

# PATENT TERM EXTENSIONS IN AUSTRALIA

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- Patent Term Extensions
  - The legislation
  - Issues of interpretation
  - Case law
  - Products produced by rDNA technology

- Eligibility for Patent Term Extension
  - Patent must “in substance disclose” and claim (a) “a pharmaceutical substance *per se*” OR (b) “a pharmaceutical substance when produced by a process which involves the use of recombinant DNA technology”
    - Pharmaceutical substance means “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 infection agent, or on a toxin or other poison, in a human body...”
  - A product “containing or consisting of” such pharmaceutical substance must be included in Australian Register of Therapeutic Goods (ARTG)
  - There must be more than five years delay between patent filing date and earliest ARTG date

# PHARMACEUTICAL PATENT TERM EXTENSION PROVISIONS

- Timing of Application
  - Within 6 months of earliest ARTG date or patent grant date, whichever is later
  - Must be filed during normal 20 year term of patent
- Term of Extension
  - Difference between earliest ARTG date and filing date minus 5 years, subject to 5 year maximum EQUIVALENT TO
  - An expiry date 15 years from earliest ARTG date subject to 25 year maximum term
- Effect of Extension
  - Whole patent extended
  - During extended term patent only enforceable in relation to unauthorised exploitation of pharmaceutical substances *per se* (or as produced by rDNA) which are claimed and in substance disclosed **for human therapeutic use.**

- Spring-boarding/Bolar provisions

From 28 July 1999 – 24 October 2006

- For extended patents it is not an infringement to exploit any pharmaceutical substance *per se* (or as produced by rDNA technology) in substance disclosed and claimed in the patent solely for purposes of supporting ARTG registration or obtaining similar regulatory approval overseas [from date of grant of extension]

From 25 October 2006

- General infringement exemption now applies to all pharmaceutical patents regardless of existence of patent term extension [only exception is when patent is extended and the pharmaceutical substance is exported for purposes associated with gaining regulatory approval]

- Issues of Interpretation/Operation
  - Can applications be filed late?
  - What is meant by “pharmaceutical substance *per se*”?
  - What is meant by “included in the ARTG”?
  - What is meant by “in substance disclosed”?
  - How much of the substance needs to be in the registered good?

- Boehringer Ingelheim International cases
  - Case #1 Application filed within six months of start date, but after expiry of patent (Ipratropium bromide)
    - Attorney failed to note application was divisional, dating from parent
    - Normal term expired two weeks prior to filing date of extension application
    - Extension of time refused due to exclusion in regulations
  - Case#2 Application filed on patent claiming a container containing an aerosol or spray composition in form suitable for nasal administration (Atrovent nasal-Ipratropium bromide)
    - Container and contents not “pharmaceutical substance *per se*”
    - Decision upheld by Federal Court and Full Federal Court
    - Leave to appeal to High Court was not granted

- LTS Lohman Therapie-Systeme GmbH
  - Patent claimed a transdermal patch having features allowing controlled release of 17[Beta] Estradiol for HRT
  - Examiner refused extension and hearing requested
  - Extension refused
  - Not a “mixture” of substances, due to controlled spatial arrangement of components
  - Not a “compound” of substances, because no chemical bond between the components, ie compound means chemical compound
  - Caused difficulty with patents relating to capsules or tablets having controlled spatial arrangement of components

- Prejay Holdings Ltd v Commissioner of Patents
  - Patent related to method of hormonally treating menopausal or post-menopausal disorders by continuously administering a combination of progestogen and estrogen
  - Prejay argued that patent claimed pharmaceutical substance per se since only reasonable use of combination would infringe due to contributory infringement provisions
  - Extension refused by Patent Office
  - Patentee appealed to Federal Court
  - Extension refused

- Zentaris Aktiengesellschaft
  - Claims directed to lyophilisate of polypeptide, Cetrorelix, characterised by general process steps, including dissolving in acetic acid and lyophilising
  - Specification described a particular morphological form of the peptide that could not be reasonably described with reference to structural characteristics, eg folding etc
  - According to information submitted in connection with extension, a particular concentration of acetic acid was required to get morphological form of registered product
  - Extension allowed on basis of omnibus claim (directed to examples) since example described the particular concentration of acetic acid

