Report to Parliament on barriers to generic medicines entering the market through the inappropriate use of intellectual property rights over product information

30 June 2011

Scope of the Report

The purpose of this report is to examine whether there are any barriers to generic medicines entering the market through the inappropriate use of intellectual property rights over medicine's product information.

In the context of the passage of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (The Bill), the Senate agreed to two amendments to the motion that the Bill be read a second time. Paragraph (b) of the amendment moved by Senator Xenophon, also on behalf of the Leader of the Family First Party was to call on the Government:

> '*to examine whether there are any barriers to generic medicines entering the market through the inappropriate use of intellectual property rights over product information, building on work currently underway, and to table a report by 30 June 2011 on these barriers and appropriate mechanisms to address them'*.[1]

This report addresses this amendment.

EXECUTIVE SUMMARY

Product Information (PI) is defined in the *Therapeutic Goods Act 1989* as information about the safe and effective use of therapeutic goods, including information regarding the usefulness and limitations of the goods.[2] PI is approved as part of the registration process for prescription and other higher risk medicines by the Therapeutic Goods Administration (TGA).

PI contains technical information about the medicine such as the characteristics of the active ingredient, its indications and contraindications, a description of the clinical trials that support the indications, precautions, possible adverse reactions, dosage and administration, over dosage, presentation and storage conditions, information about the sponsor, date of inclusion on the Australian Register of Therapeutic Goods (the Register) and other information relating to the medicine's safe and effective use.

Information contained in a medicine's PI enables prescribers to appropriately and safely prescribe prescription medicines for patients.

A generic version of a medicine has the same active ingredient, is manufactured to the same standard, and has the same clinical effect as the original version. The practice of the TGA has been to approve PI for generic versions of a medicine that is substantially similar to the PI approved for the registered version of the medicine so as to ensure that health professionals receive the same information about a medicine, irrespective of its brand. This practice is designed to protect the safety of the public by minimising the possibility that prescribers and other health professionals are

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[1] Commonwealth, *Journals of the Senate*, 22 November 2010 (12), 378.
[2] *Therapeutic Goods Act 1989* (Cth) sub-s 3(1).

misled by differences in the PIs of different brands of the same medicine through assuming there is a difference in the medicine itself.

When in 2008 a company with a registered medicine successfully obtained an interlocutory injunction preventing the marketing of a competitor's generic version of that medicine, in part based on an allegation of breach of copyright in the PI of the registered medicine, the sustainability of the TGA's practice became an issue. A number of threats of similar legal action against companies proposing to market generic medicines have been made since that time.

A successful copyright-based action would prevent the marketing of the relevant generic medicine using the approved PI which would result in one of three outcomes:

- the generic brand not being marketed thus removing any price competition for the originator;
- the generic brand being marketed without an approved PI; or
- the TGA having to abandon its long-standing practice.

On 24 February 2011 the Government introduced into Parliament the Therapeutic Goods Legislation Amendment (Copyright) Bill 2011. This Bill, passed by the Senate on 11 May 2011 and brought into effect on 27 May 2011, amended the *Copyright Act 1968* to enshrine the current practice of the TGA by effectively preventing companies from initiating copyright litigation based on the use of PIs in a similar form.

The amendments:

- allow the TGA to approve PI for a medicine in a form that is similar to that approved for another version of that medicine; and
- allow for the reproduction and use of approved PI for purposes related to the safe and effective use of the medicine even if that PI is in a form that is similar to that approved for another version of the medicine.

These amendments reflect the Government's concern that the important public health objectives of accurate, consistent information for prescribers and consumers might be jeopardised if some pharmaceutical companies claim infringement of copyright in the approved PI of their registered medicines in an attempt to delay market entry of their competitors' generic versions of those medicines.

These amendments are designed to ensure consistency of information about generic medicines to the public, and stability for the generic medicines sector. They restore the balance between ensuring timely access to generic medicines for all Australians and providing incentives for the research and development of new drugs by providing appropriate protection of intellectual property.

BACKGROUND

The Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS) provides timely, reliable and affordable access to necessary medicines for Australians. Under the PBS, the Government subsidises the cost of medicine for the Australian community. The PBS is part of the Australian Government's broader National Medicines Policy (NMP) which provides the overarching framework for the operation of the PBS.

