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High Court affirms that methods of treatment are still patentable in Australia

Recent years have presented significant challenges to the biotechnology sector, both in Australia and the United States, in terms of what types of technology are to continue to be regarded as patentable subject matter. This has resulted in uncertainty in relation to the future of biotechnology patenting. It is therefore a very welcome outcome that the High Court of Australia has now affirmed that methods of treatment remain patent eligible subject matter in Australia.

This decision cannot be further appealed and it is now only by legislative intervention or future reconsideration of this issue by the High Court that the question of the patentability of methods of treatment in Australia could be re-opened. Accordingly, although the future of gene patents and diagnostic methods remains somewhat uncertain, the question of the patentability of methods of treatment in Australia has been settled.

- page 2

Protecting Information Provided for Regulatory Approval

Most chemical substances for human health, agricultural or veterinary applications must be approved by the appropriate regulator before being sold in Australia. The regulators require substantial information, including experimental data, on safety, quality and efficacy. As part of its intellectual asset management strategy, any company selling or seeking to sell such products should carefully consider how best to manage or use the data.

- page 3

High Court affirms that methods of treatment are still patentable in Australia

From page 1

Patentability of genes

A judicial challenge to the patentability of the Myriad BRCA gene patents in the United States (Association for Molecular Pathology v Myriad Genetics) resulted in a Supreme Court ruling, earlier this year, that genes are not patentable subject matter. This decision was made on the basis that genes are naturally occurring molecules and therefore not patentable. Serious concern now exists as to what precedent this decision may have created regarding the ongoing patentability of other naturally occurring biologics in the US, such as proteins. In contrast, a decision of the Federal Court of Australia in Cancer Voices Australia v Myriad Genetics, also in respect of Myriad's BRCA gene patents, held that genes are patentable on the basis that their isolation from the natural environment can give rise to the 'artificial state of affairs' which is the threshold required to be met under Australian law for subject matter to be patent eligible. However, this decision is currently under appeal to the full Federal Court.

Patentability of diagnostic methods

The patentability of diagnostic methods has also been significantly weakened in the United States by virtue of the Supreme Court decision in Mayo Collaborative Services v Prometheus Laboratories Inc which held that patents which simply describe a natural law or relationship and provide a bare instruction to 'apply it' are not patent eligible. This decision has been used to support a finding of lack of patentability for diagnostic claims which, in addition to specifying the relationship between a marker and a disease condition, merely recite the performance of conventional diagnostic steps at a high level of generality. As a result, significant uncertainty has been created in the United States in terms of which diagnostic patents fall foul of this decision and which do not. To date, the patentability of diagnostic methods has not been challenged in Australia.

Patentability of methods of treatment - Apotex Pty Ltd v Sanofi-Aventis Australia Pty Limited

Despite the fact that the patent eligibility of diagnostic methods has so far not been challenged in Australia, the patent eligibility of methods of treatment was challenged in Apotex Pty Ltd v Sanofi-Aventis Australia Pty Limited, a case which proceeded through the Federal Court and was finally appealed to the High Court in relation to this important issue. This case was heard in the face of a backdrop of both long standing practices in Australia and the US that methods of treatment are regarded as patentable and the entirely divergent situation in Europe where methods of treatment and diagnosis are not patentable.

Apotex concerned the validity of a method directed to a new use for the off-patent drug Leflunomide, specifically a method of using leflunomide to treat psoriasis. Apotex had challenged the validity of the claims directed to this method of treatment on the ground that they did not relate to patentable subject matter.

In a decision handed down on 4 December 2013, a majority of the High Court affirmed that method of treatment claims are patentable subject matter in Australia. This decision is based on the Court's view that the 'artificially created state of affairs providing economic utility', which is the threshold that must be met in Australia for subject matter to be patentable, is met by methods of treatment. Although a number of legal and moral issues were considered in deciding this issue, one of the primary considerations rested on whether or not a method of treatment is 'an economic endeavour'. The Court considered at length the development of judicial and legislative principles in relation to the patentability of methods of treatment in Australia, UK, Europe, US and Canada and ultimately held that despite whatever views may have been held in the past, methods of medical treatment, in particular the use of a pharmaceutical drug, cannot be considered non-economic. Specifically, the method in issue was held to artificially create an improvement in human health, this having economic utility. The Court therefore concluded that to exclude methods of treatment from patentability would represent an anomaly for which no consistent foundation had previously been enunciated in Australia.

