Are Gene Patents Good for Us?

Submission to the
Senate Community Affairs Committee

Inquiry into Gene Patents

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"There is no provision for proof that the invention has actually been made or that it accomplishes anything, and no provision for skilled technical appraisal of the place which the invention occupies in the developing technology of which it is a part. Still less is there opportunity to raise questions as to the economic effect of granting or denying the patent application or of enlarging or reducing the scope of the grant. *The process comes perilously close to letting anyone have a monopoly, the size and shape of which he is allowed to formulate for himself …*"

Edwards 1949: 219-220, emphasis added

This comment was made in 1949 in respect of the US patent system.
It applies equally to the patent system in Australia today.

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1. Overview

I welcome the Senate's inquiry into the impact on Australia of granting patents for genes and related "products". This issue lies at a sensitive boundary of the judicial activism which has substantially extended the reach of the patent monopoly system. It is more than time that this intervention was scrutinised from the perspective of its impact on overall national well-being.

In considering this issue, the Committee has been asked to look at the impact of these patents. Unfortunately, despite the grant of over 14,000 such monopolies, there is little general information about their impact. Information is available about a small number of cases that have come to public attention. But no government agency collects data on the impact of the many patent monopolies granted. The government does not even know which are used, and in what ways. In this absence of direct evidence other empirical material must be sought for systematic evidence-based insights into the issues before the Committee. That is what this submission attempts to do.

The recent National Innovation Review confirmed that patent policy is economic policy (Cutler et al. 2008). This submission provides information on the general economic impact of patent systems, and the implications of this for assessing issues such as judicial elimination of long-standing exceptions to patentable subject matter. Such an economic perspective is rarely considered when aspects of patent policy are debated. The fact that this economic policy is delivered through the legal system has led to policy matters being largely considered from a legal rather than an economic perspective. This has been unfortunate. It is as inappropriate as using lawyers as the sole source of advice on tax policy.

Because patent policy is economic policy, relevant information about the economic impact of the patent system is critical background to addressing the Committee's terms of reference. I have been as succinct as possible with this broader material. And where it is possible to do so I have focussed as much as possible on methods of medical treatment and the patenting of discoveries, including genetic materials.

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

No demonstrated case has ever been made for the patent monopoly system in general or for granting patent monopolies to genes and related materials in particular.

P*atent policy is in essence quite simple,* though rule complexity is often used as a device to prevent "outsiders" from querying patents operations, or making recommendations to improve the system. Patent policy exchanges a "bad" (the patent monopoly) for a "good" (more invention or more dissemination of new knowledge). Society should receive a consideration which fully offsets the costs incurred by the monopoly grant. Overall the totality of patents granted should confer more benefits than their total cost to society in diverted resources and monopoly costs. If this does not happen, then the government's patent policy *reduces Australia's economic well-being.*

The next section in this submission looks at the overall purpose of patent policy – that the country be better off because of benefits flowing from the higher level of inventiveness induced or disseminated. Section 3 provides evidence as to whether a patent system is actually needed to induce such additional investment in invention. The conclusion is that the weight of evidence shows that the "theory" that ideas can be readily and cheaply copied is simply wrong. Normal market mechanisms provide for the opportunity to recoup the costs of invention and commercialisation except in the unusual situation where the initial investment is very large, or the imitation time is unusually short. There is no general market failure justifying patent monopolies. Normal market mechanisms provide sufficient incentives for innovation investment except in exceptional circumstances.

Section 4 considers who benefits from patent policy. After all, if the economic evidence is that patent monopolies are generally unnecessary, why has the volume of government-sanctioned monopolies grown? Is the patent system a case of regulatory capture where sectional interests are successful in obtaining benefits despite consequent reductions in general well-being? The data presented in Section 4 show that a small number of very large companies dominate use of the patent system. As is well known, most of those who receive Australian patent monopolies are overseas-based companies and individuals.

An alternative explanation, supported by much of the US literature, is that an active judiciary and administration has substantially reduced the threshold quantum of "inventiveness" required for a patent monopoly (see, e.g. Lunney 2004; Dreyfuss 2008). Inventiveness is critical to balance in the patent system. If monopolies are granted for genuine and significant inventions, then the generalised benefits flowing from them are likely to offset the costs of the granted monopolies, at least overall. However, if monopolies are granted for "inventions" that add little if anything to knowledge, then they produce no benefits and are likely to mean that the system overall operates to reduce not increase well-being. Section 5 shows how the legalistic and complex rules designed to test for "inventiveness" have led to the virtual elimination of this threshold test. These complex operational rules have grown up over the past 150 years, and have never been subjected to economic scrutiny. The section concludes by presenting evidence about the overall biases in the patent system.

The now minimal inventiveness required for a patent monopoly has interacted with expansions to the subject matter considered patentable to vastly extend the reach of patent monopolies. This issue is critical to gene patents. Techniques used to isolate and purify specific genes, gene fragments and proteins are now routine. It is highly questionable whether simple and routine "isolation and purification" merits grant of a monopoly. Nonetheless if subject matter boundaries had not very liberally interpreted by patent offices

and judges, most of the gene and related monopolies granted in Australia (some 14,000) would not have been granted.

Section 6 considers the extension, without parliamentary debate or executive government consideration, of the patent system in the period since 1990. Three areas of extension are briefly explored: software; methods of medical treatment; and materials identical to those found in nature. The factors that underlie the judicial extension of the patent monopoly system to methods of medical treatment, and the administrative extension of the patent monopoly system to genes and related "products" indicate much that is wrong with the patent system generally. In Australia the extension of the patent system to "isolated and purified" materials identical to those found in nature is shown to be based on two decisions both made by senior public servants, from a legal not an economic perspective.

It is not, of course, possible to consider extensions to the patent system without also considering "clever legal drafting". This phrase effectively refers to narrow word slicing and dicing to make the unpatentable patentable. It undermines the objectives of the law and brings it into disrepute. There are some startling examples of this type of rent-seeking strategy, including in the area of methods of medical treatment. Pre-eminent among these is the use of "Swiss medical claims" to undermine the statutory exclusion of methods of medical treatment written into the *European Patent Convention*. These semantic games are also directly relevant to the question of genes and gene patenting as it is the simple determination that "isolation and purification" turns a discovery into an invention that lies at the heart of the patent gene controversy. These issues are canvassed in Section 7.

The submission then looks briefly at the negligible data on the volume and impact of genes and related patents that can be gleaned from IPAustralia's patent databases. Section 8 presents information on the volume of patenting in the classes that probably encompass most gene and related monopolies granted in Australia. In the major class in which gene patenting occurs, over 14,000 patents have been granted in Australia. Over 8,300 are in force right now.

The submission concludes in Section 9 by looking at the impact of patent monopolies on health care costs and availabilities. The patent system works by sanctioning the charging of high prices to recoup the cost of investment in research and development. While some apologists of the patent system suggest that there are few patented products or processes that can actually extract a monopoly rent, this is to suggest that the patent system is ineffective. But if the patent system is effective in encouraging more investment in research and development (R&D) than would otherwise occur, then it inevitable leads to higher prices. If it does not allow the charging of higher prices, then it cannot be leading to additional R&D investment.

Further, the patent monopoly system *allows the preventions of independent invention*: indeed it allows independent inventors to be put out of business and fined. Where a monopoly is granted over "purified and isolated" genetic material, it effectively prevents alternative research into how this material might more effectively be used to develop diagnostic tools and medical treatments. History provides many examples where patent monopolies have been used to hold up the development of new technologies. The grant of

monopolies over genetic materials invites such hold-up. The pretence that “purification and isolation” avoids this problem does not change the facts of the matter.

There is no substantial evidence that patent monopolies are needed in this area. Many institutions and companies have been working in biotechnology since the 1980s and earlier. There was no expectation at that time that legislated monopolies would be granted.

Despite the importance of innovation in national economic development, and the role of patent monopolies in encouraging innovation, few data have been collected on the impact of granted monopolies. Sectional interests have been able to avoid the requirement that they demonstrate that the legislation generates a public good for Australia. This inquiry provides the opportunity to repair that major deficiency.

2. Patent policy objectives

In any matter regarding patent monopolies it is useful to recall the historical origins of the first *Statute of Monopolies* as this clearly articulates the goals of the policy and the need to careful constraints so that benefits are balanced against and outweigh the costs.

For there are costs. Apart from diversion of resources to transaction costs (including the large and increasing numbers of Patent Attorneys), any monopoly raises the potential of high prices being charged, with a consequent reduction in volume or diversion of resources from other areas. When it comes to patents over products or processes which affect health this can mean that people cannot access the monopoly-protected products. In worst case scenarios this means people die. In a country such as Australia it means that access is restricted through various "gate-keeping" means and that taxpayer transfers to companies are higher than they would be if the government had not handed out a monopoly.

The 1623 *Statute of Monopolies* was designed to put an end to unfettered and arbitrary grant of Royal Privileges (monopolies). Monopolies were regarded as "odious" because they place limits on known trades or industries and thus conflict with the Common Law right to carry on a trade. They also reduce output and raise prices. The 1623 *Statute of Monopolies* provided a small number of exemptions to the blanket prohibition on the grant of monopolies. One of these exceptions was for "any new manner of manufacture" (Section 6). Australian patent law derives from this clause, and its terminology still forms the definitional basis for a patentable invention under the *Patents Act 1990*.

In a series of articles Edward Walterscheid has traced the origin and evolution of patent law. Of particular interest is his reporting of the opinions of Lord Coke in his Institutes of the Laws of England (1628), providing as this does a clear insight into the *intention of the lawmakers of the time* (Walterscheid 1995a). Walterscheid points out that there were a number of caveats embedded in Section 6 of the *Statute of Monopolies*. From an economic perspective these limits are very important in ensuring that allowing monopolies for inventions does not significantly reduce economic well-being. Apart from the time limit (14 years), and the limit to the inventor, the major restrictions were:

- "it must be of such manufactures, which any other at the making of such letters Patents shall [did] not use". Modern lawyers interpret this as being a quality of the patented invention—that others may not use it. But Walterscheid shows that *this is a mis-reading of the law*: the phrase describes the invention covered by the monopoly, indicating what would now be termed "novelty" or the "newness" that needs to be possessed by a patentable invention (Walterscheid 1995a: 877).
- not "contrary to law" – that is, *not an improvement*. This restriction was overturned in 1776 when Lord Mansfield made a pragmatic decision to change the law rather than the prevailing administrative practice, on the grounds that otherwise virtually every monopoly of invention granted would become invalid (Walterscheid 1995b: 853).
- not "mischievous to the State by raising of prices of commodities at home". This restriction effectively re-iterated the quality of absolute newness, i.e. prevented the substitution of domestic manufactures for imported goods (Walterscheid 1995a: 878-9).

- it must not be "hurt trade" nor be “generally inconvenient". Lord Coke took these as part of common legal practice, giving the example that if an invention “… puts men out of work [it] will not be accorded the privilege of a patent" (Walterscheid 1995a: 879)

Originally, then it was a very clear that the grant of monopolies for inventions should occur only where this added to national economic well-being. The strict limits in Section 6 ensured that genuine benefits would flow to the nation when such a monopoly was granted.

One can assume that today it is still the objective of democratically elected governments that their patent systems operate in a balanced way – that is, that there is a “consideration” passing to society in exchange for the loss due to granting a monopoly. In modern economic parlance the patent system should enhance rather than reduce national well-being. Indeed the TRIPS Treaty specifies that:

> “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”
>
> TRIPS, Article 7 (http://www.cptech.org/ip/health/cl/cl-art7.html, accessed 9 September 2008)

Given this objective – that overall wellbeing be increased not reduced –losses due to the granted monopolies need to be offset by benefits flowing from the increased level of innovation or the greater dissemination of new technological knowledge. Such benefits are more likely when two key conditions hold:

1. there is a genuine contribution to knowledge or know-how of a reasonable quantum (this generates “spillover” benefits to the nation); and
2. it is probably that the invention would not have occurred without the inducement effect of the patent monopoly.

Modern patent policy has changed substantially, with most of these changes occurring through legal decisions. It is possible that patent law is the most active area of judge-made law. Many of the safeguards originally written into the law have been removed, and early doctrines limiting the technologies which can be patented have been stretched so far that patent monopolies seem no longer to be restricted to areas of science and technology.

Apart from the Great Patent Debate of the mid nineteenth century there is little evidence that any of these changes are based on sound evidence and parliamentary review. The Advisory Council on Intellectual Property (ACIP) has noted that:

> “Previous decisions on the patentability of other controversial areas, such as software, genes, bioinformatics and the treatment of humans, *have not been based on assessments of whether patent protection is necessary* in order to encourage innovation in those particular fields.”
>
> ACIP 2003: 33 (emphases added)

Perhaps the soundest overall economic analysis of patent systems remains Machlup’s 1958 report to the US Senate, though little empirical data was available to use in drawing firm

conclusions (Machlup 1958).[1] The 1984 Industrial Property Advisory Committee (IPAC) recommended some small changes to the patent system (IPAC 1984: 19). Some were implemented in the 1990 revisions to the *Patents Act*, some were introduced following the Ergas report (IPCRC 2000), and others – such as the collection of data on patent use at the time of patent renewal – have never been implemented.

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

Useful empirical evidence was gathered for the 1984 economic assessment of Australia's patent system.

Based on a series of surveys Mandeville, Lamberton and Bishop concluded that:

"the benefit/cost ratio of the patent system in Australia is negative, or at the very best, in balance"

(Mandeville et al. 1982: 213).

Today's patent system has emerged from a series of decisions by judges, often in settling disputes between private parties, and with no input on the public impact. Since 1990 a view seems to have developed among Australian judges that if something is not expressly excluded from the *Patents Act 1990*, then parliament did not intend to exclude it—a very questionable view. For example, despite clear precedent that methods of medical treatment were not patentable subject matter (ALRC 2004: 94), the Federal Court in 1994 decided methods of medical treatment were patentable.[2]

In Australia there does not seem to be any process to review these decisions, assess their impact on patent balance, and then recommend legislative amendments to fix the emerging problems.[3] In other arenas where economic policy is implemented through legislative instruments, both public servants and parliamentarians are vigilant in reviewing case law and making amendments to return the relevant legal systems to greater balance (usually the *status quo ante*). Key examples are tax law and competition law. There is no evidence of

[1] Machlup's famous statement that there was insufficient evidence either to justify dismantling patent systems or to instituting them is usually cut short, as when cited by the ALRC (ALRC 2004: XXX). He went straight on to state that "This last statement refers to a country such as the United States of America - not to a small country and not to a predominantly nonindustrial country, *where a different weight of argument might well suggest another conclusion* (Machlup 1958: 80, emphasis added).

