

PATENTABLE SUBJECT MATTER UNDER REVIEW IN AUSTRALIA

The Advisory Council on Intellectual Property (ACIP) is conducting a review of 'patentable subject matter' in Australia.



Dr Mark Summerfield

The ACIP is an independent body appointed by the Australian Government to provide advice to the Minister for Innovation, Industry, Science and Research, and to IP Australia (the federal agency including the Patent, Trade Marks and Designs Offices) on matters of intellectual property policy and administration. The ACIP has a brief to take a broad, strategic view of the role of intellectual property and its contribution to the development of Australian industry, and includes members from government, business and manufacturing sectors, the patent attorney and legal professions, the tertiary and research sectors, and technology and commercialisation groups.

The current review is an enquiry into what should constitute patentable subject matter (sometimes called 'statutory subject matter' in the United States). The patent system is generally understood to have the economic objective of providing benefits to society by providing incentives to innovation, as well as public access to new technologies. A patent monopoly provides an exception to free competition, and rewards innovators for their investment in new technologies with a limited period of exclusivity in return for open disclosure of new inventions. Only those inventions which satisfy appropriate thresholds of merit are considered deserving of a statutory monopoly. For the majority of innovative technologies, the most important thresholds of merit are novelty and inventiveness, which involve a determination of whether an innovation represents an advance over the state of the art in the relevant technical field. However, a fundamental threshold is whether an innovation relates to the kind of thing for which patent protection should be granted, in view of the policy objectives of the patent system.

Concerns regarding the scope and benefits of the patent system are not new. The grant of monopolies, no matter how limited in nature, necessarily involves a fine balance of competing interests. On the one hand, the patent system provides economic rewards to innovators who develop and patent successful new technologies. On the other hand, it is frequently argued that there are fields of technology in which innovation will occur regardless of the existence of statutory rewards, and that in such cases the patent system may in fact stifle advancement and reduce benefits to society by restricting competitive activities and by imposing substantial administrative and legal overhead costs. In some jurisdictions, patent protection is denied or limited in certain fields of endeavour for other public policy reasons. For example, methods of medical treatment of human beings may be excluded from patentability so that doctors are able to provide appropriate care to patients without fear of patent infringement. In many countries, including Australia, patents may not be granted for certain genetic and reproductive technologies relating to human beings, and biological processes for generating human beings, primarily on ethical grounds.

Determining the appropriate scope of patentable subject matter is widely considered to be an important tool of social and economic policy. Debates and controversy in relation to this aspect of the patent system are accordingly not uncommon. In recent times, various interested groups have questioned the appropriateness of granting patents for a range of new technologies, including genetic technologies, software (ie computer-implemented inventions) and business processes, including computer-implemented processes involving on-line information systems and electronic commerce applications. In view of the significant policy considerations involved, there is considerable divergence in the approach to patentable subject matter in different jurisdictions in relation to inventions in these areas of activity. In Australia, decisions regarding the appropriateness of granting patent protection to inventions in emerging technologies and fields of economic activity have been left largely in the hands of the courts, which are guided by a line of judicial decision-making dating back to the original English *Statute of Monopolies* of 1623.

The scope of the ACIP review is broad and will consider:

- the economic objectives of prescribing patentable subject matter,
- the appropriateness of the present approach,
- the consequences of limiting or expanding patentable subject matter,
- whether limits on patentable subject matter can be justified on ethical grounds,
- the content and structure of current Australian law, as well as the value of the existing body of case law, and various associated issues relating to the existing test applied by the courts and the Patent Office for identifying patentable subject matter,
- the value of international harmonisation of legal requirements for patentability, and the compliance of existing Australian law with various international treaties.

This review will also address a potential preferred system of patentable subject matter by considering what subject matter should be patentable, and the most appropriate legislative structure for implementing such a system.

While past reviews have generally supported maintaining the status quo in relation to patentable subject matter, it is nonetheless within the Terms of Reference of the present ACIP review to make wide-ranging recommendations, including changes to the *Patents Act 1990*, should it choose to do so.

The ACIP has recently released an Issues Paper in relation to its review of patentable subject matter. Further information on the review, including the Issues Paper, is available from the ACIP web site at <<http://www.acip.gov.au/>>.

FALSE SUGGESTION AND MISREPRESENTATION

Listed companies take considerable care to ensure that all relevant information is disclosed to the stock exchange in order to comply with corporations law. The implications of not instilling this discipline at all levels of an organisation became clear in an important recent decision.

In this decision¹ the Full Federal Court of Australia upheld a lower court finding that the claims of Warner-Lambert's patent directed to the enantiomer atorvastatin calcium should be revoked for false suggestion and misrepresentation. This finding is perhaps a portent of the manner in which revocation actions before Australian courts may proceed in future, mirroring the common practice in US patent matters in which allegations of fraud in the patent process are common.

