



Submission to the  
Advisory Council for Intellectual Property  
on the Issue of  
Patentable Subject Matter  
In Australia

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## Overview

The trigger for this Inquiry originates with the ALRC *Genes and Ingenuity Report 99* and ‘the problems with the manner of manufacture test’ identified in that Report. The first concern which the ALRC had with the current patents legislation was that the concept of ‘manner of manufacture’ in s.18(1)(a) depended upon a provision in an ancient statute that had ‘long been repealed in the jurisdiction in which it was enacted’, namely the United Kingdom. The second concern was that the proviso in s.6 of the *Statute of Monopolies, 1623* limited patentability on the ground that the subject matter was ‘generally inconvenient’.

That said, despite raising these issues, the ALRC did not actually demonstrate by way of an example how the *AU Patents Act, 1990* had resulted in the exclusion from patentability of any ‘human gene’ or isolated biological material and its biotechnological application in a device, machine, medicine, vaccine, process or method. In point of fact the ALRC accepted that ‘the legitimacy of patenting processes for isolating and purifying naturally occurring materials’ could not be denied. Additionally, the ALRC reported that although genetic sequences were ‘not foreseen when the modern patent system was established’, there was no evidence that the ‘generally inconvenient’ proviso had prevented or hindered the application and grant of patents in Australia over isolated or purified DNA or their biotechnological application.

**Thus it would seem that the so-called ‘problems’ to which the ALRC alluded to were not then, nor are they now, ‘problems’.**

While *NRDC* (1959) was, at the time, an important decision in the field of patent law because its reasoning reached the zenith of jurisprudential reasoning on the issue of patentable subject matter after nearly 350 years, its true purport and impact has been misrepresented in the Issues Paper. The decision is not generally permissive in expanding patentable subject matter. What *NRDC* and subsequent Australian court cases show is that there is now a well established test of patentable subject matter or ‘invention’ and that the Australian courts, in the main, are quite capable of acting as the gatekeepers of patentability when they are given the opportunity. That the language of the Australian test goes back in time to 1623 is not problematic at all.

**The real problem is that not enough Australian patents are subjected to the scrutiny of the Australian courts.** Consequently many patents remain on the Patents Register when they should not. Not only are the numbers of patent applications growing but, as a result, the quality of the assessment by IP Australia is falling. It is therefore critically important that the inherent patentable subject matter limitations be rigorously applied and to the extent that IP Australia is unable to do so, other mechanisms should be put in place that will. **Clearly, the problem is not the language of s.18(1)(a). The problem is the failure of IP Australia to fulfil its primary legislative duty to act as a patent gatekeeper.** Unfortunately, the Full Federal Court decisions in *Rescare* and *Bristol* have made it difficult for the Australian courts to fully perform their duty by holding that issues of public policy in relation to patentable subject matter are to be resolved by Parliament alone. These decisions are wrong and must be overturned by Parliament restating, by way of a simple amendment, its intention to have the courts assess the economic and social impact of patents as part of their assessment into patentable subject matter. A wholesale rewrite of s.18 is unnecessary.

That said, there are specific subject matters that have become problematic mainly because IP Australia is misapplying Australian patent law. Accordingly, biological materials which are identical or practically indistinguishable from natural biological materials and their derivatives should be expressly excluded from patentable subject matter under an amendment to s.18(2). Neither should patents be granted for inventions that involve the technical application of excludible subject matter, such as computer programs and isolated biological materials, in methods and processes that are obvious or that achieve obvious results, particularly, if there is no *tangible* output. As such, business methods must be expressly excluded from patentability under an amendment to s.18(2) so as to make it clear that such innovations are beyond the patent system in their entirety.

## 1. Issues and Questions

### Can placing limits on inherently patentable subject matter be justified on economic grounds?

Yes. The *Statute of Monopolies* in 1623 put into effect an economic policy to promote free trade and competition by outlawing all monopolies except those expressly exempted. One of these, described in section 6, was the genesis of the Anglo-American patent systems. When the US Congress passed the first *US Patents Act* in 1790 it applied the same economic policy by limiting the grant of patent monopolies to ‘inventions’, defined as ‘any new and useful art, manufacture, engine, machine, or device, or any improvement therein’.<sup>1</sup> One hundred years later, the US Congress reinforced the primacy of that economic policy by passing the *Sherman Act, 1890*<sup>2</sup> and shortly thereafter, the *Clayton Act, 1914*<sup>3</sup>. Indeed, the primacy of this policy was acknowledged by the US Supreme Court in 1922 when it ruled that ‘[t]he patent grant does not limit the right of Congress to enact legislation not interfering with the *legitimate rights* secured by the patent’.<sup>4</sup>

The centrepiece of Anglo-American economic policy is free trade and competition, and to the extent that patent monopolies may compromise that economic policy it must only be permitted under very limited circumstances. According to the US Supreme Court in *Motion Picture Patents Co v Universal Film Mfg Co* 243 US 502 ‘[w]hile one great object [of patent law] was, by holding out a reasonable reward to inventors and giving them as exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main objective was ‘to promote the progress of science and useful arts’.<sup>5</sup> Thus the US Supreme Court appreciates that the exclusive rights of a patent owner and the promotion of science do not always coincide. In *Laboratory Corporation of America Holdings v Metabolite Laboratories, Inc* 548 U.S. 124 (2006) (LabCorp), Breyer, Stevens and Souter JJ<sup>6</sup> of the US Supreme Court highlighted the tension generated by balancing free competition and patent monopolies explaining that ‘too much patent protection can impede rather than “promote the Progress of Science and useful Arts,”’. While on the one hand patents ‘encourage research by providing monetary incentives for investment’, they may discourage research ‘by impeding the free exchange of information’.<sup>7</sup>

Therefore, for nearly four hundred years it has been accepted that patent monopolies can, and should, be struck down on economic grounds *in limine* (at the threshold). In the Australian context this policy comes through in the proviso in s.6, *Statute of Monopolies, 1623*, which provides that an innovation, though a ‘manner of new manufacture’ (that is, something capable of being an ‘invention’), may nonetheless not be the proper subject matter of a patent because it is ‘contrary to the law ... [or] *mischievous to the state by raising prices of*

<sup>1</sup> ‘The relevant principle of law “excludes from patent protection ... laws of nature, natural phenomena, and abstract ideas”’: *Diamond v Diehr*, 450 U.S. 175, 185 (1981).

<sup>2</sup> The *Sherman Act* provides, ‘Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony.’

<sup>3</sup> The *Clayton Act* created a cause of action enabling ‘any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws’ to sue for damages.

<sup>4</sup> *Standard Fashion Co v Magrane-Houston Co* 258 US 451 (1922), 463-64 (emphasis added).

<sup>5</sup> *Motion Picture Patents Co v Universal Film Mfg Co* 243 US 502, 510.

<sup>6</sup> Their decision was in dissent, but only in respect to the decision of the majority (which excluded the Chief Justice) to dismiss the writ of certiorari.

<sup>7</sup> ‘... for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.’ As per Justices Breyer, Stevens and Souter in *Laboratory Corporation of America v Metabolite Laboratories* 548 U.S. 124 (2006).

*commodities at home, or hurt of trade, or generally inconvenient*<sup>8</sup> (emphasis added) which is why in *NRDC* the High Court of Australia held that the first and primary threshold for the grant of a patent was this: *Is [the alleged invention] a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?*'

**Should the subject matter of each individual invention be assessed to determine whether a patent is necessary to encourage innovation, or should such an assessment be done for entire fields of technology?**

It should not be assumed that patents encourage innovation across all fields of technology or in all circumstances. In fact, it is possible that there are fields of technology and circumstances where patents, as pointed out in *LabCorp*, may actually repress innovation. There is presently a real need in Australia for empirical and statistical data that can be used reliably to provide policymakers with accurate and relevant information upon which they can develop appropriate economic policies that do not *unnecessarily* erode free trade and competition.

That said, there are two patentable subject matter thresholds.

The first, however, consists of two parts.<sup>9</sup> First, the subject matter of the patent must be a 'manner of manufacture' (i.e., something capable of being an 'invention'). Secondly, 'invention' must not contravene the proviso in s.6, *Statute of Monopolies, 1623*. This threshold is referred to in the Issue Paper as 'inherently patentable subject matter' and is encapsulated in s.18(1)(a) *AU Patents Act, 1990*.

The second is a per se prohibition on patentability. Presently, s.18(2) provides that '[h]uman beings and the processes for their generation' are excluded from patentability. It is conceivable that an alleged invention may satisfy s.18(1)(a), yet be prohibited from patentability because it violates s.18(2).

Clearly, both thresholds must be satisfied by every patent application if the invention is to be the subject of a valid patent, but while it is possible to prohibit entire fields of technology from patentability as s.18(2) does, it is less likely for this to be possible under s.18(1)(a). This is because the assessment under s.18(1)(a) has two parts, the first being that the alleged invention be a 'manner of manufacture', and this threshold applies regardless of the field of technology to which the alleged invention belongs. What this means, in practical terms, is that if the alleged invention falls within a class of per se prohibited subject matter, then it will be unnecessary to assess its compliance with s.18(1)(a) because the per se prohibition renders that assessment superfluous.

**What would be the consequences on innovation of imposing or removing limits on patentable subject matter?**

The most significant consequence of removing limits on patentable subject matter is to encourage the proliferation of private patent monopolies in Australia and this is inconsistent with the economic policy put into effect by s.1, *Statute of Monopolies, 1623*.<sup>10</sup>

<sup>8</sup> 'A principled approach to the question [under s.18(1)(a)] requires the resolution of two separate issues. First, is [the alleged invention] "a manner of new manufacture" within s 6 of the *Statute of Monopolies*? Second, if such [alleged invention] is "a manner of new manufacture", does it fall within the proviso so as to be excluded from patentability?' as per Finkelstein J in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524, para 128.

<sup>9</sup> *Ibid.*

<sup>10</sup> 'All monopolies and all commissions, grants, licenses, charters and letters patent theretofore made or granted or heretofore to be made or granted to any person or persons, bodies politic or corporate whatsoever, of or for the sole buying, selling, making or using of anything within this realm ... are utterly void and of none effect.'

A by-product of the Australian patent system, indeed of any patent system, is *innovative competition*, which possibly provides the only justification for the exception in s.6, *Statute of Monopolies*. This is because innovative competition creates the incentive for technological development and scientific advancement, which are both promoters of economic growth. Accordingly, patent monopolies should only be granted with respect to ‘inventions’ and not to the elucidation of the laws of nature or to the discovery of natural phenomena or to the formulation of abstract ideas, which, as Breyer, Souter and Stevens JJ in *LabCorp* pointed out, are excluded by a principle of patent exclusion that ‘finds its roots in both English and American law’.<sup>11</sup>

At a most elementary level what this means is that patents should not be granted over subject matter that give to patent owners the power to control down-stream research with respect to anything that involves the use of that subject matter. An example of where this is presently occurring is in respect to isolated biological materials. Many of the patents which claim isolated biological materials as ‘inventions’ also claim within the scope of the patent monopoly every actual, conceivable and speculative technical application of the isolated biological material in an attempt to garner control of all diagnostic, therapeutic and medicinal uses that those biological materials may be put to.<sup>12</sup> This kind of patent monopoly destroys innovative competition, because it not only deprives others of any economic reward regarding the development of applications that involve those biological materials, but it gives to the patentee the power to control absolutely what others may do with the isolated biological materials that fall within the scope of the patent monopoly. In these circumstances it becomes virtually impossible for others to invent around the patent monopoly because the isolated biological material is the key. As Jordan Paradise, Lori Andrews and Timothy Holbrook,<sup>13</sup> professors of intellectual property law, have pointed out, when it comes to human gene sequences, ‘the “invention” is the information’<sup>14</sup> about the natural world. Consequently, ‘[g]ene patents, especially, limit what can be done in the realm of scientific research and medical care because there are no alternatives to a patented gene in diagnosis, treatment, and research.’<sup>15</sup>

Arguably, isolated biological materials are not ‘inventions’ and so patents should not be granted over these materials or their derivatives. But IP Australia, along with other patent offices around the world, has associated the step of isolation with the step of invention in order to justify the grant of patents over isolated biological materials. The consequence has been to encourage the monopolisation of medical and scientific research at very early stages of the innovation process, and this, as Harold Varmus<sup>16</sup> has observed, is having ‘detrimental effects on science and its delivery of health benefits.’<sup>17</sup>

### **Are you aware of any empirical data on such consequences?**

Yes. Between 1877 and 1968 Germany (which between 1945 and 1990 was known as West Germany) imposed patentable subject matter limitations by expressly prohibiting patents with respect to chemical substances. Other industrially developed countries followed suit.<sup>18</sup>

<sup>11</sup> Op cit 1.

<sup>12</sup> As an example the claims in AU 624,105 entitled ‘NANBV Diagnostics and Vaccines’ claim isolated polypeptides and nucleotides of any strain of hepatitis C virus and the use of those materials in all manner of therapies, including vaccines that, to date, do not exist.

<sup>13</sup> Paradise, J., Andrews, L. and Holbrook, T. (2005), ‘Patents on Human Genes: An Analysis of Scope and Claims’, *Science*, 307, 1566-1567.

<sup>14</sup> Ibid, 1566.

<sup>15</sup> Ibid.

