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This Biotechnology Intellectual Property Management Manual is intended to provide a practical guide to the identification, protection and management of biotechnology related intellectual property (IP), thereby assisting in maximising the benefits gained from investment in research. The Manual is divided into nine main chapters which outline all aspects of the IP management process from conception of an idea through to its protection and subsequent successful commercialisation.

Chapter 1: Why is Intellectual Property important to your Organisation?
Describes the importance of IP to stakeholders in the biotechnology industry.

Chapter 2: What everyone should know
Provides a basic introduction to intellectual property and the various forms by which it may be protected.

Chapter 3: What the board and CEO must know
Describes the development and implementation of an IP strategy suitable for your organisation and the manner in which IP may be leveraged for capital raising.

Chapter 4: What researchers must know
Describes the importance of identifying IP at the research planning and implementation stage to reduce the risk of infringement and maximise the potential outcomes.

Chapter 5: What managers making IP protection decisions must know
Describes how to identify the different types of IP that arise and how best to put in place effective protection of that IP.

Chapter 6: What senior management must know
Describes how IP policy is integrated into the culture of the organisation, the necessity to ensure appropriate contractual arrangements with staff and external providers, as well as IP audits and valuations.

Chapter 7: What must be known about IP commercialisation
Provides guidance to assist decision-making on various issues of IP commercialisation, such as whether the IP is ready for commercialisation and, if so, under what commercialisation structure, as well as risks of IP commercialisation.

Chapter 8: What must be known about enforcing and defending your IP rights
Discusses issues that should be considered before commencing enforcement procedures, the defence of IP infringement allegations and provides an introduction to the types of IP insurances.

Chapter 9: Where can I find out more about IP
Provides a collection of useful references.

Advice should be sought
This manual aims to provide an additional resource to be used in conjunction with existing IP management policies and practices of research institutions, companies and research funders. At all times, it is imperative that users of this Manual seek advice from IP professionals including their relevant IP officer, commercialisation body, patent attorney or legal advisors prior to taking any action that may affect IP rights.

Appendices, an index and a glossary of abbreviations, key terms and acronyms which may be new to the reader are provided at the end of the Manual.
Biotechnology is a strategic and fast growing industry in Australia and across the world. In 2008, Australia is home to over 400 biotech firms with total annual revenues of over $3 billion. By 2010, Victoria aims to be among the top five locations for biotechnology worldwide.

Victoria is a national leader in science, technology and innovation. Our achievements have been driven by the skills and expertise of specialist researchers in areas such as infectious diseases, stem cells, neuroscience, cancer and dairy innovation. These researchers are supported by strong government investments in projects and infrastructure, and by a legislative framework that provides certainty and opportunity.

The Victorian Government, through its investment in innovation initiatives have assembled the necessary foundations for the growth of the biotechnology sector. The establishment of key infrastructure and support services such as the BIO21 cluster and the Australian Synchrotron are vital to this continued growth.

Building on these strengths, the Brumby Government has recently released a new innovation statement, Innovation: Victoria’s Future which clearly focuses on innovative businesses as the value drivers for sustained economic growth and skills development in Victoria in to the future. The statement dedicates $300 million in new funding to innovation-related initiatives, bringing Victoria’s total investment to over $3.39 billion since 1999.

Generating knowledge is only part of the equation. A truly innovative economy is one that is able to manage and apply knowledge effectively. The Victorian Government has taken a strategic approach to boosting the State’s capacity to turn knowledge and ideas into commercial products, processes and services for the global marketplace.

Managing and Commercialising Intellectual Property – A Guide for Victorian Universities and Research Institutes was produced by the Victorian Government to assist universities and research institutes to effectively manage their intellectual property.

This Biotechnology Intellectual Property Manual is a guide for the management of intellectual property and is a valuable resource for all involved in the biotechnology sector.

You are vital to the development of new products and services that will deliver a healthy, sustainable and productive future for all Australians. I highly commend this Manual to you.

Gavin Jennings MLC
Minister for Innovation
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Why is Intellectual Property important to your Organisation?

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An incentive for innovation

Biotechnology – the exploitation of biological processes for industrial purposes – has been described as the "New Industrial Revolution". In the last 30 years, the biotechnology sector has experienced phenomenal growth throughout the world. Annual sales of biotechnology products in the United States alone have rocketed from virtually non-existent in 1980 to an estimated $55 billion in 2004.

In Australia, the aggregate market capitalisation of the top ten publicly listed biotech companies was over $22 billion in 2007. In the 2007/08 financial year, CSL Limited reported annual revenue of $167 million in royalty payments from the sale of the HPV vaccine GARDASIL™ alone, with a further $227 million of revenue generated from a successful immunisation programme in Australia.

In addition to the contribution to human and animal health, the impact of biotechnology in agriculture has been immense. The planting of genetically modified crops has increased 60-fold in the decade from the first commercialisation of biotech crops in 1996. In 2006 the number of countries planting biotech crops was 22, with the total value of biotech crops estimated to be over $6 billion. The United States is leading the way in terms of total and percentage area under biotech crops with transgenic cotton and soybean, for example, accounting for over 80% of the total respective crops.

Protecting Biotechnology innovation

Whilst the rewards from investing in biotechnological research may sound attractive, investment costs are often considerable. It has been estimated that in the United States, bringing a new drug to market may take some 10-12 years, at a cost of over $US400 to $800 million.

With so much investment at stake, it is imperative that the fruits of such investments are effectively protected and managed through a vigilant intellectual property strategy.

Intellectual property or IP refers to the rights granted by law for the results of creative efforts from the mind or intellect. The protection of IP provides an incentive for the biotechnology industry to invest time and money in research and development for biotechnology innovation – the driving force for the unprecedented benefits in the quality of human life that biotechnology is expected to bring. Such benefits may not be so forthcoming without the underlying profit motivation afforded by IP protection.

Effective IP management

Effective IP protection, management and exploitation are key to all sectors in the biotechnology industry.

In Australia, public sector research grants, such as those administered through the NH&MRC and the ARC, are major sources of funds for research and development in the biotechnology sector. It is essential that public and private sector researchers and technology managers have access to capabilities for managing and negotiating commercial arrangements for IP. It has been claimed that Australia has not derived adequate benefit from commercialisation of its research in the past and that Australian IP has been too frequently sold or licensed for commercialisation overseas, sometimes unnecessarily. In cases where overseas...
commercialisation is appropriate, it has been said that Australia has not always obtained the maximum possible benefit.

In recognition of the importance of ensuring appropriate protection of the outcomes of that research, national principles of IP management for publicly funded research have been developed with the intention “to improve the commercial outcomes from publicly funded research where a commercial outcome is appropriate.” The principles are aimed at assisting “researchers, research managers, and their research institutions, in ensuring that they have access to best practises for the identification, protection, and management of IP.”

In a similar vein, the Australian Government has explicitly recognised that IP created within government is a major potential source of value to the economy and the community by issuing the Statement of IP Principles, which form the basis for a whole of government approach for the management of IP, including its protection and commercialisation.

Needless to say, IP is often the principal or even the sole asset of a biotechnology company in the private sector.

Whilst principles of IP management have been formulated and published, detailed guidance on how best to put those principles into practice is often lacking. This Biotechnology IP Management Manual is intended to fill that gap by assisting all sectors to effectively and efficiently manage this most important resource and to maximise its potential benefits to society.
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What this Chapter covers

Intellectual property (IP) plays an essential role in driving innovation by providing a basis for return on investment in research and development. This is particularly the case where technology advances rapidly but where returns on investment may be slow, such as in the Biotechnology industry. Everyone involved in a technology-based industry should have a basic understanding of the different types of IP and the rights granted by them.

This Chapter explains the concept of IP in the legal context and gives a brief introduction to the different types of IP, including:

- what can be protected
- how long the IP lasts, and
- what rights the IP provides.

A general understanding of the different types of IP and its protection will aid your understanding of the later chapters of this Manual.

What is Intellectual Property?

IP is an umbrella term used to describe the results of creative efforts from the mind or intellect. The Convention Establishing the World Intellectual Property Organisation 1967 (WIPO) defines IP as “rights relating to:

- literary, artistic and scientific works
- performances of performing artists, phonograms and broadcasts
- inventions in all fields of human endeavour
- scientific discoveries
- industrial designs
- trade marks, services marks and commercial names and designations
- protection against unfair competition, and
- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.”

IP law protects creators of IP by granting to them legal rights to control the use of their IP for a certain time. These rights are not given for the physical creation of the objects but for the intellectual efforts applied to such creation. IP law and enforcement is generally similar in nature from country to country but will vary in points of detail.

Forms of Intellectual Property

IP takes a number of different forms, each with its own specific manner of protection. Different forms of IP arise in different subject matter; however, the same subject matter may attract more than one form of protection.

The diagram below illustrates seven different forms of IP and gives examples of subject matter that may be protected by them. All forms of IP, with the exception of Circuit Layout Information (which will not be discussed in detail in this Manual), will be of relevance to the Biotech industry and other technology-based industries.
Patents

What is a patent?
A patent is the right granted by the government of a country to the patent owner allowing the patent owner to exclude others from commercially exploiting an invention within that country.

In Australia, the Patents Act 1990 (Cth) (‘Patents Act’) is the primary source of patent law.

What can be protected by a patent?
A patent may be granted for any invention (which may be a device, substance, method or process) which satisfies various requirements. The invention does not need to be ‘pioneering’ – an improvement or variation over what already exists may be patentable. It is sometimes said that only a ‘scintilla’ of inventiveness is required.

A patent may be granted for methods of treating human beings, including second indication.
uses of known compounds. Australia and the United States are among the few jurisdictions in which protection for a method of treatment or diagnosis of the human body is available. In many jurisdictions, including those where claims to the methods per se of treating human beings are not allowable, such as in Europe, New Zealand and Singapore, claims to the use of a compound for the manufacture of a medicament for the method are generally held to be allowable.

However, some subject matter can not be patented in Australia. This includes subject matter such as:

- a human being and biological processes for their creation
- inventions that are contrary to law
- inventions that are ‘generally inconvenient to the public’ and
- artistic creations.

**Required elements for patent grant**

The list below illustrates the requirements for patent grant in Australia. You should always remember that patents are granted on a country by country basis. Although patent requirements in different countries are similar, important differences do exist. This Manual refers primarily to patent requirements in Australia.

- ‘Manner of Manufacture’
- Novelty
- Inventive / Innovative Step
- Usefulness
- No Prior Secret Use

**Manner of manufacture**

To be patentable, an invention must be a ‘manner of manufacture’. Patent law largely leaves the determination of patentable subject matter to the Courts. As a general rule, an invention resulting from human activity (i.e. not naturally occurring) and which has commercial potential will typically be considered to be a manner of manufacture. On the other hand, discovery of a natural phenomenon (e.g. the law of gravity) will not satisfy this requirement of patentability.

Similarly, a mathematical formula describing a natural phenomenon is not a manner of manufacture, but a device utilising the mathematical formula, or an algorithm encoding the phenomenon, that produces a useful result is likely to be considered a manner of manufacture.

**Novelty**

To be patentable, an invention must be ‘novel’ or new; that is, the invention must not have been publicly disclosed in any form, anywhere in the world as at the date of the first filed patent application (referred to as the ‘priority date’).

Disclosure includes any form of public release of the invention (e.g. publishing details of the invention in a scientific journal, uploading a description of the invention on the internet, or selling or publicly using the invention) and any statements describing the invention in a public forum (e.g. presenting the invention at a trade fair or academic conference).

In Australia, the Patents Act provides specific ‘grace periods’ for certain types of disclosures (i.e. the invention may still be considered novel if the patent application is filed within a certain
Inventiveness or Innovativeness

To be granted a **standard patent**, an invention must involve an ‘inventive step’. This means that the invention must be more than an ‘obvious’ extension, variation or combination of prior public knowledge which could be brought about by a non-inventive person skilled in the field of the invention.

An ‘obvious’ invention is one which could have been arrived at by the inventor as a matter of course (e.g. thought to be worth a try with an expectation that it might provide a useful result) in light of the common general knowledge in the relevant field, either taken or considered also with existing technical information publicly available before the priority date, known as ‘prior art information’. For more information on inventive subject matter, see Chapter 4 ‘What Researchers Must Know’.

Similarly, to be granted an **innovation patent**, an invention must involve an ‘innovative step’. This means any variation between the invention and what is currently known about that technology must make a ‘substantial contribution’ to the working of the invention. This generally is believed to be a lower threshold than an inventive step.

For more information on standard patents and innovative patents, see the Section ‘Characteristics of a Standard Patent and Innovation Patent’ in this Chapter.

Utility

A patentable invention must be useful, i.e. the invention should achieve what you say it will. This ‘utility’ requirement is analogous to an invention being industrially applicable. Lack of utility arises rarely.

No prior secret use

To be patentable, the invention must not have been secretly used in Australia before the date of the application. Case law suggests that a “secret use” which invalidates a patent is a use which has a “taint of commerciality”. There are exceptions to what constitutes a “secret use”. These include:

- use for the purpose of reasonable experiment or trial
- use by a person under obligations of confidence for non-commercial reasons
- use by the inventor (or authorised person) for a purpose other than for trade or commerce
- use by a Commonwealth, State or Territory government to which the inventor (or authorised person) has disclosed the invention.

Other application requirements

There are other important application requirements of which you must be aware when applying for grant of a patent. Failure to comply with these requirements may result in the patent being held invalid by the Patent Office or a Court.
These include:

<table>
<thead>
<tr>
<th>Suficiency of Description</th>
<th>The description of the invention in the patent specification must be sufficiently detailed for a person skilled in the field to be able to make and use the invention.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair Basis</td>
<td>The invention as claimed must be supported by or be consistent with the detailed description provided in the specification.</td>
</tr>
<tr>
<td>Clarity of Claims</td>
<td>A claim must be clear and unambiguous so that its scope can be ascertained. This requirement is one of language.</td>
</tr>
<tr>
<td>Inventorship</td>
<td>The correct inventors must be named in the application.</td>
</tr>
</tbody>
</table>

For more information on these requirements, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

For more information on the different parts of a patent application (also referred to as a patent specification) and identifying the correct inventors, see Chapter 4 ‘What Researchers Must Know’.

**Do I need to apply for protection?**

Yes. You need apply to IP Australia (i.e. the Federal Government Patent Office) to obtain the grant of a patent. The different types of patent application that may be filed with IP Australia are described below. To obtain patent protection in other countries, the application processes for those countries will need to be followed. Filing in foreign countries may include PCT applications and/or Convention applications described below. For more information on the application process for standard and innovation patents, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

**Types of patent applications**

**Provisional application**

A provisional application does not need to include claims defining the invention but usually will do so. A provisional application generally is used to secure a priority date for the invention, and affords up to 12 months to decide whether to continue with the patenting process in Australia and elsewhere.

A provisional application will lapse after 12 months, and so if patent protection is to be pursued a complete application claiming the benefit of the provisional application must be filed within this period.

Importantly, in Australia a provisional application can serve as the basis for foreign patent protection (see PCT application and Convention application below). For this reason provisional specifications should be written to satisfy all requirements for grant in other countries. You should not consider that a provisional specification need only include sketchy details of how to put the invention into practice.
**Complete application**

A complete application can be for either a standard or an innovation patent and must be accompanied by a complete specification containing at least one claim defining the invention.

A complete application is examined by the Patent Office to determine if it satisfies the requirements for grant, and if so, usually leads to the grant of patent rights.

For more information on standard patents and innovation patents, see the Section 'Characteristics of a standard patent and an innovation patent' in this Chapter.

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**PCT application**

A Patent Cooperation Treaty (PCT) application (also known as an 'International patent application') allows you to apply for patent protection in a number of different countries through one international agency, provided that the countries are signatories to the Patent Cooperation Treaty.

The PCT application will need to be 'nationalised' to the different countries of interest before a relevant deadline so that the process of local examination and grant may proceed.

Separate applications are necessary in those countries of interest not signatories to the Patent Cooperation Treaty.

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**Convention application**

The Paris Convention provides a right of priority of up to 12 months in the member countries. This means an application can be filed in other countries within 12 months of the first Australian filing, and the priority date is retained for these other countries for the purposes of the assessment of novelty and inventive step.

The first application need not be filed in Australia. For example, there may be reasons to file the application in the United States first, and then in other countries (including Australia) within 12 months.

---

**Patent of addition**

A patent of addition may be filed to protect an improvement or modification that you have made to the 'main invention' of an earlier patent or patent application. The improvement or modification must be novel - but not necessarily inventive - over the earlier main invention.

---

**Divisional application**

If the earlier patent application described more than one invention, then one or more divisional applications may be used to separately protect the other inventions without loss of priority date. A divisional application may also be used to continue pursuing a patent application if it is not accepted within the relevant deadline.
Characteristics of a standard patent and an innovation patent

Set out below are the characteristics and the application requirements of a standard patent and innovation patent:

<table>
<thead>
<tr>
<th>Standard Patent</th>
<th>Innovation Patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum term of protection is 20 years (with a possible extension of up to 5 years for certain patents), provided official renewal fees are paid.</td>
<td>Maximum term of protection is 8 years, provided renewal fees are paid.</td>
</tr>
<tr>
<td>An unlimited number of claims may be included in the application, although significant additional official fees are incurred where there are more than 20 claims.</td>
<td>Up to 5 claims may be included in the application.</td>
</tr>
<tr>
<td>Examination of the substantive validity of the application is compulsory before grant.</td>
<td>Only an administrative formalities check is compulsory. Examination of the substantive validity of the innovation patent is optional.</td>
</tr>
<tr>
<td>Need to pass the ‘higher’ inventive step threshold.</td>
<td>Need to pass the ‘lower’ innovative step threshold.</td>
</tr>
<tr>
<td>Third parties may initiate pre-grant opposition.</td>
<td>Third parties may initiate post-certification opposition.</td>
</tr>
<tr>
<td>No further examination is required after grant before enforcing the patent.</td>
<td>The substantive validity of the patent must be examined (i.e. certified) before the patent can be enforced</td>
</tr>
<tr>
<td>Very similar types of patent may be obtained in other countries.</td>
<td>Applications can only be pursued in Australia, although broadly equivalent utility model protection is available in Japan, Germany and Spain, for example.</td>
</tr>
<tr>
<td>Animals and plants and methods for their generation are potentially patentable subject matter.</td>
<td>Animals and plants and methods for their generation are not patentable subject matter.</td>
</tr>
</tbody>
</table>

What exclusive rights will I receive for a patent?

Once a patent is registered, the Patents Act grants exclusive rights to the patent owner to prevent others from stockpiling, using, selling, manufacturing or importing the patented invention or offering or authorising another to do any of these things.

Anyone else will only be able to legally exploit the invention if they have authorisation from the patent owner.

It is the patent owner’s responsibility to enforce these rights.
When would I infringe a patent?

A patent is infringed when any of the granted exclusive rights are dealt with by an unauthorised user during the term of the patent. The exclusive rights of a patentee are to make, hire, sell or otherwise dispose of a product, or offer to do any of the above, or keep a product for the purpose of doing any of the above, or to use a method or process to do any act mentioned above in respect of a product.

Whether a patent has been infringed is a question of fact. It must be proved that the alleged infringer has done an act which involves each and every feature of at least one claim of the patent. The infringing act must have occurred after the date of publication of the patent application and enforcement proceedings must commence within 3 years from the day on which the relevant patent is granted; or within 6 years from the day on which the infringing act was done.

A patent may also be indirectly infringed. This may occur where a product has knowingly been supplied to a third party who will use it in a way that will infringe the patent. In this scenario, the supply of the product would constitute indirect or ‘contributory’ infringement.

Exemptions to Patent Infringement

There are exemptions to patent infringement under certain restricted circumstances. These include, for example, where a party has been secretly using an invention prior to the filing of a patent application by another for the invention, or where a third party exploits a patented pharmaceutical substance for purposes solely connected with obtaining regulatory authority approval in Australia or overseas for the pharmaceutical substance.

Copyright

What is copyright?

Copyright protects against unauthorised reproductions and public disseminations of an original work.

Copyright protects the particular expression of an idea – not the idea itself. Consequently, copyright does not prevent the use of the same idea, as long as the ‘expression’ of the idea is original.

‘Original’ does not mean the work needs to be particularly creative or ingenious. A work is ‘original’ where the work is created independently and skill, labour and judgment is applied to it.

In Australia, the Copyright Act 1968 (Cth) (‘Copyright Act’) governs the operation of copyright law.
What can be protected by copyright?

Copyright may exist in a range of creative, intellectual or artistic subject matter. There are eight primary categories of protected forms of expression:

<table>
<thead>
<tr>
<th>Category of work</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literary works</td>
<td>All written works, including reports, lyrics, poems, books, software, database</td>
</tr>
<tr>
<td>Artistic works</td>
<td>Photographs, drawings, paintings, sculptures, architecture, graphs, computer icons</td>
</tr>
<tr>
<td>Dramatic works</td>
<td>Plays, screenplays, choreographic works</td>
</tr>
<tr>
<td>Musical works</td>
<td>All works with written musical notation, including sheet music, operas.</td>
</tr>
<tr>
<td>Cinematographic works</td>
<td>All works generating moving images, including films, computer games.</td>
</tr>
<tr>
<td>Sound recordings</td>
<td>All works with recorded sound, including CDs, DVDs, mp3, podcasts</td>
</tr>
<tr>
<td>Broadcasts</td>
<td>Television and radio broadcasts</td>
</tr>
<tr>
<td>Published editions</td>
<td>Publisher’s typeface and layout of a published work</td>
</tr>
</tbody>
</table>

Do I need to apply for protection?

No. Copyright protection arises automatically on creation of the work, provided it is original. Through an international agreement, this protection extends to most countries in the world.

The term of copyright depends on the type of work that is protected, when it was made and whether it was published. Generally, protection lasts from the date of creation of the work to 70 years after the death of the creator.

What rights will I receive for copyright?

In a very broad sense, copyright protects the ‘right to copy’ an original work.

There are three bundles of rights granted to a copyright owner: economic rights, moral rights and performer’s rights.

Economic rights

These are exclusive rights granted to the copyright owner to prevent others from commercially exploiting the copyright protected work without authorisation. These rights may be transferred by assignment or licensed.

Economic rights vary between each type of copyright protected work and are described in the following table.
### Category of work

<table>
<thead>
<tr>
<th>Category of work</th>
<th>Economic rights granted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literary works</td>
<td>✅ Reproduction, ✅ Communication to the public, ✅ Publication, ✅ Performance in public, ✅ Making adaptations, ✅ Entering into commercial rental agreements</td>
</tr>
<tr>
<td>Artistic works</td>
<td>✅ Reproduction, ✅ Communication to the public, ✅ Publication</td>
</tr>
<tr>
<td>Sound recordings and cinematographic works</td>
<td>✅ Copy, ✅ Communication to the public, ✅ Cause to be seen or heard in public, ✅ Enter into commercial rental agreements (sound recordings only)</td>
</tr>
<tr>
<td>Broadcasts</td>
<td>✅ Make a film or television copy, ✅ Make a copy of the sound recording of the broadcast, ✅ Rebroadcast or communicate to the public</td>
</tr>
<tr>
<td>Published editions</td>
<td>✅ Make a facsimile copy of the published edition</td>
</tr>
</tbody>
</table>

### Moral rights

These are personal rights protecting the integrity and attribution of the creator which are summarised in the following table.

<table>
<thead>
<tr>
<th>Right of integrity</th>
<th>The right to not have the work subjected to derogatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right of attribution</td>
<td>The right to be identified with the work</td>
</tr>
<tr>
<td>Right against false attribution</td>
<td>The right to not have the work falsely credited to another person</td>
</tr>
</tbody>
</table>

Moral rights cannot be transferred by assignment or be licensed. However, they may be waived by written consent from the creator.

The consent must be genuinely given by the owner in writing and must specify the work(s) to which the consent relates, and the acts or omissions covered by the consent.

Moral rights may also be deemed to be waived if considered ‘reasonable’ in the circumstances. Factors deciding what is ‘reasonable’ include the nature and purpose of the work, industry practice in relation to the work, and whether the author made the work as an employee.

Remedies for breach of moral rights include injunction, damages, a declaration that moral rights have been infringed, an order for a public apology, or an order that any false attribution or derogatory treatment be removed or reversed.
Performers’ rights

These are personal rights preventing unauthorised recordings, broadcasting and other uses of the performance, including copying, selling, hiring, distributing, importing and possessing.

Performers’ rights, like moral rights, cannot be transferred by assignment or be licensed. However, they may be waived and this is a common occurrence in commercial transactions.

When would I infringe copyright?

Dealing with a ‘substantial part’ of a copyright protected work does not necessarily refer to using a large amount of the work. Often, whether a ‘substantial part’ of a work has been dealt with is assessed qualitatively (i.e. having regard to the essence of the work). For example, the use of only 127 bytes from a 32 kilobyte program was held by the High Court to be copyright infringement because it was dealing with a substantial part of the work (Autodesk Inc v Dyason [No 1] (1992) 173 CLR 330).

Substantial dealing with copyright protected work extends to downloading material from the internet. It should not be assumed that everything accessible from the internet may be downloaded and used without infringing copyright.

Copyright may also be infringed indirectly, i.e. subsequent dealings with unauthorised reproductions of the work. The main forms of indirect copyright infringement involve unauthorised copies of copyright protected work being imported, sold, hired or otherwise supplied for the purpose of trade.

As the advancement of digital technology poses an increasing challenge to enforcement of IP rights, there has also been an increasing use of technological measures to prevent and restrict violations of copyright in the digital realm. These include:

Technological Protection Measures (TPMs)
These are software locks or encodings, or password protection measures on copyright works. It is an infringement to manufacture, import or deal commercially with devices or services designed to avoid TPMs.

Electronic Rights Management Information (RMI)
This is a set of electronic systems for identifying contents of copyright work, protecting copyright and tracking the usage of electronic information. It is an infringement to remove or alter electronic RMI attached to copyright works. This is also known as Digital Rights Management (DRM).

Broadcasting Decoding Devices
These provide encoded protection for copyright-protected broadcasts. It is an infringement to manufacture or deal with broadcast decoding devices which permit unauthorised access.

Civil and criminal sanctions may apply to using anti-circumvention devices to ‘unlock’ copyright protected digital content. Criminal sanctions are imposed where the person must have known or reasonably suspected that the device or service would be used to circumvent a technological prevention measure, and a convicted person may be liable to up to 5 years imprisonment.
Exceptions to copyright infringement

Fair dealing exceptions

There is no copyright infringement if you deal fairly with copyright protected work for any of the following purposes:

» reporting news
» research or study
» criticism or review
» professional advice given by a lawyer, patent attorney or trade mark attorney.

Factors deciding what use is ‘fair’ include the purpose and character of use, the nature of the work, the amount and substantiality of the portion copied, and whether the material is used for commercial purposes.

For example, making a single copy of a journal article, one chapter or 10% of a book (equivalent to 10 or more pages long), or 10% of the number of words in a work in electronic form for research or study purposes generally will be considered fair dealing.

Other exceptions:

» Computer programs
The incidental and automatic copying of software resulting from the process of normal use of the program or for back-up purposes will not infringe copyright.
To decompile, reverse-engineer, reproduce or adapt a computer program to make an interoperable product, to test its security, or to correct an error (if the required information or error-free copy is not otherwise available) will not infringe copyright.

» Home copying
As long as it is strictly for private and domestic use, your copying of a sound recording which you own or the recording of broadcasted material will not infringe copyright.

» Judicial proceedings & judicial reporting
Copyright will not be infringed where it is used for judicial proceedings and its reporting.

» Public recitation and performance
If the public performance of copyright protected work takes place at premises where people reside or sleep (e.g. at home or in an institution) copyright in the work will not be infringed.

» Libraries and archives
Libraries, museums, galleries and archives are allowed to reproduce material in their collections for students for fair dealing purposes, for Members of Parliament and for the Government without infringing copyright.

Foreign copyright

Use of a foreign copyright protected work in Australia will usually require permission. Subject to any applicable exception, use of foreign copyright protected work without permission in Australia will be an infringement of copyright.
Registered Designs

What is a registered design?

A registered design is the exclusive right(s) granted by the government to a design registration owner allowing the owner to exclude others from commercially exploiting the overall appearance of a particular design.

In Australia, the Designs Act 2003 (Cth) (‘Designs Act’) governs the operation of design registrations. However, registered designs that were in force on 17 June 2004 (and any registered designs subsequently arising from an application pending at that date) are governed by the earlier Designs Act 1906 (Cth).

This Manual deals primarily with the 2003 Act.

What can be protected as a registered design?

A registered design protects the overall appearance of a product resulting from one or more visual features of the product.

The following visual features of a product may be protected by designs registration:

- SHAPE
- PATTERN
- CONFIGURATION
- ORNAMENTATION

The feel of a product and the materials used in a product are excluded from design registration.

Some designs are not able to be registered. Examples include those featuring:

» medals
» the layout for an integrated circuit
» the Olympic rings symbol, motto or torch and flames design
» the word ‘Anzac’
» coins or money notes
» the coat of arms, flags or seal of the Commonwealth or any State or other country,
» information or graphics reasonably regarded as scandalous.

A protectable design may be two-dimensional (e.g. pattern) or three-dimensional (e.g. a shape), and either manufactured or homemade. The design does not have to be aesthetically pleasing. Although a design registration does not protect the functionality of an article, a visual feature which happens to have a functional purpose will not preclude it from obtaining a design registration.

Examples of well-known articles that have been protected by registered designs include Ken
Done bed linen, the tread of a Dunlop pneumatic tyre, Speedo swimwear, a Malleys portable cooler and a Breville electric hot water jug.

It is important to understand that the term ‘registered designs’ has a different meaning to a ‘design process’ commonly referred to by engineers in the electrical and electronics industry. Whilst a ‘design process’ typically describes the process of generating a product, a ‘registered design’ is an IP right which protects the overall impression of a product only.

**Do I need to apply for protection?**

Yes. You must apply to IP Australia to register your design for protection in Australia.

The list below illustrates the requirements for obtaining design registration in Australia.

- **New**
- **Distinctive**

‘New’ means the design has not been publicly used in Australia and has not been published within or outside Australia.

‘Distinctive’ means the design is substantially different in overall appearance to other designs already in the public domain.

The term of protection lasts for a maximum of 10 years, provided official renewal fees are paid. However, you will only have the right to enforce your registered design once it is certified. For more information on the registered design application process, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

If a design is not registered, copyright may still provide some protection – but this is very minimal. That is, copyright may provide protection where a design is based upon or consists of an artistic work. However, as a guideline, it is only registered designs that are available for the protection of products that are industrially applied, and copyright protection for such items is expressly excluded, even if it might otherwise exist.

**What rights will I receive for a registered design?**

Designs registration grants to the owner a number of exclusive rights, which include to be able to:

- licence and assign the use of the design,
- prevent others from manufacturing copies or obvious imitations of the design without authorisation.

**When would I infringe a registered design?**

A registered design will be infringed where there is an unauthorised application to a product of an identical design or one that is substantially similar in overall impression.

‘Unauthorised application’ includes the importation, sale or hire of a registered design.

Certain acts of repair or replacement of parts of a product that is protected by a registered design may be excluded from being an infringing act.
Plant Breeder’s Rights

What are Plant Breeder’s Rights?

Plant Breeder’s Rights (and Plant Variety Rights in other countries) are exclusive commercial rights to breeders of certain new varieties of plants or fungi. The rights are a form of intellectual property, like patents and copyright, and in Australia are administered under the Plant Breeder’s Rights Act 1994.

In Australia, the Plant Breeder’s Rights Act 1994 governs the operation of Plant Breeder’s Rights.

What can be protected by Plant Breeder’s Rights?

Plant Breeder’s Rights (PBR) protection extends not only to plant varieties, but also to reproductive material of the variety and to other varieties which are considered to be “essentially derived” from the protected variety. In some limited circumstances rights may also extend to material which is harvested from the plant variety. Traditionally bred plants, Algae, fungi, and transgenic plants may be protected as a “plant variety”.

To be eligible a variety must be originated by a person. Selections direct from the wild or discoveries are not eligible unless they have been propagated in some way.

Several requirements must be satisfied before Plant Breeder’s Rights protection is obtained:

» the variety or its reproductive material must not have been sold in Australia for more than one year before making the application

» the variety or its reproductive material cannot have been sold overseas for more than 6 years before making the application in the case of trees and vines, or for more than 4 years in all other cases

» the variety must adhere to three broad criteria: distinctiveness, uniformity and stability (DUS).
Do I need to apply for protection?

Yes. You must apply to IP Australia to register the plant variety. Applications are accepted by IP Australia from the original breeder of a new variety (or from their employer if the breeder is an employee of an organisation) or from a person who has acquired ownership rights from the original breeder.

The application process has two parts. In the first part, the applicant needs to reasonably demonstrate to the Examiner at first instance the characteristics that make the variety distinctive, uniform and stable, and that they are the breeder or owner of the variety. Upon acceptance of the first part, the application is published. In the second part, the application is examined for proof of distinctiveness, uniformity and stability from the results of a growing trial in Australia or overseas. Valid applications proceed to grant and the holder of the PBR is issued with a certificate for that variety.

In tree and vine varieties, PBR continues for 25 years from the date of granting and in all other varieties, for 20 years from the date of granting.

What rights will I receive?

Plant Breeder’s Rights are exclusive commercial rights to a registered variety. In relation to propagating material of the registered variety, successful applicants have exclusive rights to:

- produce or reproduce the material
- condition the material for the purpose of propagation (conditioning includes cleaning, coating, sorting, packaging and grading)
- offer the material for sale
- sell the material
- export the material
- stock the material for any of the purposes described above

When would I infringe Plant Breeder’s Rights?

Plant Breeder’s Rights are infringed by a person taking an exclusive right without the authorisation of the PBR owner.

Exceptions to infringement

There are exceptions to infringement of Plant Breeder’s Rights. These include:

- conditioning of farm saved seed under certain circumstances
- certain acts done for private or non-commercial purposes or experimental purposes, or for the purpose of breeding new plant varieties
- Plant Breeder’s Rights do not extend to some uses of propagating material of a protected variety that takes place after the material has been sold by the PBR owner or with their consent.
Confidential Information

What is confidential information?

Confidential information is information that must be kept confidential by the recipient.

In Australia, confidential information is not protected by a specific statute, but is protected under obligations of confidence arising at law (in equity) or, if the obligation of confidence is imposed by a written confidentiality agreement, the principles of contract law may also apply.

When the confidential information is kept secret and used properly, this form of protection may be very effective. The most famous well-kept and valuable confidential information is the Coca Cola recipe, said to be kept secret since 1885.

The terms ‘confidential information’ and ‘trade secrets’ are often used interchangeably but strictly speaking, trade secrets are a subset of confidential information in the context of business, commerce or trade. Other forms of confidential information include personal information (e.g. diaries, photographs) or professional information (e.g. information supplied to a lawyer or accountant in the course of his/her professional duties).

What can be protected as confidential information?

Any sort of information may be the subject of confidence. Common examples of confidential information include manufacturing processes, recipes, engineering and technical designs and drawings, product specifications, customer lists, business strategies and sales and marketing information.

Do I need to apply for protection?

No. Confidentiality obligations under equity arise automatically provided the following conditions are satisfied:

» the information has a necessary quality of confidence about it, and
» it has been imparted in circumstances involving an obligation of confidence

However, to reinforce an organisation’s position and provide certainty as to the existence of the confidential information, it is prudent practice for an organisation to enter into a written confidentiality agreement with the recipient of the information.

Foreign Rights

Plant Breeder’s Rights are territorial in nature. Where there is no registered PBR in Australia, exploitation of a plant variety in Australia will not infringe a foreign PBR. Australia is a member of the International Union for the Protection of New Varieties of Plants (UPOV). Consequently, Australian applications for PBR can claim priority from foreign applications filed not more than 12 months earlier in UPOV member countries, and Australian PBR applicants can file applications in UPOV member countries within 12 months of their Australian PBR application, claiming priority from it.
The term of protection for confidential information may potentially be perpetual, provided the information remains secret.

**What rights will I receive for confidential information?**

Confidential Information is not “property” like other forms of IP. There are no proprietary rights granted to the owner of the confidential information, and consequently there is no action for ‘theft’ of confidential information. Unlike other IP rights, owners of the confidential information have only limited avenues to prevent use of the information by unrelated third parties once the information is leaked.

However, you may be entitled to remedies if there is unauthorised disclosure. Remedies arising from breach of confidentiality and breach of contract may include:

- an injunction restraining the further use or disclosure of the information
- an order allowing the search of premises and seizure of documents and products if there is a risk that evidence may be destroyed
- an account of profits
- damages for compensation.

**When would I breach confidentiality?**

Breach of confidentiality will occur where there is an unauthorised use or disclosure of confidential information by a recipient who is under an enforceable obligation of confidence arising either in equity or under contract.

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**Trade Marks**

**What is a trade mark?**

A trade mark is a sign used in trade by a business to identify and distinguish its goods or services from those of another business.

In marketing terms, a trade mark is the ‘face’ of a business used to advertise a product, and may be the most valuable asset held by a business. For example, the world’s most valuable trade mark, Google, is valued at over US$66 billion (‘Top 100 Brand Ranking 2007’, Milward Brown Optimor).

In Australia, the Trade Marks Act 1995 (Cth) (‘Trade Marks Act’) governs the operation of trade mark law.

**What can be protected as a trade mark?**

A trade mark may consist of any stylised letter, word, name, signature, numeral, device, brand, heading, label, ticket, aspect of packaging, shape, colour, sound or scent, or a combination of any of those things.

However, the Trade Marks Act prohibits the registration of particular marks as set out in the table below.
Marks Ineligible for Trade Mark Registration

- Marks that are identical or deceptively similar to an existing trade mark, e.g. ‘Kolgate’ may be deceptively similar to ‘Colgate’.
- Marks that mislead the nature of the goods and services that it is applied to, e.g. ‘Soft pillows’ for firm pillows.
- Marks that are generic or descriptive of quality or the nature of the goods or services, e.g. ‘Soft pillows’.
- Marks consisting of a geographical location or a common surname, e.g. ‘Sydney Pies’ or ‘Smith’s Hair Salon’.
- Marks that consist of a representation of the arms, flag or seal of the Commonwealth, State or Territory.
- Marks that are scandalous or against the law, e.g. racist marks, marks that promote an illegal substance, or marks that are protected by legislation, such as the Olympic rings or ‘Medicare’.

Do I need to apply for protection?

Generally, yes. You must apply to IP Australia to obtain a registered trade mark. However, the common law right of ‘passing off’ and the Trade Practices Act 1974 (Cth) may provide some protection against inappropriate use of an unregistered trade mark. For more information on the advantages and disadvantages of trade mark registration, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

Registration establishes your legal rights and makes enforcement easier. The protection term for registered trade marks may be perpetual, provided renewal fees are paid every 10 years.

For more information on the trade mark application process, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

What rights will I receive for a trade mark?

An owner of a registered trade mark is granted exclusive rights to:

» use the mark in relation to the good or services with respect to which it is registered, and

» prevent others from using a substantially identical or deceptively similar mark in relation to the goods or services registered by the mark.

When would I infringe a trade mark?

A registered trade mark is infringed where there is unauthorised use of the registered trade mark or use of a substantially identical or deceptively similar mark:

» in relation to the goods or services for which the trade mark is registered

» in relation to similar goods or services for which the trade mark is registered, or

» where the trade mark is so well-known that the use of the infringing mark (even on unrelated goods or services) indicates a connection with the registered trade mark.
Unregistered marks may be protected by the common law right of passing off, or the prohibition on misleading or deceptive conduct under the Trade Practices Act, provided reputation in the trade mark is established.

**Foreign Trade Marks**

Trade marks rights are territorial in nature. Where a foreign trade mark is neither registered nor used in Australia, use of the trade mark in Australia may not constitute infringement. However, if a foreign trade mark is well-known in Australia, the law of passing off or the Trade Practices Act may apply.

**Trade marks on the Internet**

When using a trade mark on the Internet to offer goods or services, you should be aware of the risks of trade mark infringement in other countries as you are entering a global marketplace.

Australia and other member states of the World Intellectual Property Organisation (WIPO) have established guidelines for the protection of trade mark owners who trade over the internet, ‘Recommendation Concerning the Protection of Marks, and other Industrial Property Rights in Signs, on the Internet’. This may be accessed at: <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=1922>

If you receive a notice from an overseas trade mark owner alleging that your organisation is infringing their trade mark via the internet, you should seek legal advice from a lawyer or trade mark attorney before taking any action.