[2] Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) 50 FCR 1. Similarly, despite the government's acceptance that of the 1984 IPAC recommendation that patents were not needed for software and business methods, the *Welcome Real-Time* judgement effectively imported a decision to allow patenting for business methods. The decision was imported from the USA, a country with a radically different economic environment, especially in regard to competition-related economic institutions.

[3] In New Zealand there is evidence of a more active watch to protect the public interest.

any parallel activity in patent law. Indeed patent case law is regularly imported into statute law through Amendment Bills.

In considering the case for whether genes and related matters should be granted patent monopolies, it is useful for the Committee to be aware of these deficiencies in the general approach to patent policy. The issue of the active administrative and judicial extension of patent monopolies to new subject matter areas, without consideration by parliament or executive government, is addressed in section five. The ALRC review makes it quite clear that the extension of the patent system to genes was a decision of the Deputy Commissioner of Patents (ALRC 2004: 68),[4] and that the extension to methods of medical treatment was a judicial change overturning a long-standing understanding (ALRC 2004: 94-95).

There has not been any assessment of the economic and health impact of these changes. With respect, the ALRC consideration of gene patents collected no hard evidence and seems to have avoided addressing the most important economic issues (for example what patentable subject matter should be; the health system impacts of gene patenting). The ALRC review of gene patenting was undertaken from a legal angle. Despite being "unsure" that patent monopolies should be granted for materials which occur in nature. The ALRC did not address the issue either in legal, ethical or economic terms—it simply side-stepped it:

> "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. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are 'merely' complex organic compounds."
>
> ALRC 2004: 6.52

On such an important matter it is quite unacceptable to refuse to determine and implement the best policy simply because bad policy has been in place for some years. This is particularly the case in the area of patent policy, where it has always been the case that a patent can be declared invalid at any time in its potential 20 year life.

The fact that bad policy has been in place for some time makes it imperative to get rid of it, not to pretend that time has made it acceptable.

There is substantial scientific criticism of the way in which judges have drawn analogies between chemical and biological processes. Patent policy appears to have been changed on the basis of unsound scientific analogy, without any community debate and without any empirical evidence of the need for such a change.

Similarly it is often argued that the TRIPS Treaty prevents Australian parliamentarians from improving Australia's patent law. But nowhere in TRIPS is it obligatory to provide

[4] *Kiren-Amgen Inc v Board of Regents of the University of Washington.* The decision was subsequently appealed, but on other grounds, so the court did not consider the correctness of this critical administrative decision (ALRC 2004: 68, footnote 361).

patent monopolies for discoveries, software, methods of medical treatment nor for "inventions" which are not inventive.

Almost certainly anecdote will be presented to the Committee to "justify" gene patents. To date IPAustralia has granted over 14,000 standard patents in the C12N15 IPC class. More than anecdote is needed to justify the grant of so many monopolies. For each anecdote supporting the case for gene patents, there are other anecdotes about the grant of private monopolies for inventions already paid for by the public purse, and/or where substantial damage is done to other inventors because of the granted monopoly. The breast cancer gene patents are a prime example.

The next section looks at the scientific evidence as to whether patent monopolies are indeed needed to induce additional inventions. This shows that patents are needed only in specific circumstances, and not always then. The lack of any sound evidence base to support the need for patent monopolies is important in considering whether they are needed in the new subject matter areas (including genes and methods of medical treatment).

3. Is there evidence that patent monopolies are needed?

There is a large and growing evidence base on the relationships between patents and innovation and between competition and innovation. This provides valuable guidance on where balance in patent policy should lie. McGonigal undertook such a review for the 1984 IPAC enquiry (McGonigal 1981). He noted that US estimates on possible gains from innovation and technical change and likely "deadweight losses" from monopolistic practices rested on "fairly heroic assumptions", and considered these of doubtful validity due to their serious methodological shortcomings (McGonigal 1981: 145).[5]

McGonigal also reviewed the evidence on the then popular Schumpeterian hypothesis that market power is *necessary* for innovation. After a wide review of the available studies he concluded that any such relationship is complex, non-linear and complicated by other factors (i.e. does not always exist). More recently Bessen and Meurer have reviewed a wide range of evidence on any relationship between patents and economic growth. They find that evidence of any such relationship is both limited and contingent—*it depends critically on the design of the patent system* (Bessen and Meurer 2008: 91-93).

The current scientific evidence base includes:

- A large number of empirical studies on the mechanisms companies use to achieve returns from their investment in innovation (Scherer et al. 1959 (USA); Taylor and Silberston 1973 (UK); Mansfield 1986 (USA); Levin et al. 1987 (USA – the Yale survey); Cohen et al. 2000 (USA – the Carnegie-Mellon survey (CMS)); Arundel and van de Paal 1995 (large European firms); Harabi 1995 (Switzerland); Goto and Nagata 1996 (Japan); González-Álvarez and Nieto-Antolín 2007 (Spain):
  - these studies *all* show that in most industries patents are ranked as *the least effective* means of ensuring a return to investment in innovation;

[5] Despite these major concerns about the reliability of these estimates, the Bureau of Industry Economics (BIE) relied heavily on these reported studies in concluding that the deadweight losses of patent monopolies were unlikely to be high (BIE 1994: 42).

- the sole (and consistent) exception is the pharmaceutical and fine chemical industries, which involve highly codified technology;[6]

- in particular the Mansfield study investigates the proportion of innovations that would not have been developed or commercialised without patent monopolies (see Table 1). He finds that outside of pharmaceuticals, and to a lesser extent chemicals, most industrial innovation would occur without a patent system;

- these studies are confirmed on a much wider scale by results from various national innovation studies:
  - in 2004-05 the Australian National Innovation Survey showed that 34 per cent of Australian firms were innovating (ABS 2007: 12).
    - → about 2,100 firms were introducing 'new to the world' innovations, and about 2,800 firms 'new to the Australia' innovations (respectively 8 and 10 per cent of innovating firms) (ABS 2007: 12-13). It is these firms that might be expected to own patents;
    - → data on methods used to protect intellectual property are not provided by type of innovation. For all innovating firms, 74 per cent used no method of "protection", and 3.8 per cent used patents (21.6 per cent for firms with more than 200 employees). If all reported patent use is among new to the world/Australia innovators, then about one in five such firms use the patent system;
    - → in summary, about 5,000 firms (18 per cent of innovating firms; 6 per cent of all firms) might be expected to consider using patents. At most, however, only one in five does so.
  - These findings are replicated in national innovation surveys elsewhere: only a small minority of innovating firms use the patent system. Other means—mostly based on market mechanisms—are more effective in providing a return to innovation expenditure. For example, 1990-1992 data from the first European Community Innovation Survey (CIS1) show the most important methods of appropriating a return to innovation are lead-time advantages and complexity (Arundel 2001: 615-5). CIS3 (1998-2001) data show that, to protect innovations, 36 per cent of firms use lead-time compared to 17 per cent applying for patents and 11 per cent owning at least one valid patent at end 2000 (Eurostat 2004).

- The strength of this evidence—that in general patents are not needed to ensure a return to innovation investment—has caused at least two world experts on industrial innovation to express surprise at the growing support for patent policy in the face of this evidence (Richard Nelson and F.M. Scherer).[7]

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[6] Students of innovation frequently use a tacit to codified dimension to explore knowledge. At the broadest level codified knowledge is that which has been reduced to written form and so is more readily transferred between people, while tacit knowledge ranges from 'know-how' to the range of assumptions about how the world works that are so fundamental they are rarely written down.

[7] "The swing in the climate towards such an endorsement [of patent policy] is specially puzzling in the light of the empirical research that has been done on the efficacy of patent protection" (Mazzoleni and Nelson 1998: 274). "During the 1980s and 1990s, important … initiatives … strengthening patent … systems…. The political influences that led to these changes are interesting in their own right. Even more interesting,

Table 1 Percent of innovations that would have been affected, absent patents

Industry	Not developed	Not commercially introduced
➢ pharmaceuticals	60%	65%
➢ chemicals	38%	30%
➢ petroleum	25%	18%
➢ machinery	17%	15%
➢ fabricated metal products	12%	12%
➢ primary metals	1%	8%
➢ electrical equipment	11%	4%
➢ instruments	1%	1%
➢ office equipment	0%	0%
➢ motor vehicles	0%	0%
➢ rubber	0%	0%
➢ textiles	0%	0%

Source: Mansfield 1986: Table 1 (p. 175).

- Empirical evidence also shows that *the cost of imitating is substantial*. A low cost of imitating is one of the fundamental assumptions in the "theory" underlying a general failure in the innovation market and the need to grant patent monopolies. But theoretical (Cohen and Levinthal 1989; Mandeville 1996; Saviotti 1998) and empirical studies show that this assumption is the exception rather than the rule:
  - Mansfield and colleagues found the average ratio of imitation to original costs was 0.65, and the average ratio of imitation to original time was 0.70 (Mansfield et al. 1981). For one in seven innovations, imitation costs were no lower than the original costs;
  - data from the large 1983 Yale survey confirmed these findings. In general, imitation saved only 50 per cent of the original R&D cost. More major innovations were more expensive to replicate, and replication took longer—sometimes over 3 years; most often at least 6-12 months (Levin et al. 1987);
  - during the period of first-mover advantage the innovating firm can therefore clearly charge above marginal cost and so recoup the innovation investment (Boldrin and Levine 2004).
- Unfortunately the compulsory nature of TRIPS has put paid to natural experimentation. However there are some recent natural experiments in relation to patent protection for pharmaceutical products. These have been scientifically studied:
  - many European countries did not grant patents for chemical products until the adoption of the European Patent Convention (EPC). Italy benefitted from this situation and developed a globally-leading generics industry, selling product to the US military (Scherer 2006: 33). Adoption of patent protection led to a

however, is the fact that governmental emphasis on patent systems increased in the wake of impressive new findings from economic studies showing that patents played a surprisingly minor role in well-established corporations' decisions to invest in research, development, and technological innovation" (Scherer 2006: 1).

massive reduction in the size of the generics industry, a substantial worsening in the pharmaceuticals balance of trade, and no increase in capacity in developing new chemical entities (Scherer and Weisburst 1995);

  - in India, which has more recently adopted patent protection for chemical products, there is no evidence of any increased R&D directed to local medical needs. There has been increased R&D but this is largely directed to US regulatory compliance for generic products so is entirely unaffected by the new Indian patent statute (Chaudhuri 2007).

- Evidence on the role of competition as a driving force underlying innovation is surprisingly sparse. However Boldrin and Levine's recent work contains several small case studies of innovation in competitive circumstances:

  - these range from the development of the Cornish steam power engine, through plant innovation in the US before the introduction of monopoly protection for plant varieties,[8] to Germany's global lead in chemicals in the late nineteenth and early twentieth centuries (Boldrin and Levine 2008).

These empirical studies raise serious questions about the effectiveness of patent policy. Indeed the most interesting gap in the evidence is any systematic scientifically-based evidence that patents are needed to induce innovation.[9] If patent monopolies are usually not needed to induce invention, why are so many being handed out?

Along with this empirical evidence base, there have been developments in theoretical expositions which also challenge the validity of the conventional static neo-classical model of general market failure. Particularly useful contributions are that:

- the incentive effect of patents in a static model can be completely reversed in a dynamic model, because of the innovation benefits of imitation (Bessen and Maskin 2000). Given that innovation is quintessentially about a dynamic world, a dynamic model of innovation is clearly to be preferred;
- where first-mover advantages are significant, an industry norm of cross-licensing patents can reduce market-based incentives to innovate as the innovator is compelled to share these profits (incentives) with others (Bessen 2003); and
- unless the initial investment cost is very high relative to market size, normal first-mover advantages will allow firms to price above marginal cost, so obtaining a return on their innovation investment (Boldrin and Levine 2004).

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[8] Comparing productivity growth in US agriculture generally and corn in particular to changes in 'intellectual property protection' for plants, Boldrin and Levine find no evidence of any increase in productivity following the introduction of the 1970 US *Plant Variety Protection Act*. Agriculture is, of course, far more typical (than industrial products) of the relatively competitive markets in which the conventional 'knowledge as public good' argument for patents suggests that there will be significant failure in the innovation market.

[9] Certainly there are anecdotes, but there are also anecdotes about the damage patents have done to other innovating firms (e.g. Kodak, RIM, those sued by E-Data, etc.). But anecdote does not constitute a scientific evidence base.

This broad empirical evidence thus challenges the conventional view that patent monopolies are needed to induce invention which would not otherwise occur. Indeed, there is no evidence of any general failure in the market for innovation.[10] There may be some specific failures in markets where knowledge is highly codified or where innovation investment is very large compared to the size of the market.

There is no evidence of any general failure in the market for innovation

In summary then there is no evidence of any *general* need for patents. However, innovation markets may fail where there is a high degree of codification and/or where the initial investment is very large compared to the size of the market. This suggests that a welfare-enhancing patent policy system is one that grants patents on a narrow discretionary basis. Australia has given up the right to do this.[11] However threshold requirements for grant of a patent monopoly could be set at a much higher level—this would substantially reduce the volume of patents granted. As incremental 'inventions' are more likely to create social costs then social gains, this would improve the welfare outcome of the patent system. So a key TRIPS-compliant policy question is whether the inventiveness requirement for a patent monopoly is set sufficiently high *to ensure that Australia's patent laws leave Australia better off and not worse off.*

This inventiveness requirement is critical to the issue of patents for genes, as genes are simply discoveries, not something invented by "man".

4. If patents aren't needed, who is benefiting?

Data for 1990 show that the ratio of technology receipts to technology payments was less than one (i.e. in deficit) in Japan (0.91), Germany (0.83), the UK (0.96), France (0.76) and Canada (0.93). The ratio was strongly positive in the USA (5.26) and was also positive for Sweden (5.47) and Denmark (1.14) (Gruen et al. 1996: 9). This suggests that at the national level only a small number of countries gain a benefit from patent and copyright systems. The major winners appear to be the USA and Sweden. Except for France, other G7 countries seem to be in balance. But most of the rest of the world, including Australia, loses from the global patent system, implemented through national legislation. Some of these

[10] Despite this, there is a persistent belief in the myth that there is a general failure in the market for innovation, and that patents are therefore essential (a *sine qua non*) for innovation (Macdonald 2004). Myths are remarkably resilient to evidence. Indeed this is clear from the Ergas and Cutler reviews, both of which put forward the conventional, and unsubstantiated, view that there is general failure in the market for industrial innovation. It is to be hoped that increasing emphasis on evidence-based policy will finally lead to these conventional views being properly assessed and interrogated.