Atorvastatin calcium is the active ingredient in a prescription cholesterol-lowering medication marketed in Australia under the product name Lipitor. In 2004 Ranbaxy Australia Pty Ltd proposed to import into Australia for sale a product containing atorvastatin calcium. Warner-Lambert alleged that the importation and sale of the product would constitute infringement of two of its patents covering Lipitor. Ranbaxy commenced a proceeding seeking an order revoking the narrower patent directed to an enantiomer of the active ingredient. Warner-Lambert filed a cross-claim seeking to restrain Ranbaxy from infringing both patents.

The Full Federal Court stated that: "if a representation that was false or misleading materially contributed to the Commissioner's decision to grant a patent, even if other circumstances or causes also played a part in the making of that decision, it may be said that the patent was obtained by a false suggestion or misrepresentation. It is sufficient if the representation materially contributed to the Commissioner's decision to grant the patent or was a material, inducing factor, which led to the grant."

Ranbaxy asserted that false suggestions or misrepresentations were made in the patent specification itself and in the patent prosecution process by statements made to the examiner concerning the results of comparative testing of the enantiomer. The court agreed. In particular, it found that the data in the patent specification did not correctly represent the results of tests that were carried out by Warner-Lambert, and that in fact Warner-Lambert had selected only that data which supported a case for patentability and had withheld concurrently obtained data which showed a significantly lesser degree of activity. Further, in prosecuting the patent application, the patent attorney had highlighted the selected data and had asserted a tenfold increase in efficacy, when in fact only a twofold increase had been seen in broader trials. Since it had been proven that Warner-Lambert had been in possession of, but had withheld, data which contradicted the attorney's assertion, its actions were found to be material in misleading the Commissioner.

This brings into sharp focus the need for inventors to disclose full details of their experiments to their patent attorneys, and for patent attorneys to interrogate inventors properly so that what is drafted into a patent specification is a truthful account of an invention, rather than an attempt to obtain commercial advantage by half-truth.

Karen Sinclair

¹ *Ranbaxy Australia Pty Ltd v Warner-Lambert Company LLC* ([2008] FCAFC 82)

LESSONS FOR THE BOARDROOM

A recent Australian Federal Court decision has repercussions for the business of research and serves as a lesson for company directors and others in the boardroom.

The decision by Justice French¹, that the University of Western Australia (UWA) did **not** have a claim to ownership of IP developed at the University by Professor Bruce Gray, has provoked heated discussion about the ownership of IP in the academic sector. The decision is also relevant to private business, both in terms of how it deals with collaborative research with the academic sector, and the duties and responsibilities of company directors.

The IP in question related to the use of microspheres to specifically target a radioactive or toxic payload to kill liver cancer cells while sparing normal liver tissue. The microspheres which delivered 'selective internal radiation' became known as SIR-spheres. Various patents were filed around the technology. Professor Gray assigned his rights in the inventions (and the patent applications) to Sirtex Medical Ltd (Sirtex), a company set up to commercialise the technology, in return for shares in the company. He was the founding director on the incorporation of Sirtex in 1997. Gray remained a director of Sirtex until 2007, and is today Sirtex's largest shareholder.

UWA alleged in the Australian Federal Court that Gray had breached his contract of employment by failing to comply with its patent regulations and additionally that he had breached his fiduciary obligations to the University. UWA also claimed that Sirtex had knowingly been involved in those breaches.

Research with Universities

The case was complicated in part by the number of entities involved. Over the course of the research, three research institutes, two corporate entities and UWA were involved in providing funding and staff. Changes in employment status of staff, even during their involvement in the research, were common (for example, when one entity ran out of funds, another entity simply took over employment responsibilities). This led to a number of problems.

- Often the researcher and the other entities involved in the project were not certain who was actually employing a researcher at any given time.
- As the researcher remained with the project despite their change in employment, no exit interviews were carried out, so it was later impossible to determine exactly when an invention was created and thus who employed the inventor at the relevant time.

For corporate partners engaged in research with universities, this decision highlights the need to pay particular attention to the employment status of researchers, and in particular to ensure assignments are obtained from the correct employer. It also shows the risk of not formally addressing a change in background employment arrangements where the researcher remains with the project.

The Problems Associated with Key Researchers

Gray, as the key researcher, was also a director, medical director and/or managing director of the research institutes involved during the course of the project. This decision shows that care should be taken where key researchers hold positions of dominance in the corporate or research entities involved in the project. Such intertwined arrangements may give rise to an argument that the corporate or research entity is on notice of those matters within the knowledge of the researcher, regardless of whether the researcher has actively disclosed them.

UWA also argued that that Gray had breached his fiduciary duties to the University. While the Judge did not formally find that Gray, as a Professor of Surgery, owed fiduciary duties to the University, it can be implied that where a senior member of university staff creates an invention during the course of their employment, the courts in Australia may be willing to find that the researcher owes the university fiduciary duties in respect of the invention, similar to those owed by senior staff in a corporate context.