National Medicines Policy (NMP)

The NMP is a broad framework that aims to improve health outcomes for all Australians through access to and appropriate use of medicines. The overall aim of the policy is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The NMP has four central objectives:

- timely access to medicines that Australians need at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Under the NMP, in order to achieve optimum use of medicines, 'consumers and health practitioners should have timely access to accurate information and education about medicines and their use.'[3]

Industry also plays a part by ensuring, in relation to the quality use of medicines, 'truthful, balanced and understandable information is provided to health practitioners and consumers about medicines.'[4] The National Strategy for Quality Use of Medicines (QUM) reiterates the goals of the NMP by stating that health professionals and educators are responsible for (amongst other things):

- assisting people in making informed decisions and learning more about health issues and health care through information, education and discussion;
- becoming more aware of the risks and benefits of medicines, and
- utilising objective information, resources and services to make decisions.

PIs play a central role in providing health professionals, and through them, the health consumer, with this important information. QUM envisages cooperation between health professional and patient, so that both PI and Consumer Medicine Information (CMI) documents play a significant role. The medicines industry is also responsible for 'providing good quality, accurate, balanced information' that is conducive to QUM.[5]

The NMP clearly states that 'nationally standardised regulation of medicines should be managed through rational and transparent criteria and processes.'[6] This emphasis on transparency implies that Australians (consumers and healthcare professionals) should be able to understand and access the criteria and processes for medicine approval, review and removal from the Australian market. PI and CMI documents contribute to this transparency.

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[3] Australian Government Department of Health and Ageing, *National Medicines Policy* (2000) 3.
[4] Ibid 5.
[5] Australian Government Department of Health and Ageing, *The National Strategy for Quality Use of Medicines* (2002) 11.
[6] Australian Government Department of Health and Ageing, above n 3, 2.

The Therapeutic Goods Administration

The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices. Its overall purpose is to protect public health and safety by regulating therapeutic goods that are supplied either imported or manufactured, or exported from Australia. At the same time the TGA aims to ensure that the Australian community has access, within a reasonable timeframe, to new therapeutic goods.

The TGA administers the *Therapeutic Goods Act 1989* (the Act). The objectives of the Act are to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere or exported from Australia.[7] In carrying out its functions under the Act the TGA applies a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary. The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

Prescription and pharmacist-only medicines cannot be marketed in Australia unless they are registered. The TGA evaluates medicines for their quality, safety and efficacy as part of that registration process. In this way, the TGA has a key role in the implementation of the NMP. Communication of the TGA's structures, actions and recommendations is an essential aspect of each of the NMP objectives.

Product Information

A PI document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription or pharmacist-only medicine. The information has been written by the pharmaceutical company responsible for the medicine but cannot contain promotional material. PI is approved by the TGA as part of the registration process for the medicine.

PI provides objective information about the quality, safety and effectiveness of the medicine, as demonstrated in the data provided to the TGA by the pharmaceutical company.

The purpose of PI is to assist medical practitioners, pharmacists and other health professionals in prescribing and dispensing the medicine, and to assist them in providing patient education about the medicine to support appropriate and safe clinical care.

Under amendments made to the Therapeutic Goods Act in 2010[8] that became operational in May 2011 it is a statutory requirement for a PI (in draft form) to accompany an application for registration of prescription and pharmacy-only medicines. Applications for registration of a "restricted medicine" i.e. all prescription medicines[9] and medicines that contain a substance in Schedule 3 to the current

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[7] *Therapeutic Goods Act 1989* (Cth) sub-s 4(1).

[8] *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010* (Cth).

[9] Australian Government Department of Health and Ageing, *Standard for the Uniform Scheduling of Drugs and Poisons* (2010) schs 4 and 8.

Poisons Standard must be accompanied by PI provided in accordance with a form approved by the Secretary of the Department of Health and Ageing.[10] The Secretary can also require PI to be provided in relation to applications made under section 23 of the Act for the registration of other types of medicines.[11] If such a request is made, the PI must also be provided in accordance with the new form.

The form sets out the headings which the PI must provide. The content of the PI is part of the evaluation of the submission provided after an application for registration has been accepted.[12] The delegate of the Secretary approves the final form of the PI and informs the applicant when the approval for registration of the medicine is notified.[13]

Once approved, the PI cannot be changed without the further approval of a delegate. Changes might be made in relation to a medicine once it is on the Register in a number of ways – the person in relation to whom it is included in the Register may apply to the TGA for a change to the entry or the conditions to which that registration is subject. If as a result of either of these changes the Secretary is satisfied that a variation to the PI is required, then the Secretary can make changes to the PI.[14] These must be notified to the person in relation to whom the medicine is entered in the Register.