Medical practitioner liability for patent infringement

The Court discussed and acknowledged, at some length, the conflict between not interfering with the freedom of a medical practitioner to treat a patient without risking patent infringement versus encouraging and rewarding research and development in relation to drug therapy. To this end, the Court noted that a substantial consideration in relation to the issue of methods of treatment is in fact linked to ethical and moral considerations, more so than whether or not a method of treatment defines an 'economic endeavour'. The Court also noted that to exclude methods of treatment of the human body would introduce a lack of harmony between Australia and its major trading partners, where none is regarded to exist at the moment. This comment is somewhat curious when one considers that methods of treatment are not patentable in Europe and New Zealand, this having been discussed in detail by the Court. Ultimately, the Court also held that issues of public policy and ethics should be left for the legislature to decide and not the Courts.

Interestingly, there was an opinion expressed by the Court that a distinction exists between a method of medical treatment directed to a new use for a pharmaceutical drug versus the activities of doctors when physically treating patients. Despite acknowledging this distinction, the Court noted that it was unnecessary to decide whether or not the latter class of method of treatment should remain patent eligible. In fact, it is this very distinction which underpins the European exclusion of the patentability of methods of treatment generally, in favour of an alternative form of protection directed to the 'use' of a drug. With two members of the Court having acknowledged the issue of the existence of a distinction between these two classes of methods of treatment, and the fact that it has not been necessary to decide this question in this case, one is led to question whether the door has been left open to a future consideration of the issue of liability of medical practitioners who infringe, usually unknowingly, method of treatment claims.

Comment

This decision therefore affirms the current Australian practice that methods of treatment are patent eligible. In the face of the changing biotech landscape in the United States in relation to patents for genes and diagnostics, together with the current Australian Myriad appeal, the decision of the High Court is a welcome outcome. It provides the certainty and robustness which the healthcare industry requires in order to continue to support the translation of research from the laboratory to the clinic.

By Tania Obranovich

Dr Tania Obranovich joins the Watermark team as Special Counsel, working as a Patent Attorney and Lawyer. Tania has over 20 years experience working closely with significant Australian biotech companies to protect their IP. Tania has experience in pursuing molecular and cellular immunology research to the post-doctoral level. Tania's career has seen her lobby the Federal Government on issues relating to the patenting of genes in Australia. Academically, Tania is involved in the education of the IP profession at the University of Melbourne as well as being a member of the Professional Standards Board for Patent and Trade Mark Attorneys.

Protecting Information Provided for Regulatory Approval

From page 1

Third parties may seek to use information submitted to the regulators for a generic product, to avoid reproduction of data already submitted by the originator, or to gain competitive intelligence.

Therapeutic goods for humans are regulated by the Therapeutic Goods Administration (TGA). The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary products.

International Backdrop

The World Trade Organisation's Agreement on Trade Related aspects of Intellectual Property rights (Article 39.3) protects application data against both 'unfair commercial use' and disclosure. The Australia-United States Free Trade Agreement also includes relevant provisions.

Data Exclusivity

Data exclusivity provisions in the Australian regulatory framework provide periods of time within which the originator's data cannot be used by a generic competitor as part of the approval process for an equivalent generic product. The provisions are designed to balance the competing interests of:

- the originator, seeking reward for their efforts in generating data and providing new medicines/chemicals; and
- the generic competitor, seeking to provide competitively priced products without 'reinventing the wheel'.

Data exclusivity provisions can provide the originator with very effective protection for a period. The provisions come to the fore in situations where the originator does not have patent protection, for example if the patent has expired because an extension of patent term was unavailable or getting regulatory approval took significantly longer than usual.