[11] Scherer suggests that, for low-income countries, this was a Faustian bargain as the *quid pro quo* for TRIPS was never delivered (Scherer 2006). Whether Australia has had a similar experience is not known. It is unclear what benefit Australia expected from being a "friend of intellectual property" during the Uruguay negotiating round.

losses are substantial.[12] We have long known that lower income, relatively unindustrialised countries are losers from patent systems (Penrose 1951).[13]

Indeed it is hard to see how a country like Australia, where only 8% of patents are owned by Australian companies or individuals could benefit from a patent system. With less than 2% of the OECD market, an Australian patent is not likely to create the incentive to invent for most overseas owners of Australian patents. I estimate that perhaps 3% of Australian patents might be induced *and* might deliver the potential social benefits with which to offset the costs that flow from all granted Australian patents (Moir forthcoming: 39).

Of course, in a very much larger market such as the USA, the monopoly offer might induce a much larger level of investment in R&D. However two very well regarded US legal academics specialising in patent matters, and with long experience of the US patent system both consider this unlikely.

> "… the inventor's contribution is not the invention itself—which eventually would have been made by someone else—but the time of the invention. The patent should reward not the whole value of the invention, but for the value of being first."
>
> Kitch 1977: 285

> "In the fullness of time, it is highly likely that every invention will be made; to a large extent, the real goal of patent law is not to induce invention, but instead to induce it sooner rather than later."
>
> Dreyfuss 2008: 438

Against this background that the patent system seems to be ineffective public policy—in that it does not achieve the intended effect of a higher level of resources directed towards R&D, one has to ask who benefits. At the level of individual patent ownership, it has long been known that only a small proportion of companies benefit.[14] As noted above, in Australia, at best only one in five highly innovative companies use the patent system. Yet the only companies which can be sued for patent infringement are innovating companies.

Recent US research estimates the private value of patents for US publicly listed firms and suggests:

> "that the economic benefits of patents are very highly concentrated among a small number of firms. Over one-half of the value of worldwide patents accrues to a small number of large pharmaceutical firms; over two-thirds accrues to firms in the chemical and pharmaceutical industries."
>
> Bessen and Meurer 2008: 109

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[12] The ratio of technology receipts to payments was 0.14 in Finland, 0.18 in Spain, 0.3 in Austria, 0.53 in the Netherlands and 0.58 in Italy. In Australia it was a surprisingly high 0.79 (Gruen et al. 1996: 9).

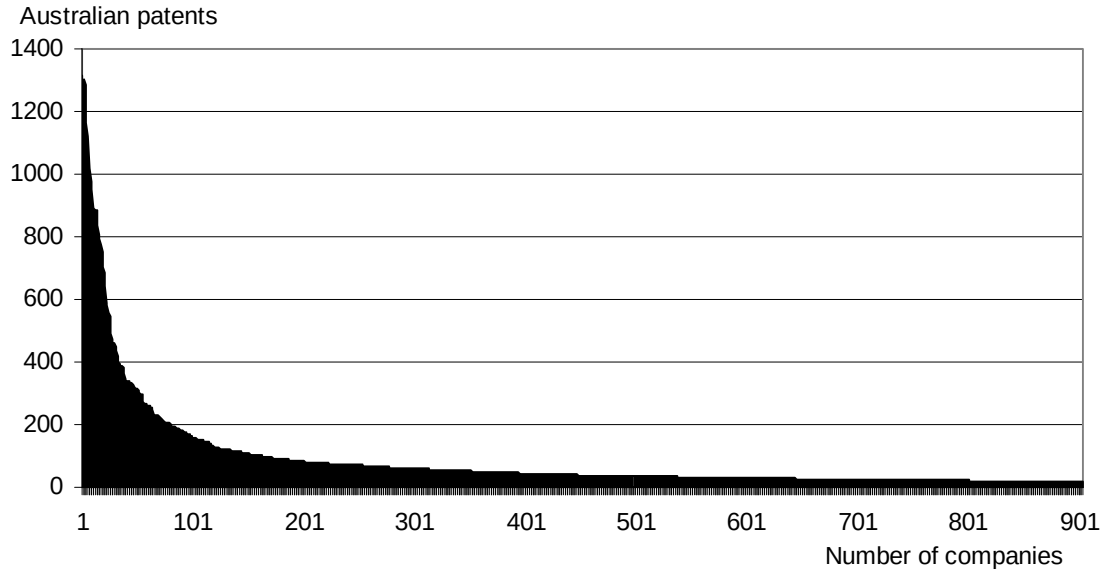
[13] Penrose and Machlup worked closely together. It is highly likely that Machlup was thinking of Penrose's 1951 study of the economic impact of the Paris Convention when he noted that the weight of evidence for smaller countries led to a clearer conclusion as to whether patent systems are welfare-enhancing. He would have had in mind the negative outcomes so clearly demonstrated by Penrose.

[14] Edwards pointed out in 1949 that only a few companies benefited from the US patent system, and went on to argue that this was a poor rationale for maintaining the patent system given the probability that its overall impact was negative (Edwards 1949). A similar argument today would be equally valid.

There is almost no literature on who benefits from the patent system. I recently developed estimates of the most frequent corporate patenters in the USA and Australia, and found that among the top 100 patent users in each country, 47 were common to both countries (Moir 2008b). Only one Australian company featured in the top 100 list – a company in the high-speed printer business where "trolley-loads" of patents are needed in cross-licensing negotiations.[15]

The concentration in patent ownership is stark, as shown in Figure 1. Indeed it is even more stark—in order that the distribution in Figure 1 is visible, three companies have been omitted at the left-hand side, and some 5,000 companies at the right hand side.

Figure 1 Ownership distribution of Australian patents, 1990-2001



Notes: Excludes three companies with most patents (Ericsson 1,858; Hoechst (Sanofi-Aventis) 1,818 and Procter & Gamble 1,526). Also excludes all companies with less than 19 patents granted in the period. Also excludes 51,387 corporately owned patents at the right hand end of the scale. Assuming a (rather high) average of ten patents per company, this would mean over 5,000 extra companies beyond the 905 shown in this figure.

Just as there is almost no literature on the beneficiaries of the patent system, there is almost no empirical work on the costs of the patent system. Again I have attempted to bring together the evidence on this matter (Moir 2008a). There would be a number of options for obtaining better information on the extent to which patents induce innovations, and their cost impacts. In particular National Innovation Surveys could be used to obtain targeted information on both costs and benefits. The ACIP review recommended the collection of data on the use of patents, but this 1984 recommendation still has not been adopted. Perhaps it is time reporting to government was required as a condition for the use of government-granted monopolies?

[15] The term "trolley-loads" was used by a Patent Attorney from that company when I asked why Silverbrook Research Pty. Ltd has so many patents.

Apart from the small group of companies which are very significant users of the patent system, another group of beneficiaries deserves mention—the intermediaries who facilitate obtaining patent monopolies. There is little written about the role of this group. Barton points out, in the US context, that the number of patent lawyers has grown at a much faster rate than expenditure on research and development (R&D) (Barton 2000). Kahin has pointed to the role of the patent bar in overturning the US Congressional intent to study the impact of business method patents.[16] Nine of the 37 submissions to the current (ACIP) inquiry into patentable subject matter are from Patent Attorneys or their associations.[17]

5. Balance and the inventive step

How inventive a patent is is critical in determining whether it confers a benefit. If it represents only a modicum of advance over existing knowledge, then it is hard to see how spillover benefits might eventuate. So there would be no "consideration" to offset the monopoly cost. Where a large majority of granted monopolies are for "inventions" which are at best only incrementally inventive, then most granted patents will produce costs but no offsetting benefits. This is likely to mean that the patent system overall is reducing welfare.

Unfortunately a series of complex and detailed rules have been developed by courts and adopted by parliaments into statute law. These have the consequence of ensuring that the critical inventiveness parameter is set at an extremely low level. For example, after reviewing the 50 best software patents against the very low standards of the USPTO Campbell-Kelly and Valduriez concluded that all were very incremental, and two were obvious (though less obvious than many other granted software patents) (Campbell-Kelly and Valduriez 2005).[18]

A brief review of these doctrines follows, so that the Committee may understand the yardstick against which the "inventiveness" of gene patents is being tested.

Patent law presumes a good, readily available, library of material demonstrating the current state of knowledge (Cohen and Lemley 2001). Clearly the presumed library is most deficient in new fields of technology, and where most existing knowledge is uncodified. The presumed library forms the "prior art" against which novelty and inventiveness is tested. *But not all knowledge is permissible as the basis for testing novelty and inventiveness.* This is the first point at which an economist is surprised. Given the purpose of a patent system, the knowledge base would be presumed to be *the existing body of knowledge*. Not in patent law. The concept of a *body of knowledge* does not seem to exist in the patent system.

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16 This proposed study was in the penultimate Senate draft of the American Inventors Protection Act of 1999 (Kahin, 2003).

17 See http://www.acip.gov.au/reviewpatentable.html.

18 I have not found any other studies which investigate the actual inventiveness of patented "inventions", so cannot supply a reference closer to the technology field being investigated by the Committee. I note however that the TRIPS Treaty prohibits discrimination by technology field in the administration of patent policy. I have recently completed a study as to whether Australian business method patents provide new knowledge or know-how, and found that of 72 recently granted standard patents, only one *might* contribute new knowledge. Three others *might* contribute marginal new ideas (Moir forthcoming).

The novelty test has become defunct because novelty is now measured against *only one piece of knowledge at a time*, not against the existing body of knowledge. This doctrine was introduced in 1880, in a case between two private parties, and subsequently adopted into UK and Australian law.[19] Inventiveness can be measured against *two* pieces of knowledge *and* common general knowledge, but there are severe limits to this "generous" interpretation of the body of existing knowledge. The *Emperor Sports* case has excised from the inventiveness knowledge base most patented knowledge in fields where the normal worker ("person skilled in the art") would not think of looking at patent databases.[20] This surreal outcome can only be changed by amending Section 7(3) of the *Patents Act 1990*.[21] It is a clear and exact application of the words in that section.

The *Patents Amendment Bill 2001* introduced a requirement for applicants to submit information from overseas patent office knowledge searches. This was first watered down, then eliminated in late 2007.[22] As long as most existing knowledge is ruled out of court for the purposes of assessing the novelty or inventiveness of a patent application, and *applicants are exempted from any obligations to provide information on relevant existing knowledge*, the standard for the grant of patents will inevitably be low. From a public good perspective it seems extraordinary that applicants for a government-sanctioned monopoly are not required to provide critical information on which the merits of their application can be judged.

These problems are compounded by the narrow approach now being taken to defining the relevant field of technology. In respect of the US patent system, Bagley (2001) has demonstrated how technology fields are now so narrowly construed that most relevant existing knowledge is ruled inadmissible in the obviousness (inventiveness) test. In a key Australian case, *Welcome Real-Time*, the way in which the relevant field was construed, not as smartcard technology, but as loyalty programs, was critical to the decision of validity. *The "invention" was stated in court to be well-known in the information technology field* (used in implementing the invention), but by defining the relevant technology as the business field of loyalty programs, this relevant existing knowledge became irrelevant to the decision. The court decided the known "invention" was inventive and that Catuity's independent development of dynamic storage techniques on smart cards infringed the "invention".[23]

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19 *Von Heyden v. Neustadt* (1880) 50 L.J.Ch. 126 at 128; 14 Ch.D. 230 (see Bochnovic 1982: 20). The single publication is to be read from the perspective of a "person skilled in the art", that is, in the light of that person's common general knowledge. But there should be *no addition* from this common general knowledge base to the document in determining the "prior art" (see IPAustralia 2008: section 2.4.5.2.3).

20 *Commissioner of Patents v Emperor Sports* (2006) 225 ALR 407;(2006) 67 IPR 488;[2006] FCAFC 26.

21 The choice of this adjective is inspired by van Caenegem's comment on the 'person skilled in the art' (see below).

22 There had never been any obligation on an applicant for an Australian patent to provide full information on previous knowledge related to their application. The 2001 amendments, though reduced in the Senate, still required applicants to provide the results of searches by overseas patent offices for previous knowledge (a recommendation originally put forward by IPAC in 1984, then again by the IPCRC in 2000). Subsequently this requirement was watered down before being substantially removed on 22 October 2007 (http://www.ipaustralia.gov.au/ pdfs/news/ON20071018%20Patents%20 Amendments%20Regulations.pdf, accessed 22 November 2007).

23 *Welcome Real Time SA v Catuity Inc* (2001) 51 IPR 327.

These limitations on the evidence that can be used to judge novelty and inventiveness are combined with various "doctrines" (i.e. policy rules) that introduce further challenges to balance in the patent system. One is the qualities imputed to the inventiveness judge—the "person skilled in the art". In his recent text on 'intellectual property' law, van Caenegem comments on the view that the person skilled in the "art" (technology) should be:

> "… a *typical uninventive worker* in the field. This again is rather *surreal*, certainly in a field where inventiveness is a common attribute of every typical worker, as for instance at the higher end of scientific research. Then all that is required is that the invention, as a step onward from the prior art, is not obvious. No ingenuity, revolutionary insight, creativity or major step forward need be shown; some small inventive spark is enough, and it matters not whether that inventive step resulted from a sudden insight, or from careful study, reflections and research"
>
> van Caenegem 2007: 85 (emphasis added)

We now live in a world where innovation is the norm not the exception. Patent policy does not yet seem to have caught up with this.[24] Rules such as requiring inventiveness to be judged by the kind of person who would never be employed at the forefront of invention sets up another bias towards the grant of monopolies for uninventive "inventions".