Applicants must upload the approved PI for a prescription medicine on the TGA website within two weeks of the inclusion of the medicine in the ARTG.

Contents of the Product Information document

The PI document contains technical information about the medicine such as the characteristics of the active ingredient, dosages, indications and contraindications, a description of the relevant clinical trials, precautions, possible adverse reactions, storage and other information related to safe and effective use.

A PI must specifically contain information about the following matters:

- the name of the medicine;
- a description (including the relevant physical and chemical characteristics and its formulations);
- pharmacology (pharmacodynamics (how it works in the human body) and pharmacokinetics (how quickly it works in the human body));
- clinical trials (usually in relation to each of the indications and both positive and negative);
- indications (the therapeutic applications i.e. conditions or diseases the treatment of which the drug has been approved);
- contraindications (situations in which the medicine should not be used);

[10] As approved under *Therapeutic Goods Act 1989* (Cth) sub-s 7D(1).
[11] *Therapeutic Goods Act 1989* (Cth) sub-para 25(1)(da). This might for instance include an application for registration of a new chemical entity that has yet to be included in a schedule to the Poisons Standard.
[12] *Therapeutic Goods Act 1989* (Cth) sub-para 25(1)(da).
[13] *Therapeutic Goods Act 1989* (Cth) sub-s 25(1).
[14] *Therapeutic Goods Act 1989* (Cth) sub-s 25AA(4).

- precautions (circumstances in which care should be taken in the use of the drug in particular in pregnant and lactating women, in children, in the elderly, and its genotoxicity and carcinogicity);
- interactions with other medicines;
- adverse effects (a description of reported adverse effects including from clinical trials and from other patients including severity, clinical importance and frequency);
- dosage and administration (how, when and how often the medicine should be used by, administered to, a patient);
- over dosage (symptoms, signs and recommended treatment);
- presentation and storage conditions (dosage form, quantity, proportion or strength of each active ingredient, container type, pack sizes and conditions under which it is to be stored);
- name and address of the sponsor;
- poison schedule of the medicine (e.g. S4 (prescription-only); S3 (pharmacist-only) if relevant);
- date of registration; and
- date of most recent variation to the PI.

The PI document is crucial to achieving the objectives of the NMP, the quality use of medicines in particular. To achieve optimum use of medicines consumers and health practitioners should have timely access to accurate information and education about medicines and their use.

Copies of the PI for prescription medicines registered in Australia can be obtained through www.ebs.tga.gov.au. As at 15 June 2011, the PIs of 83% of the prescription medicines entries in the ARTG were available on the TGA website.

Consumer Medicine Information

Prescription and pharmacist-only medicines can only be supplied in Australia if written information about the medicine is supplied with the medicine.[15] That information, known as Consumer Medicine Information (CMI), is written by the pharmaceutical company responsible for the medicine but it must be:

- written in English;
- clearly legible;
- written in language that will easily be understood by patients;
- be consistent with the approved PI for the medicine; and
- must include information about a range of matters including the name of the medicine, name of the active and inactive ingredients, the dosage of the medicine, what the medicine is used for and how it works, warnings and precautions, such as when the medicine should not be taken, interactions the medicine might have with food or other medicines, how to use the medicine properly, side effects, what to do in the case of an overdose, how to store the medicine properly, name and address of the sponsor and the date the CMI was last updated.[16]

[15] *Therapeutic Goods Regulations 1990* (Cth) reg 9A; and schs 12 and 13.
[16] *Therapeutic Goods Regulations 1990* (Cth) schs 12 and 13.

CMI are prepared by the sponsor of the product and are not assessed by the TGA. A CMI document is usually provided in the form of a leaflet either in the pack or in another manner that will enable the information to be given to the person to whom the medicine is administered or otherwise dispensed.

Copies of CMI for prescription medicines registered in Australia can be accessed through www.ebs.tga.gov.au. As at 15 June 2011, the CMIs of 59% of the prescription medicine entries in the ARTG were available on the TGA website.

