

Legal 500

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Australia

Patent Litigation

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This country-specific Q&A provides an overview of patent litigation laws and regulations applicable in Australia.

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Australia: Patent Litigation

1. What is the forum for the conduct of patent litigation?

Patent litigation is generally commenced in the Federal Court of Australia (although the Supreme Courts in each Australian State and Territory have jurisdiction, cases are very rarely commenced there). First instance patent infringement and revocation proceedings are conducted before a single judge of the Federal Court. First instance patent cases in the Federal Court are ordinarily allocated to a member of a panel of judge within the 'Patents and Associated Statutes' practice area, each of whom has experience in patent matters, some with a technical background. A party commencing a first instance patent case in the Federal Court (other than by way of cross-claim) can choose the State or Territory Registry of the Federal Court in which the proceeding is commenced and may, in this way, influence the pool of judges from which a judge is allocated to the case.

2. What is the typical timeline and form of first instance patent litigation proceedings?

In Australian patent cases, issues of infringement and validity are ordinarily heard and determined concurrently, by the same Federal Court judge (i.e., without "bifurcation"). Where a patent infringement case is commenced in the Federal Court, the respondent (defendant) may put validity in issue by filing a cross-claim in the same proceeding (and vice versa). The Federal Court has the power to order that a single issue (or a group of issues) be heard and determined separately, before all other issues in a patent case. Using that power, Federal Court judges frequently order that the quantum of any damages be determined separately, after all issues of liability have been resolved (since, if there is no infringement and/or the patent is found to be invalid, no hearing on damages will be required). Otherwise, it is relatively uncommon for issues to be determined separately in Australian patent litigation. In particular, Markman-type hearings are extremely rare and issues of claim construction are ordinarily heard and determined together with all other issues of infringement and validity. Typical steps in a Federal Court patent case include exchange of pleadings, hearing of any application for an interim ("interlocutory" or "preliminary") injunction, filing of evidence (in chief, answer and reply), discovery (if any), pre-trial steps (including an experts' conclave) and trial.

There may be interlocutory hearings on issues such as amendment, the adequacy of pleadings, and the scope of discovery. The duration of Australian patent litigation varies considerably. Commonly, the time from commencing a patent case to the conclusion of a first instance hearing is in the range of 12 to 24 months. A judgment could be expected 6 to 12 months after the conclusion of the hearing.

3. Can interim and final decisions in patent cases be appealed?

A final, first-instance decision of the Federal Court of Australia on patent infringement or validity may be appealed as of right (i.e., without leave) to a Full Court of the Federal Court ("Full Court"), comprising three to five judges. There are no permanent judges of appeal in the Federal Court. All Federal Court judges hear appeal cases from time to time. A Full Court assigned to hear an appeal in a patent case will typically include at least one judge, and usually multiple judges, with experience in patent cases.

An interim decision of the Federal Court may only be appealed to the Full Federal Court with leave. This includes decisions on interlocutory matters, such as disputes over discovery. Leave is also required to appeal to the Full Federal Court from a decision of a single Federal Court judge in an appeal from an Australian Patent Office opposition decision. It is relatively common for an application for leave to appeal, and the substantive appeal, to be heard and determined at the same time (i.e., the Court hears submissions on whether leave to appeal should be granted, and whether the appeal should be allowed if leave is granted, at the same hearing).

From 2025 the Full Federal Court sits during March, August and November each year, although urgent appeals may be heard by the Full Court at other times. The time between the making of first instance orders and the hearing of any appeal varies, but is usually less than 6 months (noting that the making of orders can take a number of months after judgment is delivered). A Full Court judgment could be expected within 6 to 12 months after the appeal is heard (more quickly in urgent cases).

A judgment of the Full Court can only be appealed to the High Court of Australia with special leave. Special leave is

only granted in significant cases dealing with new or disputed points of law. Only a minority of applications for special leave are successful.

A judgment which has been appealed will not be automatically stayed pending the outcome of the appeal. In particular, an injunction is likely to be ordered where a first instance decision upholds patent claims as valid and infringed, and may not be stayed even while an appeal on infringement or validity is being pursued. However, where one or more claims of a patent have been found invalid, it is routine for revocation of those claims to be stayed pending the determination of any appeal. In appropriate cases, a party seeking a stay of a judgment pending appeal will be required to undertake to compensate the opposing party for any losses suffering during the stay if the appeal is unsuccessful.