**Domain Names**

**What is a domain name?**

A domain name is an address on the internet. It is the unique name that identifies a website, e.g. <www.ausbiotech.org> or <www.sprusons.com.au>. This is the ‘human readable’ version of a website’s internet numeric address, e.g. 123.45.678.910

**What can be a domain name?**

Almost anything can be registered as a domain name, subject to the rules and policies of the various domain name Registrars. Domain names are registered on a first come, first served basis.

You can check the availability of a domain name by using the public WHOIS service located at <www.whois.com.au>

Many domain names consist of a business’s registered business name or company name. Recently, the domain names allocation rules have broadened, and a business’s registered trade mark or trade mark application (even if it is not its registered business name) may now form the basis of a domain name.
Do I need to apply for protection?

Yes. You must apply to any of the many domain name Registrars who will issue a licence for use of the domain name. Registrars decide whether your domain name meets the policy rules, and have direct access to the Registry so that new registrations, renewals and updates of registrant details can be processed in the database.

A list of the Registrars in the .au domain as accredited and licensed by .au Domain Administration Ltd (.auDA) can be found at www.auda.org.au. .auDA is the government-endorsed policy authority and industry self-regulatory body for the .au domain space. Its responsibilities include developing and implementing domain name policy, accrediting and licensing Registrars, implementing consumer safeguards and facilitating the .au Dispute Resolution Policy (.auDRP).

The licence term for a domain name may potentially be perpetual, provided renewal fees are paid.

What rights will I receive for a domain name?

No proprietary rights are granted for domain names. You do not own the domain name. The only ‘right’ granted is the licence to use the domain name for a specified period of time.


Having a business name, company name or registered trade mark does not necessarily give you a ‘better’ right than anyone else to a matching domain name. You may, however, bring a complaint under .auDRP if you think you have a better entitlement to a domain name. Rights under the law of passing off or relating to misleading conduct may also arise.
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What this Chapter covers

Biotechnology, along with most technology-based industries, is innovative and creative. The industry survives on continuous innovation – developing new products and services and improving existing products.

A sound IP strategy will assist your organisation in capturing and protecting the outcomes of its investment in innovation. In addition, an organisation will ideally have systems in place to stimulate and capture the creativity and innovations of its employees.

This Chapter provides guidance to the Board and CEO on how to:
  » develop an IP strategy
  » manage IP strategically and effectively
  » stimulate and capture the results of creativity within your organisation, and
  » deal with IP issues in various capital raising scenarios.

Developing an IP Strategy for your Organisation

An IP strategy cannot be developed in a vacuum. In order for your IP strategy to be relevant to your organisation it needs to address your organisation’s needs. A sound IP strategy will assist your organisation to achieve its commercial goals effectively. Your IP strategy should drive your new product development and should minimise the risks involved in investing in the development of new products.

Before formulating an IP strategy, you will need to be aware of the competitive environment in which your organisation operates, and the competitive advantage that might be gained from your organisation’s IP. Set out below are some steps to assist in the development of an effective IP strategy for your organisation:

Step 1: Identify your organisation’s commercial goals

It is likely that your organisation will have well-developed and explicit commercial objectives. In order to develop an IP strategy that works for your organisation, you may wish to assess how you can achieve those objectives from the perspective of IP. For instance, IP may be used as a tool to:
  » block competing products
  » generate income from commercialisation
  * deter potential infringers
Chapter 3: What the Board and CEO Must Know

- deter potential infringers
- defend an infringement action
- attract investment
- raise your organisation’s profile
- increase the sale price of your organisation’s shares or business.

A list of some of the factors to be taken into account when assessing how and what form of IP may be used to accomplish your commercial goals is set out below:

Considerations for using IP to accomplish your commercial goals:

<table>
<thead>
<tr>
<th>Product Cycle</th>
<th>What is the lead-time for your products to reach the market?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competitors</td>
<td>Will your competitors respect IP rights?</td>
</tr>
<tr>
<td></td>
<td>Where do your competitors manufacture and sell their products?</td>
</tr>
<tr>
<td></td>
<td>What are your competitor’s IP rights?</td>
</tr>
<tr>
<td>Markets</td>
<td>What are the key markets for your products and what is the size and value of those markets?</td>
</tr>
<tr>
<td></td>
<td>Are the markets short-term markets or long-term markets?</td>
</tr>
<tr>
<td>Exploitation Strategy</td>
<td>How will your products be exploited?</td>
</tr>
<tr>
<td></td>
<td>Will they be manufactured locally or overseas?</td>
</tr>
<tr>
<td></td>
<td>Will they be manufactured by you directly, under a licence, by a joint venture, or are you intending to assign any of your IP?</td>
</tr>
<tr>
<td>Infringement</td>
<td>Who are the potential infringers of your IP rights? Are they large entities or small entities?</td>
</tr>
<tr>
<td></td>
<td>Is there a “grey” market for your products?</td>
</tr>
<tr>
<td></td>
<td>What is the ‘value proposition’ of your IP to potential infringers (i.e. the licensing costs as opposed to the litigation costs of infringement proceedings and the likelihood of success in such proceedings)?</td>
</tr>
</tbody>
</table>

Step 2: Identify your organisation’s IP rights and the competitive IP landscape

As a next step you will need to identify the IP rights held by your organisation and the strengths of each of those IP rights, e.g. its life span, coverage, validity and strength. If this information is not readily available, you may wish to conduct an IP audit to gather such information. For more information on conducting an IP audit, see Chapter 6 ‘What Senior Management Must Know’.

You will also need to develop an understanding of the IP landscape surrounding your IP (i.e. the type and degree of IP protection held by your company and others). Awareness of the competitive IP landscape will enable you to identify potential IP barriers. Once these obstacles are known, you will be able to develop an IP strategy designed to avoid and/or minimise these obstacles. A ‘freedom to operate’ search will assist you in understanding the IP landscape.
For more information on freedom to operate searches, see Chapter 4 ‘What Researchers Must Know’.

Assessing the competitive IP landscape will also assist you to:

» identify and pursue future trends and gaps in the market strategically, and
» monitor your competitors’ activities, identify their strengths and weaknesses, and predict their next move.

**Step 3: Align your organisation’s IP rights with its business goals**

Once you have identified your organisation’s goals and IP assets, you will be able to consider how IP may assist a particular strategy or evaluate how valuable a particular IP asset is for your organisation. Some examples of issues which you may take into account are set out below.

Considerations for assessing the value of an IP asset:

<table>
<thead>
<tr>
<th>What IP supports products making up the bulk of your revenue?</th>
<th>Revenue Contribution</th>
<th>To what extent does the IP give your products an advantage over those of your competitors?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What IP supports your most profitable products?</td>
<td>Margin Contribution</td>
<td>How much more can you charge for your products because of that advantage?</td>
</tr>
<tr>
<td>Does any IP bring in revenue independently (e.g. from licences) and if</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the IP give you a marketing advantage over your competitors?</td>
<td>Marketing Benefits</td>
<td>Is the IP necessary to raise funding for expansion?</td>
</tr>
<tr>
<td>Will consumers perceive your products as being of better quality because of</td>
<td>Organisational Value</td>
<td>How do potential sources of finance view the IP?</td>
</tr>
</tbody>
</table>

**Step 4: Formulate an IP strategy for your organisation**

Once the process of aligning the IP portfolio and your organisation’s goals is completed, you will be able to identify:

<table>
<thead>
<tr>
<th>Core IP</th>
<th>IP which is core to your organisation’s business</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surplus IP</td>
<td>IP which is no longer aligned with your organisation’s strategies</td>
</tr>
<tr>
<td>IP Gaps</td>
<td>IP needed to better support your organisation’s current strategies</td>
</tr>
</tbody>
</table>

IP in each of these categories may also be rated in accordance with its technical and legal strength. Once classified, the information will assist the development of an IP strategy that is tailored to the needs of your organisation.

It is important to remember that an IP strategy must be constantly reviewed against your organisation’s goals to ensure it supports and is integrated into your organisation’s business strategy.
An IP strategy may be offensive and aim to develop IP that an organisation can use to take action against an infringing party, or defensive and intended to obtain IP to minimise the risk of being sued by others for infringement. Ideally, an IP strategy will address both fronts. Striking the correct balance between being offensive and defensive is a complex problem, and requires a thorough understanding of the information gathered from the previous steps. As the size of your organisation grows, it will generally be increasingly monitored by competitors who may own IP rights that your organisation may infringe. The need to address defensive IP issues will increase with the success of your organisation.

**Developing an offensive IP strategy**

An offensive IP strategy focuses on acquiring and protecting proprietary IP that gives your organisation an advantage over its competitors. In general, an offensive IP strategy requires high-quality rights and the resources to enforce those rights. Ideally, the IP rights should be able to block likely ‘design around’ alternatives, so far as this is possible having regard to the existing prior art.

In order to develop an offensive IP strategy, you will need to have a sound knowledge of your organisation’s products and services and the extent to which these can be protected and the relevant IP rights enforced. A comprehensive and up-to-date IP register will help to identify relevant IP rights.

For more information on establishing and maintaining an IP register, see Chapter 6 ‘What Senior Management Must Know’.

**Developing a defensive IP strategy**

In order to develop a defensive IP strategy, you will need to have a thorough understanding of the competitive IP landscape, your organisation’s goals and planned strategies and potential obstacles in your path. A defensive strategy aims to steer clear of or at least reduce the impact of any obstacles and the associated risks.

Some possible elements of a defensive IP strategy include:

- obtaining a licence to exploit any blocking IP
- designing around the blocking IP
- altering the specifications of your products/services
- releasing your products/services in stages
- developing or acquiring an IP portfolio as a ‘bargaining chip’ for cross-licensing purposes
- opposing the rights of the blocking IP
- “scorched earth” policy of pre-emptive disclosure to prevent competitors locking up IP which you may wish to use in the future
- forming an alliance within your industry
- establishing appropriate company structures
- transferring or reducing the consequences of potential risk by contractual terms (e.g. contractually limiting the types/quantum of liability)
- developing contingency plans
- arranging for IP insurance.
## Developing your IP strategy from a global perspective

Although a detailed discussion of the issues involved in developing an IP strategy from a global perspective are beyond the scope of this Manual, set out below are some general IP issues you will need to consider, especially if you plan to manufacture, import or export products outside of Australia.

### Issues to consider when developing a global IP strategy:

<table>
<thead>
<tr>
<th>IP Protection</th>
<th>Consider obtaining IP protection for your innovation in countries where your products are to be manufactured, marketed or sold or which have the potential to manufacture, or which are otherwise strategically important to your organisation. Each country will have its own legislation governing the requirements for protection of different forms of IP. You should consult a legal professional who may have associates in the relevant countries in which you are considering obtaining protection for your IP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Branding</td>
<td>When importing or manufacturing goods in a foreign country, you will need to consider whether the organisation’s existing trade mark or branding for the goods will conflict with any existing trade marks or brands within each of those markets in that country. You will need to consider whether existing trademarks or branding are appropriate when used in the context of a foreign language. Consider also whether you need to protect your trade mark in that country to prevent local competitors from taking advantage of the goodwill in your brand.</td>
</tr>
<tr>
<td>Freedom to Operate</td>
<td>Before manufacturing or importing goods into a country, you should first ensure that your organisation has the freedom to operate in that country. Seek the assistance of an IP professional to conduct a freedom to operate search in that country.</td>
</tr>
<tr>
<td>Parallel Importation</td>
<td>Parallel importation is the importation and distribution of goods by someone other than the authorised dealer in a ‘grey’ market. Parallel importers ordinarily purchase products in a first country at a cheap price and import and sell the products in a second country at a price lower than the ordinary price of the product in the second country. The issue of parallel importation is particularly important when licensing IP rights to a third party for exploitation in a particular territory, or when manufacturing products in another country.</td>
</tr>
<tr>
<td>Industry Standards</td>
<td>If your organisation is exporting goods to foreign countries, you will need to consider any applicable industry standards in those countries. On the other hand, if you are manufacturing your products in another country for sale domestically, you need to ensure all products are manufactured in accordance with your specifications and all applicable domestic industry standards and requirements.</td>
</tr>
</tbody>
</table>
Issues to consider when developing a global IP strategy:

| Regulatory Approval | If your goods are intended for a therapeutic use, it is likely that you will need to seek approval from an appropriate national regulatory authority in order to market or export the goods. In Australia, the Australian Therapeutic Goods Administration is responsible for providing regulation of therapeutic goods. |

Implementing an IP Strategy

Establishing an IP management framework

The IP strategy of your organisation needs to be translated into an appropriate IP management framework to provide guidance to your employees on effective IP management.

Typically, an IP management framework consists of two components:

- **IP Policy**: A document setting out your organisation’s IP arrangement principles
- **IP Management Framework**: The IP management framework requires detailed knowledge of the organisation’s objectives, practices and resources, and an understanding of where IP-related issues need to be addressed. These issues may change over time as the organisation’s objectives expand or change direction, and accordingly the IP management framework should be regularly reviewed and updated to reflect such changes. It is likely that the preparation of the IP policy and IP implementation plan will be supervised by one of your organisation’s senior managers.

- **IP Implementation Plan**: A plan setting out the optimal systems and the allocation of resources within your organisation to implement the IP policy

For more information on preparing an IP policy and an IP implementation plan, see Chapter 6 ‘What Senior Management Must Know’.

Once prepared, the IP management framework needs to be endorsed by the CEO and the Board.
**Stimulating creativity**

Innovation within your organisation should be encouraged rather than stifled. Creativity within your organisation may be stimulated by a strong culture of support for creative thinking and recognition of creative efforts.

**Recognition of creative efforts by employees**

Innovation amongst employees can often be promoted by recognising their contributions appropriately. Rewards for talented employees for their innovation may take the form of:

- financial rewards
- public announcement of results
- certificates
- gifts
- staff development opportunities

**Capturing creativity**

Not every new idea generated by your employees will be implemented. However, in the Biotech industry innovation often moves at a fast pace. Your organisation therefore needs to take immediate steps to preserve, develop and implement potentially significant innovations, as failure to take immediate action may effectively mean that your organisation will lose the potential benefits of the innovation.

Your IP management framework should have effective mechanisms to:

- encourage your employees to report innovations
- facilitate invention disclosures
- preserve and protect any IP disclosed by making informed and effective IP protection decisions.

**Example methods to stimulate and capture creativity**

Some example methods to stimulate and capture creativity in an organisation are to:

- establish a strong culture of support for creative thinking
- provide mechanisms to recognise efforts by employees
- allow freedom to explore new concepts
- facilitate regular discussions of IP issues
- ensure invention disclosure forms are used diligently.

**IP and Capital Raising**

**Capital raising**

The IP owned or controlled by an organisation often represents a significant proportion of the organisation’s value. Particularly for small or start-up organisations, realising the value of IP is critical in the monetization of that value.

There are a number of capital raising options open to organisations involved in the development of technological innovations. Some of these are summarised in the diagram below:
IP due diligence in capital raising

Any capital raising scenario will invariably involve a due diligence exercise to allow potential investors to gather information on the status of the company before investing in the organisation.

Due diligence is an information gathering and analytical process to:
- investigate an organisation’s assets and liabilities
- assess the organisation’s legal rights to utilise those assets
- evaluate the risks associated with the identified assets and liabilities.

A comprehensive discussion of the due diligence process is beyond the scope of this Manual. However, the basic elements of an IP due diligence exercise are set out below.

<table>
<thead>
<tr>
<th>Due Diligence Issue</th>
<th>Documents to be examined</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IP Ownership</strong></td>
<td>» Relevant IP assignments (including documents showing the correct chain of title from the original owner to the organisation)</td>
</tr>
<tr>
<td></td>
<td>» Evidence showing that the relevant assignments have been lodged or recorded with the relevant authorities</td>
</tr>
<tr>
<td></td>
<td>» Consultancy agreements</td>
</tr>
<tr>
<td></td>
<td>» Employment agreements</td>
</tr>
<tr>
<td><strong>IP Validity</strong></td>
<td>» Official filing receipts for all registrable forms of IP</td>
</tr>
<tr>
<td></td>
<td>» Examination reports and evidence of grant for standard patents and trademarks</td>
</tr>
<tr>
<td></td>
<td>» Evidence of certification for innovation patents and registered designs</td>
</tr>
<tr>
<td></td>
<td>» Evidence showing payment of all official fees</td>
</tr>
<tr>
<td></td>
<td>» Freedom to operate reports</td>
</tr>
<tr>
<td></td>
<td>» Evidence showing the date and source of inventions (including laboratory notebooks, invention disclosure statements and other records documenting the creation of the IP)</td>
</tr>
<tr>
<td></td>
<td>» Documents showing any claims and disputes that may affect the grant or validity of the IP (such as opposition and revocation proceedings).</td>
</tr>
<tr>
<td>Any other rights/obligations attached to IP</td>
<td>All agreements in relation to IP, including:</td>
</tr>
<tr>
<td></td>
<td>» licence agreements</td>
</tr>
<tr>
<td></td>
<td>» confidentiality agreements</td>
</tr>
<tr>
<td></td>
<td>» collaborative research agreements</td>
</tr>
<tr>
<td></td>
<td>» government grant agreements</td>
</tr>
<tr>
<td></td>
<td>» other funding agreements</td>
</tr>
<tr>
<td></td>
<td>» manufacturing and distribution agreements.</td>
</tr>
</tbody>
</table>
Different capital raising options

General capital raising issues are beyond the scope of this Manual and this Manual will only give a brief overview of the different capital raising options in the context of IP.

You should always seek appropriate expert advice when considering any capital or finance raising.

Government grant schemes

Government grants are offered at a Federal and State level to organisations to facilitate research, development and commercialisation of innovations. These grants are usually competitive in nature, which means that your organisation will need to apply for the funding and your application will be assessed against applications from other organisations under the required published criteria.

Government grant agreements

If your organisation is successful in the grant application, your organisation will usually be required to enter into a grant agreement with the relevant funding body. The grant agreement will govern the administration of the grant which is frequently linked to the achievement of certain deliverables or milestones set out in the agreement. Other conditions imposed by the funding body in relation to the grant will generally depend on the objective of the grant programme.

Government grant agreements raise many of the same general considerations in relation to IP that arise in contractual arrangements with non-government entities relating to research.

Provisions typically found in Government Grant Agreements include:

- Identification and ownership of background IP to be used in the funded project.
- Clear allocation of ownership of the IP resulting from activities undertaken in the course of the project (Project IP).
- Where the organisation owns the Project IP, a royalty-free licence back to the government agency to use the Project IP. In some cases, this may be limited to internal and/or non-commercial use.
- Requirement for the organisation to acknowledge the relevant government agency’s contribution to the Project IP.
- Obligations on the organisation to manage and protect the Project IP diligently.
- Obligations on the organisation to achieve certain milestones in the development of the Project IP.
- Obligations on the organisation to provide regular reports on the progress of the project.
- Obligations on the organisation to account for expenditure of funds.
- Rights for the government agency to inspect and audit the organisation’s records.
- Right for the government agency to terminate the agreement if the structure or shareholding of the organisation changes, or if the organisation breaches any conditions of the agreement.
A government grant agreement may also include government policy provisions requiring the organisation to use and commercialise the Project IP for the benefit of the Australian public, or to ensure that ownership of the Project IP remains in Australia. For example, the relevant Co-operative Research Centre agreement provides that:

"Any Commercialisation or utilisation of the Intellectual Property in Contract Material must:

a) maximise the national benefits accruing to Australia, including Australian industry, and the Australian economy generally; and

b) be consistent with the Objective of the CRC Programme."

It is recommended that your organisation seek legal advice before entering into a government grant agreement. For more information on government grant agreements, see Chapter 6 ‘What Senior Management Must Know’.

Formerly, the two main Federal government departments that offered funding were the Department of Industry, Tourism and Resources and the Department of Education, Science and Training (DEST). At the time of preparation of this Manual, the Federal Government had merged many of the relevant responsibilities into the Department of Innovation, Industry, Science and Research. Key programs delivered by this department are available from <http://www.innovation.gov.au>

AusIndustry

AusIndustry offers a range of programmes designed to assist with:

- research and development
- manufacturing and production, and
- commercialisation.

Below is a list of the some of the Federal government grant schemes or programs offered by AusIndustry available at the time of publication of this Manual.

<table>
<thead>
<tr>
<th>Grant</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercialising Emerging Technologies (COMET)</td>
<td>COMET focuses on the commercialisation of innovations by early-growth stage and spin off companies.</td>
</tr>
<tr>
<td>Innovation and Investment Fund (IIF)</td>
<td>IIF is a venture capital programme that invests venture capital funds to assist small companies in the early stages of commercialisation.</td>
</tr>
<tr>
<td>National Australian Technology Showcase (ATS)</td>
<td>ATS is a national and international campaign designed to promote leading-edge Australian technology and the skills of the companies that produce it.</td>
</tr>
<tr>
<td>Pharmaceuticals Partnerships Program (P3)</td>
<td>The P3 is an AusIndustry program that provides grants to companies to increase their pharmaceutical research and development in Australia, running until June 2009.</td>
</tr>
</tbody>
</table>
CRC programmes

The CRC programme funds collaborations between researchers and industry to improve the effectiveness of Australia’s research and development effort.

Successful applicants in the CRC programme are required to establish and register a CRC company of which all the core participants are members. The company will enter into an agreement with the Commonwealth for up to seven years. Under the agreement, the Commonwealth agrees to provide funding to the CRC company each year and the CRC will undertake certain activities assisted by the contributions (cash and in-kind) of the CRC participants.

Typically, a CRC must include at least one Australian university and one private sector participant.

The CRC programme currently operates in six different sectors, including the environment, agriculture, and medical science and technology sectors. Examples of CRCs in the Biotech sector that are in operation at the time of publication of this Manual are included in the table below.

<table>
<thead>
<tr>
<th>Examples of CRCs in the Biotech Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRC for Beef Genetic Technologies</td>
</tr>
<tr>
<td>Molecular Plant Breeding CRC</td>
</tr>
<tr>
<td>Australian Biosecurity CRC for Emerging Infectious Diseases</td>
</tr>
<tr>
<td>Environmental Biotechnology CRC</td>
</tr>
<tr>
<td>CRC for Aboriginal Health</td>
</tr>
<tr>
<td>CRC for Asthma and Airways</td>
</tr>
<tr>
<td>CRC for Biomedical Imaging Development</td>
</tr>
<tr>
<td>CRC for Chronic Inflammatory Diseases</td>
</tr>
<tr>
<td>CRC for Cochlear Implant and Hearing Aid Innovation</td>
</tr>
<tr>
<td>CRC for Biomarker Translation</td>
</tr>
<tr>
<td>Vision CRC</td>
</tr>
<tr>
<td>CRC for Oral Health Science</td>
</tr>
<tr>
<td>CRC for Cancer Therapeutics</td>
</tr>
</tbody>
</table>

For more information on the CRC program, visit: <http://www.crc.gov.au>

ARC programmes

The ARC funds a range of programmes under the National Competitive Grants Program (NCGP) to support researchers at different stages of their careers, build Australia’s research capability, expand and enhance research networks and collaborations, and develop centres of research excellence.

There are three types of programmes offered by the ARC:
**Programme** | **Description**
---|---
Discovery Programme | Funds individual researchers and projects.
Linkage Programme | Helps to broker partnerships between researchers and industry, government and community organisations and the international community.
Centres Programme | Builds research scale and focus, as well as strengthens major research partnerships and networks.

Successful applicants enter into a funding agreement with the Commonwealth (as represented by the ARC), whereby the ARC provides funding to the organisation until the obligations as set out in the agreement are fulfilled.

For more information on ARC programmes, visit: <http://www.arc.gov.au>

**National Health and Medical Research Council (NH&MRC)**

The NH&MRC provides funding for research relevant to human health and medical research. A list of different types of funding offered by the NH&MRC may be found at


**State Government Programs**

Each of the state and territory governments also provide potential funding opportunities and programs relevant to Biotechnology research and business development. Examples of these programs that are in operation at the time of publication of this Manual are included in the table below.

<table>
<thead>
<tr>
<th>Program</th>
<th>State</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioBusiness Program</td>
<td>NSW</td>
<td>BioBusiness aims to help develop export-oriented products, services and businesses, and increase the size and number of biotechnology companies in NSW. <a href="http://www.osmr.nsw.gov.au/funding_and_awards/biobusiness_programs">www.osmr.nsw.gov.au/funding_and_awards/biobusiness_programs</a></td>
</tr>
<tr>
<td>Innovation Start-up Scheme (ISUS)</td>
<td>QLD</td>
<td>ISUS is a merit-based assistance scheme that provides one-off assistance to early-stage technology companies who meet the eligibility criteria. <a href="http://www.qld.gov.au/grants/grantdetails">www.qld.gov.au/grants/grantdetails</a></td>
</tr>
</tbody>
</table>
Bio Innovation SA Grants

Bio-Innovation SA has established the

- Commercial Development Initiative (CDI) to assist the commercialisation of South Australian bioscience technologies.
- Business Development Initiative (BDI) to assist bioscience companies to develop their business.
- Commercial Infrastructure Grant to assist SA bioscience companies to buy equipment.
- Commercial Management Grant to support the employment of commercial managers within eligible research organisations.


STI Infrastructure Grants Program

STI Infrastructure grants support the development of Science and Technology and Innovation infrastructure.


Industry Cooperative Innovation Program (ICIP)

The ICIP supports innovation projects identified through an Action Agenda. ICIP aims to encourage business-to-business cooperation within industry sectors.


For more information on grants and other funding programs available from the federal, state and territory governments visit <http://www.business.gov.au/Business+Entry+Point/Business+Topics/Grants+assistance/>

Private equity

The two major sources of private equity are private investors (also known as ‘business angels’) and venture capitalists.

Business angels

Business angels are typically high net worth, non-institutional investors looking to invest part of their wealth in organisations offering high risk-high return investment opportunities. In return, they usually look for ownership of equity and voting rights in the organisation, and ultimately capital gain through an appropriate exit strategy. Business angels may be found through industry bodies that provide a central business angel register or through referrals from professional advisers.

In order to be confident about obtaining a desired return from their investment, business angels will usually seek assurances from the organisation regarding the quality and experience of its management and its market strategy. They will also want to see a well thought-out business plan before making an investment.

Before approaching business angels, you will need to ensure that your organisation has a sound IP strategy. Business angels will want to know as much as possible about your organisation’s IP assets and its IP management strategies. This is particularly so for organisations in the Biotech industry whose growth and existence is mainly driven by the creation of technology. You will therefore need to review your organisation’s IP portfolio, and confirm the IP position and the value of each IP asset before approaching business angels.
When receiving an equity investment from a business angel, it is important that the mutual expectations of the investor and the organisation are clearly set out in the investment documentation since each investor will have its own needs and expectations. Disputes concerning the needs and expectations of an investor may jeopardise the chances of your organisation in future capital raising opportunities.

**Venture capitalists**

Venture capitalists are companies that invest in relatively new organisations that may have little performance history but have a significant potential to grow. They usually participate in the management of the organisation, and the investment is generally taken on the understanding that further funding may be required before return on the investment can be made.

Investment from venture capitalists may be made in one or more stages of a company (see below) over a specified period.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Purpose of funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-seed</td>
<td>Proof-of-concept for technology or initial stages of IP protection.</td>
</tr>
<tr>
<td>Seed</td>
<td>Development of business concept.</td>
</tr>
<tr>
<td>Start-up</td>
<td>Product development and initial stages of marketing.</td>
</tr>
<tr>
<td>Expansion/Development</td>
<td>Expansion of enterprise.</td>
</tr>
</tbody>
</table>

As a venture capitalist company is likely to be closely involved in the strategic management of the organisation, the process of selecting a venture capitalist is much more important than simply finding someone with money to invest. A suitable venture capitalist should take the role of a trusted business partner who will add value to your organisation above and beyond the provision of investment funds by providing suitable mentoring and guidance.

When selecting a venture capitalist, you should consider:

- the reputation and the character of the venture capitalist
- other investments by the venture capitalist in similar organisations
- the desired exit strategy of the venture capitalist
- the time frame of the various stages of investment
- whether the venture capitalist has experience in the industry
- willingness of the venture capitalist to participate in future rounds of financing
- any previous disputes between the venture capitalist and other organisations.
Depending on the nature of discussions anticipated with the business angel, it would be prudent to consider having an appropriate non-disclosure (or confidentiality) agreement in place prior to entering detailed discussions.

The process for obtaining venture capital investment will vary depending on the interests of the parties, the nature of the transaction and time constraints. Usually, a business plan will initially be submitted to the prospective investor, who will review it against its own investment criteria.

**Business Plans**

Like business angels, venture capitalists will want to be assured that the organisation has a sound business plan which not only demonstrates the market opportunities and potential for the organisation’s growth, but also the organisation’s IP strategy outlining the management practices of its IP assets. This is again particularly important for organisations in the Biotech industry whose growth and existence is to a large extent driven by the creation of intangible assets.

A business plan may include the following:

- a detailed description of the organisation and its management team
- a description of the products and services to be offered
- an outline of the market opportunities for those products or services
- summary of the strength and value of each IP asset
- an assessment of the competitive IP landscape and the IP position for each asset
- summaries of financial reports (historical and projected)
- overview of key contracts
- the proposed use of funds provided by the venture capitalist.

After the initial review of the organisation’s business plan, meetings may be conducted to negotiate the terms and conditions of the investment.

**Initial public offerings**

Initial public offerings (IPO) are the first offering of shares in a company to the public for the purpose of raising capital to finance the company’s business. Once listed, the shares will compete against other shares being traded on the relevant stock exchange.

In Australia, only a public company can make an IPO. The company must also satisfy certain
An IPO may be conducted by a company to:

- raise capital from public investors
- enhance the corporate image of the company
- provide liquidity for the founders
- attract debt financing.

Although a successful IPO will generally increase the wealth of the original owners of the company, the IPO will usually lead to a dilution of their control over the company. In addition, increased public disclosure requirements will require a greater disclosure of information regarding the company’s affairs and impose higher governance obligations.

To provide a disclosure framework that gives guidance to organisations on the information that is desirable for investors to be kept informed on, AusBiotech and the Australian Stock Exchange have released “The Code of Best Practice for Reporting by Life Science Companies”. A copy of the Code is available at <http://www.asx.com.au/products/pdf/biotech_best_practice.pdf>

An IPO is not a trivial exercise and will often consume a tremendous amount of time and resources, which may in some instances be better spent on improving the operations of the company.

The process of an IPO is highly complex and technical. When choosing advisers to assist with the IPO of your organisation, it is essential to engage professionals who have substantial experience in this area and have developed systems for the various steps in the process leading to the IPO. Generally, the involvement of well-known firms of advisers is likely to increase investor confidence by enhancing the overall public perception of the IPO.
What this Chapter covers

Research Planning
- Research planning generally
- Why consider IP in research planning?
- Assessing the competitive landscape
- Searching strategies

Reducing the Risk of Infringement
- Performing freedom to operate searches
- Considering IP in your research process
- Obtaining rights to third party IP

Identifying Inventive Subject Matter
- Factors determining inventive step
- Preparing an invention disclosure

Identifying the Inventor
- Who is the inventor?
- Identifying joint-inventors

Managing IP in Research Practices
- Keeping laboratory notebooks
- IP record storage practices
- Personnel practices
- Identification and protection of confidential information
- Review of public disclosures
What this Chapter covers

During the development of Biotechnology products and processes, researchers may:

» generate new IP
» re-use IP previously generated by themselves or their organisation
» incorporate third party IP into their products or processes.

It is therefore essential when planning research that IP generation and capture is also managed appropriately. This Chapter provides guidance to researchers on how to:

» consider IP when planning research
» identify IP which is generated and utilised in a research process
» capture and manage IP appropriately and effectively.

Research Planning

Research planning generally

Researchers need to ensure that each product or process they generate as a result of research, development and design results in the deliverable that they or their customers expect. This can be achieved by planning the research carefully.

Research planning ideally should map out all the technical and managerial processes necessary to deliver the project requirements. The diagram on the following page outlines the elements of a research and development process for a tangible pharmaceutical product. Similar considerations apply where the invention is a method or process.
Chapter 4: What Researchers Must Know

Elements in Pharmaceutical research and development

Conception
- Need
- Timescale market research
- Existing solution
- Proposed improvement
- Requirements and specifications

Research and Analysis
- Investigate
- Evaluation
- Requirements, goals and references
- Feasibility

Bench Scale Testing
- In-vitro testing
- Cytotoxicity and tumorigenicity testing
- Animal model testing
- Pharmacodynamics and bioavailability testing
- Synthetic refinement

DECISION TO PROCEED (YES/NO)

Scale up testing
- Batch testing
- Good laboratory practice
- Good manufacturing practice

continued on the next page>><>
Phase I testing
- Human clinical safety
- Human pharmacodynamics
- Human pharmacokinetics
- Human dosage tolerance
- Mode of administration establishment

DECISION TO PROCEED (YES/NO)

Phase IIa testing
- Preliminary human therapeutic testing
- Preliminary effective dosage testing

DECISION TO PROCEED (YES/NO)

Phase IIb testing
- Human dose response relationships
- Minimum effective and maximum tolerated dose
- Preliminary human efficacy testing

DECISION TO PROCEED (YES/NO)

Phase III testing
- Confirmation of efficacy
- Confirmation of safety
- Assessment of risk/benefit

DECISION TO PROCEED (YES/NO)

MARKETING APPROVAL

VOLUME MANUFACTURING
Why consider IP in research planning?

IP generated in the course of executing a research project can add significant value beyond the ‘sale price’ of the products, system or service involved. This value arises in being able to charge customers a premium price due to the limited monopoly enjoyed by an IP owner, and the opportunity to license others to exploit the IP. Accordingly, failure to consider IP during research planning effectively ‘throws away’ potential value.

Products, systems or methods for creating or using a product may also potentially infringe the IP rights of others. As a result, it is prudent to consider ‘freedom to operate’ issues before resources are committed to a research project, to minimise the likelihood others’ IP rights may be enforced against you or any resulting losses. It cannot be assumed that the utilisation of others’ IP in the research project can be done without permission (at least) or without cost.

For all these reasons it is extremely important to consider IP in the research planning.

Assessing the competitive landscape

Before developing the research plan, competitive intelligence is essential to assist with the decision of what actual product to develop and what components are suitable to be included in your product. Carefully analysing the competitive landscape will enable you to:

» find out what products or components of the product have already been created by you, your competitors or other companies
» avoid wasting resources in re-developing existing products
» monitor your competitor’s activities
» identify future trends and gaps in the market
» make informed decisions on what product should be developed and will likely be a commercial success,
» reduce risks of IP infringement.

Analysing the competitive landscape involves having a thorough knowledge of the relevant market, the demands of that market, and knowledge of the competitors’ existing products and direction. In addition to keeping up-to-date in the developments of your field by regularly reviewing scientific and trade journals, IP information is a resource that you cannot ignore. For example, some estimates suggest that more than 70% of the world’s technical information is published only in patent specifications.

Online IP databases

There are many IP databases available online providing access to documents on registered IP, including pending patent applications and registered patents, pending and registered trademarks and designs.
**Australian IP databases and registers**

The government agency, IP Australia, maintains the Australian patent, trade mark, design and Plant breeder’s rights databases which are available for free viewing by the public. There are no registers for copyright or circuit layout rights as these rights are granted automatically on creation of the ‘work’. Other Australian IP-related databases that may be useful include the business names register, company names register and domain names register.

<table>
<thead>
<tr>
<th>Australian IP - related Databases</th>
<th>Web Address</th>
<th>Types of IP or Business Assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business Names Register</td>
<td><a href="http://www.asic.gov.au">http://www.asic.gov.au</a></td>
<td>Business names</td>
</tr>
<tr>
<td>Company Names Register</td>
<td><a href="http://www.asic.gov.au">http://www.asic.gov.au</a></td>
<td>Company names</td>
</tr>
<tr>
<td>Domain Names Register</td>
<td><a href="http://www.auda.gov.au">http://www.auda.gov.au</a></td>
<td>Domain names</td>
</tr>
</tbody>
</table>

**Other patent offices**

Most patent offices around the world publish granted and pending application for patents, trade marks, designs and other registrable IP online for free viewing by the public. The United States also provides a copyright register; however, you should note that the register is not comprehensive since entering copyright works on the register is optional only.

The World Intellectual Property (WIPO) provides free access to its international IP databases, including links to national IP Offices’ websites.

<table>
<thead>
<tr>
<th>IP Offices</th>
<th>Web Address</th>
<th>Types of IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP Office of New Zealand</td>
<td><a href="http://www.iponz.govt.nz">http://www.iponz.govt.nz</a></td>
<td>New Zealand patents, trade marks, and designs</td>
</tr>
<tr>
<td>Esp@cenet (hosted by European Patent Office)</td>
<td><a href="http://ep.espacenet.com">http://ep.espacenet.com</a></td>
<td>Patents worldwide</td>
</tr>
<tr>
<td>US Copyright Office</td>
<td><a href="http://www.copyright.gov">http://www.copyright.gov</a></td>
<td>US copyright</td>
</tr>
<tr>
<td>WIPO</td>
<td><a href="http://www.wipo.int">http://www.wipo.int</a></td>
<td>Patents (PCT), trade marks (Madrid system), and designs (Hague system)</td>
</tr>
</tbody>
</table>
**Other free databases**

There are several free sites which act as aggregators of patent information and which offer more comprehensive and simple to use searching tools.

<table>
<thead>
<tr>
<th>Database</th>
<th>Web Address</th>
<th>Types of IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free patents online</td>
<td><a href="http://www.freepatentsonline.com">http://www.freepatentsonline.com</a></td>
<td>Patents</td>
</tr>
<tr>
<td>Patent Lens</td>
<td><a href="http://www.patentlens.net/daisy/patentlens/">http://www.patentlens.net/daisy/patentlens/</a></td>
<td>Patents</td>
</tr>
<tr>
<td></td>
<td>patentlens.html</td>
<td></td>
</tr>
</tbody>
</table>

**Commercial databases**

Commercial databases provide access to online viewing of registered IP documents at a membership cost. These databases provide a more comprehensive search capability, offer more tools and features, usually have IP documents from several jurisdictions (i.e. cross-referencing) and can sometimes be industry-specific. Generally speaking, subscription databases are more information rich.

<table>
<thead>
<tr>
<th>Commercial Databases</th>
<th>Web Address</th>
<th>Types of IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delphion</td>
<td><a href="http://www.delphion.com">http://www.delphion.com</a></td>
<td>Patents</td>
</tr>
<tr>
<td>DialogWeb</td>
<td><a href="http://www.dialogweb.com">http://www.dialogweb.com</a></td>
<td>Patents, Trade Marks, Copyright</td>
</tr>
<tr>
<td>PatGenDB</td>
<td><a href="http://htsresources.fdns.net/patgen/index.php">http://htsresources.fdns.net/patgen/index.php</a></td>
<td>Consolidated patent information and patent bioinformatics sequences</td>
</tr>
<tr>
<td>Derwent &amp; Dialog IP</td>
<td><a href="http://www.dialogselect.com/ip/index.html">http://www.dialogselect.com/ip/index.html</a></td>
<td>Patents, including bioinformatics sequences, Trade Marks, Copyright</td>
</tr>
<tr>
<td>Get the Patent</td>
<td><a href="http://www.getthepatent.com">http://www.getthepatent.com</a></td>
<td>Patents</td>
</tr>
<tr>
<td>Nerac</td>
<td><a href="http://www.nerac.com">http://www.nerac.com</a></td>
<td>Patents</td>
</tr>
<tr>
<td>Software Patents Institute</td>
<td><a href="http://www.spi.org">http://www.spi.org</a></td>
<td>Patents</td>
</tr>
<tr>
<td>Trade Mark Bots</td>
<td><a href="http://www.trademarkbots.com">http://www.trademarkbots.com</a></td>
<td>Trade Marks</td>
</tr>
</tbody>
</table>

**Searching strategies**

Most of the databases mentioned allow multiple searching criteria to be employed. Where patent records are concerned, this includes:

- Applicant name and country of origin
- Title
- Application number
- Patent number
International Patent Classification (IPC)


The IPC divides all subject matter into a particular class, with five levels of granularity. At the top level, the classification is:

A. Human Necessities
B. Performing Operations; Transporting
C. Chemistry; Metallurgy
D. Textiles; Paper
E. Fixed Constructions
F. Mechanical Engineering; Lighting; Heating; Weapons; Blasting
G. Physics
H. Electricity

At the lowest level, an IPC Class is represented as, for example:
C12S 3/14 Recovery or purification of proteinaceous material from animal, plant material or microorganisms.

