BAKER & McKENZIE

Life Sciences Update

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R&D tax offset legislation passed by Parliament

Parliament has passed legislation to replace the existing Research and Development (R&D) tax concession with a simplified R&D tax incentive (also known as the R&D tax offsets). The legislation is contained in the *Tax Laws Amendment (Research and Development) Act 2011* and the *Income Tax Rates Amendment (Research and Development) Act 2011*, and includes amendments introduced by the Senate.

Certain transitional measures will apply, but in general, the new provisions provide refundable or non-refundable tax offsets to encourage more companies to engage in research and development. The Senate amendments provide for the application of the R&D tax incentive for expenditure incurred, and the use of depreciating assets, in an income year commencing on or after 1 July 2011 (rather than from 1 July 2010 as originally intended). A 45 per cent refundable tax offset, equivalent to a deduction of 150 per cent, will be available to small companies with an annual aggregate turnover of less than $20 million that undertake eligible R&D activities. These companies can receive a refundable tax offset of 45 per cent of their R&D spending as part of the processing of their income tax return.

The Senate amendments also provide for the making of regulations to enable an eligible R&D entity to, upon application, effectively anticipate the refund expected from its refundable tax offset claim by receiving quarterly credits from 1 January 2014. This will have the effect of providing more timely delivery of the incentive for conducting R&D with a reconciliation of these credits with the entity's actual entitlement to a refundable tax offset against their basic tax liability at the end of the year. A 40 per cent non-refundable tax offset will be available to companies with an annual aggregate turnover of $20 million or more – equivalent to a deduction of 133 per cent. Unused offset amounts may be able to be carried forward for use in future income years.

The new tax incentive is available to:

- corporations that are Australian residents;
- foreign corporations that are resident of a country with which Australia has a double tax agreement and carry on business through a permanent establishment in Australia; and
- public trading trusts with a corporate trustee.

The existing R&D tax concession premium and international premium will be abolished and eligibility criteria will be tightened to provide better targeted support. The implementation of the new R&D tax credit is expected to benefit, in particular, start-up innovation companies trading at a loss.

Raising the Bar

On 22 June 2011 the Australian Government introduced to Parliament the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill is intended to make improvements to intellectual property (IP) rights legislation to better support innovation by encouraging investment in research and technology in Australia. There are many areas of reform covered by the legislation including raising the quality of granted patents, free access to patented inventions for regulatory approvals and research, reducing delays in resolution of patent and trade mark applications, improving mechanisms for trade mark and copyright enforcement and simplifying the IP system. Some of the specific changes in the legislation are set out below.

- Removal of the restriction in the *Patents Act, 1990* that the common general knowledge to be taken into account when assessing the inventive step of an invention is limited to the common general knowledge in Australia only. Further, the prior art base for inventive step would be all information made publicly available before the priority date (not just information regarded as relevant by a skilled person in the art). The Bill also contains a new section requiring the patent specification to disclose "a specific, substantial and credible use", as well as a new experimental use exemption to apply to acts done for experimental purposes.
- Changes to trade mark opposition procedures including requiring opponents to file a statement of particulars of the grounds on which they intend to oppose a trade mark application and requiring applicants to give notice of their intention to defend an opposition (failing which the application will be treated as withdrawn or abandoned).
- Changes to Customs notice procedures, including to allow Customs to release the name of the exporter and consignor of seized goods to the objector at the time of seizure, which will assist copyright owners to enforce their rights. The amendments will also ensure seized goods are automatically forfeited to Customs if an importer fails to make a claim for the release of the goods.
- Additional damages for flagrant trade mark infringement in civil cases and changes to the trade mark offences regime, including to increase the penalties for indictable offences and to introduce summary trade mark offences which require negligence rather than knowledge or recklessness.
- The expansion of the Federal Magistrates Court's jurisdiction to decide trade mark and registered design matters.

The Bill will need to progress through parliament and, as the main sections of the legislation will not commence until 12 months after it receives Royal Assent, once passed the legislation is not expected to commence before late 2012.

Interchangeability of drugs, not doses

An application to declare invalid the placement of two cholesterol lowering drugs in the same therapeutic group was recently rejected by the Federal Court.

AstraZeneca Pty Ltd v Minister for Health and Ageing concerned the interchangeability of the drugs rosuvastatin (sold as Crestor tablets) and atorvastatin (sold as Lipitor tablets) on an individual patient basis for the purposes of the Pharmaceutical Benefits Scheme (PBS). The legislative framework for the listing of

drugs on the PBS is set out in the Commonwealth *National Health Act 1953*. One means by which the cost of the PBS is controlled is through reference pricing, where the price of therapeutically similar drugs in the same "therapeutic group" is determined with reference to the lowest priced drug within that group and whether that drug is protected by a patent. A commercial consequence of the placement of the drugs in the same therapeutic group is that the expiry of the atorvastatin patent in 2012, leading to the sale of generic brands, will result in a 16 per cent reduction in the price of rosuvastatin on the PBS.

The drugs are both used to lower cholesterol in patients, but they are not bioequivalent. Lipitor was not available in a single dose equivalent to Crestor 40 mg. AstraZeneca contended that the lack of correlation between dosage levels of Crestor 40mg and Lipitor meant that they should not be included in the same therapeutic group, as Crestor was not interchangeable on an individual patient basis with any formulated dose of Lipitor tablets.

AstraZeneca sought a declaration of invalidity of the determinations of the Minister for Health & Ageing. The Minister had determined that the two drugs were in the same Statins-HP therapeutic group, under powers conferred by s84AG of the National Health Act. In making such determinations, the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee (PBAC) and the PBAC had formed the view that it is the interchangeability of the drugs that must be considered, not the individual pharmaceutical item (i.e. dose) of the drugs.

