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PHARMACEUTICAL EXTENSIONS IN AUSTRALIA: A REFERENCE GUIDE

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Introduction

Research and development of a new pharmaceutical is a long process, often taking in the order of 10 to 15 years from the initial identification of a new active compound. A significant reason for that delay is the increasingly stringent requirements for expensive clinical trials to satisfy regulatory authorities, such as the US Food and Drug Administration (FDA).

In most cases, the primary mechanism by which a pharmaceutical company obtains market exclusivity to enable it to obtain a return on the significant investment required for new drug development, is through the use of the patent system. Like most other countries, an Australian standard patent has a term of 20 years from the effective date of filing. However, in view of the extensive period required to bring a new drug to market, new drugs are often not launched until well into the standard 20 year patent term. This does not leave a pharmaceutical company with much time to obtain a return on its initial investment.

In recognition of both the importance and impact of the regulatory approval process, and the need for a return on the substantial investments of money and time expended on the generation of new and effective pharmaceuticals, many countries have introduced a system of patent term extensions in relation to patents that protect regulated pharmaceutical products. In Australia, s 70 of the *Patents Act* 1990 provides for patent term extensions of up to 5 years in appropriate circumstances.

Obtaining an extension of term requires careful consideration and prosecution of a number of issues and procedures. Further, the qualifying criteria for an extension of patent term, and the calculation of the length of the extended term, do vary between different countries. This guide is an introduction to both to the patent term extension system in Australia, as well as the other various mechanisms available under Australian law to increase the period of exclusivity available to pharmaceutical originators, such as data exclusivity.

We discuss the legal and procedural matters involved in obtaining an extension of patent term, and the springboarding provisions as they currently apply. Additionally, we briefly cover the data exclusivity regime in relation to pharmaceuticals for human therapeutic use (the data protection provisions which relate to agricultural and veterinary chemicals are sufficiently distinct that they deserve an article of their own). We also briefly cover the relevant aspects of the approval process for generic medicines. Finally, a summary including several tips for gaining an extension of term is provided.

We highlight where case law, divergence of practice between countries, legislation or other policy matters create special points of interest.

1. The Extension of Term Provisions

Part 3, Chapter 6 (sections 70 to 79A) of the *Patents Act* 1990 ("the Act") governs the extension of term of a standard patent.

To be eligible for an extension, the requirements as set out in s 70 of the Act must be satisfied. In particular:

- the patent must disclose and claim a pharmaceutical substance *per se*, or a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology (ss 70(2));
- goods containing, or consisting of, the pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG) (ss 70(3)(a));
- the period from the effective filing date of the patent to the date of first regulatory approval must be at least five years (ss 70(3)(b)); and
- the term of the patent must not have been previously extended (ss 70(4)).

2. Pharmaceutical Substances

Extensions of term are only available to pharmaceutical substances. Schedule 1 of the Act defines a "pharmaceutical substance" as:

> *a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:*
>
> *(a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or*
> *(b) action on an infectious agent, or on a toxin or other poison, in a human body;*
>
> *but does not include a substance that is solely for use in* in vitro *diagnosis or* in vitro *testing.*

The term "therapeutic use" is, in turn, defined in relation to the definition of "pharmaceutical substance" as use for the purposes of:

> *(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or*
> *(b) influencing, inhibiting or modifying a physiological process in persons; or*
> *(c) testing the susceptibility of persons to a disease or ailment.*

The definition of "pharmaceutical substance" was recently considered by the Federal Court in *Pharmacia Italia SpA v Mayne Pharma Pty Ltd* [2006] FCA 305. During the proceedings, the respondent Interpharma Pty Ltd contended that a "pharmaceutical substance" must be restricted to a single active ingredient, or alternatively, a mixture (or compound) of active ingredients.

In rejecting this argument, the court noted that such an approach would effectively mean that s 70 had almost no function to perform. Almost every pharmaceutical product consists of a combination of individual substances, some of which may be intrinsically therapeutic, while others, such as excipients, serve different but essential roles. It was held that to restrict the capacity to extend a patent to those cases where every component of the compound is itself therapeutically useful would be to deprive s 70 of any real utility, and largely defeat the purpose of its enactment.