It is possible to search patent databases for broad classifications, for example:
C12S Processes using enzymes or microorganisms to liberate, separate or purify a pre-existing compound or composition.

As each patent record can be ascribed more than one IPC class, and sometimes misallocations or failure to allocate to a correct class can occur, a classification search might not find every appropriate result in all cases. For safety, a combination of IPC searching with other forms of searching such as keywords may be used.

Additionally, there is a separate US Patent Classification (USPC) system, which adopts a subject matter different to taxonomy than the IPC. The USPC is used only by the US Patent and Trademark Office. USPTO patent records are searchable by both USPC and IPC. A concordance exists between the two systems.
More information regarding the USPC system can be found at: <http://www.uspto.gov/go/classification/uspcindex/indextouspc.htm>

**How to read a patent specification**

Each patent application provides information about the inventor(s) and the owner(s), and includes a patent specification.

A patent specification is a detailed technical description of the invention, usually accompanied with figures, and with ‘claims’ defining the scope of protection. The specification will not usually include manufacturing details (i.e. exact dimensions or operating parameters), unless they are critical to the way the invention operates.

For biotechnology inventions involving polynucleotides or polypeptides there may be a "computer-readable sequence listing" either embedded as part of the specification or as an associated document. The purpose of the sequence listing is to provide sequence information in a computer-readable format so that sequences in patents can be collated and presented in databases for searching. Several online services now offer electronic searching of sequences presented in patent specifications, such as Derwent GENESEQ available at: <http://www.stn-international.de/stndatabases/databases/dgene.html>

All patent specifications have approximately the same format. To locate the relevant information you require, you will need to understand what each heading in the patent specification signifies, as outlined in the following table.

<table>
<thead>
<tr>
<th>Heading</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>Brief summary of the key features of the invention.</td>
</tr>
<tr>
<td></td>
<td><em>Caution:</em> do not rely on the Abstract as accurately representing the whole information content of the specification.</td>
</tr>
<tr>
<td>Title</td>
<td>The name of the invention. This is commonly not very descriptive of the actual invention..</td>
</tr>
<tr>
<td>Technical field</td>
<td>The technical field to which the invention is directed.</td>
</tr>
<tr>
<td>Description of background art</td>
<td>Description of the relevant background technological development within the field. This may include a description of the problems or needs of that field which are addressed by the invention.</td>
</tr>
<tr>
<td>Object(s) of the invention</td>
<td>The aims of the invention. Not all specifications contain these statements</td>
</tr>
<tr>
<td>Disclosure/Summary of the invention</td>
<td>This section usually is consistent with the broadest claims. This section may include advantages of the embodiments of the invention.</td>
</tr>
<tr>
<td>Brief description of the drawings</td>
<td>Description of any accompanying drawings or figures.</td>
</tr>
<tr>
<td>Detailed description</td>
<td>Description of the best method and other methods of performing the invention enabling a person skilled in the field of the invention to make and use the invention.</td>
</tr>
<tr>
<td></td>
<td>The detailed description provides the information content, and in effect the other sections of the specification can be largely ignored where a specification is being read as a source of information. Experimental examples are often included in this section.</td>
</tr>
</tbody>
</table>
Infringement of patent

Patents are used to protect both biotechnological products and processes. Infringement of a patent is a question of fact and depends on whether the activity conducted falls within the scope of a patent claim. Importantly, infringement of patents may be direct or contributory.

For more information on infringement of patents, see Chapter 2 ‘What Everyone Should Know’.

Reducing the Risk of Infringement

Failure to consider IP early in the research process may delay, or entirely prevent, the completion of the project, as you may be unable to use your final product due to IP infringement issues. In some instances, the cost of completing the project may drastically increase if you are required to obtain a licence to a particular piece of third party IP, which you have already incorporated into your product. Risks of IP infringement may be reduced by a number of measures. These are outlined below.

Performing freedom to operate searches

If you know the IP landscape (the type and degree of IP protection held by your organisation and others) of your project at an early stage, you can plot a course around the IP barriers or negotiate for permission to use the IP. Freedom to operate searches may assist you in ascertaining whether the research you plan will infringe IP rights of another party.

A freedom to operate search is an infringement search conducted on registered or published pending IP rights (such as patents and patent applications) to determine whether use or commercialisation of a product or a method will infringe the registered or pending IP rights. Since IP rights are territorial, you will need to conduct a freedom to operate search in each relevant country for the product or method you wish to use.

Freedom to operate searches are often performed by IP professionals who will provide a legal opinion on whether there is any infringement of existing IP rights. However, you should be aware that freedom to operate searches are often subject to time and resource constraints.
and the search may not locate key documents that were unpublished at the time of the search. It is for this reason infringement searches should be conducted periodically to avoid missing patents or designs unpublished at the time of the earlier search.

**Considering IP in your research process**

Before re-using any existing IP it is imperative that you check who owns the IP rights in the component or know-how you would like to incorporate in your product or process and whether there are obligations which arise through contracts or confidentiality agreements following acquisition of the component or know-how. If you do not own the IP rights to the component, seek authorisation to use the component (e.g. by licence) from the IP owner before using it.

You should be aware that ‘purchasing’ a component (e.g. to buy a product such as an enzyme from an authorised supplier) does not necessarily mean you are able to deal with that component in any manner. The IP right in that component may not ‘exhaust’ or become lost entirely following a sale of that component. For example, if you wish to deal with a component in any other way than initially agreed (e.g. under the sales terms and conditions), you may need authorisation from the IP owner to do so, otherwise you will be infringing their IP rights.

Set out below are some steps to assist you to plan your research process from an IP perspective:

**Step 1:** Listing components

While planning your research process, list all components which you would like to include and their anticipated use in a ‘Research Process IP Checklist’. It will be best practice to identify all the possible components required for the project (even if you believe some components may have been generated in-house) and include it in a Research Process IP Checklist. The type of IP rights and other possible legal rights attached to each component should also be identified.

For more information on what type of IP rights may apply to different research components, see Chapter 2 ‘What Everyone Should Know’.
An example Research Process IP Checklist is set out below:

<table>
<thead>
<tr>
<th>Project Name: Therapeutic kit for disease X by Company Q Pty Ltd.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Component</strong></td>
</tr>
<tr>
<td>Antibody AX237</td>
</tr>
<tr>
<td>Secret cross-linking reagent</td>
</tr>
<tr>
<td>Killing agent</td>
</tr>
</tbody>
</table>

**Step 2: Identifying the holder of the IP rights**

Once you have identified the IP rights and other legal rights attached to the required component, you will need to determine who owns the relevant IP and legal rights.

If the component is generated in-house by employees, it is likely that the IP rights are owned by your organisation. If the component is generated by a contractor, the default position (in Australia) is that the contractor will own the IP unless otherwise stated in the terms of the contract between the contractor and your organisation. For more information on ownership of IP, see Chapter 6 ‘What Senior Management Must Know’.

If your organisation does not own the IP rights in the component or if there are contractual obligations arising from purchase of the component, you will need to seek authorisation from the relevant IP owner before any use is made of it. It is an infringement of IP rights if you use the component before authorisation for that use is obtained.

If a product is protected by registered IP rights, it is common that markings or notifications are found on the packaging materials. For instance, a copyright notice will usually include the name of the owner. Patent numbers (or other IP registration numbers) included in the packaging materials will often assist you in your search of the relevant IP registers to identify the owner of the relevant IP rights. For more information on IP registers and databases, see section ‘Online IP databases’ of this Chapter.

Owners of component IP should be readily identifiable from the source of the component IP (such as through the patent number). In some instances, owners of the IP rights may not be readily identifiable and further investigation may be required. You may wish to consult your legal adviser on such occasions.

List the relevant IP right holders in the Research Process IP Checklist you generated in Step 1.
**Project Name:** Therapeutic kit for disease X by Company Q Pty Ltd.

<table>
<thead>
<tr>
<th>Component</th>
<th>Anticipated Use in Project</th>
<th>Possible IP Type or Legal Rights Attached</th>
<th>IP/ Legal Rights Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody AX237</td>
<td>To be used as targeting moiety</td>
<td>Patent and contractual restrictions</td>
<td>Patent is held by UBCA Pty Ltd. and antibody is sold for diagnostic use only</td>
</tr>
<tr>
<td>Secret cross-linking reagent</td>
<td>Cross-linking targeting moiety with killing agent</td>
<td>Confidential information and contractual restrictions</td>
<td>Designed by Contractor under confidential circumstances for research owners only</td>
</tr>
<tr>
<td>Killing agent</td>
<td>To be conjugated with antibody by cross-linking agent</td>
<td>Produced on fee for service basis</td>
<td>Produced by Company Z on fee for service basis; no IP</td>
</tr>
</tbody>
</table>

**Step 3: Seeking appropriate authorisation**

Once the identity of the IP owner has been ascertained, you will need to seek appropriate authorisation from the owner for your proposed use of the IP. Remember that not all uses of another’s IP will require permission.

In some instances, where you acquire a component and incorporate it in your research process in accordance with the terms under which you acquire the component, permission will not be required.

In general, if your use of the IP amounts to an infringement of the IP rights, permission or consent from the IP rights holder will be required. For more information on when an activity constitutes an infringement for different types of IP (including foreign IP rights), see Chapter 2 ‘What Everyone Should Know’.

The process of seeking appropriate authorisation may be relatively straight-forward, or may require more time than expected. Therefore obtain the permission as early as possible and always before any use is made of the component.

A licence is the usual mode of authorisation. A licence agreement will define the terms and conditions of use, payment structure for the use, and will preferably set out the IP ownership rights of the final product. For more information on acquiring IP components, see the section ‘Obtaining Rights to Third Party IP for Re-Use’ of this Chapter.

It will be good practice to include comment in the Research Process IP Checklist as to whether any required authorisation has been obtained and the conditions of that authorisation.
## Project Name: Therapeutic kit for disease X by Company Q Pty Ltd.

<table>
<thead>
<tr>
<th>Component</th>
<th>Anticipated Use in Project</th>
<th>Possible IP Type or Legal Rights Attached</th>
<th>IP/ Legal Rights Holder</th>
<th>Permission obtained?</th>
<th>Conditions for Anticipated Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody AX237</td>
<td>To be used as targeting moiety</td>
<td>Patent and contractual restrictions</td>
<td>Patent is held by UBCA Pty Ltd. and antibody is sold for diagnostic use only</td>
<td>Licence obtained by purchase of antibody does not authorise the anticipated use. Fresh licence under negotiation.</td>
<td>To be advised.</td>
</tr>
<tr>
<td>Secret cross-linking reagent</td>
<td>Cross-linking targeting moiety with killing agent</td>
<td>Confidential information and contractual restrictions</td>
<td>Designed by Contractor under confidential circumstances for research owners only</td>
<td>Assignment of IP sought from Contractor</td>
<td>Need to check with Contractor whether the conditions are acceptable</td>
</tr>
<tr>
<td>Killing agent</td>
<td>To be conjugated with antibody by cross-linking agent</td>
<td>Produced on fee for service basis</td>
<td>Produced by Company Z on fee for service basis; no IP</td>
<td>No action necessary</td>
<td>No action necessary</td>
</tr>
</tbody>
</table>

Below is a general checklist of activities which may reduce risks of IP infringement when designing products or processes.

- Before using any IP components, ensure your organisation owns it, or has the authorisation to use it for the purpose required for your research process.
- Ensure partners working on joint-projects have the necessary rights and permissions to use the IP they are contributing to the project.
- Read and comply with the terms and conditions of use for all IP used.
- Require written confirmation of originality from anyone who creates IP for the organisation.
- Consider using material available in the public domain. However, check whether there are applicable conditions attached to the material.
- Always document all stages of research and development in a laboratory notebook or design workbook.
- Check whether new employees are subject to any confidentiality restrictions imposed by their former employer or any other persons. Keep a record of such restrictions.
- Ensure employees under confidentiality restrictions do not work on projects where the
work is potentially covered by those obligations.

☑ Where an idea or information that is disclosed to the organisation was already known or is later disclosed by another source, notify the other party at the time. Record this notification and the basis for it.

☑ Monitor the market for new patents or other IP in trade press or through industry forums.

☑ Conduct periodic ‘freedom to operate’ searches on the Patent Register.

☑ Ensure that the chain of title for licensed material has been properly linked from all IP owners.

☑ Seek assistance from a lawyer to ensure that the scope of any licence negotiated is broad enough to include both present and anticipated uses of the material licensed (e.g. new technology). Ensure the agreement covers ownership issues, who has commercialisation rights, and how commercialisation proceeds are shared.

☑ Ensure confidentiality agreements are in place before discussing any ideas with partners with whom the organisation may be collaborating.

**Experimental use Infringement exemption**

Experimental use of a patented apparatus or method for conducting research and development has not been considered judicially in Australia, and so there is uncertainty as to the scope of this exception to patent infringement.

In the Australian Government Advisory Council on Intellectual Property (ACIP) Report ‘Patents and Experimental Use’ (2005), it was advised that ‘in some circumstances, use of a patented invention for experimental or research purposes would not constitute an infringement of a patent registered under the Act’.

However, not all commentary would agree with this position and the status of the law on experimental use does not necessarily follow this Report. The position is unpredictable, and it is recommended that use of a patented product or method with a view to leverage an improved apparatus or method should only be used with an appropriate licence from the patent owner.

You should seek advice from your patent attorney or lawyer before using any patented product or method for experimental use, research and development.

**“Springboarding” exemption to infringement of pharmaceutical patents**

“Springboarding” is an exception to patent infringement provided by Section 119A of the Patents Act 1990. Springboarding refers to activities which need to be undertaken, usually by a generic pharmaceutical company, solely in connection with obtaining regulatory approval on the Australian Register of Therapeutic Goods of pharmaceutical goods or for obtaining similar foreign regulatory approval, while one or more relevant patents are still in force. If springboarding was not permitted, such conduct during the term of a patent would amount to infringement of the patent.

Effectively, springboarding activities are now permitted as an exception to patent infringement on any pharmaceutical patent, at any time. A pharmaceutical patent is one which claims pharmaceutical substances or methods, uses or products relating to a pharmaceutical substance. The springboarding exemption is not limited to patents which have been granted an extension of term. The springboarding provision does not allow stockpiling of the pharmaceutical product (while the patent is still in force) for later sale, nor does it allow exportation of the product out of Australia in the situation where foreign regulatory approval is sought, unless the relevant patent has been granted an extension of term.
Obtaining rights to third party IP

When obtaining rights to third party IP for a component of your product or process, there are several things which require your consideration. Importantly, the terms and conditions under which the third party IP is bought or licensed need to be carefully reviewed. At a minimum, you should examine the following:

» payment structure
» restrictions on use of the IP in question
» ownership of improvements generated
» product warranties
» maintenance and support
» general warranty (e.g. on IP ownership and non-infringement).

Payment structure

Typical payment structures may include any one or a combination of the following:

» lump sum (one-off upfront fee)
» per use based (fee for each use of the IP on defined use scope)
» time based (multiple uses of the IP over a period of time)
» royalty based (fee charged when the IP is exploited)
» subscription based (fee for accessing the IP over a period of time).

Warranties, indemnities and other contractual rights

A warranty is a statement in a contract asserting a factual position. Examples of warranties include warranties confirming:

» a party owns the IP or has adequate rights to grant the licence
» registrable IP rights are being maintained
» the IP is not believed to infringe the IP right of another party.

You may further require the party to the contract to indemnify your company against any claims by another person (e.g. a claim that the relevant IP infringes his/her rights).

The inclusion of a warranty or indemnity in a licence agreement (and the extent of the warranty and indemnity) is technical and will depend on the particular circumstances of a transaction. You should consult your legal adviser for such matters.

Planning for use of products under a material transfer agreement

When creating a new product or process, researchers sometimes have a need to access materials, such as drugs, cells, viruses, vectors or toxins, which are sourced from other parties and which are subject to restricted access provisions, often termed material transfer agreements (MTA). While MTA may provide the researchers with access to goods which are otherwise not available, MTA often contain contractual conditions relating to what may be done with the materials, the ownership of intellectual property or the payment of licence fees for commercial activity which is generated as a result of using the materials.
It is important to consider the ramifications of these contractual arrangements before entering into a MTA. If the MTA results in a “dilution” of ownership of intellectual property rights, or if the agreement obliges the user to make payments of a proportion of any revenue generated as a result of the research, the use of these materials becomes much less attractive commercially.

Before entering into a MTA you should consider whether more favourable contractual arrangements could be negotiated, whether an alternative source for the material can be identified, or indeed whether it might be better to re-design around the need for that particular material.

**Conducting due diligence**

Due diligence is an information gathering and analytical process to ensure (to the extent possible) that the third party actually owns the IP or is able to grant the purported IP rights under the proposed terms and conditions.

In the context of acquiring third party IP, the due diligence process typically involves requesting the third party to, at a minimum, furnish evidence that:

» the IP rights exist
» it owns the IP or has adequate rights to grant the licence
» the IP rights are valid.

For example, the third party may produce evidence of a granted patent for the IP concerned which shows that it is the owner and that all maintenance fees have been paid.

The scope (and cost) of a due diligence process will depend on the nature of the transaction. For more complex transactions (e.g. seeking an IP licence on an exclusive basis), or where the contract amount is substantial, a more extensive due diligence process may be justified.

**Breach of contract or confidence**

Materials or know-how may be made available as confidential information under contractual relationships. Goods may also be supplied with other contractual restrictions, e.g. for a specific use only. If goods (subject to contractual or confidential obligations) are re-used, there may potentially be breach of contract or breach of confidence. Common scenarios where breach of contract may occur include researchers or designers re-using goods which are only provided for specific purposes, for example where goods are provided for a diagnostic purpose but are being used therapeutically. Breach of confidence may occur where researchers re-use materials or know-how subject to confidentiality obligations, such as know-how developed:

» whilst they were employed by their former employers
» for a collaboration for a particular use, and the project did not proceed.

For more information on breach of confidentiality obligations, see Chapter 2 ‘What Everyone Should Know’.

**Identifying Inventive Subject Matter**

Most researchers in the Biotechnology fields generate IP regularly. However, not all IP generated is sufficiently ‘inventive’ to gain patent protection. Among all the requirements for patent registration, the requirement of inventiveness (or non-obviousness) is generally
considered to be the most difficult to achieve. With the rapid advancement of technology in the Biotech industry, what is inventive today may well be obvious tomorrow.

This section discusses some of the criteria for assessing the patent requirement of inventiveness to assist researchers to identify inventive subject matter generated in a research process. For more information on other requirements for patent registration, see the section ‘Patents’ in Chapter 2 ‘What Everyone Should Know’.

**Factors determining inventive step**

In Australia, the test for assessing inventiveness for a standard patent is, generally speaking:

Would the invention be obvious to an ordinarily skilled worker in the field in Australia at the priority date, when considered against the “prior art” in light of the common general knowledge at the time, or when considered against the common general knowledge alone or when considered against the common general knowledge together with the relevant prior art?

This may be restated as “Would the ordinary skilled worker at the filing date, in all the circumstances which include a knowledge of all the relevant prior art, directly be led as a matter of course to try the invention in the expectation that it might well produce a useful alternative to or a better result than the prior art?”

This is not necessarily a straight-forward question, and so the courts look to a number of factors to assist them with such an assessment:

<table>
<thead>
<tr>
<th>Factors</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imitations by rivals</td>
<td>Evidence of copying by others is a strong indication of inventiveness.</td>
</tr>
<tr>
<td>Unexpected results</td>
<td>Evidence of comparative testing with the closest prior art that results in unexpected or surprising results is a strong indication of inventiveness.</td>
</tr>
<tr>
<td>Solutions to unsolved problems</td>
<td>Providing a solution to a previously unsolved known problem may indicate that the new invention is non-obvious.</td>
</tr>
<tr>
<td>Unrecognised problem</td>
<td>Providing a solution to a previously unrecognised problem is a strong indicator of non-obviousness.</td>
</tr>
<tr>
<td>Omission of an element</td>
<td>Omission of a part, ingredient or step in a known process may indicate inventiveness.</td>
</tr>
<tr>
<td>Long felt need</td>
<td>Satisfaction of market demands may indicate inventiveness.</td>
</tr>
<tr>
<td>Congested art</td>
<td>A seemingly small inventive leap may be non-obvious if the invention lies within a crowded art.</td>
</tr>
<tr>
<td>Assumed unworkability</td>
<td>Making something workable which was previously considered unworkable is an indication of inventiveness.</td>
</tr>
<tr>
<td>Unappreciated advantage</td>
<td>A previous unrecognised inherent advantage can be an indicator of non-obviousness.</td>
</tr>
<tr>
<td>Weak prior art</td>
<td>Proving that the prior art is inoperative, vague, teaching away from the invention, conflicting, misunderstood or never implemented may strengthen the indication of inventiveness.</td>
</tr>
</tbody>
</table>
### Factors | Explanation
--- | ---
**Acceptance by industry** | Evidence of trade articles, industry statements, requests for licences and industry restraint from infringing or challenging the invention may indicate inventiveness.

**Commercial success** | This does not demonstrate inventiveness but can be a strong indicator that the invention was needed by the market, which may help in borderline cases for registration.

Below are some examples of patentable inventions demonstrating inventive step:

- where a new combination of existing features results in an improved and preferably synergistic result (a new combination of existing features without an improved result is not an invention)
- where a solution is developed to resolve technological problems or limitations of the field
- where a known process or combination of features is modified to omit a step in the process or a feature in the combination, where previously all were considered necessary
- where the inventor makes a new and useful selection of members from among a class of substances, and as a result of the selection the inventor is able to produce new and useful results or old results in a cheaper or better manner.

**Preparing an invention disclosure**

Whenever you believe there are good grounds that inventive subject matter is created, it is important that you capture the inventive subject matter in an invention disclosure document.

The invention disclosure document will be evaluated by management to determine the best form of IP protection to apply to the invention. Management may seek the advice of a patent attorney who will assist your organisation to determine whether formal protection of a patent registration is appropriate, or whether treating the invention as confidential information is more suitable.

A properly completed invention disclosure document (signed, dated and witnessed) may be critical when trying to establish the date of invention. The date of invention is particularly important to filing patent applications in the United States, which grants patents on a ‘first-to-invent’ basis.

A standard invention disclosure form may already exist within your organisation. All invention disclosure forms vary in format and style, but they should all essentially ask the same questions. Below is an example of an invention disclosure form:
CONFIDENTIAL

INVENTION DISCLOSURE FORM

Submitted by:

Date:

Please complete the following items and return a copy to:

[Insert Management contact details]

1. Individuals who contributed to the invention:

<table>
<thead>
<tr>
<th>Full name</th>
<th>Contact information</th>
<th>Department</th>
<th>Employee, student or Contractor?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Title of invention:

3. Abstract:

4. Was any part of the project externally funded and, if so, by whom (e.g. third-party or a government grant or contract)? Provide contact details.

5. Date of first conception (dd/mm/yyyy):

Identify any written evidence of this date (e.g. drawings, sketches, project notebooks, files) and/or names of any corroborating witnesses:

6. Has the invention been described in specific detail or in a general way in a publication (e.g. thesis submission, grant application, manuscript submission, conference abstract, conference presentation, journal publication, advance on-line publication)? Has the invention been disclosed, sold or offered for sale to anyone? If so, please describe to whom and under what conditions (e.g. confidentiality agreement) and provide relevant dates. This is extremely important.

<table>
<thead>
<tr>
<th>Type of disclosure</th>
<th>To whom</th>
<th>Conditions</th>
<th>Date (dd/mm/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Are there any plans to publish or orally disclose a description of the invention in the next 12 months? Provide dates (dd/mm/yyyy).

8. List any websites, publications, patents, products, services, etc (i.e. prior art) that you are aware of that are similar to or discusses the subject matter of the invention.

9. Why do you think this invention is strategically important to the Organisation?

10. Are there any Organisation products/services/projects that utilise or may utilise the invention?
11. State the problem(s) you were trying to solve:
   a. Have others tried to solve the same problem? If so, describe how:
   b. Describe how your invention solves the problem and any other advantages of your invention. Provide a description as detailed as possible, in order for another person to understand and reproduce the invention without any inventive effort of their own.
   c. Please attach or identify any experimental results, drawings, sketches, project notes, documents, etc that describe the details of the invention.

12. Additional information:

<table>
<thead>
<tr>
<th>Submitted by:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed name:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Date:</td>
<td>WITNESS: I have read and understood this Invention Disclosure Form:</td>
</tr>
</tbody>
</table>

[The witness should be a manager, rather than a co-worker or collaborator and should not be an individual identified under Point 1]

<table>
<thead>
<tr>
<th>Printed name:</th>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>
Identifying the Inventor

Who is the inventor?

A patent for an invention may only be granted to the inventor or persons claiming ownership through the inventor. Correctly naming the inventors can be crucial to a patent application. There will often be more than one inventor.

If a mistake or omission is made in naming an inventor, there may be serious consequences. In the extreme case, this can include the patent being wholly invalidated. An ‘inventor’ is not defined in the Patents Act 1990.

There is little judicial guidance on determining inventorship, however the Australian Patent Office has provided two tests that are of assistance.

‘But For’ Test

A person is the inventor of an invention where the invention would not have occurred but for the involvement of that person, Harris v CSIRO (1993) 26 IPR 469.

‘Material Effect’ Test

A person is the inventor of an invention where his/her contribution had a material effect on the final concept of the invention, Row Weeder v Nielsen (1997) 39 IPR 400.

The issue of ‘inventorship’ should not be confused with ‘ownership’ of the invention nor with ‘authorship’ in the context of publications. ‘Inventorship’ is identifying the inventor of the invention, ‘ownership’ is identifying who is entitled to possess the patent rights in the invention and ‘authorship’ is identifying who has authored a particular publication. The inventor and the owner of an invention may not necessarily be the same entity. An author of a publication describing an invention may not necessarily be an inventor of that invention.

Identifying joint-inventors

It is common in the Biotechnology field for a team of researchers to work together to produce an invention. As a result, doubt may arise as to who has contributed to the invention and should be regarded as a joint inventor. Two or more persons will be a joint-inventor of an invention where the invention only came about because of the involvement of both of those persons.

The ‘but for’ test and ‘material effect’ test (above) may help to determine and identify joint inventors. There are some additional indicators of joint inventorship that may also assist:

<table>
<thead>
<tr>
<th>Is a Joint-Inventor</th>
<th>Not a Joint-Inventor</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑️ Materially contributes to the ultimate development of the invention</td>
<td>☑️ Merely following instructions</td>
</tr>
<tr>
<td>☑️ Solves a problem not recognised by initial inventors</td>
<td>☑️ Merely performing routine work</td>
</tr>
<tr>
<td>☑️ Solves a recognised problem that initial inventors could not solve</td>
<td>☑️ Merely engaged to construct an article to another’s design</td>
</tr>
</tbody>
</table>
Chapter 4: What Researchers Must Know

### Keeping laboratory notebooks

Laboratory notebooks should be used to record all your research and development activities. Information set out in the notebooks must be clear, dated and sufficiently detailed to record all relevant activities undertaken in the development of a product or process.

Where an invention is generated in the course of product research or development, properly kept laboratory notebooks (i.e. in addition to a properly completed Invention Disclosure Form) may be critical substantive evidence in establishing the date of invention in the event of a patentability contest in a jurisdiction where patents are awarded on a 'first to-invent' basis, such as the United States. These notebooks also provide objective evidence of who is/are the inventors.

You should ensure and encourage those under your supervision to keep laboratory notebooks up-to-date. Avoid letting days go by without making an entry. Meticulous recordkeeping will ensure that each stage of development of the project is protected. Below is a general checklist for good laboratory notebooks-keeping practices:

- Entries written up in a consecutively numbered notebook.
- The notebook must be properly bound so that pages cannot be removed or inserted.
- Permanent ink used.
- No blank spaces on finished page, no skipped pages and no removed pages.
- Each entry written consecutively, signed, dated, verified by a witness and ruled off.
- Entries are legible, thorough and complete.
- Entries include description of initial ideas, experiments conducted and work completed.
- Details of all persons involved in the project should be included with each entry.
- Any corrections made should be dated, initialled and witnessed.
- All non-standard terms, processes and abbreviations defined.
- Annexed material should be permanently attached (glue, not staple or sticky tape) and sealed, signed and dated. If it is not practical to annex it, store it separately, sign, date, witness and cross-reference it to the relevant entry.
- All laboratory notebooks and their attachments, should be stored appropriately and kept confidential.
- All laboratory notebooks and design workbooks should be kept for as long as is needed to verify the legitimacy of the work.

Below is an example page of a suitable laboratory notebook:

<table>
<thead>
<tr>
<th>Is a Joint-Inventor</th>
<th>Not a Joint-Inventor</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Produced an advantage not contemplated by initial inventors</td>
<td></td>
</tr>
</tbody>
</table>

For more information on research collaborations, see section ‘Research collaborations’ in Chapter 6 ‘What Senior Management Must Know’.
The reference number identifying the project

The name of the experiment you are conducting

Statement and description of the idea you are testing and experimenting

A complete record describing the methodology, observations, results and conclusions of the testing and experiments performed relating to the idea, including drawings and graphs.

Cross-reference to any annexed materials here.

Record names of others who assisted with the experiment.

<table>
<thead>
<tr>
<th>RESEARCH SCIENTIST</th>
<th>WITNESSED and UNDERSTOOD BY:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Printed name:</td>
<td>Printed name:</td>
</tr>
<tr>
<td>Date:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

IP record storage practices

IP records are assets with great value, and these assets can only be realised if the IP records are stored safely and the information these records contain is handled in an appropriate manner.

Any disclosure of IP records at the 'wrong' time can limit or destroy its potential commercial value. In particular, premature or inappropriate disclosure, exploitation or commercial use of information forming the basis of some IP types may prevent your organisation from obtaining IP protection or diminish the scope of protection.
Tips for Storing Intellectual Property Records

- Adopt appropriate security measures, e.g. under lock and key, encryption, password-protection.
- Use up-to-date operating systems, anti-virus and anti-spyware software. Be wary of suspicious emails which may contain viruses.
- Regularly back-up information stored on your hard-drive and store the back-up disks in locked facilities, preferably at a second site.
- If necessary, seal the information in protective covering or wrapping to prevent deterioration, and store it away from known hazards. Fire-proof and water-proof safes may be suitable.
- Avoid storing the information on storage devices, such as USB drives, and CD-ROMs – unless kept locked up when not in use, and the information is deleted when no longer required.

Personnel practices

Be familiar with your IP policy

Your organisation is likely to have an IP policy in place which sets out your organisation’s objectives for managing IP. The IP policy will set out what you should do when you have created or acquired IP and provide guidance on ongoing practices in managing IP. You should be familiar with and adhere to your organisation’s IP Policy.

Observe your confidentiality obligations

Since researchers are key IP generators within an organisation, it is likely that you and those under your supervision would have signed confidentiality agreements with your organisation. Typically, these confidentiality agreements require employees to:

- maintain the secrecy of confidential information of the organisation during and after their employment
- only use the confidential information within the scope of their employment, and
- return all confidential information in their possession to the organisation at termination of their employment.

You should adhere to, and ensure those who work under your supervision comply with, those confidentiality obligations.

Ongoing IP obligations

The registration process for some forms of IP may take a few years. Therefore, you may have an obligation under your employment agreement to assist your organisation to register the IP you created (e.g. execution of relevant documents, including assignment documents) even after your employment with your organisation finishes.

Identification and protection of confidential information

Confidential information is information not readily available to the public and gives your organisation its competitive edge. Publication of confidential information may prevent patent protection being obtained. You are likely to generate confidential information every time you record information in your laboratory notebooks. Unauthorised disclosure of confidential information may undermine the value of your organisation. Precaution must be exercised to
ensure confidentiality of the information is kept.

The IP Policy of your organisation would have outlined practices for the identification and protection of confidential information. For more information on measures to protect confidential information, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

**Review of public disclosures**

Publication of work by researchers or public announcements in most instances destroys the patentability of otherwise patentable subject matters. All drafts of public disclosures (such as technical publications) and communications (such as correspondences, press announcements and internal memoranda), should be reviewed by responsible personnel to ensure any patentable subject matter is not inadvertently disclosed.
What Managers Making IP Protection Decisions Must Know

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What this Chapter covers

IP may be the principal asset of an organisation. An organisation may risk losing its IP rights and significant opportunities to commercialise its IP if it neglects to implement proper protection measures.

This Chapter will discuss:

» the general issues arising in making IP protection decisions
» how to obtain and maintain protection for the different forms of IP, and
» the specific issues relating to IP protection decisions for the different forms of IP.

General Issues in Making IP Protection Decisions

Protection of IP does not happen automatically. You need to take active measures to preserve, defend and enforce IP rights. Some forms of IP rights (e.g. patents, designs, plant breeder’s rights and trade marks) require formal protection and you will need to apply to the relevant government authorities (e.g. IP Australia). Other, non-registrable forms of IP rights (e.g. copyright, circuit layout and confidential information) may also require careful planning and implementation for their protection, enforcement and optimal exploitation.

The following steps will assist you when considering IP protection issues for your organisation:

**STEP 1**
Identify subject matter that may need IP protection

**STEP 2**
Identify what forms of IP protection are available

**STEP 3**
Determine how to implement IP protection for the subject matter
Step 1: Identify subject matter that may need IP protection

The decision to implement IP protection for particular subject matter may occur before, during or after its creation. You may have already identified subject matter that requires IP protection as early as the planning stage of a project. Alternatively, an organisation may be unaware of the existence of an IP asset until after it has conducted an IP audit.

Not all subject matter generated or acquired by an organisation will require IP protection. The decision you make whether to implement IP protection measures for particular subject matter which is generated or acquired by your organisation usually depends on the nature, purpose and value of the subject matter and the role it plays to achieve your organisation’s objectives and business goals.

The questions below will assist you in formulating a view as to whether particular subject matter requires IP protection:

<table>
<thead>
<tr>
<th>Nature, Purpose and Value of the Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>What role does the subject matter play to achieve the objectives or business goals of the organisation?</td>
</tr>
<tr>
<td>What is the intended use and purpose for the subject matter?</td>
</tr>
<tr>
<td>Does the subject matter have sufficient commercial value or potential value to justify the expense of implementing IP protection?</td>
</tr>
<tr>
<td>Is the subject matter prone to rapid change and development?</td>
</tr>
<tr>
<td>Does the subject matter have a short commercial life span?</td>
</tr>
<tr>
<td>Is protection required to preserve the value of the subject matter?</td>
</tr>
<tr>
<td>Can the subject matter be easily reverse-engineered or reproduced?</td>
</tr>
<tr>
<td>Can the subject matter be kept secret indefinitely?</td>
</tr>
</tbody>
</table>

Step 2: Identify what forms of IP protection are available

Very often, more than one form of IP protection is available for subject matter, although you may not require all forms of protection to be implemented. For more information on the different forms of IP that may apply to a subject matter, see Chapter 2 ‘What Everyone Should Know’.

At this stage it is best practice to list all forms of IP protection that may apply to the subject matter and consider the advantages and disadvantages of the various forms of protection available.

Step 3: Determine how to implement IP protection for the subject matter

Having identified the different types of IP protection available and their respective advantages and disadvantages, you will need to form an opinion as to what form(s) of IP protection is/are appropriate. Use the following questions to assist you to determine the appropriate form(s) of IP protection for the subject matter.
Questions to consider when selecting the form of IP protection

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the protection require formal registration?</td>
</tr>
<tr>
<td>Does formal registration provide any additional useful protection?</td>
</tr>
<tr>
<td>Does the benefit of registration outweigh the costs of registration?</td>
</tr>
<tr>
<td>Is registration necessary to preserve the value of the work?</td>
</tr>
</tbody>
</table>

You will also need to take into account the IP policy of your organisation. In particular, the IP policy may specify a particular procedure that you should follow to obtain approval for your recommendations.

Consider the following questions when making recommendations for the forms of IP protection to be pursued for the subject matter:

Organisation’s IP policy and implementation plan

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the IP Policy provide guidance on the protection of IP?</td>
</tr>
<tr>
<td>What authorisation is necessary to implement IP protection?</td>
</tr>
<tr>
<td>Does the organisation have the resources to maintain the protection of IP?</td>
</tr>
<tr>
<td>Does the organisation have the resources to enforce IP rights if infringed?</td>
</tr>
</tbody>
</table>

Other sections of this Chapter will give you a general overview of how to obtain and maintain different forms of IP protection. However, implementation of IP protection, particularly registrable forms of IP, can be complex and technically difficult. If you wish to obtain formal registration of your IP asset, it is vital that you seek the assistance of an appropriate IP or legal professional.

Patents

Should the invention be registered?

Generally, an invention may be protected by one of the following ways:

<table>
<thead>
<tr>
<th>Patents</th>
<th>Confidential Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>To be formally registered as a patent.</td>
<td>To be kept secret as confidential information.</td>
</tr>
</tbody>
</table>

Determining the form of protection that is appropriate for the invention depends largely on the nature of the invention. For example, there are certain criteria that need to be met before a patent is granted for an invention. Not all inventions may meet these criteria to be
eligible for protection as a patent, and it may be appropriate for some inventions simply to be kept confidential. In addition, where it is highly unlikely that an invention could be reverse engineered it may be more appropriate to be kept as confidential information.

Of course, one alternative to protecting an invention with a patent or with confidential information is to intentionally publish details of the invention as a defensive strategy to prevent others independently gaining a monopoly position. This is known as a “scorched earth” approach.

For more information on the patentability requirements in Australia, see Chapter 2 ‘What Everyone Must Know’.

### Patents vs confidential information

The features of patent registration and confidential information are summarised below and you will need to assess the most appropriate way to protect the invention in light of the following:

<table>
<thead>
<tr>
<th>Features of Protection</th>
<th>Patents</th>
<th>Confidential Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>» Exclusive rights to prevent others from exploiting the invention.</td>
<td>» No enforceable rights against others from exploiting the invention if it is independently discovered by reverse engineering or by other legal means.</td>
</tr>
<tr>
<td></td>
<td>» Patent protection needs to be sought on a country-by-country basis.</td>
<td>» No need to pursue protection on a country-by-country basis.</td>
</tr>
<tr>
<td></td>
<td>» Published, and so cannot be kept confidential for an extended period.</td>
<td></td>
</tr>
<tr>
<td><strong>Term</strong></td>
<td>Provided renewal fees are paid, the term of protection is:</td>
<td>Protection will exist as long as the invention is kept secret.</td>
</tr>
<tr>
<td></td>
<td>» 20 years from filing of the complete application for standard patents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>» 8 years from filing of the complete application for innovation patents</td>
<td></td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td>Costs of registration can be relatively high especially if foreign protection is sought.</td>
<td>Costs associated with keeping the invention confidential will generally be internal administrative costs and costs for maintaining physical security of the confidential information.</td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td>» The patent application may not be successful, but your invention will still be published.</td>
<td>» The invention may be inadvertently disclosed.</td>
</tr>
<tr>
<td></td>
<td>» The patent application may be opposed or the granted patent invalidated.</td>
<td>» The invention may be reverse engineered or discovered by other means.</td>
</tr>
<tr>
<td></td>
<td>» The invention must be disclosed in the patent application which may increase the risk of others copying, working around or improving the invention.</td>
<td>» If discovered independently, it may be patented by someone else, which may limit your opportunity to exploit the invention.</td>
</tr>
</tbody>
</table>
When to file a patent application

Generally, a patent application should be filed as soon as the invention can be sufficiently described in a patent specification and the inventors can predict the scope of the invention.

A patent application also should be filed before any publication or commercial use of the invention takes place. Publication or disclosure of the invention may destroy the possibility of being granted a patent.

Should a provisional application be filed?

A provisional application cannot ‘mature’ into a granted patent.

Filing a provisional patent application (rather than a complete application in the first instance) is optional. However, a provisional application can be a cost-effective way to establish a priority date for your invention. The priority date is the date against which novelty and inventiveness of the invention will be assessed.

The provisional application remains pending only for 12 months and, for the priority date to be maintained, a complete application must be filed within those 12 months.

When a provisional application is filed, it allows you up to 12 months to:

- decide whether to continue with the patenting process
- do further research and development on the invention, and
- explore commercialisation opportunities of the invention by seeking potential commercialisation partners.

It is sometimes thought that a provisional specification need only describe an invention in general terms, and that the full detail can follow in the subsequent complete application. This is a very dangerous approach since the priority date established by the provisional application may then not be sustainable for lack of adequate description, particularly in other countries.

