The Guide to Life Sciences: Key issues for senior life sciences executives

2024

Australia: a toolkit for prosecution and enforcement amid patentability barriers

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The fourth edition of the Guide to Life Sciences delivers key analysis designed to help senior life sciences executives better understand the strategic and legal IP challenges that they face around the world. This specialist intelligence will help them to protect, enforce and monetise the IP rights that are so crucial to businesses in the space.

Generated: June 26, 2024

Australia: a toolkit for prosecution and enforcement amid patentability barriers

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Summary

LEGAL FRAMEWORK

Australia remains an in-demand jurisdiction for patent protection in the life sciences, with strong growth and opportunities in areas including pharmaceuticals, RNA therapeutics, gene editing, immune- and cell-based therapies and vaccines. The Australian patent system supports applicants and patentees with a legal framework closely harmonised with major jurisdictions, as standards for novelty, inventive step, support and enablement, for example, have increasingly tended to follow a European or UK law approach.

Support and enablement must be across the full breadth of the claims, with examiners and the courts closely scrutinising examples in the specification and considering the actual contribution to the art. One interesting consequence of this, which distinguishes Australian practice from other jurisdictions, is that claims to any medical uses of novel therapeutics are not automatically allowable. Medical use claims – even of novel therapeutics – are assessed against the standard one might expect for a second medical use claim, with evidence of target or pathway or in vitro or in vivo data for a disease or disease group typically required.

In another interesting departure from Europe, Australia's version of the 'added subject matter' rule states that amendments are not allowable if they would claim or disclose matter that extends beyond the specification as filed. That amendments made during prosecution were not allowable, however, is not a ground for revocation in Australia. Any validity attack on this ground needs to be launched during prosecution of the application, such as through ex parte third-party observations before acceptance or by launching an inter partes procedural (amendment) opposition prior to grant. Parties therefore need to maintain a close watch over applications of interest as they are amended during examination and be prepared to take early action if needed.

Additionally, unlike Europe, where an invention must be 'directly and unambiguously derivable' from a priority document and therefore a valid priority claim requires the same level of disclosure as an allowable amendment, a priority document need only provide an enabling disclosure of the invention, which is a different and arguably lower threshold to meet than that of allowability of amendments.

PATENTABLE SUBJECT MATTER AND PATENTABILITY ISSUES

There are a few express exclusions from patenting. The most significant is for human beings and the biological processes for their generation.

To be patentable, the claimed invention must be a 'manner of manufacture' – it must result in an artificially created state of affairs and the invention claimed must have economic utility. Judicial interpretation has recognised several categories of subject matter that fail to satisfy this test, including mere discoveries, ideas, scientific theories and laws of nature.

Subject Matter	Patentability
Naturally occurring	Isolated polypeptides (eg, antibodies, hormones), cells including stem cells, bacteria, fungi, viruses and chemical molecules, are patent eligible.
Nucleic acids	Isolated naturally occurring nucleic acid sequences, particularly DNA, RNA and cDNA are generally not patent

	eligible. However, codon - optimised genes, interfering RNA (RNAi), antisense oligonucleotides (in some circumstances) and transgenes where the naturally occurring gene sequences are operably connected to heterologous sequences such as a promoter vectors are.
Antibodies	For a new antibody to a known antigen, it is usually necessary to define the antibody by its six complementarity - determining regions (CDRs) unless it is experimentally shown that one or more of the CDRs do not interact with the target epitope or the antibody format allows epitope recognition with less than six CDRs. It is rare for claims that permit variation in the CDRs to be allowed, though this is possible if it can be shown that some variation can be tolerated and a functional criterion (affinity, specificity, therapeutic effect) is included to exclude inoperative variation. The specification will need to put the skilled person in a position to be able to predict with some certainty which of the CDR residues can be mutated while maintaining the technical effect.
Methods of medical treatment	Methods of medical treatment are patent eligible. Swiss - type or second - medical - use - type formats are also permitted. If using the EPC2000 format for second - medical - use claims, the 'for' will not be considered limiting with the claim construed as only requiring that the compound be suitable for the recited use. If novelty is derived from the use, the claim will need to be written as '[compound] when used for…', or, alternatively, 'Use of [compound] for…'.
Swiss - type claims provide additional protection being directed to a method or process of manufacturing a medicament using the compound recited and not to a product or to the use of the medicament for treating the disease recited in the claims. Advantageously, they can be enforced directly against the manufacturer of an infringing product.	
Courts have held that 'a reasoned hypothesis' detailed in an overview of a	

