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What Patents Qualify for an Extension of Term

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The following criteria are essential in order for a patent to qualify for an extension of term in Australia.

- The patent must contain at least one claim covering a pharmaceutical substance *per sé*
- That pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG)
- The first regulatory approval date for that pharmaceutical substance must have occurred more than five years after the date of filing the patent

What is a pharmaceutical substance *per sé*

- Case Law has made it quite clear that a pharmaceutical substance *per sé* is restricted to a pharmaceutical substance “*by itself*”
- This includes claims such as:
 - a) Substance X mixed with substance Y (so long as the product on the ARTG is within the scope of this claim.
 - b) A substance of formula X;
- Claims that would not be eligible include:
 - a) Substance X when used ...;
 - b) Substance X for use ...;
 - c) Substance X when produced by method Y;
 - d) A method for preparing substance X;
 - e) [a specified quantum] of substance X;
 - f) “Swiss style” claims referring to substance X;
 - g) Use of substance X in the treatment of Y.
- An exclusion to this is when the pharmaceutical substance is produced by a process that involves the use of recombinant DNA technology. That is when the substance can only be defined by the process steps that involve the use of recombinant DNA technology.

More than one patent can be extended based on the same ARTG registration

- This most commonly occurs when:
 - i) The earlier patent generically defines the substance, while the latter patent is more specific, i.e. a “selection” patent.
 - ii) The two patents claim slightly different formulations, although the substance defined on the ARTG must fall within the scope of the claims for each patent.

- Each patent must claim the pharmaceutical substance *per sé*. You must state that the ARTG registration is to be used to extend more than one patent and the Patent Office reserves the right to review the patents for novelty purposes.

Brief History of Extension of Term Provisions

- Under the 1952 Patents Act, it was necessary to petition a Court to seek an extension. Extensions were based on inadequate remuneration, and it was necessary to show significant merit. There was a 16 year patent term, but 10 year extensions were possible.
- In 1989 it was possible to extend pharmaceutical patents from 16 years to 20 years. It was necessary to amend your patent such that it was limited to the pharmaceutical.
- In 1994, to comply with TRIPS, all Australian patents were given 20 year terms.
- In 1998, the current legislation was introduced.
- There were a number of decisions made under the 1989 legislation that may remain relevant to consideration under the current (1998) legislation notably:
 - That the term of a patent could be extended if the product relates to both veterinary and human use (*Merck GmbH v Virbac*)
 - That a patent extended under the 1989 legislation (for 4 years from 16 to 20 years) could not receive a subsequent extension under the 1998 legislation (*Hasle AB*).

Case Law in Australia is slowly developing to assist in defining the criteria necessary for applying for an extension of term.

- In particular, Case Law under the current legislation has looked closely at:
 - i) what is a “*pharmaceutical substance per sé*”. Generally, a fairly strict approach has been taken to this, and claims that include process steps, spacial arrangements or devices have been denied extension.

Cases that have been accepted include solutions that are defined as having “*not been reconstituted from a lyophilizate*”, a bi-layered tablet, and a transdermal delivery system where the pharmaceutical is integral with the patch components. Such decisions may represent a softening of the approach taken in that the claims may include features that are not part of the pharmaceutical *per sé* “by itself” and still be considered to be a claim to the pharmaceutical *per sé* for the purposes of S70 of the Patents Act.

- ii) what is meant by “*the substance must be included in the Australian Register of Therapeutic Goods*”. It has been sufficient to establish that the registration need only “*contain*” the pharmaceutical without being the key active ingredient in the registration.
- iii) what is meant by the FIRST regulatory approval date. Export registration or registration of a non-commercial pharmaceutical will still be considered the first registration.

Boehringer Ingelheim v Commissioner of Patents *[2001] FCA 647* Extension denied

- The Full Federal Court upheld the decision that a claim of patent 530174 directed to: (paraphrased)
“A container containing a spray composition for nasal administration of composition X, the container provided with a nozzle”
is not entitled to an extension of term because other components are essential to the claim. That is, a container and a nozzle is required or the claim is not infringed
- Given that composition X *“by itself”* would not infringe the claim, the claim was not considered to be directed to a pharmaceutical substance *per sé*.

