

PART VIII — PATENTS

I Introduction

A Definition

A 'patent' is a monopoly that grants to its holder ('the patentee') the exclusive right to exploit an invention for a fixed term. Patents will only be granted to inventions satisfying certain requirements, viz, patentability, novelty and inventiveness, among others. The rights of a patentee are statutory in origin, deriving as they do from the *Patents Act 1990* (Cth). In return for a statutory monopoly, the patentee must make full disclosure of the details of his or her invention on a public register known as the Register of Patents.

Patent law refers to the field of intellectual property law concerned with the application, grant and exploitation of monopoly rights in patentable inventions. Several issues occupy its focus:

- What is meant by a 'patentable invention'?
- Or, more accurately, what is the proper subject of patent protection?
- Is a given patent on the register a valid patent?
- When will a patent be infringed?

The sections that follow develop the idea of patentability by reference to the history of patent law and the text and structure of the Australian patents legislation.

B Objectives

Just as nature abhors a vacuum, so too does the common law abhor a monopoly. The grant of a monopoly, even one statutory in origin, must therefore be justified by strong rationales indeed. In the case of patent protection, the tension is between the inherent right of persons to trade freely in useful goods and the need to encourage the invention and production of such goods.

Some commentators have described this tension as a paradox; others, like Lord Parker in *Attorney-General (Cth) v Adelaide Steamship Co*, have sought to reconcile these two imperatives by explaining their beneficial interaction:

A monopoly being a derogation from the common right of freedom of trade could not be granted without consideration moving to the public. ... In the case of new inventions the consideration was found either in the interest of the public to encourage inventive ingenuity or more probably in the disclosure made to the public of a new and useful article or process.

According to Lord Parker, if it is by suffering a monopoly that citizens may benefit from new inventions, then this is a necessary trade-off and an efficient level of restraint.

Patent law exists to provide incentives to create new and useful products, processes and methods. It does so by granting a monopoly to exploit such inventions commercially for a fixed period.

A patent may be viewed as a bargain between the patentee and the public. The patentee receives an exclusive right to exploit her invention. The price of this bargain is said to be the

disclosure to the public of the details of its manufacture. Such details typically include how to operate and embody the invention. This is also known as the social contract theory of patent law. Society grants a temporary monopoly to the inventor in return for that inventor granting to society knowledge about the workings of the invention, so that it will be available for society's use and benefit after that time.

The choice facing a potential patentee is therefore between reliance upon the equitable doctrine of breach of confidence and the limited protections offered by the patent regime.

C History

Patents are the oldest form of intellectual property. Their origins may be traced to the late European Middle Ages, through the crown prerogative in renaissance England, to their systematisation during the Enlightenment with its shift towards constitutionalism and limited government, from which they developed incrementally to their present form.

1 Patents in Venice

One of the earliest (and, remarkably, most recognisable) declarations of the patent is provided by the Venetian Senate, which in 1474 enacted the *Venetian Statute of 1474*. The Act provided that an inventor of any 'new and ingenious device' would be granted rights in order that the future development 'devices of great utility and benefit' would be encouraged:

We have among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our City, more such men come to us every day from diverse parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor's honour away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our Commonwealth.

Contained in this short preamble is the embryonic genesis of modern patent protection: an exploitation monopoly is granted for the purpose of encouraging the development of useful technology by protecting the interests of inventors.

2 Elizabethan England

The early English patent system took the form of royal grants made to importers and foreign craftsmen. Under the royal prerogative, the Crown had the power to grant *literae clausae* (folded, sealed grants) and *literae patens* (an unsealed document authorising the holder to do the acts stated). *Literae patens* are, literally, letters patent. A *litera* was said to be *paten* when it was unsealed and able to be read by anyone: the essence of a 'patent', then, is *paten*, or openness.

A *litera paten* would entitle the grantee to a monopoly over a specified field of activity. Such activities were not limited to inventions; they covered importation, use of colonial resources, as well as domestic manufacture. The Crown used these *letters patent* to raise revenue.

The use of the Crown prerogative to grant monopoly rights to importers of goods was a matter of considerable controversy, and was opposed by the House of Commons. This controversy reached its peak in 1602, when the Queen's Bench first considered the validity of a royal grant in the seminal case of *Darcy v Allin*. In holding the grant of letters patent to be invalid, the decision is sometimes heralded as the first example of judicial review of administrative action.

