called a plasmid) and have that plasmid produce the protein (consisting of amino acids) coded by the recombined DNA.



- Since then Cohen and Boyer's process has been modified and improved but the essence of their biotechnological process (that used genetically modified cells, such as yeast, bacteria, animal and human cells, to synthesise proteins in industrial quantities as pure as those produced by natural processes) remains the universal template for the modern biotechnology/ pharmaceutical industry.
- That is not to suggest that new biological processes which are significantly different to the Cohen/Boyer process have not been developed. They most certainly have. However, they key to recombinant protein synthesis remains the same – the use of DNA or RNA that codes for the protein.

The Genetic 'Gold' Rush

- So while the process which they had developed was something capable of being an 'invention', once it had been published (which by the mid-1970s it had been) the only thing that stood in the way of its use were the patent monopolies granted to Stanford University (Stanford) (Cohen and Boyer had assigned their interests in the invention to Stanford). Fortunately, Stanford licensed the invention on a non-exclusive basis. Thus, subject to entering into a license with Stanford, it was possible for anyone to synthesise just about any protein. What was needed before this was possible, however, was the DNA or RNA which coded for the protein of interest (whether that be insulin, erythropoietin or t-PA).
- Like the gold miners of California and Victoria in the 19th century staking claims over land which they hoped would yield gold nuggets or large seams of gold, biotechnology companies were established, mainly by molecular biologists in partnership with venture capitalists, staking claims over the DNA or RNA that coded for whatever the target protein was. For Amgen Inc, this was erythropoietin. For Genentech it

Deoxyribonucleic acid (DNA)

Is a nucleic acid that contains the genetic instructions used in the development and functioning of all known living organisms and some viruses.

For more information:

http://en.wikipedia.org/wiki/DNA

Ribonucleic acid (RNA)

Similar to DNA except that it contains ribose not dioxyribose and has the base 'uracil' instead of 'thymine'. It is usually single stranded (whereas DNA is usually double-stranded).

For more information:

http://en.wikipedia.org/wiki/DNA

was insulin. For Chiron is was the causative agent of non-A, non-B hepatitis (now called hepatitis C virus). For Biogen, Inc is was hepatitis B virus. Mostly led by American scientists and entrepreneurs, their determination caused great excitement on both sides of the Atlantic (indeed the whole world) as venture capitalists, scientists, institutional investors, governments and even mums and dads all sought to generate wealth through biotechnology – an exciting new science. Patent monopolies were increasingly seen to be crucial assets. Venture capitalists were attracted to them because they provided a vehicle through which they justified the investment of their client's money. But Cohen/Boyer's process was already known – so in the absence of any other alternative, the genes and proteins themselves became the subject of patents.

- The problem was that in the rush to patent these biological materials, no one in the US had time to consider whether this was even possible. More to the point, it would be years before the first of these patents would be granted and even longer before they would be tested in the courts. What were the patent offices to do in the meantime, while patent attorneys filed thousands of patent applications over isolated biological materials?

The problem was that in the rush to patent these biological materials, no one in the US had time to consider whether this was even possible. More to the point, it would be years before the first of these patents would be granted and even longer before they would be tested in the courts. What were the patent offices to do in the meantime, while patent attorneys filed thousands of patent applications over isolated biological materials?

The Invention/Discovery Conundrum

- Different patent offices took different approaches, but the general approach appears to have been to allow the patents until such time as the courts said otherwise. However, by the late 1980s it was becoming obvious that the UK courts were not going to be as accommodating as the proponents of gene patents had hoped. Indeed, the European Patent Office (EPO), which was developing its own case law through the appellate tribunals of the EPO (and which was, under the EPC, to be accorded some weight by national courts) was on a collision course with British patent law jurisprudence. Within a decade of the EPC coming into operation, a patent schism over biotechnology had opened up. The EPO was of the opinion that isolated biological materials were patentable subject matter. The UK courts, as *Genentech* shows, were not.