Zentaris Application

[2002] APO 41

Extension granted

- Patent Office decision.
- Patent 671881 related to a lyophilisate of a polypeptide characterised by the method of making the lyophilisate.
- A critical process step was to dissolve the polypeptide in 30% acetic acid. The morphologically different polypeptide was defined by the method of production. Claims 1 to 4 did not refer to the steps of dissolving the polypeptide in 30% acetic acid.
- The Patent Office allowed an extension based on omnibus claim 5 that read:
“A lyophilisate of a peptide with 3-15 amino acids and optionally one or several bulking agents, substantially as hereinbefore described with reference to the example.”
- All other claims were for a product produced in a particular way, but the omnibus claim was directed to the compound that included the critical process step.
- This was sufficient to support an extension of the patent as a whole, which includes extending the term for any pharmaceutical claimed in the patent.

LTS Lohmann Therapeutics

[2002] APO 12

Extension denied

- Patent Office decision
- Australian Patent 678408 related to a transdermal therapeutic system and this decision looked at what is a mixture of compound of substances
- The claim read: (paraphrased)
“Transdermal therapeutic system containing the active substance [X (known)] with a laminated structure comprising a backing layer one or more matrix layers, and where non-adhesive matrix layers are present, an adhesive layer, characterised in that the concentration of X in all matrix layers lies between its saturation concentration in dry and moist conditions”
- It was found that the case that the transdermal patch which includes a known compound is not a pharmaceutical substance *per sé* as a transdermal patch implies a set spatial configuration
- Therefore, the claim relied upon some other factor, *i.e.* the arrangement of the compound, and therefore was not directed to the pharmaceutical substance *per sé*

Merck & Co v Arrow Pharmaceuticals

59 IPR 226 [2003]

Extension granted

- Federal Court decision
- *Lovastatin* is registered in the ARTG
- It is a prodrug which converts to the beta-hydroxy form in the body
- There was an earlier patent in the name of Sankyo filed 19 February 1980 for *Lovastatin per sé* which expired in 2000
- The Merck patent 535944, filed 3 June 1980 claimed the beta-hydroxy metabolite (the Merck claim to the compound covering *Lovastatin* was deleted during prosecution)
- The Merck listing on the ARTG indicated one active – *Lovastatin*, and not the beta-hydroxy metabolite
- Merck relied upon their ARTG registration for *Lovastatin* and claimed that the “Certificate of Analysis” from the ARTG indicated the beta-hydroxy metabolite was present in the amount of 0.2%. Merck asserted the Certificate was part of the ARTG on the ARTG registration as it was listed as an impurity. The Patent Office did not agree
- On appeal, the Federal Court overturned the decision of the Patent Office and held that the beta-hydroxy form, although listed as an impurity was on the ARTG
- The Court also found that although the use of *Lovastatin* may infringe a claim to the metabolite, it was not within the scope of the claim so that argument was rejected
- This decision gave a broad construction of what it means for goods to “contain” a substance (which was also applied in *Lundbeck v Alphapharm*)

Prejay Holdings v Commissioner of Patents

[2003] FCAFC 77

Extension denied

- Full Federal Court decision
The claim for patent 582540 read: (paraphrased)
“A method of hormonally treating menopausal ... disorders comprising administering continuously and uninterruptedly both progesterone and estrogen in daily doses [quantum amount]”.
- Again, the Full Federal Court found that this claim did not include a pharmaceutical substance *per sé*, as it relied on other features, that is the method to define the claim. The compounds by themselves would not infringe the claim.
- The fact that supply of the product would lead to contributory infringement was argued, but unsuccessfully, as the scope of the claim could not be extended to include the pharmaceutical product *per sé*.

Pfizer v Commissioner of Patents

[2006] FCAFC 190

Extension denied

- Full Federal Court decision
- Pfizer had applied for an extension of term on four patents relating to two different pharmaceuticals.
- They applied on the basis of the date that the pharmaceutical was first included on the ARTG as registered goods in Australia.
- The Patent Office became aware of prior approval of the pharmaceuticals for export purposes only.
- The Full Bench upheld the decision that the FIRST regulatory approval date in Australia was the date of the export listing.
- As a result, the length of the extension was shortened as there was less time between the filing date of the patent and the date of export approval.

