

**International
Comparative
Legal Guides**



Practical cross-border insights into patent law

**Patents
2022**

12th Edition

Contributing Editor:
Katharine Stephens
Bird & Bird LLP

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1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

Both the Federal Court of Australia (**Federal Court**) and the state and territory Supreme Courts have jurisdiction to hear patent infringement matters.

Such proceedings are typically brought in the Federal Court. This is because the Federal Court has numerous judges with extensive patent (and other IP) expertise who are allocated to hear these matters.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

Parties are not required to mediate before commencing proceedings. However, the *Civil Dispute Resolution Act 2011* (Cth) requires the legal representative for the party issuing the proceeding to sign and file a genuine steps statement that sets out the steps that have been taken to try and resolve the matter before issuing proceedings.

In the course of the proceeding, the Federal Court will consider options for alternative dispute resolution, including mediation, as early as reasonably practicable, and it may order the parties to mediate. Mediation is more common than arbitration, unless the dispute is governed by a contract mandating that arbitration be undertaken before or *in lieu* of Court litigation.

1.3 Who is permitted to represent parties to a patent dispute in court?

In the Federal Court, parties in patent proceedings are represented by barristers and solicitors.

In Australia, patent attorneys are a separate profession and have a right of audience in the Australian Patent Office, but cannot appear in Court.

Litigants can self-represent, but a corporation must be represented by a legal practitioner unless leave of the Court is given.

1.4 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

To commence proceedings in the Federal Court, a party must

file an originating application. An originating application will be accompanied by a statement of claim and a genuine steps statement in accordance with the *Federal Court Rules 2011* (Cth) (**FCRs**).

The fees to file an originating application are prescribed in Schedule 1 of the *Federal Court and Federal Circuit Court Regulation 2012*. As of 1 July 2020, the fee for filing an originating application for a corporation is AUD 4,190.

The period of time that elapses between the filing of the originating application and the final trial depends on the complexity of the proceedings – for example, whether the applicant seeks to amend the patent(s), the number of patents asserted, whether experiments need to be carried out, and how long evidence preparation takes.

Generally, parties should allow anywhere between 12 and 18 months before the final trial on infringement.

1.5 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

The FCRs provide several mechanisms for disclosure of documents both before and after the commencement of proceedings.

Before commencement

A party that believes it may have the right to obtain relief against a party, but does not have sufficient information to decide whether to start a proceeding, can seek an order for “preliminary discovery” of documents from the other party.

After commencement

The FCRs also provide mechanisms to obtain “standard” and “non-standard” discovery of documents after the commencement of a proceeding.

Orders for discovery after commencement are not made as a matter of course and a party must only seek discovery (whether “standard” or “non-standard”) if it will facilitate the just resolution of the proceeding as quickly, inexpensively and efficiently as possible.

Other mechanisms

A party to a proceeding can use a **Notice to Produce**, which requires the other party to the proceeding to produce any document or thing within the party's control at the trial.

1.6 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

There are numerous steps a party must take in the lead-up to trial.

The Federal Court Practice Note, “Intellectual Property Practice Note (IP-1)”, provides some examples of special steps that may be ordered to be undertaken in patent matters. For example, the Court may order that the parties file an agreed technical primer to assist in explaining the technical background to the invention claimed in the patent in suit.

The first step in the proceeding is the pleading of each party’s case (a statement of claim, a defence and any cross-claim, defence to cross-claim and replies).

After the close of pleadings, evidence will be led by both parties.

Evidence relied on for both infringement and revocation will invariably include expert technical evidence.

In the immediate lead-up to the trial, a case management conference will occur before the judge. At the case management conference, the judge will set a timetable for the filing of submissions, objections to evidence, Court book preparation and other requirements the judge may have in preparing the matter for trial. This may include orders regarding a timetable for competing experts to confer prior to the trial and for expert evidence to be given concurrently at trial.

1.7 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

At the trial, the parties’ arguments are made by both written and oral submissions.

As to the parties’ evidence, the affidavit evidence upon which a party intends to rely will be formally “read” by the party relying on the evidence and admitted into evidence. A person that has given evidence in an affidavit form may be required for cross-examination by the other party.