4. Which acts constitute direct patent infringement?

A product claim of an Australian patent is directly infringed by making, hiring, selling or otherwise disposing of the claimed product or offering to do so, using or importing the claimed product, or keeping the claimed product for the purpose of doing any of those things. A method or process claim of an Australian patent is directly infringed by using the claimed method or process, or doing any of the acts mentioned above in respect of a product resulting from use of the claimed method or process.

5. Do the concepts of indirect patent infringement or contributory infringement exist? If, so what are the elements of such forms of infringement?

Yes. Liability for indirect or contributory infringement may arise in the following circumstances.

First, a person will be liable for patent infringement if they authorise another to engage in conduct that directly infringes the patent's claims. This follows from section 13 of Australia's Patents Act 1990, which gives a patent owner the exclusive right to authorise exploitation of their invention.

Secondly, under section 117 of Australia's Patents Act 1990, a person who supplies a product will be liable for patent infringement if: a. the product is only reasonably capable of an infringing use; b. the product is not a staple commercial product and the supplier had reason to believe that the person to whom it the product was

supplied would put it to an infringing use; or c. the supplier gave instructions or inducement for the product to be put to an infringing use.

Thirdly, at common law, a person who procures or induces another to engage in conduct that infringes an Australian patent, or joins in a common design with another to undertake conduct that infringes an Australian patent, will themselves be liable for patent infringement (joint tortfeasorship).

6. How is the scope of protection of patent claims construed?

Patent claims are given a purposive, rather than purely literal, construction according to the principles explained by Lord Diplock in the UK *Catnic Components* case. The claims are to be construed through the eyes of the hypothetical person skilled in the relevant art, having regard to the common general knowledge in their field. Experts may give evidence on the meaning of technical terms used in the claims. While claims should be construed in the context of the specification as a whole, it is not legitimate to read-down unambiguous claim language by importing "glosses" found elsewhere in the specification. Currently, the prevailing view is that there is no recognised doctrine of equivalents under Australian patent law, although this issue has not been tested in any recent case. The doctrine of prosecution history (or file wrapper) estoppel is not currently applied in Australia, although in at least one case it was suggested that this is an open question.

7. What are the key defences to patent infringement?

Beyond arguing non-infringement (i.e., absence of claim features) and invalidity of the asserted claims, allegations of patent infringement may also be contested on the basis of statutory defences including (a) prior continuing use of the claimed invention before the priority date of the relevant claim(s); (b) exploitation of the claimed invention solely for regulatory purposes in Australia or overseas; (c) experimental use; (d) use of the invention on board a foreign vessel or aircraft; (e) on the basis that the claimed invention is (or was, when the proceedings were started) the subject of a contract containing a provision, inserted by the patentee, that is void for impermissibly prohibiting the respondent (defendant) from using or acquiring a product or process not the subject of the patent. In appropriate factual scenarios, allegations of patent infringement may also be contested on the basis of equitable defences including acquiescence, waiver, delay

(laches) and promissory estoppel. These defences have received relatively little judicial consideration in Australian patent cases.

8. What are the key grounds of patent invalidity?

In relation to standard Australian patents, the key grounds of invalidity are: (a) that the claim is not directed to patent-eligible subject matter (i.e., not a "manner of manufacture" within the meaning of the Statute of Monopolies); (b) lack of novelty (anticipation) in light of information that was disclosed before the priority date in a published document, in a filed patent document or by a public act; (c) lack of inventive step (obviousness) in light of common general knowledge, taken alone or in combination with information disclosed before the priority date in a published document or by a public act; (d) lack of utility (e) prior secret use; (f) insufficient disclosure; (g) failure to disclose best method; (h) lack of support for the claims (or lack of fair basis, in the case of patents granted on applications filed before 15 April 2013 and for which examination had been requested before that date) (i) lack of clarity; (j) lack of entitlement (which has not been rectified); and (k) false suggestion.

Australia also currently has a second-tier 'innovation patent' system (subject to its phasing out discussed below). Innovation patents confer the same rights as standard patents, but for a term of 8 years rather than 20 years. The validity requirements for an innovation patent are the same as those for a standard patent, except that no inventive step is required (and therefore questions of obviousness do not arise). Instead, the claimed subject matter must possess an 'innovative step' when compared to the relevant prior art base. In simplified terms, there will be an innovative step provided that the claimed subject matter differs from each prior art document (assessed individually) by way of a feature that makes a substantial contribution to the working of the invention. This is not a particularly demanding standard.