How to obtain the grant of a patent

Patent searches

Before submitting a patent application, it is advisable to conduct patent searches to find out whether the invention:

- is anticipated by any ‘prior art’, and therefore may not be novel or inventive, or
- infringes existing patent rights of others and therefore might require a licensing
agreement before pursuing as a commercial product.

Limited patent searches may be conducted on IP Australia’s patent database ‘AusPat’ located at: [http://www.ipaustralia.gov.au/auspat/]

It is recommended that you seek the assistance of a patent attorney to ensure a comprehensive search is undertaken. A patent attorney will be able to assist with conducting the following types of search:

- **Patentability searches**: Locates prior art closely related to your invention, i.e. already published applications, patents and other documentation or information.
- **Infringement searches**: Locates existing patents or pending patent applications having claims closely related to your invention.
- **State of the art searches**: Provides an overview of a particular market or field.
- **Bibliographic searches**: Locates pending patent applications or granted patents by a particular inventor or applicant.

For more information on patent search strategies, see Chapter 4 ‘What Researchers Must Know’.

**The patent application process**

Set out in the diagrams below are the indicative overviews of the patent application process for standard and innovation patents.
**Indicative Standard Patent Application Process**

**Provisional Patent Application**
Filing a provisional patent application is optional. The filing date of the provisional application will establish a priority date.

**PCT Patent Application**
A PCT patent application may be filed within 12 months. See the 'Indicative PCT Process' diagram in this Chapter.

**Complete Patent Application**
Complete patent application for an innovation patent is filed (within 12 months from the filing date of the provisional application, assuming there is one).

**Publication**
The application will be published in the Official Journal of Patents after 18 months from the priority date (in this case lodgement of the provisional application).

**Examination of Standard Patent**
The Patent Office determines whether the standard patent application meets the validity requirements.

- **YES**
  - **Notice of Acceptance**
    - Notice of acceptance is advertised in the Official Journal of Patents.

- **NO**
  - **Examination Report**
    - This report summarises any patentability requirements that are not met.

**Granted patent**
The term of a standard patent is generally 20 years from the filing of the complete application, provided renewal fees are paid.

**Patent application refused**
Submission of response by applicant

**Possible Re-examination**
Re-examination may be initiated by the patentee or others. The patent may be revoked or its validity rectified by amendment.

**Re-examination**
Re-examination may be initiated by the Patent Office between acceptance and grant. If the applicant is unable to overcome an adverse re-examination report, the accepted patent may be refused.

**Opposition**
Opposition may be initiated by others within 3 months from the date of advertisement of the Notice of Acceptance. If opposition is successful, the accepted patent may be refused, or problems sought to be rectified by amendment.
Chapter 5: What Managers Making IP Protection Decisions Must Know

Innovation Patent Application Process

Provisional Patent Application
Filing a provisional patent application is optional. The filing date of the provisional application will establish a priority date.

Complete Patent Application
A complete patent application for a standard patent is filed (within 12 months from the filing date of the provisional application, assuming there is one).

Formalities Check of Innovation Patent
Does the innovation patent application pass the formalities check?

YES

Grant and Publication
The application will be granted and published in the Official Journals of Patents.

NO

Notice of Deficiency

Request for Examination of Innovation Patent
Does the innovation patent's claims meet the validity requirements? This step is optional, but only a certified innovation can be enforced.

YES

Patent application may lapse

Submission of response by applicant

NO

Innovation Patent Certified
The term of an innovation patent is 8 years from the filing of the complete application, subject to payment of renewal fees.

Examination Report
This report summarises any patentability requirements that are not met.

Patent application may be revoked

Submission of response by applicant

Re-examination
Re-examination may be initiated any time during the term of a certified innovation patent.

If the patentee is unable to overcome an adverse report, the certified patent may be revoked.

Opposition
Opposition may be initiated (typically by others) any time after the innovation patent is certified.

If opposition is successful, the certified patent may be revoked, or problems rectified by amendment.
Filing a patent application

A patent specification is a complex legal document that is best prepared by an experienced patent attorney. Once the patent application is lodged, the specification as filed will be assessed against patentability criteria by the Patent Office. It is generally not possible to amend the specification at a later stage to add further subject matter.

Aside from the fact that an invention as claimed needs to comply with the patentability requirements as set forth in Chapter 2 ‘What Everyone Should Know’, such as being novel and inventive, there are several specific requirements with which a patent application must comply. Failure to satisfy these requirements may lead to the subsequent granted patent being invalidated. These requirements are summarised in the diagram below.

Inventorship

All inventors who contribute to the development of an invention should be listed on the patent application.

An inventor is a person who has made a contribution to the conception of the invention which is defined in at least one of the claims of the patent application.

It is vital that the correct inventors be named on a patent application to avoid any risk of the subsequent granted patent being held invalid, such as for false suggestion or misrepresentation or failure of the patentee(s) to have proper entitlement.

You should provide your patent attorney with information outlining the contribution each individual made towards the invention to enable your patent attorney to identify the inventors.

For more information on inventorship, see the section ‘Identifying the inventor’ in Chapter 4 ‘What Researchers Must Know’.

Sufficiency of Description

A patent specification must fully describe the invention and disclose the best method of implementing the invention known to the inventors at the time of filing so that a skilled person on reading the specification is able to carry out the invention.

For Biotechnology inventions the burden on the applicant to sufficiently describe the invention may be heavier than for other technical fields, because Patent Office practices have evolved on the assumption that biotechnology processes are inherently unpredictable. As a result, each step of the invention needs to be established in the specification by evidence or by reasoned argument.
You should provide your patent attorney with adequate details of the invention, including the different methods of performing the invention and details of all experiments or trials conducted and results obtained.

**Fair Basis**

Fair basis essentially is a requirement that the claims of a patent (or a patent application) be supported by the subject matter described in:

- the patent specification, and
- any earlier applications from which priority is being claimed.

In simple terms, there must be a real and reasonably clear basis for the features of the invention, and for the specific combination of features of each claim in the described subject matter.

Fair basis is an issue with which a patent attorney will be concerned when writing a patent specification.

**Clarity of Claims**

A patent specification requires that the boundaries of the invention be stated and claimed clearly. In addition, a claim must be clear and unambiguous so that its scope can be ascertained. This requirement is one of language. The claims of a patent application should be sufficiently narrow to be novel, but be sufficiently broad as to adequately protect the invention from unauthorised use by others.

**Address for service**

An applicant for an Australian patent application must have an Australian address for service. This may be the applicant’s address or the address of their agent, such as their patent attorney.

**Briefing your Attorney**

You should provide your patent attorney with the results of any patent searches which have been conducted and details of any public disclosures of the invention to assist in determining the appropriate scope of the claims. Often a patent attorney will provide your organisation with a questionnaire for the inventors to complete to assist with the preparation of a patent application.

Preparing and filing a patent application requires specialist skills and legal knowledge. Many patent applications that are filed without professional help may not be granted, or may have their validity challenged, because they do not comply with one or more of the requirements above. It is strongly recommended that you consult a qualified patent attorney before you apply for a patent.

For more information on a description of the different types of patent applications, see Chapter 2 ‘What Everyone Should Know’.
**Application fees**

An application fee will be required to be paid at the time of filing a patent application. Additional fees will be required to be paid depending on the action taken during the application process, such as requesting examination and on acceptance.

These fees and their associated time-frames are subject to change, and accordingly care should be taken to meet deadlines. Failure to do so may result in your patent application lapsing.


**Publication**

A patent application is published officially by the Patent Office approximately 18 months after the earliest priority date. Once a patent application has been published, the organisation may disclose the invention without risk to the validity of the application, provided that the technical publication discloses no more than what is set out in the specification.

It is recommended that there is no publication of the invention by the inventor or the applicant in the 18 months after filing the first patent application, especially if it is likely there will be further developments to the invention. Publication of the invention should be restricted until official publication occurs in case a follow-up patent application is to be filed for the new developments. This ensures that the new developments are not considered as being obvious when assessed against the earlier publication of the original invention.

**Examination of standard patent applications**

A standard patent application is subject to examination by the Patent Office. The applicant must lodge a request for examination within 5 years of filing the complete specification, or within 6 months of a direction issued by the Patent Office to request examination – whichever occurs earlier. Of course, you may request examination immediately at filing, if you wish to seek early grant of a patent.

Examination of standard patent applications consists of assessing the invention’s patentability against the required criteria set out in the Patents Act. The criteria is summarised in the section ‘Requirements of patent grant’ in Chapter 2 ‘What Everyone Should Know.’

The Patent Office will issue an examination report which summarises any objections the Examiner has to the patentability of the invention. The applicant has 21 months from the date of the examiner’s first report to overcome all of the issues raised by the Patent Office.

**Certification of innovation patent applications**

Certification of an innovation patent application is optional. An innovation patent application will be accepted when it meets all requirements of an initial formalities check regarding administrative issues.

However, to enforce the rights afforded by an innovation patent, an innovation patent must be examined and certified. At examination, the Patent Office will conduct a substantive assessment of the validity of the innovation patent. If the Examiner finds any grounds for revocation of the innovation patent an adverse examination report will issue. The applicant has 6 months from the date of the report to overcome any issues raised in the report. The Patent Office will either certify or revoke the innovation patent after the substantive
examination.

Only a certified innovation patent may be enforced against an infringement.

**Opposition**

Both standard patent and innovation patent applications may be opposed on any of the following grounds set out in the Patents Act:

<table>
<thead>
<tr>
<th>Grounds for opposition to a standard patent application or an innovation patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>The applicant/patentee is not entitled to a grant of a patent for the invention.</td>
</tr>
<tr>
<td>The applicant/patentee is entitled to the grant of a patent but only in conjunction with some other person.</td>
</tr>
<tr>
<td>The specification does not describe the invention fully.</td>
</tr>
<tr>
<td>A claim(s) is not clear, succinct or fairly based on the matter described in the specification.</td>
</tr>
<tr>
<td>The invention as claimed is not a manner of manufacture.</td>
</tr>
<tr>
<td>The invention as claimed is not novel.</td>
</tr>
<tr>
<td>The invention as claimed in the standard application or innovation patent has no inventive or innovative step, respectively.</td>
</tr>
<tr>
<td>The invention as claimed is not useful.</td>
</tr>
<tr>
<td>The invention as claimed was secretly used before the priority date by or on behalf of, or with the authority of, the patentee or nominated person, or his predecessor in title to the invention.</td>
</tr>
<tr>
<td>A claim(s) encompasses a human being or involves the biological processes for the generation of human beings.</td>
</tr>
</tbody>
</table>

Additionally, and only for innovation patents, the claims are directed to a plant or animal or the biological process for the generation of a plant or animal (unless the invention is a microbiological process or a product of such a process).

A standard patent may only be opposed within 3 months of the date of a notice of acceptance being published in the Official Journal of Patents. An innovation patent may be opposed any time after it has been certified by the Patent Office.

An opposition will be heard at the Patents Office where the Commissioner of Patents will decide the matter based on the evidence (including expert evidence) filed by the parties.

A successful opposition by the opponent may result in an accepted standard patent application being refused, or may require the patent applicant to amend the claims to remove a lawful ground of invalidity before the patent can be granted. In the case of a certified innovation patent, a successful opposition may result in revocation or amendment of the patent.

You should be aware that even if an opposition is withdrawn by the opponent, the Commissioner of Patents may still consider any evidence already on file and voluntarily re-examine the patent application. See below for further information on re-examination.
Re-examination

A standard patent application may be re-examined by the Commissioner of Patents of her own volition between the date of acceptance and grant.

A standard patent may be re-examined by the Commissioner of Patents, at the Commissioner’s discretion or at the request of the patentee or any other party, at any time after grant. Similarly, an innovation patent may be re-examined at any time after it has been certified.

Re-examination of an accepted standard patent application, a standard patent, or a certified innovation patent is limited to assessing the novelty and inventive step or innovative step, respectively, of the claimed invention.

The results of a re-examination can be that the applicant/patentee may amend the claims to achieve validity, although in some instances the result can be a refusal to grant the standard patent, revocation of the granted standard patent or revocation of the certified innovation patent. However, the decision may be appealed to the Federal Court of Australia.

Revocation

Both standard patents and innovation patents may be revoked by a Court on any of the grounds set out in section 138 the Patents Act 1990 (Cth), which are broader than the grounds for opposition. Anyone can apply to the Court to revoke the patent, including in cases where the proceedings arise as a counterclaim for revocation by a party accused of infringing the patentee’s rights.

For more information on the grounds of revocation, see Chapter 8 ‘What Must Be Known About Enforcing and Defending Your IP Rights’.

Biotechnology Patent Peculiarities

Patent applications concerned with microorganisms

Under Australian patent law, if an applicant chooses to claim a life-form-type invention, such as a microorganism, a virus, a cell line, a hybridoma, a complex polynucleotide or a complex polypeptide, then a full description of the life-form, together with the best method of performing the invention known to the applicant must be provided. Because of the complexity of biological systems, however, it may be difficult or impossible to describe an invention relating to such an invention fully in words, and independently obtaining a life-form from original source material is sometimes not one hundred percent repeatable.

The Budapest Treaty provides a solution to the problem of sufficiently describing inventions concerning microorganisms, by allowing the deposit of a sample of the microorganism with an “International Depository Authority” which is recognised by contracting countries for the purposes of patent applications in treaty countries.

Australia is a signatory and contracting country to the Budapest Treaty.

In Australia if the invention is a microorganism, a deposit of the microorganism must be made, unless the microorganism can be fully described in a textual form. Thus if:

- the inventive subject matter of a patent concerns the use, modification or cultivation of a microorganism or other complex biological entity; and
- the full morphological, biochemical and taxonomic characteristics of the
microorganism cannot be described in text form in sufficient detail to permit a person skilled in the art to identify, distinguish and repeat the invention; and

» a person skilled in the art could not reasonably be expected to be able to perform the invention without having a sample of the microorganism; and

» where the microorganism is not reasonably available, for example through commercial sources, then

» a deposit of the microorganism in accordance with the Budapest Treaty at an International Depository Authority is required to meet the requirements for full description of the invention.

A Budapest Treaty deposit must be made prior to or on the date of filing the Australian application (which is the filing date of the PCT application if the Australian application is a national phase case), and preferably on or before the filing date of any priority application, such as a provisional application.

Further, it is a requirement that before the Australian specification is published (usually around 18 months from the earliest priority date), the patent specification must include the name of the prescribed International Depository Authority from which samples of the microorganism may be obtained and the file, accession or registration number of the deposit given by the institution. Thus, if a patent application was filed immediately after depositing a microorganism but before the Depository Authority issued an accession number, the applicant must add this information to the specification by way of a voluntary amendment prior to the publication of the patent specification.

The Budapest Treaty Expert Solution

Before the patent application is published, the applicant has the option to notify the Commissioner of Patents that the Budapest Treaty deposit should only be made available to other parties under restricted circumstances. This is termed the “Expert Solution”, and is intended to prevent competitors gaining unfair commercial benefit from the deposited life-form prior to the grant of a patent.

Where the Expert Solution is requested by the patent applicant, before a patent is granted on that application, or before the application has lapsed or been withdrawn or refused, the Commissioner may only authorise release of a sample of the deposited microorganism following a request by a third party to a person who is a “skilled addressee” nominated by the third party, and who does not have an interest in the invention. This approach is intended to allow third parties to determine the nature of the invention, for example to determine whether they may infringe a patent if it is ultimately granted on the application, without directly having access to the deposited material.

Extension of term for Pharmaceuticals

Many countries provide a way for a patentee to extend the life or the “term” of a pharmaceutical patent. In January 1999, the Australian Patents Act 1990 was amended to provide for extensions of term of up to 5 years for pharmaceutical patents.

Patents which are eligible for extension are existing and new standard (20 year) patents which in substance disclose and claim a “pharmaceutical substance” which is the subject of a therapeutic goods registration in the Australian Register of Therapeutic Goods (the ARTG).

The length of the extension of patent term is calculated from the period between the “date of the patent”, usually the date of filing a non-provisional application in Australia, and the day on which the registration as a therapeutic good commenced on the ARTG, reduced by 5 years. The maximum period of extension is 5 years.
If an extension of patent term is desired, the patentee must file an application for the extension. The deadline for filing an application for Extension of Term is six months from the later of

» the date of grant of the patent and,

» the date of first regulatory approval in Australia for a “pharmaceutical substance” which is in substance disclosed in the specification and which falls within the scope of at least one of the claims of the patent.

A “pharmaceutical substance” is defined as a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:

» a chemical interaction, or physico-chemical interaction, with a human physiological system; or

» action on an infectious agent, or on a toxin or other poison, in a human body; but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.

A pharmaceutical substance may be a chemical compound by itself, or a biological substance when produced by recombinant DNA technology. It does not include chemical compounds which are defined by their production by specific methods, or when used in specific therapeutic applications.

A “therapeutic use” is defined as use for the purpose of

a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

b) influencing, inhibiting or modifying a physiological process in persons; or

c) testing the susceptibility of persons to a disease or ailment.

A “first regulatory approval date” is defined as:

a) if no pre-TGA marketing approval was given in relation to the substance, the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods that contain, or consist of the substance; or

b) if pre-TGA marketing approval was given in relation to the substance, the date of first approval.

A listing on the ARTG of goods for export, rather than for marketing in Australia, is also considered to represent a “regulatory approval date”.

A “pre-TGA marketing approval” means an approval (however described) by a Minister, or a Secretary to a Department, to:

a) market the substance, or a product containing the substance, in Australia; or

b) import into Australia, for general marketing, the substance or a product containing the substance.

**Regulatory Affairs**

After an application for extension of patent term has been granted, Section 76A of the Patents Act requires the patentee to lodge with the Secretary of Health and Family Services, before the end of the following financial year, a return setting out the following information:

a) details of the amount and origin of any Commonwealth funds spent in the research and development of the drug which was the subject of the application; and
b) the name of any body;
   i) with which the applicant has a contractual agreement; and
   ii) which is in receipt of Commonwealth funds; and

c) the total amount spent on each type of research and development, including pre-clinical research and clinical trials, in respect of the drug which was the subject of the application.

The Department of Health have advised their requirements as:

The details of the amount and origin of any Commonwealth funds spent in the research and development of the drug which is the subject of the application (Section 76A[a]) and the names of any body with which the applicant has a contractual agreement and which is in receipt of Commonwealth funds (Section 76A[b]) as well as the total amount spent on each type of research and development (Section 76A[c]) relating to the activities occurring in Australia concerning the specific drug registered on the Australian Register of Therapeutic Goods (ARTG), on which the application for extension of term is based.

The total amount spent on the drug needs to cover the period from initial research up until the granting of the extension of term. The Department of Health then appears to require a supplementary return which provides the amount of research and development funds spent on the particular drug for the period from granting the extension of term up until the expiry of the patent.

Access to the information in the notification will be governed by the Freedom of Information Act. However, collective information will be publicly available.

This information must be supplied to:

Director, Prices and Remuneration Section
Pharmaceutical Benefits Branch
Mail Drop Point 83
GPO Box 9848
CANBERRA ACT 2601
AUSTRALIA

The aim of the Section 76A requirements is to allow the Australian government to assess the effect of the extension of term provisions and to determine whether the extended monopoly has contributed to increased expenditure and research and development in Australia.

The Section 76A requirement is not applicable if the products in question were not developed using any Australian government or Commonwealth funds.

The words “research and development” used in Section 76A is a reference to research and development occurring in Australia.

It is noted that Section 76A imposes an obligation to disclose potentially commercially sensitive information. This information will be available under Freedom of Information legislation, which means that the data is apparently unavailable to the general public. It does however remain to be seen as the breadth of Section 76A has not yet been tested.

The information must be provided before the end of the financial year immediately following the financial year in which the extension of term was granted.
Infringement of Pharmaceutical Patents - Springboarding

Amendments to the Australian Patents Act in October 2006 introduced a new “springboarding” provision set out in Section 119A. “Springboarding” is an exception to patent infringement and is a term used to refer to activities which need to be undertaken - usually by a generic company - solely in connection with obtaining regulatory approval on the ARTG of pharmaceutical goods or for obtaining similar foreign regulatory approval, while one or more relevant patents are still in force. In the absence of such permitted springboarding, such conduct during the term of a patent would amount to infringement of the patent.

Effectively, springboarding is now permitted as an exception to patent infringement on any pharmaceutical patent, at any time. It is not limited to patents which have been granted an extension of term. The springboarding provision does not allow stockpiling of the pharmaceutical product for later sale (while the patent is still in force), nor does it allow export of the product out of Australia in the situation where foreign regulatory approval is sought, unless the relevant patent has been granted an extension of term.

Maintaining patent rights

Renewal fees

The applicant/patentee for a standard patent must pay patent renewal fees to the Patent Office on an annual basis starting five years from the complete application filing date. These fees are required to maintain a pending standard application and to keep a granted standard patent in force. See section ‘Application fees’ in this chapter.

The same generally applies for innovation patents. An annual fee must be paid beginning on the first anniversary of the filing date after the grant occurs.

Use a patent notice

It is best practice to attach a patent notice to products or packaging of products. There is no required form of notice or specific words that need to be on the notice, but it may state: ‘Patent pending’ or ‘Australian Patent No. [xxxx]. All rights reserved.’

Obtaining foreign patent protection

Patent rights are territorial, and consequently you will need to take active steps to implement foreign patent protection of an invention. Foreign patent protection may be implemented by:

» filing a patent application (Convention application) in a country which is a signatory to the Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention) within 12 months of the first filing of an Australian patent application

» filing an international patent application (PCT application) under the Patent Cooperation Treaty 1978 (PCT) for protection in countries which are signatories to the PCT within 12 months of first filing of an Australian patent application, or

» filing a foreign patent application in a country at the same time as filing an Australian patent application, or at least before using or publishing your invention.

Australia is a signatory to both the Paris Convention and the PCT.

Where a country is not signatory to the Paris Convention or the PCT, you will need to file a patent application in that country at the time of filing an Australian provisional patent application, or at least before using or publishing your invention.
Paris Convention

The Paris Convention allows a patent application in a signatory country to claim the priority date of an earlier patent application in another signatory country.

Most, but not all countries are signatories to the Paris Convention. At the time of publication of this Manual, a list of contracting countries to the Paris Convention may be accessed at: <http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct_paris_wto.pdf>

Patent Cooperation Treaty (PCT)

The PCT allows the filing of a centrally filed patent application which can be subsequently ‘nationalised’ in countries which are contracting parties of the PCT. You should be aware that not all countries are signatories of the PCT, including Taiwan, Pakistan and many countries in South America. A list of signatory countries to the PCT at the publication of this Manual may be accessed at: <http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=6>

It is important to understand that a PCT patent application does not lead to grant of an ‘international patent’. A PCT patent application will need to be ‘nationalised’ in countries where patent protection is desired. Once nationalised, the application is examined according to the patent laws and regulations of the relevant country. Therefore a PCT application ultimately results in separate national or regional patent applications in the same way as does the Paris Convention route.

Set out in the table below are advantages and disadvantages of a PCT application compared with Convention applications:

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major costs of filing, such as filing fees and translation costs, are deferred.</td>
<td>Additional costs of filing a PCT application (but these may be recovered by efficient national phase processing).</td>
</tr>
<tr>
<td>An international search report and written opinion are given to the applicant which provides an informed view of the likelihood of securing patent protection, and allows the opportunity to amend claims and/or description.</td>
<td>Grant of patent in the countries of interest may be delayed by at least 18 months. This would delay the ability to enforce such patent rights, and reduce the potential enforceable term of a granted patent.</td>
</tr>
<tr>
<td>The applicant can defer its decision on the countries in which to seek patent protection for up to 18 months (or 30 months if no priority claim is made).</td>
<td>Any limitations introduced to the claims during the PCT process may be more than would be required under the national laws of some countries, resulting in a lesser scope of protection.</td>
</tr>
</tbody>
</table>

The PCT process

The PCT process is split into two parts referred to as ‘Chapters’:

- Chapter I relates to International Searching, Publication and an International preliminary Report on Patentability, and
- Chapter II (optional) relates to International Preliminary Examination (IPE), which results in a non binding International Preliminary Examination Report on Patentability.
The PCT process is complex. It is recommended you seek assistance from a patent attorney if you wish to apply for patent protection through the PCT.

Below is an indicative simplified flowchart of the PCT process.

### Indicative Simplified PCT Process

<table>
<thead>
<tr>
<th>First Filing of National Patent Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>The first filing of one (or more) national patent application (provisional or standard application) starts the timeline and establishes one or more priority dates.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>File PCT application</th>
</tr>
</thead>
<tbody>
<tr>
<td>A PCT application must be filed within 12 months of the earliest priority date. (In some instances, an earlier priority date may not be invoked.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter I Action: International Search Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>An International Search Report and Written Opinion on novelty and inventive step is issued by a Patent Office acting as an International Searching Authority, usually by 16 months from the earliest priority date. The claims may then be amended by the applicant.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The PCT application is published by WIPO at around 18 months from the earliest priority date.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demand for IPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A demand for an International Preliminary Examination (under Chapter II) is optional.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter II International Preliminary Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arguments and/or amendments of the specification or claims address the issues of novelty and inventive step, raised in the existing Written Opinion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter II IPRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Chapter II IPRP is issued.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National Phase Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>The National Phase must be entered for all desired countries within 30 months (31 months in some countries) of the priority date.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter I IPRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>If IPE is not demanded, then an International Preliminary Report on Patentability (Chapter I IPRP) is issued based on the earlier Written Opinion.</td>
</tr>
</tbody>
</table>
Copyright

How to implement copyright protection

Copyright protection arises automatically on creation of an original work. There is no formal process of registration required for copyright protection of a work.

However, there are steps you may implement to make others aware that your work is copyright protected. This may assist to reduce potential copyright infringement of your work.

The diagram below illustrates some of the different mechanisms of implementing copyright protection, for example in computer software.


Use a copyright notice & © symbol

It is not a legal requirement to use a copyright notice or to attach the © symbol to your work. However, by attaching a copyright notice, you are informing users that copyright exists and identifying the owner of the copyright. The ‘reserving all rights’ notice in a copyright notice is an indication that no licence is implied by the publication of the work.

There is no particular set of words required in a copyright notice. Below are some examples of copyright notices for different forms of publication.

Print publications

© [Name of organisation] [Year of creation] All rights reserved.

This work is copyright. Except as permitted under the Copyright Act 1968 (Cth), no part of this publication may be reproduced by any process, electronic or otherwise, without the specific written permission of the copyright owner. Neither may information be stored electronically in any form whatsoever without such permission.
Registered Designs

Should the design be registered?

Industrial designs need to be registered in order to receive exclusive rights and protection. If the industrial design is not registered (under the Designs Act 2003), only very minimal protection is provided by copyright and only if the design is considered to be an artistic work.

Various factors will affect whether a design should be registered, such as the organisation’s objectives, its proposed use for the design, and the nature of the design itself.

To be registrable, a design needs to comply with registration requirements. For more information on design registration requirements, see Chapter 2 ‘What Everyone Should Know’.

How to register a design

Design searches

Before submitting a design application, it is advisable to conduct design searches to ensure that:

» there are no existing registered designs that are similar or identical to the proposed design to be registered, which would prevent protection being obtained and

» the design does not infringe existing registered design rights of others.

Design searches may be conducted on IP Australia’s Australian Designs Data Searching (ADDS) system which has images of all registered designs from 1985 which is accessed at: http://www.ipaustralia.gov.au. Information and images on designs prior to 1985 are available
at IP Australia’s office in each State capital.

It is recommended you seek the assistance of a patent attorney to ensure a comprehensive search is undertaken.

**The registered design application process**

Set out in the diagram below is an overview of the registered design application process in Australia.

### Indicative Registered Design Application Process

<table>
<thead>
<tr>
<th>Design Application</th>
<th>Request for Registration</th>
<th>Application Lapses</th>
<th>Request for Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The design application must be in approved form. If filing requirements are met, a filing date is established. This will be the priority date if the application is the first filing for the design.</td>
<td>Request for registration made within 6 months of the priority date. Does the design meet the registration requirements?</td>
<td>If there is no request for registration or publication within 6 months of the priority date, the application will lapse.</td>
<td>Request for publication made within 6 months of the priority date. Does the design meet the publication requirements?</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Design Registered</td>
<td>Notice of Deficiency</td>
<td>Design Published</td>
<td>Notice of Deficiency</td>
</tr>
<tr>
<td>Registration of the design is advertised in the Official Journal of Designs. The term of protection of a registered design is a maximum of 10 years, provided a renewal fee is paid after the initial 5 years. Registered designs cannot be enforced until Certified.</td>
<td>Submission of response by applicant. Registration may be refused.</td>
<td>Publication does not grant any enforceable rights, but does prevent others from gaining any rights to the design.</td>
<td>Submission of response by applicant. Registration may be refused.</td>
</tr>
<tr>
<td>Request for Examination</td>
<td>Adverse Examination Report</td>
<td>Submission of a satisfactory response by applicant</td>
<td>Possible Revocation</td>
</tr>
<tr>
<td>Examination can be requested by the owner or anyone else. Does the registered design meet validity requirements?</td>
<td>NO</td>
<td>YES</td>
<td>A person may make an application to a Court for revocation of a Certified registered design.</td>
</tr>
</tbody>
</table>
Filing a registered design application

Registering a design involves completing and submitting a design application form and drawings of the product to which the design relates. A design application must include the following information:

<table>
<thead>
<tr>
<th>Information required for the design application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of the design applicant.</td>
</tr>
<tr>
<td>Product(s) to which the design relates.</td>
</tr>
<tr>
<td>Representations of the design.</td>
</tr>
</tbody>
</table>

Representations are illustrations of the product to which the design(s) relates, which may be in the form of drawings, photographs or digital images. In some circumstances, a sample of the design may be submitted if it can be easily mounted on a flat surface and if it can be stored with other documents. In particular, you should ensure that:

» there are five identical copies showing each view of the product
» each representation must show an accurate and complete picture of the product
» one sheet should be used for each representation, and
» each sheet the representation is printed on should be numbered on the bottom right hand corner showing the total number of sheets lodged, e.g. 1 of 5, 2 of 5, etc.

You may also provide a Statement of Newness and Distinctiveness in the application, but this is optional. The statement identifies the particular features of the design considered to be new and distinctive, and special regard will be taken to those features identified when assessing newness and distinctiveness. If providing a Statement of Newness and Distinctiveness, ensure all features of the design which are new and distinctive are identified in the application.

Once the application is filed, it may be difficult to amend the representations set out in the application. The application will be assessed against set criteria by the Designs Office.

It is recommended that you consult a patent attorney to assist with any registered design applications.

An applicant for an Australian Design registration must provide an "address for service" in Australia. This may be the applicant’s Australian address or the address of their agent, such as their patent attorney.

Application fees

An application fee will be required to be paid at the time of filing a design application. Additional fees may be required to be paid depending on the action taken during the application process, such as requesting registration or publication.

These fees and their associated time-frames are subject to change and care should be taken to meet deadlines. Failure to do so may affect the success of your design application.

A full list design fees is available on the IP Australia website located at: http://www.ipaustralia.gov.au/designs/fees_index.shtml.
Request for registration or publication

Within 6 months from the priority date of a design application, you must request registration or publication of the design. The priority date will usually be the filing date of the design application if the application is the first filing for the design. Failure to request registration or publication within the required time will result in the application lapsing.

Registration

If a request for registration is made, the Designs Office will conduct a formalities check to ensure that all the required details are disclosed, including the representations of the design. If the design meets the requirements, the design will be registered and advertised in the Australian Official Journal of Designs and in the Designs search databases (ADDS).

Publication

If a request for publication is made, and the publication requirements are met, the design will be published in the Australia Official Journal of Designs. Publication of the design does not grant any enforceable rights, but it does prevent others from gaining any registered rights to the design.

Examination

Examination of a registered design is optional. However, you will not be able to enforce your registered design rights if the registered design has not been examined and certified by the Designs Office.

Examination may be requested by the registered owner or any third party. When a third party requests examination of the design, that party may provide information to the Designs Office regarding whether the registered design meets the registration requirements. The Designs Office will either certify or revoke the registered design after examination.

Revocation

A registered design may be revoked upon application by a third party to a Court on any of the following grounds set out in the Designs Act 2003 (Cth):

- the design is not a registrable design
- that the registration of the design was obtained by fraud, false suggestion or misrepresentation
- that the design is a corresponding design to an artistic work, and copyright in the artist’s work has ceased
- one or more of the persons registered as the design’s owner was not entitled to be a registered owner of that design
- where the third party was entitled to be the registered design’s owner at the time of registration.

Maintaining registered design

Renewal fees

Registered design protection lasts for a maximum of 10 years, provided a renewal fee is paid within the required deadline after the initial 5 years.

A full list of registered design fees is available on the IP Australia website located at: http://

...

**Use a registered design notice**

It is not compulsory to attach a registered design notice to a product embodying the registered design or the packaging of the product; however it is best practice to do so. The notice not only provides an indication that the design is registered, but also puts any infringer on notice of the existence of the IP right and therefore possibly increases the damages that may be awarded by a court if there is an infringement action.

There are no particular set of words required to be used in a registered design notice, but it may state: 'Australian Registered Design No. [xxx]. All rights reserved'.

**Obtaining foreign protection**

Registered design rights are territorial and active steps will need to be taken to seek foreign registered design protection. Foreign protection of a design may be implemented by:

- filing a national application for registered design in the countries in which you wish to register the design, or
- filing a design application (Convention application) in the country which is signatory to the Paris Convention within 6 months of filing of an Australian registered design application.

At the time of publication of this Manual, a list of the countries that are members of the Paris Convention may be accessed at: <http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct_paris_wto.pdf>

The main advantage of filing a Convention application is that the priority date of the Australian application can be retained and costs deferred for six months.

Foreign registered design applications need to be prepared, and will be examined and assessed in accordance with the country’s relevant design laws and regulations. You should seek the assistance of a patent attorney to co-ordinate the various foreign registered designs protection.

A single European-wide (EU) design registration also is available, obviating the need to file in separate European countries.

Additionally, in the United Kingdom and a few other countries, a limited unregistered design right exists. Australian organisations may be able to take advantage of such rights if they choose a non-registration approach for their design products.
Plant Breeder’s Rights

Overview

Plant Breeder’s Rights (PBR) are exclusive commercial rights which are available to breeders of certain new varieties of plants, algae and fungi. These IP rights are administered in Australia under the Plant Breeder’s Rights Act 1994. Australian Plant Breeder’s Rights are largely similar to Plant Variety Rights which may be obtained in other countries which are members of the International Union for the Protection of New Varieties of Plants (the UPOV convention).

Plant Breeder’s Rights protection extends not only to plant varieties, but also to reproductive material of the variety and to other varieties which are considered to be "essentially derived" from the protected variety. In some limited circumstances rights may also extend to material which is harvested from the plant variety. Traditionally bred plants, algae, fungi, and transgenic plants can all be protected as a “plant variety”.

Plants, algae and fungi can potentially be protected under both the Australian Plant Breeders Rights Act and the Australian Patents Act, and simultaneous protection under both Acts may be possible.

Plant Breeder’s Rights are registrable rights. You must apply to IP Australia to register the plant variety. Applications are accepted by IP Australia from the original breeder of a new variety (or from their employer if the breeder is an employee of an organisation) or from a person who has acquired ownership rights from the original breeder.

Priority to a foreign filed PBR or Plant Variety Right application in a UPOV convention country may be claimed if the Australian PBR application is filed within 12 months of the foreign filing. Conversely, Australian PBR applicants can file applications in UPOV member countries within 12 months of their Australian PBR application, claiming priority from it.

Requirements for Plant Breeder’s Rights Protection

To be eligible for PBR protection a plant variety must be originated by a person, who is termed “the breeder” under the Act. Selections of plants directly from the wild or discoveries are not eligible unless they have been propagated in some way.

PBR protection is available to a plant “variety”, which represents a grouping of plants within a single botanical taxon of the lowest known rank that can be defined on the basis of common, shared characteristics which distinguish the variety from other plant groups, and which is suitable to be propagated unchanged.

There are requirements relating to the “commercial novelty” which must be satisfied if PBR protection is to be obtained:

- the variety or its reproductive material must not have been sold in Australia for more than one year before filing the PBR application; and
- the variety or its reproductive material cannot have been sold overseas for more than 6 years (in the case of trees and vines) before making the PBR application in Australia, or for more than 4 years for all other plant varieties.

An applicant for Australian PBR protection must have an “address for service” in Australia. This address for service may be an agent, such as a patent attorney, or may be their own address.
The applicant must also nominate an accredited “Qualified Person” whose role it is to take responsibility for a comparative trial (if required), including the choice of comparative varieties, experimental design, collection of data, statistical analysis and the preparation of a description of the variety. A list of currently accredited Qualified Persons is available from the IP Australia web site at <http://www.ipaustralia.gov.au/pbr/qualpers.shtml>

**DUS Requirements**

The variety must adhere to three broad criteria: distinctness, uniformity and stability (DUS).

An assessment of **distinctness** involves a comparison of selected defined morphological, molecular or performance characteristics of the plant variety with other existing varieties of common knowledge in Australia.

Characteristics may include purely morphological features such as the size, shape, colour, pattern or distribution of leaves, fruits, flowers or other plant structures. They may include features of the time to reach maturation, or to fruit, or disease or pest resistance, provided these characteristics are clear and reproducible.

**Uniformity** relates to the number of off-types which are generated following vegetative or sexual reproduction of the variety. A variety which is uniform must not exhibit an increased number of off-types than would normally be expected for a plant of a similar variety.

A variety which demonstrates **stability** is one in which the characteristics of the variety remain unchanged following repeated propagation.

**Application Process**

The PBR application process has two parts. In Part 1, the applicant needs to reasonably demonstrate to the Examiner the characteristics that make the variety distinctive, uniform and stable at first instance, and that they are the breeder or owner of the variety. No growth trials are involved. The Part 1 application procedure includes the provision of:

» an acceptable name for the variety
» information on the main distinguishing characteristics of the variety
» details of the origin of the variety and procedures used to initiate the new variety
» proof of ownership if the applicant is not the original breeder
» nomination of a Qualified Person
» authorisation of an agent to apply on behalf of the applicant (if an agent is used)
» provision of photographs showing the distinguishing characteristics, and
» payment of the application/filing fee.

Upon acceptance of the Part 1 application, the application is published.

Part 2 of the application process procedure includes payment of the examination fee, and examination of the variety for Distinctness, Uniformity and Stability. It is a requirement that a DUS trial be carried out either in Australia or overseas in a UPOV member country using official UPOV guidelines. For the Distinctness requirement, the trial needs to be carried out in comparison to all the most similar varieties of common knowledge in Australia or the variety needs to be so clearly distinct from all the Australian varieties of common knowledge that further DUS test growing is not warranted. If any overseas trials do not meet these criteria, then a further DUS trial in Australia will be required. Such trials will be carried out by the Qualified Person.
Valid applications proceed to grant and the holder of the PBR is issued with a certificate for that variety.

For tree and vine varieties, the term of PBR protection is 25 years from the date of grant of PBR, and for all other varieties 20 years from the date of grant.

Annual renewal fees are payable for a granted PBR.

A full list of PBR fees is available on the IP Australian website located at:


**Rights Obtained**

Plant Breeder’s Rights are exclusive commercial rights to a registered variety. In relation to propagating material of the registered variety, successful applicants have exclusive rights to:

- produce or reproduce the material
- condition the material for the purpose of propagation (conditioning includes cleaning, coating, sorting, packaging and grading)
- offer the material for sale
- sell the material
- export the material and
- stock the material for any of the purposes described above.

Plant Breeder’s Rights are infringed by a person taking any of the exclusive rights without the authorisation of the PBR owner.

There are exceptions to infringement of Plant Breeder’s Rights. These include:

- conditioning of farm saved seed under certain circumstances
- certain acts done for private or non-commercial purposes or experimental purposes, or for the purpose of breeding new plant varieties.

**Marking of Plant varieties subject to PBR**

Holders of Plant Breeder’s Rights should label their registered plant variety so that purchasers are aware that the goods are the subject of PBR registration. Standardised wording and logos are provided by IP Australia at: <http://www.ipaustralia.gov.au/pbr/indguide.shtml>
Confidential Information

Identification and protection of confidential information

Confidential information is information of significant importance to an organisation that is not readily available to the public. Not all information generated by an organisation is, or needs to be, confidential. Your organisation will need to have a system in place to assess if the information should be classified as 'confidential', and the level of security required to be implemented for that information.

Practical management of confidential information

Any unauthorised or inadvertent disclosure of confidential information may result in a 'loss' of its confidential status and may potentially lead to serious consequences, e.g. publication of new inventions developed by researchers before filing a patent application may destroy its patentability. Practical procedures to protect confidential information should be implemented and followed.