Director's Duties

During the proceedings, Sirtex successfully cross claimed against Gray for breach of director's duties and engaging in misleading and deceptive conduct. The relevant facts were that in 1999 Gray received correspondence from UWA in which it claimed to be entitled to some of the patents being exploited by Sirtex. Gray, who considered the claims spurious, took legal advice in relation to the letter but the matter was not resolved. Gray did not disclose the letter or his legal advice to Sirtex. Gray later failed to disclose the letter in due diligence questionnaires completed prior to the public float of Sirtex.

The Judge, in finding for Sirtex on this issue, stated that Gray's opinion that the claims were spurious was immaterial and he had a duty to disclose the letter to Sirtex. The Judge also considered that the fact UWA was ultimately unsuccessful in its claim of entitlement to the patent(s) was irrelevant to the issue of whether Gray had a duty to disclose the claim to Sirtex.

Of particular concern to His Honour was that, by omitting to disclose the letter to Sirtex, Gray had deprived Sirtex of the chance to consider the possible implications and risks associated with the claim and take action accordingly.

The decision in *UWA v Gray* thus reinforces the need for directors to disclose to their companies all issues relating to technology and its ownership, regardless of whether the director thinks the issue could be of concern.

UWA has appealed the decision to the Full Court of the Federal Court.

Robynne Sanders

¹ *University of Western Australia v Gray* (No. 20) [2008] FCA 498

EXAMINATION PROCEDURE IN AUSTRALIA

Patent applications in Australia do not automatically undergo substantive examination. Instead, the applicant must request examination within five years of the filing date (which is the filing date of the international application for a PCT national phase application).

Under Australian law, the Commissioner of Patents may also (at any time) direct the applicant to request examination. The direction must be complied with within six months of the direction being issued, otherwise the application will lapse. If the direction issues within six months of the five year deadline, the applicant may still request examination after the deadline has passed, so long as the request is made within six months of the date of the direction.

It is common practice for patent applicants to wait for an examination direction to issue, unless the applicant wishes to obtain an enforceable right within a shorter time frame. This approach provides useful additional time for the applicant to decide whether the patent application is sufficiently commercially valuable in Australia to justify the expense of proceeding with examination.

Delaying the request for examination in Australia may also be strategic when corresponding applications are pending in other jurisdictions. Increasingly, Australian Examiners are following examination reports issued by foreign patent offices, particularly the EPO and the USPTO. Accordingly, arguments and/or amendments made in response to examination reports issued in those jurisdictions can generally be adapted to overcome similar objections raised in Australia. However, there are subtle differences between the patent laws of Australia and other patent jurisdictions, particularly in relation to the assessment of inventiveness (or obviousness) and in allowability of amendments, which may sometimes enable the applicant to achieve broader protection in Australia than is possible in other jurisdictions. Your patent attorney should advise you of these possibilities where appropriate.

Examination directions previously tended to issue well before the five year deadline. However, it has become more common for directions to be received quite close to the five year mark. Applicants should be aware that where a direction to request examination issues within six months of the five year deadline, the deadline for requesting examination will actually fall after the due date for the first annuity fee. If annuities are being managed by a separate annuity service, clear communication with the Australian prosecuting attorney is therefore advisable to ensure that examination is not requested before the annuity is paid, as an application with fees outstanding will not be examined.

Where it is strategic for an applicant to progress the application to grant as soon as possible (ie in cases of possible infringement), examination can be requested immediately upon filing the application or upon entry into the national phase. It is possible to accelerate the process further by requesting expedited examination. There is no fee required for expedited examination, but reasons why expedited examination is necessary, or in the public interest, must be given. Typically, the vast majority of requests for expedited examination are allowed, thereby giving the applicant an opportunity to obtain an enforceable patent right earlier.

Ken Simpson

WATERMARK PROFESSIONAL STAFF UPDATE



Watermark is pleased to announce the appointment of Adam Hyland as a Principal of the firm on 1 July 2008.

We congratulate Adam Hyland and welcome him as a valuable addition to the firm's Principal group.

With a background in chemical and processing technologies for an Australian division of a major food multinational, Adam combines his expertise in intellectual property protection with a working knowledge of the business issues and challenges faced by clients in the food industry. He is widely regarded in the food industry as an authority on intellectual asset management, protecting the brands, food formulations, equipment, manufacturing processes and trade secrets of his clients, helping them to stay ahead in an increasingly competitive market.

Adam is based in our Sydney office.

Barry Newman has been appointed an Associate of the firm effective 1 October 2008.

We welcome Barry Newman as an Associate of Watermark at 1 October 2008.

Prior to entering the patent attorney profession, Barry worked as a mechanical engineer in the WA mining industry, in open-cut operations in the Pilbara region and underground in the WA goldfields.

Since entering the patent attorney profession, Barry's practice has centred on technologies used in the mining, oil and gas, and automotive industries. His clients have ranged from multi-national minerals and mining companies through to start-up enterprises. He has also acted for WA state government agencies in both patent and trade mark disputes and negotiations.

Barry is based in our Perth office