- In the United States the entire issue was avoided because proponents of gene patents argued that the US Supreme Court decision in *Diamond v Chakrabarty* was all that mattered – genetically modified organisms were patentable subject matter, therefore any genetically modified organism and any resulting product were deemed equally patentable. This suited the patent attorney profession and the scientists and venture capitalists that had started up biotechnology companies. The USPTO, unfortunately, conceded the point and adopted a policy that was consistent with this position. Thus if there were patent disputes over gene patents, those dispute were over which patent applicant ('inventor') had priority. Naturally, as there is only one gene and many gene hunters (biotech companies), inevitably arguments arose over who was entitled to a US patent over the gene, especially as in the US, only the 'first and true inventor' was entitled to a US patent. In the midst of resolving these 'battles over turf', as the presiding judge described the fight

between Amgen, Inc and Genetics Institute, Inc [*Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc* (1989) 706 F. Supp. 94, 95] over erythropoietin (a human protein), US patent attorneys argued that DNA was just another chemical and just as chemicals were patentable so was DNA. The problem was that no US Supreme Court had ruled that isolation of a gene was a sufficient nexus to patenting any gene. Indeed, no US Supreme Court has yet ruled on this point.

- Indeed in an attempt to influence the UK Court of Appeal in *Genentech* while the appeal was being argued, in June 1988 the EPO, USPTO and the Japanese Patent Office (JPO) issued a joint statement which read as follows:

> Purified natural products are not regarded as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds. [ALRC Report 99, para 6.36]

The US Supreme Court has not ruled that the isolation of a gene is a sufficient nexus to permit the patenting a gene.

- That attempt failed, but the protagonists who favoured the EPO/ USPTO/JPO approach began to lobby the European Commission, the administrative arm of the European Union (as the EEC had become) for 'clarification' on the state of the law. Thus began the work towards the first European Biotechnology Directive.
- In Australia it was not until 1994 that the first court action to raise the issue of patentable subject matter in respect of an isolated nucleotide and polypeptide took place. That case, *Murex Diagnostics v Chiron Corporation* [NSW Federal District Registry: NG 106 of 1994] challenged the validity of an Australian patent (AU Patent 624,105) which granted Chiron a Australian patent monopoly over the nucleotides (DNA) and polypeptides (proteins) of the hepatitis C virus in a 'isolated' or 'purified' form. This case will be discussed later in much greater detail, but for the time being it suffices to know that that the parties came to a worldwide settlement in August 1996 before the trial had concluded. Accordingly, there was never a court decision. To date no Australian court has ruled on the issue.
- In the UK the growing disquiet caused by the patent schism between the EPO and the UK courts, criticised by the European biotech industry as being against the best economic interests of the European Union, was starting to influence some British judges toward accepting the EPO's approach. The most notable example involving the hepatitis C virus. In *Chiron Corporation v Organon, Murex and UBI* (*Chiron*) Aldous J held that a claim to isolated nucleotides and polypeptides of hepatitis C virus was an invention under s.1(1) *UK Patents Act, 1977*. The UK Court of Appeal supported the reasoning of Aldous J. The House of Lords granted Murex leave-to-appeal, an indication that the Lords were not convinced that the lower courts had got the law right, but the Lords never heard the appeal as it was dismissed as part of the worldwide settlement between Murex and Chiron. This was indeed unfortunate.
- By the time the House of Lords delivered their decision in *Biogen Inc v Medeva PLC* [1997] RPC 1 (*Biogen*) in October 1996 it was obviously too late to have any effect on the UK Court of Appeal in *Chiron*, but it nonetheless confirmed that the Lords were not happy with the judicial olive branch that Aldous J had extended in the *Chiron* decision. In what was a clear rebuff,

the Lords, one of whom was Lord Mustill (one of the two majority judges in *Genentech* and elevated from the UK Court of Appeal), invalidated a patent granted to Biogen by the EPO over the hepatitis B virus. In delivering their decision (which was written by Lord Hoffmann), Lord Mustill took the opportunity to reinforce the views that he had previously expressed in *Genentech*. He said:

> There is however one matter which I should mention: namely, the necessity or otherwise for a valid patent to concern an invention, as well as satisfying the conditions expressed in paragraphs (a) to (d) of section 1(1) of the Act. This question was not contested before the House, although some reference was made to it in debate, for it was agreed (rightly in my opinion) that it has no bearing on the present appeal. My reason for referring to it is simply to make clear that in concurring with all your Lordships in the reasons for dismissing the appeal I should not be taken to accept, without full argument, that the need for an invention would always be academic, or that no such need is expressed by the words of section 1(1): nor indeed do I understand my noble and learned friend as advancing any conclusion to that effect. Certainly, in the great majority of cases, there will be no need to complicate the enquiry by looking outside the four conditions. The traditional law of patents is, however, in the course of adapting itself to new technologies, beyond contemplation when the foundations of that law were established. This process is not without strain, and I believe that in some instances a close conceptual analysis of the nature of patentability will not be a waste of time. Such a case was Genentech Inc's Patent where the claim was for a product already existing in nature, a subject far distant from the mechanical and chemical inventions to which so much of traditional patent law relates. There may well be others in the future.