<sup>16</sup> Harold Varmus was the Director of the US National Institutes of Health between 1993 and 1999.

<sup>17</sup> Testimony of Harold Varmus before a US House Judiciary Subcommittee On Courts And Intellectual Property, July 13, 2000, Hearing on *Gene Patents And Other Genomic Inventions*.

<sup>18</sup> These included France which prohibited patents on chemical substances as products until 1960; Italy,

According to a 1990 World Bank Report<sup>19</sup>, in 1988 forty-eight countries prohibited patents over pharmaceuticals.<sup>20</sup> Furthermore Australia was among eight countries<sup>21</sup> that also prohibited patents on pharmaceutical processes. According to this Report, the exclusion of pharmaceutical product patents was part of ‘a policy for enhancing competition in the drug market’ in those countries.

Even the United Kingdom prohibited the patenting of chemical substances in 1919;<sup>22</sup> although this was lifted by the *UK Patents Act, 1949*, the extremely broad compulsory licensing powers exercisable by the Comptroller of Patents which replaced it meant that generic versions of patented medicines would be ‘available to the public *at the lowest prices* consistent with the patentees’ deriving a reasonable advantage from their patent rights’.<sup>23</sup> And while the primary objective of these compulsory licensing powers was to control the price of patented medicines,<sup>24</sup> the secondary purpose was to enhance national security by encouraging the domestic production of generic pharmaceuticals, which also had the effect of promoting British medical and scientific research, industrial development, economic growth and employment.

However, during the 1960s and 1970s US pharmaceutical companies tired of what they saw to be discriminatory patent practices aimed at pharmaceutical products and began to lobby European governments for a change in this policy. Success came swiftly with the first draft of the European Patent Convention (EPC) in 1963. Under this draft the technological discrimination of ‘inventions’ was prohibited.<sup>25</sup> By 1968 Germany had lifted the limitation of the patenting of chemical substances<sup>26</sup> and, by 1973, the final version of the EPC confirmed that all members of the European Economic Community would follow Germany’s lead. By the late 1980s the prohibition on the technological discrimination of inventions that was incorporated into art. 52(1) EPC had become the subject of the European Union’s draft of TRIPS during the Uruguay Round of the GATT and by 1995 was incorporated into art. 27.1 TRIPS.

Unfortunately for Italy’s generic pharmaceutical industry the EPC was an economic disaster<sup>27</sup> and India’s accession to TRIPS has not significantly enhanced India’s pharmaceutical industry.<sup>28</sup> Rather, it has significantly retarded India’s ability to provide essential medicines to people in developing countries who do not have the capacity to pay the price of patented

1978; Japan, 1976; Sweden, 1978 and Switzerland, 1977.

<sup>19</sup> Noguees, J. (1990), ‘Patents and Pharmaceutical Drugs’, World Bank Working Papers.

<sup>20</sup> Argentina, Australia, Bolivia, Brazil, Bulgaria, Chad, China, Columbia, Cuba, Czechoslovakia, Ecuador, Egypt, Finland, Germany (East), Greece, Ghana, Hungary, Iceland, India, Iran, Iraq, Korea, Lebanon, Libya, Malawi, Mexico, Monaco, Mongolia, Morocco, New Zealand, Norway, Pakistan, Peru, Poland, Portugal, Romania, Soviet Union, Spain, Syria, Thailand, Tunisia, Turkey, Uruguay, Venezuela, Vietnam, Yugoslavia, Zambia and Zimbabwe.

<sup>21</sup> Australia, Brazil, Columbia, Malawi, Mexico, New Zealand, Zambia and Zimbabwe.

<sup>22</sup> This ban (s.38A of the *UK Patents & Designs Act, 1907*) was introduced as part of the UK government’s response to the shortage of medicines during WWI when Germany, then the world’s leading producer of chemicals and pharmaceuticals, imposed an embargo on the export of chemicals and medicines in 1914.

<sup>23</sup> Section 41(2) *UK Patents Act, 1949*.

<sup>24</sup> In 1948 the National Health Service was established and because prescribed medicines were free to UK citizens, their price was of particular concern.

<sup>25</sup> Oudemans, G. (1963), *The Draft European Patent Convention*, London: Stevens & Sons Ltd; New York, US: Mathew Bender & Co. Inc.

<sup>26</sup> This was mainly due to the efforts of Kurt Haertel, who not only chaired the EPC drafting committee in 1963, but was the President of the German Patent Office between 1963 and 1975.

<sup>27</sup> Scherer, F.M. (2000), ‘The Pharmaceutical Industry and World Intellectual Property Standards’, *Vanderbilt Law Review*, 53, 2245-2254.

<sup>28</sup> Chaudhuri, S. (2007), ‘Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS’, Indian Institute of Management Calcutta, Working Paper Series, No 614.

medicines. This fact has been already pointed out by Dr Yusif Hamid, the Chairman of Cipla Limited, an Indian pharmaceutical company, who said in 2005:

‘The global pharma patent system to which India now subscribes denies the poor access to healthcare and curtails their right to life. The third world pharmaceutical industry has been chastised for making copycat drugs and condemned for engaging in so-called piracy. What is overlooked is that this industry had made affordable drugs available to the nations of the South, home to 6 billion people, most of whom are poor and battling a crippling disease burden with little or no help from their governments. But now, with the amendment in the Indian Patent Act (in effect from January 1, 2005) in compliance with WTO patent laws and TRIPs our ability to perform this social function will be reduced dramatically. We will no longer be able to produce and export cheap generic copies of patented medicines. Besides, since it takes at least ten years to bring a drug to market from the time of filing the patent, all new drugs are going to be under monopoly and thus beyond the reach of most Indians, as well as the poor in other parts of the world. And the supply of affordable new medicines will dry up in due course.’

What is even more illuminating is that even with all thirty-four EPC countries repealing their per se prohibitions on the patenting of pharmaceuticals in 1978 and given that since 1995 all WTO members (except for developing countries between 1995 and 2005) have followed suit, according to the World Intellectual Property Organization (WIPO) patent statistics for 2008, the number of pharmaceutical patent applications filed worldwide between 2001 and 2005 grew by a very low 1.7% annually and in the field of biotechnology actually diminished by -2.7% annually.<sup>29</sup> So the obvious question is this: if patent protection supposedly encourages invention how is it that pharmaceutical and biotechnological innovations have either stagnated or regressed since 2001?

What this data suggests is that too much patent protection may actually suppress innovation in some fields.<sup>30</sup> Thousands of patents have been granted over isolated biological materials, including human genes, creating a labyrinth of gene patents that act as a barrier to entry by increasing the transactions costs of basic medical and scientific research. And this hypothesis is supported by the study undertaken by Kyle Jensen and Fiona Murray.<sup>31</sup> They found that ‘nearly 20% of human genes are explicitly claimed as US IP’<sup>32</sup> and of the 23,688 human genes that made up the human genome database of the National Center for Biotechnology Information, 4,382 were the subject of 4,270 patents within 3,050 patent families<sup>33</sup> and were controlled by 1,156 patent owners, of which 63% were private firms.<sup>34</sup> The largest single patent owner of some 2,000 human genes was Incyte Genomics, a US corporation.

There is a very strong argument to be made that isolated genes are not (or should not be) patentable subject matter<sup>35</sup> particularly since anecdotal evidence is emerging that legal and economic control over human genes is inhibiting medical and scientific research.<sup>36</sup> For

<sup>29</sup> 2008 World Patent Report, WIPO, 41.

<sup>30</sup> As pointed out by Breyer, Stevens and Souter JJ in *LabCorp*: ‘[t]he problem arises from the fact that patents ... can discourage research by impeding the free exchange of information.’

<sup>31</sup> Jensen, K. and Murray, F. (2005), ‘Intellectual Property Landscape of the Human Genome’, *Science*, 310 (5746), 238-240.

<sup>32</sup> *Ibid*, 239.

<sup>33</sup> *Ibid*.

<sup>34</sup> *Ibid*, 240.

<sup>35</sup> Palombi, Luigi (2004), *The Patenting of Biological Materials in the Context of TRIPS*, PhD thesis, University of New South Wales, Sydney, Australia. [http://cgkd.anu.edu.au/menus/PDFs/Palombi-PhD\\_Thesis.pdf](http://cgkd.anu.edu.au/menus/PDFs/Palombi-PhD_Thesis.pdf); Carlos Correa (2008), ‘Patenting Human DNA: What Flexibilities Does the TRIPS Agreement Allow?’, *The Journal of World Intellectual Property*, 10 (6), 419-437.

<sup>36</sup> Matthijs G. (2006), ‘The European Opposition Against the BRCA1 Gene Patent’, *Familial Cancer*,

instance, in the context of the patents that have been granted over human breast and ovarian cancer gene mutations, Gert Matthijs, a professor in the Department of Human Genetics at the Catholic University in Leuven, observed that while it has been ‘difficult to put or get the information on paper’ that several manufacturers in the field of mutation analysis have ‘refrained from developing novel tests for BRCA1/BRCA2 screening, because of these patents.’<sup>37</sup>

**Can placing limits on inherently patentable subject matter be justified on ethical grounds?**

Yes. It is not only desirable but essential that Australian courts, and not merely Parliament, be able to strike down patent monopolies on moral and ethical grounds.

Certainly arts 27.2 and 27.3 TRIPS permit WTO member countries to legislate to prohibit patentability with respect to entire classes of subject matter for the purpose of protecting (a) *ordre public* or morality, or (b) human, animal or plant life, or (c) health, or to avoid serious prejudice to the environment. Furthermore they may also exclude from patentability (a) ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’ and (b) ‘plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes’.

Section 18(2) *AU Patents Act, 1990* is an example of the type of prohibition permitted under art. 27.2 TRIPS.<sup>38</sup> Clearly, s.18(2) was inserted by Parliament because of it believed that the cloning of human beings violated the ‘*ordre public* or morality’ of Australian society.

However the kind of patentability restrictions permitted by arts 27.2 and 27.3 TRIPS and exemplified by s18(2) *AU Patents Act, 1990* are quite different from the limits that apply to the ‘inherently patentable subject matter’ threshold in s.18(1)(a).

*What this means is that the Parliament has distinguished between innovations that are patentable subject matter (s.18(1)(a)) and innovations that, regardless, cannot be the subject of a patent (s.18(2)).*

Unfortunately the Full Federal Court of Australia has misunderstood the difference between these two types of patentable subject matter thresholds.

In *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) 122 ALR 141 (*Rescare*) Lockhart and Wilcox JJ held that a method for the treatment of sleep apnoea, a human medical condition, was patentable subject matter because they interpreted the failure of the Australian Parliament to expressly exclude such methods from patentability, as had been done in s.18(2) in respect of biological processes for human reproduction, as indicative of a Parliamentary intention to permit patents with respect to methods of human treatment.<sup>39</sup>

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5, 95-102; Matthijs G. and Hodgson S. (2008), ‘The Impact of Patenting on DNA Diagnostic Practice’, *Clinical Medicine*, 8 (1), 58-60.

<sup>37</sup> Matthijs, G. ‘DNA Diagnostics in Practice’ in Van Overwalle, G. (ed), (2007) *Gene Patents and Public Health*, Etablissements Emile Bruylant, Brussels.

<sup>38</sup> Art. 27.2 TRIPS: ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.’

<sup>39</sup> ‘There is no statutory provision in Australia prohibiting the grant of a patent for a process of medical treatment of a human ailment or disease in a human being. It is noteworthy that the Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990 Act, but the limit of the exclusion was s. 18(2), namely: “human beings, and the biological processes for their generation, are not patentable inventions” cf. s.4, Patents Act 1977 (UK)’ per Lockhart J, para 77.

‘The important point, it seems to me, is that the Australian Parliament has not been persuaded by the policy considerations arguing against patentability. Parliament has never excluded a method of human

Sheppard J, however, dissented. While he accepted that there was no binding authority in Australia to the effect that ‘there cannot be a valid grant of a patent in respect of a method of treatment of the human body’, he believed that the High Court in *NRDC*, on which sat ‘judges of great distinction’, had held that whether such methods were patentable was a matter for a court ‘to decide’.<sup>40</sup> The fact that Parliament had not, in the 1990 patents legislation, expressly prohibited patents over such methods was not indicative of an intent to restrict the court’s ability to assess inherent patentable subject matter nor was it indicative of permitting such patents. Sheppard J explained that it was ‘not going too far’ for a court to consider whether the grant of a patent was appropriate in circumstances where the exercise of a patent owner’s exclusive patent rights over the use of an invention ‘might mean the death or unnecessary suffering of countless people’.<sup>41</sup> Having examined the technology and the human disease, which he described as ‘life-threatening’, he held that the patent claims to the treatment of this disease were invalid because they violated the proviso in s.6, *Statute of Monopolies, 1623*.

