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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.

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Adapting brand strategy for generic top-level domains

New generic top-level domains (gTLDs) will soon be added to the domain name system. In addition to gTLDs such as ".com" and country code top-level domains such as ".com.au", users will be able to register domain names such as "yourbrand.clothing" and "yourbrand.melbourne". These changes present both opportunities and threats to brand owners, so it is important to be aware of how these developments will affect your business.

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

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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.

Adapting brand strategy for generic top-level domains

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The Challenge

As a protection mechanism it is generally uneconomical to yourself register all domain name combinations for your trade mark.

Deciding whether to assert your rights against third parties who are using a domain name which incorporates your trade mark will depend on a variety of factors such as the importance and value of the trade mark to your business, and whether your trade mark is being used on the third party's website. You may choose to tolerate 'parked' domain names, or the legitimate use of "yourbrand.net.au" for unrelated goods or services, if your website located at "yourbrand.com.au" is optimised to receive maximum internet traffic.

However, if you have invested heavily in securing multiple domain names in numerous countries, the thought of third parties registering your key trade marks as part of new gTLDs is likely to be concerning.

IAM Strategy – The Trademark Clearinghouse

In the new gTLD ecosystem, one mechanism for protecting brand owners is the Trademark Clearinghouse (TCH), a central repository where brand owners can have their trade marks verified to give certain benefits, including:

1. the ability to register their trade marks as part of new gTLDs during a 'Sunrise Period' prior to the release of a new gTLD to the general public; and
2. the option of being notified when a third party registers a domain name corresponding to a trade mark verified by the TCH.

For example, the Sunrise Period for the release of the ".clothing" gTLD was 26 November 2013 to 24 January 2014. Brand owners, particularly clothing brand owners, with registered trade marks verified by the TCH prior to the Sunrise Period had the opportunity to register "theirbrand.clothing" before 24 January 2014, after which the gTLD was opened to the public. If there are competing claims lodged during this period, there will typically be an auction between trade mark owners – the highest bidder winning.

Even if the trade mark owner decides not to take advantage of the Sunrise Period to register their own domain name, the owner will be notified of any third party registering "theirbrand.clothing". This notification, which is also given to the registrant, enables the trade mark owner to act promptly if the domain name is of concern. Such action would include filing a Complaint through the Uniform Domain Name Dispute Resolution Policy (UDRP) or through the new cheaper, faster Uniform Rapid Suspension System (URS) in straightforward cases.

Summary

Brand owners need to be aware of the opportunities and risks associated with the release of new gTLDs. If securing registration of core trade marks as domain names during Sunrise Periods aligns with your branding strategy, or if obtaining additional market intelligence of domain name registrations is desirable, then submitting your key trade marks for verification by the Trademark Clearinghouse will help mitigate the risk of misappropriation of your trade mark by others.

On the other hand, if holding numerous domain names is not a part of your strategy, then be aware that new gTLDs are coming to the internet and put in place appropriate strategies to manage the risk of trade mark misappropriation. You should monitor new domain names through either internal or external surveillance mechanisms and take appropriate action on a case by case basis.

By Sean McGuire

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, and
- 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

Financing Innovation

An update on Government programs

Government seeks to restrict R&D Tax Incentive

The R&D Tax Incentive aims to promote innovation by providing companies with an opportunity to offset a percentage of their R&D expenditure. Currently, the scheme offers two levels of benefit:

- a 45% refundable tax offset to eligible entities with an aggregated turnover less than $20M.
- a 40% non-refundable tax offset to eligible entities with an aggregated turnover greater than $20M.

Recent legislative changes have been drafted to add a third tier in which entities with an aggregated turnover greater than $20 billion will no longer be eligible to receive the incentive. If this proposed change comes into effect, the Government estimates that only 15 to 20 of Australia's largest companies will be affected.

New R&D Tax Incentive Registration form

AusIndustry released a new version of the R&D Tax Incentive Registration form in mid-October 2013. The new form further highlights the need for contemporaneous documentary substantiation of registered R&D activities.

With respect to the nature of their R&D activities applicants must now:

- describe the new knowledge intended to be produced from the core activities in the project and explain why it differs from the current knowledge database. This is not a new legislative requirement, but must now be explicitly covered in the application form.
- explain why the outcomes of the R&D project could not be determined in advance using the current level of knowledge, information and experience available. This helps assess whether the R&D undertaken was reasonable.
- describe how each supporting activity contributed to it's relevant core R&D activity. This minimizes contention around application of the dominant-purpose test for supporting activities.

The new form also provides further guidance to allow applicants to appropriately self-assess their R&D activities and promotes adherence to the legislation.

Deadline for registering R&D activities

For the 2012/13 financial year, applicants must register by 30 April 2014. For more information on how to access the R&D Tax Incentive, contact Kate Mahady or Cleo de la Harpe on (03) 9810 1462.

Export Market Development Grants: Helping Australian SMEs grow

The government-sponsored Export Market Development Grant (EMDG) scheme seeks to assist small and medium (SME) enterprises to compete in international markets by reimbursing up to $150K of eligible expenditure associated with developing export markets.

What is the EMDG?

The EMDG scheme is administered by Austrade and can reimburse 50% of eligible export activity expenses, up to a limit of $150K, to entitled Australian businesses.

These expenses can include:

- overseas representation costs such as salaries, travel, rent and relocation costs
- engagement costs for marketing consultants
- costs of marketing visits such as travel, accommodation and meal expenses
- communication costs such as ISD/IDD calls
- costs associated with providing free samples to potential buyers
- participating in overseas trade fairs, seminars and in-store promotions
- promotional literature and advertising costs such as domain registration, website development and printing costs
- costs associated with bringing potential buyers to Australia, and
- IP registration, renewal and insurance costs.

Am I eligible?

To be eligible, you need to:

- be an Australian entity (individual, partnership, company association, trust, or statutory cooperation)
- have an annual income of no more than $50M for the financial year preceding the grant year, and
- be the principal owner of the Australian goods or services and an Australian citizen at the time of incurring the expense.

IP expenses & the EMDG

The EMDG scheme provides a cost category to cover up to $50K of costs associated with granting, registering or renewing IP rights under a foreign law. These expenses can be incurred in Australia, so long as it is for securing rights overseas. If a business chooses to obtain IP insurance, the premium costs for worldwide protection may also be claimable under the EMDG.

These costs are eligible only if they are done for promotional purposes, i.e. there is documented intent that the IP or 'know-how' will be used overseas to develop an export market for the good/service.

What is the deadline for applications?

Applications for the 2014 grant year open from 1 July 2014 to 1 December 2014 and are assessed on a 'first come, first served' basis.

Anyone considering applying for the grant is encouraged to contact Watermark Advisory Services on (03) 9819 1664 for further information.

By Ashanie Perera

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

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