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Intellectual Property Laws Amendment Bill 2006

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Intellectual Property Laws Amendment Bill 2006

Date introduced: 30 March 2006

House: House of Representatives

Portfolio: Industry, Tourism and Resources

Commencement: The formal provisions commence on Royal Assent. The substantive provisions commence on various dates. Details are provided in the 'Main provisions' section of this Digest.

Purpose

The purpose of this Bill is to:

- amend the *Patents Act 1990* in order to:
  - broaden the springboarding regime for pharmaceutical patents
  - allow for awards for exemplary damages in patent infringement actions
  - clarify prior users' rights in the granting of patents
- amend provisions of the *Trade Marks Act 1995* relating to revocation of trade marks and public access to trade mark files, and
- make minor technical amendments to the *Patents Act 1990*, *Trade Marks Act 1995*, *Designs Act 2003*, and *Plant Breeder's Rights Act 1994*.

Background

As there is no central theme to the Bill, the background to the various measures will be described below.

Main provisions

Schedules 1-4—Amendments to the Trade Marks Act 1995

The amendments in **Schedules 1, 2, 4 and Part 2** of **Schedule 3** commence six months after Royal Assent unless commenced earlier by proclamation. **Part 1** of **Schedule 3** commences the day after Royal Assent **(clause 2).**

Trade marks law

A trade mark is a 'sign' which signifies a connection to particular goods or services and which distinguishes it from similar goods or services. It can be a letter, number, word, phrase, shape, logo, picture, aspect of packaging, sound or even a smell. A mark can become a very valuable commercial asset and trade mark disputes are common.

To obtain the property and other valuable rights on offer under the Trade Marks Act, the owner of a trade mark must secure registration from the Trade Marks Office. The owner of a registered trade mark has the exclusive right to use it for the nominated goods and services and can sue those who infringe his or her rights. Registration lasts 10 years but can be endlessly renewed if fees are paid on time and basic conditions about use of the trade mark are met. A registered trade mark is an item of property and the associated rights can be bought and sold.

The registration system is similar for patents, trade marks and designs. The applicant lodges details of the trade mark and specifies with which goods and services the mark is associated. The Trade Marks Office checks the application against statutory criteria and exclusions. If accepted, the application is advertised in the Official Journal of Trade Marks. Opponents have three months to object to registration on specified grounds, but if there is no successful opposition the trade mark is registered from the date of filing the application.

Revoking registration of trade marks etc. (Schedule 1)

Revoking *acceptance* of a trade mark

If a trade mark has been accepted in error by the Trade Marks Office, and this is realised before the trade mark proceeds to registration, the Registrar has the power to revoke that acceptance under section 38 of the Trade Marks Act. **Item 1** repeals and replaces subsection 38(1) with the effect of expanding the grounds on which the Registrar may revoke acceptance of a trade mark. **New subsection 38(1)** allows the Registrar to revoke the acceptance of a trade mark if he or she is satisfied that it is reasonable to do so taking into account all of the circumstances. The Explanatory Memorandum states that the intention of this provision is to focus attention on the reasonableness of the Registrar's actions, and not on whether or not an 'error or omission' or a 'special circumstance' preceded the acceptance of the trade mark.

Revoking a *registered* trade mark

Trade marks can be mistakenly registered due to administrative oversight or error.[1] Under the current law, if an error is not realised until after the trade mark has been registered, there is no administrative remedy. Instead, legal action would have to be pursued through the courts in order to rectify the situation.[2]

Item 7 proposes amendments (**new sections 84A–84D**) that will give the Registrar, in certain circumstances, the power to revoke the registration of a trade mark on his or her own initiative. The Registrar may revoke registration if satisfied that:

- the trade mark should not have been registered, taking account of all the circumstances that existed when the trade mark became registered (whether or not the Registrar knew then of their existence) **(new paragraph 84A(1)(a)),** and
- it is reasonable to revoke the registration, taking account of all the circumstances **(new paragraph 84A(1)(b)).**

The kind of circumstances that the Registrar must take into account under paragraph 84A(1)(a) include:

- any errors (including errors of judgment) or omissions that led directly or indirectly to the registration;
- any relevant obligations of Australia under an international agreement, and
- any special circumstances making it appropriate not to register the trade mark or to register it subject to conditions or limitations **(new subsection 84A(2))**.