Although the position adopted by Lockhart and Wilcox JJ was followed by a subsequent Full Federal Court in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524 (*Bristol-Myers*), what persuaded both Black CJ and Lehane J was, first, ‘the insurmountable problem ... 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’<sup>42</sup>, and secondly, ‘the very limited extent to which the Parliament dealt with patents with respect to the human body when it enacted the 1990 Act’.<sup>43</sup> Finkelstein J, while not dissenting, delivered a separate decision in which he confirmed that ‘the debate concerning the ethics of medical patents continues’.<sup>44</sup> He accepted that an assessment of s.18(1)(a) should be divided into two parts and having decided that a method for the medical treatment of humans was a ‘manner of manufacture’ he turned to consider whether the invention violated the proviso in s.6, *Statute of Monopolies*. However, instead of coming to a decision based upon a consideration of the opposing arguments, he simply ruled that a method of treatment was patentable because it was ‘not the function of a court [to adjudicate] on an issue such as this ... [and] if public policy requires a different result, it is for the Parliament to amend the 1990 Act.’<sup>45</sup>

Regrettably, both *Rescare* and *Bristol-Myers* are decisions of the Full Federal Court and consequently are binding authority on Australia’s lower courts, but the fact remains that they were not necessarily correctly decided and it is possible that they may be overturned by the High Court of Australia in the future.

In the meantime, however, the three decisions of all five judges (Black CJ, Lockhart, Wilcox, Lehane and Finkelstein JJ) are open to criticism because all of them seemed to have placed an undue emphasis on art. 27 TRIPS in their interpretation of s.18(1)(a) – an emphasis that was simply specious. Accordingly, they made a number of errors in their deliberations.

First, s.18(1)(a) was enacted well before TRIPS came into effect and although Australia became bound by TRIPS in 1995, the fact remains that s.18(1)(a) was not subsequently

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medical treatment from patentability or the definition of “invention”; not even in the recent statute, the Patents Act 1990, that revised Australian patent law and made a specific provision (s.18(2)) dealing with the patentability of human beings and the biological processes for their generation. I appreciate that both this statute and its predecessor, the 1952 Act, left intact the principles developed by the courts in connection with the application of s.6 of the Statute of Monopolies: see the definition of “invention” in both Acts and s.35 of the 1952 Act and s.18(1) of the 1990 Act. However, I believe that, in the face of apparently deliberate decisions by Parliament not to build this particular exclusion into its legislation, courts should be hesitant to introduce the exclusion by reference to those very general principles.’ *Rescare*, per Wilcox J, para 3.

<sup>40</sup> *Rescare*, per Sheppard J at paras 52-53.

<sup>41</sup> *Ibid*, para 58.

<sup>42</sup> *Bristol-Myers*, para 15.

<sup>43</sup> *Ibid*, para 16.

<sup>44</sup> *Ibid*, para 100.

<sup>45</sup> *Ibid*, para 142.

amended. What this irrefutably means is that s.18(1)(a) was not considered by the Parliament to be inconsistent with TRIPS. More importantly, it implies that the limitations on patentable subject matter that TRIPS allowed had nothing to do with s.18(1)(a). Indeed, that was the specific and exclusive purpose of s.18(2).

Secondly, that Parliament did not expressly prohibit patentability beyond ‘[h]uman beings and the processes for the generation’ was not suggestive of a Parliamentary intention to weaken or remove the limitations that applied to patentable subject matter by virtue of the proviso in s.6, *Statute of Monopolies*, rather it was indicative of Parliament’s intention to make it clear that such inventions *as a class* would not be patentable in Australia. The effect of the express prohibition was to deem *this* class of invention to be contrary to the *ordre public* and morality of Australian society.

Thirdly, there was no need to draw a distinction between a *product* for treating the human body and a *method* of treatment, as Black CJ and Lehane J did in *Bristol*, because the true issue was not whether an invention was a product as opposed to a method, rather the true issue was how the invention (regardless of what it was) could be used to treat the human body and the *impact which that specific form of treatment would have on Australian society*. That pharmaceutical products have not been denied patentability *as a class* either under s.18(1)(a) or under s.18(2) does not mean that every pharmaceutical product of every kind will, or should, in the future be automatically deemed to be ‘inherently patentable subject matter’ under s.18(1)(a). It is conceivable that there might be pharmaceutical products which will violate the proviso in s.6, *Statute of Monopolies* and a hypothetical example may be a medicine that is illegal to import, manufacture or to possess under Australian law. This was the point that Sheppard J alluded to in his dissent, which is undoubtedly correct, because not only was his reasoning consistent with the High Court in *NRDC*, but it took into account the impact or potential impact which the method of treatment in *Rescare* may have on Australian society. In this respect, the ability of a patent owner to deny access to a form of treatment or to impose unreasonable or unrealistic conditions upon access to treatment is relevant to that assessment under s.18(1)(a).

Finally, that it may be difficult for courts to make such assessments does not, with respect, absolve them of their duty to make such assessments. Courts are required every day in other fields of law, such as family, defamation and criminal law, to have to deal with sometimes difficult and challenging evidence that requires a subjective assessment which calls upon judges, as members of society, to put into effect their perceptions of propriety, yet judges in those courts are quite capable of making them. Patent law is no different, especially when the legislation imposes a requirement that limits patentable subject matter to inventions that are not contrary to the proviso in s.6, *Statute of Monopolies*. It has never been proper for judges to ignore an unambiguous statutory requirement.

<p><b>Is it appropriate for legislation to predetermine ethical limitations on patentable subject matter, or is it more appropriate for courts to determine such limitations on a case-by-case basis?</b></p>
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For nearly four hundred years the Anglo-American courts have played a major role in assessing compliance with the inherent patentability threshold on a case-by-case basis. As stated, in *NRDC* the proper question under Australian patent law is this: *Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the Statute of Monopolies?*

It is appropriate, therefore, that Australian courts consider moral and ethical issues in the context of answering this question. Regardless of the *per se prohibition of patentability* that may be expressly provided by Parliament, as is the case in s.18(2), it is possible that the subject matter of an invention may be immoral, unethical or illegal or may advance or promote immoral, unethical or illegal activities. This is one of the purposes behind the proviso in s.6, *Statute of Monopolies, 1623*: namely, to ensure that the patent monopolies do

not undermine the Australian economy or society.

Other examples of where it would be appropriate for a court to make such an assessment may be in the case of an invention that facilitates the circumvention of anti-pornographic computer blocks designed to protect children from sexual exploitation. Another may be a synthetic biological material unknown to nature that has the capacity to replicate and mutate into a pathogen. Another might be an invention that is a weapon of mass destruction. Presently, the *AU Patent Act, 1990* does not contain express *per se prohibitions* with regard to these types of inventions. Perhaps it should, but, irrespective of that fact, at the present time the proviso in s.6, *Statute of Monopolies, 1623* provides a notional safety net that enables the Australian courts, in an appropriate case, to take into account moral, ethical and other issues that may be raised, either by the parties during the course of litigation, or *sua sponte* (of its own volition). In *Smithkline Beecham Corp v Apotex Inc* (2005) 403 F 3d 1331 Judge Gajarsa of the US Court of Appeals for the Federal Circuit (CAFC) raised the issue of patentable subject matter even though it had not been pleaded because, in his opinion, there is a ‘significant public policy interest in removing invalid patents from the public arena’ and on the basis of US Supreme Court authority ‘established long ago’, whether something ‘is patentable or not is always open to the consideration of the court, whether the point is raised by the answer or not’.

One problem with the present patent system in Australia is that only about 1% of all patents are ever subjected to the scrutiny of the Australian courts and, as a result, many Australian patents that are of questionable validity remain unchallenged. This is an understandable situation given the costs and risks of litigation, especially patent litigation which can be scientifically complex and thus even more expensive and riskier than other kinds of litigation. As a result, the incentive for non-profit or community interest groups to challenge a patent, which they might otherwise consider, is non-existent in Australia. Understandably, the prospect of an award of costs being made against a losing party in patent litigation acts as a positive disincentive to challenging patents through the courts.

Independent scrutiny of the patent system is critically important to the maintenance of a proper balance between free trade and competition and patent monopolies. This means that the courts should be the only authorities empowered to assess the validity of a granted patent. Patent offices, which are patent-granting institutions, and their partial appellate tribunals such as provided under the European Patent Convention should be expressly excluded from undertaking this role.<sup>46</sup> The situation in Europe is particularly troublesome because of the potential for there to be conflicting decisions between the European Patent Office (EPO) and its Technical and Enlarged Boards of Appeal and the various national courts, and conflicting decisions among the national courts themselves, regarding validity of a European patent. Consequently, the validity of a European patent as granted by the EPO is uncertain and this kind of uncertainty only further increases the public and private costs of maintaining a patent system.

The reality is that at the present time the courts only serve the interests of parties that have the commercial incentives and capacity to bring expensive and time consuming patent litigation, and this tends to undermine the ability of the courts to act as an independent arbiter of the Australian patent system. Thus the patent gatekeeping role that the Australian courts supposedly provide is not as effective as it should and could be and, unfortunately, the Full Federal Court decisions in *Rescare* and *Bristol-Myers* have further eroded the importance of this role.

It is proposed here that a specific authority should be established under separate legislation to the *AU Patents Act* to audit IP Australia so as to assess compliance with patent legislation and

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<sup>46</sup> What is suggested is that all patents must be able to be subjected to pre-grant Opposition. For instance the post-grant Opposition permitted under the EPC, currently undertaken by the Opposition Division of the EPO and subject to appeals to the Technical Board of Appeal of the EPO and the Enlarged Board of Appeal, should be replaced with post-grant revocation by a European Patents Court.

to ensure that the Australian patent system is not improperly eroding the primacy of free trade and competition. The establishment of an independent authority, such as the *Australian Intellectual Property Audit and Compliance Authority* (AIPACA), should facilitate this. Accordingly, it is suggested that such an Authority would have the duty to ensure that the patent system works efficiently. This Authority would also challenge the validity of patents that were brought to its attention by formal complaint and after investigation, if satisfied that a prima facie case of invalidity is made out, to bring action before the Federal Court of Australia to challenge the validity of such patent.

In the event that a patent is invalidated, the patentee should be required to pay just compensation equal to the value of the patent monopoly exploited during the life of the patent. Penalties should also be imposed by way of extra damages and/or fines when it can be shown that the actions of the patentee caused specific economic harm or injury. Furthermore, to the extent that the actions of the patentee during the life of the patent had, but for the patent, breached provisions of Part IV of the *Trade Practices Act, 1975*, such action should become retrospectively actionable under both criminal and civil law.

**Is patent law an appropriate avenue for dealing with ethical issues? If not, what is an appropriate avenue?**

In the context of what is and what is not an ‘invention’ or what should and what should not be patentable, patent law is an appropriate avenue for dealing with ethical issues.

**What would be the ethical consequences of imposing or removing limits on patentable subject matter?**

First, it would no longer be possible for the courts to stop *in limine* (at the threshold) the patenting of inventions that could damage the Australian economy or corrupt or damage Australian society if limits were removed.

Secondly, it would impose upon the Australian Parliament a greater burden to monitor the impact of technological developments on Australian economy and society and to respond legislatively in a proactive manner. Unfortunately, Parliament is not in the best position to predict or react to technological innovations that may bring economic, moral or ethical considerations into the assessment of patentability. Therefore, Parliament is more likely to be reactive and not proactive. Notably, the inclusion of s.18(2) *AU Patents Act, 1990* was in response to, not in anticipation of, the possible impact of cloning technology on Australian society.

It is completely appropriate for the Australian Parliament to expressly prohibit certain technologies from patentability regardless of their eligibility for the grant of a patent under s.18(1)(a), and the subject matter defined in s.18(2) is presently the only example. However, it is relevant to note that such a limitation is not imposed so as to limit ‘patentable subject matter’ under s.18(1)(a). Rather, it is an express patentability prohibition that applies regardless of s.18(1)(a).

Clearly, the Full Federal Court decisions in *Rescare* and *Bristol-Myers* have reduced the ability of Australian courts to fulfil their legislative duty in this respect and while they may be wrongly decided, they remain the law until the High Court of Australia overturns these decisions or until the Australian Parliament reverses them by amending the *AU Patents Act, 1990*. The problem with the former is that it may be some time before an appropriate case presents itself to the High Court and in the meantime these decisions apply. While it may be tempting for the Parliament to do as Finkelstein J suggested in *Bristol*, namely, that matters of public policy ‘should be resolved by the Parliament’, it is recommended that his advice not be followed. Rather, Parliament should amend the patents legislation to reverse the effect of *Rescare* and *Bristol*.

Of course the Australian Parliament could also consider adopting the European approach, which casts a general ‘ethics and morality’ net. Art. 53 of the European Patent Convention

(EPC) provides that ‘inventions ... which would be contrary to “*ordre public*” or morality’ are subject to a *per se patentability prohibition*. But what would this achieve given that presently the Australian courts are empowered, indeed duty bound, to make such assessments by virtue of the proviso in s.6, *Statute of Monopolies, 1623*? In this respect it should be noted that art.52 EPC, which defines patentable subject matter, does not contain an equivalent to s.6, *Statute of Monopolies, 1623*. Specifically, the only express exclusion to inherent patentability in art. 52 is contained in art. 52(4) which provides that ‘[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body’ are unpatentable, not on the basis that such inventions are unethical or immoral but by deeming such inventions to be incapable of ‘industrial application’.

Accordingly, is not suggested that Parliament amend s.18(2) to prohibit from patentability all methods of medical treatment *as a class of invention*, rather what is suggested is that it reinforce the obligation that s.18(1)(a) imposes upon the courts to adjudicate on the validity of specific inventions on a case-by-case basis by taking into account the economic, ethical and moral impact of an invention on Australian society. Sheppard J in *Rescare* recognised that s.18(1)(a) provides a more nuanced approach than does an express prohibition, which applies to any invention that falls within that class, regardless of its merits as an invention and regardless of its potential or actual impact upon the Australian economy or society.