The IP policy of your organisation may outline practices for the identification and protection of confidential information.

<table>
<thead>
<tr>
<th>Standard practices for identifying and protecting confidential information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Keeping confidential information secure</strong></td>
</tr>
<tr>
<td>Prominently mark in red all sensitive, confidential documents as 'CONFIDENTIAL'.</td>
</tr>
<tr>
<td>Restrict the number of copies of confidential information. If there are copies made, keep a record of the number of copies, and number them accordingly.</td>
</tr>
<tr>
<td>Limit the access and circulation of confidential information on a need-to-know basis. Authorisation may be required to access the information depending on its sensitivity.</td>
</tr>
<tr>
<td>Electronically stored confidential information should be technologically protected, such as by password-protection and encryption. For more information on Digital Rights Management &amp; Technological Prevention Measures, see section ‘Copyright’ in Chapter 4 ‘What Researchers Must Know’</td>
</tr>
<tr>
<td>All documents identified as confidential should be recorded and its confidential status should be periodically reassessed.</td>
</tr>
<tr>
<td>The location of the confidential information should be recorded. Adopt appropriate security measures, e.g. under lock and key, encryption and password protection.</td>
</tr>
<tr>
<td>Use log books or electronic audit trails to monitor access to confidential information.</td>
</tr>
<tr>
<td>Ensure documents classified as confidential are kept separately from non-confidential information.</td>
</tr>
<tr>
<td>Periodically review the confidentiality status of the document and ensure proper destruction procedures are followed, such as shredding and locked disposal bins.</td>
</tr>
<tr>
<td>Keep confidential information on the organisation’s premises and store it securely.</td>
</tr>
<tr>
<td>Enter into confidentiality agreements with all employees, contractors and anyone else that may come in contact with confidential information.</td>
</tr>
</tbody>
</table>
Standard practices for identifying and protecting confidential information

Ensure all employees are aware of their confidentiality obligations and the procedures that are in place relating to dealings with confidential information.

Conduct exit interviews with employees, reminding them of their post-employment confidentiality obligations

**Disclosing Confidential Information**

Review all drafts of communications, press releases and technical publications prior to disclosure to ensure confidential information is not inadvertently disclosed.

Use generic descriptions or internal reference codes where possible.

Ensure that there is a confidentiality agreement in place between your organisation and the recipient of the confidential information.

Mark all communications of confidential information ‘CONFIDENTIAL’.

Ensure that the recipient of confidential information is aware of the confidential nature of the information.

When speaking about confidential information, ensure your conversation will not be overheard by unauthorised persons.

Before communicating confidential information, verify the email-address, fax number or the identity of the person you are speaking to on the phone. Attach a confidentiality notice to the communication.

Confidentiality agreements

When communicating confidential information to a third party, simply attaching a confidentiality notice to the communication will not necessarily create an obligation of confidence on the recipient. You will need to ensure the recipient has agreed in advance that the information received will remain secret. It is standard practice to obtain from the proposed recipient a signed confidentiality agreement defining the confidential information before revealing the sensitive information.

It is recommended that you consult a patent attorney or lawyer to assist with the preparation of any confidentiality agreements.
Trade Marks

Should the trade mark be registered?

A trade mark does not need to be registered to receive protection. Unregistered trade marks may be protected by the common law of passing off, and/or by the law of misleading and deceptive conduct under the Trade Practices Act 1974 (Cth). However, registration of a trade mark will grant you exclusive rights to use the mark in relation to particular goods or services.

Trade mark registration vs. passing off

The following table summarises the advantages and disadvantages of registering a trade mark or leaving it unregistered.

<table>
<thead>
<tr>
<th>Trade Mark Registration</th>
<th>No registration: Passing off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade mark is protected from the date of application for registration, without the necessity of proving reputation.</td>
<td>Reputation needs to be proved to protect the trade mark.</td>
</tr>
<tr>
<td>Protection is limited to classes for which the trade mark is registered.</td>
<td>Protection may be provided for a wider variety of material for which evidence of a reputation may be demonstrated.</td>
</tr>
<tr>
<td>Protection term may be perpetual provided renewal fees are paid every 10 years.</td>
<td>Protection term may be perpetual, provided there is maintenance of goodwill and reputation.</td>
</tr>
<tr>
<td>Expense required to apply for and maintain trade mark registration.</td>
<td>No expense required to apply for and maintain a trade mark.</td>
</tr>
<tr>
<td>Proof of infringement is easier to achieve.</td>
<td>Proof of infringement requires proof of reputation in the trade mark.</td>
</tr>
<tr>
<td>Protection of the trade mark is throughout Australia.</td>
<td>Protection of the trade mark may be limited geographically to areas where the trade mark is used.</td>
</tr>
</tbody>
</table>

How to register a trade mark

Selecting a trade mark

Almost anything can be registered as a trade mark, provided that it is distinctive and meets the eligibility criteria. For more information, see Chapter 2 ‘What Everyone Should Know’.

A trade mark may take a number of forms as illustrated below.

<table>
<thead>
<tr>
<th>Forms of trade marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Word</td>
</tr>
<tr>
<td>Phrase</td>
</tr>
<tr>
<td>Letter</td>
</tr>
<tr>
<td>Numeral</td>
</tr>
</tbody>
</table>
Apart from registration requirements, when selecting a trade mark, you should also consider marketing issues to ensure the chosen trade mark stands out and attracts consumer attention. The following Table provides a checklist of issues to consider when selecting a trade mark.

<table>
<thead>
<tr>
<th>Issues to Consider when Selecting a Trade Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the nature of the mark? e.g. inventive word, graphics only, stylised</td>
</tr>
<tr>
<td>Is the mark distinctive?</td>
</tr>
<tr>
<td>Is the mark legible and easy to pronounce?</td>
</tr>
<tr>
<td>Will the mark be used in colour?</td>
</tr>
<tr>
<td>Is the nature of the mark appropriate for the goods and/or services?</td>
</tr>
<tr>
<td>Are there identical or similar existing marks for similar goods and/or services?</td>
</tr>
<tr>
<td>Have trade mark clearances been conducted so the organisation is free to use the mark?</td>
</tr>
<tr>
<td>Is the mark already in use?</td>
</tr>
<tr>
<td>Does the organisation own the copyright in the artwork of the mark?</td>
</tr>
<tr>
<td>Does the mark achieve other marketing objectives?</td>
</tr>
<tr>
<td>Is the mark offensive or misleading?</td>
</tr>
<tr>
<td>Is the mark adopted from a foreign trade mark?</td>
</tr>
</tbody>
</table>

It is important to consider what goods or services you want to protect by your trade mark, because once the application is filed, the list of goods or services may not be expanded. Currently, there are 34 classes of goods and 11 classes of services. You may conduct a search of the different goods and services classes on IP Australia’s Classification Database: http://www.ipaustralia.gov.au.

The following Table lists some of the issues that should be considered when selecting the goods and services to be protected by the trade mark registration.

<table>
<thead>
<tr>
<th>Issues to Consider when Selecting the Goods and Services to be Protected</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the nature of your business?</td>
</tr>
<tr>
<td>Where do you derive your business income?</td>
</tr>
<tr>
<td>What goods or services will your organisation provide?</td>
</tr>
<tr>
<td>What are you known for doing by your customers?</td>
</tr>
</tbody>
</table>

Below are examples of different forms of trade marks and the issues regarding their registration:
<table>
<thead>
<tr>
<th>Form of trade mark</th>
<th>Example</th>
<th>Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventive words</td>
<td>Trade Mark Number 359104 KODAK FILM K, CHEVRON PENTAGON STRIPES</td>
<td>Inventive words are generally distinctive because there is no known meaning or connotation arising from it. Plain words (i.e. not stylised) provide the broadest protection, and avoid the need to update the registration to reflect the particular style in use.</td>
</tr>
<tr>
<td>Stylised words</td>
<td>Trade Mark Number 93487 COCA-COLA</td>
<td>Stylised words may be distinctive; however, they will need to be updated when the style of the word changes.</td>
</tr>
<tr>
<td>Inventive words</td>
<td>Trade Mark Number 489050 NIKE, STRIPE.CURVED &amp; TAPERED FORMS SYMBOL, CORRECT OR SUNVISOR</td>
<td>Incorporation of a logo with a word can make a mark distinctive.</td>
</tr>
<tr>
<td>Graphics only</td>
<td>Trade Mark Number 497026 APPLE, SILHOUETTE WITH BITE APPLE STRIPED WITH BITE</td>
<td>Any kind of graphic representation may be used as a trade mark provided it is distinctive.</td>
</tr>
<tr>
<td>Colour</td>
<td>Trade Mark Number 1100096 SKYY VODKA, COLOUR BLUE BOTTLE</td>
<td>Colour marks are difficult to register because colour marks do not inherently distinguish goods/services from each other. It may only be registered if the colour is distinctive of the goods/services it offers.</td>
</tr>
</tbody>
</table>
Trade mark searches

It is vital you conduct a clearance search on the trade mark register to confirm that there are no existing similar trade marks for similar goods and services that could prevent you from registering your proposed trade mark. Further, it will avoid any potential trade mark infringement that may occur by your use if the trade mark is registered by another party.

Preliminary clearance searches may be conducted in-house, on the internet and through discussions with the marketing department and/or other employees familiar with current brands available on the market, then followed up with formal comprehensive searches by trade mark attorneys.

IP Australia offers free access to its trade mark database ‘ATMOSS’ located at: <http://www.ipaustralia.gov.au>

When conducting clearance searches, review other trade marks that are identical or similar to your proposed mark, and which relate to similar classes of goods and services to your proposed goods and services to which the proposed mark is to be attached.

The Australian Trade Mark Office offers use of their Assisted Filing Service (AFS) which provides an assessment of whether your proposed mark can be used and identifies if there are barriers to the registration of your mark. Further information on AFS is available at: <http://www.ipaustralia.gov.au/trademarks/afsbenefits.shtml>

It is recommended you seek the assistance of a trade mark attorney to ensure a comprehensive search is undertaken.

The trade mark application process

Set out in the diagram below is the procedure for applying for the registration of a trade mark.
### Trade Mark Application

The trade mark application must be in approved form. If filing requirements are met, a filing date is established. This will be the priority date if the application is the first filing for the trade mark.

### Examination of Trade Mark Application

Does the trade mark application meet registration requirements?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acceptance</strong> Notice of acceptance will be sent to the applicant.</td>
<td><strong>Examination Report</strong> This report summarises any registration requirements that need to be addressed.</td>
</tr>
</tbody>
</table>

### Opposition

Opposition may be initiated within 3 months of the date of notice in the Official Journal of Trade Marks. If opposition is successful, the accepted trade mark may be revoked.

### Publication

Accepted trade mark is published in the Official Journal of Trade Marks.

### Trade Mark Registered

The term of a trade mark is for an initial period of 10 years from the filing date of the application. Registration may be renewed perpetually, provided renewal fees are paid every 10 years.

### Submission of response by applicant

The applicant may request a hearing regarding the objections.
Preparing the trade mark application

Registering a trade mark involves completing a trade mark application obtained from IP Australia in hard copy format, or by completing the application form online. A trade mark application must include the following information:

<table>
<thead>
<tr>
<th>Information</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of the trade mark applicant</td>
<td>The applicant must have a legal personality, e.g. individual, company, incorporated association, or combination of these.</td>
</tr>
<tr>
<td></td>
<td>If the applicant is a company, use the company name and provide the company number (ACN). A business name or trading name is not acceptable because these names cannot own property.</td>
</tr>
<tr>
<td>Representations of the trade mark</td>
<td>The mark must be clear and legible for publication in the Official Journal of Trade Marks.</td>
</tr>
<tr>
<td></td>
<td>The mark must be reduced to 8cm by 8cm to fit into the box provided in the application form.</td>
</tr>
<tr>
<td>Description of the trade mark</td>
<td>The description of the mark must be clear and precise, especially if the mark is a shape, scent, sound or colour.</td>
</tr>
<tr>
<td>Classes of goods and services</td>
<td>Since some goods and services may fall into multiple classes, it is recommended that you consult with an IP professional to determine the necessary classes in which the application should be filed to meet the needs of your organisation.</td>
</tr>
<tr>
<td>Description of goods and services of each class</td>
<td>The description of the goods and services with which the mark is to be associated must be clear and succinct.</td>
</tr>
</tbody>
</table>

You should be aware that once the application has been filed and details are published you cannot alter the trade mark substantially or add classes of goods and/or services, and the application fee cannot be refunded.

It is recommended that you consult a trade mark attorney to assist with trade mark applications.

Application fees

An application fee will be required to be paid at the time of filing a trade mark application. Additional fees may be required to be paid depending on the action taken during the application process, such as requesting an extension of time, or filing a notice of opposition.

These fees and their associated time-frames are subject to change and care should be taken to meet deadlines. Failure to do so may affect the success of your trade mark application.

A full list of trade mark fees is available on the IP Australia website located at: <http://www.ipaustralia.gov.au/trademarks/fees_index.shtml>
Examination of the trade mark application

Generally, applications are examined within 4-6 months from filing of the application.

It is possible to request accelerated examination if the examination and/or registration of a trade mark is urgent, such as where there is an infringement issue or a need to commit to an expensive marketing plan. The examination period may then be reduced to 4-6 weeks.

If the application does not meet all of the registration requirements, a report will be sent outlining the deficiencies in the application. You will need to reply to the examiner in writing and address the matters which have been raised within 15 months from the date of the examiner’s first report. Extensions of time may be requested with the appropriate fee. Failure to respond to the examiner’s report or request for an extension of time may result in the lapse of the application.

Once an application has been accepted, it is published in the Official Journal of Trade Marks.

Opposition

A trade mark application may be opposed by any interested party within 3 months of the date of notice in the Official Journal of Trade Marks, with a possible further 3 months extension.

A trade mark application may be opposed on any of the following grounds set out in the Trade Marks Act 1995 (Cth):

<table>
<thead>
<tr>
<th>Grounds for opposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>The trade mark is a prohibited sign</td>
</tr>
<tr>
<td>The trade mark is not capable of distinguishing the applicant’s goods or services in respect of which the trade mark is sought to be registered</td>
</tr>
<tr>
<td>The trade mark contains or consists of scandalous matter or its use would be contrary to law</td>
</tr>
<tr>
<td>The trade mark is likely to deceive or cause confusion</td>
</tr>
<tr>
<td>The trade mark is substantially identical with, or deceptively similar to a trade mark registered by another person in respect of similar goods or closely related services</td>
</tr>
<tr>
<td>The applicant is not the owner of the trade mark</td>
</tr>
<tr>
<td>The applicant is not intending to use the trade mark</td>
</tr>
<tr>
<td>The trade mark is similar to trade marks that have already acquired reputation in Australia</td>
</tr>
<tr>
<td>The trade mark contains or consists of a false geographical indication</td>
</tr>
<tr>
<td>The application was made in bad faith</td>
</tr>
</tbody>
</table>

Registration of the trade mark

If no opposition has been filed against your application, or if the opposition is unsuccessful, your trade mark will be registered once the registration fee is paid. The fee should be paid within 6 months from the date that that acceptance is advertised.
A Certificate of Registration will be sent to you and IP Australia will record the details of your trade mark in the Register of Trade Marks. The trade mark is registered from the date you filed the application, not the date it was examined, accepted or registered.

**Maintaining trade mark registration**

**Maintenance fees**

Trade mark registration may potentially be perpetual, provided renewal fees are paid every 10 years. Each renewal fee must be paid within 12 months prior to the renewal date.

A full list of trade mark fees is available on the IP Australia website located at: <http://www.ipaustralia.gov.au/trademarks/fees_index.shtml>

**Use the trade mark**

A trade mark must be used as a trade mark (i.e. to indicate a connection in the course of trade between the organisation and the goods and services to which it is applied) to maintain registration; otherwise it may be revoked for non-use.

**Use the ® and ™ symbol**

It is not a legal requirement to use the ® and ™ symbol to identify your trade mark, however it is advisable to do so.

The symbol ™ may be used with any registered or unregistered trade mark.

The symbol ® may be used with any registered trade mark in the territory within which it is registered.

**Avoid generic use of the trade mark**

If a trade mark becomes a generic word, the organisation may lose its trade mark protection because the mark is no longer distinctive or indicative of the organisation. For example, aspirin, nylon and cellophane were initially registered as trade marks but are now used to indicate goods of the kind rather than the source.

When using a trade mark, always avoid using the trade mark as a generic description of the goods/services by:

» using a ® or ™ after the trade mark,

» distinguishing the trade mark by capitalising the first letter of the trade mark, and

» always using the trade mark as an adjective - not as a noun.

For example, Xerox® or Xerox™, Xerox® photocopier, and copy a document on a Xerox® brand copy machine.

**Obtaining foreign protection**

Registered trade marks are territorial in nature and active steps will need to be taken to secure foreign trade mark registration. You may file for trade mark registration in foreign countries by:

» filing a national trade mark application in each country in which you wish to seek registration
filing a single Community Trade Mark application (CTM) for the European Union countries

» filing an international application through the Madrid system for countries which are signatories to the Madrid Protocol. Madrid Protocol applications may be filed through IP Australia.

At the time of publication of this Manual, a list of countries that are signatories to the Madrid Protocol may be accessed at: <http://www.wipo.int/treaties/en/SearchForm.jsp?search_what=C>

A foreign trade mark application will be examined and assessed according to the relevant trade mark laws and regulations of that country. Once registered, the foreign registration may be perpetual provided renewal fees are paid and maintenance requirements are met.

It is recommended that you seek the assistance of a trade marks attorney to co ordinate foreign trade mark protection.

Domain Names

Should the domain name be registered?

The only avenue of gaining access to a domain name on the internet is by registration.

You should be aware that registration of a domain name does not give you any proprietary rights. Registration of a domain name gives the organisation exclusive use of that domain name for an agreed period of time.

How to register a domain name

Domain names are obtained through domain name registrars which are private companies that offer domain names for a fee to the public. An organisation may register any name as their domain name provided that it is not already registered by another entity, and it bears a valid domain suffix (see below on ‘Choosing a domain name’).

The registrar will request contact details and other information for the registration of the organisation’s selected domain name, which will be submitted to a central directory, the ‘Registry’. The Registry provides information to internet users on the organisation’s domain name, such as its Internet Protocol number, its registrar, and its technical administration contact.

A domain name registration contract will be entered into with the registrar setting out the terms and conditions under which the domain name registration is accepted and the obligations which the organisation needs to comply with.

Selecting a domain name

A domain name is a unique address that identifies a website. It is the human-readable version of a website’s internet protocol number. An organisation may register any domain name provided that it is not already registered by another entity and provided it bears a valid domain suffix.

A domain name must contain at least 2 characters and contain no more than 63 characters (excluding ‘http://www’) and may consist of:
Other special characters, such as ! # * $, are not permitted.

Many organisations use the name of their organisation or their trade mark as their domain name. You will need to conduct a search to ensure that the proposed domain name is not already registered by another entity or individual. Searches can be conducted as a general search on an internet search engine, or on search engines offered by some domain name registrars.

If the domain name is already registered by another entity or an individual, it may be possible to purchase the domain name from them. However, it is likely they will charge a higher fee than buying a brand new domain name.

In some instances, legal action may be taken against those individuals or entities that have registered your proposed domain name without any legitimate interest, registered it in ‘bad faith’, and intended to profit from selling it to your organisation. This is referred to as ‘cyber squatting’. Seek legal advice if you suspect cyber squatting by the individual or entity before taking any action.

**Top level domain name**

The suffix of a domain name identifies the domain as belonging to a specific top level domain (TLD). TLDs are released by the Internet Corporation for Assigned Names and Numbers (ICANN) which is responsible for managing and coordinating the Domain Name System. There are different TLDs, some of which may be restricted for use only by those entities that meet eligibility requirements. Examples of TLDs include:

<table>
<thead>
<tr>
<th>TLD Suffix</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>.com</td>
<td>Commercial</td>
</tr>
<tr>
<td>.net</td>
<td>Network</td>
</tr>
<tr>
<td>.org</td>
<td>Non-profit organisation</td>
</tr>
<tr>
<td>.gov</td>
<td>Government department &amp; agencies</td>
</tr>
<tr>
<td>.edu</td>
<td>Educational institutions</td>
</tr>
<tr>
<td>.mil</td>
<td>Military organisations</td>
</tr>
<tr>
<td>.au</td>
<td>Australia</td>
</tr>
<tr>
<td>.biz</td>
<td>Business</td>
</tr>
<tr>
<td>.int</td>
<td>International treaty organisations</td>
</tr>
</tbody>
</table>

In reality the .com suffix includes almost everything and the .net suffix is used when the .com suffix is not available.
Second level domain name

In Australia, there are also .au second level domain (SLD) suffixes available for registration by Australian organisations. SLDs are restricted and must meet certain requirements. Examples of SLDs include:

<table>
<thead>
<tr>
<th>SLD Suffix</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>.com.au</td>
<td>For use by commercial entities registered and trading in Australia and Australian commercial products and services.</td>
</tr>
<tr>
<td>.net.au</td>
<td>For use by Australian entities involved with internet networking and communications. In reality, commercial entities registered and trading in Australia and Australian commercial products and services may use this suffix.</td>
</tr>
<tr>
<td>.org.au</td>
<td>For use by Australian not-for-profit organisations, such as churches and charities.</td>
</tr>
<tr>
<td>.asn.au</td>
<td>For use by Australian associations incorporated under state legislation, such as trade unions, sporting and special interest clubs.</td>
</tr>
<tr>
<td>.id.au</td>
<td>For use by individuals who are Australian citizens or residents.</td>
</tr>
</tbody>
</table>

Selecting a domain name registrar

Domain name registrars are companies that sell or licence domain names for a fee. There are many registrars available that offer different TLDs and they compete with each other to provide the best support and services at the lowest price.

A simple search on domain name registrars in Australia will provide a list of Australian domain name registrars.

You may also refer to ICANN’s list of accredited domain name registrars from around the world, including Australia. This is located at: <http://www.icann.org/registrars/accredited-list.html>

Australian Domain Name Administrator (.auDA), the delegated authority by the Australian government to manage the .au domain and the representative of .au at ICANN, also provides a list of accredited domain name registrars: <http://www.au-da.org.au/registrars/accredited-registrars/>

When selecting a domain name registrar, consider the following issues:

<table>
<thead>
<tr>
<th>Issues to Consider when Selecting a Domain Name Registrar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the domain name registrar accredited by .auDA or ICANN?</td>
</tr>
<tr>
<td>How much will it cost to register the domain name?</td>
</tr>
<tr>
<td>How long is the initial period of registration?</td>
</tr>
<tr>
<td>How long will you have to wait before you can use the domain name?</td>
</tr>
<tr>
<td>Does the domain name registrar offer the appropriate TLD or SDL you are seeking?</td>
</tr>
</tbody>
</table>
Chapter 5: What Managers Making IP Protection Decisions Must Know

Issues to Consider when Selecting a Domain Name Registrar

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the domain name registrar offer web hosting services?</td>
<td></td>
</tr>
<tr>
<td>What are the terms and conditions of the contract?</td>
<td></td>
</tr>
<tr>
<td>Does the domain name registrar reserve the right to revoke your domain name for specific reasons?</td>
<td></td>
</tr>
<tr>
<td>Does the registrar reserve the right to change the terms and conditions without informing the organisation?</td>
<td></td>
</tr>
<tr>
<td>Will the organisation be able to transfer the domain name to another registrar?</td>
<td></td>
</tr>
<tr>
<td>Does the domain name registrar inform the organisation of upcoming renewal of the domain name registration?</td>
<td></td>
</tr>
</tbody>
</table>

Maintaining domain name registration

You should ensure that renewal fees for the domain name are paid on time. A delay in payment may result in a loss of the domain name because after a certain period of time the registrar will offer the domain name to the general public.

The initial protection term of a domain name may vary from 1 to 10 years depending on the domain name registrar with which you register and the type of domain name licensed.
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What this Chapter covers

Senior managers are responsible for the management of the assets of an organisation and need to be aware of and familiar with the issues involved in the management of IP within the organisation, especially in the biotechnology industry, where IP assets usually are the results of many years of research and involve a high cost of development.

This Chapter provides guidance to senior managers on how to:

- retain ownership of IP created by employees and contractors
- establish an IP management framework for the effective management of IP within an organisation
- conduct an IP audit
- assess and value IP assets
- account for IP in financial statements, and
- deal with IP rights in contracts, including an overview of the different ownership positions that may arise in contracts involving IP.

Ownership of IP by the Organisation

IP created by employees

An organisation will usually wish to ensure that it owns the IP generated by its employees.

As a general principle of law in Australia, IP created by employees of an organisation in the normal course of their employment belongs to the organisation. Nevertheless, it is good practice to ensure that employment contracts contain express provisions governing IP ownership. This may include clauses to the effect that:

- all IP generated, modified or improved by the employee in the course of his or her employment with the organisation will vest in the organisation, and
- the employee will sign all necessary documents to assign the IP to the employer.

Many IP ownership disputes between employers and employees involve debates on whether the IP in question was created by the employee ‘during the normal course of employment’. It is extremely important to specify clearly in the employment agreement the scope of employment (such as the job description and the duties of the employee). If an employee is expected to create IP, it is beneficial to make specific reference to such a duty.

Under some IP legislation in Australia (e.g. Patents Act 1990 (Cth) and Copyright Act 1968 (Cth)), assignment of IP from the owner to another entity must be in writing and signed by both the assignor and assignee before it will be recognised. Where such formal assignments are required it is good practice for the organisation also to ensure that the formal assignments are executed by the employee promptly upon the creation of the IP.
Moral rights

Moral rights are the rights of an author of a copyright work to be identified as the author of his or her work, not to have a work falsely attributed to him or her, and not to have the work subjected to derogatory treatment.

Unlike other IP rights, moral rights are personal in nature and cannot be assigned to the organisation. However, the organisation may wish to obtain consents from the employee to any act by the organisation which may otherwise infringe their moral rights. This is important if an employee is expected to generate copyright works, such as written contents for websites, photographs or other publications. Provision of such consents may again be included in the organisation’s employment contracts or relevant confidentiality/IP agreements.

IP created by contractors

Generally, unless there is a written agreement to the contrary, IP generated by an independent contractor will belong to the contractor, with the organisation which engaged the contractor being entitled to use the IP only for the purpose for which it was provided to the organisation under the contract.

All services, consultancy and other agreements with contractors will therefore need to deal with ownership of IP and may need to include (where otherwise appropriate) an assignment clause transferring to the organisation the rights in any IP created by the contractor in the course of carrying out the work. It is also usual, where ownership is transferred, to require the contractor to do all things necessary to give effect to the organisation’s right to ownership, including executing formal IP assignments.

All arrangements for work to be undertaken by contractors should be set out in a written agreement and such agreements should be subject to legal review to ensure all necessary rights are obtained by the organisation.

For more information on different ways of dealing with IP in contracts, see the section ‘IP Ownership Positions in Contracts’ in this Chapter.

IP Issues in Employment Contracts

Some of the other issues, apart from IP ownership, which an organisation will need to consider with respect to IP created by employees and contractors are set out below.

Confidentiality obligations

It is good practice to require employees to undertake specific obligations of confidentiality in relation to the organisation’s trade secrets, financial information, technical know how and other valuable information. Such obligations may be included in the employment contract or in separate confidentiality agreements which employees are asked to sign as a condition of their employment.

The confidentiality provisions need to state clearly:

- the information to which the obligations apply
- the actual obligations and restrictions imposed on the employee
- the consequences of any unauthorised use or disclosure of the organisation’s confidential information, and
that the obligations will continue to apply after termination of their employment with the organisation.

**Other obligations of employees**

It is important that employees are aware of their other more general obligations relating to IP, both with respect to the organisation’s existing IP as well as any new IP they generate. This may include obligations to comply with an organisation’s IP policy, laboratory notebook policy and public disclosure policy. The obligations need to be clearly defined and set out in the organisation’s employment contract, as well as in its IP policy and IP implementation plan.

For more information on the development of an organisation’s IP policy and IP implementation plan, see the section entitled ‘Establishment of an IP Management Framework’ in this Chapter.

**Post employment**

Confidentiality obligations in employment contracts usually continue to apply after the employee has left the organisation. Upon termination of employment, employees should be required to return to the organisation all material in their possession which refers to or contains any of the organisation’s IP or confidential information.

Registration of patent rights usually takes a few years and it may be the case that an employee who is an inventor has left the organisation during the application process. It will therefore be beneficial to include a provision in the employee agreement to require the employee to execute further documents (e.g. confirmation of assignments) even if the employee has left the organisation.

Employment contracts may also include restraints which limit an employee’s right to act in competition with the organisation for a specific period after their employment with the organisation ends. The restraint on the employee may not be broader in terms of geographical area and duration than is reasonably necessary for the protection of the organisation’s legitimate interests. This type of clause therefore needs to be carefully worded as any unreasonable restraint of trade will be unenforceable. Inclusion of a restraint will usually be dependent upon the nature of the position, seniority and the role of the employee.

All employment contracts and confidentiality agreements should be the subject of legal review to ensure that they give all necessary rights to the organisation.

The checklist below summarises the key IP issues which should be addressed in the organisation’s employment agreements.

**Provisions in employment contracts relating to IP may include:**

<table>
<thead>
<tr>
<th>Provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obligations to keep the organisation’s existing IP and confidential information secret.</td>
</tr>
<tr>
<td>Restrictions on the employee’s use of the organisation’s IP and confidential information.</td>
</tr>
<tr>
<td>Requirement to comply with the organisation’s policies, practices and procedures relating to IP, including record keeping procedures and security measures.</td>
</tr>
<tr>
<td>Agreement that all IP developed by the employee in the course of employment will be owned by the organisation.</td>
</tr>
</tbody>
</table>
Provisions in employment contracts relating to IP may include:

- Obligation to provide all necessary assistance to give effect to the organisation’s ownership rights, including signing additional documents to that effect (even after the employee has left the organisation).
- Necessary consents from an employee regarding acts which may otherwise infringe any moral rights the employee may have in any work created in the course of employment.
- Conditions of use with respect to any IP the employee brings to the organisation.
- Obligation to return all material in their possession which refers to or contains any of the organisation’s IP or confidential information.
- (Dependent on role and responsibilities) Restraint on employee acting in competition for a specific period after their employment with the organisation ends.

Establishing an IP Management Framework

What is an IP management framework?

Building a culture of IP awareness throughout the organisation, maintaining continued protection of IP rights and ensuring proper management of IP assets is ideally underpinned by the establishment of an effective IP management framework.

An example of IP management framework is represented in the following diagram.

The IP management framework assists an organisation to manage its IP by:

- aligning policies on IP management with the organisation’s core functions and objectives
- providing guidance on making a range of decisions regarding the management of IP assets
- increasing awareness of the importance of IP throughout the organisation, and
- encouraging better IP management practices.

An IP management framework will be most effective when it becomes an integral part of the organisation’s existing management and operational structure.

Developing an IP policy

An IP policy is a statement of principles governing the organisation’s management and practices in relation to IP. It provides guidance to officers and employees on the importance an organisation places on its IP and the practices for protecting and managing IP assets.
The development of an IP policy generally involves three steps:

**Step 1: Conducting research**

An IP policy needs to be tailored to an organisation’s corporate objectives. Identifying the organisation’s mission, business objectives, core functions and relevant policies is essential for determining the organisation’s IP management needs.

Throughout Step 1, it is vital to involve and consult with all relevant officers and employees of the organisation who may be able to provide relevant information. The knowledge and experience of employees may provide valuable insight into the shortcomings of the organisation’s existing IP practices and potential for improvements.

**Recommended actions for Step 1**

- Locate and review all documentation that defines the organisation’s corporate mission.
- Review all policies that may be relevant to IP management, such as privacy, use of software, e-mail, security, record keeping, public disclosure and confidentiality polices.
- Review all standard documents that deal with IP assets, such as IP ownership provisions in employee agreements and standard contracts used to engage contractors, IP reporting mechanisms and procedures on maintaining laboratory workbooks.
- Consult with all relevant parties.
- List all types of IP commonly developed, acquired or dealt with by the organisation, and the relative importance of each to the organisation.
- Research current practices for managing IP by interviewing relevant employees.
- Identify possible alternatives to the organisation’s current IP practices. For more information on what forms of IP protection that are available for different subject matter, see Chapter 2 ‘What Everyone Must Know’ and Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

**Step 2: Formulating the IP policy**

When formulating and drafting the IP policy, it is important to use clear, concise language that can be easily read and understood by employees at all levels.

An IP policy will typically include principles dealing with the following issues:
<table>
<thead>
<tr>
<th>Principle</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy objective</td>
<td>Summary of the organisation’s aims and business objectives, including an explanation of how the creation, protection, management and exploitation of IP are important for achieving those aims and objectives.</td>
</tr>
<tr>
<td>Scope</td>
<td>Overview of the persons to whom the IP policy will apply, such as employees and contractors, visitors and volunteers of the organisation and its related entities. The scope may also limit the application of the IP policy to certain types of IP.</td>
</tr>
<tr>
<td>Nature and forms of IP</td>
<td>Outline of the different forms of IP commonly created or acquired by the organisation, and the particular forms of IP that are of most value to the organisation.</td>
</tr>
<tr>
<td>Identification and reporting of IP</td>
<td>Guidance on how to recognise an IP asset that may have potential commercial value to the organisation, including an explanation of the need to report all newly developed IP for the organisation to determine how best to protect and exploit it.</td>
</tr>
<tr>
<td></td>
<td>For more information on identifying IP, see the section entitled ‘IP Audit’ of this Chapter.</td>
</tr>
<tr>
<td></td>
<td>For more information on reporting IP, see Chapter 4 ‘What Researchers Must Know’.</td>
</tr>
<tr>
<td>Ownership of IP</td>
<td>Direction on the organisation’s policy regarding ownership of IP developed by employees, contractors, visitors, volunteers and other third parties.</td>
</tr>
<tr>
<td></td>
<td>For more information on IP ownership, see the section entitled ‘Ownership of IP by the Organisation’ of this Chapter.</td>
</tr>
<tr>
<td>Protection of IP</td>
<td>Explanation of the importance of actively protecting IP and the consequences if protection is not maintained. This should include guidance on how to make IP protection decisions for each form of IP that is relevant to the organisation.</td>
</tr>
<tr>
<td></td>
<td>For more information on making IP protection decisions, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know.’</td>
</tr>
<tr>
<td>Ongoing management of IP</td>
<td>Procedures for the proper management of IP including:</td>
</tr>
<tr>
<td></td>
<td>» the conduct of periodic reviews of existing IP assets;</td>
</tr>
<tr>
<td></td>
<td>» the ongoing decision-making process regarding IP protection and commercialisation, and</td>
</tr>
<tr>
<td></td>
<td>» disposal of IP.</td>
</tr>
<tr>
<td></td>
<td>For more information on the ongoing management of IP, see Chapter 4 ‘What Researchers Must Know’ and Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.</td>
</tr>
<tr>
<td>IP Valuation</td>
<td>Guidance on the organisation’s approach to quantitative and qualitative valuations of IP.</td>
</tr>
<tr>
<td></td>
<td>For more information on IP valuation, see the section entitled ‘IP Valuation’ in this Chapter.</td>
</tr>
</tbody>
</table>
### Step 3: Review & finalisation

The development of an IP policy will usually involve numerous reviews and revisions. It may also be necessary to re-examine and refine the organisation’s IP management needs in order to align them with the organisation’s overall objectives and operational needs.

It may be appropriate to seek advice from an IP professional to ensure your IP policy is tailored to your organisation’s needs.

### Example extracts of an IP policy

The structure of an IP policy will vary from one organisation to another. Some organisations may not have the time or resources necessary to conduct a thorough and organisation-wide research and formulation exercise and will instead focus only on issues which present the greatest risk or are likely to have the greatest impact on achieving its business objectives. Other organisations may have sufficient time and resources to develop a more comprehensive IP policy dealing with all areas of IP management.

#### Policy Objective

‘Our corporate mission is to provide innovative and creative solutions designed to exceed market expectations in every facet of the biotechnology industry. The creation of each innovative solution is a valuable form of Intellectual Property (IP).

The objectives of this IP policy are to provide guidance on best practice and appropriate procedures for the protection, management and commercialisation of IP. We will develop and maintain appropriate processes for the management of IP through our IP implementation plan.

Below are several examples of IP principles which may be found in some IP policies.
Chapter 6: What Senior Management Must Know

Developing the IP implementation plan

An IP implementation plan sets out the chosen processes and procedures for the implementation of the organisation’s IP policy. It provides guidance on a practical and operational level on the practices and procedures to be followed by the organisation’s employees in relation to the management of IP.

The process of developing an IP implementation plan is similar to the development of the IP policy, but with emphasis on integrating the policy into operations and dealing with the practicalities involved in managing IP.

The development of an IP implementation plan usually involves the following three steps:

**STEP 1**
Review the organisation’s IP policy and identify available resources

**STEP 2**
Formulate an IP implementation plan

**STEP 3**
Review and finalise the IP implementation plan

Identification and Reporting of IP – Patents

‘The IP Officer should be immediately made aware of all new inventions when they occur by completion of an invention disclosure form. An evaluation will be made by the IP Committee as to whether the invention warrants patent protection.’

Protection of IP – Confidential Information

‘Everyone should take all reasonable precautions and steps to preserve all of our confidential information. Before disclosing any confidential information, you need to consult and obtain approval from management. Appropriate confidentiality agreements must be entered into with the recipients of the confidential information before any disclosure is made.

Failure to observe these rules will result in unnecessary loss of protection of our confidential information which could negatively impact on our competitive advantage.’

Commercialisation of IP

‘The organisation aims to commercialise all IP that it develops for the advancement and profit of the organisation.

You should consult your manager on the prospects of commercialisation of a particular IP asset. A proposal for the commercialisation of the IP asset should be prepared for evaluation and approval by the Board who will make a decision as to whether it should be commercialised, and if so, when and how.’
### Step 1: Reviewing the organisation’s IP policy and identifying available resource

The IP implementation plan is a tool to implement an organisation’s IP policy. The organisation’s IP policy will need to be reviewed in order to ensure each IP principle is addressed in the IP implementation plan at an operational level.

An IP implementation plan will usually incorporate and build on systems which are already in place within the organisation. The need to create entirely new processes or systems should be avoided or minimised where possible. Relevant existing processes and systems may include:

<table>
<thead>
<tr>
<th>System</th>
<th>Relevant issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asset Management</td>
<td>Are all IP assets included in the existing asset register?</td>
</tr>
<tr>
<td></td>
<td>Are all IP assets included in financial reports and annual reports?</td>
</tr>
<tr>
<td></td>
<td>What is the process for employees to report newly generated or created assets?</td>
</tr>
<tr>
<td>Risk Management</td>
<td>Do the existing risk management systems take into account the risks relating to the protection, management, use and commercialisation of IP?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation adequately protect its position with respect to IP when dealing with third parties by including appropriate provisions in agreements regarding warranties, indemnities, limitation of liability and insurance?</td>
</tr>
<tr>
<td></td>
<td>Has the organisation obtained any IP insurance?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation obtain professional legal advice relating to IP where necessary?</td>
</tr>
<tr>
<td>Contract Management</td>
<td>Do all contracts dealing with the creation of IP (such as employment contracts, consulting contracts, research collaboration contracts) address IP ownership issues?</td>
</tr>
<tr>
<td></td>
<td>Do the organisation’s standard form contracts contain appropriate IP clauses, including different alternatives depending on the type of transaction?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation provide clear guidelines on its preferred position in relation to IP clauses?</td>
</tr>
<tr>
<td>Financial Approval and Budgeting</td>
<td>Does the annual budget provide for the costs of managing IP?</td>
</tr>
<tr>
<td></td>
<td>Are there processes in place for obtaining financial approval for the development of new IP?</td>
</tr>
<tr>
<td>Record Keeping</td>
<td>Are there procedures in place for documenting the creation and development of IP in laboratory workbooks?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation have an IP register which is properly maintained and updated, including regular reviews and re-assessments of the IP?</td>
</tr>
<tr>
<td>Employee Management</td>
<td>Are there any formal or informal programmes in place recognising and rewarding the contribution of employees to the creation of IP?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation provide regular training sessions on IP management?</td>
</tr>
<tr>
<td></td>
<td>What are the incentives or motivational tools in place to stimulate creativity?</td>
</tr>
</tbody>
</table>

You will also need to consult with all relevant stakeholders within your organisation regarding practical measures to implement the organisation’s IP policy.
Step 2: Formulating the IP implementation plan

Effective IP management requires all employees to be familiar with and adhere to the provisions set out in the IP implementation plan. Ideally, the IP implementation plan should be written in clear, concise language that can be easily read and understood by all employees, including the use of visual tools such as diagrams, checklists and tables where appropriate.