Below, we summarise the applicable data exclusivity periods:

Goods/product for approval		**Exclusivity Period**	**Source**
Purpose	**Type**		
Human health	**New** goods consisting of, or containing, an active component active component	5 years	Therapeutic Goods Act 1989 s 25A
Agricultural or veterinary	Product being or containing a **new** active constituent (but not a device); or Corresponding container label	Up to 11 years	Agricultural and Veterinary Chemicals Code Act 1994 s 34F
Agricultural	**Another** product of a **previously endorsed** active constituent; or Corresponding container label	5 years	
Veterinary		3 years	

Confidentiality

Consistent with their international obligations, the TGA and APVMA resist the disclosure of 'Commercially Confidential Information' (CCI). Requests by third parties for information are governed by the Freedom of Information Act 1982. Consultation provisions require that the regulator consult with the originator before releasing any information, and the originator has the opportunity to request a review by the Administrative Appeals Tribunal.

The TGA recently completed a consultation process on its disclosure of 'Commercially Confidential Information'. In its draft approach, CCI is defined, in broad terms, as information:

- specifically identified
- having the necessary quality of confidence
- identified to the TGA as being confidential, and
- of such a nature that its release would diminish its value or otherwise cause damage to the originator.

The TGA confirmed it 'takes all reasonable steps to ensure that CCI provided to it by a company is protected', subject to its legal obligations, including under the FOI Act.

A company working in commercial fields in which regulatory approval is mandatory should, as part of its intellectual asset management strategy, monitor the relevant product registration register for applications made and data provided.

By Geordie Oldfield

Patent drafting lessons for computer-implemented inventions in Australia

The Federal Court of Australia is currently considering the patentability of computer-implemented inventions in the cases of Research Affiliates and RPL Central. Research Affiliates concerns patentability of a method, system and computer program product for passive investing.

The physical result of the method is a file containing a financial index. RPL Central concerns a method for assessing competency or qualifications of individuals against recognized standards ('Recognition of Prior Learning' or 'RPL').

The Research Affiliates claims were held unpatentable in both the Patent Office and Federal Court on appeal. On the other hand, the Federal Court has decided that the RPL Central claims held unpatentable by the Patent Office are patentable. What contrasts the two decisions and what lessons do they provide for drafting patent specifications for computer-implemented inventions in Australia and more broadly, the management of this type of intellectual asset in Australia?

An artificial state of affairs is important

The Research Affiliates refusal partly resulted from the Applicant's admission that the physical result generated by the claimed method was a file containing a financial index, i.e. data alone. Untransformed data, of itself, cannot create the 'artificial state of affairs' necessary for patentability under Australian law. This finding was bolstered by insufficient description of how the computer implemented the investment method to create the 'artificial state of affairs' or 'physical effect' necessary for patentability. Whether or not the investment scheme presented a 'paradigm of economic endeavour' was considered irrelevant in this case.

The RPL Central case provided a significant factual contrast. The Court remarked, at some length, on the detailed description of improvements in existing RPL processes which involved the automated generation of a wizard or similar user interface to perform administrative work necessary to gather evidence from a prospective candidate and enable qualifications recognition from a wide range of training organisations. The Court found a useful result in the capacity of the invention to overcome difficulties in seeking out relevant education providers and the necessary information to enable recognition of prior learning. The invention provided the necessary 'artificial state of affairs' because data was not just collated or indexed, but actually transformed. The Court also found that the invention provided economic benefit to the educational sector of the economy. The invention was found patentable.

How to draft computer-implemented inventions in future

Some practitioners in the computer-implemented invention field have found it difficult to reconcile the

Continued page 4

A Sneak Peak at the TPP Agreement Chapter on IP

Australia is no bystander when it comes to free trade agreements. Having already signed seven FTAs with various trading countries, Australia is currently negotiating a further nine. By far the largest FTA on Australia's agenda is the Trans-Pacific Partnership Agreement (TPP).

The TPP will account for 25% of world trade once (and if) it is executed.[1] There are 11 other countries negotiating the TPP: Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the USA and Vietnam.