Australia's innovation patent system is currently being phased out. It has not been possible to file new applications for innovation patents since 26 August 2021 (although innovation patents can be pursued via divisional applications based on standard patent applications that were filed before 26 August 2021). Innovation patents granted on applications filed before 26 August 2021 remain in force (subject to payment of renewal fees).

9. How is prior art considered in the context of an

invalidity action?

For the purposes of assessing novelty, the prior art base includes information in a document that was made publicly available, anywhere in the world, before the priority date. Acts done in public before the priority date can also be novelty-defeating, subject to evidence being adduced and accepted in relation to what act was done and what would have been disclosed to a person observing the act. The prior art base for assessing novelty also includes information contained in a co-pending patent specification that was published on or after the priority date of the claim under consideration, but which has (or would have, if the information was made the subject of a claim) a priority date earlier than that of the claim under consideration.

For the purpose of assessing novelty, prior art documents and prior art acts may only be combined where the documents or acts are related, such that a person skilled in the relevant art would treat them as a single source of information. This is a restrictive test and 'mosaicing' of prior art documents (or acts) is not common.

For the purposes of assessing inventive step (obviousness), the prior art base includes the common general knowledge in the relevant art before the priority date. In the case of patents granted on applications for which examination had been requested before 15 April 2013, only common general knowledge in Australia's "patent area" may be considered. For all other patents, common general knowledge is assessed on a worldwide basis.

For the purposes of assessing inventive step (obviousness), common general knowledge may be combined with information made publicly available, before the priority date, in a document published anywhere in the world or by the doing of an act anywhere in the world. For this purpose, documents or acts may only be combined if a relevantly skilled person could reasonably be expected to have done so before the priority date. This is again a restrictive test which generally precludes mosaicing of prior art. In the case of patents granted on applications for which examination had been requested before 15 April 2013, information disclosed in a document or by the doing of an act may only be taken into account when assessing inventive step (obviousness) if a person skilled in the relevant art could reasonably be expected, before the priority date, to have ascertained that information, understood it, and regarded it as relevant. This is a significant additional burden for many prior art documents and even more so for prior art acts. Accordingly, the removal of this requirement has made patents for which examination was requested after

15 April 2013 easier to attack on obviousness grounds.

Australia has a number of grace period provisions, which may have the effect of excluding publications from the prior art base for assessing novelty, inventive step and innovative step, including information disclosed in co-pending patent applications.

10. Can a patentee seek to amend a patent that is in the midst of patent litigation?

Yes, however any amendment application must be made to the Court that has carriage of the patent litigation. Australia's Patent Office may not consider an application to amend a patent that is the subject of current litigation. In the case of patents granted on applications filed before 15 April 2013 (and for which examination had been requested by that date) amendments will not be permitted if they would result in the patent claiming matter that was not in substance disclosed in the specification-as-filed, if the amended claims would not fall within the scope of the pre-amendment claims, or if the amended specification would not comply with the internal validity requirements of Australia's Patents Act 1990. Later patents are also subject to an additional requirement: amendments will not be permitted if they would result in the specification disclosing matter that extends beyond the information that was disclosed in the specification-as-filed (i.e., no "added matter").

Where the above requirements are met, the Court retains a discretion to allow or refuse amendment. To satisfy the Court that amendments should be allowed, the patentee will need to disclose all relevant matters and satisfy the Court that they did not delay unreasonably after learning of the need to amend. For this reason amendments should generally be sought as early as possible in the course of patent litigation.

The Court may exercise its discretion to refuse amendment if the patentee sought to obtain an unfair advantage from the unamended claims. Although a patentee is not obliged to waive privilege over communications with its attorneys, if the patentee refuses to do so, it may be unable to satisfy the Court that the discretion to allow amendment should be exercised..

An application for amendment must be notified to the Commissioner for Patents and advertised in the Official Journal, providing an opportunity for a third party to oppose the proposed amendments. Any other party in the litigation may also oppose the application for amendment.

A similar process, subject to the same discretion of the Court, is available during Federal Court appeals from Patent Office opposition decisions. Post-acceptance amendments can also be sought with respect to both patent applications and granted patents in the Patent Office (i.e., before litigation, or afterwards if the patent/application has survived), where the test for allowability of amendments is the same but the Patent Office does not have discretion to refuse the amendments if those requirements are met, and therefore associated disclosure by the applicant/patentee is not required.