When formulating the IP implementation plan, list the systems or procedures that are required and compare them with the existing systems that may be utilised. Once you have performed the above analysis, you will be able to identify:

» existing systems into which IP management can integrate, and
» systems or procedures that need to be put in place.

An IP implementation plan will generally address the following issues:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective</strong></td>
<td>Statement of the organisation’s aims for the IP implementation plan, e.g. to set out operational practices and procedures for implementing the organisation’s IP policy.</td>
</tr>
<tr>
<td><strong>Strategies for Implementation</strong></td>
<td>Outline of the organisation’s strategies for the management of IP which correspond with the IP principles contained in its IP policy. These strategies are ideally incorporated into existing processes and systems identified in Step 1.</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td>Overview of the resources to be used for the management of IP, which will usually include the utilisation of existing systems, time spent by senior management, as well as adequate corporate support from relevant employees.</td>
</tr>
<tr>
<td><strong>Authority and Responsibility</strong></td>
<td>Explanation of the organisation’s IP management structure, including an overview of the persons responsible for making decisions at the different levels of IP management and the scope of authority for those dealing with IP.</td>
</tr>
<tr>
<td><strong>Increasing IP Awareness</strong></td>
<td>Statement of planned actions to promote knowledge and awareness of IP such as:</td>
</tr>
<tr>
<td></td>
<td>» including IP issues in staff inductions</td>
</tr>
<tr>
<td></td>
<td>» providing regular training on IP</td>
</tr>
<tr>
<td></td>
<td>» communicating the organisation’s IP policy and IP implementation plan to all employees, and</td>
</tr>
<tr>
<td></td>
<td>» developing standard contracts that address IP issues.</td>
</tr>
<tr>
<td><strong>Sources of Expert Advice</strong></td>
<td>Guidance on sources of expert advice and assistance. These may include internal advice from in-house lawyers or senior management responsible for managing IP, or external advice from legal advisers, patent and trademark attorneys or other consultants such as market researchers or business advisers. For more information on obtaining expert advice, see Chapter 9 ‘Where Can I Find Out More About IP’.</td>
</tr>
<tr>
<td><strong>Review Mechanism</strong></td>
<td>Outline of a mechanism for the review of the IP implementation plan to evaluate the effectiveness of the organisation’s practices in light of its objectives set out in the IP policy.</td>
</tr>
</tbody>
</table>
Step 3: Review & finalisation

The IP implementation plan is the organisation’s “instruction manual” regarding its approach to the management of IP. It will be referred to frequently by employees at all levels within the organisation for guidance on the practices and procedures relating to IP. The IP implementation plan may therefore need to be reviewed and revised several times before it can be finalised. All relevant employees should be consulted in the process to ensure the most appropriate operational practices are adopted for the implementation of the IP policy.

IP Audits

Purpose of IP audits

The identification of an organisation’s IP assets provides the basis for good IP management. An IP audit may be conducted as part of an organisation’s IP management framework and will assist senior management to:

» shape the organisation’s research and product development strategy
» identify risks associated with the organisation’s IP assets
» make informed decisions regarding IP protection and enforcement
» develop an IP commercialisation strategy
» avoid duplication in the acquisition or development of IP, and
» minimise the risk of infringing third party IP rights.

How to conduct an IP audit

Conducting an IP audit is a complex, detail-orientated exercise.

It is recommended that you seek the assistance of an IP professional to carry out a comprehensive IP audit.

Conducting an IP audit involves four steps, as illustrated by the diagram below:

Step 1: Scoping the IP audit

The first step in an IP audit is the identification of an organisation’s objectives for and the extent of the audit. An organisation may undertake an IP audit for such purposes as:

» complying with a requirement of the organisation’s IP management framework
» assessing the organisation’s IP portfolio
> reviewing existing research and product development strategies
> identifying new IP created or acquired by an organisation
> conducting a due diligence exercise, or
> pursuing the enforcement or defence of IP rights.

The scope of the audit may be affected by the availability of the organisation’s finances and other resources to conduct the IP audit. Depending on those factors and the objectives of the IP audit, an organisation may undertake an IP audit limited to specific types of IP or particular departments within the organisation.

**Step 2: Identifying existing IP assets**

Existing IP assets held within an organisation may be identified in a number of ways depending on the scope of the IP audit. This process will generally require a significant amount of time and resources. Examples of how IP assets may be identified include:

> review of documentation
> targeted requests for specific information directed at relevant employees
> an organisation-wide IP survey, and
> site visits and interviews.

It is important that the process for gathering information is effective, comprehensive and in line with the objectives of the audit. In some instances, introductory workshops for the relevant staff regarding the IP audit may assist. The auditor should ensure that each answer to a survey, request for information or interview is supported by relevant documentation.

**Supporting documentation may include:**

<table>
<thead>
<tr>
<th>Laboratory notebooks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment contracts</td>
</tr>
<tr>
<td>Consultancy or service contracts</td>
</tr>
<tr>
<td>Funding agreements</td>
</tr>
<tr>
<td>Confidentiality agreements</td>
</tr>
<tr>
<td>Licences, assignments or other agreements dealing with the relevant IP asset</td>
</tr>
<tr>
<td>Official documents from IP Australia or overseas IP offices</td>
</tr>
</tbody>
</table>

A checklist of information that is ideally obtained for each IP asset may resemble the following:

**Information to be obtained:**

- ✔ Description of the IP asset, including form, expression and format
- ✔ Date of creation
- ✔ Expected date of expiration of IP rights
- ✔ Details of creators, including inventors and other contributors to patentable inventions
- ✔ Status of all creators (such as employee or contractor)
- ✔ Where the IP asset was acquired from a third party, description of the relationship with the third party, including details of any contractual arrangements
Step 3: Analysing the information

The information and supporting documentation collected at Step 2 will need to be analysed carefully in light of the objectives of the IP audit. This analysis will require a detailed review and assessment of all the supporting documentation in order to confirm each detail obtained at Step 2, including:

- the validity and ownership of each IP asset
- the existence of any third party rights
- any restrictions on the organisation’s rights to use the IP asset, and
- the likely remaining life of the IP asset.

Step 4: Reporting results of the IP audit

The final step in the IP audit process is the preparation of a report of the results of Steps 2 and 3. The report needs to be tailored to the organisation’s objectives of the IP audit established in Step 1. In addition, the report may provide information on:

- the effectiveness of the organisation’s IP management framework
- the strengths and weaknesses of the organisation’s overall IP position
- appropriate ways to monitor IP development in the future
- possible improvements to the organisation’s IP protection strategy
- areas of potential overlap with third party activities where the organisation may be infringing third party rights, and
- IP assets for which management decisions are necessary.

IP Valuation

Importance of IP valuation

Understanding the value of the organisation’s various IP assets is essential for the effective management of IP. Valuation of IP is not just concerned with the quantifiable value of an IP asset, but also with its qualitative value to the organisation.
Assessing the worth of an organisation’s IP will assist an organisation to form a view about whether particular IP is essential, secondary or surplus to the organisation. You should however be aware that any valuation reflects the value of the IP at a certain time. The value of an IP asset may change over time depending on the nature of the IP, its strategic importance to the organisation and market conditions.

**Qualitative valuation**

A qualitative valuation of an IP asset involves assessing the importance of the IP to the organisation.

An organisation may wish to conduct a qualitative assessment of its IP portfolio in one or more of the following scenarios:

<table>
<thead>
<tr>
<th>When to Conduct Qualitative IP Valuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>When deciding whether to continue with a particular research project.</td>
</tr>
<tr>
<td>When deciding whether to apply for formal protection of an IP asset (e.g. patents, trade marks, designs).</td>
</tr>
<tr>
<td>When deciding whether to dispose of IP.</td>
</tr>
<tr>
<td>When licensing-in third party technology.</td>
</tr>
<tr>
<td>When granting access to the organisation’s IP to third parties.</td>
</tr>
<tr>
<td>When deciding how best to commercialise an IP asset.</td>
</tr>
</tbody>
</table>

**How to qualitatively value IP**

The issues that need to be considered when undertaking a qualitative valuation of an IP asset may include the following:

<table>
<thead>
<tr>
<th>Area</th>
<th>Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strategic and operational significance</strong></td>
<td>Is the IP asset essential to carrying out the organisation’s functions or achieving its objectives?</td>
</tr>
<tr>
<td></td>
<td>Is the IP asset necessary for the performance of a particular key task?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation require continued access to the IP?</td>
</tr>
<tr>
<td></td>
<td>How much has the organisation invested in the creation and development of the IP asset?</td>
</tr>
<tr>
<td></td>
<td>What are the future maintenance costs of the IP asset?</td>
</tr>
<tr>
<td></td>
<td>Could the IP asset be replaced, and if so, at what cost?</td>
</tr>
<tr>
<td></td>
<td>How does the performance of the IP compare with available alternatives?</td>
</tr>
<tr>
<td>Area</td>
<td>Issues</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Commercial potential</td>
<td>What is the nature of the IP asset?</td>
</tr>
<tr>
<td></td>
<td>At what stage of development is the IP asset?</td>
</tr>
<tr>
<td></td>
<td>Can the IP asset be commercialised without much further adaptation or development?</td>
</tr>
<tr>
<td></td>
<td>Is there a demand for products or services applying the IP?</td>
</tr>
<tr>
<td></td>
<td>If so, what is the estimated market size?</td>
</tr>
<tr>
<td></td>
<td>Are other organisations likely to be interested in using, buying or licensing the IP asset?</td>
</tr>
<tr>
<td></td>
<td>Can the IP asset be formally registered and protected, e.g. as a patent, registered design or trade mark?</td>
</tr>
<tr>
<td></td>
<td>Does the organisation have the unrestricted right to commercialise the IP asset?</td>
</tr>
<tr>
<td></td>
<td>Does the IP support products making up a substantive part of the organisation’s revenue?</td>
</tr>
<tr>
<td></td>
<td>What IP supports your most profitable products?</td>
</tr>
<tr>
<td></td>
<td>Does your IP bring in revenue independently (e.g. from licences) and how much?</td>
</tr>
<tr>
<td></td>
<td>To what extent does your IP give your products an advantage over those of your competitors?</td>
</tr>
<tr>
<td></td>
<td>How much can you charge for your products above your competitors because of that advantage?</td>
</tr>
<tr>
<td></td>
<td>Does your IP confer a marketing advantage over your competitor?</td>
</tr>
<tr>
<td></td>
<td>Will consumers perceive your products as better quality because of the IP?</td>
</tr>
<tr>
<td></td>
<td>Is your IP necessary to raise funding for expansion?</td>
</tr>
<tr>
<td></td>
<td>How do potential sources of finance view your IP?</td>
</tr>
</tbody>
</table>

Below are some examples as to how the above criteria are applied in various scenarios of IP management. The relative importance of the IP in that criterion may be ranked ‘high’, ‘medium’, or ‘low’. It should be noted that the examples provided below are highly simplified illustrations and a thorough analysis should be conducted for each of the criteria above when valuing IP.
Example 1

An organisation has filed a PCT application for a novel drug delivery method and the deadline for filing national phase applications is approaching. The novel drug delivery method may be used to administer a generic drug orally. The usual method for administering the generic drug is through injection. The International Search Report has identified some relatively close prior art.

Should the organisation pursue national phase filing?

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rank</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategic and operational</td>
<td>High</td>
<td>The research project is one of the key research projects of the organisation.</td>
</tr>
<tr>
<td>operational significance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial potential</td>
<td>High</td>
<td>If successful, the organisation would have a key position in delivering the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>generic drug using the patented method in the market.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The strength of the patent application is in some question, due to the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>prior art; however due to the potentially high value of a granted patent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>this is of lesser significance.</td>
</tr>
</tbody>
</table>

**Conclusion:** The organisation should consider pursuing complete patent filings after it has performed detailed analysis of its key markets.

Example 2

An organisation plans to commercialise a medical device under a trade mark. The organisation has used the trade mark for some time but the trade mark was not registered.

Should the organisation register the trade mark?

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rank</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategic and operational</td>
<td>High</td>
<td>The trade mark functions as a badge of origin in distinguishing the</td>
</tr>
<tr>
<td>operational significance</td>
<td></td>
<td>organisation’s goods and services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial potential</td>
<td>High</td>
<td>The organisation has been using the trade mark for a while and therefore</td>
</tr>
<tr>
<td></td>
<td></td>
<td>it is likely that there is goodwill attached to the trade mark. In addition,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the commercial potential is high because the organisation will soon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>commence commercialisation of the medical device under the trade mark.</td>
</tr>
</tbody>
</table>

**Conclusion:** The organisation should register the trade mark.
Quantitative valuation

In general, quantitative valuation of an IP asset focuses on assigning a dollar amount to the IP asset.

An organisation may wish to conduct a quantitative assessment of its IP portfolio in scenarios including one or more of the following:

**When to Conduct a Quantitative IP Valuation**

<table>
<thead>
<tr>
<th>When to Conduct a Quantitative IP Valuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>When preparing financial statements.</td>
</tr>
<tr>
<td>When determining the sale or purchase price for a transaction involving IP (e.g. in an IP assignment or an IP licence).</td>
</tr>
<tr>
<td>When seeking investment or raising finance.</td>
</tr>
<tr>
<td>When facing a merger/acquisition of the organisation.</td>
</tr>
<tr>
<td>When deciding how best to commercialise an IP asset.</td>
</tr>
<tr>
<td>When determining potential damages in a legal action involving IP.</td>
</tr>
</tbody>
</table>

**How to quantitatively value IP**

There are various methods for quantitatively valuing IP. Each method has its advantages and disadvantages and not all methods will be appropriate for valuing all types of IP assets. The method chosen will also depend on the purpose of the valuation and the information available.

In general, the following information will be assessed when valuing IP quantitatively:

- the strength of the IP rights
- the expected life of the IP asset
- the stage of development of the IP asset
- the size of the potential market, and
- the availability of alternative technologies.

The three common quantitative valuation methods for IP assets are:

<table>
<thead>
<tr>
<th>Cost Approach</th>
<th>Income Approach</th>
<th>Market Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>To determine the reproduction or replacement cost of the IP at the date of the valuation</td>
<td>To determine the estimated future income to be generated by the IP asset over its effective life</td>
<td>To determine the comparable price or royalty that could be achieved by similar IP in the market</td>
</tr>
</tbody>
</table>
Quantitative valuation of IP typically involves the following steps:

**Step 1: Scoping the valuation**

When an organisation decides to undertake quantitative IP valuation, it should first determine the scope of the valuation.

*Issues to be Considered When Scoping the Quantitative IP Valuation*

<table>
<thead>
<tr>
<th>What is the purpose of the valuation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which IP portfolio is to be valued?</td>
</tr>
<tr>
<td>What is the date at which the IP is to be valued?</td>
</tr>
<tr>
<td>Who will be relying on the outcome of the valuation?</td>
</tr>
<tr>
<td>What resources should be used for the valuation?</td>
</tr>
</tbody>
</table>

The kind of information required for IP valuation will depend on the method for quantitative valuation.

**Step 2: Gathering information**

The kind of information required for IP valuation will depend on the method for quantitative valuation.

*It is recommended that you seek the assistance of a valuation expert when selecting the most appropriate valuation approach and undertaking the valuation process.*

**Cost approach**

The cost approach determines the value of an IP asset by reference to the reproduction or replacement costs that would be incurred in creating the IP asset again.

These costs are not necessarily the same as the historic costs incurred by the organisation in creating the IP asset as the price of materials, resources and labour may have changed.

**Reproduction Costs**

- The costs that will be incurred in order to reproduce exactly the same IP asset

**Replacement Costs**

- The costs of replacing the IP asset with an asset of similar utility, but not necessarily the same IP asset
The following information is usually required for a quantitative valuation of IP using the cost approach:

<table>
<thead>
<tr>
<th>Area</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material costs</td>
<td>The costs of tangible materials necessary for the development of the IP, such as reagents, equipment and licence fees</td>
</tr>
<tr>
<td>Labour costs</td>
<td>The costs of staff and contractors required for the development of the IP, including wages, salaries, consultancy fees, workers compensation, insurance costs and superannuation contributions.</td>
</tr>
<tr>
<td>Overhead costs</td>
<td>A proportion of the costs of utilities and administration.</td>
</tr>
<tr>
<td>Other information</td>
<td>Any other information required for the calculation of the costs of recreating or replacing the IP asset, including time and resources</td>
</tr>
<tr>
<td>Profit/incentive component</td>
<td>The amount of profit that would be sufficient to motivate the organisation to enter into the development process.</td>
</tr>
</tbody>
</table>

The cost approach may be useful in determining the minimum value of an IP asset that the organisation intends to sell or purchase. However, this approach does not take into account a wide range of other factors that may increase or decrease the value of the IP asset, such as the strength of the IP rights or the length of time needed to create alternatives.

**Income approach**

The income based approach values an IP asset by establishing the anticipated future income to be generated by the IP asset over the course of its life.

The following information is generally needed for an income based valuation:

<table>
<thead>
<tr>
<th>Area</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected profits</td>
<td>Current market information, including market opportunities, competition and selling prices.</td>
</tr>
<tr>
<td></td>
<td>Future sale prices.</td>
</tr>
<tr>
<td></td>
<td>Expected market share and volume of products expected to be sold.</td>
</tr>
<tr>
<td></td>
<td>Historical market information on the effective life of comparable IP assets.</td>
</tr>
<tr>
<td></td>
<td>Cost of goods sold.</td>
</tr>
<tr>
<td></td>
<td>Future capital expenditure, marketing and other expenses.</td>
</tr>
<tr>
<td>Risks and costs of development</td>
<td>Length of time required before the IP asset is ready for commercialisation.</td>
</tr>
<tr>
<td></td>
<td>Further development costs likely to be incurred.</td>
</tr>
<tr>
<td></td>
<td>Legal and other regulatory requirements.</td>
</tr>
<tr>
<td></td>
<td>Difficulty of reverse-engineering or working around the IP.</td>
</tr>
<tr>
<td></td>
<td>Risk of marketing plan failing.</td>
</tr>
</tbody>
</table>

The income based approach is most useful where reliable data is available in relation to the estimated effective life and projected profits of an IP asset. The main weakness of the income approach is that the valuation is based on a significant number of estimates and assumptions. Relatively small variations of the estimated effective life or the projected profits can significantly reduce or increase the final value arrived at using this approach.
**Market approach**

The market approach values an IP asset based on comparisons with sales or licensing income of similar IP assets in the market place.

This approach requires accurate and complete data for commercial transactions involving comparable IP assets, such as licences and assignments.

The following information on comparable IP asset is generally needed for a valuation of an IP asset using the market approach:

<table>
<thead>
<tr>
<th>Area</th>
<th>Information on comparable IP asset</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type of IP asset</td>
</tr>
<tr>
<td></td>
<td>Expected life of the IP asset</td>
</tr>
<tr>
<td></td>
<td>Strength of IP rights</td>
</tr>
<tr>
<td></td>
<td>Relevant industry</td>
</tr>
<tr>
<td></td>
<td>Geographical constraints affecting the commercialisation of the IP asset</td>
</tr>
<tr>
<td></td>
<td>Nature of transaction (e.g. exclusive or non-exclusive licence or sale)</td>
</tr>
<tr>
<td></td>
<td>Nature of the parties, including whether they were dealing on arms’ length terms</td>
</tr>
<tr>
<td></td>
<td>Other information affecting the price, such as the parties’ relative bargaining power and market conditions</td>
</tr>
<tr>
<td></td>
<td>For assignments, the sale price</td>
</tr>
<tr>
<td></td>
<td>For licences, the licence fees, including upfront and ongoing licence fees and royalties</td>
</tr>
<tr>
<td></td>
<td>Minimum payments</td>
</tr>
</tbody>
</table>

This approach can be very useful for confirming the value of an IP asset arrived at using other valuation methods. However, on its own, this approach can lead to uncertain or misleading results as it may be difficult or even impossible to find sufficiently detailed publicly available information on assignments or licences of truly comparable IP assets.

**Step 3: Valuing and reporting**

You should consult with a valuation expert as to what method of valuation is most appropriate for the purpose of the IP valuation of your organisation. At times a valuer may apply multiple techniques when conducting the quantitative IP valuation.

The valuation report should be in a format that meets the needs of your organisation. In particular, the valuation report should at a minimum:

» identify and describe the IP which is the subject of the valuation  
» describe the purpose and intended use of the valuation  
» state the method of valuation adopted  
» identify all assumptions and basis for the valuation approach, and  
» list all limiting and contingent conditions that may affect the valuation

In addition, the valuation report should ideally be certified by the valuer that:

» statements of facts in the report are true and correct  
» any assumptions and limiting conditions are unbiased
Dealing with IP Rights in Contracts

Senior managers are responsible for making decisions as to whether or not an organisation should enter into a particular contract with a third party. Where a contract will lead to the creation, use or grant of IP rights, it is essential that IP issues are adequately addressed.

IP ownership positions in contracts

IP ownership interests and rights to use IP may be structured in a number of different ways in a contract. It is important to understand the different types of IP ownership interests and rights of use and their implications in order to determine which position is the most favourable to the organisation in a particular situation.

The diagram below illustrates a range of IP ownership interests that may be adopted by the parties to a contract that has an IP component.

![Different IP Ownership Positions in a Contract](image)

**Sole ownership**

Sole ownership of IP occurs where all rights in the IP asset are owned by a single entity.

Sole ownership is the simplest form of interest. The transfer of the entire right and title to an IP asset to another party means the original owner of the IP will be unable to re-use or re-sell all or part of the IP. In general, an obligation for a contractor to provide for a total transfer of ownership to the organisation may add a substantial cost of the contract as the contractor will have no right to reuse that IP.

Transfer of ownership usually takes the form of an assignment. When a contract stipulates the complete, permanent transfer of IP rights and ownership to another party, sometimes a licence is granted back to the assignor from the assignee to use the IP asset on the terms of a licence (referred to as a ‘licence back’). This allows the original owner to access the assigned IP for an agreed purpose in the licence granted back to the original owner.

For more information on IP assignment, see Chapter 7 ‘What Must Be Known About IP Commercialisation’.
Joint ownership

Joint ownership of IP is where two or more individuals or organisations together own the rights in an IP asset.

In a project where the creation of IP is anticipated as a result of a collaborative effort, the parties to a contract may agree that any IP generated will be jointly owned. Unless otherwise agreed, each joint owner will usually own an undivided equal share of the rights in the IP asset.

However, you should be aware that management of jointly owned IP may be complex. Importantly, unless otherwise agreed in a contract between the joint owners, the respective rights of the joint owners to the IP are governed by applicable IP legislation, depending on the type of IP. In the case where the joint owners are from different jurisdictions or where IP registrations are obtained in multiple countries, another level of complexity will be introduced since the rights conferred on joint owners of IP may vary from country to country.

It is important that the details of any joint ownership arrangement are recorded in a written agreement which clearly sets out the parties’ rights and obligations regarding the protection, enforcement, use and commercialisation of the relevant IP asset.

Set out below is a summary of the rights of joint owners of different types of IP assets under Australian law which will apply unless otherwise agreed:

<table>
<thead>
<tr>
<th>Type of IP</th>
<th>Rights of Joint Owners when Dealing with the Example Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent</td>
<td>Each joint owner may separately use all the exclusive rights granted by the patent to make and sell the patented <strong>subject matter</strong> without accounting to the other joint owners. However, no joint owner can license or assign the patent to third parties without the consent of all other joint owners. You should note that different positions apply in some foreign jurisdictions.</td>
</tr>
<tr>
<td>Copyright</td>
<td>Each joint owner may only use the copyright material for its own benefit without accounting to the other owners. However, each joint owner requires all other joint owners’ consent to exercise copyright in the copyright material (e.g. altering the copyright material for distribution to third parties).</td>
</tr>
<tr>
<td>Registered Design</td>
<td>Each joint owner may separately use all the exclusive rights granted by the design registration to make and sell products incorporating the registered design. However, a joint owner cannot license or assign the registered design to a third party without the consent of all other joint owners.</td>
</tr>
<tr>
<td>Trade Mark</td>
<td>Joint owners may not use the trade mark other than on behalf of all joint owners and in relation to goods/services with which all of them are connected in the course of trade. (Note that it is rare for a trade mark to be jointly owned by two or more organisations.)</td>
</tr>
<tr>
<td>Plant Breeder’s Rights</td>
<td>It is unclear from the current legislation the scope of respective rights for each joint owner in the plant variety registered under the Plant Breeder’s Rights Act 1994. It is recommended that you seek professional advice regarding your rights when dealing with plant breeder’s right as a joint owner.</td>
</tr>
</tbody>
</table>
**Licence rights**

An IP licence is the right to use IP for a specified period of time in accordance with agreed conditions. An IP licence provides great flexibility as to the scope of rights granted to the licensee whilst allowing the licensor to retain ownership and the desired degree of control over the IP asset.

Depending on the needs of the parties to the licence, various licensing approaches may be used to accommodate those needs. For example, a licence may be exclusive, sole or non-exclusive.

<table>
<thead>
<tr>
<th>Exclusive Licence</th>
<th>Sole Licence</th>
<th>Non-Exclusive Licence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A licence where the licensee is the only entity which has the right to deal with the licensed IP, in addition to the licensor</td>
<td>A licence where the licensee is the only entity which has the right to deal with the licensed IP, even to the exclusion of the licensor</td>
<td>A licence where the licensor retains the right to grant licences of the licensed IP to third parties</td>
</tr>
</tbody>
</table>

In addition, IP rights granted in a licence may be limited by multiple parameters, (including territory, field of use, purpose, term and sublicensing rights), as illustrated by the following example.

Example: IP licence granted to three different entities by licensor.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Company ABC</th>
<th>Company XYZ</th>
<th>Government Authority X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclusivity</td>
<td>Exclusive in territory</td>
<td>Non-exclusive</td>
<td>Non-exclusive</td>
</tr>
<tr>
<td>Territory</td>
<td>Australia</td>
<td>US</td>
<td>US</td>
</tr>
<tr>
<td>Purpose</td>
<td>To commercialise the IP</td>
<td>Licensed IP only be used internally by Company XYZ</td>
<td>Licensed IP only be used internally by government authority X</td>
</tr>
<tr>
<td>Term</td>
<td>10 years</td>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>Sublicensing rights</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

For more information on IP licences, see Chapter 7 ‘What Must be known about IP Commercialisation’.

**Sole and joint ownership and licence rights compared**

The table below sets out some of the advantages and disadvantages of sole and joint ownership and licence rights from the perspective of an IP acquirer.
### Type of right

<table>
<thead>
<tr>
<th>Type of right</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sole ownership</strong></td>
<td>» Gives complete control over the IP asset to the organisation</td>
<td>» May be difficult to negotiate where the IP asset is (at least partly) created by a third party.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>» May increase the price of the contract.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>» Shifts all risks associated with the IP asset to the organisation.</td>
</tr>
<tr>
<td><strong>Joint ownership</strong></td>
<td>» May be easier to negotiate than sole ownership.</td>
<td>» Is likely to require the consent of all owners for the use or commercialisation of the IP asset.</td>
</tr>
<tr>
<td></td>
<td>» Spreads the risks associated with the IP asset between the joint owners.</td>
<td>» May render the decision making process for the protection, enforcement and exploitation of the IP asset complex, costly and inefficient.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>» May lead to potential disputes between the joint owners.</td>
</tr>
<tr>
<td><strong>Licence Rights</strong></td>
<td>» Allows the organisation to obtain access to an IP asset without having to take on all the associated risks.</td>
<td>» Provides the lowest degree of control over the IP asset.</td>
</tr>
<tr>
<td></td>
<td>» Provides flexibility in how access to the IP asset may be structured.</td>
<td>» Does not provide access to the IP asset after termination of the licence.</td>
</tr>
<tr>
<td></td>
<td>» Is likely to be cheaper than obtaining ownership.</td>
<td>» Requires careful drafting to ensure the organisation is granted all necessary rights.</td>
</tr>
</tbody>
</table>

### IP due diligence when acquiring IP

When acquiring IP from a third party, it is vital that appropriate IP due diligence be conducted. At a minimum, you should consider the issues listed in the section entitled ‘IP due diligence in capital raising’ in Chapter 3 ‘What the Board and CEO Must Know’ to confirm that the IP your organisation is acquiring is consistent with its understanding of what the IP rights entail.

### Research collaborations

Collaborations within industry and between industry and public sector institutions are frequently undertaken by many organisations in the biotechnology area. The pooling of resources and experience in collaborations can reduce the time it takes to bring a product to market, lower R&D expenditure, and spread or reduce the risks involved.

Research collaborations can range from a relatively short and simple research programme between two organisations to a series of complex, interdependent projects between a number of industry organisations and public sector research institutions. It is recommended that the rights and obligations of each collaborator are documented in advance to minimise the chance of potential disputes and to protect pre-existing rights and other rights in the research outcome of all parties.

Agreements that may be utilised in a collaborative research context include:
Confidentiality Agreements

A confidentiality agreement is also known as a confidential disclosure agreement (CDA) or secrecy agreement. It is also often referred to as a non-disclosure agreement (NDA).

Confidentiality agreements are commonly entered into by parties considering doing business or committing to a form of collaboration with each other. This is especially important for technology-based industries such as the biotechnology industry because the unauthorised disclosure of any confidential information may adversely affect the patentability of certain inventions.

As well as being stand-alone documents utilised at the beginning of the relationship between two parties, obligations of confidentiality will usually also be included subsequent agreements, such as a research collaboration agreement.

Confidentiality agreements may be ‘mutual’ (i.e. where both parties are restricted in their disclosure and use of the confidential information provided) or ‘one way’ (i.e. where only one party is disclosing confidential information and imposing restriction on the use and disclosure by the recipient party).

A confidentiality agreement should not, however, be viewed as providing absolute protection to the supplier of the confidential information as any unauthorised disclosure by the recipient may seriously impact on the patentability of an invention. In addition, there is always a risk that some recipients of confidential information may attempt to work around the information provided in order to develop a related rival invention. Therefore, if possible, rather than relying solely on a confidentiality agreement, practical steps to limit the information provided should be taken. In addition, it may be appropriate to file a provisional patent application in advance of any discussions with a third party (particularly when the invention to be disclosed is considered to be of material importance).

Equally, a recipient of confidential information should assess its contents to ensure that it is not similar to other information already in the recipient’s possession. Such an initial assessment will help to avoid any later need to prove inventorship or ownership.
Checklist for confidentiality agreements

The following checklist includes some of the primary issues that should be addressed in confidentiality agreements. As with any agreement, each confidentiality agreement will need to be customised to the specific requirements of each situation.

<table>
<thead>
<tr>
<th>Checklist of issues in Confidentiality Agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Specify the disclosing and receiving parties of the agreement and deal with associated entities if appropriate.</td>
</tr>
<tr>
<td>☑ Indicate the intentions and expectations of the parties to ensure that the context of the agreement is understood.</td>
</tr>
<tr>
<td>☑ Define the information which is the subject of the confidentiality agreement, this may include information disclosed to or created by a party. Such information should be clearly described.</td>
</tr>
<tr>
<td>☑ Specify what information is excluded from the confidentiality obligations, such as information entering the public domain through no fault of the recipient.</td>
</tr>
<tr>
<td>☑ Define the obligations imposed on the recipient regarding non-disclosure and use, including the permitted use to which the information may be put (e.g. for technical assessment of the IP only).</td>
</tr>
<tr>
<td>☑ Include appropriate indemnification, disclaimers or exclusions in relation to claims resulting from the use of the information.</td>
</tr>
<tr>
<td>☑ Address related IP issues, such as ownership rights in the confidential information and any subsequent IP generated through use of confidential information.</td>
</tr>
<tr>
<td>☑ Consider the term of the agreement (which will usually extend beyond the end date of the discussion).</td>
</tr>
</tbody>
</table>

Material Transfer Agreements

Another type of agreement which frequently arises in R&D scenarios is the Material Transfer Agreements (MTA). MTA define rights and obligations when materials are transferred from one organisation to another. Frequently transferred materials between organisations in the biotechnology industry include biological materials such as cell lines, plasmids, vectors, proteins, antibodies and microbiological agents etc. The materials will usually be used by the recipient organisation for research purposes only. For owners of materials MTA are of critical importance to control use of the transferred materials and set out the rights and obligations in relation to ownership of research results, confidentiality, publication and liability of the parties.

Checklist for Material Transfer Agreements

MTA will need to deal with various issues regarding ownership of IP subsisting in the materials and outcomes of the research, which may include the issues listed in the following table. However, as with all agreements, MTA should be tailored to the specific requirements of the situation. For example, MTA governing the transfer of confidential materials available only from a unique source will obviously be different to MTA governing the transfer of publicly available materials.

<table>
<thead>
<tr>
<th>Checklist of issues in Material Transfer Agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Ensure that all confidential information exchanged between the parties (both prior to and during the performance of the research) is kept confidential under confidentiality obligations.</td>
</tr>
</tbody>
</table>
Checklist of issues in Material Transfer Agreements

☑ Specify the materials to be transferred and ownership rights of the materials.

☑ Specify how the materials may be used (e.g. for internal research purpose only).

☑ Specify whether the materials may be modified and the ownership rights in any modified materials or derivatives of the materials.

☑ Set up a register of all background and third party IP which is used in the research involving the materials.

☑ Set out the rights of access to all background and third party IP during and after the research project.

☑ Specify ownership of any IP resulting from the research using the materials. Where appropriate, set out the parties’ rights of access to the IP generated in the course of the research, including any appropriate conditions (e.g. a first right to negotiate for a licence). IP ownership by the provider of the materials may impact on future research building on the IP generated using the materials.

☑ State which party is responsible for the protection and enforcement of the IP generated in the course of the research, including associated costs.

☑ Include appropriate indemnification, disclaimers or exclusions in relation to claims resulting from the use of the materials.

☑ Restrict the publication of results or provide for a review of each researcher’s manuscripts, abstracts, proposed publications and presentations so that any patentable IP may be protected prior to publication.

Research collaboration agreements

The three most common types of agreements governing research collaborations between industry and universities or other external R&D sources are:

» collaborative research agreements

» sponsored research agreements, and

» consortium agreements.

In some cases, a collaborative effort between different parties is structured as a licensing arrangement or a joint venture.

For more information on licence agreements and joint ventures, see Chapter 9 ‘What Must Be Known About IP Commercialisation’.

Collaborative research agreements

Collaborative research agreements usually provide for the participation of two parties in a project in order to achieve specific common goals and develop defined deliverables. Both parties will contribute to the project by way of knowledge, experience, financial and in-kind resources and technologies.

The collaborative research agreement will set out each party’s rights and responsibilities in relation to the project. Importantly, the agreement will also deal with the ownership, management and rights to use any new IP created in the course of the project.
Sponsored research agreements

Sponsored research is research which is financially funded and directed by an organisation in order to achieve a specific objective of the organisation. It is probably the most frequent form of industry-research institution collaboration. The research is generally aimed at solving a particular problem or fulfilling a particular need identified by the organisation.

Research sponsorships are usually formalised in a written agreement specifying the organisation’s requirements. Sponsored research agreements will commonly have a detailed project plan setting out the goals and expected deliverables for each project attached.

Consortium agreements

Consortium agreements are commonly used where a number of organisations participate in and contribute their resources towards a set of shared research goals.

A written agreement for this type of collaborative project can be fairly complex as it will need to take into account all the requirements and objectives of each party. The agreement will also need to deal with the ownership and management of any newly generated IP and the parties’ rights to access and exploit it. Typically, all consortium members will have a non-exclusive licence for internal use and commercial exploitation of all IP generated in the course of the project.

Checklist for research collaborations

An agreement governing collaborative research between two or more parties will need to deal with various issues regarding the project and its outcomes, which may include the following:

<table>
<thead>
<tr>
<th>Checklist of Issues in Collaborative Research Agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Ensure that all confidential information exchanged between the parties (both prior to and during the project) is kept confidential under confidentiality obligations.</td>
</tr>
<tr>
<td>✓ Specify the resources (both financial and in-kind) which each party is required to contribute to the project.</td>
</tr>
<tr>
<td>✓ Specify who will be responsible for the overall management of the project. The parties may wish to establish a project committee for this purpose.</td>
</tr>
<tr>
<td>✓ Set out the objectives of the project including measurable criteria for determining if and when those objectives are met.</td>
</tr>
<tr>
<td>✓ Provide for a regular review of the performance of the project, including the opportunity for a party to opt out of the project if agreed milestones are not met.</td>
</tr>
<tr>
<td>✓ Set up a register of all background and third party IP which is used in the course of the project.</td>
</tr>
<tr>
<td>✓ Set out the rights of access to all background and third party IP.</td>
</tr>
<tr>
<td>✓ Specify ownership of any project IP.</td>
</tr>
<tr>
<td>✓ State which party is responsible for the protection and enforcement of project IP including associated costs.</td>
</tr>
<tr>
<td>✓ Provide for a review of each researcher’s manuscripts, abstracts, proposed publications and presentations so that any patentable project IP may be protected prior to publication.</td>
</tr>
</tbody>
</table>
### Checklist of Issues in Collaborative Research Agreements

| ✓ | Set out the parties’ rights of access to project IP, including any appropriate conditions such as the sharing of revenue arising out of the commercialisation of project IP. |
| ✓ | Include appropriate indemnification, disclaimers or exclusions in relation to claims resulting from the conduct of the project. |

It is strongly recommended you seek legal advice when entering into any type of research collaboration.

### Government grants

The Federal government and state governments offer different types of grants to organisations to encourage the development of IP, subject to certain eligibility criteria.

A grant recipient is usually required to enter into an agreement documenting the grant of funds. The agreement will define the roles and responsibilities of the funding body and the grant recipient.

The objectives of the grant programme will play an important part in determining the conditions imposed by the funding bodies. Typically, the grant recipient will be required to provide some form of deliverables, including proper accounts of expenditure and reports of activities. There may also be a requirement that the research programme be conducted for the benefit of the Australian public. IP issues will also be addressed in the grant agreement.

For more information on the different government grant schemes offered by AusIndustry, the CRC and other programmes, see Chapter 3 ‘What the Board and CEO Must Know’.
What Must be Known about IP Commercialisation

What this Chapter covers

Issues to consider before undertaking IP commercialisation

Is the IP ready for commercialisation?

Business Considerations

IP Due Diligence

IP Commercialisation Structures

Direct Exploitation

Licence

Assignment

Spin-off companies

Joint ventures

Choosing a Commercialisation Partner

Issues to consider

Risks of IP Commercialisation

Identifying risks

Types of risks

How to manage risks
What this Chapter covers

IP commercialisation is the exploitation of IP in the marketplace for the purpose of generating income. Successful commercialisation of IP is usually an important goal of an organisation in the biotechnology sector for undertaking research and development. IP commercialisation is a complicated process and requires consideration of a wide range of factors.

This Chapter provides guidance when undertaking the IP commercialisation process, including:

» the issues to be considered prior to conducting commercialisation activities
» the fundamental characteristics of common commercialisation structures and approaches that may be adopted, and
» the risks involved in commercialisation and how to manage those risks.

One form of commercialisation of IP is the direct commercialisation of the IP by the organisation owning the IP. Although the issues to consider outlined in this Chapter are relevant to this form of commercialisation, many other elements of running a successful business and expertise for getting the necessary approvals of products by relevant authorities (which are beyond the scope of this Manual) will also obviously be highly relevant. However, direct exploitation of IP rights by their owner may not always be possible. The parts of this Chapter following the section ‘Issues to consider before undertaking IP commercialisation’ focus primarily on forms of commercialisation external to the organisation.

Issues to consider before undertaking IP commercialisation

Is the IP ready for commercialisation?

Successful commercialisation of IP is often one of the primary goals of an organisation’s IP strategy. Ideally, technological and commercial merits of an organisation’s IP are assessed at an early stage during the development of IP. However, not all IP created will be ready for commercialisation immediately and some IP may be created for use internally on an operational basis, which may not be suitable for commercialisation. There are a range of issues that need to be considered before commercialising an IP asset. You may consider referring to your organisation’s IP strategy for direction on dealing with the IP asset generated. For more information on IP strategies, see Chapter 3 ‘What the Board and CEO Must Know’.