Point of Interest: Current Australian case law (*e.g*. *Sanofi-Aventis* [2007] APO 35 (2 October 2007), discussed further below) suggests that an extension of term is available for formulations, even where the active ingredient has previously been the subject of an extension of term – unlike the position adopted by the European Court of Justice in the *Gliadel* decision (ECJ C-431/04), which held that products comprising the combination of a known active ingredient with an excipient to form a novel formulation are not entitled to SPC protection, however different the novel formulation may be in terms of characteristics in use.

The definition of pharmaceutical substance means that patent term extensions are not available in relation to medical devices that do not include an active ingredient, such as implants and contact lenses. This is essentially the same as the position in Europe, whereas in the US, patent term extensions are available for any medical device (which includes *in vitro* reagents or other related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease) which is subject to regulation under the Federal Food, Drug, and Cosmetic Act.

3. A Pharmaceutical Substance "*per se*"

The meaning of the expression "pharmaceutical substance *per se*" in s 70(2)(a) has been considered by the Federal Court in *Boehringer Ingelheim International GmbH v Commissioner of Patents* [2001] FCA 647 and *Prejay Holdings Ltd v Commissioner of Patents* [2003] FCAFC 77.

In *Boehringer,* the Full Court had to consider a claim for a container provided with a nozzle for delivering a pharmaceutical substance by nasal administration. The patentee had argued that the phrase "pharmaceutical substance *per se*" as used in s 70(2)(a) "requires ... no more than that a pharmaceutical substance must be included in one or more of those claims as an essential feature".

In rejecting this argument, the Full Court held that the words "*per se*" indicated a clear intention, on the part of the legislature, to limit the operation of s 70 to patents disclosing and claiming a pharmaceutical substance as such, as opposed to a substance forming part of a method or process. As all of the claims of the patent in suit were for modes of treatment involving a substance, and not for the substance itself, an extension of term was not available.

In *Prejay*, the Full Court considered a patent where the claims were to a method of treatment by administering a pharmaceutical substance. In following *Boehringer*, the court held that a substance that is mentioned in the context of a method claim does not meet the requirement of ss 70(2)(a) that the substance *per se* fall within the scope of a claim. The court also noted that claims to a known product produced by a new process or a known product used in a new method of treatment cannot be extended.

The Australian Patent Office has delivered three decisions which further clarify the concept of a "pharmaceutical substance *per se*".

In *Euro-Celtique, SA* [2007] APO 13 (26 March 2007), an extension was sought for a transdermal delivery system comprising a known opioid analgesic. The Delegate held that, unlike a tablet which may consist of a mixture of chemical entities, a transdermal system suggests the presence of a backing layer or patch upon which the mixture of chemical entities is applied. Thus, the phrase "transdermal delivery system" in the context of the patent represented a "separate physical integer unrelated to the mixture of chemical entities". Accordingly, the Delegate concluded that a claim to "a pharmaceutical formulation … in a transdermal delivery system" was not directed to a pharmaceutical substance *per se*. The extension was refused.

In *Sanofi-Aventis* [2007] APO 35 (2 October 2007), the claims were to a bi-phasic tablet, specifically a controlled-release dosage form comprising an immediate release layer and a prolonged release layer. The Delegate was of the view that, in isolation, each layer could be considered a pharmaceutical substance *per se*. The critical question was whether the *combination* of the two layers, which had a defined spatial relationship, met the requirements of the legislation.

The Delegate concluded that a bi-phasic tablet formed by the combination or union of two layers fell within the meaning of the term 'compound' as it appears in the definition of a "pharmaceutical substance" in Schedule 1. Accordingly, the extension of term was granted.

In the recent decision of *N.V. Organon* [2009] APO 8 (28 May 2009), the Delegate considered whether a claim to a vaginal ring adapted for the slow release of a steroidal mixture was directed to a pharmaceutical substance *per se*. The claims defined a thermoplastic polymer core comprising a mixture of a steroidal progestogenic compound and a steroidal estrogenic compound over which a thermoplastic polymer skin was laid.