clinical trial study that is publicly available before the priority date can deprive a later patent application of novelty even if the 'reasoned hypothesis' has not yet been validated. This is particularly relevant for claims to new dosage regimes.	
Diagnostic methods	Diagnostic methods are patent eligible.
Software	Diagnostic methods, methods of medical treatment, medical devices that use software are patent eligible. However, it can be challenging to get claims to the software or software implemented by a generic computer. Patent specifications should be drafted carefully to emphasise technical features of the invention or technical outcomes resulting from the invention. Thought must be given to the 'actors' (eg, servers, processors) within a claim and where they are located to avoid divided infringement.
Artificial intelligence (AI)	AI is increasingly being used to identify new targets, validate candidate drug compounds, predict drug properties, for de novo drug design, candidate drug prioritisation and generating synthesis pathways. Diagnostic methods, methods of medical treatment, therapeutic compounds made with the help of AI or that incorporate AI are patent eligible. Inventions made with the help of AI will likely meet the present inventive step requirements. But as artificial intelligence becomes part of the normal toolkit for the person skilled in the art, the bar for inventiveness will likely increase.

STRATEGIES FOR ENFORCEMENT (INCLUDING WHETHER INJUNCTIONS ARE NECESSARY OR EASILY AVAILABLE)

Patent infringement proceedings are generally commenced by a patentee or exclusive licensee in the Federal Court of Australia and conducted before a single judge with experience in patent matters. Infringement proceedings are often accompanied by a cross-claim for revocation and it is usual for issues of liability or validity to be bifurcated from issues of quantum.

The parties can appeal a first instance decision to the Full Court of the Federal Court.

Typically, proceedings begin with an exchange of pleadings and determination of any application for a preliminary injunction (PI) following which there will be discovery, exchange

of evidence (generally through independent experts), necessary pretrial steps and a final hearing. The time from commencement to trial is typically 18–24 months and further 6–12 months for judgment.

While PIs are available, it is uncommon for them to be sought or granted outside of pharmaceutical litigation.

To obtain a PI, the patentee must establish that there is a serious question to be tried on infringement, that damages will not be an inadequate remedy and that the balance of convenience favours the grant of the injunction. The Court retains a broad discretion and delay on the part of the patentee can be significant. A patentee must act quickly after becoming aware of the potentially infringing conduct or threat thereof to be granted a PI, a patentee must also give the 'usual undertaking as to damages', an undertaking to pay compensation to any person (whether a party or not) affected by the undertaking if it is ultimately overturned.

Historically, PIs were routinely granted to originators in pharmaceutical cases where the mandatory price reduction resulting from the first generic listing of a pharmaceutical substance on Australia's Pharmaceutical Benefits Scheme has been considered a factor weighing strongly in favour of granting an injunction preventing a generic entry. More recently, the Court has taken a different approach, and recent cases indicate the balance has shifted away from the granting of an injunction. This shift follows the realisation of the difficulty in calculating damages suffered by a generic restrained by a PI granted in a respect of a patent found invalid. Ultimately, it is easier for an originator to prove its loss from a generic entry.

A further development relevant to the granting of a PI in pharmaceutical cases has been the Commonwealth of Australia's pursuit of compensation under the 'usual undertaking as to damages'. The Commonwealth has made several claims on the undertaking for loss suffered as a result of delayed generic entry. While a number of these claims have settled, the Commonwealth's A$325 million claim against Sanofi in respect of the drug clopidogrel will be heard by the High Court in 2024 following the Full Federal Court's rejection of its claim on the basis that it has not been proven that the generic (Apotex) would have launched at risk.

While originators no doubt face increased hurdles and risks to obtaining PIs, they are still available to patentee in appropriate cases. A patentee can now rely simply on the mandatory price reduction and must give considerations to the calculation of compensation, the strength of its prima facie case on infringement and, importantly, invalidity and the potential effect on third parties such as the Commonwealth.

STRATEGIES FOR EXTENDING PROTECTION

A patent that claims a pharmaceutical substance (or a process using recombinant DNA technology to produce the pharmaceutical substance) contained in a drug that is either registered or will be registered on the Australian Register of Therapeutic Goods (ARTG) may be eligible for an extension of term of up to five years. Medical use claims, such as methods of treatment, cannot be extended.

'Pharmaceutical substance' includes not only novel active agents but also includes new formulations and combinations of active agents.