- Pfizer Inc v Commissioner of Patents
  - Pfizer had previously extended a selection patent relating to the oral or intravenous antifungal agent VFEND (voriconazole)
  - Pfizer then sought to extend an earlier generic patent which encompassed voriconazole, but which did not specifically describe the compound.
  - Pfizer argued that voriconazole was in substance disclosed in earlier generic patent, and that the existence of the selection patent was irrelevant to that determination
  - Hearing officer equated “in substance disclosed” test with “fair basis” test
  - Extension refused and appeal to Federal Court
  - Extension allowed by Federal Court on basis that “in substance disclosed” test is “a lesser requirement” than fair basis test

- Merck & Co, Inc v Arrow Pharmaceuticals
  - Patent claimed metabolite of Lovastatin (originally claimed lovastatin but limited to metabolite due to prior claim by Sankyo)
  - Extension based on export listing for Mevacor (Lovastatin, but analysis showing presence of 0.2% metabolite)
  - Patent Office refused extension after opposition by Arrow, so Merck appealed to Federal Court
  - Merck argued that (i) Lovastatin fell within the scope of the claims since only reasonable use of Lovastatin produced metabolite, therefore contributory infringement and (ii) Listed product contained metabolite
  - Second argument was accepted by Federal Court and the extension allowed

- Pfizer Corp v Commissioner of Patents
  - Case concerned 4 patents relating to amlodipine (NORVASC) and eletriptan hydrobromide (REPLAX)
  - Patents were extended on basis of first registrations in ARTG
  - Commissioner became aware of earlier “Export Only” listings in ARTG and amended regulations to provide power to amend term of extension on the patent register
  - The Commissioner issued a notice setting out intention to reduce the terms of the patents by between 10 and 13 months, and in the case of one patent, to an extension of “zero”
  - After unsuccessful hearing, and unsuccessful appeal to the Federal Court, Pfizer appealed to Full Federal Court
  - Appeal dismissed on basis that export listing is relevant ARTG inclusion for calculating term of extension

- Pharmacia Italia S.p.A. v Mayne Pharma P/L and others
  - Claim 1 related to sterile, pyrogen-free anthracycline glycoside solution comprising **dissolved** glycoside which **had not been reconstituted** from a lyophilisate, and the pH of the solution **has been adjusted** [to] from 2.5 to 5 solely with a physiologically acceptable acid
  - Extension was based on ARTG registration for daunorubicin solution
  - Mayne (and Interpharma) objected to the extension on the basis that claim did not relate to pharmaceutical substance per se and that extension should not have been granted (this followed earlier proceedings which found infringement by Mayne and issued injunction against Interpharma)
  - Court found claim did relate to pharmaceutical substance per se and that extension was validly granted
  - In subsequent proceedings initiated by the patent office the extension was reduced to zero due to an earlier registration of adriamycin solution

- Euro-Celtique, SA
  - Patent claimed a formulation containing buprenorphine in a transdermal delivery system with instructions for application
  - Extension requested based on registration of NORSPAN transdermal patch
  - Examiner refused extension and hearing requested
  - Hearing was unsuccessful and the extension refused
  - Claims not directed to pharmaceutical substance *per se* because:
    - claims require presence of instructions
    - claims require a “transdermal delivery system”, suggesting presence of backing layer or patch

- Sanofi-Aventis
  - Patent claimed a pharmaceutical formulation comprising zolpidem in a controlled release dosage form adapted to release active according to biphasic *in vitro* dissolution profile
  - Extension requested based on STILNOX CR bi-layered tablet having intermediate release layer and prolonged release layer
  - Patent Office refused extension and hearing requested (with hearing officer with pharmaceutical background)
  - Extension allowed
  - Claims are directed to pharmaceutical substance *per se* because, although formulation not a mixture of substances, the formulation does represent a “compound” of substances, as that term is used in the pharmaceutical arts