The Delegate noted that "the thermoplastic materials … have a physical purpose to position, contain and provide for the controlled release of the steroidal components" and that these factors "could well suggest that the thermoplastic materials in the core and skin are more in the nature of separate physical integers." In following the *Sanofi* decision, the Delegate cautioned that the terms "substance" and "compound" should be given broad meanings, and found that the question to be asked is "whether the characteristics of what is being claimed more predominantly lies with it being a substance rather than a substance in combination with a separate integer".

The Delegate concluded that one must look to the "level of integration or interaction" when deciding whether the claim is to a substance, or to a substance in combination with a separate integer. Based on the expert evidence filed by the patentee, it was held that "the steroidal components … are mixed with and necessarily diffuse through the thermoplastic materials in the core and skin regions and as such the product as a whole exhibits a level of integration or interaction between the component parts that … is more characteristic of a pharmaceutical substance in itself rather than a substance combined with another element or thing." Accordingly, the extension of term was granted.

On this basis, it would appear that at least impregnated transdermal patches are now suitable subject matter for an extension. To demonstrate the required level of integration or interaction, it may be necessary to provide expert evidence indicating how any physical integer influences the liberation, absorption and/or distribution of the active ingredients.

Point of Interest: It is therefore essential that at least one claim in the patent to be extended is directed to the active ingredient(s) or a mixture (or compound) containing the active ingredient(s). This is in marked contrast to the situation in Europe, where an SPC may be based on a method of producing the active ingredient(s) or an application of the active ingredient(s). Extensions of term are not available in Australia for patents which are directed solely to methods of treatment or to second medical use ("Swiss type" claims).

This emphasizes the importance of including at least some (perhaps narrow) product claims (and possibly formulation claims) within the specification. Furthermore, in view of the decision in *Sanofi-Aventis*, it seems that combinations of known active ingredients may fall within the meaning of the term "compound", and thereby justify an extension of term in Australia.

Indeed, the availability of extensions of patent term to claims covering such "compounds" of more than one active agent distinguishes Australian practice at least from that of the US (*e.g. Arnold Partnership v. Dudas,* 362 F.3d 1338, 1343 (Fed. Cir. 2004). It is possible to extend the term of a US patent claiming a composition comprising two active ingredients if at least one of the actives has not been previously marketed. In other words, at least one of the claimed active ingredients must be new to the marketplace as a drug product.

Similarly, in Europe an SPC is available for a combination, if at least one of the actives has not previously been the subject of an SPC.

4. Goods Containing or Consisting

To satisfy s 70(3), goods containing or consisting of the pharmaceutical substance must be included on the Register. However, it is not necessary for the particular pharmaceutical substance to be a named active ingredient in the Register.

In *Merck & Co Inc v Arrow Pharmaceuticals Ltd* [2003] FCA 1344, the Federal Court considered whether an impurity present in a registered good was sufficient for the purposes of inclusion on the Register. The Merck patent concerned the compound Lovastatin, which is used for the control of cholesterol. Lovastatin is a pro-drug which, when administered, is metabolised into the beta-hydroxy form, and it is this metabolite which produces the therapeutic effect.

There was no dispute that such a pro-drug fell within the definition of "pharmaceutical substance" in s 70 of the Act. However, due to the existence of a prior patent, the patent for which extension was sought did not claim Lovastatin. The only claims were directed to the beta-hydroxy metabolite.

Mevacor®, a drug manufactured by Merck, is registered on the ARTG and contains Lovastatin as a primary active ingredient. Evidence was presented that each tablet of Mevacor® contained between

0.1% to 0.6% of the beta-hydroxy form. It was argued that as the metabolite was included as an impurity in Mevacor®, then the metabolite was listed on the ARTG.

The court concluded that it was irrelevant whether or not the beta-hydroxy form of Lovastatin itself was included in the ARTG. It was enough that it was contained in a good (Mevacor®) that was included in the ARTG, and it did not matter if it was present only in minute quantities. The court also pointed out that the Act did not stipulate any particular quantity or proportion of the substance in the registered goods.