Aside from regulating trading activities, the TPP is also expected to impose obligations on national regulation of intellectual property. There has been little in the way of official announcements regarding progress of negotiations for the TPP, including on matters concerning IP. Not to be outmanoeuvred by this secrecy, well-known whistleblower website WikiLeaks recently published a draft of the TPP chapter on IP.[2] The draft provisions published by WikiLeaks provide some interesting insights into the different positions being adopted by negotiating countries towards IP.

Public response

Many online commentators have been quick to claim that the draft chapter suggests a number of countries may need to make major changes to their national IP laws as a consequence of signing the TPP. Areas of international public concern relate to medicines, publishers, internet service providers, criminal offences and biological patents, and include:

- restrictions on the making of 'temporary copies' of copyright works in electronic form
- allowing the patentability of surgical methods
- placing limitations on access to affordable medicines
- making ISPs responsible for policing copyright infringement
- lengthening the term of copyright protection

Much criticism from the online community has been directed towards the so-called hard line approach being taken by the US. While it is not easy to reconcile this criticism with the content of the draft chapter released by WikiLeaks, which is a complex and convoluted document by any standard, there are a substantial number of US proposals in the draft which stand out as being contrary to proposals from a majority of other negotiators.

Australia a key US supporter on IP

Although the draft chapter does not point to Australia supporting a wholesale adoption of US proposals, Australia is nonetheless the most outspoken supporter of US proposals of all the TPP participating countries.[3]

From Australia's perspective at least, it would appear that the prospect of aligning national IP laws more closely with the US position is not a barrier to signing the TPP. This attitude is arguably consistent with the approach Australia took in negotiating the bilateral FTA which it entered into with the US in January 2005.

It is yet to be seen whether other countries such as Canada and New Zealand will be as willing as Australia appears to be in supporting US proposals regarding IP under the TPP.

At least one thing appears certain from the partial draft TPP released by WikiLeaks: there remains much negotiation to be had between the 12 prospective parties before consensus is reached on IP issues enabling all to sign the TPP agreement.

By Len Hickey

Len recently joined Watermark as a Senior Associate Lawyer in the dispute and litigation team of Watermark Intellectual Property Lawyers. Len has particular expertise in the fast moving consumer goods and fashion industries where he works closely with clients to manage and resolve branding and technological issues associated with their products.

[1] http://www.dfat.gov.au/fta/tpp/
[2] http://wikileaks.org/tpp/
[3] http://wikileaks.org/US-Australia-isolated-in-TPP.html

IAM on the move

Watermark proudly welcomes:

Guy Provan: Special Counsel, Lawyer
Perth
Expertise in: Litigation & Commercialisation

Ken Bolton: Senior Associate, Patent Attorney
Sydney
Expertise in: Engineering

Nigel King: Associate, Lawyer & Patent Attorney
Sydney
Expertise in: Litigation & Pharmaceuticals

Patent drafting lessons for computer-implemented inventions in Australia

From page 3

two decisions, which are now both under further appeal. At the time of writing the Australian Patent Office is stubbornly applying the Research Affiliates approach. Subjectivity is perhaps unavoidable in this area as minds differ as to where the line between patentable and unpatentable invention lies. Nevertheless, this writer sees some useful guidance on drafting patent specifications for computer implemented inventions in these Federal Court decisions.

At least until the full bench of the Federal Court decides otherwise, computer-implemented inventions should be considered patentable if the learnings from RPL Central are adopted. The specification must describe the computer-generated processes in implementing the invention. Where a method with a number of steps is involved, each step should require or involve a computer generated process. The specification should clearly demonstrate the physical effects of the invention in the form of a change of state or information in part of the computer (at least). There are echoes here of the US originating machine or transformation patentability test.

In looking so closely at the specification to assess patentability, well established principles that the invention must be defined by the claims are seemingly altered. The Australian Patent Office and Courts are looking to more than the claims and to description of the invention to clearly demonstrate working of a computer as a machine to transform information into an economically useful 'physical effect' or 'artificial state of affairs'. Patent specifications need to be drafted to meet these requirements.

By Richard Baddeley

Watermark's Dr Mark Summerfield acted for RPL Central in drafting the patent application at issue. Watermark also advised RPL Central in appealing its rejection by the Commissioner of Patents to the Federal Court of Australia.