The Patent Prosecution Review

2024

Australia: Computer-related Inventions, Patent Term Extensions and Stricter Examination Trends

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The first edition of theIAM Patent Prosecution Review takes a wide-ranging view of best strategies for securing patents in the key regions of the Americas, the Asia-Pacific, and Europe, the Middle East and Africa. The review combines on-the-ground knowledge and analytic insight to offer an unparalleled deep dive into the prosecution landscape in specific markets.

Generated: July 6, 2024

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Australia: Computer-related Inventions, Patent Term Extensions and Stricter Examination Trends

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Summary

IN SUMMARY

No substantive changes in Australian patent law or practice have occurred recently, although it has been clarified that artificial intelligence may not be validly listed as an inventor on a patent. There is a general continuing trend for higher new patent filings in health technology fields. Anecdotally, Australian examiners appear to be applying support, enablement and manner of manufacture (patentability) requirements more strictly across a number of technology fields.

DISCUSSION POINTS

- Manner of manufacture continues to be a contentious issue for computer-implemented inventions
- Australian examiners are raising increasingly strict support, enablement and manner of manufacture objections
- Significant delays are being observed for commencement of examination in pharmaceutical, chemical, biotechnology and biotherapeutics fields
- For pharmaceutical related inventions, patent term extensions should be based on the earliest regulatory approval date regardless of whether the substance was developed by the patentee or a competitor

REFERENCED IN THIS ARTICLE

- Patents Act 1990 (Cth)
- *Commissioner of Patents v Ono Pharmaceutical Co Ltd [2022] FCAFC 39 (Ono)*
- *Merck Sharp & Dohme Corp v Sandoz Pty Ltd [2022] FCAFC 40 (MSD)*
- *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents> [2022] HCA 29 (17 August 2022)*
- *Commissioner of Patents v Thaler [2022] FCAFC 62*

ELIGIBILITY

In Australia, a patent can be granted on a wide range of inventions such as pharmaceuticals, mechanical devices and consumer products. However, there are some exclusions. In particular, Australian law expressly states that human beings or the biological processes for their generation are not patentable.

Additionally, an invention must be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies to be patentable subject matter,[1] the meaning of which has been developed through case law. In general, artistic creations, mathematical models and plans, schemes or purely mental processes are not held to be patentable.

Computer-implemented

Computer-implemented inventions can be patentable subject matter, subject to the case law developed for manner of manufacture. Numerous recent decisions have developed

the case law of what constitutes a manner of manufacture of a computer-implemented invention.[2] Current Australian Patent Office (APO) practice in assessing whether a computer-implemented invention is for a manner of manufacture typically involves identifying the substance of the claimed invention (ie, the contribution that the invention makes over the state of the art), and determining whether the substance lies within established principles of what does not constitute a patentable invention or lies outside of existing concepts of manner of manufacture,[3] utilising the following guidelines derived from case law:[4]

- whether the invention achieves a practical, tangible and useful result;
- whether the invention solves a technical problem within the computer or outside the computer or whether it results in an improvement in the functioning of the computer, irrespective of the data being processed;
- whether the claimed method merely requires generic computer implementation;
- whether the computer is merely an intermediary or tool for performing the method while adding nothing of substance to the idea;
- whether the ingenuity in the invention is in a physical phenomenon in which an artificial effect can be observed rather than in the scheme itself;
- whether the alleged invention lies in the way the method or scheme is carried out in a computer; and
- whether the alleged invention lies in more than the generation, presentation or arrangement of intellectual information.

Applicants for patents of computer-implemented inventions in Australia should therefore endeavour to highlight technical advantages and technical problems in the state of the art and include detailed technical descriptions of the invention in patent specifications.

Biotechnological And Medical

Claims in substance consisting of naturally occurring genetic information have been found to lack a manner of manufacture and are considered unpatentable.[5] However, methods of using naturally occurring genetic sequences have been found patentable, and transgenes comprising naturally occurring gene sequences operably connected to heterologous sequences are typically accepted by the APO. Biological materials including isolated micro-organisms and isolated peptides are patentable even when the same as naturally occurring counterparts as they are considered to be 'made'.