Another policy rule that seems particularly welfare-reducing is the "combinations" doctrine. Australian patent examiners (like many counterparts overseas, including in the USA) are not allowed to deem the combination of two or more old ideas obvious, unless there is *documentation* suggesting such a combination, or unless that would be the *sole* combination that a practitioner would come up with, given common general knowledge and the problem to be solved. The Australian Patent Examiner's Manual (Section 2.5.3.5) quotes from case law:

> "The proper question is … whether it would have been obvious to a *non-inventive* skilled worker in the field to select from a possibly very large range of publications *the particular combination* subsequently chosen by the opponent in the glare of hindsight … The prior existence of publications revealing those integers, as separate items, and other possible integers *does not of itself* make an alleged invention obvious. It is the selection of the integers out of, perhaps many possibilities, which must be shown to be obvious. ... The opening of a safe is easy when the combination has been already provided."
>
> *Minnesota Mining and Manufacturing v Beiersdorf* (1980) 144 CLR 253 at 293 (emphasis added)

From this perspective the fact that many people would have come up with the same invention does not make it obvious, unless *everyone* would come up with *only* that combination. Because at least some others would have come up with a somewhat different combination, it is not obvious under patent law. Indeed this suggests that the more old ideas you combine, the less likely it will be that a patent office can reject your combination as obvious. From an economic policy perspective, this development in patent law appears dysfunctional. It results in Australia granting such silly monopolies as "A Financial Education System", (AU 2003203582, sealed December 2003), which is a system for

[24] Though the US Supreme Court has recently indicated that the "person skilled in the art" should have "normal" creativity (*KSR v Teleflex*, 127 S. Ct. 1717 (2007): at 1741-2).

teaching children about finance based on the concept of a child working for her pocket money, but including credit, insurance and investment options.

It also indicates the problems that can arise when using analogy as a basis for determining economic policy. The challenges of technological innovation are quite different and far more varied than opening a combination safe.

Inventiveness has virtually disappeared as a requirement for a patent grant

There also seems to be something of a disconnect between modern patent judgements and those that occurred some time back. The *3M v Beiersdorf* decision cited above can be contrasted with such judgements as that which set up the (seemingly now rarely used) analogous use principle. In 1865 the Lord Chancellor said:

> "Upon that I think that the law is well and rightly settled, *for there would be no end to the interference with trade, and with the liberty of any mechanical contrivance being adapted*, if every slight difference in the application of a well-known thing were held to constitute a patent …" [25]

This 1865 decision is very much in the vein of the earlier (1838) decision where a similar principle was enunciated:

> "It would be a very extraordinary thing to say, that because all mankind have been accustomed to eat soup with a spoon, that a man could take out a patent because he says you might eat peas with a spoon. The law on this subject is this: that you cannot have a patent for applying to a well-known thing, which might be applied to 50,000 different purposes, for applying it to an operation which is exactly analogous to what was done before."
>
> (1838) 3 Hayward's Patent Cases 125, 141 (from Brennan and Christie 1997: 29)

In Australia this sentiment was repeated in the 1959 *Microcell* judgement. The High Court ruled that:

> "If stainless steel and its properties were known, and many kinds of articles had been made of it, it would not be possible for a man to claim a monopoly for making kitchen sinks of stainless steel merely because he was the first man who ever thought of doing this. … *It is not an inventive idea for which a monopoly can be claimed to take a substance which is known and used for the making of various articles, and to make out of it an article for which its known properties make it suitable, although it has not been used to make that article before.*
>
> (1959) 102 CLR 232, 248 and 249 (from Brennan 2002: 29 (emphasis added))

And where the patent involves a process rather than a product these two judgements directly imply that a new use for a known process where the known process is clearly suitable for the new use should be equally unpatentable.

These earlier decisions ensured that balance between the public good and the incentive to the innovator was present in the patent system. Somehow that seems to have changed.

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[25] *Hamilton E. Harwood and Another v The Directors, etc of the Great Northern Railway Company*, (1865) 11 HLC 654 at 682-3, 11 ER 1488 at 1499 (emphasis added).

Australia is now regularly granting patents for the use of known procedures in new (and not so new) situations, such as audit for tracing chemicals, benchmarking for real estate, financial ratios in financial systems, general ledger codes in accounting systems.[26] In the pharmaceutical area many more patents are being granted than new chemical entities developed. While some of these cover such issues as new delivery methods with important therapeutic effects, many others are for simple variations of known products or processes, with no new therapeutic effect. I understand that in the Brazilian system patent monopolies cannot be granted for chemical entities unless these have a useful therapeutic effect. This type of enhancement to the patent administration system ensures that in at least one important area there is a consideration passing to the public.

The Cutler review of the National Innovation System has 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."
>
> Cutler et al. 2008: 86

This recommendation effectively has two parts, one dealing with inventiveness and the other with claim clarity. Both are to be commended.

5.1. Overall balance and risks of error

It is unreasonable to expect that there will never be any errors in decisions to grant or refuse patents. However it is also reasonable to consider whether there is a greater public interest in risking the grant of a monopoly for an uninventive invention that refusing one for an inventive invention. As the recent Grant case shows, there are many opportunities for the owner of a rejected application to challenge the decision.[27]

There is a substantial asymmetry in the incentive to litigate a patent between the patent-holder and alleged infringers, allowing many uninventive patents to remain unchallenged.[28] There are many biases against appealing the grant monopolies for uninventive invention. A single party has to bear all the costs, while if the appeal is successful the benefits of eliminating the unjustified monopoly flow to all innovators working in that field. There also appear to be a number of general rules for legal proceedings make it extremely difficult for non-profit organisations to challenge invalid patents, particularly when faced by well-resourced patent owners. It is also appropriate that the would-be monopolist bear the cost of the appeal, as the party with most to gain.

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[26] A system for validation of chemical usage in the production of foodstuffs (AU2004233489); Method and Tool for Assessing the Sustainability of a Development (AU2004200942); System and Method for On-line Analysis and Reporting of Financial Operation Data from Community Pharmacies (AU2003204214); and Transaction accounting processing system and approach (AU2005255399).

[27] This rejected innovation application (for a method of moving assets to a trust structure to "protect" them from legitimate creditors) went through four appeals, and was rejected on different grounds each time. These decisions are well reviewed by Tyacke and Webb 2007.

[28] While Australia has a pre-sealing opposition process, this presumes firms will actively monitor acceptances, at some substantial cost. It is also interesting that the fee for lodging an opposition is far higher than the fee for acceptance.

From the perspective of the public good and the importance of achieving a probably balance in the patent system between costs and benefits, the preferred bias would be towards the rejection of inventive patents, rather than the grant of monopolies for uninventive inventions.

Unfortunately as the system has developed, both in Australia and in many overseas countries (particularly the USA), it appears that in each of the myriad decision rules and procedures there is a strong bias to avoiding the rejection of inventive patents.[29] This directly implies the frequent grant of monopolies for uninventive inventions.

There are many small rules in the patent system which create a bias towards grant, once an application has been filed. The outcome is that the patent playing field is substantially sloped, with the would-be monopolist at the top, and the public benefit at the bottom. An incomplete list of the biases towards the grant of 'bad' patents is:

- *legislative presumptions of novelty and inventiveness* mean that the government has to show that a patent application is uninventive, rather than the applicant showing that it is inventive.
  - the onus of proof should be consistent with regulatory norms and lie with the applicant;[30]
- the body of existing knowledge used as the basis for testing novelty and inventiveness has been severely reduced by doctrinal rules, codified into the statute;
  - novelty can be tested against only one document at a time;
  - a reference in one document to a second document is insufficient to allow the second document to also be considered;
  - all patent documentation can be disregarded in the inventiveness test in low technology fields;
  - technology fields are so narrowly defined that considerable existing knowledge is often ruled inadmissible;
- there is no obligation on the applicant to provide full information on the body of existing knowledge relevant to their 'invention;
- there are extensive opportunities for the applicant to negotiate with the examiner and amend the application, including bringing in as key features of the "invention" aspects which were not originally deemed salient, but which allow the application to pass the very low novelty and inventiveness tests;
- the judge for the inventiveness test is required to be unimaginative;

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29 See, for example Jensen and Webster 2004 on Australia, and Dreyfuss 2008 on the USA.

30 Extraordinarily, the TRIPS Treaty includes an Article requiring that the normal burden of proof be reversed in the case of process patents. Article 34 sets out circumstances where a product shall be deemed to have been produced using a patented process unless the alleged infringer (the accused) proves otherwise (http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm, accessed 30 April 2008). However Article 34 applies only to litigation about infringement of a granted patent. Nothing in the TRIPS Treaty prevents an administrative requirement that applicants for patents be required to demonstrate that their inventions meet the statutory requirements of novelty, utility and inventiveness.

- the decision-making rule is *balance of probabilities*. The norm for regulatory intervention in markets is that the benefit of the intervention must be *significantly greater* than the harm. Such an option was dismissed by the IPCRC as being inappropriate for a civil matter (IPCRC 2000: 166). But patent policy is a tool of economic policy, and the appropriate decision-making standard should be economic not legal. The standard should be *beyond reasonable doubt*; and
- "inventions" which combine well-known elements are not dismissed as obvious unless someone *has specifically suggested* that combination in writing.

The net effect of these biases is that the patent system is far more likely to grant patents for uninventive "inventions" than to reject applications for inventive inventions.

6. Subject matter extensions

This section briefly reviews the active approach taken by the Australian Patent Office and Australian judges to extending the boundaries of the patent system. We have now reached the situation where the courts are suggesting that no technological basis is needed for a patent to be granted. This active approach to extending the boundaries of patentable subject matter has largely been in the period since passage of the *Patents Act 1990*.

Three major areas of extension are discussed, two of which are directly relevant to the work if this Committee. In the discussion it has not been possible to completely separate consideration of substantive extensions in the reach of the patent system from issues of legal drafting, which are more appropriately considered in the next section. This is because legal drafting (semantic invention) is regularly used to make what should not be patentable patentable:

> "As it reaches the patent office the application combines technological and legal invention, and the latter, if of superior quality, may do much to offset deficiencies in the former."
>
> Edwards 1949: 218

Such legal drafting is akin to the kinds of financial products that were created prior to the introduction of anti-avoidance provisions into tax law. The objective of both is to avoid / undermine the intent of the relevant legislation.

6.1. Mathematical algorithms, including software.

The key cases were *IBM* and *CCOM*. In *IBM* the Federal Court overruled the Commissioner for Patents. The Federal Court considered a patent should be grant for software using two algorithms to produce an improved representation of a curve, *as it had a commercially useful effect.*[31] In *CCOM* the Full Federal Court overruled an earlier Federal Court decision that an "invention" which merely used a computer in a conventional manner to reproduce known mental processes was not patentable.[32] The Full Federal Court's decision drew heavily on UK law, arguing:

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[31] *International Business Machines Corporation v Smith, Commissioner of Patents* (1991) 33 FCR 218; (1991) 105 ALR 388; (1991) 22 IPR 417; (1992) AIPC 90-853.

[32] *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481.

> "that more than a mental process was involved in claiming the process of application of certain steps represented by a computer program on a standard computer, since the method as claimed was incorporated in the program and in apparatus in a physical form."
>
> van Caenegem 2002: 46

From the perspective of balance in the patent system, or, indeed from the perspective of software operations, this argument seems to involve semantics not substance. Issues of the use of legal semantics to undermine parliamentary intent, and balance in patent law are dealt with in the next section. But from a technical perspective it is hard to understand the key argument used in this decision—that writing software for a known process involves more than mental steps.

Extensions based on the overturning of the long-standing prohibition on the patenting of mathematical algorithms have subsequently led to the extension of patent monopolies to business methods. Justice Heerey's decision in *Welcome Real Time* cast doubt on whether *any physical aspect* was necessary for patentability, and *as a consequence* the Australian Patent Office revised its examination guidelines to *remove any such requirement* (ACIP 2003: 12). Most recently the Federal Court has even queried whether the Australian Patent Office is correct in suggesting that patents should be restricted to areas of technology.[33]

To date there has been no legislative response to this very active judicial intervention in the grant of patent monopolies. The Patent Office seems not to take action to recommend to government statutory reform of welfare-reducing changes to the system, such as the 2006 interpretation of the wording of Section 7(3) to excise patented knowledge from the body of existing knowledge for the inventiveness test in non-technology fields, or the views expressed in the Grant case suggesting that no technology basis is required for a patent monopoly.

Another useful insight from the software example is the way in which legal semantics ("clever legal drafting") can be used to undermine the intent of legislation. Here the *European Patent Convention* (EPC) provides an interesting example. Software *per se* is not patentable. However the European Patent Office (EPO) has apparently granted well over 40,000 software patents (Miceli 2005). Legal semantics have been used to pretend that software is not software but a "device" or a "method" etc. However, as Prescott J said in rejecting an Australian business method application in the UK:

> "You are not allowed to get round the objection—that you are attempting to patent a computer program—by claiming it as a physical artefact, a mere change of form."
>
> [2005] EWHC 1589 (Pat) at 36

Exclusions can work, but they will work only if the judiciary is alert to word games, and parliamentarians to the need to patch holes when specific decisions undermine legislative intent.

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[33] The Full Federal Court, in considering the Grant case (*Grant v Commissioner of Patents* (2006) FCFCA 120), took the opportunity to pass an opinion on the Szabo case (*Re Peter Szabo and Associates Pty Ltd* (2005) 66 IPR 370) and stated that *they were not sure that the argument that a science or technology base was required for patentability was correct* ((2006) FCAFC 120: 37-38). The outcome of this possible proscription remains to be seen.

6.2. Methods of medical treatment

Despite clear precedent that methods of medical treatment were not patentable subject matter (ALRC 2004: 94 citing *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619), the Federal Court in 1994 decided methods of medical treatment were patentable.[34] Arguments used to support this radical change in policy were "that there was no reason in principle" for the exclusion and that "Parliament had an opportunity to include an exception in the *Patents Act* when it was re-enacted in 1990, and had chosen not to."[35]

This is to misunderstand government and parliamentary processes. The *Patents Act 1990* was introduced in response to the 1984 IPAC review. That review committee considered, among other things, whether chemical compounds should be patentable or not (split decision), whether software should be patentable (unanimous view not) and whether the "manner of new manufacture" definition needed change (recommendation no change). The then government effectively determined not to exclude chemical compounds, that patents were not needed for software and that the "manner of new manufacture" definition did not need change. It should be noted that the IPAC study was commissioned by the Fraser Government but received by the Hawke Government. There was in fact bi-partisan support for the subsequently proposed legislation. The specific exclusion added to the draft legislation, during Senate negotiations, was a narrower exclusion than originally proposed by the Democrats.[36] The fact that one specific exclusion was added during Senate negotiations with a minor party simply cannot be taken to mean that it was *the view of parliamentarians that all existing precedents regarding non-patentable subject matter should be overturned by the courts*.

One might have anticipated that information and advice on this problem would have reached parliament, and that the government would have proposed legislative amendments to return the situation to the status quo ante.[37]

In their consideration of the matter the ALRC made no comment about whether this major shift in policy was one that was appropriately made by judges. They simply noted that the *Rescare* decision was confirmed by the Full Federal Court in 2000[38] and cited comments by Black CJ and Lehane J on "the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a *product* for treating the human body, but deny patentability for a *method* of treatment."[39]

The ALRC did, however note that other jurisdictions have not followed this path. The *European Patent Convention* expressly excludes methods of medical treatment of the

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34 *Anaesthic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1. The invention was a method (and device) to prevent sleep apnoea.