In terms of seeking amendments to a pleaded case, the Court is generally receptive to applications for amendment (but may award costs or vacate orders because of the amendment). The FCRs provide that:

- a party must seek leave from the Court to amend its originating application both before and at trial;
- a party may amend a pleading once without leave of the Court at any time before pleadings close; and
- after pleadings close (as well as during the trial), any amendment is only by leave of the Court or with the consent of the opposing party.

1.8 How long does the trial generally last and how long is it before a judgment is made available?

The length of a trial will depend on the complexity of the issues before the Court. On average, trials concerning one patent can run from anywhere between five and 15 days.

Judgment can be anticipated some six to 12 months after the end of the trial.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

Parties are able to seek an expedited or truncated hearing process and a tailored or concise pleading process in any proceeding. Whether a proceeding will be expedited will depend on whether the Court is of the view that there are circumstances that make the matter appropriate to be determined expeditiously.

A party should make known its request for an expedited procedure and hearing at the time of filing an originating application. A party should otherwise make its request for an informal or abbreviated pleadings process known as the first case management hearing.

The impact on overall timing will depend on the complexity of the proceeding. It is unlikely that a patent proceeding would be finalised in under three months if expedition is ordered.

1.10 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

Judgments are made publicly available online in Australia, typically within 24 hours of being handed down by the judge.

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

The doctrine of precedent is central to the Australian judicial system. Australian Courts are bound to follow the *ratio decidendi* (reasons for the decision) of superior Australian Courts, and will not depart from decisions of the same Court without good reason.

Older decisions from the United Kingdom may be persuasive (Australian patent law has departed from UK patent law), but they are not binding. Decisions of European and US Courts are of interest, but are less persuasive. See: *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41 for an example of this consideration.

1.12 Are there specialist judges or hearing officers, and if so, do they have a technical background?

There are currently 16 judges in the Federal Court’s Intellectual Property National Practice Area – Patents & Associated Statutes, who can be assigned to patent cases.

There is no requirement for these judges to have a technical background, though some of them do.

1.13 What interest must a party have to bring (i) infringement, (ii) revocation, and (iii) declaratory proceedings?

■ Infringement

Only the patentee and the exclusive licensee can bring infringement proceedings.

The exclusive licensee is defined in the *Patents Act 1990* (Cth) (*Patents Act*) as the licensee that has the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons.

■ Revocation

Any person has standing to bring an application to either the Federal Court or state and territory Courts for an order revoking the patent.

A defendant in any infringement proceedings may also cross-claim for revocation.

■ Declaratory proceedings

A person can apply to the Federal Court for a declaration that an act does not or would not infringe a patent, whether or not the patentee has made an assertion that the doing of the act would infringe a claim.

The person cannot apply to the Federal Court for a declaration unless the patentee has refused or failed to make a written admission of non-infringement.

The person must have given the patentee full written particulars of the act and asked the patentee in writing for a written admission that the doing of the act does not or would not infringe the patent. The person must also undertake to pay the patentee's reasonable costs of obtaining advice as to whether the act has or would infringe the claim. The patentee must be joined as a respondent in the proceeding.

1.14 If declarations are available, can they (i) address non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

Yes. Non-infringement declarations can be sought in relation to technical standards and hypothetical activity.

1.15 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of, but not all of, the infringing product or process?

In Australia, a party can be liable for "indirect" or "contributory" infringement of a patent.

The Patents Act (section 117) provides that if the use of the product by a person would infringe a patent, then the supply of that product by one person to another is an infringement of the patent by the supplier, unless the supplier is the patentee or licensee.

1.16 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes. A person can be liable for infringement of an Australian process patent by importing a product into Australia made by the patented process outside of Australia because the acts of importation and sale occur in Australia. See: *Apotex Pty Ltd v Warner-Lambert Company LLC* (No 2) [2016] FCA 1238.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

Australia does not have a doctrine of non-literal equivalents. It can be argued that integers are inessential and need not be present for an infringement finding, but this is rarely successful.

1.18 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

A respondent can assert in infringement proceedings, in response to an allegation of patent infringement, that it has not infringed the patent because the patent is invalid and should be revoked. This claim does not arise in relation to a patent application (i.e., a patent application under opposition).