### Does the content of current Australian law meet the objectives of the system?

This begs the question: what *are* the objectives of the Australian patent system?

The idea that the patent system is there merely to encourage technological innovation by providing a 20-year state sanctioned monopoly which enables any patentee to exclude all others from exploiting the invention in Australia is far too simplistic.

As already explained, the genesis of the Australian patent system is s.6, *Statute of Monopolies, 1623*. The central objective of the *Statute of Monopolies*, as provided by s.1, was to encourage free trade and competition by rendering null and void *all* monopolies, including those granted under the authority of the King’s letters patent. The effect of s.6, however, was to quarantine from that prohibition monopolies of less than 14 years duration that were granted with respect to ‘manners of new manufacture’ that were not injurious to the State, and its objective was to encourage the development of new industries, provide employment and reduce imports of new and useful commodities that were in demand but that were unavailable in England. This, for instance, is why in 1718 John Lombe was granted a patent monopoly by the English Parliament over the manufacture of silk cloth as a reward for him bringing the closely guarded Italian secrets of silk milling (and which included the migration of two skilled Italian silk workers) to England.<sup>47</sup>

Regardless of the fact that these events took place hundreds of years ago, the central rationale behind the Australian patent system remains the same. Therefore, its objective is to encourage the use of new technologies in Australia for the manufacture of commodities, or the provision of services, in Australia for the benefit of the Australian economy and Australian society. It follows from this that the manner in which foreign owners of Australian patents exercise their

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<sup>47</sup> In fact the details of the silk milling machines had been published in 1607 in a book by Vittorio Zonica which, by 1656, was well known and widely available throughout Europe. Thus details of silk milling machines were not secret, but what was secret was the know-how that enabled the use of those machines. Lombe literally risked his life by gathering this intelligence in Piedmont, because industrial espionage was punishable by death. For more details see Cipolla, C.M. (1972), ‘The Diffusions of Innovations in Early Modern Europe’, *Comparative Studies in Society and History*, 14 (1), 46-52, 47-48. Cipolla writes, ‘... to paraphrase Professor Oakeshott ... a printed or written page is ‘not an independently generated beginning from which activity can spring; it is nothing more than an abstract of somebody’s knowledge; it is the stepchild not the parent of activity. The printed or written page speaks only to those who already know the kind of thing to expect from it, and consequently how to interpret it.’ Oakeshott, M. (1951), ‘Political Education’, Cambridge, UK, 15.

patent rights in Australia is relevant to the Australian patent system meeting this objective. This is particularly the case with respect to technologies that are critical to maintaining or improving the physical health of Australians, such as pharmaceuticals and prophylactic and therapeutic treatments and diagnostics.

Thus the suppression of the use and deployment of technology in Australia by foreign patent owners of Australian patents or their exclusive licensees, either by refusing to license Australian patent technology to Australian researchers or manufacturers or by their decision not to use or deploy that technology in Australia, is contrary to the proper working of the Australian patent system. And this potential is a relevant consideration in determining the limits of patentability. There is more than one example of where foreign owners of Australian patents have deliberately, and without regard to the needs of Australian society, suppressed the production of patented technology, but for the sake of brevity only one will be given.

Between 1991, when the first hepatitis C virus (HCV) immunoassays were made available in Australia by Abbott Laboratories (a US corporation) under license from Chiron Corporation (a US corporation), and 2000, when the more accurate and expensive nucleic acid based diagnostics replaced HCV immunoassays, there was a need for a variety of HCV immunoassays. The need was brought about by the discovery by medical and scientific researchers that there were more than six strains of HCV<sup>48</sup> around the world and thus the accuracy of any specific HCV immunoassay was affected by the genetic diversity between these six HCV strains.<sup>49</sup> The Abbott-made HCV immunoassays used, as a component, a fused polypeptide that was derived from HCV strain 1a (the predominant strain of HCV in North America). Under the terms of the worldwide licence agreement, Abbott was required to purchase this component from Chiron and was prohibited from using an alternative component. Unfortunately, it was found that the Chiron-licensed Abbott HCV immunoassays produced an error rate of 10% in Australia<sup>50</sup> and so the NHMRC, Australia's peak medical and scientific research body, established an HCV Task Force to investigate. The HCV Task Force eventually produced a Report which it published in November 1993<sup>51</sup> recommending that secondary HCV immunoassays be made available as a matter of urgency in order to reduce the risk of error in HCV diagnostics in Australia.<sup>52</sup> Despite repeated requests by companies such as Murex Australia to produce a secondary HCV immunoassay under license, Chiron refused. Moreover, Chiron refused any other manufacturer (including F Hoffman La Roche AG) to provide a secondary HCV immunoassay or to make an HCV immunoassay that satisfied the recommendation contained in that Report.

The problem is that even though there were provisions in the *AU Patents Act, 1990* for compulsory licensing and crown use of Chiron's HCV patents, neither were used in an attempt to overcome Chiron's refusal to meet what was an immediate and very important health issue in Australia. So the answer to the question is: No.

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<sup>48</sup> McOmish et al., (1994) 'Geographical Distribution of Hepatitis C Virus Genotypes in Blood Donors: An International Collaborative Survey', *Journal of Clinical Microbiology*, April 1994, 884-892.

<sup>49</sup> The Hepatitis C Task Force Report referred to studies from Western Australia which showed that of the 23 Australians in one study, 13 of 23 (56%) were genotype 1, 3 of 23 (13%) were genotype 2; and 7 of 23 (31%) were genotype 3. In another study conducted at Fairfield Infectious Diseases Laboratory in Victoria showed that 45% were genotype 1a; 10% were 1b; and 45% were 3a. The significant point is that genotype 3 is an important strain in Australia.

<sup>50</sup> Breschkin A, Locarnini S. (1993), 'Comparison of Three Second Generation Immunoassays for Detection of Hepatitis C virus Antibodies', *Aust J Med Sci*, 14, 17 -21.

<sup>51</sup> 'Report On The Epidemiology, Natural History And Control Of Hepatitis C', NHMRC, Hepatitis C Task Force, November 1993.

<sup>52</sup> The first recommendation of the report was that Australian research laboratories 'be encouraged to undertake full nucleotide sequence studies on Australian strains of hepatitis C virus'. The reason for this recommendation was that cases of post-transfusion hepatitis C were occurring in the community that were being missed by the existing 'second generation' screening tests. The Ortho/Abbott second generation screening kits were introduced in Australia in May 1991.

It is particularly noteworthy that IP Australia granted a patent, 624,105 to Chiron Corporation without requiring any amendment to the claims applied for in its PCT patent application. This is in marked contrast to the European Patent Office, which required extensive amendments, and although Chiron was eventually granted a European patent, 0,318,216, most of the patent claims, particularly those to isolated proteins of HCV, were invalidated by the EPO some 7 years later. In Australia, Chiron eventually replaced its originally granted claims with those identical to the claims granted by the EPO. Unfortunately, for Australia, IP Australia has not revoked any of those claims.

**Is current Australian law compliant with our international obligations? Is it more important to achieve best practice or to harmonise with a major jurisdiction? Are any jurisdictions preferable over others?**

Australian law is compliant with Australia's international obligations. While it is important to achieve best practice and also to harmonise patent law wherever possible, these steps must not overtake what is in best interests of Australia. Just as the US continues to refuse to move to a first-to-file patent system because it is considered to be in the best interests of the US to maintain a first-to-invent system, it is important that Australian policy and decision makers apply the same strategy with respect to issues that are pertinent to Australia's economy and society *as a whole*.

No other jurisdiction is preferable.

**What are the appropriate objectives and constraints of the patent system, what sorts of subject matters do you think should be inherently patentable and what should not?**

In the context of the global system of trade and commerce which has the objective under the World Trade Agreement (WTA)<sup>53</sup> to foster free trade and commerce between *all* nations there is, frankly, no justification for maintaining any patent system. While it is true that patent monopolies may in certain circumstances reward handsomely the owners of patents, this is more an exception than a rule. Furthermore, when the costs of obtaining effective patent protection across the globe together with the potential costs associated with litigation to enforce those patent rights, in the event of their infringement, are accounted for, it is difficult to understand how the prospect of a patent monopoly can act as an incentive to innovation. These costs may run into the tens of millions of dollars, and while this level of expenditure will undoubtedly occur only if a patent monopoly is extremely valuable, they are very substantial and often beyond the capacity of individual inventors or small to medium companies and research institutions. Surely these costs must act as a disincentive, not as an incentive, to use the patent system? Which brings us to this point: who really benefits from patent monopolies?

It must be acknowledged that patents place an economic impost that is akin to a tax or a tariff on consumers and in many instances are instruments through which anti-competitive business practices are camouflaged in order to realise higher than normal prices. Naturally, patent monopolies are particularly attractive to large multi-national corporations whose need to maintain control of competition, especially in their global markets, encourage the use of patents to avoid the normal competitive rules that apply in business. Accordingly, because patents provide the owner with the absolute legal right to exclude others from using or working an invention which they control through patent monopolies, they are a device through which multi-national corporations may be insulated from the effects of most antitrust and anti-competition laws.<sup>54</sup> For corporations that already have extensive distribution

<sup>53</sup> The Agreement Establishing the World Trade Organization (WTO) entered force in Australia on January 1, 1995.

<sup>54</sup> Bloxam, G A (1957), 'Letters Patent for Inventions: Their Use and Misuse', *The Journal of Industrial Economics*, 5 (3), 157-179.

networks across the globe, the costs imposed by the world's many patents systems and the risks inherent in patent litigation are not considered significant when the potential or realisable profits generated by patent monopolies vastly exceed those costs. Therefore, for multi-national corporations a patent monopoly is a powerful economic tool.

However, the right of patent owners to exclude all others from using the invention without their authority is suboptimal in achieving the WTA's objective<sup>55</sup> because it provides unfettered discretion to these multi-national corporations, many of which act without regard to the economic, social or other consequences. Indeed, by their very nature, these multi-national institutions are unlikely to owe allegiance to any particular country. This has led in the past, and will continue to lead in the future, to the suppression of production<sup>56</sup> and research and development into technologies that fall within the scope of a patent monopoly. In the context of pharmaceuticals and biotechnological products and processes, there are serious implications for developing and lesser developed countries who need medicines which their people are unable to afford because of the enormous gap between the price of those medicines charged by patent owners and the meagre incomes of their people. And it is clear that the compulsory licensing provisions in TRIPS are not sufficiently strong to overcome the prejudicial effects that the capricious exercise of patent monopolies can have on society.

When, in late 2006 and early 2007, the Thai government made the legitimate decision to issue compulsory licenses over a number of HIV drugs, the reaction of the pharmaceutical industry was ferocious. In spite of acting in accordance with Thai law and within the parameters of TRIPS, the Thai government was described by *Managing Intellectual Property*, a leading intellectual property publication read by patent lawyers around the world, as having 'broken three drug patents within the past four months'.<sup>57</sup> Rather than understanding the humanitarianism behind its decision, the patent attorney and legal professions portrayed the Thai government as duplicitous, 'playing an elaborate game of bluff, using compulsory licensing as a negotiating tactic to lower the cost of its highly successful, but increasingly expensive, health programme'.<sup>58</sup> Even Peter Mandleson, the EU's trade commissioner, wrote to the Thai Health Minister expressing his concerns 'that the Thai government may be taking a new approach to access to medicines', taking the opportunity to remind him that his ministry's policy of compulsory licensing 'would be detrimental to the patent system and *so to innovation and the development of new medicines*'.<sup>59</sup> Ignoring the fact that under the Thai license these companies would be paid a royalty of 5 per cent on all sales, what Mandleson seemed to have rejected is that the Thais were facing an enormous health catastrophe that required them to have access to HIV medicines at prices that were *affordable*. Unrelenting, Abbott Laboratories retaliated by withdrawing seven pending drugs<sup>60</sup> from the Thai drug regulatory approval process.<sup>61</sup> The reason given by Abbott's Director of Public Affairs was, unsurprisingly, 'the Thai government's decision *not to support innovation* by breaking the

<sup>55</sup> The recital to the WTA states: '*Recognizing* that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development'.

<sup>56</sup> Vaughan, F.W. (1919), 'Suppression and Non-Working of Patents, With Special Reference to the Dye and Chemical Industries', *The American Economic Review*, 9 (4), 693-700.

<sup>57</sup> 'Why Thailand is at the centre of a patent storm', *Managing intellectual Property*, March 2007 (emphasis added).

<sup>58</sup> *Ibid.*

<sup>59</sup> 'More drugs under threat in Thailand', *Managing Intellectual Property*, 24 September 2007 (emphasis added).

<sup>60</sup> These are Kaletra (HIV); Brufen (pain killer); Abbotic (antibiotic); Clivarine (blood clotting); Humira (arthritis); Tarka (blood pressure); Zemplar (kidney disease).

<sup>61</sup> 'Drug maker hits back in Thai patent row', *Managing Intellectual Property*, 1 March 2007.

patents of numerous medicines.’<sup>62</sup>

It is important to appreciate that the majority of WTO member countries are not from the developed world.