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Lord Mustill
House of Lords, *Biogen v Medeva*, 1996

- Despite the need, as Lord Hoffmann emphasised, for the UK courts to take judicial note of the decisions of the EPO's appellate board, the House of Lords in this instance rejected the reasoning of the EPO and came to a contrary result – the patent was invalid in the UK.
- Then in 1998 the European Parliament passed the European Biotechnology Directive (EBD) after the first attempt, in 1995, failed. According to art. 5.2 EBD:

  > 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.

- While the EBD imposed an inter-

government solution to the patent schism, behind the scenes there was considerable unease in some quarters of the EU, notably the Italian, French, German, Belgian and Dutch governments who were concerned that the EBD had gone too far. Consequently, the deadline for transposing the EBD into national patent law came and went with 8 of the 15 EU member countries refusing to comply. Even in the UK, a country which did comply, the judicial tensions were not eased as it became abundantly clear when Amgen, Inc's appeal, concerning the first of its European patents over erythropoietin, came before the House of Lords in July 2004. [*Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* and others [2005] 1 All ER 667]

- In the decision appealed to the Lords, the UK Court of Appeal had stated that it had drawn 'comfort from the Directive' accepting that an isolated biological material could be taken to be an invention under the EPC. Certainly that was an appropriate comment given that the European Parliament had endorsed this view through the EBD and its ruling that '[t]he patentee could not monopolise the gene per se as that existed in nature' but could monopolise 'the DNA sequence encoding for DNA when isolated', was consistent with the EBD (and the EPO's approach). That said, the Court of Appeal held that Amgen's patent had not been infringed because the scope of its patent monopoly to the isolated DNA sequence of the human erythropoietin gene was not as broad as Amgen had asserted. Despite its primary claim to the invention of biotechnological process that utilised the isolated gene sequence to synthesise purified erythropoietin, the Court ruled that the Respondent's biological process, though making use of the same gene sequence, synthesised the purified erythropoietin in a different way so as not to infringe Amgen's patent.
- This finding frustrated Amgen. It had argued from the very beginning that the key to the production of purified erythropoietin was the human gene sequence which its scientist, Dr Lin, had deduced. Indeed it would be fair to say that Amgen pursued a line of argument to the effect that the scope of the patent monopoly of the primary process claim in the patent captured the synthesis of purified erythropoietin howsoever made. Dissatisfied, Amgen appealed.
- The resulting House of Lords decision, however, did not please Amgen.
- First, to make matters even worse for Amgen, the Lords found that the claims to isolated erythropoietin were invalid because 'even when isolated, [erythropoietin] was not new'. Naturally, it was not new because erythropoietin is a naturally occurring substance and the Lords understood that its isolation or purification did not alter that fact.

The House of Lords held in *Kirin-Amgen v Hoechst* (2004) that the claims to isolated erythropoietin were invalid because 'even when isolated, [erythropoietin] was not new'.

- Secondly, the Lords were critical of the trial judge's finding that 'the whole thrust of the specification, and, indeed with commercial common sense, indicates that the patentee is getting at the production of erythropoietin'. Clearly, the trial judge (Neuberger J) had accepted Amgen's assertion that the disclosure of the gene sequence in Table VI (a document referred to in the patent which described the human gene sequence) was the key to the invention and thus it was entitled to the benefit of a broad patent monopoly. But the Lords disagreed, because to have accepted this argument would have been to permit the patenting of human genes and, having rejected the rationale that isolation was a point of

distinction, they could not allow this. Lord Hoffmann explained:

> I think that the Court of Appeal was right in saying that Table VI could not have been the invention. Standing alone, it was a 'discovery...as such' within the meaning of section 1(2) of the Act: see Genentech Inc's Patent [1989] RPC 147, per Purchas LJ at p 204 and per Dillon LJ at p 237.