Product Information for generic medicines

A generic medicine is a medicine that, in comparison to a registered medicine:
(a) has the same quantitative composition of therapeutically active substances that are of similar quality to those used in the registered medicine;
(b) has the same pharmaceutical form;
(c) is bioequivalent; and
(d) has the same safety and efficacy properties.[17]

Generally the applicant for a generic version of a registered prescription medicine need only demonstrate "bioequivalence" with that medicine to gain regulatory approval. "Bioequivalence" is the absence of a significant difference between the generic medicine and the original medicine in the rate and extent to which the active ingredient in a medicine reaches the systemic circulation or becomes available at the site of action.

The TGA has a longstanding practice of approving the text of PIs for a generic medicine that is essentially the same in relevant respects as that of the PI approved for other versions of the same medicine. The practice is based on sound public health reasons. It is considered critical that doctors and pharmacists receive the same information when prescribing and dispensing all brands of the same medicine. Providing consistent information in this manner minimises the possibility that misconceptions about non-existent clinical or pharmacological differences between the brands if the text of approved PI varies between those brands. This in turn supports the NMP in promoting quality use of medicines.

Applicants for registration of a generic version of a registered medicine will usually supply a draft PI that reflects the information in the approved PI for that medicine. The content of the PI will be finalised as part of the evaluation process that precedes registration of the generic version.

The actual content of the PI approved for a generic version of a medicine will necessarily vary from that of the registered medicine in some respects, for instance to reflect the fact that the generic version will have a different trade name, the details of the inactive ingredient's may be different, the goods may have a different appearance (which would result in a different description) and of course there will be a different name and address for the sponsor.

[17] *Therapeutic Goods Regulations 1990* (Cth) reg 2.

Legal action in relation to PI

A number of originator companies have been looking to use their copyright on PI to initiate litigation as a means to interrupt the marketing of their competitors' products. The use of copyright injunctions to prevent generic medicines being marketed could provide a company that holds a patent for a medicine with a substantial additional period of market exclusivity.

This is a relatively recent development as there does not appear to have been legal action taken prior to 2008 based on the assertion of copyright interests notwithstanding the administrative practice of the TGA over many years to require similar wording for PI across brands of the same medicine.

In 2008 Sanofi-Aventis Australia Pty Ltd was granted an interlocutory injunction by the Federal Court with the effect that Apotex Pty Ltd was prevented from marketing its generic version of the medicine leflunomide. The injunction was granted partly on the basis that the approved PI for the Apotex version breached Sanofi's copyright in the approved PI for its registered medicine containing leflunomide. The legal argument about whether any copyright exists in the Sanofi-Aventis PI for its brand of leflunomide and if so, whether the approved Apotex PI would have breached that copyright is set to be heard by the Federal Court at some stage later in the year. The Federal Court set down a preliminary decision for the case in March 2011. No consideration was given to the use of copyright on PI was in this decision.

Should the court ultimately find that copyright did not exist in the PI under consideration in this case, it is possible that may only be a specific reflection of the facts of the case and would not necessarily provide the level of certainty that Australian consumers and the industry need to ensure that the timely supply of generic medicines to the Australian market is not unduly interrupted. The Government believes that the clear rules set out in the amendments to the Copyright Act are justified and appropriate to achieve the kind of certainty that is required.

A number of threats of similar legal action against companies proposing to market generic medicines have been made since 2008. This has resulted in requests being made to the TGA to approve changes to the approved PI for these medicines in an attempt to avoid the argument being made that the use of those PI documents would involve a breach of copyright. This would have required the TGA to depart from its long-standing practice and could have involved a costly and resource-intensive consideration of the proposed changes in relation to the characteristics of the medicine that was not required if the text of the PI approved for the original medicine could be used. Even if approved, the risk of prescribers and other health professionals being misled by differences in the text of the information provided in the PI would have remained.

There was also one instance where a generic medicine was marketed without a PI, apparently in response to a fear that injunctive action would be taken to prevent its marketing if the approved PI was used. While not unlawful, this practice is not conducive to the quality use of medicines and good prescribing practice.

MECHANISMS TO ADDRESS THIS BARRIER

In order to put an end to the uncertainty about the use of approved PI, the Government decided to take legislative action to ensure that the TGA practice could continue. The Therapeutic Goods Legislation Amendment (Copyright) Bill 2011 was introduced into the House of Representatives on 24 February 2011. The Bill was supported by the Opposition in both Houses and it received the Royal Assent on 27 May 2011.