Consequently, the unencumbered right of the patent owner to exclude all others from working an invention is inappropriate in the context of the central objectives of the World Trade Organization (WTO). It is possible that a fair and adequate reward for inventors is a non-exclusive royalty, so that use of the invention will generate income in the form of licence fees appropriate to the use. This is the very proposal that was put forward by President Roosevelt in his message to the US Congress on April 29, 1938.<sup>63</sup>

That said, there is an immediate need to improve the transparency of all patent systems so that it is possible for anyone to freely access accurate and detailed information about inventions, particularly how to use inventions in ways that enable commercial and industrial scale production. The present systems of patent searching are inadequate and the present requirements to publish data about how the invention was arrived at, at the present time, almost useless. It is far too easy for patent applicants to provide only rudimentary data, some of which is either incorrect, misleading or useless in terms of enabling or facilitating large scale or commercial use.

Furthermore, if the patent system is to continue in Australia then patents should be restricted to inventions that are not trivial – more specifically, the inventions should be significant. In this regard, the bar for invention should be raised so that the ‘inventive step’ necessary for the grant of a patent is not so easily reached. The idea that the ‘mere scintilla’ of invention is enough to satisfy the threshold of invention is far too low. This action, were it taken, should reduce the number of patent applications, thus improving the ability of patent-examining authorities to properly assess patent applications and their compliance with patent thresholds.

Finally, biological materials which are identical or practically indistinguishable from natural biological materials and their derivatives should be expressly excluded from patentable subject matter under an amendment to s.18(2). This is necessary so as to reverse and correct the errant practice of IP Australia of allowing the grant of patents in respect of such materials. Neither should patents be granted for inventions that involve the technical application of excludible subject matter, such as computer programs and isolated biological materials, in methods and processes that are obvious or that achieve obvious results, particularly, if there is no *tangible* output. As such, business methods must be expressly excluded from patentability under an amendment to s.18(2) so as to make it clear that such innovations are beyond the patent system in their entirety.

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<sup>62</sup> Ibid (emphasis added).

<sup>63</sup> President Roosevelt’s concerns included the concentration of power in patent portfolios owned by multi-national corporations, recommending to Congress that it amend the patent law, ‘to prevent their use to suppress inventions and to create industrial monopolies’, so that patented inventions would, ‘be made available for use by anyone upon payment of appropriate royalties’. See Feuer, M (1938), ‘The Patent Monopoly and the Anti-Trust Laws’, *Columbia Law Review*, 38 (7), 1145-1178, 1149.

## 2. Background to the Submission

### Introduction

Whatever the historical beginnings of patent law in Australia, this country, like all countries that are signatories to The Agreement Establishing the World Trade Organization (WTO), is bound by The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Additionally, but always within the bounds of the terms of this document, countries like the United States and Australia have entered into bilateral trade agreements for the purpose of encouraging free trade between them.<sup>64</sup> Essentially, these agreements, but principally TRIPS, provide a legislative floor below which a country may not fall and still be considered to be in compliance with its international obligations under the WTO.

The mandate of the World Trade Organization (WTO) established by the WTA, broadly, is to foster international trade, 'with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand' for all. Of course, the economic and social disparities that exist between countries means that these objectives cannot be achieved at the same rate and time. TRIPS, for instance, in 1995 provided lesser developed countries, such as India, with a ten year allowance.<sup>65</sup>

That intellectual property was, in 1995, finally included in the basket of issues that are the subject of international trade and commerce negotiations, some fifty years after the IMF and World Bank were established, means that intellectual property, such as patents, can no longer be considered as they have been in the past - as the instruments of nationalist economic policies - but are instead now to be seen as one of many components in the complex matrix of international economics. In effect, membership of the WTO *supposedly* requires countries to relinquish levels of economic independence in order that the objectives of the WTA will one day be achieved for the greater good.

Unfortunately, the most recent WTO trade talks (known as the Doha round) collapsed on July 29, 2008. The crucial issues during those talks were the freeing up of global markets for agricultural products and the reduction of farm subsidies – issues that were raised in the Uruguay round and which were part of the *quid pro quo* offered by the developed countries to developing countries in return for their support of TRIPS. Clearly the developing countries, led by China and India, are insistent that western countries, led by the US and the EU, make concessions in terms of agricultural access to their domestic markets.

When it is understood that patent systems have been used as protectionist economic tools to foster domestic economic production, either by encouraging new technologies to be imported<sup>66</sup> or used to deliberately suppress economic production in competing countries,<sup>67</sup> the naivety of the statement that patents 'promote technological innovation and the dissemination of technology to the mutual advantage of producers and users in a manner conducive to social and economic welfare' becomes obvious. That patents, may in some circumstances, act as an incentive for innovation is merely an accident of history – a by-product. This was never the

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<sup>64</sup> The Australia-US Free Trade Agreement (AUSFTA) entered force on January 1, 2005.

<sup>65</sup> India amended its *Patents Act, 1970* to be TRIPS compliant by January 1, 2005.

<sup>66</sup> For example Henry VI's (1421-1471; also King of France from 1422 to 1453) first grant of letters patent in 1449 was to a Flemish man for the manufacture of stained glass in England.

<sup>67</sup> Vaughan, F.W. (1919), 'Suppression and Non-Working of Patents, With Special Reference to the Dye and Chemical Industries', *The American Economic Review*, 9 (4), 693-700. See also Swan, Kenneth R. (1908), *The Law and Commercial Usage of Patents, Designs and Trade Marks*, London, UK: Archibald Constable & Co Ltd. Swan wrote, 'Latter-day commercial methods have ... shown that in the hands of unscrupulous [patent] proprietors a British patent can be turned to great profit for the patentee without a corresponding benefit to the public. Patents have occasionally been acquired not for the purpose of establishing a new manufacture "within the realm", but ... as a means of suppressing the manufacture in this country, whilst the invention is being worked abroad and the patented article imported into England and sold at exorbitant prices.'

principal purpose of patents.

The truth of this assertion is demonstrated by the fact that until 1968 practically all European countries excluded inventions for medicines from patentability and that in 1988 forty-eight countries (including Australia) still did.<sup>68</sup> Indeed, when Germany passed its first national patent law in 1877 it expressly prohibited patents on chemical products. Between 1919<sup>69</sup> and 1949 the UK, one of the world's leading industrialised economies, followed suit and also prohibited patents on chemical products.<sup>70</sup> India adopted this policy in its *Patents Act, 1970*. That countries did so confirms that patents were (and arguably still are) about protecting economies, and patent systems were used to fine tune economic performance.

In 1910 David Fulton, a British patent law commentator, wrote in response to the passing of the *Patents & Designs Act, 1907*:

It is indisputable that, under the Statute of Monopolies patents *were not granted to inventors as a reward for being ingenious, but for the purpose of introducing new manufactures into the country and to create increased employment for the working classes*. It is equally indisputable that, under the conditions existing before the coming into force of the present Act, many a patent granted to a foreigner, so far from being an encouragement to native industry, was a positive fetter upon the wrists of those who would otherwise have found profitable employment had working in this country been made compulsory. (Emphasis added)

The 1907 patents legislation ushered in an era of compulsory licensing in the UK in an attempt by the government of Herbert Asquith<sup>71</sup> to encourage British industry to manufacture (and thus create employment) patented articles in the UK. In a country as economically advanced as England was, it had become apparent that patents were being used by German chemical companies to suppress the production of chemicals and pharmaceuticals in the UK and, in so doing, maximising prices and profits.

This policy of compulsory licensing was continued and strengthened in the UK under the *Patents Act, 1949*, after Sir Kenneth Swan recommended to the government of Clement Attlee that the prohibition of the patenting of chemicals be repealed.<sup>72</sup> Compulsory licensing was particularly important to Attlee because his government ushered in the National Health Service – the UK's universal health scheme that provided prescription medicines at no cost to the patient. Thus, containing the cost of pharmaceutical medicines became a priority for the UK government. Unfortunately as the rapidly escalating costs of the NHS indicated, this policy was a spectacular failure.<sup>73</sup>

After a number of inquiries into the NHS during the fifties, Lord Sainsbury was appointed in 1965 to undertake yet another inquiry. Interestingly, it was the British pharmaceutical

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<sup>68</sup> Argentina, Australia, Bolivia, Brazil, Bulgaria, Chad, China, Columbia, Cuba, Czechoslovakia, Ecuador, Egypt, Finland, Germany (East), Greece, Ghana, Hungary, Iceland, India, Iran, Iraq, Korea, Lebanon, Libya, Malawi, Mexico, Monaco, Mongolia, Morocco, New Zealand, Norway, Pakistan, Peru, Poland, Portugal, Romania, Soviet Union, Spain, Syria, Thailand, Tunisia, Turkey, Uruguay, Venezuela, Vietnam, Yugoslavia, Zambia and Zimbabwe.

<sup>69</sup> Section 38A prohibited the patenting of chemical substances. It was introduced into the *Patents & Designs Act, 1907* in 1919.

<sup>70</sup> The prohibition was introduced to encourage British production of pharmaceuticals which were in short supply during WWI, mainly due to the fact that German chemical companies had deliberately concentrated production in Germany. When an embargo was declared at the outbreak of hostilities between Germany and Great Britain in 1914 essential pharmaceuticals become unavailable in the UK.

<sup>71</sup> 1852-1928; Prime Minister of the UK, 1908-1916. Lloyd George (1863-1945) was Chancellor of the Exchequer at the time and succeed him as the Prime Minister of the UK, 1916-1922.

<sup>72</sup> This recommendation was made because it had become apparent that the prohibition had failed due to the practice by patent attorneys of filing claims for every conceivable process for chemical production thereby achieving product protection by default.

<sup>73</sup> Slinn, J (2005), 'Prescription Pharmaceuticals in the UK,' *Business History*, 47 (3), 352-366, 353.

companies (many which were owned by US and Swiss interests) which were vocal in their opposition to what they claimed to be discriminatory treatment imposed upon them through the compulsory licensing of medicines. The objective of the global pharmaceutical industry was to remove the ability of governments to exclude specific technologies from patentability.

Moreover, the Association of British Pharmaceutical Industry (ABPI) argued that in order to ‘induce adequate research and development and innovation in the pharmaceutical industry’<sup>74</sup>, not only should pharmaceuticals not be made the subject of compulsory licensing but, consistent with the draft EPC<sup>75</sup> of 1963, the patent term of British patents should be increased from 16 to 20 years. The Sainsbury Committee, however, remained circumspect. In rejecting this submission, not only did its 1967 Report<sup>76</sup> state that the current patent monopoly of 16 years was ‘too long’<sup>77</sup> but it suggested that the incentive for R&D could be provided for ‘by a right to receive royalties under a licence of right’.<sup>78</sup>

Unfortunately, by the time the Report was presented to the government of Harold Wilson<sup>79</sup>, it had become clear that the Sainsbury Committee’s rejection of the ABPI’s submission collided with the government’s objective of joining the EEC.<sup>80</sup> With the drafting of the EPC advancing beyond the original draft of 1963, by 1973, when the UK eventually joined the EEC, the final version of the EPC provided for:

1. A patent term of 20 years; and
2. No patentable subject matter discrimination.

Both of these allowances were subsequently incorporated into TRIPS in 1995.

That these allowances now apply globally is partially as a result of a more relaxed approach being taken by the US Department of Justice and the US Federal Trade Commission (and other antitrust authorities around the world) towards the relationship between free trade and competition and patent monopolies. In their report entitled, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* and published in 2007, they state that the idea that antitrust and patent laws ‘were in tension’ or that they were ‘incompatible’ with each other has been ‘relegated to the past’. Today the accepted view, according to the Report, is that these laws ‘share the same fundamental goals of enhancing consumer welfare and promoting innovation’. Not only that, the ‘modern understanding’ is that these laws ‘work in tandem to bring new and better technologies, products and services to consumers at lower prices’.<sup>81</sup>

Recently, however, the European Commission (EC) began an antitrust investigation into the activities of the pharmaceutical industry over allegations that they have been blocking generic manufacturers from getting their medicines onto the European market. In January 2008 it was reported that the EC’s investigators had conducted raids on a number of European pharmaceutical companies and had ‘seized information about intellectual property rights, litigation and settlements in patent disputes’.<sup>82</sup> According to the EC, ‘fewer new

<sup>74</sup> Ibid, 76 (265).

<sup>75</sup> Oudemans, G. (1963), *The Draft European Patent Convention*, London: Stevens & Sons Ltd; New York, US: Mathew Bender & Co. Inc.

<sup>76</sup> Committee of Inquiry, Lord Sainsbury, (1967), *Relationship of the Pharmaceutical Industry with the National Health Services, 1965-1967*, [Cmd 3410].

<sup>77</sup> Ibid, 45 (150).

<sup>78</sup> Ibid, 76 (265).

<sup>79</sup> 1916-1995; Prime Minister of the UK, 1964 – 1970, 1974-1976.

<sup>80</sup> In 1967 the UK made a second application to join the EEC. The first application in 1961 was vetoed in 1963 by Charles de Gaulle, the President of France.

<sup>81</sup> U.S. Dep’t Of Justice & Fed. Trade Comm’n, *Antitrust Enforcement And Intellectual Property Rights: Promoting Innovation And Competition* (2007), 1.