In this regard, in any proceedings for infringement, the alleged infringer can counter-claim for revocation of the patent, including on the basis that the patent is not a patentable invention.

Issues of validity and infringement are usually heard in the same proceeding. However, a Court may consider issues of infringement before issues relating to validity in appropriate circumstances, or the Court may consider it appropriate to hear issues of validity and infringement concurrently.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the "Formstein defence")?

No; there is no such defence under Australian patent law as there is no doctrine of equivalence.

1.20 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

In proceedings in the Federal Court, other than lack of novelty and inventive step, the validity of a patent may be challenged on the grounds that:

- the invention has been secretly used in the patent area;
- the patentee is not entitled to the patent;
- it is not a manner of manufacture;
- it is not useful;
- the patent was obtained by fraud, false suggestion or misrepresentation; and
- the specification does not comply with section 40(2) and (3) of the Patents Act, being internal support, "best method" and clarity requirements.

1.21 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

Court proceedings are the superior proceedings, so no procedure can take place in the Australian Patent Office if there are pending Court proceedings.

If two separate proceedings concerning the patent are ongoing, a party may seek to have the matters listed together, but there is no rule that a revocation claim be determined before parallel infringement proceedings.

1.22 What other grounds of defence can be raised in addition to non-infringement or invalidity?

Australian patent law includes these specific exemptions to infringement:

- immediately before the priority date of the claim, the person was already exploiting, or had taken definitive steps (contractually or otherwise) to exploit the product, method or process in Australia;
- use of a patented invention occurred on board or in a foreign vessel, and the vessel came into Australian territory only temporarily or accidentally;
- use of a patented invention occurred in the construction or working of a foreign aircraft or land vehicle if the aircraft or land vehicle came into Australian territory only temporarily or accidentally;

- exploitation was connected with obtaining regulatory approval in Australia; and
- an act was done for experimental purposes relating to the subject matter of the invention.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

Preliminary injunctions

Preliminary injunctions are available on an *ex parte* and *inter partes* basis.

In deciding whether to grant a preliminary injunction against an alleged infringer, the Court will make two enquiries:

- does the patentee have a *prima facie* case (there is a probability that the patentee will succeed at final hearing); and
- does the balance of convenience favour the granting of the injunction (this involves an assessment of the harm to the applicant and prejudice to the respondent in ordering the injunction, and whether damages are likely to be an adequate remedy if the applicant is successful at the final hearing).

There is no requirement for a bond. Rather, the patentee will have to give the “usual undertaking as to damages”; that is, it undertakes to the Court to submit to any order the Court may consider to be just for the payment of compensation to any person affected by the operation of the injunction.

If the person in whose favour the preliminary injunction is granted is resident overseas and has no assets in Australia, or is otherwise unlikely to be able to satisfy a call on the undertaking as to damages, the Court may require that person to provide security for the undertaking as to damages.

Final injunctions

Relief that a Court may grant for infringement of a patent includes an injunction, subject to such terms that the Court thinks fit.

Public interest defence

Australian Courts have not dealt with this issue. The final form of the injunction is a matter within the Federal Court’s discretion, and it is likely that public interest can be a factor for consideration. There is *obiter dicta* in recent Federal Court cases that if infringement had been found in respect of a method of treatment patent that an injunction against all supply of that product that would encompass non-infringing uses would not be an appropriate remedy (e.g., *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* (No 4) [2015] FCA 634).

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive damages available?

It is typical for an order to be made that the issue of liability for infringement/validity be heard prior to and separately from determination of any damages/account of profits.

Damages are compensatory in nature and so the assessment is made on the basis of the actual loss suffered by the patentee.

The analysis will require the Court to determine what proportion of the infringer’s sales would have been sales of the patentee or the exclusive licensee, and then determine the profit that would have been made by reason of the sales.

Additional (punitive) damages can also be awarded, but this provision is rarely applied, with the most award of additional damages overturned on appeal: see *Oxworks Trading Pty Ltd v Gram Engineering Pty Ltd* [2019] FCAFC 240.