Both method of treatment claims and Swiss style claims are patentable in Australia.[6],-[7] European Patent Convention 2000 'for use' style claims are patentable in Australia but are not considered to be limited to the recited therapeutic use and are therefore often not valid. Such a claim may be converted to both a method of treatment claim and a Swiss style claim, which can be advantageous as there are different requirements to prove infringement of these claim formats.

EXAMINATION TRENDS

Chemical

There has been a trend in certain types of claims for chemical inventions having support and/or enablement objections raised against them.

Australian examiners generally object to claims with undefined optional substituents or medical use claims specifying broad treatments. Additionally, Australian examiners typically take the view that very small changes in the composition of an alloy or peaks of an x-ray diffraction (XRD) spectrum can result in materials having completely different physical properties. In view of this, support or enablement objections are generally raised against broad alloy claims that define hypothetical equivalent alloys that are not exemplified in the specification, or crystalline polymorph claims that are defined by reference to only a small number of peaks of their XRD spectrum.

Biotechnological

It is becoming increasingly difficult to obtain broad claims to antibodies in Australia. Objections are generally raised against claims that define an antibody by fewer than six complementarity-determining region (CDR) sequences, or that encompass variation within one or more CDR sequences. On the other hand, where the claimed antibody is defined by all six CDR sequences, it is generally sufficiently enabled as the CDRs can be synthesised and inserted into the various antibody frameworks as a matter of routine. Note, however, asserting that a claimed antibody is sufficiently enabled on this basis may raise issues for inventive step.

Claims directed to antisense oligonucleotides have recently been alleged to be claims to 'genetic information' per se, even though the claimed sequences are not present in the genome. Such claims may need to be further defined in terms of modifications that contribute towards an improved function.

Mechanical And Electrical

The trend for mechanical and electrical examination remains relatively consistent, with Australian examiners continuing to primarily draw upon foreign examination results when accessible. In cases where foreign examination results are unavailable, examiners conduct independent searches, the results of which are generally of a high standard.

Support objections seem to have increased in frequency compared to previous years, with examiners typically asserting that the claim scope extends beyond the disclosure of the specification.

Software

The frequency of non-patentable subject matter objections being raised against software inventions also seems to have increased. The most viable option for overcoming this type of objection is presenting the technical features of the invention. However, examiners increasingly respond by asserting that the technical features are not sufficiently described in the specification (ie, an enablement objection is raised).

APPEALING OFFICE DECISIONS

The avenues available to seek a judicial appeal or administrative review of a decision of the Commissioner of Patents vary depending on the nature of the decision that is sought to be appealed, and are specified in the Patents Act 1990 (Cth).

Appeals To The Federal Court Of Australia

Decisions relating to acceptance or opposition to the grant of an accepted standard patent application, and the examination, re-examination or opposition of an innovation patent, are

appealed to the Federal Court of Australia (FCA). An innovation patent is a 'second tier' form of patent protection with a shorter (eight year) term and with a lower threshold of patentability. They still exist in Australia but are currently being phased out.

Typically, the deadline to file an appeal to the FCA is 21 days from the date of the decision. As this deadline can be difficult to extend, it is important to treat it as final and to act promptly (including to seek appropriate legal advice) before its expiration.

An appeal to the FCA from a decision of the Commissioner is conducted as a hearing de novo. This means that the FCA 'stands in the shoes' of the Commissioner and makes the decision afresh without being limited to the arguments, grounds or evidence that were before the Commissioner. Accordingly, the parties can generally set out additional grounds and particulars in the notice of appeal and file new evidence.[8]

Reviews To The Administrative Appeals Tribunal Or The FCA

Decisions such as in patent eligibility disputes and certain extensions of time requests are reviewed by the Administrative Appeals Tribunal (AAT).

Where the Patents Act does not specify a right of appeal or review, generally the only avenue is judicial review under the Administrative Decisions (Judicial Review) Act (ADJR Act).

Typically, the deadline to apply for a review to the AAT, or the FCA under the ADJR Act, is 28 days from the date of the decision, and a similar order of steps follows as that of appeals before the FCA.

OPPOSITIONS AND RE-EXAMINATION

Oppositions and requests for re-examinations are commenced before the APO.