Outlined below are some questions that may assist you to assess whether certain IP is ready or suitable for commercialisation. You are likely to make better informed decisions on whether and when to commercialise a particular IP asset once you have considered these questions. Further, these IP specific issues may be relevant when preparing your business plan for the commercialisation of IP.
Ownership of IP

Does the organisation own the IP and, if so, are there any joint owners?

Does the organisation have the necessary rights to commercialise the IP?

Are there any contracts relating to the IP restricting the organisation’s rights to commercialise?

Nature of IP

Are the IP rights valid?

What is the strength of the IP?

What is the remaining IP life?

Has the IP got broad claim coverage?

Is the IP formally protected?

Will the IP asset require further development?

What is the estimated commercial life of the IP (as opposed to its legal life)?

Stage of Development

Is the IP at a stage in its development where it is ready or suitable for commercialisation?

Will commercialising particular IP require more effort, be less certain of success, and generate smaller returns because the IP is at an early stage of development?

Response to Potential Infringement Actions

How willing and ready is the organisation to defend or prosecute IP infringement actions?

Who are your competitors and are they respectful of IP rights?

Who will be the likely infringers?

Business Considerations

When preparing a business plan for the commercialisation of IP, there will be other general business issues that you may need to consider. Detailed discussion of preparing a business plan is outside the scope of this Manual, although examples of some general business issues are outlined below.
Potential Market

Who are the prospective licensees, buyers and other customers?

What is the size of the potential market?

What is the likelihood of the IP successfully entering and staying in the market?

Are there any competing/substitute products?

What are the estimated financial returns?

Will commercialisation contribute to the organisation’s competitive edge?

Resources Required

Does the organisation have the appropriate skills as well as sufficient human and other resources to commercialise the IP?

What is the financial budget for commercialising the IP?

What is the method of commercialisation? (See the following section ‘Commercialisation Structures’ for more information.)

IP Due Diligence

Unless an organisation chooses to exploit the IP directly, IP commercialisation involving another party will commonly involve a due diligence exercise in which a potential licensee or assignee may identify and gather information on the subject of the proposed transaction. A due diligence exercise relating to IP assets may only be part of a broader due diligence in a multi-faceted transaction (which is beyond the scope of this Manual).

Common issues that may be raised by a potential licensee or assignee in an IP due diligence will be similar to those listed in the section entitled ‘IP due diligence in capital raising’ in Chapter 3 ‘What the Board and CEO Must Know’ and your organisation should be familiar with those issues when preparing for an IP due diligence on your IP in a commercialisation context.

IP Commercialisation Structures

Choosing and establishing the most appropriate commercial structure is critical to the success of IP commercialisation.

The commercialisation structure to be adopted will depend on:

» the organisation’s goals and expectations
» the nature of the IP and any issues identified, and
» the availability of funds and resources to commercialise the IP.

There are number of different ways to bring newly developed IP to the market place. The five most common structures for the commercialisation of IP are illustrated in the diagram below.
Chapter 7: What must be known about IP Commercialisation

A brief description of each type of commercial structure is outlined below.

It is strongly recommended that you seek professional legal advice and assistance when deciding on and establishing the desired IP commercialisation structure.

**Direct Exploitation**

An organisation may choose to commercialise its IP assets by developing and supplying goods or services based on the IP on its own, rather than by leveraging the IP by provision to some external party as is outlined in the following sections of this Chapter. For the biotechnology sector, commercialisation of IP may require additional research and development, product development, clinical trials and development of techniques to scale-up production prior to taking the results of the research to the market. It is often the case that an organisation does not have the resources to commercialise the IP itself. Whether IP should be commercialised internally, as against some form of external commercialisation, should always be something which is considered as part of the business planning process.

Although internal commercialisation obviously involves numerous other elements of operating a successful business and relevant expertise in complying with regulatory requirements, the development and supply of biomedical products still relies on careful and appropriate management of the underlying IP. As has been outlined in other parts of this Manual, identifying, protecting and managing IP embodied in the organisation’s products provides, among other things, a basis for the investment in new products, a defence against others’ business strategies and a competitive advantage in the market place. Refer to the other Chapters of this Manual for guidance on managing IP within the organisation which have application to IP to be commercialised internally.

**Licence**

An IP licence grants another entity the right to access and use the IP for a certain time period where such access or use would otherwise infringe the rights of the IP owner. A licence is one of the most common forms of IP commercialisation as it is a very flexible option allowing the expectations of both parties to be accommodated. Importantly, a licence does not permanently transfer ownership of IP or the rights attached to it.

A licence may be exclusive or non-exclusive, and may be restricted to a particular territory or a field. A licence may also be granted for a specific activity or a set of activities, such as researching, developing, modifying, manufacturing or selling products or services incorporating the IP.

A licensor (the party allowing the use) may require the licensee (the party taking the licence)
to comply with certain performance obligations in a licence agreement. Failure to meet those performance obligations may result in the licence being terminated.

The diagram below illustrates some different forms of licensing that may be utilised by your organisation. These include:

- direct licensing of IP to an end-user
- granting rights to a distributor (who may already have an established position in a market) to distribute the products to end users, and
- licensing of IP to a commercialising party who will further develop and commercialise the IP.

Using a distributor

Where you have a product ready to be distributed in the market, you may want to appoint a distributor to promote, distribute and sell products to end users on your behalf. Distribution arrangements usually involve the distributor purchasing finished products from the licensor and on-selling these to end users at a margin. This differs from an agency arrangement, where an agent promotes products and solicits orders but end users acquire these products directly from the licensor. Distributors may also be responsible for after-sales support and handling product warranty claims (e.g. for medical devices) on behalf of the licensor.

If a distributor is to be granted exclusive rights in a particular territory or for sales in a certain manner (e.g. via the internet), you will need to consider whether this may contravene the Trade Practices Act 1974 (Cth). This Act also prohibits licensors from prescribing minimum prices at which distributors must re-sell products.

Distributors are generally granted a limited licence of IP rights in order for them to fulfil their obligations under the distribution agreement. A common form of IP right in this context is rights in a brand, such as a registered trade mark.

Distribution agreements typically include the following features:

<table>
<thead>
<tr>
<th>Common features of distribution agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restrictions on the territory and the manner in which, or customers to which, products can be promoted and sold, usually in return for exclusive rights in defined areas.</td>
</tr>
<tr>
<td>Conduct of promotional activities by the distributor, including minimum obligations, conditions on which the licensor’s trade marks may be used and provision of training or other assistance by the licensor.</td>
</tr>
<tr>
<td>Acquisition of products from the licensor or its approved manufacturers, with a mechanism for future price increases.</td>
</tr>
</tbody>
</table>
Chapter 7: What must be known about IP Commercialisation

Common features of distribution agreements

- Provisions regarding the purchase of products, including forecasts, orders, freight, insurance, risk, title and payment terms.
- Responsibility for customer service, warranty claims and the conduct of recalls.
- Minimum performance requirements in order to maintain distribution rights.
- Licences of any associated trade marks and provisions regarding their manner of use.
- Non-compete obligations during the term of the distribution arrangement and for a limited period afterwards.
- Termination and its consequences e.g. an obligation on the licensor to repurchase the distributor’s unsold stock or the ability for it to do so.

Licensing commercialisation rights to third parties

When negotiating a licence, it is essential that you understand and are aware of the nature and extent of the rights you are negotiating. For more information on the different forms of licence, see Chapter 6 ‘What Senior Management Must Know’.

A licence agreement typically includes terms dealing with the following issues:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parties</td>
<td>Include details of each party, including name, ABN/ACN, and address of registered office or principal place of business, as well as details of the appropriate contact person for each party.</td>
</tr>
<tr>
<td>Licensed Rights</td>
<td>Describe the subject matter of the licence, e.g. the IP asset, including any patent and trade mark registration particulars and detailed descriptions of any unregistered IP.</td>
</tr>
</tbody>
</table>
| Type of Licence  | State whether the licence is exclusive, sole or non exclusive:  
|                  | » **Exclusive licence**: The licensee is the only person who has the right to deal with the licensed IP, even to the exclusion of the licensor.  
|                  | » **Sole licence**: The licensee is the only person who has the right to deal with the licensed IP in addition to the licensor.  
<p>|                  | » <strong>Non-exclusive licence</strong>: The licensor may also grant licences to third parties. |
| Licensed Territory | State the country or region in which the licensee may use the licensed IP. |
| Field            | Nominate the field in which the licensee may use the licensed IP. This can be limited by technology field, market segment or distribution channel. |
| Term             | Consider the period for which the licensee may use the licensed IP. This may be the life of the IP asset or any other specified period of time, provided this is no longer than the life of the IP asset in the case of registered rights. |
| Sublicence       | Consider whether the licensee will have rights to grant sublicences to other people and on what terms. |
| Improvements     | Consider whether improvements to the licensed IP are to be included in the licensed IP and which party will own them. |</p>
<table>
<thead>
<tr>
<th>Issue</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royalties and Licence Fees</td>
<td>Describe the calculation and payment of financial consideration for the use of the licensed IP.</td>
</tr>
<tr>
<td>Termination</td>
<td>Consider when your organisation and the licensee may terminate the licence. Describe any post-termination obligations. These will usually include the licensee ceasing the exploitation of the licensed IP and returning any materials and confidential information provided by the licensor.</td>
</tr>
<tr>
<td>Obligations of Licensor</td>
<td>These may include:</td>
</tr>
<tr>
<td></td>
<td>» provision of technical assistance or know-how, and</td>
</tr>
<tr>
<td></td>
<td>» responsibility for prosecution and maintenance of formal intellectual property rights for the licensed IP (this will generally be the case if the licence is non-exclusive).</td>
</tr>
<tr>
<td>Obligations of Licensee</td>
<td>These may include:</td>
</tr>
<tr>
<td></td>
<td>» payment of royalties and licence fees</td>
</tr>
<tr>
<td></td>
<td>» conducting further research and development on licensed IP</td>
</tr>
<tr>
<td></td>
<td>» obtaining regulatory approvals</td>
</tr>
<tr>
<td></td>
<td>» manufacture of products using the licensed IP to certain quality standards</td>
</tr>
<tr>
<td></td>
<td>» efforts to promote and sell products made according to the licensed IP</td>
</tr>
<tr>
<td></td>
<td>» accounting and reporting, and</td>
</tr>
<tr>
<td></td>
<td>» preservation of confidentiality of licensed know-how</td>
</tr>
<tr>
<td>Product Liability</td>
<td>Consider product liability issues, for example, who will bear responsibility for product liability claims by end users.</td>
</tr>
<tr>
<td></td>
<td>Note that the licensee will usually be required to maintain a product liability insurance policy to a specified value</td>
</tr>
<tr>
<td>Governing Law and Jurisdiction</td>
<td>State the governing law of the agreement and jurisdiction. This is usually where the principal office of the licensor or licensee is located.</td>
</tr>
</tbody>
</table>

You should be aware that certain contractual provisions may be unenforceable if they contravene the Trade Practices Act 1974 (Cth) or the Patents Act 1990 (Cth).

Development of a licence agreement requires a clear understanding of the relevant issues involved. It will usually be appropriate to enlist specialist expertise when preparing a licence to address the needs of your organisation.

**Assignment**

An IP assignment is the permanent transfer of the ownership of the IP asset to another entity. IP is usually assigned in return for financial consideration in the form of a lump sum payment. However, it is possible to assign an IP asset in return for royalties, or a combination of a lump sum payment and royalties.
Chapter 7: What must be known about IP Commercialisation

Financial consideration for the assignment may cover:

- All direct costs of research and development incurred by the organisation up to the date of the assignment, including all out of pocket expenses such as costs of materials and equipment
- All indirect costs of research and development such as salaries and rental of laboratory space
- Any outsourcing costs
- The costs of protecting and maintaining the IP
- Any other costs that contributed to the costs of developing the IP to its current state
- A profit component

You should be aware that a lump sum payment may be treated differently to royalty payments for tax purposes. You should therefore obtain advice from a tax specialist before deciding on how to structure the financial aspects of an assignment.

It is important to understand that once an IP asset is assigned, the original owner of the IP asset no longer has the right to use the IP asset (unless the assignment includes a licence-back clause). Ownership of the IP asset will not usually automatically revert back to the original owner at any time in the future.

Under most IP legislation in Australia, assignments of IP must be in writing. Written assignments of registered IP rights generally need to be recorded with the relevant authority.

Assignments vs. licences

The table below summarises some of the characteristics and potential advantages and disadvantages of assignments and licences of IP.

<table>
<thead>
<tr>
<th>Assignments</th>
<th>Licences</th>
</tr>
</thead>
<tbody>
<tr>
<td>All responsibility and risks are transferred to the assignee. However, the assignor will no longer have any control over the development and commercialisation of the IP asset</td>
<td>Licensor usually retains a certain degree of control regarding the development and commercialisation of the IP asset. However, the licensor may be exposed to certain risks in relation to these activities (depending on the terms of the licence)</td>
</tr>
<tr>
<td>The assignor only has to deal with a one-off transaction. However, IP rights may be lost if the assignee decides to abandon the project.</td>
<td>Licensor will need to monitor the commercialisation activities of the licensee. However, there is greater control over the IP asset.</td>
</tr>
<tr>
<td>The assignor is likely to receive a larger upfront payment. However, it may be difficult to value the IP asset to establish an appropriate sale price (especially where the IP is in an early stage of development). There will be no opportunity to share additional profits if the IP generates more revenue than expected, unless revenue-based royalties are payable.</td>
<td>Usually, the upfront payment amount is less. However, subsequent financial return may be greater if the IP turns out to be valuable. There is a risk of only minimum return if commercialisation is not successful.</td>
</tr>
</tbody>
</table>
Spin-off companies

A spin-off company is a separate company established by an organisation for the purposes of undertaking a particular activity, such as the commercialisation of a specific IP asset. A spin-off company usually starts out as a wholly-owned subsidiary of the organisation, although this is likely to change over time if external investment is sought. Once the spin-off company has been established, the organisation will licence or assign the relevant IP asset to the spin-off company to enable it to commercialise the IP.

Undertaking commercialisation activities via a spin-off company will transfer the responsibilities and risks associated with the commercialisation out of the organisation and into the spin-off company. The organisation may also attract new sources of funding for further development of the IP asset by offering to issue shares to potential investors in the spin-off company.

A spin-off company is a separate legal entity distinct from the organisation, and as such it will have to comply separately with the various requirements of the Corporations Act 2001 (Cth).

Using spin-off companies

Establishing a spin-off company is probably the most complex and expensive form of IP commercialisation. However, the transfer of the responsibility and risks out of the organisation, the focus achieved by formation of a separate business with dedicated management, the potential to raise funds, as well as a potentially larger long term return may justify the effort and time, in particular where the IP requires extensive additional development.

Before establishing a spin-off company, you should at a minimum consider the following:

<table>
<thead>
<tr>
<th>Issues to be considered before establishment of a spin-off company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the IP ‘essential’ to the primary organisation?</td>
</tr>
<tr>
<td>Is the spin-off company approach consistent with the organisation’s objectives and goals?</td>
</tr>
<tr>
<td>What are the objectives of the spin-off company?</td>
</tr>
<tr>
<td>What are the measures of success for the spin-off company?</td>
</tr>
<tr>
<td>What are the expected financial returns?</td>
</tr>
<tr>
<td>What are the tax implications for the organisation and the spin-off company?</td>
</tr>
<tr>
<td>Is there a business plan for the planned activities of the spin-off company?</td>
</tr>
<tr>
<td>Will there be competition or a potential conflict of interest between the organisation and the spin-off company?</td>
</tr>
<tr>
<td>How much control will the organisation have over the management and decision making of the spin-off company?</td>
</tr>
<tr>
<td>Has the organisation consulted the views of other stakeholders?</td>
</tr>
<tr>
<td>What are the exit options for the future?</td>
</tr>
</tbody>
</table>

Joint ventures

A joint venture is a collaboration of two or more parties to undertake a common project or to pursue a specific objective, such as commercialising IP. All parties to the joint venture will contribute their efforts, personnel, financial resources and/or existing IP towards the joint venture project.
A joint venture can be set up simply by the parties entering into a contractual arrangement setting out their rights and obligations in relation to the project (“unincorporated joint venture”). Alternatively, the parties may decide to set up a separate, jointly-owned company to carry out the planned activities (“incorporated joint venture”).

It is important that for any joint venture, the rights, responsibilities and contributions of the parties as well as the ownership of IP created in the course of the joint venture activities are clearly defined and documented. Usually, in the case of an unincorporated joint venture, the new IP will be owned jointly by all parties, with rights to the benefits of such IP shared in accordance with their contributions to the project. In the case of an incorporated joint venture, the new IP will usually be owned by the joint venture company.

**Checklist for joint venture agreements**

The nature, size and complexity of the project will determine the level of detail contained in the joint venture agreement, but the following issues should generally be considered. As joint venture arrangements can be very complex, it is recommended that you seek the advice of your legal adviser in relation to the preparation of a joint venture agreement.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parties</strong></td>
<td>- Who are the parties to the joint venture?</td>
</tr>
<tr>
<td></td>
<td>- Can new parties join the project in the future? If so, how?</td>
</tr>
<tr>
<td></td>
<td>- How can existing parties to the joint venture leave the project?</td>
</tr>
<tr>
<td></td>
<td>- What happens to the joint venture if a party becomes insolvent?</td>
</tr>
<tr>
<td><strong>Nature of Joint Venture</strong></td>
<td>- Under which name will the joint venture do business?</td>
</tr>
<tr>
<td></td>
<td>- What is the objective of the joint venture?</td>
</tr>
<tr>
<td></td>
<td>- Does the agreement clearly specify that the relationship of the parties is a joint venture, not a partnership?</td>
</tr>
<tr>
<td><strong>Financials</strong></td>
<td>- Specify each party’s financial contribution. Consider setting up a fund to finance the joint venture activities.</td>
</tr>
<tr>
<td></td>
<td>- Will financial contributions be dependent on certain milestones being achieved?</td>
</tr>
<tr>
<td></td>
<td>- Is there an obligation on all parties to provide additional funding for the project?</td>
</tr>
<tr>
<td></td>
<td>- How are profits and losses shared among the parties?</td>
</tr>
<tr>
<td></td>
<td>- What is the financial reporting procedure?</td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td>- What are the management responsibilities of each party? Consider establishing a management committee and nominating a project director.</td>
</tr>
<tr>
<td></td>
<td>- When, where and how often should meetings be held?</td>
</tr>
<tr>
<td></td>
<td>- What is the mechanism to resolve disputes and deadlocks?</td>
</tr>
<tr>
<td><strong>Activities</strong></td>
<td>- Have the joint venture activities been clearly defined in a project plan?</td>
</tr>
<tr>
<td></td>
<td>- Who decides on changes to the project plan?</td>
</tr>
<tr>
<td></td>
<td>- Is any special equipment required? Who is providing it and who will own it?</td>
</tr>
<tr>
<td></td>
<td>- Will licences of any third party rights be taken in the name of the joint venture or each party?</td>
</tr>
<tr>
<td></td>
<td>- What kind of insurance will the joint venture need to obtain?</td>
</tr>
<tr>
<td>Issue</td>
<td>Explanation</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>IP</strong></td>
<td>» What background IP is made available by the parties?</td>
</tr>
<tr>
<td></td>
<td>» Who will own any new IP created in the course of the project?</td>
</tr>
<tr>
<td></td>
<td>» Who is responsible for obtaining formal protection for new IP?</td>
</tr>
<tr>
<td></td>
<td>» Do all parties have the right to use new IP? If so, for what purposes?</td>
</tr>
<tr>
<td></td>
<td>» If the parties have the right to use new IP, do they also have the right to use each other’s background IP for that purpose?</td>
</tr>
<tr>
<td><strong>Term and Termination</strong></td>
<td>» For how long will the joint venture operate?</td>
</tr>
<tr>
<td></td>
<td>» What are the provisions dealing with termination of the agreement?</td>
</tr>
<tr>
<td></td>
<td>» How will guarantees, defects and insurance be handled after termination?</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td>» Are there any obligations on the parties to sign all necessary documents relating to the joint venture, such as bank loans, bonds, indemnity agreements, etc?</td>
</tr>
<tr>
<td></td>
<td>» Will a chartered accountant and a lawyer be appointed?</td>
</tr>
</tbody>
</table>

### Choosing a Commercialisation Partner

Choosing the right partner for the commercialisation of an IP asset is just as critical as choosing the right commercialisation structure. In order for the commercialisation to be successful, it is essential that the commercialisation partner shares the same goals as your organisation.

### Issues to consider

Issues which an organisation should consider when deciding to partner with a particular entity include:

<table>
<thead>
<tr>
<th>Issues</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The resources (both financial and other) the entity is prepared to commit to the commercialisation project</td>
<td></td>
</tr>
<tr>
<td>The level of expertise the entity has in the relevant technology</td>
<td></td>
</tr>
<tr>
<td>The level of expertise the entity has generally in commercialising IP</td>
<td></td>
</tr>
<tr>
<td>The entity’s reputation and influence in the marketplace</td>
<td></td>
</tr>
<tr>
<td>The entity’s access to relevant networks</td>
<td></td>
</tr>
<tr>
<td>The equity position sought by the entity if the commercialisation is to be via a spin-off company or incorporated joint venture</td>
<td></td>
</tr>
</tbody>
</table>

Before entering into an agreement with a potential commercialisation partner, it is essential that the organisation carry out comprehensive due diligence on the relevant entity to investigate (and confirm) that the entity:

» has the necessary resources and expertise to undertake commercialisation activities, and

» is capable of meeting relevant performance requirements.
A comprehensive due diligence process should include a detailed assessment of the entity’s financial stability, legal risks, technical experience and infrastructure, as well as any existing contractual relationships with third parties.

An organisation should seek the advice and assistance of a legal professional when conducting due diligence on any prospective commercialisation partner.

Risks of IP Commercialisation

Identifying risks

Commercialising IP will invariably involve risks. The nature of the risks will differ depending on the organisation, the nature of the IP, the chosen commercialisation pathway, and what the organisation wants to achieve. Such risks need to be identified, assessed and appropriately managed so that the organisation is only exposed to an acceptable level of risks throughout the commercialisation process.

To identify potential risks, an organisation will need to conduct appropriate internal due diligence, which is essentially an exercise to gather information concerning the risks and liabilities associated with the commercialisation of a particular IP asset and assessment of the identified risks and liabilities.

Types of risks

The IP specific risks involved in the commercialisation of IP include:

<table>
<thead>
<tr>
<th>Nature of IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the organisation own the IP?</td>
</tr>
<tr>
<td>Does the organisation have the rights to commercialise the IP?</td>
</tr>
<tr>
<td>What is the strength of the IP protection?</td>
</tr>
<tr>
<td>Is the organisation managing IP properly?</td>
</tr>
<tr>
<td>Is the use of the IP likely to infringe any third party rights?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confidentiality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can the confidentiality of the IP be maintained?</td>
</tr>
</tbody>
</table>

For more information on the protection of confidential information, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’.

Other general commercial risks in the commercialisation of IP include:

<table>
<thead>
<tr>
<th>Nature of the Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the product likely to deliver what it promises?</td>
</tr>
<tr>
<td>What is the potential liability for using the product?</td>
</tr>
<tr>
<td>If access to upgrades (e.g. for a bioinformatics tool) or product warranty (e.g. for a medical device) is to be provided, can the organisation deliver on this promise?</td>
</tr>
</tbody>
</table>
### Business and Financial

What are the financial risks of the commercialisation project?

What are the chances of failing to recover the costs associated with commercialisation?

Will the organisation be appropriately rewarded by the commercialisation process? Are the market returns or the licence fees and royalty rates appropriate?

### Legal

Do the planned commercialisation activities comply with all applicable laws, regulations, policies and contractual obligations or restrictions?

Do the marketing strategies comply with the Trade Practices Act, state Fair Trading Acts and/or other consumer protection laws?

Have all necessary approvals been obtained for the manufacture, distribution and sale of products?

### Resources

Can the project be adequately resourced?

### Reputation

Is there a risk that the reputation of the organisation will be tainted?

## How to manage risks

Once identified, the organisation may assess the risks using the method below:

### Step 1: What is the likelihood of the risk event happening?

The organisation will need to collect information to ascertain whether the risk event is likely to occur. In most cases, the organisation will already have some form of information to assess the likelihood of the risk happening. For example, information concerning whether a particular IP asset is the subject of an ownership dispute, or whether the product is likely to deliver what it promises. In the example risk assessment table below, the likelihood of each risk event is ranked on a numerical scale from 1 (very unlikely) to 5 (very likely).

### Step 2: What will be the consequences?

The organisation will need to consider the likely severity of the impact of each risk event on the organisation. In the simple example below of two identified risk events for the Project XYZ, the severity of the consequences is ranked on a scale from minor to moderate to significant.
## PROJECT XYZ

<table>
<thead>
<tr>
<th>Risk Event</th>
<th>Likelihood of risk event happening</th>
<th>Severity of consequences</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infringement of third party rights</td>
<td>1 2 3 4 5</td>
<td>Minor Moderate Significant</td>
<td>Take out insurance to cover the risk and consequences of litigation.</td>
</tr>
<tr>
<td>Ownership dispute (creator of the IP is a disgruntled employee who was let go by the organisation)</td>
<td>1 2 3 4</td>
<td>Minor Moderate Significant</td>
<td>Check employment agreement and seek advice from legal adviser regarding IP ownership.</td>
</tr>
</tbody>
</table>

Based on the results of Step 1 and Step 2, the organisation will be able to assess the risks involved in commercialising a particular IP asset and make an informed decision on which form of risk management mechanism to implement. The section below outlines a range of risk management mechanisms that could be used by your organisation.

### Risk management mechanisms

Once the various risks have been assessed, the organisation needs to decide on the most appropriate risk management mechanism to adopt. There are a number of ways to manage the potential risks that may arise in commercialising IP, and the most appropriate risk management mechanisms will depend on the nature of the IP and type of risk.

The risk management mechanisms that an organisation may implement to minimise risks include the following:

<table>
<thead>
<tr>
<th>Type of risk</th>
<th>Checklist of Risk Management Mechanisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of IP</td>
<td>Keep proper IP records</td>
</tr>
<tr>
<td></td>
<td>Conduct appropriate IP due diligence</td>
</tr>
<tr>
<td></td>
<td>Ensure that the organisation owns the IP or has the necessary rights to commercialise the IP</td>
</tr>
<tr>
<td></td>
<td>Carry out validity and infringement searches</td>
</tr>
<tr>
<td></td>
<td>Take out IP insurance (For more information, see the section ‘IP Insurance’ below.)</td>
</tr>
<tr>
<td>Nature of Product</td>
<td>Avoid or minimise liability for ongoing maintenance, support or upgrade of the IP</td>
</tr>
<tr>
<td></td>
<td>Take out or require the relevant commercialisation partner to take out product liability insurance and other suitable insurance, (for more information, see the section ‘IP Insurance’ below)</td>
</tr>
<tr>
<td>Type of risk</td>
<td>Checklist of Risk Management Mechanisms</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Business and Financial</td>
<td>Limit the risk by capping liability in agreements</td>
</tr>
<tr>
<td></td>
<td>Include appropriate termination rights, including post-termination requirements</td>
</tr>
<tr>
<td></td>
<td>Monitor commercialisation activities according to business plans and agreements</td>
</tr>
<tr>
<td>Legal</td>
<td>Obtain expert advice where necessary</td>
</tr>
<tr>
<td></td>
<td>Ensure agreements are reviewed by legal advisor</td>
</tr>
<tr>
<td>Resources</td>
<td>Ensure there are adequate resources and systems for the ongoing management of the commercialisation activities</td>
</tr>
<tr>
<td></td>
<td>Allocate sufficient resources to manage the business relationship with any commercialisation partner</td>
</tr>
<tr>
<td>Reputation</td>
<td>Retain control over further product development to protect the organisation’s reputation</td>
</tr>
</tbody>
</table>

**IP insurance**

The three most common types of insurance an organisation may take out to help transfer the risks involved in IP commercialisation are as follows:

<table>
<thead>
<tr>
<th>Offensive insurance</th>
<th>Defensive insurance</th>
<th>Product liability insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>This type of insurance provides funding where an organisation enforces its IP by taking action against a third party infringer.</td>
<td>This type of insurance covers the costs of proceedings brought against an organisation for infringement of IP owned by a third party.</td>
<td>This provides cover for an organisation’s liability where a person has suffered damage as a result of a product manufactured, repaired, altered or imported by the organisation.</td>
</tr>
</tbody>
</table>

For more information on offensive and defensive IP insurance, see Chapter 8: ‘What Must be Known about Enforcing and Defending your IP Rights’. 
What Must be Known about Enforcing and Defending your IP Rights

What this Chapter covers

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Nature of IP..........................................................................................................................172
Costs.......................................................................................................................................172

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What this Chapter covers

The ability to enforce and defend your organisation’s IP against unauthorised users is an integral part of an effective IP strategy.

Enforcing IP rights is a major undertaking, and you should always consider the issues outlined in this Chapter and seek advice from legal advisers before making any decision regarding the enforcement of your organisation’s IP rights.

This Chapter provides guidance on:

» issues to consider before enforcing IP rights
» different avenues to enforce your organisation’s IP rights
» defending IP rights in revocation proceedings, and
» obtaining IP insurance.

Issues to Consider Before Enforcing IP Rights

When you believe that others are using or exploiting your organisation’s IP without permission, you should consider taking steps to enforce your organisation’s IP rights; however, there is no obligation to do so. You should always consult with senior managers of your organisation and your legal advisers whenever there is any suspected infringement.

It is up to you to monitor third party activities actively for any infringement of your organisation’s IP rights and to take steps to enforce and/or defend those rights. An action for infringement of IP is a private legal action, and Federal or State authorities do not police registered IP rights for the IP owners. For information on what constitutes IP infringement for different types of IP, see Chapter 2 ‘What Everyone Should Know’.

There are a number of issues which require careful consideration before deciding whether you should take measures to enforce your organisation’s IP rights and what those measures might be. These are summarised in the following diagram.
Value of the IP

Before you take any steps to enforce your organisation’s IP, you should always assess the impact of the alleged infringement on your organisation. Enforcement of IP rights may be required to:

- retain your organisation’s competitive edge conferred by the relevant IP
- protect the value of the relevant IP
- protect your organisation’s reputation against damage that may be caused by an infringer placing infringing products of inferior quality on the market
- deter other potential infringers
- comply with a contractual obligation (e.g. where your organisation is an exclusive licensee and is required to institute enforcement proceedings against any infringers), or
- raise the profile of your organisation by positioning it as a technology innovator.

Nature of IP

The nature of IP that is being infringed is also an important factor to consider when deciding what action to take. You will need to take into account the following:

- the strength of the relevant IP (including in the case of a patent, its validity and claim coverage)
- the remaining life of the IP, and
- the product cycle of the technology protected by the IP

Costs

The financial costs of enforcing IP rights are significant as litigation can be lengthy, complex, and require considerable sums of money - a large proportion of which may not be recovered, even if your action is successful. The lack of financial resources is generally the main obstacle for IP owners when enforcing their IP rights. Set out below is an overview of the type of financial costs involved in bringing IP enforcement proceedings.

<table>
<thead>
<tr>
<th>Costs involved in IP enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs of legal proceedings</td>
</tr>
<tr>
<td>Costs of gathering specialist evidence</td>
</tr>
</tbody>
</table>
Costs involved in IP enforcement

In most IP infringement proceedings, infringers will make a cross-claim challenging the validity of the IP. Proving the validity of your IP involves the identification of creators and the establishment of ownership rights. This can add significant costs to the litigation.

The Australian Law Reform Commission (ALRC) conducted research on litigation costs for IP matters in the Federal Court of Australia in 1999:

<table>
<thead>
<tr>
<th>Party</th>
<th>Professional Fees</th>
<th>Disbursement Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average</td>
<td>Range</td>
</tr>
<tr>
<td><strong>Applicant</strong> (the party who brought the legal action)</td>
<td>$76,900</td>
<td>$8,000 - $400,000</td>
</tr>
<tr>
<td><strong>Respondent</strong> (the party who is responding to the legal action)</td>
<td>$36,100</td>
<td>$2,100 - $280,000</td>
</tr>
</tbody>
</table>

The present day litigation costs are likely to be considerably higher.

Apart from significant financial costs, IP enforcement proceedings will also take up considerable time and resources of your organisation and cause substantial stress to your employees. It is therefore crucial to allocate sufficient resources and budget accordingly when pursuing IP enforcement proceedings. This factor is almost always underestimated and it is not possible to claim compensation from the infringer for such costs, even if your action is successful.

**Risks**

Any decision to pursue IP enforcement proceedings should be preceded by a risk assessment. As with any legal dispute, a number of risks may arise when bringing IP enforcement proceedings. These include:

- potential financial liability
- inability for the organisation to continue to use the relevant IP
- adverse effect on the organisation's reputation, and
- risks that the enforcement action be classified as an unjustified (and therefore unlawful) threat.
<table>
<thead>
<tr>
<th>Risks</th>
<th>Explanation</th>
</tr>
</thead>
</table>
| **Financial Liability** | As with all forms of litigation, success is not guaranteed. The unsuccessful party to legal proceedings is usually ordered by the court to pay the other party’s legal costs, in addition to its own costs.  

**Solicitor-client costs**  
Solicitor-client costs are costs paid to a solicitor for work done on the instructions of a client. You will be liable to pay these costs to your solicitor, even where there is a possibility of recovering those costs from the other party of the legal action.  

It is compulsory for solicitors to provide a costs agreement to you for any legal work carried out on your behalf.  

Other information the solicitor may provide in terms of costs are barrister’s fees, costs of carrying out searches, expert reports and other work that may be incurred depending on the nature of the legal action. You should be informed of any significant increase in the estimated costs.  

**Party-party costs**  
Party-party costs are cost orders generally made by the court ordering a party to pay the costs of the legal proceedings to the other party.  

Party-party costs are intended to reimburse one party, usually the successful party, for the legal costs incurred as a result of the legal proceedings, provided these costs have been determined as fair and reasonable. The amount of party-party costs is usually significantly lower than the amount of solicitor-client costs actually incurred.  

**Continued Use of IP** | In all IP enforcement proceedings, it is common for an infringer to submit cross-claims. This may be on the basis that you do not own the IP or that the IP is invalid. If the cross-claims are successful, not only will your infringement claim fail, but you also risk losing your rights in the IP.  

For more information, see the section entitled ‘Defences and Cross-Claims to IP Infringement Actions’ of this Chapter.  

**Reputation** | An unfavourable outcome of a court action may affect your organisation’s image and reputation in the eyes of consumers and investors.  

In an extreme situation, an unsuccessful action may effectively cause a loss of the market share once held by the organisation for the relevant product and even to a reduction of the market share of other products of the organisation. It may take significant time and effort to regain consumer and investor trust and loyalty.  

**Unjustified Threats** | Where there are no legitimate grounds to commence enforcement proceedings, a threat to bring an action may be found to be unjustified. In this case, the threatened party can commence its own legal proceedings against you, and if successful, your organisation may be liable to pay damages to the other party for loss resulting from the unjustified threat. It is therefore crucial to obtain expert advice regarding the basis of the claim and to ensure the claim is able to be supported by sufficient evidence. |
Enforcing your IP rights

There are a number of ways to enforce your organisation’s IP rights which range from relatively simple measures, such as sending a letter of demand, to complex litigation.

Before taking any action to enforce your organisation’s IP rights, it is imperative you seek legal advice and assistance from a lawyer.

Letter of demand

A letter of demand is a letter sent to a person whom you believe is infringing your IP rights. The letter will advise the person of the specific rights it is believed to be infringing and that court action may be taken if the infringing activities do not stop within a certain period of time.

In some situations, issuing a letter of demand may be sufficient to put an immediate stop to infringing activities.

When sending a letter of demand:

<table>
<thead>
<tr>
<th>DO</th>
<th>DO NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Send the letter by a means which allows you to confirm receipt.</td>
<td>☑ Do not harass or make unjustified threats to the other party.</td>
</tr>
<tr>
<td>☑ Be prepared to act on your claim by commencing legal proceedings if the infringing activities do not cease.</td>
<td>☑ Do not format the letter to look like a court document.</td>
</tr>
</tbody>
</table>

It is important to consult with your legal advisers before sending out any letter of demand as threatening someone with infringement proceedings may incur legal liability if not done correctly.

Breach of contract

Where there is a contract setting out the terms and conditions governing the use of the IP, and those terms and conditions are not observed this may constitute a breach of contract for which the non-breaching party may be able to claim damages or another type of remedy. For more information on available remedies, see the section entitled ‘Remedies’ of this Chapter.

The terms of the contract may set out the preferred avenue to resolve a dispute, and this may involve using non-litigious measures, such as an informal conference by senior managers, mediation or arbitration, before pursuing an action in court. For more information on non-litigious methods for resolving disputes, see the section entitled ‘Alternative Dispute Resolution’ of this Chapter.
**Customs notice**

A customs notice (or ‘Notice of Objection’) may be lodged with Australian Customs to protect an organisation’s trade marks and copyright from counterfeit, pirated or unauthorised importation of goods. Once this notice is lodged with Australian Customs, Customs has the power to seize infringing goods that are imported into Australia.

<table>
<thead>
<tr>
<th>To lodge a customs notice, you will need to supply:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of IP owner or authorised user</td>
</tr>
<tr>
<td>Details of the trade marks or copyright</td>
</tr>
<tr>
<td>A written undertaking to the Australian Customs Service to cover any costs the Australian Customs Service may incur as a result of seizing infringing goods.</td>
</tr>
</tbody>
</table>

Any goods seized by Customs are held for 10 working days. During this period, the organisation may either commence legal action or consent to the release of the goods. The importer may also voluntarily forfeit the goods, provided no civil action has yet commenced.

A customs notice is valid for two years. After this period it may be re-lodged for ongoing protection. It may also be withdrawn at any time when it is no longer required.

**Litigation**

Court proceedings for IP infringement may be instituted in the Federal Court of Australia, and in some cases also in the Federal Magistrate Courts and State Supreme Courts. IP infringement litigation is usually complex and legal representation is required.

**Issues to keep in mind when enforcing your organisation’s IP rights:**

- **Keep records of correspondences and action taken.**
  A record should be kept of all correspondence (sent and received, including letters, e-mails and faxes and noters of any telephone conversations) and all enforcement measures taken concerning the alleged infringement, especially those at an initial stage.

- **Avoid delays in enforcement.**
  Do not wait long to take enforcement action against any suspected infringers as any delay in enforcing your IP may jeopardise your legal rights.

- **Be prepared to pursue IP enforcement.**
  Once you have commenced action enforcing your IP rights, you should be prepared to pursue that enforcement so the alleged infringer knows that you are serious about protecting your IP. You will need to allocate sufficient time and resources for the enforcement proceedings.

**Alternative Dispute Resolutions**

Alternative dispute resolution (ADR) refers to non-litigious methods to resolve disputes. ADR may involve an informal settlement conference attended by the parties and their legal representatives, or a more formal process such as mediation or arbitration where a neutral independent third party is involved.

Parties may agree in advance to resolve any disputes by ADR before commencing any court action (for example when entering into a contract), or a court may order the parties to pursue a specific form of ADR.
Mediation

Mediation involves a neutral third party (the ‘mediator’) assisting in the negotiation of a settlement. The mediator will only act as a facilitator to assist the parties to reach settlement and has no formal power to force the parties to settle.

Key features of mediation are:

- a structured negotiation process between the parties with a neutral third party
- dispute is resolved by a settlement agreed by both parties
- the mediator has no formal power to force settlement, and
- if the dispute is resolved, terms of settlement are signed.

Arbitration

Arbitration involves a neutral third party (the ‘arbitrator’) acting as a private judge in a closed and private court context where each party has the opportunity to present its evidence and testimony. The parties will need to agree in advance to be bound by the arbitrator’s decision.

Key features of arbitration are:

- evidence and testimony is heard from both parties
- a decision by the arbitrator is made based upon the points of law and the evidence heard, and
- the arbitrator’s decision is usually final and legally binding; however, there may be a right of appeal to the relevant court of law depending on the rules governing the arbitration.

IP enforcement overseas

If your IP rights are being infringed in an overseas market you may consider enforcing your IP right in that particular territory.

As with litigation in Australia, litigation in a foreign jurisdiction will be time consuming and complex. The costs are likely to be higher than in Australia, and in the case of the United States, usually much higher. In addition to the issue of costs, you may need to address the following when instituting proceedings in a foreign country:

- language barriers
- limited foreign IP knowledge
- need for local advice
- differences in foreign IP systems
- unfamiliar business climate, and
- weak IP enforcement regimes in some countries.