The approach taken in *Merck* met with approval in the decision of *Alphapharm Pty Ltd v H Lundbeck A/S* [2008] FCA 559, although in this case to the disadvantage of the patentee seeking the patent term extension. The Lundbeck patent concerned the compound escitalopram, which is the (+) enantiomer of the known compound citalopram. Citalopram is a racemate, a chemical consisting of equal amounts of two enantiomers that are mirror images of each other. Lundbeck had obtained an extension of term of the patent, on the basis that the date of first inclusion of (+)-citalopram on the Register was for the drug Lexapro® on 16 September 2003.

The Commissioner became aware that Cipramil®, a drug containing the racemic compound citalopram, had been included on the Register since 9 December 1997. Though the date of Lundbeck's filing of its application for the extension, 22 December 2003, was well within six months of the inclusion of Lexapro® in the ARTG on 16 September 2003, this was well out of time based on the inclusion of Cipramil®. Lundbeck was notified that the Commissioner intended to amend the patent register to reflect the shorter term (in effect, amending the extension of term to zero days). Lundbeck submitted that escitalopram was a different pharmaceutical substance than citalopram and had different properties, and that the date of inclusion of Lexapro® was the appropriate date on which to base the extension.

The Federal Court rejected the argument that the racemate should not be considered to "contain" the (+)-enantiomer in the relevant sense, which Lindgren J described as an "ordinary English word". Accordingly, the request for an extension of term was refused.

In the recent Full Federal Court appeal (*H Lundbeck A/S v Alphapharm Pty Ltd* [2009] FCAFC 70 (11 June 2009)), Bennett J (with whom Middleton J agreed; Emmett J not needing to decide as the patent was found invalid for want of novelty) upheld Justice Lindgren's finding that, for the purposes of s 70(3), citalopram consisted of, or contained, the (+)-enantiomer. Bennett J reserved her decision in respect of whether it was sufficient for the purposes of s 70(3) to have a *de minimis* inclusion of the pharmaceutical substance in the ARTG listing, but noted at [239] that "The level of the inquiry required by s 70(3) does not look to the therapeutic effect of the pharmaceutical substance. Rather, it is a simple comparison of the pharmaceutical substance with the "ingredients" of the goods on the ARTG".

The consequence of these decisions is that where a later product is a particular enantiomer of a previously approved racemic product, an extension of term may not be available.

5. The Australian Register of Therapeutic Goods (ARTG)

According to ss 70(3)(a) of the Act, the pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG). Schedule 1 of the Act defines the Australian Register of Therapeutic Goods as "the register maintained under section 9A of the Therapeutic Goods Act 1989".

Section 9A of the *Therapeutic Goods Act* 1989 (Cth) states:

> *(1) The Secretary is to cause to be maintained a register, to be known as the Australian Register of Therapeutic Goods, for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans.*
> *(2) Subject to subsection (3), the Register is to be kept in such form as the Secretary determines.*
> *(3) The Register is to contain these 3 parts:*
> *(a) a part for goods to be known as registered goods; and*
> *(b) a part for goods to be known as listed goods; and*
> *(c) a part for medical devices included in the Register under Chapter 4.*
> *(4) ……*

It is clear from ss 9A(3) of the *Therapeutic Goods Act* that the ARTG is comprised of three distinct parts which perform different functions but are nevertheless part of the one Register. Notably, the *Patents Act* does not distinguish between the different parts of the Register, as it does not adopt the phrases "registered goods", "listed goods" or "medical devices". Rather, the Act refers to "inclusion" on the Register.

Point of Interest: Once a pharmaceutical substance is included in any part of the ARTG for any reason (including export listing), it is the date of this inclusion which is relevant for determining the period of extension.

6. First Regulatory Approval

In order to qualify for an extension, the period beginning on the date of the patent (usually the filing date) and ending on the first regulatory approval date must be at least five years.