<sup>82</sup> *International Herald Tribune*, January 17, 2008, ‘Decline in generic drugs draws EU scrutiny and raids’.

pharmaceuticals are being brought to the market ... and if innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases delayed, then we need to find out why'.<sup>83</sup> In May 2008 the EC announced that investigators were expanding the scope of the inquiry.

What this suggests is that the European governments are beginning to realise that having provided pharmaceutical companies with strong patent protection on the premise that this was needed to encourage research and development into new pharmaceuticals, not only are there now fewer new pharmaceuticals in the development pipeline, but pharmaceutical companies are using their distribution networks and their patent portfolios to hinder competition from generic pharmaceutical manufacturers. The cost implications to the health budgets of the European Union is obvious.

What it also suggests is that the 'modern' perspective of the relationship between antitrust and patents laws is quite wrong and is in urgent need of reassessment.

### **TRIPS and Patentable Subject Matter**

Article 27 of TRIPS sets out the minimum criteria for patentability. As acknowledged in the Issues Paper at 8.1.4, for Australia this means that only 'an invention' can be the subject of the grant of a valid patent. Specifically, TRIPS provides that 'patents shall be available for any inventions whether products or processes, in all fields of technology' - meaning only inventions. Consistent with TRIPS, the patent legislations of other countries also provide that patents be granted only for inventions. The European Patent Convention (EPC), which applies in 34 countries, including some that are not members of the European Union, provides in art. 52(1) that, 'European patents shall be granted for any inventions, in all fields of technology.' Notably, the language between the principle EPC and TRIPS provisions are almost identical.

As to what constitutes an invention, neither TRIPS nor the EPC provides an express definition, although the EPC does stipulate that certain things are expressly excluded. These things, such as 'discoveries, scientific theories, mathematical methods', 'methods for performing mental acts', 'programs for computers' and 'presentations of information', are not the kinds of things that are or have in the past been considered to be 'inventions', and so are useful indicia of what is *not* an 'invention'. But this list is not exhaustive, as the UK House of Lords confirmed in *Biogen v Medeva* [1997] RPC 1. There Lord Hoffmann held that while the subsidiary conditions of patentability, namely novelty, inventive step and industrial applicability, may 'contain every element of the concept of an invention in ordinary speech'<sup>84</sup>, they are not the exclusive indicia of invention, 'because in the absence of a definition one cannot say with certainty that one might not come across something which satisfied all the conditions but could not be described as an invention.'<sup>85</sup> Lord Hoffmann's obiter in *Biogen* contradicts the suggestion made by some legal commentators<sup>86</sup> that the absence of a definition of 'invention' in TRIPS allows for any subject matter to be patentable provided that it meets these secondary conditions. Clearly, such an interpretation would open the flood gates on patentability and would render otiose the requirement in TRIPS that patents be granted only with respect to 'inventions'.

Moreover, the absence in art.27.1 TRIPS of a list of excluded subject matter has never given rise to the suggestion that art. 52(1) EPC is more restrictive. Indeed, the closeness of the

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<sup>83</sup> Ibid.

<sup>84</sup> *Biogen v Medeva* per Lord Hoffmann at para 55.

<sup>85</sup> Ibid.

<sup>86</sup> Li Westerlund, *Biotech Patents: Equivalence and Exclusions under European and U.S. Patent Law*, Kluwer Law International, 2002, writes that, as a result, 'in principle it does not prevent the exclusion of naturally occurring substances, such as genes and cells, from patent protection' (p24). Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd Ed., London, Sweet & Maxwell, 2003, writes, 'the three usual criteria, i.e., novelty, industrial applicability and involving an inventive step' are the indicia of invention in TRIPS. (p220)

language in art. 52(1) EPC and art. 27.1 TRIPS is not a coincidence and cannot be overlooked, especially as the TRIPS negotiations were conducted as part of the Uruguay GATT round in a multilateral forum that included the United States. Under US patent law, as the US Supreme Court has held repeatedly, in the context of the definition of patentable subject matter, ‘laws of nature, physical phenomena, and abstract ideas have been held not patentable’.<sup>87</sup> Yet there is no express statutory exclusion to that effect in the *US Patents Act, 1952*. Thus in agreeing to TRIPS the US was neither turning its back on its patent statute nor its patent law jurisprudence, both going back to 1790.

Neither did Australia, in agreeing to TRIPS, turn its back on its patent statute nor the jurisprudence which had developed over hundreds of years. Notably, when TRIPS came into force in 1995, neither the Australian government of the day nor any subsequent Australian government, nor even the Intellectual Property and Competition Review (IPCR) in 2000, suggested that the *AU Patents Act, 1990* required amendment in order to comply with art. 27.1 TRIPS. Rather, as the Issues Paper confirms at p43, the IPCR recommended, and the Australian government accepted, that the existing manner of manufacture test ‘be retained’.

It is a requirement of TRIPS that subject matter must be an ‘invention’, which is a condition of patentability that is *separate to* and *distinct from* the subsidiary conditions of patentability of novelty, inventive step and industrial application. The Issues Paper confirms that this is the ‘first and most fundamental threshold’ of patentability. Therefore, this inquiry has nothing whatsoever to do with the subsidiary conditions of patentability. Rather the focus of this inquiry is to examine whether the existing thresholds of patentable subject matter in s.18 *AU Patents Act, 1990* are satisfactory.

### **The Patenting of Biological Materials and the ALRC *Genes and Ingenuity Report 99***

The trigger for this Inquiry originates, as the Issues Paper confirms at p45, with the ALRC *Genes and Ingenuity Report 99* and ‘the problems with the manner of manufacture test’ identified in that Report. It is therefore relevant for this Inquiry to examine what those problems were because here, unlike the ALRC which was examining the application of patent law to a specific situation, namely isolated biological materials and their biotechnological applications, ACIP is obliged to consider the adequacy of the manner of manufacture test across the entire technological spectrum. This is a significant distinction and one that cannot be ignored.

#### **The ALRC’s concerns with the manner of manufacture test**

The first concern which the ALRC had with the current patents legislation was that the concept of ‘manner of manufacture’ in s.18(1)(a) depended upon a provision in an ancient statute that had ‘long been repealed in the jurisdiction in which it was enacted’, namely the United Kingdom. The second concern was that the proviso in s.6 of the *Statute of Monopolies, 1623* limited patentability on the ground that the subject matter was ‘generally inconvenient’.

That said, despite raising these issues, the ALRC did not actually demonstrate by way of an example how the *AU Patents Act, 1990* had resulted in the exclusion from patentability of any ‘human gene’ or isolated biological material and its biotechnological application in a device, machine, medicine, vaccine, process or method. In point of fact, the ALRC accepted that ‘the legitimacy of patenting processes for isolating and purifying naturally occurring materials’ could not be denied. Additionally, the ALRC reported that although genetic sequences were ‘not foreseen when the modern patent system was established’, there was no evidence that the

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<sup>87</sup> *Diamond v Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v. Morse*, 15 How. 62, 112-121 (1854); *Le Roy v. Tatham*, 14 How. 156, 175 (1853).

‘generally inconvenient’ proviso had prevented or hindered the application and grant of patents in Australia over isolated or purified DNA or their biotechnological application.

Thus it would seem that the so-called ‘problems’ to which the ALRC alluded to were not then, nor are they now, ‘problems’.

### **Ancient Statute Argument**

First, the ‘ancient statute’ argument fails to take into account that had it not been for the UK’s entry into the European Economic Community (as the EU was then known) in 1973 and the subsequent decision to adopt the EPC, it is unlikely that the UK Parliament would have replaced the ‘manner of manufacture test’ with a modern language equivalent. The Banks Inquiry (1967-1970) into the UK patent system made no such recommendation.

Secondly, as both IPAC in 1984 and IPCR in 2000 found, the jurisprudence that has developed around that statute language has provided legal certainty and shown to be sufficiently flexibility so as to deal with the kinds of inventions that were beyond comprehension in 1623.

Thirdly, the language of s.101 *US Patents Act, 1952*, being the patentable subject matter provision in the United States, is, apart from one word (‘process’ instead of ‘art’), identical to that in the *US Patents Act, 1793*. Thus, even the statutory language in the US patent statute is over 200 years old, yet there is no call in legislative or patent circles in the US to modernise that language.

Frankly, the ‘ancient statute’ argument is specious and provides no justification whatsoever for disturbing the status quo in Australia.

### **‘Generally Inconvenient’ Argument**

First, while it is true that the majority of the Full Federal Court in *Rescare* and entire Full Federal Court in *Bristol* were ‘reluctant to rely on this proviso to deny patent protection to particular inventions’, the generalisation that this applies to ‘Australian courts’ is inaccurate. In fact, until the decision in *Rescare*, no decision of any Australian court had ever contained a suggestion that an inquiry under the proviso contained in s.6, *Statute of Monopolies* was something that was inappropriate for a court to undertake. That *Rescare* was followed by *Bristol* is regrettable but, even so, this should not be used as an excuse for the wholesale rejection of the test of inherent patentable subject matter that has had the benefit of nearly four hundred years of jurisprudence. Clearly, as has been already stated, both *Rescare* and *Bristol* are most likely wrong on this point, but the solution is not to rewrite the test; rather, the solution is to amend the existing statute so as to restate Parliament’s intention that the courts continue to monitor the economic and social impacts of patents. This could be easily achieved by way of a simple amendment to s.18 *AU Patents Act, 1990*.

Secondly, as the ALRC acknowledged at para 6.45 of its Report, not only did IP Australia question ‘whether a review of the test is warranted’ but that submissions were made to the effect: ‘the test has proven to be ‘flexible and able to take account of developing technologies and developing inventive concepts’.

Given that two independent reviews have examined this test in the past, one in 1984 (IPAC) and the other in 2000 (IPCR), the claim by the ALRC that it would be useful for ACIP to undertake a further review of the adequacy of the ‘manner of manufacture’ test, within the space of a decade, without producing a shred of evidence to show that it was unreasonably interfering with the efficiency or administration of the patent system in Australia, is also regrettable. Even more so when it is understood that the ALRC was prompted to make the recommendation on the basis of its inquiry into a narrow field of technology, namely gene patents.

### **The Limits of Patentable Subject Matter**

There are undoubtedly limits to patentable subject matter, the principle limitation being that

the subject of the grant of a patent be an ‘invention’. That must be accepted, given art. 27.1 TRIPS. However, whether one applies the ‘manner of manufacture’ test or the US definition in s.101 *US Patents Act, 1952* or art. 52 EPC or some other legislative formula, any attempt to assess which is best at defining that limitation is, with respect, almost a futile exercise. This is because no matter how one defines the word ‘invention’ or describes what an invention is, technology will confound both. No concoction of words put together at a specific point in time is likely ever to be able to cover all future contingencies.

This is why for over two hundred years, in the case of the US and Canada, and nearly four hundred years in the case of the UK, Australia and New Zealand, the courts have played an important role in delineating the precise limits of where there is invention and where there is not. That is not to say that this is a faultless process, but when one considers the breadth of human ingenuity displayed over the past four centuries, the courts have on the whole performed extremely well in drawing the ‘invention’ line.

This, however, is not to suggest that the European Patent Office (EPO) tribunals, such as the Technical Boards of Appeal or the Enlarged Board of Appeal, which have been accorded the status of quasi-judicial office by virtue of the EPC, have performed that function, nor should they. It must be understood that these tribunals are not independent of the EPO and are not judicial. Their members are appointed from the EPO and some are even former EPO patent examiners. Accordingly, and this undoubtedly must be so, the tribunals are merely adjuncts of the EPO – a patent-granting authority. The result is that in EPC countries there has been absent a proper check and balance on the EPO, facilitating the implementation of EPO patent policy under the guise of patent harmonisation. This has enabled, as Professor Peter Drahos maintains, the EPO to be ‘singularly successful in giving a narrow reading to the limits on invention and patentability contained in Articles 52 and 53 EPC’ [based upon a] ... ‘foundational interpretive assumption for European patent law...[t]he effect of [which] is to make the restrictions on patentability function weakly, if at all.’<sup>88</sup>

Nor does it mean that the United States Court of Appeals for the Federal Circuit (CAFC) has been immune from the influence of political policy. Possibly the most controversial court in US legal history, since it was established in 1982 the CAFC has been the subject of significant criticism for failing in its role as patent gatekeeper.<sup>89</sup> Indeed, Professor Arti Rai has argued that the CAFC’s refusal to defer to the USPTO contributed to the biotechnological patent gold rush in the United States.<sup>90</sup>

That there is a limit to patentable subject matter is incontrovertible. Fundamentally, modern society accepts that monopolies of any kind are an economic interference that create market distortions that usually result in higher than normal prices. Monopolists can also effect the choices that society may otherwise make in other respects, including the development of technology. It is for this reason that in 1623 the Parliament of England, under the careful direction of Lord Edward Coke, passed the *Statute of Monopolies*. Section 1 provided:

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

But Lord Coke appreciated that monopolies had their uses and that not all monopolies could be, or should be, vitiated by this legislation. Thus Parliament made a number of exceptions.

<sup>88</sup> Drahos, P. (1999), ‘Biotechnology Patents, Markets And Morality’, 21(9) *EIPR*, 441-44, 442.

<sup>89</sup> Olson, D.S. (2006), Patentable Subject Matter: The problem of the Absent Gatekeeper, *SSRN*, 933167.