An award of additional damages may be appropriate, having regard to:

- the flagrancy of the infringement;
- the need to deter similar infringements;
- the conduct of the infringing party, including after it was informed that it had allegedly infringed;
- any benefit accrued to the infringer because of the infringement; and
- any other relevant matters.

Profits are assessed by calculation of the profit earned by the infringer by reason of the conduct. This is a forensic accounting exercise.

1.25 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

Enforcement of a judgment or orders in the Federal Court are ordinarily an *ex parte* procedure that commences with the filing of a Request for Enforcement and supporting documentation. A registrar will consider the Request for Enforcement, and if satisfied, issue the enforcement process, which is then handled by the Sheriff’s office.

The methods of enforcement include:

- warrants for the seizure and sale of property;
- order for possession or delivery of goods; and
- an enforcement hearing.

An application may also be made for contempt. This is a broad power of the Court, and includes the power to fine and imprison.

1.26 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

Other relief that a Court may grant for infringement of a patent includes declarations of infringement. Cross-border relief will not be ordered.

1.27 How common is settlement of infringement proceedings prior to trial?

Settlement prior to trial is common – it is estimated to occur in 50% of cases.

1.28 After what period is a claim for patent infringement time-barred?

Infringement proceedings cannot be brought unless started within:

- three years from the day on which the relevant patent is granted; or
- six years from the day on which the infringing act was done,

whichever period ends later.

1.29 Is there a right of appeal from a first instance judgment, and if so, is it a right to contest all aspects of the judgment?

A party can appeal judgment of a single judge of the Federal Court to the Full Federal Court of Australia. An appeal is of right in respect of any aspects of the judgment but will only succeed if the Full Federal Court finds that the judge at first instance made an error of law.

1.30 What effect does an appeal have on the award of: (i) an injunction; (ii) an enquiry as to damages or an account of profits; or (iii) an order that a patent be revoked?

The filing of an appeal has no automatic effect on the award of: (i) an injunction; (ii) an enquiry as to damages or account of profits; or (iii) an order that a patent be revoked.

A party would have to seek a stay of any such order, pending the outcome of the appeal. Stay orders are made at the Court's discretion, and only in circumstances where the Court is satisfied that the appeal has some merit, having regard to potential prejudice that might be suffered by the parties as the result of the granting or refusal of the stay.

1.31 Is an appeal by way of a review or a rehearing? Can new evidence be adduced on appeal?

An appeal is not a rehearing. It is limited to the issues raised on appeal, and is confined to written and oral submissions. The Court will not consider new evidence or any argument that was not made before the Court below except in exceptional circumstances.

1.32 How long does it usually take for an appeal to be heard?

Between four and six months.

1.33 How many levels of appeal are there? Is there a right to a second level of appeal? How often in practice is there a second level of appeal in patent cases?

An appeal from a single judge of the Federal Court is to a Full Court of the Federal Court (either three or five judges). From a decision of the Full Court, a party can seek leave to appeal to the High Court of Australia. A case will only be granted special leave if it raises a new point of law, or a matter of public importance. Less than 10% of all cases that seek leave are granted special leave to appeal to the High Court of Australia. The most recent patent case to be granted leave to appeal to the High Court of Australia was *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41 in relation to the doctrine of exhaustion.

1.34 What are the typical costs of proceedings to a first instance judgment on: (i) infringement; and (ii) validity? How much of such costs are recoverable from the losing party? What are the typical costs of an appeal and are they recoverable?

The range of expected costs in running/defending an infringement case or running/defending a combined infringement and revocation case ranges between AUD 700,000 and

AUD 2.5 million. The successful party would anticipate recovering between 55% and 75% of its costs from the unsuccessful party.

On appeal, typical costs range from AUD 150,000–300,000 depending on the number of issues raised on appeal. The successful party would anticipate recovering between 60% and 75% of its costs.

2 Patent Amendment

2.1 Can a patent be amended *ex parte* after grant, and if so, how?

A patentee may seek the leave of the Commissioner of Patents to amend a patent after grant (section 104 of the Patents Act) or during infringement proceedings with leave of the Court – see question 2.2.