The term "first regulatory approval date" is given by s 70(5) as follows:

> *(a) if no pre-TGA marketing approval was given in relation to the substance—the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain, or consist of, the substance; or*
> *(b) if pre-TGA marketing approval was given in relation to the substance—the date of the first approval.*

The scope of s 70(5) was recently considered by the Full Court in *Pfizer Corp v Commissioner of Patents* [2006] FCAFC 190. Pfizer had obtained an extension of term based on the date that their goods containing the pharmaceutical substance had been registered. The Commissioner had become aware that the goods had previously been included in the Register as listed goods, and

notified Pfizer that she intended to amend the patent register to reflect the shorter term (r 10.7(7)). Pfizer submitted that the date of first inclusion should be restricted solely to the date of marketing approval in Australia.

The court held that the meaning of the expression "first inclusion in" the Therapeutic Register was found to clearly and unambiguously mean "the first time when goods are included in the Therapeutic Register … irrespective of the part of the Therapeutic Register in which they are included". Hence, an export only listing on the ARTG is an inclusion in the ARTG for the purpose of s 70 of the Act. The court noted that this interpretation was consistent with the purpose of the extension provisions because manufacture for export involves commercial exploitation of the patented invention by the patentee.

Point of Interest: First inclusion in the Register means inclusion in any part of the Register. However, the date of inclusion in the Register may not be the earliest relevant date. There could be circumstances under the present regime (such as the provision of experimental drugs during a pandemic) where it is possible for pre-TGA marketing approval to be given prior to inclusion of the goods in the Register, and this may constitute the relevant date from which an extension of term may be calculated.

7. Term of the Extension

The legislation aims to provide an effective patent life of fifteen years from the first regulatory approval date to the expiry date of the extension of term, subject to a maximum twenty-five year patent term. This is similar to the situation in Europe.

According to s 77(1), if the Commissioner grants an extension of term, the term of the extension is equal to the period beginning on the date of the patent and ending on the earliest first regulatory approval date, less five years.

Under s 77(2), the term of the extension is capped at a maximum of five years.

No further extensions beyond the five year term are possible. This is unlike Europe (and the US) which allow for a six month extension of the basic SPC term for paediatric medicines in certain circumstances.

8. Rights of the Patentee

Section 78 of the Act sets out the exclusive rights of the patentee during the term of the extension. The effect of this section is to limit the scope of the patentee's monopoly on the patent so that the exclusive right to exploit the invention is limited to a pharmaceutical substance which has satisfied the extension criteria in s 70(2)(a).

According to s 78(a) of the Act, if the term of a pharmaceutical patent is extended, it is not an infringement during the extended term to exploit the pharmaceutical substance for a purpose other than human therapeutic use.

Furthermore, under s 78(b), it is not an infringement to exploit any form of the invention other than the pharmaceutical substance. This section therefore has the capacity to provide potential competitors with a defence if they proceed to exploit their own version of an active ingredient during the term of the extension.

Point of Interest: Generally, it is accepted that a competitor could, under s 78, manufacture or stockpile the relevant pharmaceutical, as long as it was not "exploited" (*i.e.* sold) for therapeutic use. This is the "springboarding" provision of the extension of term, which is discussed further below. However, and even though the scope of acts that would still constitute infringement during an extended term is clearly of central interest to the patentee, there has yet to be any definitive judicial interpretation of these provisions.

9. Making the Application

According to s 70(1), an application for an extension of term may only be made by the patentee. The application must be made on the approved form (available from the IP Australia website at http://www.ipaustralia.gov.au/resources/forms_patents.shtml), which must identify:

- the patentee;
- their address;
- the patent number; and
- the address for service in Australia.

The form must also indicate that the goods containing, or consisting of, a specified pharmaceutical substance are included in the ARTG and provide the date on which the first regulatory approval was given (r 6.8(2)). The application must also:

- provide an indication of how the pharmaceutical substance registered on the ARTG relates to the disclosure and claims of the patent in question (r 6.8(3));
- state that there are no relevant proceedings in relation to the patent (or alternatively, provide details of the relevant proceedings); and
- identify related patents reliant on the same ARTG registration.