Justice Buchanan stressed that the focus is on the interchangeable nature of the drugs, as opposed to particular doses of drugs or of individual pharmaceutical items, and found that there were no grounds on which it could be suggested that the Minister or PBAC misunderstood the nature of the functions conferred upon them under the National Health Act. AstraZeneca's application was dismissed and the Minister's determinations upheld.

The case makes it clear that the concept of interchangeability in the context of determinations of therapeutic groups applies to the drug, not its dose.

Transparency Review – Report published

The Final Report of the Pearce Review to improve the transparency of the Therapeutic Goods Administration (TGA) was released in June 2011. The intention of the review, announced in November 2010, was to improve public knowledge of regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods.

The Report sets out 21 recommendations. Four recommendations in relation to the market authorisation process will be of particular interest to pharmaceutical companies. These recommendations are that the TGA:

- develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for each therapeutic product type and taking into account the practices followed by comparable international regulators;
- explore mechanisms for providing explanations on its various regulatory processes and adopt publication principles on the outcomes of application assessments using as an exemplar the Australia Public Assessment Reports (AusPAR);
- assess and report on the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, which enables the sponsor to ascertain the progress of an application; and

- work with stakeholders to improve labelling and packaging requirements to educate and assist consumers and health practitioners to make informed decisions about the quality and use of therapeutic goods.

The TGA has postponed the beginning of its review of medicine labelling and packaging, which was due to begin in July 2011. However, a consultation paper is expected to be released in October. The review's recommendations are currently being considered by the TGA. In the Report, the Transparency Review Panel recognised that the effective implementation of its recommendations will, in some cases, be dependent upon the availability of resources over and above those presently available to the TGA.

Anti-bribery and corruption regulation – increasing risks for Life Sciences companies

Some recent changes to anti-bribery and corruption laws in a number of jurisdictions, together with current high levels of regulator activity, have increased the compliance risks for both companies and individuals. This is particularly so for those operating across borders and interacting with governments and public officials. This has been a significant risk area for Life Sciences companies for a number of years, and these changes highlight the need to ensure that your anti-compliance measures are appropriate and effective. Some of the significant recent developments and trends to be aware of include the following.

In 2011 we have seen the first ever prosecutions under s70 of the Australian *Criminal Code Act 1995* for bribery of foreign public officials. The penalties for the offence of bribing a foreign public official under s70 were substantially increased in February 2010. The maximum penalty for an individual is now 10 years' imprisonment and/or a fine of A$1.1 million. The maximum penalty for a corporation was increased to the greater of A$11 million or three times the value of the benefit obtained (or 10 per cent of the annual turnover of the corporation if the value of the benefit cannot be determined).

The UK *Bribery Act 2010* commenced on 1 July 2011, and applies to individuals and companies with a connection to the United Kingdom. The Act makes it an offence for a corporation to fail to prevent its employees, agents or subsidiaries from engaging in bribery unless it can demonstrate that it had implemented adequate procedures to prevent the conduct. The introduction of this legislation makes it increasingly important for companies to ensure their anti-corruption measures are effective. This should include reviewing the effectiveness of their due diligence and the monitoring of intermediaries, and conducting risk assessments or "health checks".

The commencement of the US Dodd–Frank Wall Street Reform and Consumer Protection Act on 21 July 2010 allows whistleblowers in the US to obtain financial rewards of 10 per cent – 30 per cent of the monetary sanction where information provided to the Securities and Exchange Commission (SEC) leads to a prosecution and the wrongdoer is required to pay an amount in excess of US$1 million.

The Department of Justice (DOJ) and the SEC continue to vigorously enforce the US Foreign Corrupt Practices Act (FCPA) in relation to parties located both within and outside the US. On several occasions fines in the order of hundreds of millions of dollars have been imposed.

The life sciences sector is a particular target for FCPA enforcement activity. It has accounted for 13 per cent of all prosecutions under the FCPA since the Act's

inception in 1977 (second only to the oil and gas sector). Life sciences companies should only expect the level of prosecutions to increase, with the DOJ openly singling out life sciences (especially pharmaceutical) companies as a particular focus of FCPA investigations since 2009.

In light of these developments, life sciences companies would be well advised to conduct a review of their activities and their current exposure to bribery and corruption risk. For companies that already have some anti-corruption measures in place, some well advised steps include a review of policies and procedures, and an assessment of changes to the company's risk profile in light of changed business practices. Conducting health checks or audits is also a valuable way to ensure that anti-corruption measures are working effectively.

Companies that do not have existing anti-corruption measures in place should consider the geographical area of their operations, the type of entities they engage with (particularly, but not limited to, government entities) and the level of due diligence and monitoring associated with agents and intermediaries acting on behalf of the company. As a starting point, we have produced a 13 point action plan – the Baker's dozen of anti-bribery and anti-corruption – and would be happy to assist life sciences companies in implementing any aspect of the plan.

Forthcoming Events

Members of the Life Sciences group regularly speak at conferences, both here and overseas.

Simon De Young and Eric Boone will speak at the AusBiotech Conference in Adelaide in October (16th – 19th). They will be joined by Meera Verma from Hospira and Trent Donnelly from Ord Minnett on their speaking post.

Ben McLaughlin will be hosting a Life Sciences Round Table on October 12, at the Baker & McKenzie Sydney office. Fiona Carlin of the Baker & McKenzie Brussels office, will present via video conference. Fiona will discuss the European Commission's enforcement priorities in the wake of the recent sector inquiry, and in particular the investigations into allegations that pharmaceutical companies abuse the patent system to unduly delay generic entry.

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