Darcy v Allin (1602) UK QB:Facts

- Darcy is a favoured courtier in the Court of Elizabeth I
- Darcy is awarded the playing card patent, entitling him to be the sole manufacturer and distributor of playing cards in England
- Allin is a haberdasher (a purveyor of sewing equipment); he contests the validity of the grant as an unreasonable restraint of trade.

Issue

- Is the grant of *literae patens* a valid exercise of the royal prerogative?

Reasoning

- This grant is an unreasonable restraint of trade: it has the effect of increasing the price of playing cards and reducing their quality
- However, the grant of 'monopoly patents' in return for an inventor's 'own wit or invention' would not be unreasonable
 - '[1139] where any man ... by his own ... industry or ... invention doth bring any new trade into the realm, or any engine tending to the furtherance of a trade that never was used before — and that for the good of the realm — ... the King may grant him a monopoly patent for some reasonable time until the subjects may learn the same in consideration of the good he doth bring by his invention to the Commonwealth. Otherwise not.'
- As this is not the nature of the present grant, it is void

Decision

- The grant is invalid, so the patent is void

Darcy v Allin was the first time a common law court reviewed the exercise of the royal prerogative. The case is important for two reasons. First, to the administrative lawyer: because it fundamentally changed the nature of the relationship between courts and Crown. Second, to the patent lawyer: because it reaffirms that monopoly grants can be made to inventors.

3 *Jacobian England and the Statute of Monopolies*

Upon the succession of James I, the royal prerogative was further eroded. In 1623, the Commons enacted the *Statute of Monopolies 1624* (UK), which is essentially an early example of trade practices law (the title is best read as the statute *against* monopolies).

This Act outlawed monopolies in all forms as restraints of trade, save as to s 6, which provided for monopoly rights in certain circumstances:

***Statute of Monopolies 1624* (UK) s 6:**

Provided also, ... that any declaration .. shall not extent to any letters-patent and grants of privilege, for the term of fourteen years or under, hereafter to be made of the sole working or making of **any manner of new manufacture** within this realm, to the true and first inventor and inventors of such manufactures, which others, at the time of making such letters-patent or grant, shall not use, so as also they **be not contrary to the law, nor mischievous to the state**, by

raising prices of commodities at home, or hurt of trade, or generally inconvenient; the said fourteen years to be accounted from the date of the first letters-patent or grant of such privilege, hereafter to be made, but that the same shall be of such force, as they should be, if this act had never been made and of none other.

Essentially, this section provides that the Act's declaration that all monopolies are invalid does not apply to monopolies granted to the inventors of 'any manner of new manufacture'. However, such a manufacture must not be either 'contrary to the law' or 'mischievous to the state'. It will be mischievous if it has the effect of raising the prices of commodities, restraining trade or 'generally inconvenient'. These requirements being satisfied, the monopoly will be valid if it is for a term of fourteen years or fewer. (The significance of 'fourteen' years seems only to be that it was the length of two apprenticeships.)

Remarkably, the *Statute of Monopolies* continues to have direct relevance to modern Australian and English patent law. In the case of the former jurisdiction, this is because it is incorporated by express reference into the definition of 'invention' in the *Patents Act 1990* (Cth).

4 Subsequent evolution and the industrial revolution

Existing practices and procedures relating to the grant of privileges and letters-patent with respect to inventions were codified by the United Kingdom Parliament in 1883, when it passed the *Patents Designs and Trade Marks Act 1883* (Imp) to meet its obligations under the *Paris Convention for the Protection of Industrial Property 1883*.