The kind of circumstances that the Registrar must take into account under paragraph 84A(1)(b) include:

- any use that has been made of the trade mark
- any relevant legal proceedings or other action taken in relation to the trade mark
- any special circumstances that make it appropriate to revoke or not revoke the registration **(new subsection 84A(3))**.

In order to revoke registration, the Registrar must notify the owner or approved user within 12 months of registration **(new subsection 84A(4))** and must provide such persons with an opportunity to be heard **(new subsection 84A(5))**. Revocation outside that 12 month time frame would still be available via the courts. A decision to revoke registration under section 84A is appealable to the Federal Court of Australia **(new section 84D).**

New section 84B sets out a circumstance in which the Registrar is *obliged* to revoke the registration of a trade mark. The Registrar will be obliged to revoke registration if the Registrar has failed to take account of a notice of opposition which has been filed within the appropriate time and the Registrar becomes aware of the failure within 1 month of filing of the notice. A revocation under section 84B is not appealable to the Federal Court, although administrative law remedies would be available.

Non-payment of fees relating to trade marks (Schedule 2)

Items 1 and **2** of **Schedule 2** amend section 223 of the Trade Marks Act in order to provide that many of the fee payment requirements of trade mark registration will be set

out in the Trade Marks Regulations 1995. The Explanatory Memorandum states that these amendments will bring the fee payment provisions of the Trade Marks Act into line with the fee payment provisions in section 227 of the Patents Act and section 130 of the Designs Act.[3]

Registration process for certification trade marks (Schedule 3)

A trade mark is essentially about branding. It is a 'sign' which signifies a connection to particular goods or services and which distinguishes it from similar goods or services.

In contrast, a certification trade mark (CTM) shows that goods meet a particular standard or accuracy or have a particular origin or composition etc. For example, the Woolmark is a certification trade mark indicating that a garment uses 100% pure new wool.

Part 16 of the Trade Marks Act sets out the requirements for the registration of a CTM. The process for obtaining a CTM involves both the Trade Marks Office and the Australian Competition and Consumer Commission (the Commission).

In order to obtain a CTM the trade mark owner must make an application to the Registrar for a CTM and provide a copy of the rules regarding its use (subsection 173(1)). Once the Registrar is satisfied with the application, he or she forwards it with the rules to the Commission (subsection 174(1)) If the Commission finds that the rules are acceptable and are not detrimental to the public interest, a certificate is issued (subsection 175(2)). The Registrar, upon notification, must accept the CTM (section 176) and advertise the decision in the Official Journal (subsection 176(3)).

The Explanatory Memorandum states that the proposed amendments to this process are not aimed at changing the requirements an applicant for a CTM must fulfil, the documentation they must provide, or the rights that a CTM gives to the registered owner. Rather the changes 'are targeted at the administrative aspects of how applications for CTMs are processed, and affect only the internal workings of the Trade Marks Office and the Commission.'[4]

Item 1 repeals subsection 173(2) of the Trade Marks Act and substitutes **new subsections 173(2) to 173(4)**. **New subsection 173(2)** provides that the rules governing a CTM must specify the following:

- the certification requirements that the goods and/or services must meet (e.g. specific ingredients, method of production)
- the process for determining whether goods and/or services meet the certification requirements (e.g. specific method for determining the strength of the material used)
- the attributes of an approved CTM certifier (e.g. specific qualifications)

- the requirements that an owner or approved user of a CTM must meet (e.g. annual fees)
- the use of the CTM by the owner or an approved user of the CTM, and
- the procedure for resolving disputes relating to the CTM.

The rules must also include any other matters the Commission requires or permits to be included **(new subsections 173(3) and (4)).**

Section 175 deals with the Commission's role in certification. **Item 3** repeals and replaces paragraph 175(2)(a) with the effect that before issuing a certificate, the Commission must be satisfied that the attributes that the rules require an approved certifier to possess are of a suitable standard. The proposed amendment is intended to clarify that the CTM owner (and not the Commission) is responsible for determining whether an approved certifier meets the criteria set out in the rules.