Patent term extension (PTE) is calculated by reference to the date of the patent that substantially claims and discloses the pharmaceutical substance and the first regulatory approval date of the pharmaceutical substance on the ARTG. In other words, the regulatory approval of the pharmaceutical substance that is the subject of the PTE must mark the first time that the pharmaceutical substance has been approved for marketing and use in Australia.

When a patent covers two pharmaceutical substances, a PTE application must be based on the pharmaceutical substance having the earliest regulatory approval date. So, where a patent application covers two or more potentially registerable products (eg, a single active product and combination product), applicants should strongly consider filing divisional applications to quarantine these substances. In that way, an earlier registration in respect of one product will not preclude a PTE for the later registered product.

Regulatory approval is often sought later in Australia, resulting in trailing PTE protection in a global context.

Protection	PTE
Legislation	Patent Act (sections 70–79, 79A and schedule 1).
Guidance	Patent Manual of Practice and Procedure (section 7.12).
Covered	Pharmaceutical substances.
Term	Up to five years.
How to calculate the term	PTE = ([date of first regulatory approval] – [date of filing of corresponding patent]) – five years.
Paediatric/orphan extension	No.
Eligible patent for drug products	Patent must in substance disclose and claim a pharmaceutical substance per se, or a pharmaceutical substance when produced by recombinant DNA technology.
Goods containing or consisting of the substance must be included in the ARTG.	
Scope of protection	Entire claim scope, applies to any pharmaceutical substance claimed but limited to the therapeutic use.
Assertable under linkage regulations	Yes.
Authority to grant	IP Australia.
Deadline for filing application	Six months or later of the first inclusion of goods containing the substance in the ARTG or patent grant date.
Protection by patent in force requirement	Yes, patent must be in force on the date the PTE application is filed.

First authorisation requirement for drug products	PTE application must be based on the first regulatory approval (human) for goods containing or consisting of the pharmaceutical substance.
Active agent	Pharmaceutical substance per se is not limited to the active agent and includes a compound, an active metabolite, a composition or a mixture of substances for therapeutic use whose application involves either a chemical or physicochemical interaction, with a human physiological system, or 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 within in vitro diagnosis or in vitro testing (the Act, Sch 1).
Number of patents extendible based on one approval	Multiple patents can be extended based on the same regulatory approval date.
Number of extensions	One (can cover multiple products; shorter term awarded).
Third - party filing	Yes, the patentee does not need to be the holder of ARTG registration.
Consideration of third - party observations during pendency of application review	No indication yet that IP Australia will consider any such observations.
Declaration of invalidity of application	Determined by patent office (re - examination or opposition) or on application to the federal court.
Infringement proceedings	The patentee and exclusive licensee have the right to start infringement proceedings (section 120) unless the PTE is granted after expiry of the patent, in which case only the patentee has standing to sue for infringement that occurred during the PTE period (section 79). This could be an issue where party that suffers loss is an exclusive licensee.

NON-PATENT EXCLUSIVITIES

Australia also provides an automatic five-year data exclusivity period for therapeutic goods containing a new active component, where no other therapeutic goods consisting of or containing that active component were included in the ARTG (first registration or export listing).

An 'active component' is defined as a substance that is, or substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

GENERICS TO MARKET

Section 26B of the Therapeutic Goods Act requires a generic applicant to certify to the Therapeutic Goods Administration (TGA) that it is either:

- not infringing a valid patent; or
- proposes to market a product before the expiry of a patent and has given the patentee notice of its application.

In practice, generic applicants do not notify originators of their anticipated market entry. Originators become aware of market authorisation of a generic competitor only on the inclusion of the generic in the register.

Notification after entry of generics on the register leaves little time for originators to consider whether its patents are infringed and, consequently, to prepare for infringement litigation.

However, given the difficulties now faced by originators in obtaining PIs, consideration should be given to pre-emptive revocation actions to clear the way. We also suggest placing a watch on the register to identify any generic entrants as soon as possible to start infringement proceedings and obtain final judgement prior to the generic's launch, avoiding the need for interlocutory relief.

Relevantly, following consultation in 2019–2020, the TGA proposed a patent notification scheme for a first generic to address originator concerns. The scheme was intended to provide greater opportunity for early negotiation and resolution of patent disputes before first generic entry. While keenly anticipated by originators, as at December 2023, the change had not been progressed and, disappointingly, now appears in doubt.

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