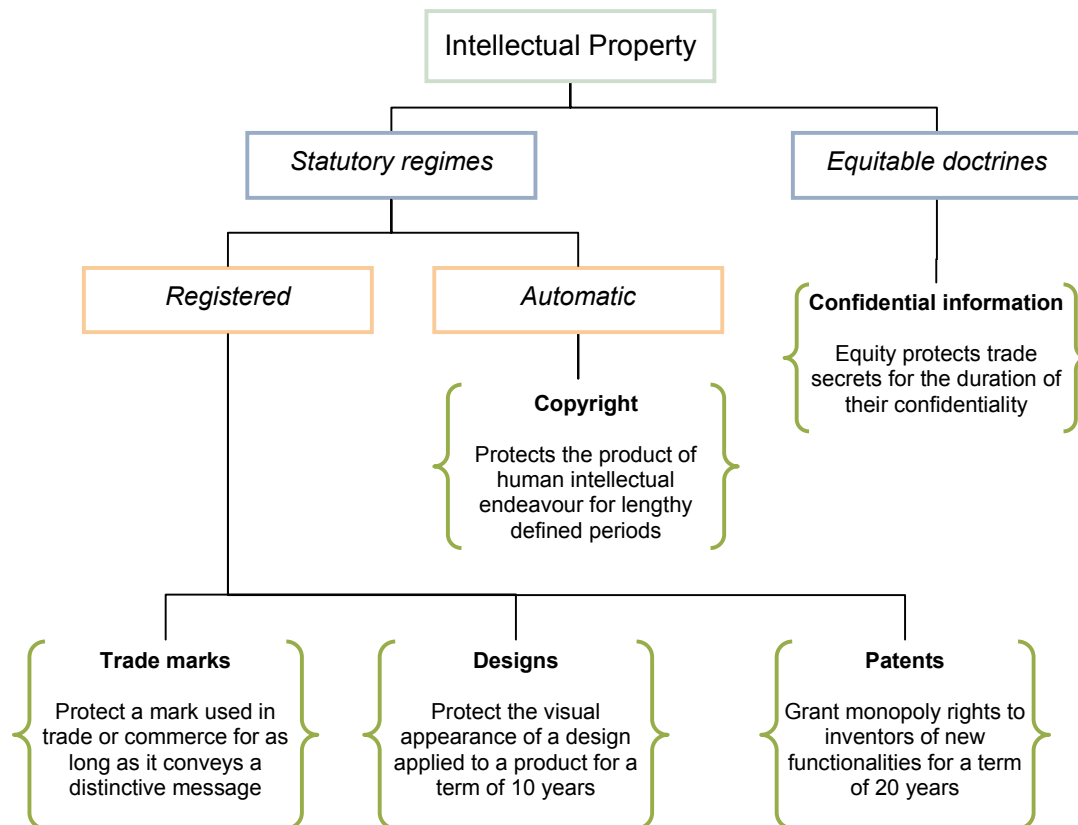
By virtue of colonial supremacy, the 1883 Act was in force in Australia at Federation, until repealed in 1904 by the *Patents Act 1903* (Cth). In England, the *Patents Act 1952* (UK) extended the patent term to sixteen years, and created a formal administrative structure for assessing and processing patent applications. In the years following the United Kingdom's accession to the *European Patent Convention*, Australian and United Kingdom patent laws have progressively diverged.

D Contextualisation

Patents are a form of intellectual property in the same way as copyright and designs. Like the designs regime, rights are conferred by registration and not automatically. Like copyright, but unlike designs (which is supported by trade practices legislation and common law actions in passing off), no patent rights exist outside of the statutory protection.

Patents come in several flavours, each with differing application requirements, renewal fees and associated levels and durations of protection. The two patents considered are the 'standard patent' (20 years, normal registration requirements) and the 'innovation patent' (8 years, streamlined application process).

Patents may be situated within the intellectual property taxonomy in the following manner:



E The Patents Act 1990 (Cth)

1 Broad themes

The Australian patent regime is found in the *Patents Act 1990* (Cth) ('*Patents Act*'). The *Patents Act* contains provisions which, *inter alia*, encompass four broad areas:

- **Requirements of patentability**
When will an invention be eligible for patent protection? (see below Chapter IX);
- **Incidents of protection**
What rights are afforded to a patentee? (see below Chapter X);
- **Infringement**
When will those rights be infringed? (see below Chapter X); and
- **Administrative processes**
How is a patent application made, assessed, granted, opposed or revoked? (see below)

2 Text and structure

The *Patents Act* is structured into several divisions; these are:

- **Chapter 1—Introductory**
Definitions, interpretation, flow chart diagrams and plain English summaries;
- **Chapter 2 — Patent rights, ownership and validity**
Nature of exclusive rights, co-ownership, external validity factors;
- **Chapter 3 — From application to acceptance**
Procedural requirements, examination stages, internal validity factors;
- **Chapter 4 — Publication**
Disclosure of the specification on a public register, &c;
- **Chapter 5 — Opposition to grant of standard patent**
Procedures to challenge acceptance of a patent;
- **Chapter 6 — Grant and term of patents**
Start and end dates of patent grants, duration, and pharmaceutical patent exceptions;
- **Chapter 11 — Infringement**
Acts constituting infringement (supply, use, exploitation, &c), exemptions, causes of action, possible counter-claims, remedies, declarations, unjustified threats;
- **Chapter 12 — Compulsory licences and revocation of patents**
Automatic licensing of patents and loss of patent rights on certain conditions;
- **Chapter 14 — Contracts**
Terms in a contract that are void if contrary to the Act; and
- **Schedule 1 — Dictionary**
A glorified interpretation section; contains definitions of defined terms.