This information should be readily available to the patentee if the related patents are all owned by the same company. However, where the patents are owned by different companies, patentees are not expected to ascertain the intentions of the other companies.

The application must be accompanied by the certificate of registration or other documentation supporting the application (r 6.9(2)). Where there is TGA approval, this would usually entail a copy of the certificate of registration of the relevant goods. There is no requirement for an original certificate of registration to be provided. Also, if the certificate of registration does not contain the name of the active substances, then a print out from the ARTG with this information is required.

In circumstances where a copy of the certificate of registration is not available (for example, where a licensee may have the certificate and refuses to provide it to the patentee, or where the certificate is lost), the patentee will have to explain why the certificate of registration is not available, and provide

sufficient information for the Commissioner to be reasonably satisfied as to the date of first inclusion in the ARTG of goods that contain, or consist of, the substance (r 6.9(3)).

In the very rare circumstance where pre-TGA approval has occurred, the patentee will need to provide a copy of a written statement by the person who gave the approval (usually the Minister, or a Secretary to a Department, who has approved the marketing or importing of the relevant goods) and which shows the date of that approval (r 6.10(2)).

Finally, whether there has been either TGA or pre-TGA approval, the Commissioner also requires evidence that the goods are currently included in the ARTG to meet the requirements of s 70(3)(a). A copy of a current print out from the ARTG is sufficient for these purposes.

10. Time for Applying

A patentee requesting an extension of term must apply before the expiry of the normal twenty year term of the patent but cannot apply before the patent is granted. The primary timing requirements are set out in s 71(2), which specifies that an application for an extension of term must be made within six months after the latest of the following dates:

- the date the patent was granted;
- the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain or consist of any of the pharmaceutical substances referred to in sec 70(3);
- the date of commencement of the extension of term provisions (27 January 1999).

It is important to note that under r 22.11(4), a request for an extension of time under s 223 cannot be made to extend the time for filing an application for an extension of term beyond the twenty year term.

11. The Examination Process

In our experience, extension of term applications are given high priority by the Australian Patent Office, and are normally examined within a few weeks. If the Commissioner identifies any deficiencies, the Commissioner will issue a written notice outlining the deficiencies and provide the patentee with an initial two month period in which to provide further information (r 6.11). This period is extendible, generally up to six months from the initial notice, and there is no limit to the number of responses that the patentee may make.

If the patentee requires any longer than this, they will need to use the provisions of s 223 and show that either there was an error or omission by the person concerned or by his agent or attorney; or that there were circumstances beyond the control of the person concerned.

Where the patentee does not take steps to rectify the deficiencies identified within the time allowed, the Commissioner will initiate action to refuse the application. Where the patentee attempts to rectify the deficiencies, but the Commissioner finds that deficiencies still remain, the Commissioner may

again notify the patentee. Alternatively, the Commissioner may initiate action to refuse the application.

If the Commissioner is satisfied that the requirements of s 70 and s 71 are satisfied, the application for an extension of term will be accepted and advertised for opposition purposes. If there is no opposition or if the opposition is not upheld, the extension of term will be granted and advertised accordingly.

Patentees should ensure that all annuities are timely paid, as the patent must be in force at each stage of processing (unless the patent term has expired).

Point of Interest: During examination of extension of term applications, several of the most common issues that arise include:

- That it is not clear that the registered substance falls within the scope of the claims – often it is not readily apparent that the pharmacokinetic or pharmacodynamic properties which are claimed are exhibited by the registered substance.
- Not providing a copy of the certificate of registration.
- Incorrectly specifying the date of first inclusion on the ARTG – either by mistakenly providing the date of marketing approval rather than an earlier date of export listing, or by providing an inclusion date for a first substance when the patent covers more than one substance and the second substance has an earlier date of inclusion on the ARTG.

By supplying appropriate evidence in the first instance, patentees can maximise their chances of their application being accepted without a notice being issued.

12. Springboarding

"Springboarding" is intended to allow generic products to enter the market immediately upon expiry of a patent. Prior to passage of the *Intellectual Property Laws Amendment Act* 2006 (Cth), springboarding was permitted only in relation to the small number of patents that had been granted an extension of term.