Amendments to the Copyright Act 1968 – what they do

The *Therapeutic Goods Amendment (2011 Measures No. 1) Act 2011* inserted a new section 44BA into the *Copyright Act 1968* the effect of which is that:

- actions under the Therapeutic Goods Act for the purposes of approving product information, or of approving variations to approved product information, for medicines will not be an infringement of copyright subsisting in any product information previously approved by the TGA; and
- the supply, reproduction, publication, communication or adaptation of any approved product information of a registered medicine will not be an infringement of copyright in any other approved product information where such an act is done for a purpose related to the safe and effective use of the medicine concerned. This exemption applies to such acts irrespective of when the product information was approved by the TGA. It would cover, for instance, acts of the Commonwealth (including by the TGA), pharmaceutical companies and healthcare professionals and all those involved in making product information available to health professionals.

The amendments to the Copyright Act ensure that the provision by the applicant of PI in this form and its evaluation and approval by the TGA cannot breach any copyright in any PI previously approved by the TGA. The amendments do not however purport to protect the TGA or any other person (including an applicant) from any claim of copyright where material provided for this purpose copies material from another source.

The applicant is notified of an approved PI at the same time they are notified that the medicine can be registered. Once the prescription medicine is entered in the Register, the applicant is required to make the approved PI available for uploading on the TGA website within 2 weeks.[18]

Any use (whether by way of supply, reproduction, publication, communication or adaptation) of a PI approved for a medicine, or any part of it, by the applicant or any other person that is done for the purpose of the safe and effective use of the medicine will not be a breach of copyright. This protection is intended to extend to the use by pharmaceutical companies and their employees and agents of approved PI in presentations about the relevant medicine and to those who make available online of approved PI for the use of health professionals.

[18] *Therapeutic Goods Act 1989* (Cth) sub-s 25(4).

This will ensure, for instance, that a person applying for the registration of a generic version of a registered medicine will not infringe copyright a draft PI document is provided to the TGA that contains text similar to the PI already approved by the TGA for another version of that medicine. This exemption will apply irrespective of when the second-mentioned PI was approved, that is, whether it was approved before or after the amendments come into effect.

Further, any publication or use of an approved PI for a generic version of an originator medicine occurring after the date of commencement of the amendments (27 May 2011) will not be a breach of copyright in the approved PI of the originator medicine even where the PIs of the originator and generic version were approved before that date.

In other words, the amendments operate to provide protection for any actions taking place after 27 May 2011 in relation to an approved PI irrespective of when that PI was approved. Thus there is no need for currently approved PIs to be reconsidered by the TGA to obtain that protection.

The amendments do not however affect acts that occurred before 27 May 2011 i.e. the date they came into effect. They will have no impact on whether, as in the case of the litigation currently before the Federal Court, the relevant company can demonstrate that copyright subsisted in the PI that was approved for its registered medicine, that it owned that copyright and that copyright was breached by the publication or use of PI that was approved for a generic version of that medicine if those acts occurred before that date.

This means that the amendments do not purport to affect the legal rights of the parties in the Sanofi-Aventis/Apotex litigation current before the Federal Court. They would have nothing to say about whether, if the relevant medicine had been marketed with its approved product information back in 2008, there would have been a breach of the plaintiff's copyright.

The *Therapeutic Goods Amendment (2011 Measures No. 1) Act 2011* also included a so-called 'historic shipwrecks clause' which, in the unlikely event that the amendments would result in the acquisition of property from a person otherwise than on 'just terms', requires the Commonwealth to pay 'reasonable compensation' to that person. This provision was included as a precautionary measure and has the effect of ensuring constitutional validity for the amendments.

The proposed amendments reflect the importance the government places on ensuring the highest levels of health consumer safety through the provision of accurate information to prescribers and other health professionals about higher risk medicines.

Existing intellectual property rights – patent protection

The copyright action threatened to dislodge the carefully calibrated balance between the rights enjoyed by companies that invest in the development of new medicines and the rights of their competitors to register generic versions of patented medicines and to lawfully market them.