Item 8 repeals and replaces section 174 with the effect that the regulations rather than the Act will specify the conditions for sending of prescribed documents relating to a CTM application to the Commission.

Item 10 repeals and replaces subsection 176(1) with the effect of clarifying how to apply for CTM registration. **New subsection 176(1)** specifies that the Registrar must accept an application for registration of a CTM if:

- the application has been made in accordance with the Act
- there are no grounds for rejection, and
- the Commission has issued a certificate.

If these criteria have not been met, the Registrar must reject the application, although not before giving the applicant the opportunity to be heard.

Section 178 of the Trade Marks Act deals with procedures for varying the rules governing CTMs. **Items 12** and **13** propose amendments to section 178 with the effect that certain administrative aspects of variation will be set out in the regulations rather than the Act.

Item 15 repeals and replaces section 179 with the effect that the Registrar must publish the rules governing the use of a CTM in accordance with the regulations.

Availability of documents about trade marks (Schedule 4)

The purpose of **Schedule 4** is to amend the Trade Marks Act so as to make documents relating to trade marks publicly available. The Explanatory Memorandum states that this amendment is in line with section 55 of the Patents Act and section 60 of the Designs Act which provide for certain documents to be publicly available.

Item 1 inserts **new section 217** with the effect that all prescribed documents on a trade mark file will be available for public inspection from the time they are received and processed by the Trade Marks Office. **New section 226A (item 3)** limits this provision to the extent that the Registrar may specify information in a document that has to be held confidentially in the Trade Marks Office.

Schedules 5–10—Amendments to the *Patents Act 1990*

Commencement: The amendments in **schedules 5-6 and 8-9** commence the day after Royal Assent. S**chedule 7** commences 28 days after Royal Assent and **Schedule 10** commence six months after Royal Assent unless commenced earlier by proclamation **(clause 2).**

Springboarding and patents (Schedule 7)

Commencement: 28 days after Royal Assent.

Australia's patent scheme—Patent extensions and springboarding

Under the *Patents Act 1990* holders of a standard patent are granted exclusive rights to make, hire, sell or otherwise dispose of their invention for up to twenty years. The Act also grants an exclusive right to manufacture a potential product in Australia for sale in Australia or for export.

The *Intellectual Property Laws Amendments Act 1998* that came into effect on 27 January 1999 amended the Patents Act in two important respects relevant to the pharmaceuticals industry. Firstly, it provided for the extension of the effective patent life by up to five years, and secondly it introduced springboarding for the manufacturers of generic or off-patent pharmaceuticals in cases where an extension of the patent life has been granted.

The introduction of a five year extension was largely in recognition of the lengthy regulatory approval process required before pharmaceuticals can be marketed, which can leave limited patent life in which to recoup the investment. Only patents which over an active pharmaceutical ingredient (API) are currently eligible for patent extension in Australia. The Explanatory Memorandum at page 19 explains that there are broadly four types of pharmaceutical patents: patents on the active pharmaceutical ingredient (API), patents on the formulation of the medication, patents on the process for making the API, and patents on the methods of use of the medication.

Springboarding is an activity that allows manufacturers of generic drugs[5] to undertake certain activities prior to the expiry of the patent solely for the purposes of meeting pre-marketing regulatory approval requirements. The 1999 amendments to the Patents Act allowed for limited springboarding activity to be undertaken by generic manufacturers.[6] The purpose of the amendment was to allow earlier regulatory approval for generic pharmaceuticals, faster market entry upon patent expiry and to prevent originator

companies from receiving further de facto extensions of patent terms. However the provision is limited because it only applies to pharmaceutical substance (i.e. API) patents once an extension is granted. Pharmaceutical products are frequently the subject of multiple patents which cover different aspects of the products. These patents are potentially of different types, some of which may not be eligible for extension. In some cases the most important patent may not be extended and thus the most important springboarding work cannot be done until this patent expires in Australia.