35 Wilcox, J. Cited in ALRC 2004: 95.

36 Effectively the exclusion was negotiated with the independent Tasmanian Senator Harradine.

37 However public choice theory indicates that this might be difficult where a small number of beneficiaries are active lobbyists. Additional impediments are that outsiders to "the patent community" are warned about the extreme dangers of interfering in such a complex area of law and that there have been many decades of propaganda about the "rights" of inventors and creators.

38 *Bristol-Myers Squibb v FH Faulding & Co Ltd* (2000) 170 ALR 439. The invention was a method of administering a drug to treat cancer.

39 Ibid, 444.

human body, on the basis that such inventions are not to be taken to be capable of "industrial application". This apparently arcane distinction is important.

At the time patent law was developed the various "arts" or fields of endeavour fell into three broad categories: the "industrial arts",[40] the professions, and the "fine arts". Only the former came within the ambit of the patent monopoly system. The professions were not then considered to fall into a field of economic activity; nor was it considered appropriate to grant monopolies to the professions. This perspective that the professions are not driven by economic imperatives appears quaint now, when every aspect of life is scrutinised through an economic lens. But the fact that the professions are now viewed differently does not automatically mean that all these previously excluded subject matters would merit legislatively sanctioned monopolies. The view at the time—some 30 to 40 years ago—was that there were certain areas where it was inappropriate to grant monopolies.

In many legal decisions a distinction is drawn between the useful (industrial) arts and the "fine" arts. No mention is made of the third important category, the professions. This omission underlies decisions to extend patent monopolies to areas of activity never previously considered patentable.

The literature analysing patent case law is doctrinal, that is it is undertaken from a legal perspective. In her otherwise extremely useful review of UK and Australian case law on methods of medical treatment, Pila takes a strictly legal perspective. She thus criticises the UK Solicitor-General's decision in *C&W's Application*[41] for requiring that a "manner of new manufacture" be one of relevance to manufacturing or trade (Pila 2001: 432-4). Given the economic goals of patent policy, such a criticism seems extraordinary.

Fundamental understandings are often poorly documented, if at all. As Hirschman notes "… propositions and opinions shared by a group and so obvious to it … are never fully or systematically articulated" (Hirschman 1977: 69). The view that patent monopolies are for the "useful arts" not the professions is one of these fundamental understandings. It is only by reading into the economic and social history surrounding the grant of limited monopolies for inventions that one can understand the full parameters of patent law. That is why this submission commenced with Walterscheid's excellent exposition of the beginnings of Anglo-Australian patent law.

Without this understanding, and without a clear perspective that the purpose of patent policy is economic not legal, one might well conclude that a decision that an invention outside the area of manufacturing or trade is merely a "useful expedient". But this is to misunderstand the importance of the definition of a patentable invention as a "manner of new manufacture". Pila notes that the *C&W's Application* did not cite precedents in relation to methods of medical treatment as there were none, and cites from the decision regarding the common understanding that members of the medical profession were very strongly discouraged from applying for patent monopolies. These facts confirm the fundamental nature of the understanding that the medical professions were not included within the ambit

[40] The "industrial arts" were what we would now call the technologies—the direct application of science to produce useful methods and artefacts. The principal fields are engineering and the physical and biological sciences.

[41] *Re C & W's Application for a Patent* (1914) 31 RPC 235.

of patent monopolies. As Pila notes, in the watershed *NRDC* case, the High Court contrasted the non-economic nature of methods of medical treatment with the economic nature of an agricultural process.[42]

> "The exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic."
>
> *NRDC* (1959) 102 CLR 252: 275

Certainly there is a difficult boundary question between the grant of a monopoly for chemical compounds used to treat humans and the refusal of a monopoly for a method of treating a human. Difficult boundaries are part and parcel of intervention into markets. The essence of the current inquiry is looking from a national good perspective at the pros and cons of one of these border-line issues. Given the centrality of genes and gene-related "inventions" to methods of medical treatment, the Committee will undoubtedly need to give some consideration to this issue.

Very fine distinctions have been made in different jurisdictions in legal cases concerning methods of medical treatment. In Canada such methods are considered not to meet the "utility" requirement—that is they do not fall into the "industrial arts". In New Zealand the exclusion is maintained on the basis that methods of medical treatment are not a "manner of manufacture". As this is the exact definition of a patentable invention in the Australian legislation, and as New Zealand draws on the same body of case law as Australia, this radical difference in findings merits further exploration.[43]

The TRIPS Treaty specifically permits exclusion of "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" from the patent monopoly system (Article 27(3)(a)). At the time TRIPS was being negotiated most nations did not allow such inventions to be patented, nor did they allow the patenting of chemical compounds.

The intent of the sovereign European nations which are signatories to the *European Patent Convention* (EPC) is to deny patent monopolies to methods of medical treatment of the human body. However there is substantial evidence to suggest that this clear intent is regularly undermined by the European Patent Office (EPO), particularly through its Technical Boards of Appeal (TBA) (an administrative appeal body not a judicial body).[44]

Despite the clear exclusion of methods of medical treatment under the EPC, the first medical use of a known substance is patentable. Ignoring this illogicality, a clear example of undermining the legislative intent is with regard to *second* medical uses of known entities. These can be commercially significant as costs have already been offset through the first use, so the income is pure profit. However a second medical use of a known

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42 Pila interprets the fact that this contrast was in parentheses as indicating that it was a tentative view. But given the economic context and background this is a false assumption.

43 The New Zealand Ministry of Economic Development has recommended amendment of their patent legislation to end a possible doubt to this interpretation created by a decision in their Court of Appeal (ALRC 2004: 95). This has been caught up in a complete review of the patent legislation which has been held up by extensive negotiations with interested parties and subsequently by a change of government.

44 This is also evident in relation to the series of decisions extending patentability to software despite the express prohibition of monopolies for software. The TBA decisions on what software inventions are patentable and what are not "seems rather arbitrary" (Bakels and Hugenholtz 2002: 10).

substance is clearly acknowledged to be a "method" of medical treatment and is therefore unpatentable. Legal semantics have been used to undermine this exclusion, just as the pretence that a software program, when it is operating, becomes a device and ceases to be software undermines the software exclusion. This specific form of legal drafting is known as a "Swiss medical claim" (Thambisetty 2008: 17). Thambisetty provides three forms of drafting the same underlying method, two of which fail the test for a patent monopoly, and the third of which passes. Pila notes that UK judges have been caught in a trap between wishing to preserve a consistent approach to interpretation of the EPC (by conforming to EPO decisions), and wishing to preserve the legislative intent of the Convention and its enabling legislation the UK *Patents Act 1977*. They have found several innovative means to deny patentability for "Swiss medical claims" (Pila 2001: 453-4).

6.3. Isolated and purified materials identical to materials existing in nature

In 2000 the committee which reviewed the *Patents Act* in the light of the Australian Government's Competition Principles[45] considered several aspects of patentable subject matter. In regard to discoveries[46] it took the view that competition goals "are well served by a patent policy that rigorously distinguishes between *discoveries* … and *inventions* … [and] only the latter should qualify for patent protection" (IPCRC 2000: 151). This is because "[p]roperty rights in discoveries … could give rise to unreasonable barriers to potential competitors or to those who wished to use the 'discovery' in other fields of endeavour" (IPCRC 2000: 152). The committee made no recommendations on the matter. But the principle enunciated—that competition goals are severely undermined if patent monopolies are granted for discoveries is important to this inquiry.

Competition goals are severely undermined if patent monopolies are granted for discoveries

In an extremely influential 1959 case, Australia's High Court noted that "the distinction between discovery and invention is not precise enough to be other than misleading *in this area of discussion*".[47] While legal texts regularly warn about the impropriety of importing judgements from one case to another, this comment appears to have had some considerable influence. Certainly there are very difficult boundary cases—one of the reasons economists are critical of unnecessary regulatory intervention in markets is the costs associated with arguing boundaries—but it is still a fundamental and important principle.

Many of the "inventions" claimed for "gene patents" are claims over materials that are identical to those found in nature. This raises important issues as to whether these

45 These principles have been agreed between the Commonwealth and State governments and are embodied in the Competition Principles Agreement and the National Competition Policy. The objective is the removal of anti-competitive elements of existing and proposed regulation. The agreements are oversighted by the National Competition Council (http://www.ncc.gov.au, accessed 14 August 2008).

46 That is, things that are found (e.g. gene sequences) as opposed to things that are created (e.g. methods for determining gene sequences).

47 *NRDC* [1959] HCA 67; (1959) 102 CLR 252: 8.

"inventions" are in fact inventions or whether they are merely discoveries. The ALRC reviewed this issue briefly. The ALRC started by looking at whether "man"-made organisms were considered eligible for monopoly grants. It referred to two cases. *Ranks Hovis McDougall's Application* is a case determined by the Australian Patent Office.[48] The second cited authority is far more authoritative, but derives from the USA. In 1980, on a split 5-4 decision, the US Supreme Court allowed a patent for a micro-organism that was significantly different from any organism existing in nature, and where these significantly different properties had the very high value of degrading crude oil.[49]

As is more eloquently argued by Palombi, this judgement hinged not on whether life forms were patentable, but on whether the "invention" was identical to anything found in nature (Palombi 2004). It is widely quoted as allowing the patenting of life forms, but a careful reading of the majority decision provides no such authority. Given the Supreme Court's emphasis on the radical difference from what is found in nature, it is hard to see how this can create a precedent for the patenting of isolated and purified genes and gene fragments, given that these are identical to naturally occurring materials, and there is no useful *different* property. The ALRC simply noted that in *Diamond v Chakrabarty*, the Supreme Court had referred to the concept of patentable subject matter in the USA being "anything under the sun that is made by man" and went on to the view that this laid the basis for a large expansion in patenting biological material (ALRC 2004: 69). This quotation is correct but limited and thus gives quite a false impression of the *Chakrabarty* decision.[50] Chief Justice Burger, delivering the opinion of the Supreme Court went straight on to say:

> "This is not to suggest that § 101 [the patentable subject matter test] has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. … Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. … Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." … Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but *to a nonnaturally occurring* manufacture or *composition of matter* -- a product of human ingenuity "*having a distinctive* name, *character* [and] *use*." "
>
> *Diamond v. Chakrabarty*, 447 U.S. 303: 309-310 (emphasis added)

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48 *Ranks Hovis McDougall's Application* [1976] AOJP 3915. It is clear from the citation that this is a decision by the Australian Patent Office. The IPAustralia website advises that all decisions since 1983 are available at the Austlii site (http://www.austlii.edu.au/au/cases/cth/APO/). Earlier copies of the Australian Official Journal of Patents have to be accessed as hard-copy through the National Library. The legal method of citing only the start page number, rather than the volume and full page references makes this extra challenging. It would be of great public benefit if IPAustralia made the full record of all its non-routine decisions available on-line. I have not had time to access and review this particular decision.

49 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

50 Indeed this quotation—always taken out of context—is regularly misquoted and misinterpreted, as the original text goes straight on to say "… but it is not necessarily patentable". This is clearly demonstrated by Menell, who provides a useful comparison of US Congressional intent and subsequent case law (Menell 2006). The full quotation is "A person may have "invented" a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled" (H.R. Rep. No. 1923 at 6).

It is clear from this fuller consideration of the *Diamond v Chakrabarty* decision that this decision would have raised no expectations that a monopoly claim over material identical to that found in nature would qualify for a patent monopoly.

Against this background of a very short and therefore misleading presentation of the *Chakrabarty* decision, the ALRC summarised the situation in Australia "and overseas" as being that a distinction had been drawn "between genetic materials in their natural state and those that have been isolated and purified" (ALRC 2004: 68). This seems very like legal semantics. There is not in fact any difference between the material over which property rights are being claimed and material existing in nature.

In Australia this fine distinction has given rise to the grant of over 14,000 standard patent monopolies over genes and gene-related "inventions" (see Section 8). What was the authority for this radical expansion in the grant of monopolies by the Australian government? It was another decision by a senior official from the Australian Patent Office, on the basis that purification and isolation could be considered to lead to "an artificially created state of affairs" despite the fact that no new material was created.[51] This is a direct reference to the 1959 High Court *NRDC* decision. But the *NRDC* decision—taken as a whole—is much broader than simply determining whether the alleged invention is "an artificially created state of affairs". Central to the *NRDC* decision was the view that that invention created a significant national economic benefit.

Certainly the isolation of erythropoietin has potentially significant global benefits in the treatment of anaemia as it is the protein that initiates the production of red blood cells in bone marrow. It is clear from the decision that many parties were working in this area commencing from 1980: the California Institute of Technology, Genetics Institute, Biogen, Genentech and Amgen. All had commenced work before the end of 1981. At that time, as indicated above, there would have been little expectation of a patent monopoly for materials identical to those occurring in nature. This suggests that this research was not motivated (induced) by the patent system.

In considering whether the invention was inventive in respect to knowledge at that time in Australia,[52] the Deputy Commissioner of Patents noted *the* critical factor in the successful isolation of erythropoietin was *actually obtaining sufficient supplies of erythropoietin*. From this he concluded that the invention was not obvious or all participants in the research would have invested in obtaining sufficient erythropoietin to analyse. This is an interesting perspective. It does not address the issue of whether going on to derive the information claimed in the monopoly involved a "manner of new manufacture". The mere fact of "purification and isolation" was the basis for allowing a monopoly over all commercial uses of identical material to that existing in nature. Effectively the decision to invest heavily in purchasing erythropoietin was the key "inventive" element, and so the crucial factor in the decision to grant a monopoly.

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51 *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557.

52 The earliest claimed priority date for the Kiren-Amgen patent is 13 December 1983, and the application was filed in Australia in December 1984. The decision was therefore determined under the *Patents Act 1953*, when the obviousness test was in respect only of what was obvious in Australia. The application was accepted in June 1990. The patent expired in April 2006, after a 22 year life (http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=1985037467 as at 14 March 2009).

To date this matter—whether the mere fact of isolation and purification should allow the grant of an exclusive monopoly over material identical to that existing in nature— has not been tested in court. It was noted but not analysed by the ALRC.