Pharmacia Italia S.p.A. v Mayne Pharma Pty Ltd [2006] FCA 305

Extension granted (but denied in subsequent related decision)

- Federal Court hearing
- Federal Court had previously held that a claim to Pharmacia patent 598197 relating to the pharmaceutical Zavedos had been infringed by Mayne
- 20 year term of patent expired on 19 June 2006, and Mayne were restricted from exploiting claims until 19 June 2006 “*or such later date as the Court may hereafter order.*”
- Pharmacia applied to the Court for a further 5 years injunction as they had previously been granted a 5 year extension of term
- The claim read: (paraphrased)
“A sterile, pyrogan-free, anthracycline glycoside solution which comprises ... a salt of ... glycoside dissolved in a ... solvent ... at a concentration ... of from 0.1 to 50 mg/ml, which has not been reconstituted from a lyophilizate and the pH ... adjusted ... from 2.5 to 5.0 solely ... with an acid.”
- Held to be a claim to a pharmaceutical substance *per sé*
- References to various processes in the claim were “*merely referring incidentally to some element of the process, that are not themselves novel, in order to better describe the new and inventive substance*”
- An application for a review of the grant of the extension was dismissed, and the 5 year extension remained in place
- Subsequent decision (Pfizer Italia) found that the patent related to several pharmaceuticals having an earlier ARTG registration date, and ultimately no extension was granted

Pfizer Italia S.r.l.

[2007] APO 2

Extension denied

- Patent Office decision. This decision was subsequent to the Pharmacia Italia decision, but also related to patent 598197
- Extension had previously been granted based on the ARTG inclusion of *Zavedos*
- Pfizer advised Patent Office of a number of other pharmaceuticals that fell within the scope of the claims that had earlier ARTG registration dates than *Zavedos*
- The Patent Office went to amend the register to include the earlier dates, thus denying Pfizer an extension, but Pfizer appealed
- Held that the Commissioner does have the power to correct the register if she subsequently becomes aware of an earlier registration, so the extension was ultimately denied
- See also Pharmacia Italia decision

Euro-Celtique S.A.

[2007] APO 13

Extension denied

- Claims directed to a pharmaceutical formulation comprising an active ingredient in a transdermal delivery system.
- The claim read (paraphrased):
“A pharmaceutical formulation for treating pain comprising [active X] in a transdermal delivery system on to the skin containing X as the active ingredient together with instructions for applying said transdermal delivery system on to the skin of a human patient to provide a first order plasma level increase of X over (a designated dose regime for maintaining plasma concentration)
- The transdermal delivery system included “*instructions for applying*” and as such cannot be directed to a pharmaceutical substance per sé
- Lohmann was considered (which included a similar patch although it was noted that this did not involve a spacial arrangement), and the extension was denied.

Sanofi-Aventis

[2007] APO 35

Extension granted

- Patent Office decision
- Claims of Sanofi-Aventis patent 771902 related to a pharmaceutical composition (*zolpidem*) in a controlled release dosage form, where the first phase is an immediate release, and the second phase is a prolonged release.
- The claim read: (paraphrased)
“A pharmaceutical composition comprising zolpidem said composition consists of a controlled release dosage form adapted to release zolpidem over a predetermined time period where the first phase is an immediate release phase having a maximum duration of 30 minutes and the second phase is a prolonged release phase”
- Held that a bi-layered tablet is a “*compound*”.
- Looked at various definitions of what is a compound, and the formation of a tablet was considered to be a compound

G.D. Searle LLC

[2008] APO 31

Extension denied

- Patent Office decision
- An extension of term for patent 680635 was granted based on product *darunavir*
- During examination, the Examiner located an earlier registration for *amprenavir*
- As a consequence, application for an extension was not made within 6 months of first ARTG approval
- The earlier pharmaceutical was sponsored by GlaxoSmithKline
- Hearing concerned “*intention*” of legislation, as G.D. Searle did not receive full benefit of extension for the product *darunavir*
- Found that extension must still be based on FIRST inclusion, so the extension was based on the registration of *amprenavir*
- Similar decision to Pfizer Italia decision
- Could be overcome (possibly) by filing one or more divisionals prior to grant so that the extension of term may be sought in respect of each first inclusion of a pharmaceutical substance, but this was not done in this case

