

REGULATORY INSTITUTIONS NETWORK (RegNet)
Genetic Sequence Right Project
Centre for the Governance of Knowledge and Development
Research School of Asia and Pacific Studies
H. C. Coombs Building, Cnr Fellows & Garran Roads
The Australian National University
Canberra ACT 0200
AUSTRALIA

t: +61 2 6125 5465
m: +61 400 606 263
f: +61 2 6125 8503
e: luigi.palombi@anu.edu.au
<http://cgkd.anu.edu.au/>

October 8, 2009

Patentable Subject Matter Review
ACIP Secretariat
PO Box 200
WODEN ACT 2606

Sent via Email

Dear Mr Bourke

ACIP Options Paper – Patentable Subject Matter

I thank ACIP for the opportunity to respond to its options paper regarding Patentable subject matter.

ACIP has invited written comments to the four options specified in the paper.

Summary

The ALRC's recommendation for a review of the patentable subject matter test was ill conceived, lacked a critical mass of support from those that made submissions, and was beyond its brief.

Given that only 4 years earlier the IPRCR, which had concluded a broader review of all aspects of intellectual property on the Australian economy, recommended the retention of the current test, ACIP should recommend that the existing test of patentable subject matter specified in the *Patents Act, 1990* be retained. All other options should be rejected.

Response

For 106 years Australian patent legislation has prescribed the same test for patentable subject matter. Not only has the test been the subject of judicial interpretation by the High Court of Australia, but the Court's decision in *NRDC v The Commissioner of Patents (NRDC)*, which was decided 50 years ago, remains the leading case in Australian patent jurisprudence on the issue. Furthermore, the decision has been cited with approval by appellate courts in other English common law countries, and only 9 years ago, the High Court in *Grain Pools of WA v The Commonwealth (Grain Pools)* reinforced its relevance by referring to it as the "celebrated judgment". Indeed, both the Industrial Property Advisory Committee (IPAC) Report in 1984 and the Intellectual Property and Competition Review Committee (IPCR) Report in 2000 approved of the *NRDC* decision and recommended the retention of the existing test.

In its Report, IPCRC stated:

Almost all submissions to the Committee argued for retention of the current Australian definition of what is patentable as 'manner of manufacture'. For example, the Institute of Patent Attorneys and Trade Mark Attorneys said that 'IPTA considers that the current test of what is patentable subject matter as set out in s. 18 of the *Patents Act 1990* is suitable both for the needs of established technologies and for the needs of newly emerging technologies...Application of this principle has allowed development of the concept of patentable subject matter to move with the advance of technology over the years to encompass biological processes and other aspects of biotechnology, as well as computer software and so on. IPTA considers this position is far preferable to the position which exists in some other countries which have a static, more precise definition of patentable subject matter, as this latter situation has resulted in many of these other countries struggling to develop the concept of patentable subject matter with the advance in technology.'

Now let's take a moment to focus on these findings made just 4 years before the ALRC recommended that the test be changed.

First, the IPCRC found that "almost all submissions" favoured the retention of the existing test.

Next in agreeing with the Institute of Patent and Trademark Attorneys (IPTA), it found the current test was "suitable both for the needs of established technologies and for the needs of newly emerging technologies".

Finally, in adopting the submission of the IPTA, it found that "this principle [from *NRDC*] has allowed development of the concept of patentable subject matter to move with the advance of technology over the years to encompass biological processes and other aspects of biotechnology."

It must be remembered that both IPAC and IPCRC examined the patent system and how it operated across all technologies and not, as the ALRC did, only with an eye to gene patents. The ALRC was merely looking at the patenting of genes and other biological materials, many of which, but for their being isolated or purified, were identical or substantially identical to those materials as they existed in nature. This raised the question of whether these things were 'inventions'? But instead of referring the debate to the High Court, as was done with horticultural processes by *NRDC* in the late 1950s, IP Australia took it upon itself to apply a policy that had been put forward by the US, Japanese and European patent offices, and thereby allowed the grant of patents in Australia over these biological materials. That decision, absent any judicial scrutiny or interpretation, directly led to the grant of over 15,000 gene related patents in Australia, and because they were directed to biological materials per se and not merely to the processes of their synthesis or manufacture, they have impacted on medical and scientific research and on the provision of clinical and health related services in laboratories and hospitals in ways that had not been anticipated.

Indeed, it was a letter of demand sent in 2002 by Genetic Technologies Limited (GTL), the exclusive licensee of Australian patents 686004, 691331, 691958 and 773601, to the public laboratories providing genetic testing for hereditary forms of breast and ovarian cancer that was the catalyst for the referral from the Attorney-General to the ALRC. In this letter of demand, GTL asserted a patent monopoly over

the very genetic mutations in the BRCA 1 and BRCA 2 human genes that were discovered to be linked to these types of cancers and their diagnosis by genetic testing.

Therefore, the ALRC's terms of reference were relatively narrow when compared to those that applied to IPAC and IPCRC. The narrowness of the terms of reference was acknowledged by the ALRC in its Report. It stated:

The Terms of Reference directed the ALRC to consider—with a particular focus on human health issues—the impact of current patenting laws and practices related to genes and genetic and related technologies on:

- research and its subsequent application and commercialisation;
- the Australian biotechnology sector; and
- the cost-effective provision of healthcare in Australia.