- Alphapharm P/L v H Lundbeck (24 April 2008)
  - Patent claims (+)-citalopram (escitalopram) and method for preparation
  - Extension of term requested and granted (5 years) on basis of ARTG registration of LEXAPRO (containing escitalopram)
  - Alphapharm (and Arrow) argued that earlier registration of CIPRAMIL (containing racemate) was earliest in respect of product containing escitalopram. [In an earlier proceeding before patent office the Delegate of the Commissioner determined that the relevant product was CIPRAMIL and this proceeding in part was appeal from that decision]
  - Federal Court held that CIPRAMIL contains (+)-citalopram and that all reference to extension of term should be removed from register
  - No opportunity to recalculate extension based on CIPRAMIL registration, but reasons for this not provided
  - Decision also looked at validity, infringement, spring-boarding provisions and data protection
  - Appeal to Full Federal Court unsuccessful, and leave to appeal to High Court refused

- Alphapharm P/L v H Lundbeck
  - Extension of time of more than 10 years granted by IP Australia to file new application based on CIPRAMIL [A product the patent doesn't cover!]
  - Alphapharm P/L unsuccessfully appealed to AAT and Full Federal Court
  - Alphapharm P/L obtained leave to appeal to High Court on question of whether Regulations allow extensions of time for filing PTEs
  - According to Patent Act 1990 extensions of time are not available for “prescribed” acts
  - According to Regulation 22.11(4)(b) the following is a prescribed act:  
*“filing, during the term of a standard patent under subsection 7(2) of the Act, an application under subsection 70(1) of the Act for an extension of term of the patent”*
  - The extension of time was granted by High Court and Lundbeck obtained extension of term based on CIPRAMIL.

- G.D Searle (5 December 2008)
  - Claims of patent (filed 24 August 1993) encompassed two products which were the subject of ARTG registrations:
    - amprenavir 5 June 2001 (AGENERASE – GSKA)
    - darunavir 15 March 2007 (PREVISTA – Janssen-Cilag)
  - Extension application filed by G. D. Searle on 29 August 2007 based on darunavir was rejected by Examiner due to earlier registration of amprenavir
  - Patentee argued unsuccessfully that any ARTG inclusion which is the “first” for a particular good can be used for extension application
  - Patentee requested hearing but was unsuccessful and application rejected
  - Patentee was invited to (and did!) make new application based on amprenavir, by requesting an extension of time under s223 for more than 7 years
  - Extension must be based on earliest inclusion of any product satisfying requirements, otherwise incorrect information will be recorded in patent register. Therefore consider divisionals where there are multiple products.

- N.V. Organon (29 May 2009)
  - Claims of patent (related to a drug delivery system in ring shaped form for vaginal administration comprising thermoplastic polymer components in which a mixture of steroidal compounds is dissolved)
  - Extension application filed by Organon on basis of ARTG registration of NUVARING
  - Examiner rejected application on basis that the delivery system was not a pharmaceutical substance
  - Patentee requested a hearing and was extension allowed since the delivery device was a “compound of substances”, as per Sanofi decision

# PRODUCTS PRODUCED BY rDNA TECHNOLOGY

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- No “per se” limitation: method and use claims may be extendible
- Heery J in Boehringer: *“The 1990 Act in its present form manifests a policy which draws a distinction between, on the one hand, a pharmaceutical substance that is the subject of a patent claim and, on the other hand, a pharmaceutical substance that forms part of a method or process claim. The specific exception to the latter (an exception which proves the rule) is the provision for recombinant DNA technology in s 70(.2)(b).”*
- Consider Swiss claims:
  - Use of known biologic in the manufacture of a medicament for the treatment of new condition, wherein biologic is produced by a process involving rDNA technology
  - Full Federal Court has confirmed extensions of term not available for such claims, however question has not yet been considered by High Court

- Extensions may be available for claim to process for making pharmaceutical substances:

- If rDNA involved in the process
- Or, if process only way to describe conjugate
- AU Patent 678613

Claim 1: In a method for preparing a vaccine comprising an immunogenic construct and a pharmaceutically acceptable carrier, the improvement comprising producing the immunogenic construct by a process comprising

- a) activating at least one first carbohydrate-containing moiety with an organic cyanating reagent; and
  - b) covalently joining said activated carbohydrate-containing moiety to a second moiety.
- Extension allowed in this case, as well as for method of making vaccine comprising combining a protein antigen with an adjuvant

# THANK YOU

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