The term for a standard patent in Australia is 20 years from the date of the patent.[19] A standard patent for a pharmaceutical substance included in goods that are on the Register can however be extended for a period of up to five years if there was a gap of more than five years between the grant of the patent and the first regulatory approval date for the substance.[20]

Under section 119A of the *Patents Act 1990* it is not a breach of the rights of a patentee of a pharmaceutical patent for an application to be made to the TGA to register a generic version of the medicine; nor is it a breach of any patent rights for the TGA to evaluate that application and make a decision to register the generic version. This "springboarding" provision was included in the Patents Act to allow generic manufacturers to enter the Australian market more rapidly post-patent expiry, replacing a provision which only allowed springboarding on patents in relation to which a patent extension had been granted and brought the Australian position into line with similar provisions overseas.

However, the rights of patent holders are protected in a number of ways.

First, data protection provisions in the Therapeutic Goods Act prevent information provided to the TGA for the purposes of the registration of a medicine containing a new chemical entity from being used by the Secretary to evaluate a generic version of that medicine for a period of at least five years from the day on which that medicine was registered.[21]

Second, a generic version of a medicine cannot be included in the Register unless and until one of the following has occurred:

- the applicant has provided a certificate to the Secretary to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the medicine in a manner, or in circumstances, that would infringe a valid claim of a patent; or
- the applicant has provided a certificate to the Secretary to the effect that a patent has been granted in relation to the therapeutic goods, the applicant proposes to market the therapeutic goods before the end of the term of the patent and the applicant has given the patentee notice of its application.[22]

It is an offence for a person to provide a certificate that is false or misleading in a material particular.[23]

While not common, it is not unknown for some months to elapse between the time that an applicant is notified of the approval for registration of a generic medicine and its inclusion in the Register because of a delay in the provision of a certificate. If the

[19] *Patents Act 1990* (Cth) s 67.
[20] This would normally be the date that a therapeutic good containing that substance was first included in the Register. See *Patents Act 1990* (Cth) pt 3 of ch 6.
[21] *Therapeutic Goods Act 1989* (Cth) s 25A.
[22] *Therapeutic Goods Act 1989* (Cth) sub-s 26B(1).
[23] *Therapeutic Goods Act 1989* (Cth) sub-s 25B(2).

medicine is not in the Register it cannot be marketed lawfully in Australia thus there can be no breach of the rights of any patent holder.[24]

The Therapeutic Goods Act also includes provisions designed to ensure the bona fides of any patent action taken in relation to such generic medicines. Any company proposing to take action under the Patents Act against an applicant that has provided a certificate to the Secretary must, prior to commencing such legal action, certify to the Secretary that the proceedings:

- are to be commenced in good faith and;
- have reasonable prospects of success; and
- will be conducted without unreasonable delay.[25]

If the certificate is false or misleading in a material particular or an undertaking in the certificate is breached, a court can order that a pecuniary penalty of up to $10 million be paid to the Commonwealth taking into account any profits obtained by the company and any loss or damage to any person[26] or where an interlocutory injunction was granted, pay compensation to the Commonwealth for any damages sustained or costs incurred.[27] Where a patent holder to whom the applicant for the generic medicine gave the notice of the application succeeds in getting an interlocutory injunction but a court then determines (if the proceedings are withdrawn or dismissed) that the patentee did not have reasonable grounds to take the action or the action was vexatious, to award the applicant and the Commonwealth damages.[28]

The issue of the capacity of patent holders to take action to enforce their rights in a timely way in relation to therapeutic goods has been the subject of representations made to the Government over the recent months. So as to ensure transparency and timely access to information about medicines included in the Register, the online version of the Register on the TGA website now facilitates access to information about medicines and medical devices included in the Register in the previous 2, 7, 14 and 31 days. In addition, the whole of the online Register is now searchable by reference to a medicine's active ingredient which facilitates the identification generic versions of a medicine. The online Register can be found at https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuDevices?OpenView.

The use of copyright injunctions would have overridden this careful balance of the rights of patent holders and those seeking access to the Australian market for approved generic medicines to the detriment of Australian health consumers.

INTERNATIONAL EXPERIENCE

Internationally there have been a number of court cases dealing with copyright infringement issues where a generic company uses an originator's product information as part of marketing its own version of the medicine.