Oppositions

Oppositions are available in relation to both standard patents (pre-grant) and innovation patents (post-certification). In the case of a standard patent, as the opposition procedure is available pre-grant, it can prevent the application ever being granted.

However, innovation patents are subject to a different registration process where they are initially granted without examination (provided formalities are complied with) and certified (if examination is requested) so that they can be enforced. Oppositions can only be commenced after certification is completed.[9]

As deadlines during opposition proceedings can be difficult to extend, it is important to treat these deadlines as final and to act promptly.

Re-examination

The patentee or any other person can request re-examination any time after acceptance of a standard patent, or certification of an innovation patent. The Commissioner is not obliged to carry out a re-examination of a standard patent before grant and may take the view that it is appropriate that an opposition be brought in such circumstances.

In some circumstances, the Commissioner may decide (at their discretion) to re-examine a patent without a request for re-examination. This is typically in circumstances where additional prior art comes to the attention of the APO, which was not previously considered during examination, or where grounds are raised in an opposition that are subsequently withdrawn.

Unlike oppositions, once a third-party requests re-examination, they play no subsequent role in the re-examination process, which continues between the APO and the patentee.[10]

During re-examination, an examination report will issue that outlines the examiner's findings. In the case of an adverse report, the patentee will be given the opportunity to respond with written submissions or amendments within a set deadline. If the patentee cannot resolve issues encountered during re-examination, the Commissioner will typically set the matter for a hearing prior to revoking the patent either wholly or in so far as it relates to a particular claim.

For completeness, we note that once any proceedings concerning a patent are commenced before the FCA, any proceedings before the APO (including re-examination) cannot proceed until the FCA proceedings are finalised. This creates strategic considerations for both patentees and challengers in determining the best forum for a patent challenge.

INVALIDATION AND INTER PARTES REVIEW

Revocation (ie, invalidation) proceedings are commenced before the FCA. While typically such proceedings are commenced in response to infringement proceedings, they can be commenced pre-emptively with the FCA.[11]

Revocation proceedings are typically heard and determined at first instance by a single judge. An appeal is available as of right to the Full Court of the FCA, typically consisting of three judges. There are no jury trials in Australia for patent cases.

There is no exact equivalence in Australia of the inter partes review procedure available before the US Patent and Trademark Office. The pre-grant procedure in Australia in relation to standard patent applications is the closest that is available.

PATENT TERM EXTENSIONS

The Act provides patent term extensions (PTE) for patents disclosing and claiming a pharmaceutical substance per se, or a pharmaceutical substance produced by a process that involves the use of recombinant DNA technology that is registered on the Australian Register of Therapeutic Goods (ARTG).[12] While method of treatment and Swiss style claims do not render a patent eligible for a PTE, extensions have been granted on slow release formulations, transdermal patches, unit doses and nanoparticulates, in contrast to the position in other jurisdictions such as Europe.

The term of a patent cannot be extended more than once;[13] however, the term of multiple patents can be extended on the basis of a single registration of a pharmaceutical product.

The date of first regulatory approval is of particular importance for eligibility of a PTE as the Act provides that this date is utilised to determine whether the patent is eligible to be extended,[14] the date by which the PTE request must be filed,[15] and the length of extension permitted.[16]

Determining the date of first regulatory approval when more than one product falls within the scope of the claims has been contentious in recent years. The Full Federal Court of Australia clarified that a PTE should be based on the earliest Australian regulatory approval date of any pharmaceutical substance that is disclosed and claimed in the patent, irrespective of whether the substance was developed by the patentee or a competitor.[17] Accordingly,

owners of pharmaceutical patents or applications should monitor competitor activities within Australia.

For patent applications covering multiple potentially registrable products, it is prudent to file divisional applications such that each potentially registrable product is covered by a separate patent. This approach facilitates independent PTEs based on the respective regulatory approval dates for each product.