11. Is some form of patent term extension available?

Standard Australian patents claiming a pharmaceutical substance *per se* are eligible for a term extension of up to 5 years provided that certain statutory conditions are fulfilled. The pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG) and there must be a delay of at least 5 years between the filing date of the patent application and the first regulatory approval of any product containing or consisting of the pharmaceutical substance. The patent must claim a 'pharmaceutical substance *per se*' (including a mixture of substances) which is contained within the relevant approved pharmaceutical product. An application for term extension must be made during the term of the patent and within 6 months after the date the patent was granted or the date that goods containing or consisting of the pharmaceutical substance were entered on the ARTG, whichever is later. An application to extend the term of a patent must be advertised in the Official Journal and any person may oppose the extension.

A patent term extension extends the life of the patent as a whole, not just in relation to the ARTG registered product. However the rights of the patentee are limited in certain respects during any term extension (including that claims directed other than to pharmaceutical substances *per se* cannot be enforced).

There has been a recent trend towards generic pharmaceutical companies challenging the validity of pharmaceutical patent term extensions, particularly with respect to patents claiming formulated or composite products, and in relation to patents claiming multiple products.

12. How are technical matters considered in patent litigation proceedings?

Expert evidence on technical matters is of primary importance in Australian patent litigation and its preparation accounts for a significant proportion of total litigation costs. The evidence is ordinarily given in affidavit form (i.e., a sworn written statement). Ordinarily, the parties' legal representatives work together with the expert witnesses to prepare an affidavit, to ensure their evidence is presented in an admissible form. Experts may be (and usually are) cross-examined at trial. Expert witnesses are usually retained by (and compensated for their time) by the parties. However at the time they are retained, expert witnesses must be provided with a copy of the Court's code of conduct which details their obligations, including as regards independence and impartiality. Court-appointed experts are uncommon in Australian patent cases, although some newer judges have expressed interest in utilising that practice more frequently.

Joint expert evidence processes are encouraged by the Court. This can include pre-trial expert conclaves in the absence of lawyers, during which the experts prepare a joint report setting out matters of agreement and disagreement, and concurrent expert evidence ('hot tubs') at trial, with the parties' respective expert witnesses giving evidence together addressing an agreed set of topics. The Federal Court also actively encourages use of summary documents, such as agreed technology primers, process descriptions and position statements on infringement and validity.

13. Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?

Documentary discovery is common in Australian patent litigation, although it is not available as of right. A party applying for discovery must satisfy the Court that the discovery is relevant and proportionate to the proceeding. General discovery is not usually available; rather, in most cases, discovery is given by reference to specific categories of documents. Increasingly, discovery is being deferred until after the close of evidence in Australian patent cases, in the expectation that the issues in dispute will then be more clearly defined, allowing the scope of discovery to be limited. Interrogatories (that is, a form of discovery in which a party to the proceeding is required to provide sworn written answers to questions relevant to the proceeding) are available in Australian patent litigation, although used relatively infrequently.

Preliminary discovery is a distinct process that may be sought before commencing patent infringement proceedings, to determine whether a cause of action exists and/or to assess the potential value of a claim. A party seeking preliminary discovery must satisfy a number of statutory criteria, including demonstrating a reasonable belief that they may be entitled to final relief.

Anton Piller orders (i.e., ex parte orders for search and the seizure of documents or property to preserve evidence) and Mareva orders (i.e., ex parte orders to prevent a party from disposing of assets so as to frustrate enforcement of a judgment) are available in Australian patent litigation in appropriate circumstances, but are used infrequently.

14. Are there procedures available which would assist a patentee to determine infringement of a process patent?

The preliminary discovery process described above can be used to assess infringement of a process patent. In existing proceedings, standard discovery or interrogatories can also be sought with regard to an allegedly infringing process. The Court may also require a respondent (defendant) to file a process description (under oath from a senior employee or director of the relevant company), detailing the steps of the allegedly infringing process.

15. Are there established mechanisms to protect confidential information required to be disclosed/exchanged in the course of patent litigation (e.g. confidentiality clubs)?