The ALRC went on to review the submissions made to it, citing a number of submissions from researchers and the healthcare sector opposing the legal fiction that isolated and purified genes and related material are inventions and therefore patentable. It also noted that other submissions considered that patenting of such materials was a "well-established principle" (ALRC 2004: 71). It is interesting to note that the cited submission for this second view were one group of academic lawyers, the Commonwealth Industry Department and four interested parties (two bio-technology companies, a Patent Attorney firm and IPAustralia). As demonstrated above, this "well-established principle" was of quite recent origin, and the Australian precedents involved only two cases, each determined by a senior bureaucrat from the Patent Office.

The ALRC appears to have sought no hard evidence or economic or scientific input. The report concluded that:

> "Although one cannot deny the legitimacy of patenting *processes* for isolating and purifying naturally occurring materials, or the legitimacy of patenting new chemical substances that are the product of human ingenuity, *there are attractive arguments for the view that such materials should not have been treated as patentable subject matter*.
>
> "*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. *This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are 'merely' complex organic compounds.* This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration."
>
> ALRC 2004: 71 (emphasis added)

In other words the ALRC simply did not address a central aspect of its terms of reference. It indicated that the policy of patenting naturally occurring material was not necessarily a good one. But it effectively refused to recommend a better policy simply on the grounds or existing practices. The "existing practices" had in fact been in place in Australia for a very short time. It claimed that change would be out-of-line with international practice, despite clear evidence that not all countries followed the US/EU model. And it made no effort to determine whether the application of an analogy from chemistry to fragments of human and animal bodies was correct.

Thambisetty notes that as biotechnology applications arrived, most patent offices treated gene sequences as variations of chemical products. She notes that this rote approach:

> "is credited with a number of oddities in the way in which genes are now treated in the patent system, including the reliance on structural elements rather than the essential function or 'information' nature of gene sequences."
>
> Thambisetty 2008: 23

In regard to the patenting of genes and related "inventions" Thambisetty points out that the EPO has adopted the European Union Biotechnology Directive without debate, *though it has no legal basis in the EPC* (Thambisetty 2008: 13). She goes on to cite the Economic and Social Committee of the European Commission that the EPO is "naturally attempting to extend its own area of competence and sources of revenue".[53] This suggests that the EPC precedent in regard to gene patenting may have been a self-interested decision by a small group of bureaucrats. Hardly a sound basis for a policy that can substantially raise the cost of access to good health treatments.

In Australia too the decision to grant patent monopolies to materials identical to those found in nature has been made by public servants. The matter has not yet been subject to proper review from the perspective of whether such monopolies are in fact either necessary or provide benefits which exceed their costs. The Committee's deliberations will therefore be of great public interest.

7. Ensuring parliamentary intent is not undermined

There are many areas where parliamentary intent appears to be undermined by specific legal decisions. In some areas—such as tax law, and to a lesser extent competition law—parliamentarians are active in amending legislation to ensure that the policy objectives enshrined in the legislation are not undermined. As noted above there do not appear to be any such cases in regard to patent policy in Australia. Although the Australian government had only recently accepted the IPAC recommendation not to extend patent monopolies to software, no action was taken to reverse the effects of the unfortunate *IBM* decision which opened the floodgates to patenting software. Nor was any action taken to reverse the effects of the Federal Court decision in *CCOM*, where it was decided that the simple computerisation of known mental steps merited grant of a 20-year monopoly.

In defence of judges, it must be said that the *Patents Act 1990* does not have any stated objective.[54] Indeed the Ergas Committee had to go back to 1981 to find a stated purpose for the Patents Act in a Second Reading speech (IPCRC 2000: 136).[55] Nor is it stated anywhere in the Act, except in the definitional reference to the 1623 *Statute of Monopolies*, that there should be balance in the patent system both through its limitation to certain kinds of inventions and through a genuine consideration passing to the Australian people. Lawyers are apparently divided in their views as to whether it is appropriate to include objectives in legislation. However, one might remember that patent policy is economic policy. Most people, economists or not, would agree that if you don't know where you are going, you are unlikely to get there. The patent system is a prime example where the objective is to reach a welfare-enhancing situation, but the destination has been a welfare-reducing one.

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53 Thambisetty 2008: 13 citing ESC Opinion, COM (2002) 92 Final – 2002/0047 (COD) 19 September 2002) 5.4.

54 Lawson also reaches the conclusion that this lack of clarity about objectives is an important factor in the virtual elimination of the inventive step in Australian patent law. He comments that "part of the problem … is that there is no clear statement from the Australian Government about what it believes the patent scheme is intended to achieve" (Lawson 2008: 53).

55 Citing The Hon David Thompson Minister for Science and Technology, April 1981, Second Reading Speech, *Patents Amendment Bill 1981*.

Specifying and including objectives in the patents legislation would do much to assist judges to make decisions which further the innovation objectives of this legislation, and do so in a way that makes Australia better off. Re-introduction of a genuine inventive step would do much to assist. So too would limiting patent monopolies to fields of technology.

It is interesting to speculate as to whether the problem of gene and related patents would ever have arisen had these three improvements to the patent system been adopted. It may well be that the original *processes* for the purification and isolation of genes might have been granted patent monopolies, as these certainly seem to meet the criteria of an invention with sufficient new knowledge to deliver a probable benefit to society. It would be less likely that claims over materials identical to those found in nature would have been allowed. Whether they would have been deemed to be a "manner of new manufacture" under a more balanced interpretation of patent law is moot.

In Australian patent law the key definition of a patentable invention remains a "manner of manufacture within the meaning of Section 6 of the Statute of Monopolies" (Section 18(1)(a)). This definition remained unchanged in the UK from 1624 until it acceded to the EPC in the late 1970s. Australia inherited this definition and has not changed it. As discussed in the introduction, Section 6 comes complete with many caveats. Today these are rarely used. The most recent case where the judge has considered these caveats is the third judgement in the series of four appeals in the *Grant* case. This "invention" was for a method of shifting one's assets to a trust to protect them from legitimate creditors. The judgement by Branson, J is worth quoting at length as it is the most balanced and economically sound patent decision in some time. She commenced with Section 6:

> "Section 6 of the Statute of Monopolies was intended to allow the grant of monopolies limited in time where the public benefit derived from the grant of the monopoly might be expected to outweigh the public cost of the resultant interference with free trade. The same principle underlies modern legislation authorising the grant of patents.
>
> "The principle which has been developed for the application of s 6 of the Statute of Monopolies that seems to me to be critical in this case is the principle that an invention should only enjoy the protection of a patent if the social cost of the resulting restrictions upon the use of the invention is counterbalanced by resulting social benefits. This principle is derived from the theoretical justification for the grant of a patent; that is, the assumed value of inventive ingenuity to the economy of the country. The monopoly granted by a patent to an inventor is assumed to serve the public interest both by rewarding, and thus encouraging, inventive ingenuity and by ensuring the disclosure to the public of a new article or process."
>
> *Grant v Commissioner of Patents* [2005] FCA 1100, 13, 20

This decision was implicitly criticised by Justices Heerey, Kiefel and Bennett in the second Federal Court dismissal of the Grant appeal (on different grounds). In relation to the decision by Branson J, the court held that:

> "It is not relevant, in our view, that some may think that a method or product will not advance the public interest. Once a product or process has been patented, its use is subject to the laws of the land, such as (to take but a few examples) those concerned with environmental protection, pharmaceutical product approval and occupational health and safety.
>
> "Nor is the Court in a position to determine the balance between social cost and public benefit. *Parliament has already made that judgment, as its predecessor did in 1623, by rewarding innovation with time-limited monopoly*."
>
> *Grant v Commissioner of Patents* [2006] FCAFC 120, 44-45 (emphasis added)

This is an extraordinary statement. It totally confuses decisions about overall policy (made by parliament) with decisions on specific cases (to be made by courts).[56] Parliament has certainly decided that it wants a patent *system*, providing a monopoly incentive to invention. But it can hardly be alleged that parliament wants this system to operate *to reduce Australia's well-being*. If the patent system is to deliver a benefit, then most granted monopolies must be for inventions where the public benefit exceeds the social cost. Parliament has left that matter to the courts, and it is extraordinary that the courts are unable to see the difference between the decision in regard to a specific "invention" and the overall outcome for the patent system as a whole. Clearly the courts are in need of greater parliamentary guidance.

Several examples were given above as to the way in which legal semantics are used to undermine the intent and objectives of the law. This is most evident in the UK and at the EPO, given the specific statutory exclusions written into the EPC. It is clear that it also occurs in Australia, though judges here have been so pro-patent that common legal pretences (e.g. that computer software is actually a device or a machine) have been less needed.[57] In regard to the more obvious undermining of the law in Europe examples were given above in relation to software and methods of medical treatment. Another example is in regard to the patenting of animals.

Article 53 of the EPC states that patents shall not be granted in respect of:

> "(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

This seems clear enough. However the EPO has narrowed the meaning of "animal" in this context and has granted patent monopolies for many animal varieties. As long as the whole

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[56] Not to mention the confusion, in the first quoted paragraph, of issues of patentability and issues concerning the rights granted to the holder of a valid patent monopoly.

[57] In delivering a judgement on patent granted by the EPO for the antidepressant drug escitalopram, Justice Kitchen remarked that "currently Australian courts seem to be taking a very propatent view of obviousness and that *patents are being upheld there which are not upheld elsewhere*. The Hässle case and the Viagra case, Pfizer v Lilley (held by the Federal Court of Appeal non-obvious though invalid on other grounds) are perhaps examples of this" ([2007] EWHC 1040 (Pat): at 43 (emphasis added)).

animal is not claimed, the EPO will allow patents on genetically modified animals (Thambisetty 2008: 15-16).[58]

The ability of lawyers to use "clever legal drafting" to undermine the specific exclusions in the EPC is often cited as a reason not to change from S6 of the *Statute of Monopolies*. In both the 1984 IPAC review and the 2000 IPCRC review there were many parties advocating the retention of the "flexible" "manner of new manufacture" approach.[59] However in the period since 1990, the "flexible" approach exhibited by Australian courts has effectively allowed massive extensions in the reach of the patent monopoly system *without any assessment of whether this is good economic policy*.

The "flexible" application of the "manner of new manufacture" test by Australian courts has avoided the normal competition policy requirement that there be a clear demonstration of benefit before introducing new regulation.[60] ACIP has noted that:

> "Previous decisions on the patentability of other controversial areas, such as software, genes, bioinformatics and the treatment of humans, *have not been based on assessments of whether patent protection is necessary* in order to encourage innovation in those particular fields."
>
> ACIP 2003: 33 (emphasis added)

This approach to determining patent policy—argument between private parties with no consideration of hard evidence or the net impact on the community as a whole—has created considerable problems, of which the extension of monopoly privileges to genes and related materials is just one.

Before leaving the important issue of ensuring that parliamentary intent is not undermined, the Committee's attention is drawn to another way in which standard legal practice causes problems in the administration of this particular economic policy. It is conventional that in dealing with particular cases courts only deal with very narrow and specific issues, not the whole of a case. In the ground-breaking 1981 US Supreme Court decision on software, there was a split 5-4 decision. The decision was only in respect of §101 of the relevant statute (patentable subject matter), and did not deal with §§102 and 103 (novelty and inventiveness). But it is clear from the text of the majority decision that the "invention" would probably have failed the §103 test.[61] As the court did not consider this matter the patent was judged valid and opened the floodgates to granting monopolies for software. Had the court also considered §103 the patent may well have been declared invalid.

This is not the only example of courts upholding a monopoly where a condition (for the monopoly grant) is not met. Thus by narrowly considering just one issue, courts permit

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58 Thambisetty goes on to note that the Canadian Supreme Court has taken quite a different position and "concluding by a 5:4 majority that 'higher' animals may not be classified as 'a method of manufacture' or 'composition of matter', although these terms may apply to micro-organisms" (Thambisetty 2008: 16).

59 Data on who supported such a view are not readily available. It is likely that many supporting this view were from the patent community (patent lawyers and frequent users of the patent system).

60 Competition Principles Agreement, clause 5.1 (http://www.ncc.gov.au/pdf/CPAam-001.pdf as at 16 March 2009).

61 "In this case, it may later be determined that the respondents' process is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under §102 or nonobviousness under §103" (Diamond v Diehr 450 US 175; 67 L Ed 2d 155 (1981): 191).

invalid patents to stand. In *Welcome Real-Time*, Heerey J referred to a UK decision about an IBM application for automatic calculation of sale prices for shares by comparing buy and sell orders.[62] He noted that *despite it being accepted that the scheme was not novel*, the patent was held to be valid. That seems an extraordinary decision, and not a sound one to use as precedent if the overall patent system is to be welfare-enhancing.

Clearly there are significant problems in ensuring the integrity of patent monopoly policy. The courts are in need of much greater guidance, and government and parliament need to be more vigilant in providing such guidance. It is inappropriate to allow the objectives of such an important economic policy to be undermined so consistently.

8. Volume of gene patenting in Australia

The Committee's terms of reference ask it to give particular attention to the *impact* of the grant of gene and related monopolies. As noted above, it is rare that any assessment of patent policy asks for actual facts. Indeed patent data systems are structured such that it is difficult to extract data to answer policy questions. Further, the Commonwealth has shown no interest in understanding the impact of the monopolies it so readily grants. The Commonwealth does not require holders of its patent monopolies to provide information on how they are being used, despite a recommendation to this effect by IPAC in 1984. It is therefore unlikely that there will be any systematic evidence available to the Committee to determine the facts of the case.

These empirical difficulties revolve around several issues:

1. identifying all relevant patent monopolies granted in Australia;
2. assessing the boundaries of each such patent monopoly, and considering the benefit provided in the way of genuinely new knowledge, products or processes;
3. identifying whether there are competing products (either patented or not) which provide effectively the same result, and comparing prices of these products.

These issues are discussed below.

8.1. Identifying all relevant patent monopolies granted in Australia

Gene and related "inventions" can be found in IPC classes C12N15 and C12Q168.[63] Table 2 shows some data on the volume of applications and grants in the C12N15 class.

These data show a massive increase in the volume of applications from the early 1990s, as companies realised that patents could be obtained for these "inventions". In total over 42,000 applications had been filed in this class by early February 2009. The volume

62 *IBM Corp's Application* [1980] FSR 564.

63 There are substantial difficulties in identifying patents of a particular type as part of the craft of writing applications is to hide as much as possible. Important key words can often be missing (Stallman 2001; Murphy 2002). Using patent classes might mean some relevant patents are missed, yet it is the simplest and easiest available approach. Because patent classes are very heterogeneous, it may then be necessary to review the identified patents to eliminate those that are not of interest. In some technologies patents can be found in many different classes—for example one study searched over 2,400 patent subclasses to ensure a complete identification for semiconductor product, device and design inventions (Sorensen and Stuart 2000: 91).