- But Amgen was very fortunate to have retained a partially valid patent at all because had the Lords accepted its argument that the 'invention' was the gene sequence (in Table VI) and that therefore the patent monopoly of the primary process claim captured erythropoietin howsoever produced, the Lords would have had to invalidate the entire patent. Thus in taking a narrow approach - defining the 'invention' to be a specific biotechnological process, not the isolated gene – the Lords were able to avoid reopening the patent schism by partially maintaining Amgen's patent (a patent which the Technical Appeal Board of the EPO had upheld as valid in its entirety), while at the same time criticising the EBD's central rationale – that used isolation to distinguish between something naturally occurring from something patentable.

"I think that the Court of Appeal was right in saying that [the DNA sequence of the isolated human gene to erythropoietin] could not have been the invention. Standing alone, it was a 'discovery..."

Lord Hoffmann
House of Lords, *Kirin-Amgen v Hoechst*, 2004

- In the United States, however, Amgen was having a better time in its patent litigation against the same Respondents, mainly because the litigation never reached the US Supreme Court. But, a patent case that would reach the US Supreme Court in 2006 between Laboratory Corporation of America (LCA) and Metabolite Laboratories (Metabolite) was just beginning and this was to have ramifications for gene patents in the US. Indeed, it was one of a number of patent cases which the US Supreme Court accepted during the 2006-2007 term; an indication that the Court was not prepared to leave the development of US patent law solely to the CAFC.

- The dispute in *Laboratory Corporation of America v Metabolite Laboratories* (*LabCorp*) involved a US patent that gave a patent monopoly to Metabolite for the diagnosis of a vitamin deficiency based upon the measure of a naturally occurring amino acid, homocysteine, in the human body. Although it was not raised as an issue in the lower courts, in an application for leave to appeal to the US Supreme Court, LCA argued that the patent was invalid because the invention was not patentable subject matter, namely, that it was 'a monopoly over a basic scientific relationship'. This was a consequence of the lower courts having granted and upheld an injunction that enjoined LCA from using any tests 'that would lead the doctors to order diagnostic tests for measuring homocysteine'. What was controversial about this result was that the association of homocysteine levels in a person's body and a vitamin deficiency, a mental action that any doctor could perform, was, in effect, made the subject of a patent monopoly.

- Clearly, the patent was not a gene patent, but it is relevant for this Committee to understand that the parameters of what is and what is not patentable subject matter are very important and the consequences to society and the economy can be severe if those boundaries are transgressed.

- Unfortunately, having been granted leave to appeal, the US Supreme

Court subsequently withdrew that leave. That it did so is unusual, but the majority believed that this step was warranted because LCA had not raised the issue before the lower courts. This was a tactical omission deliberately made by LCA and so it was punished.

- Regardless, Justices Breyer, Stevens and Souter were keen to take the opportunity to remind the lower courts that patentable subject matter is an important patentability parameter. In referring to the principle of US patent law which 'excludes from patent protection … laws of nature, natural phenomena and abstract ideas', they not only confirmed that 'this principle finds its roots in both English and American law' but confirmed that its existence 'does not lie in any claim that "laws of nature" are obvious, or that their discovery is easy, or that they are not useful …. to the contrary'. While conceding that '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', they reemphasised that 'the reason for the exclusion is that *sometimes too much patent protection can impede rather than "promote the Progress of Science and useful Arts*"'. (Emphasis added)

The principle that 'excludes from patent protection … laws of nature, natural phenomena and abstract ideas ... finds its roots in both English and American law... [and] the reason for the exclusion is that sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts'".

Justices Breyer, Stevens and Souter, US Supreme Court, *Laboratory Corp v Metabolite Laboratories* (2006).

- Bearing this in mind, the next patent case which the US Supreme Court dealt with was not about patentable subject matter at all, but was about the test to be applied in assessing inventive step - a secondary condition of patentability. [*KSR International Co v Teleflex Inc* (2007) 127 S Ct 1727] Nonetheless, it is relevant to this discussion because the decision has impacted upon gene patents in as much as the inventive step of gene patents, as the Amgen argument before the House of Lords demonstrated, is often the genetic sequence itself. Of course, if the inventive step is the gene sequence, then how can the application of that gene sequence in a technology that is itself not novel and is obvious, give rise to a 'patentable invention'?