It is routine for parties to Australian patent litigation to establish an inter partes agreement to restrict access to and preserve the confidentiality of documents and information exchanged by the parties over the course of the proceeding. Often the confidentiality club is limited to external lawyers, patent attorneys and independent experts, but in appropriate cases one or more in-house lawyers may also be included. The Federal Court may make interim or final suppression orders to preserve the confidentiality of documents and information placed before the Court during patent litigation. Commonly, interim orders will be made to preserve the confidentiality of such material until the conclusion of the trial. In that case, the parties would need to seek final suppression orders at the conclusion of the trial to preserve the confidentiality of material that was admitted into evidence or disclosed in submissions over the course of the proceeding. A more rigorous standard applies where

final, rather than interim, suppression orders are sought.

16. Is there a system of post-grant opposition proceedings? If so, how does this system interact with the patent litigation system?

Australia has a pre-grant opposition system for standard patents, administered by the Australian Patent Office (APO), but no post-grant opposition procedure. As patent litigation (i.e., patent infringement and revocation proceedings before the Federal Court) may not be commenced until after grant, interaction between opposition proceedings and litigation does not arise in a strict or formal sense. However, it is possible for one or more granted patents to be the subject of revocation proceedings before the Federal Court at the same time as one or more related divisional applications are the subject of opposition proceedings before the APO, or vice versa. In those circumstances, complex strategic considerations may arise concerning the timing of steps in the Federal Court and APO, including the timing of evidence and any application for amendment. It cannot be assumed that the opposition proceedings will be stayed by the APO pending the outcome of the litigation in the Federal Court. While it is not possible to oppose an Australian patent post-grant, proposed amendments to an Australian patent may be opposed at any time after acceptance of the patent application, including post-grant and in the course of litigation before the Federal Court. Where litigation in relation to a patent is on foot, or such litigation is subsequently commenced, any application to amend the patent, and any opposition to the proposed amendments, must be heard and determined by the Court that has carriage of the litigation (amendments may not be considered by the APO in respect of a patent that is the subject of current litigation).

The APO may undertake re-examination of a patent at any time post-grant, either at the request of a third party (with no standing requirement) or of its own initiative (such as following settlement of opposition proceedings). If litigation is commenced in the Federal Court, the APO cannot revoke a patent following re-examination or allow any amendment of the patent while the litigation remains on foot.

Innovation patents are granted without substantive examination, and can only be opposed post-grant, following substantive examination and certification. If Court proceedings are commenced by the patentee for alleged infringement of a certified innovation patent, any opposition proceedings will be stayed by the APO pending the outcome of the litigation. A decision of the

APO in opposition proceedings may be appealed as of right (i.e., without leave) to a single judge of the Federal Court. Such appeals are conducted as a hearing de novo, and the Court may (and frequently does) permit new grounds of opposition to be raised and new evidence to be filed in the appeal that was not before the APO. Following a decision of a single judge of the Federal Court in opposition proceedings, any further appeal to the Full Federal Court is only available with leave.

17. To what extent are decisions from other fora/jurisdictions relevant or influential, and if so, are there any particularly influential fora/jurisdictions?

Australia is a common law jurisdiction. Decisions of other common law jurisdictions, including the United Kingdom, the United States, Canada and New Zealand, may be relevant (although not binding) in relation to topics on which the patent laws of the jurisdictions are substantially similar, particularly where Australia's superior courts (i.e., the High Court and the Full Federal Court) have not yet issued any relevant decisions. Although historically influential, decisions of UK courts were cited in Australian patent cases much less frequently following the UK's accession to the European Patent Convention. However, in 2013, Australian patent law on sufficiency and support was substantially aligned with the law on those topics applied by the European Patent Office (EPO) and UK courts. For this reason, precedential decisions of the EPO and UK courts concerning sufficiency and support are likely to be highly influential in relation to patents to which the amended provisions apply (that is, patents granted on applications for which examination was requested after 15 April 2013).

18. How does a court determine whether it has jurisdiction to hear a patent action?

Australia's Federal Court, and the High Court of Australia, have jurisdiction over disputes relating to granted Australian patents and applications for Australian patents. The Supreme Courts in each Australian State and Territory also have original jurisdiction to hear patent matters, but this rarely occurs, particularly as there is a legislative requirement that any appeal from a first instance patent decision be heard by the Full Federal Court.