However, in order to comply with the *Australia-United States Free Trade Agreement* (AUSFTA) which came into force on 1 January 2005, Australia was required to widen the springboarding provisions to cover all "pharmaceutical patents", irrespective of whether such patents had been granted, or were even eligible for, an extension of term. This brings Australia into line with the US, Europe and New Zealand.

Section 119A of the Act provides that a "pharmaceutical patent" is not infringed by exploitation of an invention for purposes solely in connection with obtaining inclusion of goods intended for therapeutic use in the ARTG or obtaining a similar foreign regulatory approval. However, where foreign regulatory approval is sought, the pharmaceutical product cannot be exported from Australia for regulatory purposes unless the relevant patent has been granted an extension of term.

The phrase “pharmaceutical patent” is defined in ss 119A(3) to mean a patent that claims a pharmaceutical substance or a method, use or product relating to a pharmaceutical substance. Thus, unlike the previous exemption which was limited to patents that disclosed and claimed a pharmaceutical substance *per se*, the new exemption (other than with respect to the export of goods for the purpose of obtaining regulatory approval overseas) applies to patents claiming a pharmaceutical substance, compounds of substances, metabolites resulting from the enzymatic degradation of the parent drug, medical indications to which the pharmaceutical can be applied and methods of treatment.

Of interest to pharmaceutical originators is that the springboarding exemption does not apply to agricultural and veterinary chemicals, due to the restriction of s 119A to “pharmaceutical patents” for human therapeutic use.

Point of Interest: The springboarding exemption does not extend to activities in relation to medical devices. Nor does it include the export of pharmaceutical products from Australia for the purpose of obtaining regulatory approval overseas except in the extended term of a patent.

13. Data Exclusivity

The data exclusivity regime is set out in section 25A of the *Therapeutic Goods Act* 1989 (“the TGA Act”), which provides that "protected information" about other therapeutic goods may not be used by the Secretary of the Department of Health when evaluating a new therapeutic good for registration.

Under section 25A, "protected information" is referred to as information (not in the public domain) about an active component relating to an application to register therapeutic goods. Section 25A(3) of the TGA Act defines an “active component” as a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

The prohibition lasts five years from the date the therapeutic goods were first registered. However, the prohibition only applies where there are no other therapeutic goods "consisting of or containing" the same active component already on the register.

This was one of the issues considered by Lindgren J in *Alphapharm Pty Ltd v H Lundbeck A/S* [2008] FCA 559. Lundbeck had sought a declaration that the information it had provided to the Secretary of the Department of Health in respect of its application for registration of Lexapro® was "protected information". Lundbeck had also sought an injunction prohibiting the Secretary from using the information or permitting it to be used when evaluating any application by a person other than Lundbeck for the registration of therapeutic goods pursuant to section 25(1) of the TGA Act.

On the basis that Cipramil® contained escitalopram as an active component, the court refused to provide Lundbeck with the declaration and injunction. In Lindgren J's view, s 25A(3) clearly contemplated that therapeutic goods may contain more than one active component. Consequently, data exclusivity applied only for five years from the date that Cipramil®, rather than Lexapro®, was included in the ARTG. This meant that the five year protection for the data submitted to the TGA had expired.

The court also indicated that once Lundbeck had sought declaratory and injunctive relief, it would bear the onus of identifying information that fell within the definition of "protected information". Furthermore, any injunctive relief to be granted in aid of s 25A would have to be subject to a condition that once the information to which the relief referred subsequently became available to the public, it would then cease to fall within the scope of the injunction.

14. Generic medicines

As a result of the *Australia-United States Free Trade Agreement* (AUSFTA), Australia was required to provide measures in its marketing approval process to prevent a person from entering the market with a generic version of a patented medicine before a patent covering that product had expired.

To implement this requirement, the *Therapeutic Goods Act* 1989 was amended to require that an applicant seeking to include therapeutic goods in the ARTG must provide a certificate under s 26B to the TGA. The TGA must receive the s 26B certificate from the applicant prior to listing the therapeutic good on the ARTG.