Lohmann Therapie-System AG and Schwarz Pharma

[2009] APO 16

Extension denied (but on appeal)

- Patent Office decision
- Claim 1 of patent 746856 read as follows: (paraphrased)
“A pharmaceutical compound for the treatment of [X] comprising an effective amount of a free baseand an acrylate or silicone based non-aqueous polymer adhesive compound, wherein the solubility of the base is greater than or equal to 5% (per weight), and a backing layer which is inert to the base and the adhesive compound, having a protective layer, which is to be removed prior to administration of the pharmaceutical compound.... .to the patient”
- Held not directed to a compound *per sé* because of the inclusion of the backing layer and protective layer in the claim
- They had difficulty amending claims post-acceptance to remove reference to the backing layer and the protective layer, because they couldn't broaden the claims. Therefore, care should be taken to draft claims to product *per sé* BEFORE acceptance.
- This matter has been appealed to the Federal Court

N.V. Organon

[2009] APO 8

Extension granted

- Patent Office decision
- A drug delivery system which is a mixture of two active ingredients dissolved in a thermoplastic core material over which is laid a permeable thermoplastic skin. This is the product *NuvaRing*
- Claim 1 of patent 726934 read as follows: (paraphrased)
“A drug delivery system comprising a therapeutic polymer core and a thermoplastic polymer skin covering the core, said core comprising a mixture of [two known pharmaceutical compounds] in a ratio by weight that allows a direct release from the polymer of [both pharmaceuticals, the pharmaceuticals being dissolved in the polymer core in varying dosages] said thermoplastic polymer skin being permeable for the [pharmaceuticals].
- This extension was allowed because *“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”*
- In this decision the Delegate observed that where it is difficult to determine whether a particular feature of a product can correctly be considered part of a *“substance”* rather than a separate physical integer, it is convenient to consider whether the characteristic of what is claimed more predominantly lies with its being a substance, rather than a substance in combination with a separate integer
- This is a more generous decision on what may be considered to be a *“pharmaceutical substance”*.

H. Lundbeck A/S v Alphapharm/Arrow [2009] FCAFC 70

Extension denied (still to be appealed) – went other way in Europe

- Full Federal Court decision
- *Cipramil (Citalopram)*, is a racemic mixture and was included on the ARTG on 29 December 1997. It is the subject of Australian patent 509445.
- *Lexapro (Escitalopram)* is the (+) enantiomer of *citalopram* and was included on the ARTG on 16 September 2003. It is the subject of Australian patent 623144
- Lundbeck argued that the racemate and the (+) enantiomer are different pharmaceuticals *per sé*
- The Federal Court held that the racemate “*contained*” the (+) enantiomer together with the (-) enantiomer) and therefore the extension should be based on the first inclusion in the ARTG namely December 1997
- Earlier decision held that the Commissioner was entitled to amend the term of the extension in accordance with reg. 10.7(1), despite having already granted the extension, once the Commissioner is notified of an earlier ARTG registration
- This decision confirms the Federal Court’s view that it will apply a “*broad*” interpretation as to what is on the ARTG Register
- Lundbeck have sought leave to appeal to the High Court (still to be heard)

Other matters

- It is no longer an infringement of any claim during the 20 year term of a patent for third parties to seek regulatory approval either in Australia or overseas of a pharmaceutical substance *per sé* that is claimed
- Australia provides a five year data exclusivity period (from the date of product registration)

New Zealand

- New Zealand does not have any extension of term provisions, and it is not proposed to include such a provision in the revision of the Patents Act
- There is a Bolar-type exemption to allow a third party to exploit the invention solely for uses reasonably related to obtaining regulatory approval of pharmaceutical substance in New Zealand or overseas
- There is a five year data exclusivity from the date of product registration in New Zealand

Research Exemption

- Neither Australia nor New Zealand currently allows for a research exemption to infringement, although this is currently being reviewed in both Australia and New Zealand