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[24] Under the *Therapeutic Goods Act 1989* (Cth) sub-s 25(4) the Secretary must, where there is a decision to register the goods, to notify the applicant that the goods will be included in the Register if the relevant certificate is provided and include the goods in the Register if the certificate is given.
[25] *Therapeutic Goods Act 1989* (Cth) sub-s 26C(3).
[26] *Therapeutic Goods Act 1989* (Cth) sub-ss 26C(5), (5A) and (6).
[27] *Therapeutic Goods Act 1989* (Cth) sub-s 26C(8).
[28] *Therapeutic Goods Act 1989* (Cth) s26D.

In the United States case of *Watson Pharmaceuticals*, the court found that there is no copyright infringement upon use by a generic manufacturer of a package insert (leaflet) that is almost identical to that of the Brand product.

SmithKline Beecham vs Watson (US District Court for the Southern District of New York) concerned a user guide and audiotape for Nicorette gum. The court initially granted a preliminary injunction against Watson from marketing a competing generic product with strikingly or substantially similar labelling. However, subsequent events, including a change in Food and Drug Administration's position on labelling, led to the Court dissolving the preliminary injunction.

The Court of Appeal affirmed the District Court's decision regarding preliminary injunction, as well as dismissing the complaint, as they recognised that SmithKline Beecham's claims would undermine the so called 'Waxman-Hatch' Act provisions. The *US Drug Price Competition and Patent Term Restoration Act of 1984* (known as the Waxman-Hatch Act) was designed to facilitate faster introduction of generic drugs. It amended the *Federal Food, Drug and Cosmetic Act* to provide, amongst other things, for exemption to generic manufacturers from patent infringement for work related to regulatory marketing approval and a process by which generic drugs could be approved through the lodgment of an abbreviated application for approval which demonstrated that the active ingredient was the same as the already listed drug.

IMPLICATIONS FOR THE PHARMACEUTICAL BENEFITS SCHEME

The entry of generic medicines into the market and their listing on the PBS is crucial to the ongoing sustainability of the PBS, and the Government's continued commitment to ensure that all Australians have continued timely access to affordable medicines.

Brand substitution policy was introduced in Australia in 1994 to encourage the use of generic medicines. The policy makes it possible to substitute, where appropriate, the prescribed drug brand at the time of dispensing in the pharmacy. This practice is a vital component of pharmaceutical policy in Australia as it contributes directly to improved access and affordability of pharmaceuticals to both the government and health consumers. Timely availability of generic medicines is an essential feature of this policy.

The 2007 PBS reforms were pricing reforms, based primarily on competition to take advantage of the fact that patents on a number of PBS medicines would expire in the next few years. These reforms included statutory price reductions, when a new brand entered the market, and price disclosure.

Price disclosure recognises that there is significant discounting of the off patent medicines in Australia. Pharmaceutical companies give discounts to pharmacists to get them to stock their items over their competitors' items. Price disclosure takes a share of these discounts for the taxpayer and the patients. Under this policy, the price the government pays for PBS medicines will move closer to the actual price at which those medicines are supplied to the market.

Further reforms were introduced in 2010, implemented under the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010*. Under these reforms the first listing of a generic version of a medicine now triggers a 16 per cent reduction in the price the Commonwealth pays for the medicine.

The objective of both 2007 and 2010 reforms reflect that Australian taxpayers should benefit from that competition and the lower prices that result. In addition both the 2007 and 2010 reforms to the PBS included a generic medicines awareness campaign, to build consumer confidence in the safety and efficacy of generic medicines.

Any barriers that have the effect of preventing or delaying entry of new brands of medicines into a commodity market will have significant financial implications for both Government and consumers by reducing the effectiveness of these reform measures.

CONCLUSION

The use of intellectual property rights over product information, in particular copyright, emerged in recent years as a potential barrier to generic medicines entering the market. This barrier to generic market entry had the potential to pose significant problems to the generic medicines industry in Australia, to the quality use of medicines, and the ongoing sustainability of the PBS.

The amendments to the *Copyright Act 1968* will substantially alleviate these problems by exempting the legitimate use and reproduction of similar product information from legal action. The amendments will enhance the quality use of medicine, support the maintenance of Australia's responsible and viable medicines industry, and will secure access to safe, effective and affordable medicines for all Australian's through ensuring the ongoing sustainability of the PBS.

These amendments will address this problem directly, removing potential health and safety issues, providing stability for the generic medicines sector and ensuring the ongoing sustainability of the PBS.