In 2002 an interdepartmental Committee, established by the Minister for Industry, Tourism and Resources, examined the impact of the patent extensions and 'springboarding' provisions on generic manufacturers. The Committee concluded that Australia's springboarding provisions were limited compared to those in competing markets (e.g. USA, Canada and New Zealand) and that under the current springboarding provisions, Australian manufacturers of generic drugs were prevented from competing in export markets on equal terms with their overseas competitors.[7] The Government has concluded that 'this disadvantages the Australian generics industry and provides an incentive for companies to move their development activity offshore.'[8] The purpose, therefore, of the amendments in **Schedule 7** is to address this problem by implementing a wider springboarding scheme for generic pharmaceuticals than is currently provided under the Patents Act.

Item 2 repeals subsection 78(2), the current springboarding provision.

Item 3 inserts **new section 119A**. Its effect is to allow springboarding on any pharmaceutical patent at any time for purposes related to generating information necessary to support an application for regulatory approval of a pharmaceutical product in Australia or foreign country. Regulatory approval of a pharmaceutical product in Australia means obtaining inclusion in the Australian Register of Therapeutic Goods[9] **(new paragraph 119A(1)(a)).** Where the purpose of the generics manufacturer is approval overseas, the rights of the manufacturer do not extend to export unless the patient is of a particular type and an extension has been granted (**new subsection 119A(2))**. The Explanatory Memorandum states that Australia's international obligations including AUSFTA and TRIPS limit Australia's capacity to implement this provision more broadly.[10]

The new springboarding provisions will apply to the 'exploitation'[11] of patents that occurs after the Schedule commences **(item 4).**

Pros and Cons of broadening the springboarding provisions

The Parliamentary Secretary to the Minister for Industry, Tourism and Resources, Bob Baldwin, in his Second Reading Speech said the changes would stimulate greater competition in the generics market and encourage companies to develop generic pharmaceuticals in Australia rather than offshore.

> The objective […] is to encourage generic pharmaceutical development in Australia, consistent with the National Medicines Policy objective of maintaining a responsible and viable medicines industry.[12]

The Generic Medicines Industry Association has welcomed the Bill, and has been reported as saying it would increase the international competitiveness of Australia's generic medicines industry and bring Australian patent law in line with other countries especially the US and Europe.

"The widening of springboarding provisions enables the local industry to compete more fairly with overseas players," GMIA chair, John Montgomery, said.[13]

AusBiotech, in its submission to the Interdepartmental Review mentioned above, supported the existing springboarding provisions and argued that broadening the provisions would shorten the effective patent life of pharmaceutical patents and negatively impact investment by pharmaceutical companies in Australia.[14] The Explanatory Memorandum also confirms that submissions by pharmaceutical companies to the Review (10 companies and the industry association) were all in favour of the status quo and argued that springboarding should remain linked to the extension of patent term scheme.[15]

Paul Jones, a partner in the patents and trademarks practice of Freehills, says the changes may make innovator pharmaceutical companies more willing to litigate to protect their market share. He has been reported as saying:

> Clearly this new provision favours generic companies over innovators. The springboarding amendment will raise the stakes for innovators with generic pharmaceutical products likely to be on the market sooner after patent expiry and in greater numbers. Consequently, innovators may be more willing to litigate to protect their market share.[16]

Media reports have suggested that the proposed amendments will mean generic drugs worth millions of dollars could be ready for the market as soon as medicines' patents expire.[17] The Explanatory Memorandum does state that 'to the extent that a broader springboarding regime would enable generic medicines to enter the market more quickly, this proposal has the potential to increase competition and lower Pharmaceutical Benefits Scheme costs'. However the EM appears to downplay this potential effect and actually states that there are unlikely to be significant costs or benefits to Government from the proposed changes.[18] It acknowledges that competition from generic drugs produced overseas already happens as soon as a patent expires.[19] The Government's rationale for the change seems to focus more on the benefits of encouraging the retention and growth of a competitive generic pharmaceuticals R&D industry in Australia than on immediate savings to Government and consumers in the form of cheaper pharmaceuticals.