You should also be aware that the successful enforcement of your IP rights in one country does not guarantee a successful outcome in other countries.

Your local legal advisers may have access to foreign legal expertise to assist with the enforcement of your IP rights overseas.
Defence and Cross-Claims to IP Infringement Actions

Revocation

When an IP infringement claim proceeds to court, the alleged infringer will usually submit a defence and most likely make a cross-claim to challenge the relevant IP rights. If the cross-claim is successful, your organisation will lose the IP rights and your infringement claim will fail.

For example, an alleged infringer of a patent may:

- use a defence that its goods do not fall within the scope of any claim of your organisation’s patent, and
- cross-claim that your organisation’s patent is invalid and should be revoked based on one of the grounds set out in the Patents Act 1990 (Cth).

The grounds of revocation of a patent are set out below (these are not the same as the grounds for Patent Office opposition proceedings). For more information on opposition proceedings, see Chapter 5 ‘What Managers Making IP Protection Decisions Must Know’:

<table>
<thead>
<tr>
<th>Grounds for Revocation of Patents:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patentee is not entitled to a grant of a patent for the invention.</td>
</tr>
<tr>
<td>The patentee is entitled to the grant of a patent but only in conjunction with some other person.</td>
</tr>
<tr>
<td>The invention is not a patentable invention.</td>
</tr>
<tr>
<td>The invention is not novel.</td>
</tr>
<tr>
<td>The invention does not involve an inventive/innovative step.</td>
</tr>
<tr>
<td>The invention lacks utility.</td>
</tr>
<tr>
<td>The invention has been subject to prior secret use.</td>
</tr>
<tr>
<td>The specification of the patent does not fairly describe the invention (including the best method known to perform the invention).</td>
</tr>
<tr>
<td>The claims of the patent are not fully based on the matter described in the specification.</td>
</tr>
<tr>
<td>The standard patent was obtained by fraud, false suggestion or misrepresentation.</td>
</tr>
</tbody>
</table>

Defences

Defences available to an IP infringer include the common law doctrines of estoppel and acquiescence.

There is also an important exemption from infringement for prior use. If a person has been using a product or method within the scope of protection of the patented invention at a time before the priority date of the patent, and has continued that use to the present time, then the person is exempt from infringement.
**Estoppel**

The alleged infringer may claim estoppel where the alleged infringer acted on the understanding that IP rights would not be enforced based upon words said or actions taken by the IP owner.

**Acquiescence**

Under the doctrine of acquiescence the alleged infringer may assert that the IP owner acquiesced to the infringement or delayed taking enforcement action despite having knowledge of the infringement and thereby effectively gave permission to the infringing activities.

Acquiescence will not prevent a court from ordering an injunction to stop the infringing activities, but it may substantially reduce the damages awarded by a court or even lead to no damages being awarded.

**Laches**

Laches refers to a delay in enforcing IP rights, where a subsequent enforcement would prejudice the rights of the other party.

Laches is distinct from acquiescence. For example, failing to object to the use of a label or the registration of that label as a trade mark may amount to acquiescence. Failing to sue an infringer for several years from the first time the label was used may amount to laches.

**Remedies**

An IP owner may seek a number of civil remedies (including temporary and permanent remedies) in a legal action for infringement of IP. These are summarised in the diagram below.

Interim remedies are temporary orders made against an infringing party before or during the trial which will be in effect until the court has had an opportunity to hear the full case and make a final order. Permanent remedies are ordered by the court in a judgment delivered by the trial judge after a full hearing. Judgments in IP cases are reserved at the end of the hearing and handed down later.
Chapter 8: What Must be Known about Enforcing and Defending your IP Rights

**Remedies**

- **Interim Remedies**
  - **Anton Pillar Order**
    - An order authorising the search of premises for the purpose of seizing infringing articles, where they are likely to be removed or destroyed if the infringer is given notice of the alleged infringement.
  - **Interlocutory injunction**
    - An order restraining the infringing party from continuing the infringing activities until a final order is made.
  - **Mareva Injunction**
    - An order freezing the infringing party’s assets preventing them from being utilised or transferred out of the jurisdiction prior to the conclusion of the full trial.

- **Permanent Remedies**
  - **Damages**
    - Monetary compensation for the loss suffered as a direct result of the infringing activities. Damages are not granted where the infringing party was not aware and had no reason to be aware that the activities were infringing IP rights.
  - **Account of Profits**
    - An order requiring the infringing party to deliver the profits made from the infringing act to the IP owner.
  - **Final injunction**
    - An order restraining the infringing party from continuing the infringing act for the lifetime of the IP.

IP infringement proceedings are often effectively decided at the interlocutory or “interim” stage and only a small number of actions proceed to a full hearing.

**Insuring your IP Rights**

**Obtaining IP insurance**

Considering the significant amount of time, effort and resources spent in creating and protecting IP assets, it may be appropriate to insure your organisation against the financial costs of enforcement proceedings. Since bringing or defending an infringement claim is expensive, obtaining IP insurance will help to spread the risks and financial costs involved in IP litigation. It may also act as a deterrent to potential infringers.

An insurance policy may be cheaper if obtained at an early stage. Insurance underwriters may not be prepared to cover your IP if it has already been “exposed” to risks.

IP insurance policies vary from insurer to insurer. Generally, the following types of insurance may be relevant in the context of IP enforcement litigation:

- offensive IP insurance, and
- defensive IP insurance.

**Offensive IP insurance**

‘Offensive insurance’, also known as IP enforcement litigation insurance, covers the costs of bringing legal action to prevent or stop IP infringement by unauthorised users.
Offensive IP insurance usually covers:

» costs of legal expenses to enforce the IP right, (including legal fees, expert
witnesses and investigators fees), and

» costs of defending cross-claims brought by the alleged infringer, (including costs
of any revocation proceedings of a patent cross-claim).

However, offensive insurance will usually not cover compensatory or consequential damages,
fines, punitive damages and multiple damages.

If the infringement claim is successful, any amount awarded for legal costs and damages may
have to be shared on a pro-rata basis between the insurer and the insured organisation up to
the amount that the insurer has paid in supporting the litigation.

If the infringement claim is unsuccessful, the insurer will generally bear the costs of the court
action, subject to any deductible amounts payable by the insured organisation.

Defensive IP insurance

‘Defensive insurance’, also known as IP infringement liability insurance, covers the costs of
legal action in defending a third party claim alleging that the organisation is infringing the IP
rights of the third party.

A defensive IP insurance policy usually covers:

» expenses incurred in defending third party claims brought against the
organisation (including legal fees, declaratory injunctions and appeals), and

» damages payable by the organisation (including judgement and settlements,
lost royalties and lost profits, interest and costs, and legal fees assessed by the
court).

Exclusions in insurance policies

As with any insurance policy, there will be circumstances which are not covered. Typical
exclusions include loss arising out of:

» the insured organisation’s own wrongful acts

» failure to notify the insurer of pre-existing claims

» breach of contract by the insured organisation’s licensees

» criminal acts by the organisation, and

» cross-claims for breach of trade practices law.

Choosing your IP insurance

Care must be taken when choosing an IP insurance policy. Policies vary between different
insurance companies and a comparative analysis will assist in selecting the most appropriate
cover for your organisation’s IP.

The product disclosure statement and the relevant insurance policy will need to be carefully
reviewed and you should consult with an expert in the field before purchasing any type of
insurance.
## Considerations for choosing your IP insurance

<table>
<thead>
<tr>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organisation’s needs and objectives</td>
</tr>
<tr>
<td>The value of the IP</td>
</tr>
<tr>
<td>The likelihood of the IP being infringed by others</td>
</tr>
<tr>
<td>The likelihood of your organisation infringing the rights of others</td>
</tr>
<tr>
<td>The organisation’s financial resources</td>
</tr>
<tr>
<td>The extent of cover required for the IP</td>
</tr>
<tr>
<td>Any existing insurance covering the IP, and if it is still sufficient</td>
</tr>
<tr>
<td>The premium of the policy</td>
</tr>
</tbody>
</table>

IP insurance is generally underwritten by a major insurer and is made available to insurance retail agents.

<table>
<thead>
<tr>
<th>For IP insurance involving patents, an insurance underwriter may require the following details before issuing insurance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- the organisation’s history of handling enforcement of patent rights</td>
</tr>
<tr>
<td>- the scope and strength of the patent claims</td>
</tr>
<tr>
<td>- actions taken to protect and monitor conflicting patents</td>
</tr>
<tr>
<td>- existing licences of relevant patents</td>
</tr>
<tr>
<td>- existing and potential competitors in related markets</td>
</tr>
<tr>
<td>- key patents in the field, and</td>
</tr>
<tr>
<td>- a validity and infringement opinion from a patent attorney.</td>
</tr>
</tbody>
</table>
Where Can I Find Out More About IP?

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Where Can I Find Out More About IP?

The identification, protection, management and commercialisation of IP can be complex to understand, and you may require the advice and expertise of IP professionals when making IP-related decisions.

IP professionals

There are different types of IP professionals specialising in different areas of IP, and depending on the nature of your enquiry, you may require advice from a variety of IP professionals.

As IP is a very specialised field, you should ensure the IP professional you engage has the appropriate level of expertise and experience to assist with your enquiry.

Patent and trade mark attorneys

Patent and trade mark attorneys provide advice and assistance with the protection of registrable forms of IP, such as patents, trade marks and designs.

A listing of registered patent and trade mark attorneys may be found at the following websites:

» IP Australia  

» Professional Standards Board of Patent and Trade Mark Attorneys  

IP lawyers

IP lawyers are legal specialists in the field of IP, and they provide advice on IP management and enforcement, and assistance with IP-related commercial dealings.

A listing of registered IP lawyers may be found at your local Law Society or business centre, and at the IP Australia website:


Other IP professionals

Other IP professionals may assist with other IP related issues, such as IP development, accounting for IP and planning the IP business strategy.

These other IP professionals include industry specific advisors, management consultants, financial consultants and market researchers.

Internal resources

For assistance on your organisation’s IP management practices and procedures, refer to your organisation’s IP Management Framework (including the IP Policy and IP Implementation Plan). Relevant staff responsible for managing these may also provide advice and guidance.
Plenty of resources on IP management are provided to the public by the Australian Government and other organisations. Some examples are set out below:

<table>
<thead>
<tr>
<th><strong>Public resources</strong></th>
<th><strong>Australian IP law</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australian Copyright Council</strong></td>
<td>The Australian Copyright Council provides information, advice and training about copyright in Australia. <a href="http://www.copyright.org.au">http://www.copyright.org.au</a></td>
</tr>
<tr>
<td><strong>Australian Law Online</strong></td>
<td>Australian Law Online provides information about the Australian legal system and the government organisations that are part of the Australian legal system. <a href="http://www.law.gov.au">http://www.law.gov.au</a></td>
</tr>
<tr>
<td><strong>Australian Legal Information Institute (Austlii)</strong></td>
<td>Austlii provides free online access to Australasian legal materials, including Australian legislation, cases and commentary. <a href="http://www.austlii.edu.au">http://www.austlii.edu.au</a></td>
</tr>
<tr>
<td><strong>AusBiotech</strong></td>
<td>AusBiotech is an organisation which represents the Australian Biotechnology Industry, with members working in human health, agricultural, medical device, bioinformatics, environmental and industrial sectors in biotechnology. <a href="http://www.ausbiotech.org">http://www.ausbiotech.org</a></td>
</tr>
<tr>
<td><strong>Department of Broadband, Communication and the Digital Economy (DBCDE)</strong></td>
<td>DBCDE provides information about the Australian Government policy and legislation that govern the broadcasting and online content management programs and services <a href="http://www.dbcde.gov.au">http://www.dbcde.gov.au</a></td>
</tr>
<tr>
<td><strong>IP Australia</strong></td>
<td>IP Australia provides information about patents, trade marks, designs and plant breeders’ rights. It offers online IP registration searches and lodgement tools, and free access to its publication ‘IP Toolbox’. <a href="http://www.ipaustralia.gov.au">http://www.ipaustralia.gov.au</a></td>
</tr>
</tbody>
</table>
### IP laws in other countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Organization/Office</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>Copyright Council of New Zealand</td>
<td><a href="http://www.copyright.org.nz">http://www.copyright.org.nz</a></td>
</tr>
<tr>
<td></td>
<td>IP Office of New Zealand</td>
<td><a href="http://www.iponz.govt.nz">http://www.iponz.govt.nz</a></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>British and Irish Legal Information Institute</td>
<td><a href="http://www.bailii.org">http://www.bailii.org</a></td>
</tr>
<tr>
<td></td>
<td>United Kingdom Patent Office</td>
<td>&lt;<a href="http://www.patent.gov.uk">http://www.patent.gov.uk</a> &gt;</td>
</tr>
<tr>
<td>United States</td>
<td>Copyright Office of United States</td>
<td><a href="http://www.copyright.org">http://www.copyright.org</a></td>
</tr>
<tr>
<td>European Union</td>
<td>Europa provides an access to information (press releases, legislation, fact sheets) published by the European Union and its institutions</td>
<td><a href="http://europa.eu/index_en.html">http://europa.eu/index_en.html</a></td>
</tr>
<tr>
<td></td>
<td>European Patent Office</td>
<td><a href="http://www.epo.org">http://www.epo.org</a></td>
</tr>
</tbody>
</table>

### Further reading

There is a wealth of information available on the subject of IP, available in textbooks, loose leaf services and articles. Examples of such are provided below.

### Textbooks

Chapter 9: Where Can I Find Out More About IP?


**Loose leaf services**

» *Australian Industrial & Intellectual Property*, (edited by A Liberman) CCH Australia Ltd

» *Copyright & Designs*, (edited by J Lahore) Butterworths

» The Law of Intellectual Property, Copyright, Designs & Confidential Information, (edited by S Ricketson and C Creswell) LBC Information Services

**Manuals**


Legislation

» Circuit Layouts Act 1989 (Cth)
» Copyright Act 1968 (Cth)
» Designs Act 2003 (Cth)
» Freedom of Information Act 1982 (Cth)
» Patents Act 1990 (Cth)
» Plant Breeder’s Rights Act 1994 (Cth)
» Privacy Act 1998 (Cth)
» Trade Marks Act 1995 (Cth)
» Trade Practices Act 1974 (Cth)

International Treaties and Agreements

» World Trade Organisation, Trade-related aspects of intellectual property rights (TRIPS) agreement, 1994
» The International Union for the Protection of New Varieties of Plants (UPOV) established by the International Convention for the Protection of New Varieties of Plants (“UPOV Convention”), 1961

Textbooks & Journal Articles

» Anson W, Fundamentals of Intellectual Property Valuation: A Primer for identifying and Determining Value, American Bar Association, 2005
» Bodkin C, Patent Law in Australia, Lawbook Company, Pyrmont, N.S.W., 2008


**Loose Leaf Services**

- *Australian Industrial & Intellectual Property*, edited by Liberman A, CCH Australia
- *Copyright and Designs*, edited by Lahore J, Butterworths

**Web-based Publications**


Millward Brown Optimor, 2007 Brandz: Top 100 Most Powerful Brands, viewed 24 September 2008,
Bibliography


Websites

» Arts Law Centre of Australia, Arts Law Centre of Australia online, <http://www.artslaw.com.au>

» Australasian Legal Information Institute, Australasian Legal Information Institute (AustLII), <http://www.austlii.edu.au>


» Australian Copyright Council, Australian Copyright Council’s Online Information Centre, Australian Council for the Arts, <http://www.copyright.org.au>


» Australian Research Council, <http://www.arc.gov.au>
» Australian Society of Authors, The Australian Society of Authors Online, <http://www.asauthors.org>
» Cooperative Research Centres, <https://www.crc.gov.au>
» Defective by Design, GNU General Public License – GNU Project – Free Software Foundation (FSF), <www.gnu.org/licenses/gpl.html>
» Domain Names, Domain name: domain name registration, domain name, web hosting, <http://www.domainnames.com.au>
» National Health and Medical Research Council, <http://www.nhmrc.gov.au>
» NSW Office for Science and Medical Research <http://www.osmr.nsw.gov.au/>
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AASB</td>
<td>Australian Accounting Standards Board</td>
</tr>
<tr>
<td>ABN</td>
<td>Australian Business Number</td>
</tr>
<tr>
<td>ACIP</td>
<td>Australian Advisory Council on Intellectual Property</td>
</tr>
<tr>
<td>ACN</td>
<td>Australian Company Number</td>
</tr>
<tr>
<td>ADDS</td>
<td>Australian Designs Data Searching</td>
</tr>
<tr>
<td>ADR</td>
<td>Australian Dispute Resolution</td>
</tr>
<tr>
<td>ALRC</td>
<td>Australian Law Reform Commission</td>
</tr>
<tr>
<td>ARC</td>
<td>Australian Research Council</td>
</tr>
<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
</tr>
<tr>
<td>ASIC</td>
<td>Australian Securities and Investment Commission</td>
</tr>
<tr>
<td>ATMOSS</td>
<td>Australian Trade Mark On-line Search System</td>
</tr>
<tr>
<td>ATS</td>
<td>National Australian Technology Showcase</td>
</tr>
<tr>
<td>.auDA</td>
<td>.au Domain Administration Limited</td>
</tr>
<tr>
<td>.auDRP</td>
<td>.au Dispute Resolution Policy</td>
</tr>
<tr>
<td>CDA</td>
<td>Confidential Disclosure Agreement</td>
</tr>
<tr>
<td>CLR Act</td>
<td>Circuit Layout Rights Act 1989 (Cth)</td>
</tr>
<tr>
<td>COMET</td>
<td>Commercialising Emerging Technologies</td>
</tr>
<tr>
<td>Copyright Act</td>
<td>Copyright Act 1968 (Cth)</td>
</tr>
<tr>
<td>CRA</td>
<td>Collaborative Research Agreement</td>
</tr>
<tr>
<td>CRC</td>
<td>Cooperative Research Centre</td>
</tr>
<tr>
<td>Cth</td>
<td>Commonwealth of Australia</td>
</tr>
<tr>
<td>CTM</td>
<td>Community Trade Mark (European Union)</td>
</tr>
<tr>
<td>Designs Act</td>
<td>Designs Act 2003 (Cth)</td>
</tr>
<tr>
<td>DEST</td>
<td>Department of Education, Science and Training</td>
</tr>
<tr>
<td>DNS</td>
<td>Domain Name System</td>
</tr>
<tr>
<td>DRM</td>
<td>Digital Rights Management</td>
</tr>
<tr>
<td>EDA</td>
<td>Electronic Design Automation</td>
</tr>
<tr>
<td>EULAs</td>
<td>End User Licence Agreements</td>
</tr>
<tr>
<td>ICIP</td>
<td>Industry Cooperative Innovation Program (Victoria)</td>
</tr>
<tr>
<td>IIF</td>
<td>Innovation and Investment Fund</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>IPC</td>
<td>International Patent Classification</td>
</tr>
<tr>
<td>IPE</td>
<td>International Preliminary Examination</td>
</tr>
<tr>
<td>IPO</td>
<td>Initial Public Offerings</td>
</tr>
<tr>
<td>ISR</td>
<td>International Search Report</td>
</tr>
<tr>
<td>ISUS</td>
<td>Innovation Start-up Scheme (Queensland)</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>MTA</td>
<td>Material Transfer Agreement</td>
</tr>
</tbody>
</table>
NCGP .............................. National Competitive Grants Program
NDA ........................................ Non-disclosure Agreement
NH&MRC ......................... National Health and Medical Research Council
Paris Convention ........ Paris Convention for the Protection of Industrial Property 1883
Patents Act ........................................ Patents Act 1990 (Cth)
PBR ........................................ Plant Breeder’s Rights
P3 ........................................ Pharmaceutical Partnership Program
R&D .......................................... Research and Development
RMI ........................................ Electronic Rights Management Information
STI Infrastructure ........ Science and Technology and Innovation Infrastructure (Victoria)
TGA ........................................ Therapeutic Goods Administration
TPM ........................................... Technological Protection Measures
Trade Marks Act .................... Trade Marks Act 1995 (Cth)
TRIPS .................................. Trade-Related Aspects of Intellectual Property Rights Agreement
UPOV ................................ International Union for the Protection of New Varieties of Plants
USPC ................................... United States Patent Classification System
WIPO .................................. World Intellectual Property Organisation
WIPO Convention .... Convention establishing the World Intellectual Property Organisation
WTO ................................. World Trade Organisation
## Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account of profits</td>
<td>Account of profits is an order by a court requiring the infringing party to deliver profits made from unauthorised use of rights.</td>
</tr>
<tr>
<td>Acquiescence</td>
<td>Acquiescence is a legal doctrine where permission or acceptance is deemed to be given by silence or passiveness.</td>
</tr>
<tr>
<td>All rights reserved</td>
<td>All rights reserved is a notice usually found on copyright works. An ‘all rights reserved’ notice indicates that all rights granted under copyright law are retained (including the rights to take legal action if there is any infringement).</td>
</tr>
<tr>
<td>Alternative dispute resolutions (ADR)</td>
<td>ADRs are non-litigious methods of resolving disputes, such as informal settlement conferences, mediation or arbitration.</td>
</tr>
<tr>
<td>Anton Pillar Order</td>
<td>Anton Pillar Order is an order by a court authorising the search of premises for the purpose of seizing infringing articles that are likely to removed or destroyed by the infringer is notice of alleged infringement is given.</td>
</tr>
<tr>
<td>Arbitration</td>
<td>Arbitration is where a neutral third party (‘arbitrator’) acts as a private judge in a closed court to make a decision on the dispute which the parties agree to be bound by.</td>
</tr>
<tr>
<td>Artistic works</td>
<td>Artistic works is one of the categories of works that is protected by the Copyright Act 1968 (Cth). Artistic works include photographs, drawings, paintings, sculptures, architecture, graphs and computer icons.</td>
</tr>
<tr>
<td>Assignment</td>
<td>An assignment is the legal term for the permanent transfer of rights to another individual or entity.</td>
</tr>
<tr>
<td>Breach of contract</td>
<td>A breach of contract is where there is a failure by a party of the contract to comply with the terms and conditions set out in the contract.</td>
</tr>
<tr>
<td>Broadcasts</td>
<td>Broadcasts are one of the categories of works that is protected by the Copyright Act 1968 (Cth). This refers to a communication to the public via television and radio broadcasts.</td>
</tr>
<tr>
<td>Broadcasting decoding devices</td>
<td>Broadcasting decoding devices are devices which enables unauthorised access to an encoded broadcast.</td>
</tr>
</tbody>
</table>
Cinematographic works

Cinematographic works is one of the categories of works that is protected by the Copyright Act 1968 (Cth). Cinematographic works are works generating moving images, including films and computer games.

Circuit layouts

A circuit layout is a representation (i.e. mask) describing the layout of the design of an integrated circuit. In Australia, the Circuit Layouts Act 1989 (Cth) grants an exclusive set of rights automatically upon creation of an original circuit layout for a limited period of time.

Collaborative Research Agreement (CRA)

CRA is a contract which defines the terms and conditions under which collaborative research will be undertaken.

Claims

The claims of a patent are written statements in the patent defining the boundaries of an invention as set out in a patent specification.

Community Trade Mark (CTM)

CTM refers to a trade mark registered with the European Communities Trade Mark Office and is enforceable throughout the European Union.

Complete application

A complete application is a patent application for a standard or innovation patent that includes a full and complete specification and claims of the invention.

Confidential information

Confidential information is information and materials of a confidential nature (and may include information of a personal or commercial nature) that is not readily available to the public.

Copyright

Copyright is a form of intellectual property that protects the expression of an idea, but not the idea itself. In Australia, copyright is governed by the Copyright Act 1968 (Cth) where an exclusive set of rights are automatically granted upon creation of an original copyright work for a limited period of time.

Cost approach

The cost approach to IP valuation values IP by calculating the savings on costs an organisation would expect to make as a result of acquiring an IP asset instead of creating it from scratch.

Cross claim

A cross claim is a claim made in response to another claim, such as where a defendant brings a claim against the plaintiff in the same lawsuit.

Customs notice

A customs notice is a notice lodged with Australian Customs to seize imported goods that infringe an organisation’s trade mark or copyright.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Damages</td>
<td>Damages are monetary compensation that an infringer is required by a court to pay the owner for loss suffered as a result of the infringing act.</td>
</tr>
<tr>
<td>Data exclusivity</td>
<td>Data exclusivity refers to the protection of clinical data which is submitted to a regulatory agency for the purposes of obtaining regulatory approval of a drug.</td>
</tr>
<tr>
<td>Defensive insurance</td>
<td>Defensive insurance is a type of insurance where funding is provided to cover the costs of legal proceedings brought against the insured for IP infringement owned by a third party.</td>
</tr>
<tr>
<td>Designs</td>
<td>See ’Registered design’.</td>
</tr>
<tr>
<td>Digital Rights Management (DRM)</td>
<td>DRM refers to the management and protection of copyright material in the digital environment using technological protection tools.</td>
</tr>
<tr>
<td>Divisional application</td>
<td>A divisional application is a patent application filed to separate two inventions described in one earlier patent application, without losing its priority date.</td>
</tr>
<tr>
<td>Domain names</td>
<td>Domain names are sequences of words which are translations of numeric internet protocol addresses.</td>
</tr>
<tr>
<td>Dramatic works</td>
<td>Dramatic works is one of the categories of works that is protected by the Copyright Act 1968 (Cth). Dramatic Works include plays, screenplays and choreographic works.</td>
</tr>
<tr>
<td>Due diligence</td>
<td>Due diligence is a comprehensive investigation and analysis of an organisation’s IP assets to confirm its ownership status over the assets and the organisation’s ability to authorise the proposed use of the IP assets.</td>
</tr>
<tr>
<td>Economic rights</td>
<td>Economic rights are a set of exclusive rights granted to a copyright owner by the Copyright Act 1968 (Cth), which may be assigned or licensed.</td>
</tr>
<tr>
<td>Electronic Rights Management Information (RMI)</td>
<td>RMI is a set of electronic systems for identifying, protecting and tracking copyright work in electronic form. The Copyright Act 1968 (Cth) prohibits the removal or alteration of RMI.</td>
</tr>
<tr>
<td>End User Licence Agreement (EULA)</td>
<td>EULA is a legal contract between author or publisher of a software application and the user of that application. The user agrees to pay for the use of the software and to comply with all restrictions stated in the EULA.</td>
</tr>
<tr>
<td>Estoppel</td>
<td>Estoppel is a legal doctrine under which a person is prevented from asserting or denying a fact because of the person’s previous acts or words.</td>
</tr>
<tr>
<td>Exclusive licence</td>
<td>An exclusive licence is where the licensee is the only person who has the right to deal with the licensed rights to the exclusion of all others, including the licensor.</td>
</tr>
<tr>
<td>Experimental use</td>
<td>The use of an invention for the purposes of determining how it works, determining the scope of patent protection, or for seeking an improvement of the invention, may in some countries, be exempt from patent infringement. Australia currently does not have an experimental use exemption.</td>
</tr>
<tr>
<td>Fair Basis</td>
<td>The invention as claimed must be supported by or be consistent with the detailed description provided in the specification.</td>
</tr>
</tbody>
</table>
**Fair dealing**

Fair dealing refers to categories of acts that do not constitute copyright infringement under the Copyright Act 1968 (Cth). Fair dealing includes use of copyright works to report news, for research or study, for criticism and review, and for professional advice given by a lawyer, patent attorney or trade marks attorney.

**Freedom to operate**

Freedom to operate refers to being able to freely use a product without infringing registered or pending IP rights.

**Filing date**

Filing date refers to the date an application for registrable IP is lodged with the relevant IP office. A filing date may be the same or different to a priority date.

**Final injunction**

Final injunction is an order by a court requiring the infringing party to permanently cease the infringing act.

**Goodwill**

Goodwill is the reputation acquired from use of a particular registered or unregistered trade mark. A passing off action prevents others from trading on the goodwill acquired by a particular mark.

**Grace period**

An extended period during which an act may be done, when usually the act could not be done. For example, a disclosure of the invention before filing a patent application will usually prevent a valid patent being granted, but in Australia there is a grace period of 12 months from the date of first disclosure by an inventor.

**Income approach**

The income approach to IP valuation values IP by calculating the expected future income stream (or cost savings) to be generated by an IP asset.

**In escrow**

In escrow refers to the holding of items by a neutral third party until certain conditions are met to release them.

**Innovation Patent**

An innovation patent is a type of patent that involves an innovative step, in addition to other requirements of patentability. Protection generally lasts for 8 years from the first date of filing a complete application.

**Infringement of a patent**

The act of taking an exclusive right of the patentee, such as selling, making or using the patented invention without authorisation.

**Innovative Step**

Innovative step is one of the requirements for innovation patent registration under the Patents Act 1990 (Cth).

**Intellectual Property (IP)**

IP is intangible property that attracts rights resulting from creative efforts from the mind or intellect. IP are rights relating to:

- literary, artistic and scientific works
- performances of performing artists, phonograms and broadcasts
- inventions in all fields of human endeavour
- scientific discoveries
- industrial designs
- trade marks, services marks and commercial names and designations
- protection against unfair competition, and
- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.
<table>
<thead>
<tr>
<th><strong>Interim remedies</strong></th>
<th>Interim remedies are types of remedies granted temporarily until the court has heard the full case to grant permanent remedies.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interlocutory injunction</strong></td>
<td>Interlocutory injunction is an order by the court restraining an infringing party from continuing the infringing act until conclusion of the relevant trial.</td>
</tr>
<tr>
<td><strong>Invention disclosure form</strong></td>
<td>An invention disclosure form is a document for completion by the creators of a particular IP setting out the details of its development, as well as details on how it is distinguished from existing IP.</td>
</tr>
<tr>
<td><strong>Inventive Step</strong></td>
<td>Inventive step is one of the requirements for standard patent registration under the Patents Act 1990 (Cth).</td>
</tr>
<tr>
<td><strong>IP Implementation Plan</strong></td>
<td>An IP Implementation Plan is a document setting out a system on an operational level to implement the IP Policy within an organisation.</td>
</tr>
<tr>
<td><strong>IP inventory audit</strong></td>
<td>An IP inventory audit is an exercise identifying all existing IP assets held by the organisation.</td>
</tr>
<tr>
<td><strong>IP Policy</strong></td>
<td>An IP Policy is a document setting out an organisation’s aims and objectives for the management of IP.</td>
</tr>
<tr>
<td><strong>IP valuation</strong></td>
<td>IP valuation is an assessment of the value of a particular IP asset. IP valuation may be quantitative or qualitative in nature. There are a range of methods to value IP.</td>
</tr>
<tr>
<td><strong>Joint ownership</strong></td>
<td>Joint ownership is where two or more individuals or organisations develop an IP asset together as a collaborative effort.</td>
</tr>
<tr>
<td><strong>Joint venture</strong></td>
<td>A joint venture is a legal construction where two parties join together to undertake a common project to reach a shared goal.</td>
</tr>
<tr>
<td><strong>Letter of demand</strong></td>
<td>A letter of demand is a letter setting out certain demands to a person suspected of infringing IP rights issued by the owner of those IP rights.</td>
</tr>
<tr>
<td><strong>Licence</strong></td>
<td>A licence is the grant of particular rights to another individual or entity (‘licensee’) by the owner of those rights (‘licensor’) to use the rights for a period of time. The licensor of the rights retains the legal ownership of the rights and may exercise a varying degree of control.</td>
</tr>
<tr>
<td><strong>Madrid System</strong></td>
<td>The Madrid System refers to the Madrid System for the International Registration of Marks established under the Madrid Agreement 1891 and the Madrid Protocol 1989. It is administered by the World Intellectual Property Organisation granting trade mark protection in countries party to the Madrid Union by filing one application directly in their own national or regional trade mark office.</td>
</tr>
<tr>
<td><strong>Manner of Manufacture</strong></td>
<td>Manner of manufacture is one of the requirements for patent registration under the Patents Act 1990 (Cth).</td>
</tr>
<tr>
<td><strong>Mareva injunction</strong></td>
<td>Mareva injunction is an order by the court freezing the infringing party’s assets so they cannot be consumed or transferred out of jurisdiction before the conclusion of trial.</td>
</tr>
<tr>
<td>Glossary Term</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Market approach</td>
<td>The market approach to IP valuation values IP by assessing the comparable price or royalty that could be achieved by similar technologies or IP in the market.</td>
</tr>
<tr>
<td>Mediation</td>
<td>Mediation is where a neutral third party (‘mediator’) assists and facilitates the negotiation between parties in dispute.</td>
</tr>
<tr>
<td>Metadata</td>
<td>Metadata is information that describes a particular piece of content being held digitally.</td>
</tr>
<tr>
<td>Moral rights</td>
<td>Moral rights are personal rights granted to the creator of a copyright work by the Copyright Act 1968 (Cth) protecting the integrity and right of attribution of their work. These rights cannot be assigned or licensed.</td>
</tr>
<tr>
<td>Musical works</td>
<td>Musical works is one of the categories of works that is protected by the Copyright Act 1968 (Cth). Musical works are works with written musical notation, including sheet music and operas.</td>
</tr>
<tr>
<td>Non-exclusive licence</td>
<td>A non-exclusive licence is where the licensor retains the right to grant an unlimited number of licences to third parties.</td>
</tr>
<tr>
<td>Notice of objection</td>
<td>See Customs notice.</td>
</tr>
<tr>
<td>Novelty</td>
<td>Novelty is one of the requirements for patent registration under the Patents Act 1990 (Cth).</td>
</tr>
<tr>
<td>Object code</td>
<td>This is the machine-readable code of a software program.</td>
</tr>
<tr>
<td>Offensive insurance</td>
<td>Offensive insurance is a type of insurance where funding is provided to cover the costs of legal proceedings where IP rights are being enforced by the insured against a third party infringer.</td>
</tr>
<tr>
<td>Open source</td>
<td>Open source refers to any software program whose source code is made available for use, modification and redistribution to any user.</td>
</tr>
<tr>
<td>Paris Convention</td>
<td>A Paris Convention application allows an invention to be granted patent protection in other Paris Convention-signatory countries whilst retaining the priority date of the first filing of a complete patent application in a Paris Convention-signatory country.</td>
</tr>
<tr>
<td>application</td>
<td></td>
</tr>
<tr>
<td>Passing off</td>
<td>Passing off is a common law tort action that protects the reputation or goodwill of unregistered marks.</td>
</tr>
<tr>
<td>Patent</td>
<td>A patent is a form of intellectual property that protects an invention. A patent grants a set of exclusive rights to the patent owner to commercially exploit the invention for a limited period of time. The grant of a patent is governed by the Patents Act 1990 (Cth) in Australia.</td>
</tr>
<tr>
<td>Patent of addition</td>
<td>A patent of addition is a patent application filed to protect an improvement or modification of an invention set out in an earlier patent application.</td>
</tr>
<tr>
<td>Patent attorney</td>
<td>A patent attorney is a professional qualified in a scientific discipline and qualified to act in the obtainment of patent and design registrations.</td>
</tr>
<tr>
<td>Term</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Patent term extension</td>
<td>The “term” or life of certain pharmaceutical patents may be extended for up to 5 years to compensate the patentee for loss of patent life the patentee experienced while obtaining regulatory approval for the pharmaceutical.</td>
</tr>
<tr>
<td>Performers’ rights</td>
<td>Performers’ rights are personal rights granted to the performer of a copyright work by the Copyright Act 1968 (Cth) protecting against unauthorised recordings and broadcasting of performances.</td>
</tr>
<tr>
<td>Person skilled in the art</td>
<td>A person skilled in the art is a legal term referring to a person who has the ordinary level of skills and knowledge in the relevant field of an invention.</td>
</tr>
<tr>
<td>Permanent remedies</td>
<td>Permanent remedies are remedies granted by the court at the conclusion of a trial.</td>
</tr>
<tr>
<td>Plant breeders rights</td>
<td>Plant breeders rights is a form of intellectual property that protects a registered plant variety. In Australia, plant breeders rights are governed by the Plant Breeders’ Rights Act 1994 (Cth) where an exclusive set of rights are granted to the registered owner for limited period of time.</td>
</tr>
<tr>
<td>Prior art</td>
<td>Prior art is a legal term referring to information previously disclosed to the public in any form relating to the invention before its priority date.</td>
</tr>
<tr>
<td>Priority date</td>
<td>Priority date is the date of filing of the first application of a registrable IP. This is the date against which the application is assessed in light of the relevant prior act.</td>
</tr>
<tr>
<td>Product liability insurance</td>
<td>Product liability insurance is a type of insurance where funding is provided to cover costs when a person has suffered damage as a result of a product manufactured, repaired or altered by the insured.</td>
</tr>
<tr>
<td>Public domain</td>
<td>Public domain refers to when expired copyright works are made available for unrestricted use to the public.</td>
</tr>
<tr>
<td>Published editions</td>
<td>Published editions are one of the categories of works that is protected by the Copyright Act 1968 (Cth). These refer to publisher’s typeface and layout of a published work.</td>
</tr>
<tr>
<td>Registered design</td>
<td>A registered design is a form of intellectual property that protects the overall appearance of a new and distinctive design. In Australia, the Designs Act 2003 (Cth) grants a set of exclusive rights to the registered designs owner to commercially exploit the design for a limited period of time.</td>
</tr>
<tr>
<td>Reverse-engineering</td>
<td>Reverse-engineering is the process by which a finished product is examined in order to obtain information relating to its construction.</td>
</tr>
<tr>
<td>Right of attribution</td>
<td>The right of attribution is a type of moral right granted to the creator of a copyright protected work. The Copyright Act 1968 (Cth) defines the right of attribution as the right of a creator to be identified with his or her work.</td>
</tr>
<tr>
<td>Right of integrity</td>
<td>The right of integrity is a type of moral right granted to the creator of a copyright protected work. The Copyright Act 1968 (Cth) defines the right of integrity as a right to not have the work subjected to derogatory treatment.</td>
</tr>
<tr>
<td>Royalty</td>
<td>A royalty is a fee paid to the IP owner for the right to use their IP. Royalties may be calculated as a percentage of profit, as a fee per usage or as a lump sum payment.</td>
</tr>
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<td>Sole licence</td>
<td>A sole licence is a licence where the licensee has the right to deal with the licensed rights to the exclusion of everyone else except the licensor.</td>
</tr>
<tr>
<td>Sole ownership</td>
<td>Sole ownership is where all rights in an IP asset are owned by one individual or organisation.</td>
</tr>
<tr>
<td>Sound recordings</td>
<td>Sound recordings are one of the categories of works that is protected by the Copyright Act 1968 (Cth). This refers to works with recorded sound, including CDs, DVDs, mp3s and podcasts.</td>
</tr>
<tr>
<td>Source code</td>
<td>This is the human-readable code of a software program.</td>
</tr>
<tr>
<td>Specification</td>
<td>A patent specification is a detailed technical description of an invention, usually accompanied with drawings, set out in a patent application.</td>
</tr>
<tr>
<td>Spin off companies</td>
<td>A spin off company is a separate company established by an organisation for the purposes of undertaking a particular activity, such as the commercialisation of a specific IP asset.</td>
</tr>
<tr>
<td>Standard Patent</td>
<td>A standard patent is a type of patent that involves an inventive step, in addition to other requirements of patentability. Protection generally lasts for 20 years from the first date of filing the complete application.</td>
</tr>
<tr>
<td>Substantial part</td>
<td>A substantial part under the Copyright Act 1968 (Cth) refers to both the quantitative and qualitative taking of a copyright-protected work.</td>
</tr>
<tr>
<td>Technological Protection Measures (TPMs)</td>
<td>TPMs are technologies aiding the protection of IP works and restricting access to it, such as password-protection, encryption and read-only access.</td>
</tr>
<tr>
<td>Trade mark</td>
<td>A trade mark is a form of intellectual property that is a sign used in trade to identify and distinguish a business’s goods and services from other businesses.</td>
</tr>
<tr>
<td>Trade mark attorney</td>
<td>A trade mark attorney is a professional qualified to act in obtaining trade mark registrations.</td>
</tr>
<tr>
<td>Trade secrets</td>
<td>Trade secrets are confidential information in the context of business, commerce or trade.</td>
</tr>
<tr>
<td>Utility</td>
<td>Utility is one of the requirements for patent registration under the Patents Act 1990 (Cth).</td>
</tr>
<tr>
<td>Warranty</td>
<td>A warranty is an assurance that a provision in a contract is true.</td>
</tr>
<tr>
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<td>WIPO is a specialised agency of the United Nations dedicated to promoting the use and protection of IP works, such as administering various international treaties dealing with the harmonisation of different aspects of IP protection.</td>
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