This is not some trifling distinction which can be easily brushed aside. Any amendment to the test of patentable subject matter will not only impact on biotechnology and the healthcare sectors but will impact on all industries across the board. So what was it about the current patentable subject matter test that the ALRC found so wanting that, rather than deal with gene patents by way of specific legislation (a course of action which it considered but rejected), it preferable to recommend to the government that a wholesale review of that test be conducted?

Well, in one word, it was 'language' ("The Inquiry considers that the 'manner of manufacture' test (which is based on the *Statute of Monopolies 1623*) is ambiguous and obscure, and recommends that it be reviewed, with a particular focus on the requirement that an invention must not be 'generally inconvenient'"). And in complete contrast to the IPAC and IPCRC reviews, where "almost all submissions" favoured the retention of the current patentable subject matter test, the ALRC was able to refer only to "a number of submissions" that supported the call for its reform. Even IP Australia itself "questioned whether a review of the test is warranted", noting that the "test has proven to be 'flexible and able to take account of developing technologies and developing inventive concepts'".

Given that the issue germane to the ALRC was the patenting of genes and their impact, principally on the biotechnology and healthcare sectors, it is astounding that with very little support for its proposal for a review of the patentable subject matter test, and contrary to the recommendations of the IPCRC which only 4 years earlier had conducted a much broader review of all aspects of intellectual property and its economic impact on the Australian economy and recommended the exact opposite, the ALRC felt justified in pursuing its recommendation. Clearly, it was not so justified.

One could almost be forgiven for thinking that the ALRC's recommendation was nothing more than a last ditch attempt at diverting attention away from its own inability to deal with the real issue – the patenting of genes. While it was able to grasp the nettle when it came to the test for patentable subject matter, with little more than a handful of submissions supporting its own proposal, when it came to gene patents the ALRC had no difficulty in ignoring the "many submissions [that] asserted that genetic materials, and in particular genetic sequences, are discoveries and should not be patentable." It was as if the "concerns [that] were expressed primarily by participants in the research and healthcare sectors" were irrelevant. But the situation has deteriorated. It was not just submissions from this sector that the

ALRC chose to ignore, indeed there were “[o]ther submissions [which] were critical of the basis upon which the patentability of genetic materials and technologies is justified—namely, that isolated and purified genetic material is an invention, not a discovery.”

What is puzzling, however, is that the ALRC conceded that there were “attractive arguments for the view that such materials should not have been treated as patentable subject matter.” So why did it not recommend that the patenting of these materials be expressly banned? Here is its answer:

... the time for taking this approach to the patenting of products and materials has long since passed. For decades, naturally occurring chemicals have been regarded by patent offices in many jurisdictions as patentable subject matter, when they are isolated and purified. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are ‘merely’ complex organic compounds. This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration.

Really, since when does a bedrock principle of patent law (that “natural phenomena, mathematical formula and abstract ideas are not patentable subject matter”) become irrelevant merely because an aberrant policy has been allowed to stand uncorrected for a long period of time?

But even if we assume that the ALRC was right in concluding that the current patentable subject matter test is overdue for reform, what would replace it?

One has only to look to the United States, the United Kingdom and the European Union to understand that changing the arrangement of words that define patentable subject matter does not resolve the ‘issues’ which the ALRC and “some submissions” have identified. For instance, the United States has a arrangement of words in s.101 *US Patents Act, 1952* which has been unchanged (except for one word; ‘arts’ replaced with ‘process’) since 1793. The words have been the subject of judicial review for more than 200 years. Yet there has been no call in the US to change that arrangement even though patents over genes and business methods and computer software have been granted by the US Patent and Trade Mark Office (USPTO) and are all controversial and problematic. In Europe, the *European Patent Convention* (EPC) was changed by effect of the European Biotechnology Directive to overcome concerns that gene patents may have been expressly excluded, by the exclusion of ‘discoveries’ from being ‘inventions’ in art 52 *EPC*. In the UK, the Court of Appeal in *Genentech’s Patent*, a case about the patentability of an isolated human protein, ruled that the subject was not patentable because it was not an ‘invention’ within the meaning of s.1(1) *UK Patents Act, 1977*.

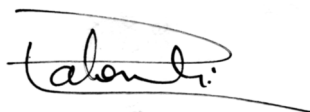
Despite this, the ALRC believes that “that the key concept of ‘manner of manufacture’ [which] depends on a provision in a 380 year old English statute that has long since been repealed in the jurisdiction in which it was enacted” is reason enough to change a test that has itself stood the test of time since 1903. I would argue that age is not a good enough reason.

I would also argue that nothing that is contained in either the ALRC’s Report or the ACIP Options Paper can justify replacing the current test of patentable subject matter with some other test.

The fact is, if we are to have a patent system that is optimal then it must balance the social benefits that the disclosure of an 'invention' brings to society against the social costs that a patent monopoly imposes on society. The test for patentable subject matter, that is the filter of what is and what is not capable of being the subject of a patent monopoly, is critically important to the maintenance of a proper balance between them. Without doubt gene patents, business method patents and patents on computer software have tested and continue to test that filter, and the most effective mechanism to maintain that filter is the court system. Unfortunately, in the case of gene patents, there has been no judicial review of a policy that was unilaterally implemented by IP Australia and, I hasten to add, had there been, then perhaps there would not have been a need for the ALRC to review the impact of gene patents in the first place.

That said, courts are not infallible and they do not always get it right and when that happens Parliament is there to intervene.

Yours truly,

A handwritten signature in black ink, appearing to read 'Luigi Palombi', with a long horizontal flourish extending to the right.

Luigi Palombi, LLB, BEc, PhD.