IPCRC Report on Competition and Intellectual Property Law

The Review of Intellectual Property Legislation under the Competition Principles Agreement (the Ergas Report) was delivered to the Government on 30 September 2000. It was produced by the Intellectual Property and Competition Review Committee (IPCRC) chaired by Mr Henry Ergas.

The IPCRC saw intellectual property laws and competition policy as 'largely complementary', on the basis that the former promote innovation, 'which is a key form of competition'. It acknowledged however that the two are also in tension because intellectual property laws usually confer exclusive rights:

> While conferring intellectual property rights encourages investment in creative effort, it can allow the owners of the results of this effort to unduly restrict the diffusion and use of these results.[20]

The Ergas Report went on:

> It must also be recognised that the rights granted by the intellectual property laws can be used for anti-competitive ends. This occurs when the rights are used to claim for the creator not merely a share of the efficiency gains society obtains from the creation, but also super-normal profits that arise from market power unrelated to the creation.[21]

Two questions guided the IPCRC in trying to better harmonise the interests of competition and innovation:

- whether exclusive rights available under intellectual property laws need to be reined in because they go beyond what is needed 'to encourage an efficient level of investment in creative effort' and
- whether adequate enforcement remedies are available under those laws, as 'the community's interest in competitive markets needs to be protected by ensuring that abuse of those rights is prevented'.[22]

In the area of patents, the IPCRC concluded that it should be harder to obtain a patent in the first place. Its rationale was that inventions which are not genuinely innovative should not obtain the monopolistic rights available under the Patents Act, because it excessively restricts competition. The IPCRC recommended making the threshold test for obtaining a patent more demanding and the examination process by the Patents Office more rigorous.

The *Patents Amendment Act 2001* and the regulations implemented some of these recommendations, particularly in relation to a more stringent threshold test. However some recommendations for legislative change made in the IPCRC report were not adopted in the 2001 legislation—the Government's rationale being that the initial changes were 'fast tracked ahead of any formal government response to the recommendations of the IPCRC' review.[23] The Government's formal response to the IPCRC report was finally

released in January 2003. **Schedules 6** and **8** of the Bill represent the Government's response to two further recommendations of the IPCRC report.[24]

Prior Use Defence (Schedule 6)

Not everyone who duplicates a patented invention will infringe the patent. One exemption, known as 'prior use', permits someone to continue using a process or making a product, where they were doing so (or about to do so) at the time a patent application was lodged by someone else, but that prior use was not publicly known.

The prior use exemption (found in section 119) is currently unavailable if the person derived information about the invention from the patentee or they had abandoned use or intention to use before the date of lodgement by the patentee.

The IPCRC considered the exemption and heard from a number of parties, some of whom alleged that prior users who have sunk a lot of investment into a product over a long period of time were not adequately protected. It recommended against allowing a prior user to assign, licence or sell their right under section 119. A majority thought that 'extending the exemption might tilt the benefits too far toward a de facto right for the prior secret user'.[25] The IPCRC did however make 2 recommendations for amendment of section 119:

- prior use be confined to use within the patent area (ie Australia), and
- prior use include experimental use.

The Government accepted these recommendations in part[26], agreeing that the prior use should be limited to use in the patent area, but rejecting the idea that it was necessary to clarify that the prior use included experimental use. The Government also considered that assignees, but not licensees[27], of the prior user should also have the benefit of the prior use defence. The Government further considered that the prior use exception should not be limited to the making of a product or the use of a process but that prior use should also encompass other acts such as selling, hiring or otherwise disposing of the product.

Schedule 6 of the Bill implements the Government's response to the IPCRC recommendations regarding prior use.

Item 1 repeals and replaces section 119 of the Patents Act. The effect of **new section 119** is that if a person had, before the relevant priority date,[28] been 'exploiting' a product, method or process (for example, if they had been making a particular product, or using a particular method or process), then even when the patent has been granted, they would have a right to continue to do that, but in addition, they would have the right to do any other act that would constitute an exploitation of that product, method or process (such as a right to sell the product they had been making, or to sell a product resulting from using the method or process).

New subsection 119(4) allows the prior user to assign his or her prior use right. The assignee may then have the full benefit of the prior use exemption. There is no provision for the prior user to licence his or her prior use right.