2.2 Can a patent be amended in *inter partes* revocation/invalidity proceedings?

Yes, a patentee may make an application to a Court during any relevant proceedings for an order that the patent be amended (section 105 of the Patents Act).

2.3 Are there any constraints upon the amendments that may be made?

An amendment must meet the requirements in section 102 of the Patents Act – an amendment is not allowable if the amended specification claims or discloses matter extending beyond the complete specification as filed.

If the application to amend is made to the Court during proceedings, then the Court must also be satisfied that there is no matter that should dissuade the Court from exercising its discretion to allow the amendment (e.g., delay by the patentee in seeking amendment after knowing that it should so amend; covetous claiming).

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

A term of a patent licence may be void in certain circumstances (section 144 of the Patents Act), including where the effect of a term is to:

- prohibit or restrict the use of a product or process (whether patented or not) supplied or owned by a person other than the lessor or licensor; or
- require the acquisition of a product not protected by the patent, lessor or licensor.

3.2 Can a patent be the subject of a compulsory licence, and if so, how are the terms settled and how common is this type of licence?

After a period of three years from when the grant has elapsed, a person may apply to the Federal Court for an order requiring the patentee to grant the applicant a licence to work the patented invention (section 133 of the Patents Act). If the fee is not agreed, the Court sets the fee.

Very few compulsory licences have been ordered.

4 Patent Term Extension

4.1 Can the term of a patent be extended, and if so, (i) on what grounds, and (ii) for how long?

The term of a patent relating to a pharmaceutical substance can be extended if regulatory approval was not obtained until at least five years after the date of the patent.

The extension period is the difference of the time period from the filing date of the patent to the first regulatory approval date – this should take less than five years.

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable, and if not, what types are excluded?

Not all subject matter is patentable, for example:

- Human beings and processes for their biological generation are not patentable (section 18(3) of the Patents Act).
- Pure business processes are not patentable subject matter, even if they are computer-implemented: *Commissioner of Patents v RPL Central Pty Ltd* [2015] FCAFC 177; *Encompass Corporation Pty Ltd v InfoTrack Pty Ltd* [2019] FCAFC 161; and *Commissioner of Patents v Rokt Pte Ltd* [2020] FCAFC 86.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

There is no such duty.

5.3 May the grant of a patent by the Patent Office be opposed by a third party, and if so, when can this be done?

A third party has three months after the patent application has been advertised as accepted by the Patent Office to oppose the grant of the patent by filing a notice of opposition and a statement of grounds.

5.4 Is there a right of appeal from a decision of the Patent Office, and if so, to whom?

There is a right of appeal under the Patents Act from a decision of the Patent Office to the Federal Court from:

- a refusal to grant a patent (section 100A);
- an opposition decision (section 60);
- a decision to revoke after re-examination (section 101); and
- refusal or grant of, or direction to make, an amendment (sections 104 and 109).

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

Disputes over ownership can be resolved in the Patent Office (section 32 of the Patents Act), or by the grant of the patent after an opposition in the Patent Office (section 33 of the Patents Act) or by application to the Court.

5.6 Is there a “grace period” in your jurisdiction, and if so, how long is it?

Yes – there is a grace period of 12 months.

5.7 What is the term of a patent?

A standard patent has a maximum term of 20 years (or up to 25 years for pharmaceutical substances). An innovation patent has a term of up to eight years (innovation patents are in the process of being phased out, and cannot be filed after 25 August 2021).

5.8 Is double patenting allowed?

No, it is not (section 64(2) of the Patents Act for standard patents and section 101B(2)(h) for innovation patents).

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products, and if so, how quickly are such measures resolved?

There is no such mechanism.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

The *Competition & Consumer Act 2010* (Cth) (CCA) can be deployed against a patentee. This was argued in *Apple v Samsung*, but whilst the case proceeded to concluded trial, the case settled before judgment.

7.2 What limitations are put on patent licensing due to antitrust law?

The licensing, assignment and other contractual arrangements in relation to IP rights are the subject of the same competition laws as other commercial transactions.