- That is precisely the question which confronted the US Board of Patent Appeals and Interferences (BPAI) in the case of *In ex parte Kubin and Goodwin* (*Kubin*) after the US Supreme Court had overruled the CAFC in *KSR* and, in the process, took the opportunity to criticise two of its decisions handed down in the mid-1990s concerning gene patents. Applying *KSR,* the BPAI explained that the '"problem" facing those in the art', namely molecular geneticists, is the limited number of methodologies available to isolate the cDNA (that encoded the disputed Natural Killer Cell Activation Inducing Ligand polypeptides (NAIL)) provide them 'with the reasonable expectation that at least one would be successful'. As a result the BPAI concluded that isolating NAIL cDNA was 'the product not of innovation but of ordinary skill and common sense' and this in turn meant that 'NAIL cDNA [was] not patentable as it would have been obvious to isolate it.'

- Thus if one accepts that the step of isolation is not sufficient to distinguish a natural gene from an artificial gene (House of Lords in *Amgen*) and that the 'isolation' of genetic material is obvious (BPAI in *Kubin*) and a non-inventive step, a patent over an isolated biological material that is identical to or substantially identical to a naturally occurring biological material is neither an 'invention' nor

'patentable'.

- In other words, an isolated human gene is still a human gene even when removed from its natural environment or synthesised using a biotechnological process when the step of isolation is obvious and not inventive.
- Incidentally, *Kubin* is now on appeal to the CAFC. It may eventually reach the US Supreme Court. Which ever way one looks at the issue, to suggest, as the ALRC did in its 2004 report, that the patenting of isolated biological materials is an internationally accepted and settled practice is both mischievous and untrue.

11. An example of a Gene Patent which has been granted in Australia which claims as an invention 'isolated biological materials'.

- It will be necessary for this Committee to have a thorough understanding of gene patents, particularly those that were granted by IP Australia and which were also the subject of patent litigation in this country. The reason for this is twofold. First, it is important that the Committee understand the structure of these kinds of patents, namely, how they are written and what they typically claim. The claims are particularly important because these define the boundaries of the patent monopoly. They are like land title deeds – just as landownership confers exclusive rights to occupy land, so a patent confers the exclusive right to exploit the invention described in the claims. Therefore, *anything* that is done by a third party that is an *exploitation* and which comes within the scope of the patent monopoly interferes with the patentees right. Secondly, patent litigation is a good barometer of the impact which the patent has on the economy. There are millions of patents, but those that make it before the courts are the ones that are the most valuable and, therefore, the ones that are most likely to impact on the economy in measurable and significant ways. The following is one example.

Anything that is done by a third party that is an exploitation and which comes within the scope of the patent monopoly interferes with the patentees right.

- The word 'exploit' is defined in the AU Patents Act, 1990 as follows:

  > (a) where the invention is a product—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; or
  >
  > (b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

- Note: there is no express exclusion for 'experimental use'. The word 'make' includes *any* activity that comes within the meaning of that word regardless of whether it is commercially motivated or not.

AU Patent 624,105 entitled NANBH Diagnostics and Vaccines

- This patent was granted by IP Australia to Chiron Corporation (Chiron) in September 1992. The patent monopoly commenced on 18 November 1988 and expired on 18 November 2008. The subject of the patent, in general terms, was the hepatitis C virus (HCV) and, as the title suggests, included the exploitation of the biological components of the virus in *all* diagnostic and therapeutic applications, including in a prophylactic vaccine that was capable of inducing permanent immunity to HCV infection.

- Previously known as non-A, non-B hepatitis (NANBH), the causative agent of NANBH became known as HCV after it was identified and characterised by scientists at Chiron. The Chiron team was headed by Dr Michael Houghton and he was named as one of the inventors. The other named inventors were his Chiron colleagues, Dr George Kuo and Dr Qui-Lim Choo. That said, there was some controversy over the issue of inventorship as Chiron were formally collaborating with the US government agency, the Centres for Disease Control (CDC), and a team headed by Dr Daniel Bradley from

the CDC that had worked closely with the Chiron scientists for over fours years when the crucial breakthrough occurred. That came in January 1987 when five clones of HCV were detected in an experiment conducted at Chiron's laboratories. In the period 1983 to 1987 the value of the publicly funded research undertaken by the CDC in accordance with the collaboration with Chiron was estimated in 1988 to be about $US8 million.