Compulsory licensing of patents (Schedule 8)

A patent grant is, in essence, a right to stop others from doing certain things and a patentee may decide not to work the patent. The decision may be due to lack of resources, unavailability of raw materials or similar reasons. However it is also possible that the patentee's failure to work the patent is due to a desire to exploit a different patent, or promote a different product or simply to stifle the inventions. The Patents Act recognises that failure to work an invention may be contrary to the interests of the public and provides for the granting of compulsory license and for the revocation of a patent on the grounds of non working. Section 133 of the Patents Act provides that a prescribed court can order a patentee to grant a licence to work their patented invention in certain circumstances. Subsection 133(2) allows the court to make the order if the reasonable requirements of the public with respect to the invention have not been satisfied and the patentee has given no satisfactory reason for failing to exploit the invention. Subsection 135(1) provides that the 'reasonable requirements of the public' have not been satisfied if:

- an existing trade or industry in Australia is unfairly prejudiced by the patentee's failure to work the invention, or an essential part of the invention, or to grant licences on reasonable terms
- an Australian trade or industry is unfairly prejudiced by conditions imposed by the patentee on the working of the patent, or
- the patent is not being commercially worked in Australia but is capable of being worked.

The IPCR Committee considered the conditions currently prescribed for the grant of a compulsory licence to be outdated, poorly aligned to achieve their purpose and deficient, in that they do not include an explicit competition test and do not sufficiently take the legitimate interests of the patentee into account. However, the IPCR Committee acknowledged that 'the threat of a compulsory licence may lead to innovations being worked sooner and more widely than they would otherwise have been' and that the current provisions 'have a continuing impact on licence negotiations, notably between foreign rights owners and potential users of patents in Australia'.[29]

The IPCR Committee goes on to say, that 'the conditions for grant of a compulsory licence should be stringent' and has recommended that the existing compulsory licensing provisions be replaced with a stringent competition test.[30]

The Government in its response to the IPCR Committee report supported in principle the recommendation to make the compulsory licensing of patents subject to a competition test but argued that a competition test alone is not sufficient as:

> (a) the recommended test may be more stringent in some circumstances than the existing tests and may result in the compulsory licensing provisions ceasing to act as an incentive to negotiate a voluntary licence; and
>
> (b) a competition test will not cover some situations where the non-working of the invention, or other effective denial of reasonable access to it, has some negative effect on the public interest which is not dependant on competition in the market.[31]

Accordingly, the Government believes that the existing tests should be retained and a competition test be added as an additional ground on which a compulsory licence can be obtained. The amendments in **Schedule 8** implement this response. In particular, **items 2 and 3** repeal and replace the existing test for grant of compulsory licences for patents. The existing limbs of the test are now contained in **new subparagraphs 133 (2)(a)(ii) and (iii). New paragraph 133(2)(b)** represents the additional competition test for compulsory licences. Under this test, if the patentee contravenes Part IV of the Trade Practices Act or an application law in connection with a patent, then a compulsory licence is available as a remedy for that contravention. The Trade Practices Act is part of a national scheme of legislation restricting anti-competitive conduct. An application law[32] refers to the various State and Territory Competition Policy Reform Acts.

The effect of **item 1** is that applications for compulsory licences will only be made in the Federal Court. Currently applications can be heard by the Federal Court and State and Territory Supreme Courts.

Exemplary damages (Schedule 5)

Exemplary damages are damages, over and above those necessary to compensate the plaintiff, that are awarded to punish the defendant and provide retribution, to act as a deterrent to the defendant and others minded to behave in a similar way, and to demonstrate the court's disapproval of such conduct.

Item 1 of **Schedule 5** inserts a **new subsection 122(1A)** into the Patents Act to allow for exemplary damages to be awarded by a court in patent infringement actions, for example, in the case of flagrant or wilful infringement of a patent **(new paragraph 122(1A)(a).** This amendment represents part of the Government's response to the recommendations of the Advisory Council on Intellectual Property review of patent enforcement report, 2002.