3 Notable features

The *Patents Act* is said to be an example of ‘plain English drafting’. True it is that the Act includes pictorial representations of the patent application procedures through the use of diagrams. True, perhaps, in that it attempts a simplification of the drafting by moving the familiar, easily-accessible ‘interpretation’ section from the beginning of the Act to a new and mysteriously-titled ‘Dictionary’ section at the opposite end. Perplexingly, however, the Act continues to make reference to a 1624 statute of the English Parliament for its definition of ‘method of new manufacture’. That definition is not extracted, and the reader is given no direction as to its location or possible contents.

These features of the Act led it to be characterised by the Prime Minister’s Science and Engineering Council in the following terms:

The *Patents Act* (1990) was drafted in a ‘Plain English’ style that was obviously intended to make this area of law more comprehensible to users of the patent system. Unfortunately, this laudable object has not been achieved and concepts that were previously clear ... are now more difficult to understand and apply. A good example of this can be illustrated with regard to the question of obviousness and inventive step: under the [old legislation], a five line provision set out the ground of obviousness ..., but under the [new legislation] the application of this concept now requires the

reader to 'track' through three separate sections of the Act, refer to the Dictionary in Schedule 1, refer to the *Acts Interpretation Act*, and read more than fifty lines of text.

F International Context

Like copyright, patent protection is territorial: there is no such thing as a 'world patent'. The only way to obtain truly global protection is to seek patents in each jurisdiction for which an invention might conceivably have a market.

As a signatory to the *Agreement on TRIPS*, Australia is obliged to implement its treaty obligations under art 27 of that Agreement, which provide for the protection of patents 'in all fields of technology' subject to three requirements:

- Novelty;
- Inventive step; and
- Capacity for industrial application.

The article also requires that signatories do not discriminate against foreign inventors, particular fields of technology or imported products. However, the article does enable states to retain discretion to exclude any invention from patent protection if it is necessary to protect '[public order] or morality', or to avoid health or environmental damage. Presumably this reservation is directed squarely at situations where pharmaceutical patents can halt a pandemic.

The full text of art 27 reads as follows:

Agreement on TRIPS art 27 — Patentable subject matter:

- (1) ... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
- (2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
- (3) Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. ...

Article 28 of the *Agreement on TRIPS* sets out the content of protection required to be afforded to patentable subject matter:

Agreement on TRIPS art 28 — Rights Conferred:

- (1) A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
- (2) Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 30 also confers upon signatories the ability to create limited exemptions from infringement.

Agreement on TRIPS art 30 — Exceptions to Rights Conferred:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The *Paris Convention* is roughly analogous to the *Berne Convention* for copyright. That is to say, it precedes *TRIPS* and is incorporated into it. The chief features of the *Paris Convention* are its provision for equal treatment of foreign inventors and its recognition of the authority of foreign priority dates.

The other major international instrument relating to patent protection is the *Patent Co-operation Treaty 1970* ('*PCT*'). The *PCT* is a largely symbolic agreement that provides for a common application framework. The framework enables a prospective patentee to apply to multiple jurisdictions with a single application, thereby streamlining the formalities required for the grant of patents. However, it does not have any substantive effect upon the domestic laws of signatories. The rights granted under a co-operative application remain territorial, and an application must still be made with respect to each jurisdiction in which the patentee seeks protection.

G Policy Themes

Cornish has made six observations of the policy themes emerging in contemporary patent law:

- (a) **Basic and applied research**
In grants concerning technological improvements, the line between applied and basic research is becoming increasingly blurred (see, eg, *University of Rochester*);
- (b) **Term of protection**
The patent has been the subject of gradual extension to a term now of 20 years, accompanied by broad rights of exploitation and use;
- (c) **Priority dates**
Priority is traditionally given to the first person to file a patent application ('the first to file approach'); however, the position differs in the United States;
- (d) **Economic miscorrelation**
The legal protection afforded to a patent is unrelated to its economic value; a useless or almost useless invention is given the same rights and protection as one that is intrinsically beneficial;
- (e) **Economic policy**
'Unquestionably' economic policy objectives are behind the development of the modern patent system; and
- (f) **Fairness**
At times, the patent system is a blunt instrument, particularly as applied to developing economies, and may unfairly hinder growth in many cases.