The following are examples of the type of conduct prohibited under the CCA that may arise in relation to patent licensing:

- (a) cartel conduct;
- (b) the making or giving effect to agreements, arrangements or understandings that have the purpose, effect or likely effect of substantially lessening competition in a market; and
- (c) engaging in the practice of exclusive dealing.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts set FRAND terms (or would they do so in principle)? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

There is potential for patent validity and infringement matters to be heard separately in all proceedings relating to FRAND

licences. However, the case of *Apple v Samsung*, which ran over a large number of Court hearing days, did not separate the issues.

There are no injunction decisions or any delivered judgments on SEPs in Australia or FRAND terms, but in principle, there is no reason why the Australian Courts would not grant a FRAND injunction or set FRAND terms. It is expected that the *Unwired Planet* decision will be influential on Australian Courts.

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

- The High Court of Australia endorsed the “exhaustion of rights” principle, confirming that all exclusive rights of a patentee (use, sell, dispose of, etc., and other than the right to make the patented article) are exhausted at the time of sale of the product that embodies that patent when it is sold without conditions as to use: *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41.
- A five-member bench of the Full Federal Court of Australia has:
 - (i) found that a hypothesis published in a clinical trial protocol was sufficient enough to destroy the novelty of Swiss-style claims – it was not relevant that the hypothesis had not been tested, the question is simply whether the invention had been published; and
 - (ii) clarified the infringement position of Swiss-style claims and skinny labelling, saying that “infringement of a Swiss-type claim is concerned with what the allegedly infringing manufacturer has done, not what it intended to do”. The most important consideration is “the physical characteristics of the medication as it emerges as a product of the manufacturing process, including its formulation and dosage, packaging and labelling, and its patient information”. In finding that the relevant product did not infringe, the Court referred to the PI, which states the indications for which the product is registered, and inferentially, the therapeutic purpose (which did not include the patented use).
See: *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* [2020] FCAFC 116.
- For the first time, the Federal Court considered the more stringent requirement of section 40(3) of the Patents Act (introduced by the *Raising the Bar Act 2012* (Cth)), that claims must be “clear and succinct and supported by matter disclosed in the specification”, and found that a claim to a composition comprising various serotypes conjugated to a specified carrier protein lacked support because “comprising” is to be construed inclusively, and there was

no disclosure of any additional serotypes to the carrier protein (which would be a difficult process). As such, the claim lacked support: *Merck Sharp & Dohme Corporation v Wyeth LLC* (No 3) [2020] FCA 1477.

- In the first decision of its kind, the Federal Court dismissed a claim by the Commonwealth Government for AUD 325 million in compensation on an undertaking as to damages when a generic was enjoined from launching on the Pharmaceutical Benefits Scheme (PBS) (which would have caused a statutory price drop in the originator product). Nicholas J accepted that the Commonwealth was entitled to make such a claim, but he was not satisfied that the generic (absent the interlocutory injunction) would have applied for PBS listing notwithstanding the risk of damages for patent infringement: *Commonwealth of Australia v Sanofi* (No 5) [2020] FCA 543.

8.2 Are there any significant developments expected in the next year?

The innovation system will be phased out. From 26 August 2021, no new innovation patent applications can be filed, other than divisional applications based on applications filed on or before 25 August 2021.

8.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There appears to be a growing trend of refusal or consideration of refusal by the Courts of preliminary injunctions (driven by the complexity of determination of compensation under the usual undertaking as to damages when a patent is revoked after a preliminary injunction was granted). There is also a developing groundswell of reluctance to grant blanket restraint against supply where there is more than one possible manner of use of the product in suit (e.g., second medical uses). It is possible that this is depressing the number of preliminary injunction applications being sought in the pharma field. See: discussion in *F.Hoffman La Roche AG v Sandoz* [2018] FCA 874 for a discussion of these factors.

Another growing trend is the almost as of right availability of preaction discovery – since the *Pfizer v Samsung Bioepis AU* decision, provided the applicant has a subjective belief in the availability of a potential cause of action, discovery is ordered as of right. Compare, however, *Pfizer Ireland Pharmaceuticals v Sandoz Pty Ltd* [2020] FCA 1648 where discovery was refused when the respondent had already provided an undertaking not to deal in an alleged infringing product, but preliminary discovery application was brought.



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