PENDENCY LEVELS

A record number of standard patents were filed in 2021, and this decreased slightly in 2022, when 32,264 standard Australian patent applications were filed and 16,407 patents were granted.[18] In recent years, new patent filings in healthcare fields have dominated patent filings compared with other fields, with 13.8 per cent, 12.5 per cent and 10.3 per cent of new filings occurring in pharmaceutical, medical technology and biotechnology fields, respectively.[19]

The time between requesting examination and receipt of an examination report is presently stretching well beyond the 12 months targeted by IP Australia in some fields. This is particularly true for applications in pharmaceutical and related healthcare technologies.[20]

IP Australia provides timeframes for examination for each subject area as follows:[21]

Subject area	Examination time
CHEM 1 – Biotechnology	19 months
CHEM 2 – Chemical compounds	19 months
CHEM 3 – Biotherapeutics	26 months
CHEM 4 – Polymers and applied chemistry	12 months
CHEM 5 – Pharmaceuticals	16 months
ELEC 1 – Physics	10 months
ELEC 2 – Electronics and communications	8 months
ELEC 3 – Computing	9 months
ELEC 4 – Data processing and measurements	11 months
MECH 1 – Mechanical engineering	14 months
MECH 2 – Construction and mining	14 months
MECH 3 – Process engineering	11 months
MECH 4 – Medical devices	12 months
MECH 5 – Packaging and appliances	14 months

Options to reduce the wait time for issuance of examination include requesting examination early (eg, upon entering the Australian national phase or filing an Australian standard patent application) and requesting expedited examination as detailed below.[22]

An examination report can be expected four to eight weeks following the acceptance of a request to expedite examination. Once an examination report issues, the application must be accepted within 12 months.

AUSTRALIAN PROSECUTION POINTERS

Divisional Applications Can Be Daisy-chained

Under Australian law, successive divisional applications can be 'daisy-chained' to maintain pendency of patent claims throughout the 20-year term of an original parent patent. Maintaining the pendency of patent claims via a divisional application offers numerous strategic advantages from a commercial and litigation standpoint.

Expired Innovation Patents

The innovation patent was phased out on 25 August 2021 and all innovation patents will have expired by 26 August 2029; however, even expired and unexamined innovation patents remain a risk for potential infringers. Innovation patents were granted without examination but are not enforceable until examined and certified.

The APO recently examined two innovation patents after they had expired. Under Australian law, there is no requirement for an innovation patent to be alive when examined or certified. Therefore, a dead innovation patent could be retrospectively certified and enforced, although there is an overriding statute of limitations for patent infringement of six years.

Computer-related Inventions

Currently, Australia's view on the patentability of computer-implemented inventions is not in line with the United States and Europe. For the reasons discussed above, it is becoming increasingly difficult in Australia to patent a computer-related invention as there are widespread differences in opinions about the circumstances and requirements a computer-implemented invention must satisfy in order to be deemed patentable under Australian law.

It had been hoped that the highly anticipated decision of Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents [2022] HCA 29 would clarify the requirements for finding a manner of manufacture for a computer-implemented invention. However, the High Court handed down an evenly split decision, leaving the door open to further consideration of the patentability of computer-implemented inventions in the future.

Expedited Examination Options

Australia is a member of the Global Patent Prosecution Highway programme.[23] There is also a separate Patent Prosecution Highway pilot programme between IP Australia and the European Patent Office.[24]

Alternatively, it is possible to request expedited examination for commercial or legal (eg, infringement) reasons, if the applicant is a small to medium sized enterprise, or if the invention is in the field of 'green technology', without the use of the Patent Prosecution Highway.

Requesting expedited examination offers a number of advantages over using the Patent Prosecution Highway. As there is no requirement for formal claim comparison charts or preliminary amendments to conform claims to a corresponding patent in another

jurisdiction, the costs of requesting expedited examination may be less. Further, there is no need to have a prior corresponding allowed or granted patent in an overseas jurisdiction. Expedited examination also takes place at the same pace as with the Patent Prosecution Highway programme and a rapid turnaround of an examination report can accordingly be expected.

Artificial Intelligence Inventorship

The High Court of Australia recently rejected an appeal that challenged a decision in-Commissioner of Patents v Thaler [2022] FCAFC 62. In the Thaler case, an AI system referred to as DABUS was alleged to be an inventor. However, it was decided an 'inventor' in an application for a patent must be a natural person.

In view of that decision, the current state of Australian law is that an inventor on a patent application cannot be an AI system.

Endnotes

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