<sup>90</sup> Rai, A. (2000), ‘Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials’, USD School of Law, Public Working Paper No 5 and Law and Economics Research Paper 2, *SSRN*, 223758.

The first of these was in section 6, which allowed the King to issue letters patent for ‘any manner of new manufactures’ to ‘the true and first inventor and inventors’, provided that the monopoly did not extend beyond 14 years and ‘be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient’.

The remaining exceptions concerned activities that were considered necessary for the defence of the realm, such as printing and the production of saltpetre (section 7); the activities of the courts provided by ‘warrant or privy seal’ (s.8); certain ‘liberties’ for the regulation of ‘city, borough or town’; trading companies, such as the Spanish, East India and Virginia Companies; and guilds ‘erected for the maintenance, enlargement, or ordering of any trade or merchandise’ as existed before the Statute (s.9). It also provided in s.4 for triple damages for those who were ‘hindered, grieved, disturbed, or disquieted, or by means of having his or their goods or chattels, seized, attached, distrained, taken, carried away, or detained’ in the attempted enforcement of a monopoly voided by s.1, and provided that the ‘courts of kings bench, common pleas, and exchequer’ were to have jurisdiction over the grant of any crown privilege, although it should be noted that the Privy Council did not actually cede this jurisdiction to the common law courts until 1753.

Plainly Coke believed that some monopolies were important to the economy of England and this agenda was supported by the need for the Parliament to be able to grant ‘letters patent’ as an economic tool that could be used to entice foreign artisans, craftsmen and tradesmen to come to England and bring with them their specialised knowledge to impart to the locals, so as to make the English economy more robust; and it is for this reason that for two hundred and fifty years the phrase ‘the true and first inventor’ included the first to import a new technology to England.

So, if modern society accepts that monopolies should be restrained and not encouraged, except insofar as they contribute more to society than they cost, then some care must be exercised and from time to time a review undertaken to examine whether the exceptions to the general rule against monopolies are performing as they should.

Accordingly, to the extent that the courts (or other mechanisms such as the EPO tribunals) are no longer able nor willing to properly fulfil their supervisory role in determining the limits of patentable subject matter, then, to that extent, the patent system is failing to achieve an economic objective that justifies its retention.

### **The Role of the Courts and Patentable Subject Matter**

Without doubt the leading case in Australia on the issue of patentable subject matter remains *NRDC*, despite being decided nearly fifty years ago when the predecessor of the current patents legislation, the *Patents Act, 1952*, had been in force for only 7 years. According to Professor Andrew Christie, *NRDC* was more than a ‘watershed’<sup>91</sup>, it was ‘a “bombshell decision”’, because, in his opinion, ‘it so generalised the concept of and test for inherent patentability that in practice the requirement has been annihilated.’<sup>92</sup>

According to Christie, *NRDC* and CAFC decisions, such as *State Street Bank v Signature Financial Group* (1998) 149 F. 3d 1368 (*State Street*), mean ‘the inherent patentability requirement has no practical meaning’<sup>93</sup> and thus he hypothesises that the formula  $E=mc^2$  is ‘inherently patentable’. He maintains that the threshold for what he calls ‘inherent patentability’ has been rendered ineffectual because as long as the claims in a patent are drafted so that what is defined as the invention is ‘some “reduction to a practical application”’

<sup>91</sup> So described by Chief Justice Barwick in *Joos v The Commissioner of Patents* (1972) 126 CLR 611 at para 9.

<sup>92</sup> Christie, A. ‘*Business Method Patents and Beyond: Why  $E=mc^2$  is inherently patentable*’, [http://www.wipo.int/edocs/mdocs/e-commerce/en/wipo\\_ec\\_conf\\_01/wipo\\_ec\\_conf\\_01\\_spk\\_3c.pdf](http://www.wipo.int/edocs/mdocs/e-commerce/en/wipo_ec_conf_01/wipo_ec_conf_01_spk_3c.pdf)

<sup>93</sup> *Ibid*, 7.

(under US law) or some “manner of implementation” (under Australian law)’ then virtually anything, even things that are expressly prohibited from patentability, such as discoveries, computer programs and abstract ideas, can be made the subject of patent protection. His hypothesis, if it is correct, means that the original and most fundamental threshold of patentability, the invention, is irrelevant and that, as a result, patent monopolies, which today may range from between 20 to 25 years (and even more in some cases depending on the patent strategy employed), may now be granted in respect to virtually anything. Literally, then, anything that is novel, involves an inventive step and is industrially applicable is capable of being the subject of a granted patent.

The problem with this hypothesis is that it is not only contrary to the objective of s.1 of the *Statute of Monopolies, 1623*, the historic and legislative mother of the Anglo-American patent systems, it is plainly inconsistent with the accepted economic rationale that generally monopolies should not be tolerated. Thus, adopting Lord Coke’s reasoning, unless a patent monopoly concerns a ‘manner of new manufacture’ it is ‘utterly void and of none effect’. Furthermore, if Christie’s hypothesis is correct, then the rationale for maintaining patents is completely negated.

It is unlikely, however, that Christie is correct. What he has overlooked is that in *NRDC* the High Court of Australia did not overrule nearly four hundred years of jurisprudence that was consistent with s.6 of the Statute of Monopolies. Accordingly, if that were so, the formulation of the question ‘Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the Statute of Monopolies?’ would have been a wasted exercise.

In *NRDC* the High Court decided that the use of a known herbicide in a process that eradicated certain types of weeds from certain crop pastures without harming the crops was an ‘invention’, even though the herbicide was known. Although the invention was a process using a known chemical in a herbicide in a new way, so that both the process and the active ingredient were intrinsically artificial, the human intervention lay in its *new use*, which the Court held produced an ‘artificial state of affairs’ and one which displayed ‘a remarkable advantage, indeed to the lay mind a sensational advantage’ and ‘[t]he method cannot be classed as a variant of ancient procedures’ as it is ‘additional to the cultivation’ in that it ‘achieves a separate result, *and the result possesses its own economic utility* consisting in an important improvement in the conditions in which the crop is to grow, whereby it is afforded a better opportunity to flourish and yield a good harvest.’

Reading into *NRDC* in the manner which Christie does, is going way too far. After all the central message, which the High Court was determined to get across, was that it was wrong for the Australian Patent Office to reject the patent application on the ground that ‘agricultural or horticultural processes are, by reason of their nature, outside the limits of patentable inventions’. The fact that the processes were for agricultural or horticultural pursuits should not act as a per se bar to patentability.

Furthermore, the High Court recognised that even though agricultural or horticultural processes were capable of being patentable subject matter, the results of those processes were not if they were indistinguishable from products of nature.<sup>94</sup>

Thus the analysis of *NRDC* at Section 7.2 (pp24-25) of the Issues Paper, particularly the statement that ‘*NRDC* led to a complete rethinking of the historical categories of unpatentable

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<sup>94</sup> “In *Re R.H.F.’s Application* (1944) 61 RPC 49 Morton J. approved a statement of the examiner which had been made to illustrate that the vendible product test enunciated in the *G.E.C. Case* (1942) 60 RPC 1 was not definitive. The statement was that fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a “manner of manufacture”. This may be agreed. *However advantageously man may alter the conditions of growth, the fruit is still not produced by his action.*” Per the High Court of Australia in *NRDC* at 279 (emphasis added).

subject matter’, is an exaggeration and the statement that it led to an ‘expansion of patentable subject matter’ quite wrong. While it is true that its reasoning did reinforce the importance of looking beyond the word ‘manufacture’ in the sense that one normally considers the word, it did not give the Australian Patent Office carte blanche in terms of patentable subject matter.

In terms of the United States, while the CAFC decision in *State Street* appeared to undermine the effect of s.101 *US Patents Act, 1952*, the fact remains that the US Supreme Court, a court that is binding over the CAFC, has held on numerous occasions that there are limits to patentable subject matter.<sup>95</sup> That *State Street* has not be reversed by the US Supreme Court is due to circumstance, but, arguably, had the decision been appealed it would have been overruled. Thus *State Street* does not provide the legal litmus test of patentability in the United States and is currently under review by an *en banc* panel of the CAFC.<sup>96</sup>

More recently, the US Supreme Court has accepted appeals from CAFC patent decisions and so far has reversed the CAFC on every occasion.

### ‘Anything under the sun made by man’

The US Supreme Court in its decision in *Diamond v Chakrabarty* 447 U.S. 303 (1980) referred to the testimony of P J Federico, an American patent law academic and one of the principal draftsmen of the *US Patents Act, 1952*, which he gave before a US Congressional Committee that was examining what was then a Bill. He testified: ‘[Under] section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man ...’.<sup>97</sup>

The phrase ‘anything under the sun made by man’, having been adopted by the US Supreme Court with approval, has since been interpreted by some legal commentators to mean that literally anything touched by human hands can be considered to be patentable subject matter in the United States. Given that the USPTO has been granting patents for isolated biological materials that are identical to naturally occurring biological materials, one may be forgiven for believing this to be a reflection of the law. In fact, if the act of isolation<sup>98</sup> is sufficient to transform a product of nature into a product of human ingenuity, then Christie could be forgiven for his hypothesis.

The proponents of this thinking, however, have repeatedly failed to appreciate that in *Chakrabarty* the human intervention was not simply confined to the isolation of the bacterium which Dr Chakrabarty claimed to be his invention. This was not merely the case of him identifying a link between a gene and a disease, as is often the case with modern gene patents. Dr Chakrabarty was actually able to significantly modify the genome of the bacterium so that it performed a function that was hitherto unprecedented in nature, namely that it would degrade crude oil. No other bacteria that was naturally occurring could perform this function. So in deciding that Dr Chakrabarty was entitled to a US patent Chief Justice Berger, who wrote the unanimous opinion of the 5 to 4 majority held:

... the patentee has produced a *new* bacterium with *markedly different characteristics from any found in nature* and one having the potential for *significant utility*. (Emphasis added)

The words ‘markedly different’ in this context raised the bar of patentability well beyond the mere isolation of naturally occurring biological materials. This threshold was alluded to by Professor Rebecca Eisenberg, an American law professor, who noted in 1987: ‘the Supreme Court did not reach the issue of whether naturally-occurring microorganisms that have been newly isolated or purified also fall within the ambit of “manufactures” or “compositions of

<sup>95</sup> *Diamond v Diehr* 450 U.S. 175 (1980).

<sup>96</sup> *In re Bilksi* No 2007-1130, slip op at 1 (Fed. Cir. Feb. 15, 2008). Oral argument was heard on May 8, 2008.

<sup>97</sup> *Diamond v Chakrabarty*, 308 fn 6.

<sup>98</sup> This step merely entails the removal of biological material from its normal environment.

matter”<sup>99</sup>.

In adopting Federico’s phrase, however, the Chief Justice also made the point that ‘broad’ as the construction ‘plainly contemplated’ by Congress was, he did not mean to suggest that s.101 had ‘no limits’ or that it embraced ‘every discovery’. His proviso, of course, was not something that was revolutionary. It had been part of the established jurisprudence of US patent law for over a hundred years and according to Breyer, Stevens and Souter JJ (in dissent) in *Laboratory Corporation of America Holdings v Metabolite Laboratories, Inc* (LabCorp) 548 U.S. 124 (2006): ‘[t]his principle finds its roots in both English and American law.’<sup>100</sup> Quoting from the decision of the Chief Justice in *Chakrabarty*, they also cited *Diehr* to reinforce the point that ‘[t]he principle means that Einstein could not have patent[ed] his celebrated law that  $E=mc^2$ .’

### **The Supposed Impact of NRDC on the Scope of Patentable Subject Matter**

The Issues Paper (pp24-5) maintains that *NRDC* led to a ‘complete rethinking of the historical categories of unpatentable subject matter’. It provides a number of examples, supposedly supporting this conclusion. Unfortunately, the conclusion is incorrect and the examples contain in the Issues Paper to support it are, at best, inaccurate descriptions of the cases referred to and, at worst, misleading.

#### **Methods of Human Treatment**

In 1972 the High Court, exercising its original jurisdiction (as it did then) as a court of appeal from the decision of the Commissioner of Patents, had cause to review a decision rejecting a patent application for a process for ‘improving strength and elasticity of keratinous material’, namely human hair and nails. It was hardly a case about a method for the treatment of human illness or disease, which Chief Justice Barwick plainly stated was not patentable subject matter.<sup>101</sup>

In *Joos v Commissioner of Patents* (1972) 126 CLR 611 Barwick CJ made it clear that ‘the only matter for consideration in this appeal is whether a process, otherwise appropriate for the grant of a monopoly under the Statute, must be held not to be a proper subject for a grant simply because it is a process for ‘treatment’ of a part of the human body.’<sup>102</sup> This was a very narrow point. The question therefore was: was a cosmetic process applied to a human body a ‘medical treatment’? It was not about extending the scope of patentable subject matter to cover the medical treatment of human illness and disease, a category which was at the time and remains unpatentable.<sup>103</sup> Thus Barwick CJ did not understand *NRDC* to be permissive authority that extended patentable subject matter to cover methods of medical treatment of human illness and disease.

This was also the view of Lockhart J, one of the three appeal judges in the Full Federal Court decision in *Rescare*. Lockhart J observed:

<sup>99</sup> Eisenberg, E., ‘Proprietary Rights and the Norms of Science in Biotechnology Research’, *The Yale Law Journal*, 97 (2), 177-231, 189.