A granted Australian patent has effect throughout Australia, including its continental shelf, the waters overlying the continental shelf and the airspace overlying Australia and its continental shelf. Acts done anywhere in

that territory may involve infringement of an Australian patent and thus fall within the Federal Court's jurisdiction. There are at least two ways in which conduct outside of Australia may involve infringement of an Australian patent and thus fall within the jurisdiction of Australian courts. First, a person who imports patented goods into Australia may be liable for direct infringement, regardless of their location. This may include goods produced outside of Australia by a method which is the subject of an Australian patent. Secondly, a person located outside Australia may be held jointly liable for infringement of an Australian patent if they authorise, procure, induce or join in a common design with another person to engage in conduct that directly infringes the patent (e.g., an overseas parent company may be held jointly liable with its Australian subsidiary for infringing conduct in Australia).

There is very limited authority concerning the willingness of Australian courts to consider issues of validity or infringement in relation to foreign patents. Speaking generally, an Australian Court would be unlikely to rule on the validity of a foreign patent. However, in appropriate cases, an Australian court may consider questions of infringement of a foreign patent if this was relevant to a cause of action otherwise within the court's jurisdiction.

19. What are the options for alternative dispute resolution (ADR) in patent cases? Are they commonly used? Are there any mandatory ADR provisions in patent cases?

The Federal Court of Australia has the power to direct mediation of patent disputes. A majority of court-ordered mediations are conducted by Registrars who are trained and accredited by the Court, although parties can and often do choose to engage private accredited mediators. While it is possible to oppose mediation, if mediation is ordered by the Court, the parties must attend. The use of mediation is increasing in frequency in Australian intellectual property disputes, particularly where the quantum of any damages is likely to be small relative to the cost of litigation.

20. What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?

Before commencing litigation in the Federal Court of Australia, there is a statutory obligation to facilitate and encourage settlement of the dispute. At the

commencement of proceedings, a "genuine steps statement" must be filed, outlining the steps that were taken to attempt to resolve the dispute without litigation, such as communicating the basis for the dispute to the opposing party, responding constructively to such communications, considering alternatives to litigation and cooperating with any such alternatives. In addition to a "genuine steps statement", a party commencing patent litigation in the Federal Court must file an application identifying the relief sought and a statement of claim identifying the facts relied upon, together with particulars of infringement or invalidity (as appropriate). Proceedings for alleged infringement of an Australian patent must be commenced by the later of three years from patent grant or six years from the date of infringement. Subject to equitable defences including acquiescence, waiver and delay (laches), infringement proceedings may be commenced at any time during this limitation period. Distinct considerations apply where a party intends to apply for an interim injunction (also referred to as an interlocutory or preliminary injunction) to restrain the allegedly infringing conduct until the conclusion of the proceeding. Delay is an important factor influencing the exercise of the Court's discretion to grant or refuse injunctive relief. For this reason, a party intending to apply for an interim injunction must proceed as expeditiously as possible after learning of the allegedly infringing conduct (or of a threat to engage in infringing conduct). Delay/acquiescence can also potentially limit the damages or profits a patentee can recover, depending on the circumstances.

21. Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?

Only a patentee and any exclusive licensee have standing to sue for infringement of an Australian patent. If infringement proceedings are commenced by an exclusive licensee, the patentee must be joined as an additional applicant (plaintiff) (or, if they do not consent to be joined, as an additional respondent/defendant). The definition of "exclusive licensee" under Australian patent law is restrictive. As the law currently stands, a licence will not be regarded as exclusive if it reserves to the patentee any right to exploit the claimed invention within Australia's patent area (e.g., a right to manufacture the patented goods) or gives the patentee a right to grant additional licences. A non-exclusive licensee does not have standing to sue for infringement of an Australian patent and is not a proper party to infringement proceedings.

22. Who has standing to bring an invalidity action against a patent? Is any particular connection to the patentee or patent required?

There are no special standing requirements for challenges to the validity of an Australian patent. Any natural or corporate person can seek revocation of a granted Australian patent in the Federal Court of Australia. Similarly, any natural or corporate person can oppose the grant of an Australian patent application (pre-grant) or request re-examination of an Australian patent in the Patent Office.