H The Discovery–Invention Distinction

Patent protection is not afforded to mere discoveries because these are not 'manner[s] of new manufacture' or 'invention[s]'. Instead, protection is reserved for the practical applications of such discoveries in the form of products or methods.

This requirement — that a discovery be put to some use — is sometimes referred to as the distinction between discovery and invention: discovery, it is said, is mere knowledge, but an invention requires application. This involves a level of human intervention. Thus, patent law rarely — subject to some exceptions — protects genes or chemical substances *per se*, unless, for example, the isolation of those compounds is itself an inventive application of their discovery. This may be the case where, for example, those compounds do not naturally occur in isolation.

The discovery–invention distinction has been likened to its dichotomous cousin, the idea–expression dichotomy in copyright law. The principle in patent law is perhaps not as granular as its copyright equivalent, in that a patent will not subsist in an invention at all if it is not inventive, whereas copyright may subsist in a work to the extent of its expression. True it is that all inventions embody or rely upon some discovery, but it seems artificial to separate the discovery from its application in many cases. Rather, the question which must be asked is simply whether the claim, in its present form, discloses a manner of manufacture such as to be patentable.

I Registration Requirement

To obtain patent rights in relation to an invention, it is necessary to register that invention. This occurs by way of application to the Registrar of Patents for inclusion on the Register. In the event of a successful patent grant, the functionality of the invention is protected for the applicable term to the extent of the claims and specifications disclosed in the patent application. In the case of a standard patent, this term is 20 years from the date of the grant.

The requirement of registration means that patent rights arise only by virtue of registration. This is a system of title by registration — that is, title is obtained by registration, rather than registration taking place of some pre-existing title. In this sense, the patent registration system is more similar to the Register of Designs, the Register of Trade Marks and the Torrens system. This requirement has no counterpart in the law of copyright, which rights are conferred automatically upon the fulfilment of certain subsistence conditions.

However, unlike the Torrens system registration is no guarantee of validity: *Patents Act* s 20. Registration is *prima facie* evidence of validity, but this is always subject to challenge, whether under ss 121 (counterclaim for invalidity in an infringement proceeding), 138 (grounds for revocation) or otherwise.

J Examples

1 Golf ball holder

This patent defines a product, being a golf ball holder:

CLAIMS —

- (1) A golf ball holder comprising:
 - (a) a tube open at one end,
 - (b) whose diameter is less than the diameter of a golf ball, and
 - (c) which tube is made from a resilient, elastic material, such that
 - (d) the tube will expand around the ball and 'neck' in front of and behind the ball to retain that ball.
- (2) A golf ball holder in claim 1 where the tube is made of a foam material.
- (3) A golf ball holder in claim 2 where the foam material is laminated with a fabric so that the tube has greater resilience along its axis rather than its circumference.

This invention may be thought of as a new use (namely, storing gold balls) for a known thing (namely, elastic neoprene material). It combines known things (material in cylindrical design) to produce an invention that serves a function, being the function of storing golf balls.

Note that the claims are listed in increasing order of specificity, and that the first claim comprises four distinct integers.

Issue: would the following products infringe any of these claims?

A tubular golf ball container which fits loosely around the balls, sealed at one end and with a zipper at the other.

In order to infringe a claim, it must embody all its essential integers. In the case of claim 1, the issue is whether a zipper end can be regarded as 'open', such as to make the container embody claim 1 integer (a). If a purpose interpretation of that integer is adopted, the skilled addressee would regard the open end as being necessary for the insertion of the balls. The zippered end is also capable of having balls inserted through it, and so may be treated as embodying the integer.

The second issue is whether 'fit[ting] loosely around the balls' can have a diameter less than the diameter of a golf ball. This seems difficult to argue, and also makes it unlikely that claim (c) is embodied. For this reason, the product probably does not infringe claim 1. For the same reasons, it is unnecessary to consider claims 2 or 3.

An open golf ball pocket made from elastic material attached to a golf club bag and the side of the bag forms the inner wall of the pocket.