<sup>100</sup> The principle of law which excludes ‘laws of nature, natural phenomena, and abstract ideas’ was reinforced only a year later by the US Supreme Court in *Diamond v Diehr* 450 U.S. 175, 185 (1981).

<sup>101</sup> ‘For the purpose of deciding this question it may be granted that a process for the treatment of the human body as a means of curing or preventing a disease, correcting a malfunction or removing or ameliorating an incapacity is not a proper subject matter for the grant of a monopoly under the Act.’ Per Barwick CJ in *Joos v Commissioner of Patents* (1972) 126 CLR 611, para 15.

<sup>102</sup> *Ibid*.

<sup>103</sup> ‘To be treatment, in the relevant sense, it seems to me that the purpose of the application to the body whether of a substance or a process must be the arrest or cure of a disease or diseased condition or the correction of some malfunction or the amelioration of some incapacity or disability. With that sense of “treatment”, I see no difficulty in conceding, for the purpose of the decision of this case, that a process for the medical treatment of a part of the human body is not a proper subject of letters patent.’ Per Barwick CJ, para 16.

I am not aware of any case in Australia where a process for the treatment of a human ailment or disease has arisen for consideration. *In the NRDC Case the judges expressed in very tentative language their doubts about its patentability.*<sup>104</sup> (emphasis added)

While a majority of the Full Federal Court in *Rescare* did agree that a method for the treatment of sleep apnoea, a human medical condition, was a ‘manner of manufacture’ and that it did not violate the proviso in s.6, *Statute of Monopolies*, it is misleading to suggest that it did so on the basis of *NRDC*. What Lockhart J stated is that ‘Australian courts must now take a realistic view of the matter in the light of current scientific development and legal process; the law must move with changing needs and times.’<sup>105</sup> In his opinion, the *Patents Act, 1990* did not expressly prohibit methods of medical treatment for human illness and disease and this was indicative of a *new* legislative intent that the courts not exclude such methods, as a class, from patentability. This he made clear when he held:

There is no statutory provision in Australia prohibiting the grant of a patent for a process of medical treatment of a human ailment or disease in a human being. It is noteworthy that the Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990 Act, but the limit of the exclusion was s. 18(2), namely: "human beings, and the biological processes for their generation, are not patentable inventions" cf. s.4, Patents Act 1977 (UK).<sup>106</sup>

If the Full Federal Court did expand patentable subject matter to include methods of treating human illness and disease it did so, not because of *NRDC*, but despite it.

### Genetic Materials

The case cited to support this contention (*Kirin-Amgen Inc v Board of Regents of University of Washington*) is a decision of the Deputy Commissioner of Patents of the Australian Patent Office which arose from a pre-grant Opposition that did not raise patentable subject matter as an issue.<sup>107</sup> When the decision was appealed to the Federal Court,<sup>108</sup> patentable subject matter was again not in issue. Consequently, the issue has never been decided in Australia by an Australian court. As such, the statement in the Issues Paper that the Deputy Commissioner’s decision made it clear that ‘a purified and isolated DNA sequence satisfied the *NRDC* concept of an “artificially created state of affairs”’ is wrong.

### Mathematical algorithms

First, the case cited in support of the contention that ‘mathematical algorithms were determined to be patentable subject matter provided they are implemented in a useful way’ is not the decision of an Australian court. It is the decision of the US Supreme Court.

Secondly, and more importantly, the patent in issue in *Diamond v Diehr* 450 U.S. 175 (1980) defined the invention as a process that turned uncured synthetic rubber into precision parts made of cured rubber. The process, however, employed a computer which in turn used a mathematical equation known as ‘the Arrhenius equation’. There was nothing new about this equation and there was no claim to that equation in the patent, since the equation had been used in the manufacture of rubber parts for some time. What was novel about the invention was that the process employed a computer to regulate the curing of the raw synthetic rubber so that it was made into precision rubber parts. This process represented a technological advance because by enabling the constant measurement of the temperature of curing rubber, which was then fed to a computer, a more efficient process resulted.

<sup>104</sup> *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) 122 ALR 141 per Lockhart J at para 74.

<sup>105</sup> *Ibid*, para 75.

<sup>106</sup> *Ibid*, para 77.

<sup>107</sup> The decision of the Deputy Commissioner does refer to manner of manufacture but confirms that this was not raised as an issue in the Opposition.

<sup>108</sup> *Genetics Institute, Inc. v Kirin-Amgen, Inc (No 3)* (1998) 156 ALR 30.

Therefore this case does not stand for the proposed contention. It merely confirms that a process is patentable and that if one component of that process involves the use of a ‘mathematical equation’ (which by itself is not patentable) then ‘the process *as a whole* does not thereby become unpatentable subject matter’.<sup>109</sup> (Authors emphasis)

The invention in that case was a complete process that produced cured rubber parts. It was not about a mathematical algorithm per se being used in a useful way – rather, the use of the algorithm on the facts of the case was not even novel except in the context of that specific process. And, *NRDC* was not even mentioned.

### **Computer software**

First, the case referred to, namely *IBM v Smith, The Commissioner of Patents* (1991) 105 ALR 388, was not about computer software per se, but about the use of a computer program in a method that used a computer to generate the image of a curve on a computer screen. Much like the patent in *Diamond v Diehr*, the patent in this case had to be assessed in terms of patentable subject matter as a complete method.

Secondly, the essential objection raised to the patent by the Commissioner of Patents was that the ‘mathematical formula’ used by the computer to generate the curve on the computer screen was ‘not applied in any manner to physical elements or process steps’. Thus the objection related more to the fact that the end product was an image of a curve and not a physical product, such as a cured rubber part as in *Diehr*, than it did to the fact that what had been employed was a mathematical formula in a computer program. As Burchett J explained, the Commissioner’s argument was:

... if the end-product of a claimed invention is a pure number, as in *Benson and Flook*, the invention is nonstatutory regardless of any post-solution activity which makes it available for use by a person or machine for other purposes. If, however, the claimed invention produces a physical thing, such as the noiseless seismic trace in *In re Johnson* (what this case involved will be indicated infra) the fact that it is represented in numerical form does not render the claim nonstatutory.<sup>110</sup>

Therefore, the issue that Burchett J dealt with there was whether it was necessary for the end product of the method, defined as the invention, to be physical for the method to be patentable subject matter?

Finally, nowhere in that decision did Burchett J ‘emphasise that the *NRDC* approach’ resulted in the ‘reformulation’ of the law with regard to patentable subject matter. What Burchett J did, however, was to use *NRDC* and *Diehr* to confirm that the new use of known things in a process or method that produces a product, whether that product be physical (as in a rubber part) or an effect (as in killing weeds in a field) or an image on a computer screen (as in the image of a curve), does not render the process or method unpatentable.

That was neither revolutionary in 1959 nor subsequently.

### **Business methods**

First, the case referred to, namely *Welcome Real-Time SA v Catuity Inc* [2001] FCA 445 (*Catuity*), was not about the patenting of business methods, as Heerey J stated:

... in the sense of a particular method or scheme for carrying on a business - for example a manufacturer appointing wholesalers to deal with particular categories of retailers rather than all retailers in particular geographical areas, or Henry Ford's

<sup>109</sup> *Diamond v Diehr* 450 U.S. 175, 187 (1980).

<sup>110</sup> *IBM v Smith, The Commissioner of Patents* (1991) 105 ALR 388, para 6. In the Commissioner’s reasoning the invention was unpatentable subject matter for the reason: ‘the curved image is not defined as being shown on any particular apparatus for example, the ‘computations’ are not specified as being done in any particular environment, a hand-held calculator for example could be used, and there is no definition of how the ‘control points’ are ‘input’. Quoted by Burchett J at para 7.

idea of stipulating that suppliers deliver goods in packing cases with timbers of particular dimensions which could then be used for floorboards in the Model T.

There is no doubt that under *NRDC*, no matter how useful and commercially valuable the end products of such methods as described by Heerey J, these would not have been patentable subject matter.

Secondly, the case concerned a patent that claimed a method that used smart cards and a POS terminal as components. A critical component was a chip that recorded information in a specific computer file, called the 'Behaviour file', that was developed specifically for use in the method described in the patent. The complete method, which required use of all of these components, produced a useful result that was economically valuable.

Thirdly, Heerey J did not find that a 'physical effect' was not present. In his opinion there was a physical effect in 'the writing of new information to the Behaviour file and the printing of the coupon.'

Finally, to the extent that Heerey J did refer to *NRDC* it was only to reinforce that the proper test is this: *Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6. of the Statute of Monopolies?'*

#### **'Pure' business methods**

First, the description of the method in *Grant v Commissioner of Patents* [2005] FCA 1100, Full Federal Court [2006] FCA 120 is misleading because it implies that there is a distinction between the method referred to in *Catuity* and the method in *Grant*, both being 'business methods', when realistically the patent in *Catuity* did not concern a 'business method' at all.

It is important to appreciate that the method defined as the invention (which is an innovation patent, not a standard patent) in *Grant* is actually a *business* method and a closer examination of the patent makes this apparent.

1. *an asset protection method for protecting an asset owned by an owner, the method comprising the steps of:*
  - (a) *establishing a trust having a trustee,*
  - (b) *the owner making a gift of a sum of money to the trust,*
  - (c) *the trustee making a loan of said sum of money from the trust to the owner, and*
  - (d) *the trustee securing the loan by taking a charge for said sum of money over the asset.'*

Consequently, the Full Federal Court, which consisted of Heerey, Kiefel and Bennett JJ, had no difficulty in making this distinction, stating: '[i]t is quite different from the invention in *Catuity*, ...'.<sup>111</sup>

Secondly, the Full Federal Court explained that in accordance with *NRDC* this business method was not patentable subject matter because 'the method of his patent does not produce any artificial state of affairs, in the sense of a concrete, tangible, physical, or observable effect.'<sup>112</sup> Rather, what the alleged invention did, 'at best', according to the Full Federal Court, was produce 'an abstract, intangible situation, namely that a hypothetical unsecured creditor who recovered judgment against a user of the method could not levy against the user's assets to the extent they were subject to the charge.'<sup>113</sup> The Full Federal Court held that the method described in the patent was merely a 'scheme, an abstract idea, mere intellectual information' and confirmed that these things have 'never been held to be patentable'.<sup>114</sup>

The fact that the Full Federal Court commented that it was not in a position to 'determine the

<sup>111</sup> *Grant v Commissioner of Patents* [2006] FCA 120 at para 30.

<sup>112</sup> *Ibid.*

<sup>113</sup> *Ibid.*, para 31.

<sup>114</sup> *Ibid.*, para 32.

balance between social cost and public benefit' merely emphasised that patent monopolies are restricted to innovations that *are* 'inventions'. Thus, no matter how innovative the method in *Grant* or its ability to contribute to the economic wealth of Australia or its ability to advance the public interest, in terms of what it was, it simply was not an innovation that was suitable for the grant of a patent – namely, it was not 'a manner of manufacture'.

## Conclusion

While *NRDC* was, at the time, an important decision in the field of patent law because its reasoning was the zenith of jurisprudential reasoning on the issue of patentable subject matter after nearly 350 years, its true purport and impact has been misrepresented in the Issues Paper. The decision is not generally permissive in expanding patentable subject matter.

What *NRDC* and subsequent Australian court cases show is that there is now a well established test of patentable subject matter or 'invention' and that the Australian courts, in the main, are quite capable of acting as the gatekeepers of patentability when they are given the opportunity. That the language of the Australian test goes back in time to 1623 is not problematic at all and the suggestion that it is, as the Issues Paper does, is simply unjustified.

The real problem is that not enough Australian patents are subjected to the scrutiny of the Australian courts. Consequently many patents remain on the Patents Register when they should not. Not only are the numbers of patent applications growing, but as a result the quality of the assessment by IP Australia is falling. As the resources of IP Australia are stretched so the quality of Australian patents continues to fall. It is therefore critically important that the inherent patentable subject matter limitations be rigorously applied and to the extent that IP Australia is unable to do so, other mechanisms should be put in place that will. Clearly, the problem does not lie with the language of s.18(1)(a). The problem lies in the failure of IP Australia to fulfil its primary legislative duty to act as a patent gatekeeper.

Unfortunately, the Full Federal Court decisions in *Rescare* and *Bristol* have made it difficult for the Australian courts to fully perform their duty, by suggesting that matters of public policy in relation to patentable subject matter are to be resolved by Parliament alone. These decisions are wrong, but the solution, as has already been stated, is to simply reinstate the proper role of the courts, not by way of a wholesale rewrite of s.18(1)(a), but by way of a simple amendment which makes it clear that the courts should assess the economic and social impact of patents as part of their assessment into patentable subject matter.

Nonetheless, there are specific subject matters that have become problematic, mainly because of the approach of IP Australia. Accordingly, biological materials which are identical or practically indistinguishable from natural biological materials and their derivatives should be expressly excluded from patentable subject matter under an amendment to s.18(2). Moreover, neither should patents be granted for inventions that involve the technical application of excluded subject matter, such as computer programs, in obvious apparatuses or to achieve obvious results, particularly if the results produce no *tangible* output. As such, business methods must be expressly excluded from patentability under an amendment to s.18(2) so as to make it clear that such innovations are beyond the patent system in their entirety.