23. Are interim injunctions available in patent litigation proceedings?

Yes, in appropriate circumstances, interim injunctions (alternatively referred to as interlocutory or preliminary injunctions) are available in Australian patent litigation. Interim injunctions are most commonly sought in pharmaceutical cases where "irreparable" harm may be easier to demonstrate, although even in this area it is becoming less predictable whether an interim injunction will be granted on the facts of any particular case. Outside of the pharmaceutical field, interim injunctions are not commonly sought or granted in Australian patent cases. Applications for interim injunctions are usually dealt with inter partes in Australian patent litigation. However, in cases of special urgency, a claimant may apply ex parte for a temporary injunction covering the period until an inter partes hearing can be held. The time taken to apply for and obtain an interim injunction is typically in the range of 4 to 8 weeks (up to 12 weeks in less urgent matters). To obtain an interim injunction, the patentee (or their exclusive licensee) must establish that: (a) there is a serious question to be tried on infringement; (b) damages will not be an inadequate remedy; and (c) the balance of convenience and justice favour grant of the injunction. Even if each of those conditions is met, the Court retains a discretion to grant or refuse an interim injunction. Delay is an important factor in the Court's consideration of whether to grant an interim injunction. It is important that the claimant act as quickly as possible after learning of the allegedly infringing activity (or the threat to engage in infringing activity), as failure to do so will be relevant to consideration of the balance of convenience. A party applying for an interim injunction must undertake to the Court that, if the defendant is ultimately found not to infringe and/or if the patent is ultimately held to be invalid, they will compensate the respondent/defendant and any third party found to have been adversely affected by the grant of the injunction. In recent years, the Australian Government, relying on such

undertakings, has sought compensation for additional expenses incurred under Australia's Pharmaceutical Benefits Scheme where patent claims, although ultimately unsuccessful, delayed market entry of generic pharmaceutical products in Australia. Those cases have served to illustrate the complexities in calculating the losses suffered by parties held off the market by an interim injunction. In subsequent cases, Courts have cited these complexities as a factor weighing against the grant of interim injunctions.

24. What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought and which are typically ordered?

The remedies available for infringement of an Australian patent include: (a) a declaration that the relevant conduct has infringed the patentee's rights; (b) a final injunction restraining the respondent (defendant) from repeating the infringing conduct or engaging in any other conduct that infringes the relevant patent; and (c) either damages or an account of profits, at the election of the successful patentee. It will generally be possible for a successful patentee to defer their election between damages or an account of profits until the "quantum" stage of the proceedings, after discovery of the respondent's (defendant's) relevant books and accounts has been obtained. More recently, additional damages have also been made available for patent infringement, for example, where the infringing conduct is deemed to have been flagrant (and the patentee has elected damages rather than an account of profits).

25. On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages? Can the successful party elect between different monetary remedies?

A patentee or exclusive licensee successful in infringement proceedings may choose to receive either damages (i.e., compensation for its losses caused by the infringing conduct) or an account of the infringer's profits due to the infringing conduct. An account of profits will be calculated according to established accounting principles, such as discounted cashflow models taking into account overheads and other costs. Damages may be assessed on a variety of bases. Most commonly, damages are assessed by reference to the profits lost by the patentee and any exclusive licensee by reason of the infringing conduct. Alternatively, damages may be

assessed on the basis of a reasonable royalty for the infringer's (unauthorised) use of the patented invention. In some more recent intellectual property cases where neither lost profits nor a reasonable royalty could be made out, Australian courts have instead awarded damages on the basis of the "user principle", however the jurisprudence in the latter area is still developing. Following recent reforms, Australian courts have a discretion to award additional damages in patent cases where the infringer's conduct is regarded by the court to be flagrant or where, for any other reason, compensatory damages are regarded by the court to be inadequate. The amount of any additional damages is not limited by statute. Current case law suggests that additional damages will not be available if the patentee chooses to obtain an account of profits from the infringer.

26. How readily are final injunctions granted in patent litigation proceedings?

A final injunction is granted in a significant majority of cases in which infringement of one or more valid claims of an Australian patent has been established. Nevertheless, a final injunction is a discretionary remedy and the Court will have regard to all of the relevant circumstances in deciding whether injunctive relief is appropriate. The question of whether a final injunction should be refused on discretionary grounds has arisen particularly in pharmaceutical cases where the asserted patent claims are directed to a second (or subsequent) medical use, the medicine in question has substantial non-infringing use and there is no practical means of framing an injunction to ensure that it does not interfere with such non-infringing use. In at least two relatively recent cases where such circumstances have arisen, the Court indicated that, had the relevant patent claims been held valid and infringed, it may have declined to grant a final injunction (although other remedies would have remained available).