Innovation patents—minor technical amendments (schedules 9–10)

Schedule 9 commences the day after Royal Assent. **Schedule 10** commence six months after Royal Assent unless commenced earlier by proclamation **(clause 2).**

Innovation patents are a type of second tier patent for minor or incremental innovations. They have a lower inventive threshold than standard patents, do not require a substantive

examination before grant, have a maximum possible term of 8 years (compared to 20 years for a standard patent) and provide the ability to make up to 5 claims in the specification.

Item 1 of Schedule 9 is a technical amendment to clarify that *claims* of an innovation patent define the invention.[33]

Schedule 10 makes technical amendments to correct ambiguities in wording relating to divisional applications for innovation patents. Divisional applications are later-in-time applications made from within the four corners of the specification in an earlier 'parent' application. In other words, the later invention must be disclosed in the earlier specification. **Items 1** and **2** clarify that a divisional application from a granted parent innovation patent must be made in accordance with the regulations and may only be made between the period starting when the examination of the parent patent begins and ending when the parent patent either ends, ceases or is revoked.

Schedules 11–16 — Miscellaneous technical amendments

Schedules 11, 13–15 commence the day after Royal Assent, **Schedule 12** commences six months after Royal Assent unless commenced earlier by proclamation, and **Schedule 16** commences retrospectively **(clause 2)**.

Setting dates by regulations (Schedule 11)

The *Trade Marks Act 1995* and *Plant Breeder's Rights Act 1994*, like other intellectual property laws are concerned with obtaining property and other valuable rights. For this reason, filing dates, priority dates and time periods generally assume importance. For example, the filing date of a trade mark application[34] is important because the term of registration of any mark is generally counted from that date.

The effect of the amendments in Schedule 11 is to allow regulations to be made to determine priority and filing dates of plant breeder's right applications and trade mark applications. The Explanatory Memorandum states that this is to overcome problems that may arise where only partial applications have been filed or where on-line lodgement fails due to disruption of online services. In these cases filing dates could be affected, thus jeopardising applicants' rights. These amendments are consistent with similar provisions in other intellectual property laws, specifically the Designs and Patents Acts.

Effect of office not being open for business (Schedule 12)

As stated above, intellectual property laws are concerned with obtaining property and other valuable rights and for this reason, filing dates, priority dates and time periods generally assume importance. **Items 2–4** and **7-8** make identical amendments to the *Patents Act 1990*, *Trade Marks Act 1995*, *Designs Act 2003* and *Plant Breeder's Rights Act 1994* to provide clarification regarding the effect of offices not being open for

business. For example, in the case of trade marks, if a person wishes to object to registration of a trade mark and lodges their opposition on the final day of the three month objection period and the Trade Marks Office is closed on that date, then lodgement could be done on the next day of business **(item 8).**

Extension of time (Schedule 13)

Schedule 13 makes a minor amendment to the Trade Marks Act to clarify the effect of subsection 224(7). This subsection provides that applications may be made to the Administrative Appeals Tribunal requesting review of certain decisions of the Registrar not to grant extensions of time.

Approving forms (Schedule 14)

The *Plant Breeder's Rights Act 1994* provides for approved forms, such as application forms, plant description forms and plant breeder's rights certificates. These are forms approved, by instrument in writing, by the Departmental Secretary. These forms are currently disallowable instruments meaning that they must be tabled in Parliament and are subject to disallowance by the House of Representatives or the Senate. **Item 2** repeals section 7 of the Plant Breeder's Rights Act with the effect that these forms will no longer be legislative instruments or disallowable instruments for the purposes of the *Legislative Instruments Act 2003.*

Delegation (Schedule 15)

Item 1 amends the Designs Act to clarify that the delegation of the Registrar's powers and functions under the Designs Act include those powers and functions provided in the Designs Regulations 2004.

Item 2 amends the *Plant Breeder's Rights Act 1994* to enable a wider delegation of the powers of the Minister, Departmental Secretary and Registrar. Its effect will be to allow delegation to prescribed employees, such as Australian Public Service employees. The Explanatory Memorandum states that this brings the Plant Breeder's Rights Act into line with similar provisions in the Patents, Trade Marks and Designs Acts.[35]

Retrospective technical amendments (Schedule 16)

Schedule 16 makes minor retrospective technical amendments to the Patents Act and the Trade Marks Act.