According to s 26B(1), the certificate must state that, either:

- the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

- the applicant intends to market a generic version of a patented product before the patent expires, because they believe the patent is invalid, and they have notified the patent owner of their application to include the therapeutic good in the ARTG.

A person is guilty of an offence if the person gives the TGA a certificate that is false or misleading (s 26B(2)).

According to s 26B(1A), only those applications that have relied (in whole or part) on evidence or information that another person submitted to the Secretary to establish the safety or efficacy of other therapeutic goods that have already been listed or registered are required to provide a certification. In all other cases, all that is required is a notification to the Secretary that the provisions of s 26B(1) do not apply to the application to register or list the medicine on the ARTG.

Amendments were also made to the *Therapeutic Goods Act* 1989 which impose penalties and damages on pharmaceutical patent owners if they take unreasonable legal action against generic manufacturers. According to s 26C(2), a patent owner must also notify the Attorney-General of the Commonwealth, State or Territory before it can apply for an interlocutory injunction against a generic manufacturer who has notified the patent owner of its intention to enter the market before the end of the patent.

15. Summary

The extension of term provisions are designed to compensate pharmaceutical companies who have been unable to take full advantage of the twenty year patent term due to delays in obtaining regulatory approval.

Like any legislation, however, its ultimate operation and scope is open to interpretation and regulation. Indeed, it is apparent that, at least with respect to the availability of extensions of term for claims to combination formulations as compounds *per se*, Australian practice may substantially diverge from that of other important jurisdictions.

Patent holders will be well advised to carefully consider the details of the law and process of obtaining patent term extension in Australia so they can maximize their return on investment in research and patent protection. Early attention to some of the more common issues encountered in the patent term extension process can put the patentee in a better position for efficient exploitation of their patent position, generating greater resources for finding and bringing to market important medicines.

To maximize the possibility of an extension of term being granted, we suggest that applicants:

- At filing, or soon thereafter, ensure that at least one claim in the patent to be extended is directed to the active ingredient(s) or a mixture (or compound) containing the active ingredient(s). In circumstances where it is not possible to define the product by reference to its structural or chemical features, a “product by process” claim should be included.

- Monitor (i) the date that the patent is granted and (ii) the date on which the pharmaceutical is included on the ARTG, as the extension of term application must be made within 6 months of the latest of these two dates;

- Apply for an extension of term by using the approved form available from the IP Australia website at http://www.ipaustralia.gov.au/resources/forms_patents.shtml;

- Ensure that all annuities are timely paid, as the patent must be in force at each stage of processing;

- Provide a copy of the certificate of registration and a copy of a printout from the ARTG indicating that the pharmaceutical is registered with the application for an extension of term;

- If the patent claim specifies certain pharmacokinetic or pharmacodynamic properties, ensure that evidence is available to confirm that the pharmaceutical included on the ARTG exhibits these properties;

- For a patent claim where it may be argued that a physical integer is present, consider providing expert evidence indicating how the physical integer influences the liberation, absorption and/or distribution of the active ingredients.

About the Authors

Robert Finzi was a Deputy Commissioner of Patents and Assistant General Manager of the Patents and Plant Breeder's Rights Group at IP Australia. For various periods throughout 2004-2007, he was head of the Pharmaceutical Section responsible for processing extension of term applications. His extensive experience in examining these applications provides Pizzeys with valuable insight and experience in the operation of Section 70.

As a hearing officer in the Patents Group, Robert helped to develop and articulate IP Australia's position on pharmaceutical extensions of term. He has also briefed Counsel in several Federal Court matters, including *Pfizer Corp v Commissioner of Patents* (No 2) [2006] FCA 1176 (11 September 2006) and *Pfizer Corp v Commissioner of Patents* [2006] FCAFC 190 (20 December 2006).

Thomas Boyce is a partner in Pizzeys. He is registered to practice in Australia, New Zealand, and the US and has practiced patent law in these jurisdictions. He drafts, prosecutes, and advises clients in relation to pharmaceutical and biotechnology related inventions.

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