27. Are there provisions for obtaining declaratory relief, and if so, what are the legal and procedural requirements for obtaining such relief?

Declaratory relief is routinely granted where one or more valid claims of an Australian patent are held to have been infringed. Other than specifying that a declaration is sought in the originating application by which the infringement proceeding is commenced, there are no special procedural requirements for obtaining such relief. Non-infringement declarations are also available and protect against liability for damages or an account of profits even where the non-infringement declaration is

later revoked. There is currently no precedent in Australia for grant of an 'Arrow declaration' as granted by the UK Courts, however, the Federal Court of Australia has a general power to grant declarations and there may be scope to argue for relief of this type if a suitable case arises in the future.

28. What are the costs typically incurred by each party to patent litigation proceedings at first instance? What are the typical costs of an appeal at each appellate level?

Costs vary markedly depending on the nature and scope of patent proceedings and only very general guidance can be given. At the lower end of the scale, except in the simplest of cases, the costs of conducting a first instance patent proceeding through to the conclusion of trial are unlikely to be less than AU\$500,000. First instance costs in the range of AU\$1-5 million are common. Costs may be substantially higher in very large and complex disputes between multinationals. In most cases, costs on appeal are considerably lower than costs at first instance, in part because it is unusual for new evidence to be permitted at the appeal stage.

29. Can the successful party to a patent litigation action recover its costs?

The successful party in Australian patent litigation is generally entitled to an award of costs. Generally speaking, the amount awarded in costs represents around 50-70% of the actual costs incurred by the successful party. Formal offers of compromise compliant with the Federal Court Rules have specific costs consequences. In addition, less formal 'Calderbank' letters of settlement may be taken into account by the Court as a discretionary matter relevant to any award of costs. Security for costs may be sought in appropriate circumstances, particularly where an applicant does not appear to have sufficient assets to meet any costs award, or has few assets located within the Court's jurisdiction (i.e., within Australia).

30. What are the biggest patent litigation growth areas in your jurisdiction in terms of industry sector?

Mining: This is among the biggest industries in Australia. During the past decade there has been a significant increase in the number of patent cases between suppliers to mining companies, many of which go through to trial. Computer-implemented inventions: The patent-eligibility

of computer-implemented methods has proven controversial in Australia and in recent years this issue has generated considerable litigation. Biologics, biosimilars and other novel therapeutics: There has been a steady growth in the number of Australian patent cases relating to biologics and other novel therapeutics in recent years.

31. How has or will the Unified Patent Court impact patent litigation in your jurisdiction?

Australian patents are not subject to the Unified Patent Court (UPC), but European patent law is increasingly influential to Australian patent decisions. In particular, the "raised bar" law of support and sufficiency in Australia was introduced from 15 April 2013 with the express intention of Australian Parliament to align Australia's law on the written description requirements for patent specifications more closely with those of Europe. Accordingly, decisions of the UPC relating to sufficiency, in particular, may become influential in Australian patent jurisprudence in due course. More indirectly, European patentees frequently file their patent applications as national phase applications in Australia and it can therefore reasonably be expected that UPC influences on the drafting and prosecution of specifications and claims will flow through to a significant number of Australian patent applications with European origins or counterparts.

32. What do you predict will be the most contentious patent litigation issues in your jurisdiction over the next twelve months?

The availability and scope of injunctive relief for infringement of second-medical use patents remains a controversial issue in Australian patent law. Further decisions on this issue can be expected over the coming years. The scope of patent-eligibility of computer-implemented methods also remains controversial and is likely to be subject of further consideration by the Courts. The High Court also considered in 2024 the question of a claim by the Commonwealth government to damages arising from an undertaking as to damages on an interim injunction granted in a pharmaceutical patent case, where the relevant patent was ultimately found invalid, and judgment is pending.

33. Which aspects of patent litigation, either substantive or procedural, are most in need of reform in your jurisdiction?

Ensuring appropriate limits on discovery, which can prove one of the most time-consuming and expensive aspects of patent litigation.

34. What are the biggest challenges and opportunities confronting the international patent system?

A major challenge is the multiplication of litigation costs where proceedings on corresponding patents are conducted in multiple jurisdictions. A major opportunity is for centralised or regionalised enforcement and revocation of granted patents, as now implemented in the Unified Patent Court, a model that could be emulated in other parts of the world.

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