Endnotes

1. Explanatory Memorandum, paragraph 6.
2. Section 86 of the Trade Marks Act provides for the Federal Court to cancel a registered trade mark.
3. Explanatory Memorandum, paragraph 77.
4. ibid., paragraph 81.
5. A generic version of a drug has the same active ingredient, is manufactured to the same standard, and has the same clinical effect as the original version. The generic pharmaceuticals sector worldwide is expanding rapidly, fuelled by the expiration of patents on many high-selling medications and Government incentives to increase usage of low cost generics.
6. Subsection 78(2).
7. Explanatory Memorandum, p. 19.
8. ibid., p.20.
9. The Therapeutic Goods Act requires that therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully imported into, exported from, manufactured or supplied in Australia, unless the goods are the subject of an exemption, approval or authority under the Act. Pharmaceutical products containing a new chemical entity are normally considered as high risk medicines and require stringent assessment in relation to safety, quality and efficacy. Applicants for the entry of these goods in the ARTG are required to provide substantial information to the Therapeutic Goods Administration (TGA), including information relating to pre-clinical studies, clinical or toxicological information, chemistry, quality control and manufacturing information. Under current rules, generics may not springboard during the first five years that the original drug has marketing approval. This is known as the 'data exclusivity' period. For a fuller explanation of drug patenting, approval and listing see the Parliamentary Library Research Note, 2004-05, no. 3, 21 July 2004, 'The PBS and the Australia-US Free Trade Agreement'.
10. Explanatory Memorandum, p. 20.
11. Exploitation is defined to mean: make, hire, sell, or otherwise dispose of the invention […] use or import it (Schedule 1 of the Patents Act).
12. Bob Baldwin, MP, Second reading speech, Intellectual Property Laws Amendment Bill 2006, House of Representatives, Hansard, 30 March 2006, p. 14.
13. 'Generics given a new springboard', Pharma in Focus, 17 April 2006.
14. http://www.ausbiotech.org/pdf/review1.pdf
15. Explanatory Memorandum, p. 23.
16. 'Generics given a new springboard', *Pharma in Focus*, 17 April 2006.
17. 'Springboard for generic drugs surge', *Australian Financial Review*, 8 April 2006.
18. Explanatory Memorandum, p. 21.

19. ibid., p. 23.
20. Intellectual Property and Competition Review Committee (IPCRC), *Review of Intellectual Property Legislation under the Competition Principles Agreement*, 30 September 2000, p 6.
21. ibid.
22. ibid., p. 7.
23. Warren Entsch, Parliamentary Secretary to the Minister for Industry Science and Resources, House of Representatives, *Debates*, 28 June 2001, p. 28951.
24. Schedule 6 implements in part recommendation 15 and Schedule 8 implements recommendation 18.
25. IPCRC, op. cit, p. 158.
26. Government response is available at: http://www.ag.gov.au/www/securitylawHome.nsf/Web+Pages/A6C3825011D8A8B1CA256C330000CF9A?OpenDocument
27. When a patent right is assigned, the right is transferred completely to a third party and the right owner does not retain any interest in the right. When a patent right is licensed, the licensee is authorised to use the right according to the terms of the licence. However the patent owner retains the right and may licence it to others on the same or different terms.
28. The priority date of a claim is usually the date for filing the specification of the invention with the Patent Office (section 43). It assumes importance for a number of reasons, particularly if someone subsequently decides to dispute entitlement to the patent.
29. IPCRC, op cit, p. 162.
30. ibid., p.163.
31. Government response, op. cit.
32. Defined in section 150A of the Trade Practices Act.
33. A specification describes the invention and innovation patent specifications can include up to 5 *claims* about the invention.
34. Defined in section 6 of the Trade Marks Act.
35. Explanatory Memorandum, para 237.

Members, Senators and Parliamentary staff can obtain further information from the Parliamentary Library on (02) 6277 2438.