Table 2 Australian patent applications and grants in Class C12N15

File Year	Applications	Ceased	Expired	Currently operating	Ever granted	Still in system	Cumulative ever granted	% granted in cohort	% of grants ceased	Cumulative currently operating
2008	329			5	5	309	14,306	2%		**8,352**
2007	745			18	18	677	14,301	2%		8,347
2006	900			47	47	802	14,283	5%		8,329
2005	940			123	123	717	14,236	13%		8,282
2004	1,076	4		250	254	607	14,113	24%	2%	8,159
2003	3,759	16		565	581	510	13,859	15%	3%	7,909
2002	4,740	48		981	1,029	87	13,278	22%	5%	7,344
2001	5,928	136	1	1,062	1,199	1	12,249	20%	11%	6,363
2000	4,487	334	1	958	1,293		11,050	29%	26%	5,301
1999	3,686	491		914	1,405		9,757	38%	35%	4,343
1998	3,031	560		697	1,257		8,352	41%	45%	3,429
1997	2,241	492		534	1,026		7,095	46%	48%	2,732
1996	1,875	461	1	516	978		6,069	52%	47%	2,198
1995	1,552	430		405	835		5,091	54%	51%	1,682
1994	1,321	359		320	679		4,256	51%	53%	1,277
1993	1,045	289	1	246	536		3,577	51%	54%	957
1992	837	280	4	193	477		3,041	57%	59%	711
1991	827	319	6	184	509		2,564	62%	63%	518
1990	685	276	9	161	446		2,055	65%	62%	334
1989	591	271	9	113	393		1,609	66%	69%	173
1988	459	214	60	49	323		1,216	70%	66%	60
1987	371	171	77	2	250		893	67%	68%	11
1986	281	122	66	5	193		643	69%	63%	9
1985	217	108	54	2	164		450	76%	66%	4
1984	171	75	44	1	120		286	70%	62%	2
1983	94	44	20	1	65		166	69%	68%	1
1982	61	26	18		44		101	72%	59%	
1981	46	14	15		29		57	63%	48%	
1980	23	7	13		20		28	87%	35%	
1970s	8	5	3		8		8	100%		
Total	**42,326**	**5,552**	**402**	**8,352**	**14,306**					

Source: AusPat, downloaded 12 February 2009.

appears to have peaked around 2001-02. However the apparent drop in the volume of applications will, at least partly, be caused by the time-lags in overseas applications. The Patent Cooperation Treaty (PCT) allows up to 30 months after first application to definitely proceed in any country.[64] Applications numbers for 2008, 2007 and 2006 will almost certainly be revised upwards over time. Nonetheless it is clear that there has been a large reduction in the volume of applications in this class. Reasons could include a genuine fall in the volume of "inventions" being produced, or applicants might now be trying to avoid this class.

The data also suggest that over time a larger percentage of applications failed to achieve a granted patent. In the early 1980s grant rates were in the 60-70% range, but since 1992 have been substantially lower. Examination is largely incomplete for the years 2003-08, but for years between 1999 and 2003 the grant rates have been in the 20-40% range. The Australian Patent Office rarely refuses to grant a patent. In this class a total of four applications have been refused ever.[65] However if an applicant does not succeed in obtaining acceptance within 21 months of the first examiner's report I believe the application automatically lapses.[66]

As shown in Figure 2, the volume of granted patents built up slowly in the period through to about 1993. Of these early patents, most have now ceased (voluntarily surrendered before expiry) or expired (run their full term). Sixty patents granted from applications in 1988 or earlier are still operating (see Table 2). After 1994 the volume of grants increased markedly, with nearly 1,000 patents being granted from applications in 1996 and just over 1,400 granted from applications in 1999. Figure 2 shows that a certain proportion of these have ceased to operate. In the period 1990 to 1998 between 45 and 63% of patents in each cohort have now ceased. Most patents granted from applications since 1998 are still operating.

Overall this adds up to quite a large volume of gene and gene related patents ever granted—14,306. It should be remembered that this C12N15 class is not the only class in which gene and related patents may be found. It is merely the largest such class. Others are to be found in at least class C12Q168. Recalling that as a pre-condition of WTO membership patents are now required to be granted for a life of at least 20 years, the cumulative impact of these grants is quite considerable. As at 12 February 2009 there were 8,352 operational patent monopolies from applications in this one class. This number has not increased much since 2003 due to the fall in applications since then (see Figure 3).

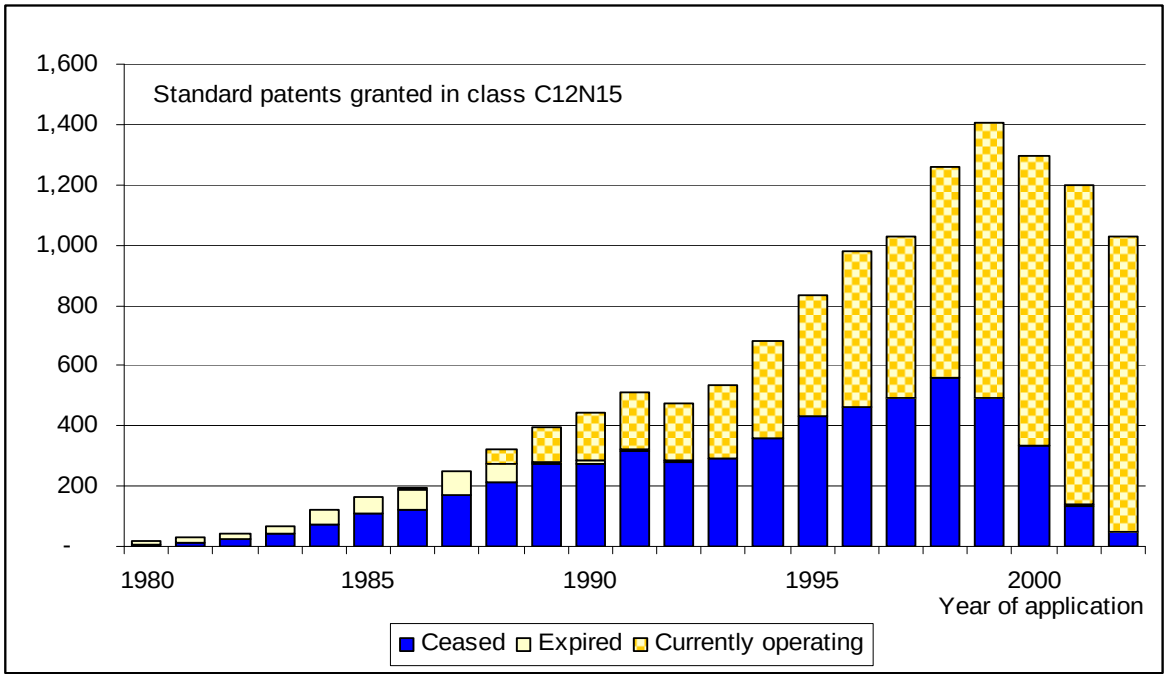
There are, of course, no data on how many of these patents are actively used, either to extract high prices from consumers or Health Departments, to limit the availability of new medical procedures through rationing processes, or to prevent other innovators operating within the "boundaries" of the monopolised knowledge application. Certainly the volume

64 See http://www.wipo.int/pct/en/seminar/basic_1/timeline.pdf for a useful diagrammatic illustration of these timelines (accessed 14 August 2007).

65 Thirteen patents granted from this class have also been revoked (that is granted and then ungranted).

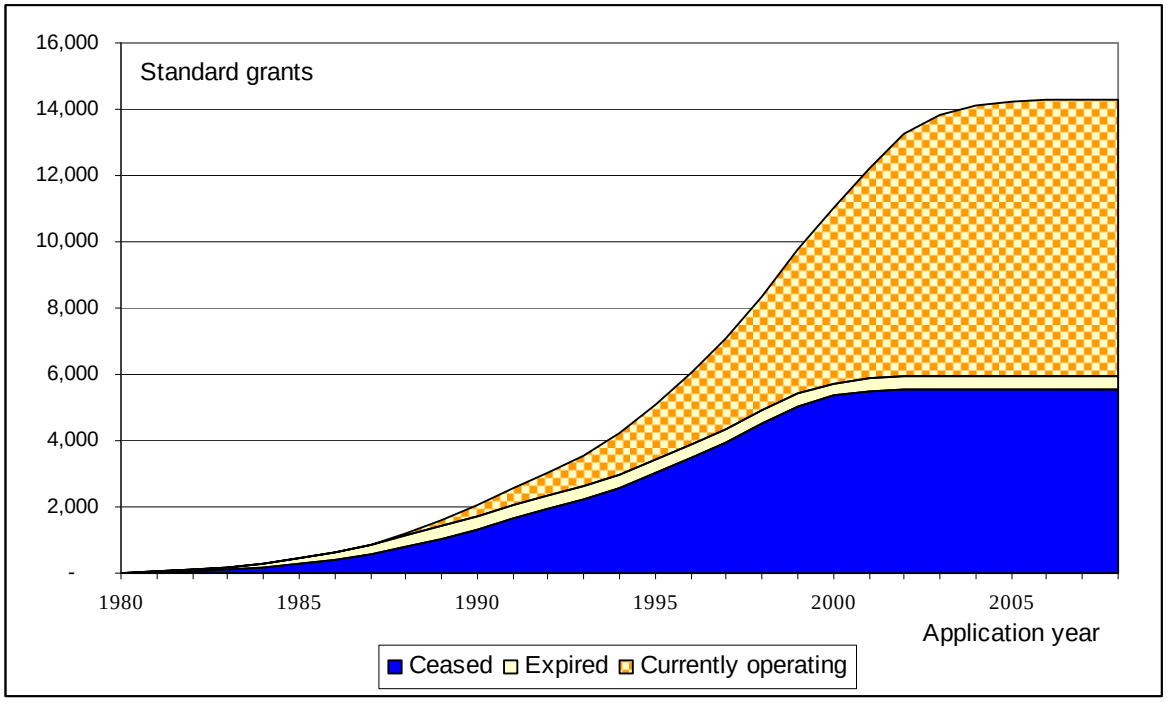
66 I do not know whether an extension can be requested. There are many aspects of patent procedures where extensions are routinely allowed, even where the request is made after the deadline expiry.

Figure 2 Granted biotechnology patents by year of application: 1980-2002



Source: Calculated from Auspat data as shown in Table 12. Data are as at 12 February 2009.

Figure 3 Granted Australian standard patents, class C12N15: by current status



Source: Calculated from Auspat data as shown in Table 12. Data are as at 12 February 2009.

confirms the anecdotal evidence that very many researchers pretend the patent system does not exist, at least in the early stages of research.

This lack of information on the ways in which granted monopolies are used in Australia is a major problem for the development of sound policy. Perhaps the government might now consider heeding the advice of IPAC in 1984 to collect regular information on how the monopolies it grants are used. There are several ways to do this. The Patent Office could develop a short form that would be an essential part of the renewal process, say every second year after sealing. One could go further and require that the Patent Office be notified before any monopoly is used. This sounds draconian, but information on the uses of monopolies is surely a very small price to pay for their grant.

Further, such an approach might avoid the recent contretemps with the breast cancer predisposing gene patents (BRCA1 and BRCA2). In Australia these patents—and there are several of them—are controlled by Genetics Technologies Ltd (GTL), a publicly listed company. The actions of this company in enforcing its patents were a key factor leading to the establishment of the ALRC inquiry into gene patents. In May 2003, during the inquiry, GTL announced it would not enforce its patent rights, describing this as a "gift to the people of Australia." Despite this gift, in July 2008 GTL wrote to many Australian laboratories advising that within 7 days it would commence enforcing its patents. Naturally this led to a loud public outcry, and I understand the revulsion at this company's behaviour was a precipitating factor in the establishment of the current enquiry. Had GTL been required to register its intent to use its patent, it would also have registered its gift to the nation in 2003. The Patent Office would then have been able to remind the company last July that it could not then re-enforce the patent as it had alreadymade a gift of the use rights.

In GTL's defence, it is important to note that what they tried to do was simply to exercise the rights granted by the Australian government through the Patent Office. The right to charge high prices and limit use is the essence of the patent monopoly.

If the government does not want to risk such incidents, it needs to cease the current practice of granting patents for genes and related materials and for methods of medical treatment.

8.2. Assessing patent boundaries and benefits

In addressing the impact of these granted patents on the provision of healthcare, the pursuit of medical research, and the general health and well-being of the Australian people it would be useful to know the boundaries of the monopolies granted. It is often argued that one reason property rights are essential is so that people may clearly understand who owns what. Good boundary identification and signalling is essential for property rights to work well, and with physical property there are few disputes about inadvertent trespass. Boundaries are clearly established and signalled.

It is quite otherwise with patent monopolies. Bessen and Meurer have recently shown, for the USA, how poor is the boundary signalling of the US patent system (Bessen and Meurer 2008). They find that *almost every dispute that reaches court involves <u>inadvertent</u> trespass*. The allegedly infringing firms *simply did not know* they were trespassing. The remarkable story of the 1986 *Kodak v Polaroid* case, which involved massive damages as well loss of

many jobs and much investment (Jaffe and Lerner 2004: 113-114),[67] was one where Kodak had gone to extraordinary lengths to ensure it was not trespassing on Polaroid's patents, changing their research to accommodate this. The court disagreed.

If this alleged "property" system does not allow other innovators to avoid trespass, then it fundamentally fails as an efficient economic institution.[68]

Patent boundaries are unclear because they are written in legalese, and because applicants frequently claim ownership of technologies they do not fully possess. This over-claiming (through broad and vague claims) is a particular problem the closer the patent lies to the area of pure science. The over-claiming in the case of the Harvard mouse is famous. In some jurisdictions DuPont has been granted monopoly rights for "all mammals" not just those on which the inventors of the oncomouse worked.

The patent system is not designed to give monopolies over knowledge—that would be clearly welfare-reducing. Rather, it is designed to allow monopolies over the first development of new and inventive artefacts based on knowledge. But when a patent claim is for a method of testing for the existence of a mutant gene—as in the GTL breast cancer gene patents—the owner is given the right to monopolise much more than they have actually discovered. For example, where the monopoly is for a medical test, and the owner requires that all tests be done in their laboratories, this provides the owner with a vast new database that is withheld from other researchers. At no time was it envisaged that such additional property could be appropriated as a result of a patent for invention.