- US patent applications were then filed in the USPTO, the first, filed on 18 November 1987, marked the earliest priority date against which the novelty and inventive step of the patented invention would be assessed and the final, filed on 14 November 1988, became the basis of the Australian patent application which was filed in accordance with the Paris Convention on 18 November 1988 – the date which, when the patent was granted, would signify the beginning of the patent term in Australia (which by virtue of amendments to the *AU Patent Act, 1990* made in accordance with TRIPS, was 20 years).
- Thus it is important for the Committee to understand that although IP Australia did not actually grant the patent until September 1992, the exclusive rights of the patent owner effectively commenced some 4 years earlier. What this means is that even though Chiron's legal right had not crystallised until then, between the time that the patent application became known (or open for public inspection) and the sealing of the patent, the patent owner had the right to retrospectively sue in respect of anything done within Australia that would have amounted to an infringement of the patent once granted. Of course, that would not have been easy to gauge, as the final claims would not be known to third parties until the grant of the patent, so those that may have been tempted to infringe the ungranted patent would have had to rely on the patent claims as applied for. In this case, however, there was almost no difference – the claims as applied for and the claims as originally granted were virtually identical.

The Original Patent Claims (as granted)

- There were 39 claims originally granted. These included the following claims to isolated or purified biological materials that are identical or substantially identical to HCV as it occurs in nature:

  Claim 1: A purified HCV polynucleotide

  Claim 2: A recombinant HCV polynucleotide

  Claim 4: A recombinant polynucleotide encoding an epitope of HCV.

  Claim 10: Purified HCV.

  Claim 12: A purified HCV polypeptide.

  Claim 14: A recombinant HCV polypeptide.

  Claim 16: A recombinant polypeptide comprised of an HCV epitope.

- Then there are claims to the *use* of these materials in various applications including protein production, diagnostics and therapeutics (such as vaccines). For example:

  Claim 32: A vaccine for treatment of HCV infection comprising an immunogenic polypeptide containing an HCV epitope wherein the immunogenic polypeptide is present in a pharmacologically effective dose in a pharmaceutically acceptable excipient.

  Claim 33: A vaccine for treatment of HCV infection comprising inactivated HCV in a pharmacologically effective dose in a pharmaceutically acceptable excipient.

  Claim 34: A vaccine for treatment of HCV infection

comprising attenuated HCV in a pharmacologically effective dose in a pharmaceutically acceptable excipient.

- This inquiry is primarily concerned with claims of the first kind –the question being: are these things or should these things be 'inventions' for the purposes of the *AU Patents Act, 1990*?
- However, the inquiry is also concerned with claims of the second kind, for although it can be conceded that these things generally meet the threshold of patentable subject matter (that is, they are the kind of things that are likely to be 'inventions'), it is important (a) that the 'invention' be sufficiently clear to a person of ordinary skill in the relevant technology so that that person can understand and make the invention without undue experimentation and (b) that the inventive step not be so elementary as to be obvious to that person.

"Chiron claim a monopoly to the vaccine and they have only given a description in the specification which, if followed, would be likely to take another company 30 man years of scientific research and development ... "

Justice Aldous, Chiron Corp v Organon & Others, UK Patents Court, 1993

- The latter kinds of claims are important for two reasons:
- First, if by way of example, one looks at the claims to the use of HCV biological materials in a vaccine, one would expect to find information in the patent which would direct a person of the requisite skill to be able to make an HCV vaccine without the need for undue experimentation. Thus, whether there was sufficient information for this to happen should have been fairly obvious to a patent examiner. Yet IP Australia granted an Australian patent with such a claim (as did the British Patent Office which granted a British Patent GB 2,212,511). It is mentioned at this point merely to illustrate how easy it is for a patentee to obtain a patent without producing any meaningful scientific data to support the claims. The lack of data was confirmed by the UK Patents Court when the UK equivalent patent was litigated in 1993. There Aldous J invalidated the claims to the HCV vaccines. He held:

> The law requires the specification to be sufficiently detailed so that the skilled man can produce a vaccine without undue experimentation. If the description was sufficient, I would have expected a company with Chiron's expertise to be able to produce a trial vaccine without the need for 30 man years of qualified scientific work. The plaintiffs did not dispute that in normal cases the need to expend 30 man years of work would indicate that the description was insufficient, but submitted that this was an exceptional case where length of time was not an indication of insufficiency. I accept that in this case, a substantial time may be needed to test a vaccine, but 30 man years to achieve animal testing seems excessive.
>
> The actual way that Chiron have produced their vaccine has been kept confidential to ensure that others will have to go through the same testing procedure that Chiron have carried out. No doubt that is commercially wise. However Chiron claim a monopoly to the vaccine and they have only given a description in the specification which, if followed, would be likely to take another company 30 man years of scientific research and development

> to arrive at a stage where successful trials could be carried out on chimpanzees. I believe that such a description is insufficient

- So another 30 man years was going to be required before an HCV vaccine would be available. Well, here we are, more than 20 years has passed since the discovery of HCV and there is no HCV vaccine, nor is there any on the horizon.
- One has to ask why this is so? Perhaps Prof Baruch Blumberg (winner of the Nobel prize in medicine in 1976 for his discovery of the hepatitis B virus and the development of the HBV vaccine) provides the answer. He said this in his affidavit which was filed in the Australian Federal Court proceedings in *Murex Diagnostics v Chiron Corp* NSW Federal Court Registry NG 106 of 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. I do not subscribe to this view. Such a view infers that all other information about the proteins and their effects, including post-translational changes in the gene-produced proteins, interactions of viral proteins with each other, interactions of the viral gene products with the host, the biology of the virus and its host, demonstration of effectiveness, etc. is redundant. It states in effect: *"Anything that is done with the HCV virus is covered by this patent and all research and development on the virus is subservient to it."* The issue can also be stated in scientific terms. This patent essentially does not distinguish between genotype and phenotype, whereas geneticists are very aware that such a distinction should be made. It is the reductionism argument taken to the extreme and it is not supported by the great weight of the history of scientific discovery in biology and medicine. To the extent that this extreme view is backed-up by broad claims, which it is in this patent, the effect will likely be inhibition of research on HCV.
>
> Based on the unusually broad nature of the patent, if I were a research director for anti-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.

- In this respect, claims to the isolated or purified biological materials are critical because they provide the patentee with patent rights over what is the *foundation* of anything that can be made with the use of those materials, including vaccines.

- The question that Prof Blumberg raised is this: why should anyone invest in the research needed to produce an HCV vaccine when ultimately someone else will control the biological material that is used in that vaccine? Thus the downstream technological developments, which are more important in terms of human health, are made subservient to the patentee that has the patent rights over the primary biological materials – and why should this be so?
- Secondly, some of the downstream applications are so elementary as to be obvious. For instance, there are claims to the use of these materials in diagnostics. But even in 1987 it was obvious to a person of ordinary skill in the manufacture of immunoassays or nucleic acid (DNA) tests that the HCV proteins and genetic materials could be used in these ways. Rather than requiring 30 man years, as in the case of vaccines, developing HCV diagnostics was relatively simple once the genetic sequence of the virus (which is a discovery) was in the public domain (which is what happens when scientists publish a scientific paper about their experiments). This is normally how science works.
- Indeed Chiron knew that this was the case because it deliberately delayed publication of the HCV genome until such time as its patent position was protected. That, in effect, delayed publication by some 17 months.
- Apart from which, once that information was made available, any competent molecular biologist would have been capable of making an HCV diagnostic assay. Yet, IP Australia, as did the British Patent Office, granted Chiron claims to the use of these materials in all manner of diagnostics. The result for Australia was particularly grave.

"Based on the unusually broad nature of the patent, if I were a research director for anti-virals and had the option of working on several viruses, the existence of this patent would weigh against my deciding to undertake HCV research."

Prof Baruch Blumberg
(winner of the Nobel prize in medicine in 1976)

Part 2 of this submission will provide details of the impact which this patent and other gene patents have had on the provision of healthcare in Australia.

End of Part One