Ideally the Committee will receive from IPAustralia a full, detailed and precise description of all gene and related monopolies granted in Australia. In fact this would probably take vast resources. If it is not reasonable for a well-resourced government agency to provide a full description of the boundaries over which monopoly rights have been granted, how reasonable is it for medical researchers and other innovators in this field? This directly suggests that action needs to be taken to radically improve the clarity and precision of patent monopoly claims. The Cutler review (of the national innovation system) has made a recommendation to this effect. Further, the Patent Office should be charged to ensure that applicants are not allowed to continue with claims over matters they do not own.

Given the above, perhaps the Committee could ask IPAustralia to identify the more important of the granted monopolies, and clearly describe the boundaries of these. This would allow the Committee to determine the likely impact of these monopolies on the health system, medical research and the well-being of Australians generally. Importance could be determined in terms of those patents most used for medical testing and those at leading areas of research into important human and animal diseases. An example of the basic analysis that could be done was published in *Science* in 2005 (Jensen and Murray 2005). This focused on US patent claims over human protein-encoding nucleotide

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[67] Kodak paid US$925m and closed the plant that had employed nearly 1,000 full-time workers and nearly 4,000 part-time workers.

[68] The "property rights" approach to patent monopolies derives from spin-doctoring during the French Revolution, where key interested parties changed the language from Royal Prerogative to fit the new human rights agenda (Machlup and Penrose 1950: 16). In Anglo-based legal/economic systems it has always been understood that patent monopoly systems are an instrument of economic policy, not a "right". Given the frequency of simultaneous invention the rights-based theory is not credible.

sequences, and found that heavily monopolised genes were those relevant to human health. They noted "hot spots" of patenting activity, usually in the one-gene-many-patents format. This scenario of dense overlapping patent monopoly claims is exactly where boundaries are most difficult to discern, raising the strong likelihood that resources will be wasted in patent litigation.

8.3. Identifying closely competing products and comparing prices

Until the information recommended above is produced, it is simply not possible to identify which of the 8,352 operating gene and related patents are for products or processes where a viable alternative is available. Where no alternative is available, then it is inevitable that a high price will be charged. *This is after all the essential right granted by the patent system.*

Once important patents (and their boundaries) have been identified it will be possible to estimate the cost to Australia of the grant of these rights. These estimated costs can then be assessed against any benefits flowing from the grant of monopoly rights. The principal of these alleged benefits is the (earlier) invention of useful new products and processes.

Where there are no good substitutes for diagnostic tools or other methods important in effective treatment of the health problems of Australians, there is likely to be a strong price effect. The breast cancer gene patent is perhaps the best known example.

It is in this area that the problems of granting monopolies over genes and gene fragments become particularly evident. Granting the right to prevent any commercial use of "isolated and purified" genes and related materials effectively prevents the development of alternative artefacts based on these naturally occurring materials.

A long-standing important tradition in the patent monopoly system has been that knowledge cannot be patented. Patent monopolies are only for the derived *artefacts*. This ensures that knowledge remains in the public domain for all to use freely. This was (and remains) a major reason for not allowing monopolies on materials that exist in nature. If monopolies are granted over the use of such materials, this removes them from the public realm, thus inhibiting (or greatly increasing the cost of) alternative lines of research.

There was a longstanding view that patent monopolies for chemical compositions were bad economic policy, although monopolies were granted for processes to produce chemicals. The well-known global competitiveness of the German chemical industry was based on a system which allowed patents on processes but not on products (Dutfield 2003). The UK only ceased to prohibit patents on chemicals as it was unable to prevent lawyers patenting every possible method and thus effectively patenting the product. Since then we have learned (through procedures introduced into taxation law) how to stop intermediaries undermining the intent of legislation (Braithwaite 2005). The effectiveness of such procedures is solely dependent on a government's willingness to ensure its policy objectives are not undermined by self-interested parties.

In regard to genes and related materials the patent owner is granted all commercial rights over the actual genetic material in its isolated and purified form. This prevents other researchers from developing alternative tests and procedures. Such alternatives might be of higher quality (including faster) and/or of lower price.

As part of the general expansion in the reach of the patent system, there has been a trend to allowing the patent system to venture further into the realms of pure science and away from technological artefacts. The granting of monopolies over materials identical to those existing in nature is part of this trend. It has the same negative consequences, by unnecessarily prohibiting competition in research, once a monopoly has been granted. Further, modern legal techniques of developing a surrounding "fence" or "thicket" of patents effectively extends the monopoly period beyond 20 years.[69]

8.4. Are monopolies needed to induce research in this area?

In the *Kiren-Amgen* case discussed above (p. 28) it is quite clear that many different teams were attempting to develop sufficient understanding of erythropoietin to be able to develop useful medical tests. This research commenced in 1980-81 *when there was no expectation that patents would be granted for these materials*.

There is general agreement that, to the extent there is any case for intervening in the innovation market, it is in those areas where initial development costs are too high to be recouped in the period when the innovator is the only seller in the market. This "first in the market" period can be short in those relatively rare cases where copying costs are insubstantial. It is often alleged that pharmaceuticals and fine chemicals are the pre-eminent cases where these two characteristics combine to create failure in the innovation market. By analogy the biotechnology industry has claimed a similar situation.

It is useful to consider whether the evidence supports these claims.

Mansfield's original research (reported above, p. 10) shows that the pharmaceutical and chemicals are more dependent on patent monopolies than any other industry/technology. yet his research also shows that over a third of pharmaceutical innovations and over 60% of chemical innovations *would have been commercially developed in a world without patents.*

Boldrin and Levine provide an extremely useful perspective on the monopoly claims of the pharmaceutical industry. Indeed they devote a chapter to it. They report that 1,390 new active chemical compounds were discovered in the period 1961-1982.[70] They investigate the 15 top medical and pharmaceutical milestones nominated by readers of the *British Medical Journal* in 2005. Only two were motivated by the possibility of a patent monopoly (chlorpromazine and the contraceptive pill) (Boldrin and Levine 2008: 259). As a second test they considered the list of top pharmaceuticals published on the website of the Chemical and Engineering News. They investigated all 46 of these and found:

> "Patents had pretty much nothing to do with the development of 20 among the 46 top selling drugs … . For the remaining 26 products patents did play an important role … .. Notice though that of these 26, 4 were discovered completely by chance and then patented (cisplatin, librium, taxol, thorazin) ... Further, a few were simultaneously discovered by more than one company leading to long and expensive legal battles."
>
> Boldrin and Levine 2008: 259-260

[69] Of 174 Australian standard patent applications with the word "erythropoietin" in the title, 12 by Kirin-Amgen Inc (priority dates from 1983 to 1989) and a further 5 by Amgen, Inc (priority dates from 1994 to 2006) (AusPat search 18 March 2009).

[70] This is of course a small fraction of the number of pharmaceutical patents granted in the same period.

Beyond these pieces of evidence, there are of course the well-known problems of diseases where no effective treatments are being developed as the populations at risk provide an insufficiently large market to attract the global pharmaceutical companies. Further, a very large part of the funding for the basic medical research on which patented products are based is often provided by governments or non-profit foundations. In these last cases it seems hard that Health Departments should then have to pay monopoly prices for products whose development was largely funded by taxpayers or philanthropists.

Finally it should be noted that the players in the biotechnology industry were very divided about the need for and possible benefits or costs of patent monopolies in the period before patents began being granted in this technology field. An interesting academic evaluation of the growth of the US biotechnology industry in the period 1976-1989 emphasises the importance of intellectual capital in the industry's development, but does not mention patents once (Zucker et al. 1998).[71] They find that it is the expert and tacit knowledge embodied in individual scientists which was critical in the development of the industry, and that this provides "natural excludability". This is economic jargon for saying that the investment costs can be recouped as there will be a sufficient period of time before others are competent to use the new applications of knowledge and enter the market with competing products. At later stages in the development of the industry, of course, knowledge and its use becomes more routine and more codified, and is thus less expensive to copy. Of course it is by definition then very much less inventive. The Zucker article is a lovely example of how natural mechanisms work very well to ensure a good level of innovative investment without any need for patent monopolies.

Brief as these pieces of evidence are, they are a clear indication of the need for proof concerning the inevitable allegations by interested parties that patent monopolies are essential for the development of new treatments.

9. Impact of patent monopolies on health and general well-being

The patent system works by sanctioning the charging of high prices to recoup the cost of investment in research and development.

Further, the patent right is the right to exclude—that is, to prevent others from using similar *but independently invented* products and processes.

In general there are few if any data available on the impact of the high prices of patented drugs on mortality and morbidity. We all know that many thousands if not millions of poor people in low income countries are unable to access needed medicines. We know that there are multiple causes for this (poverty, isolation, generally poor medical infrastructure), but we all also know that high prices play a role. Providing for patent monopolies on medicines directly increases mortality and morbidity rates, through this price effect. In richer countries with public health systems, it increases the taxpayer cost of health care provision.

Consideration of the issue of whether monopolies should be granted for genes and related materials and processes should be on a sound basis of specific and credible evidence that the market intervention is:

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[71] Except, that is, in the bibliography, where some of the cited literature has the word patent in the title.

(i) necessary;

(ii) that its benefits exceed its costs; and

(iii) that there is no alternative better means of achieving those benefits.

One might note here that the patent monopoly system pre-dated public financing of research, and taxpayer subsidies for many aspects of private investment in research (such as the R&D tax concession). There has not been any re-assessment of the need to maintain the patent monopoly system in this new environment.

The decision to allow 20-year monopolies in Australia for materials identical to those found in nature is based on two decisions by public servants (ALRC 2004: 68). This is an inadequate way to make such an important decision in a democracy. The decision needs revisiting *ab initio*, and the following questions need to be answered in the affirmative, and on the basis of strong empirical evidence if such monopolies are to be granted.

- Are patent monopolies demonstrably needed to encourage R&D that would not otherwise take place?
- Do these monopolies simply bring forward in time research findings?
- What additional costs do individuals and the taxpayer incur in paying higher prices for patented health products?
- Can it be shown that downstream invention and the development of improved tests is not inhibited?
- What about the double-dipping in regard to public funding of medical research?
- What about the double-dipping in regard to copyright protection of databases where a condition of the patent use is use of a particular laboratory?

As indicated above, there is strong empirical evidence that patents are generally not needed to induce R&D investment—market mechanisms provide the possibility of a good return. In a country such as Australia only about 3% of patents might be induced by the monopoly incentive and it is these which must provide sufficient benefits to offset the costs they and the other 97% impose. This is because most Australian patent monopolies are not owned by Australians, so the benefits flow overseas. In a country like Australia, it is essential in answering the above questions to check whether benefits or costs are incurred by Australian or overseas companies and individuals.

It is well-known that simultaneous invention is frequent (Mokyr 2002). It is also well-known that knowledge is cumulative. As patent monopolies prevent independent invention they can have a potentially chilling effect on later invention. At its extreme the prevention of independent invention can hold up major technology developments. Perhaps the most famous example is James Watt, whose refusal to license his patents is generally considered to have held up the Industrial Revolution by several decades (Ashton 1948; Boldrin and Levine 2008). Other famous examples are the Wright brothers' stabilisation and steering systems for aircraft and Edison's incandescent lamp (Cohen 2005).

Examples of technological hold-ups do not need to be pervasive to have a large social cost: if "the technology in question is sufficiently important, only one or a few instances … may impose considerable social cost" (Cohen 2005: 63).

In the health area, the earlier availability of an improved treatment can reduce suffering and save lives. But this benefit must be considered against the cost of the research impeded and the health treatments foregone because of high prices. The possibility of technological hold-up must also be considered where monopolies are granted over “isolated and purified” genes and gene fragments.

The patent monopoly system is usually considered in isolation and from a legal perspective. But its objectives are economic. It is directed to an economic variable of significant national interest—innovation. It is just one of many tools operating together to achieve a socially optimal level of investment in the development of new products and processes. In a technology area like health, where a significant part of the R&D investment is funded publicly or by philanthropists, and where there are grant and tax programs to offset the cost of corporate investment, it is entirely appropriate to ask about double-dipping. Why should a private monopoly be granted to offset the costs of investment where most of these costs have not been privately incurred?

The expansion in the reach of the patent system has been accompanied by an expansion in the reach of the copyright system. The copyright system in Australia no longer requires creativity, and copyrights are now granted for such matters as databases and surveyors’ plans of house plots (blocks and sections). Overseas cases have been reported of copyright being claimed over the wording of patent specifications. The important issue of the extension of market power through the acquisition of very valuable databases has been raised. This side-effect of allowing patent owners to control where medical tests are performed raises major competitive and public interests issues in its own right.

In essence monopoly grants for human and microbial genes and non-coding sequences, proteins, and their derivatives is an issue of competition policy. Does this regulatory intervention in the innovation market create sufficient benefits to offset the costs? Has it been *demonstrated* that the market is not working?

Despite patent policy being a regulatory intervention into the innovation market, and indeed a policy which alters the overall allocation of resources between sectors, it has not been properly assessed under the Competition Principles Agreement. That requires that:

> “legislation should not restrict competition unless it can be demonstrated that:
> (a) the benefits of the restriction to the community as a whole outweigh the costs; and
> (b) the objectives of the legislation can only be achieved by restricting competition.[72]

This principle is fundamental to ensuring that public policy is shaped in the public interest. It achieves this by requiring that the proponents of a regulatory intervention produce evidence *demonstrating* that the benefits exceed the costs. It is an excellent example of the evidence-based approach to policy, and a key plank in ensuring that democratically – elected governments are not suborned by well-resourced private interests.

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[72] Competition Principles Agreement, http://www.ncc.gov.au/pdf/CPAam-001.pdf, clause 5.1.

I have actively searched for evidence that there has ever been such a review of any patent system. I have found none.[73] This Committee has the opportunity to put the public interest first and require that the narrow sectional interests seeking a private advantage through the use of government power *demonstrate* that this will benefit all Australians.

[73] The 1984 IPAC review was set up as an economic review, and collected a wide range of economic data. The researchers concluded that "this study leaves little room for doubt that the benefit/cost ratio of the patent system in Australia is negative, or at the very best, in balance" (Mandeville et al. 1982: 213). Nonetheless IPAC recommended only minor changes, and the sole economist on IPAC lodged a dissenting statement (IPAC 1984: 79-80). The Ergas Committee did an excellent job reviewing the issue of the parallel importation of copyrighted material, but ducked applying the Competition Principles when it came to the patent system (Lawson 2005).

Terms of Reference

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

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

(i) the provision and costs of healthcare,

(ii) the provision of training and accreditation for healthcare professionals,

(iii) the progress in medical research, and

(iv) the health and wellbeing of the Australian people;

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

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

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