In relation to claim 1, the primary issue is whether an open pocket, one of whose ends is covered by another object, amounts to 'a tube open at one end'. Integer (a) does not specify whether the tube must actually be sealed at one of the ends. However, it is unlikely that a skilled addressee (someone skilled in the art of sports equipment design) would regard the requirement that it be closed at one end as inessential — otherwise, balls could easily fall out the bottom end. However, even if, on a construction of the terms of integer (a), a golf club bag could be treated as making the inner wall closed, the pocket would only exhibit this integer when paired with the bag, and not on its own. For this reason, although the other integers are embodied, it is unlikely that claim 1 would be infringed.

A tubular squash ball holder made from elastic nylon material which fits snugly around the balls and open at both ends.

A similar issue arises in relation to claim 1, the first integer of which refers to a tube 'open at one end'. This product, although a tube, is open at two ends. For this reason alone, it probably does not exhibit the first integer. However, assuming the contrary is true: claim 1 is expressly described to be for the storage of a 'golf ball'. The precise type of ball being stored would probably not be regarded as essential by a skilled addressee — so long as the ball that was being stored is of similar dimensions to the golf ball. Thus, despite the fact that the term 'golf ball' is used twice in the body of claim 1, a squash ball container — being of a similar diameter to a golf ball — may embody the second integer. Assuming that nylon is 'resilient', it is also elastic, and would embody integers (c) and (d). However, 'nylon' not being 'foam' it would not infringe claims 2 or 3.

A tube made from pig bladder, with an opening at one end, the tube diameter less than golf ball diameter whereby the bladder expands and necks around a golf ball.

Claim 1 is clearly infringed, being a tube made from a resilient, elastic material with a diameter less than a golf ball, the tube open at one end, and the tube capable of expanding around inserted balls to store them. The issue is whether 'pig bladder' can be regarded as a type of 'foam' and thereby infringe claim 2. The *Concise Oxford Dictionary* defines 'foam' as '(1) a collection of small bubbles formed in liquid by agitation; ... (2) rubber or plastic in a cellular form'. Rubber, in turn, is a type of synthetic elastic material. If pig bladder is actually made from rubber, then, being in cellular form, it may be construed as falling within the term 'foam', and thereby infringe claim 2. However, a pig bladder is presumably made from organic cells and not the product of a rubber tree, so, although cellular, could not be said to be foam.

2 Light bulb

The following example illustrates how a complete patent might be worded. First, the specification:

COMPLETE SPECIFICATION FOR THE INVENTION ENTITLED: 'LOW-PRESSURE MERCURY VAPOUR DISCHARGE LAMP' —

The invention relates to a low-pressure mercury vapour discharge lamp having a vacuum-tight radiation-permeable envelope provided with a luminescent layer, a gas filling comprising mercury and a rare gas, and means for maintaining a column discharge in the gas filling, the power consumed by the column being at least 500 W/m² surface area of the luminescent layer.

Low-pressure mercury vapour discharge lamps are radiation sources which are used on a very large scale both for general illumination and for special purposes (for example, activating photochemical processes), because they convert the electric power supplied very efficiently into radiation.

In general these lamps consist of a tubular envelope, which may be straight or curved, for example in the form of a circle or U-shaped. This envelope contains a gas mixture comprising mercury and one or more rare gases in which a column discharge is produced. This column discharge is maintained by supplying electric energy to the gas mixture, usually through two electrodes.

Mainly ultra-violet radiation is produced in the discharge, a comparatively small part of which radiation has wavelengths of approximately 185 nm, the greatest part of the radiation having wavelengths of approximately 254 nm. This ultra-violet radiation is converted by means of a luminescent layer located on the inner wall of the lamp envelope, into radiation having a longer wavelength and a spectral distribution, depending on the luminescent material used, in the near ultra-violet or in the visible part of the lamp ...

The specification forms 'the inventive disclosure' of the patent. That is, it sets out the manner in which the invention operates in sufficient detail to enable an informed reader to implement the invention themselves.

Now, the claims:

CLAIMS FOR THE ABOVE-DESCRIBED INVENTION —

- 1 A low-pressure mercury vapour discharge lamp having a vacuum-tight, radiation-permeable envelope bearing a luminescent layer and containing a gas filling comprising mercury and a rare gas, and means for maintaining a column discharge in the gas filling, the power consumed during operation by the column discharge being at least 500 W/m^2 surface area of the luminescent layer.
- 2 An invention as described in claim 1, wherein the luminescent layer contains a luminescent material which has the property of having at 254 nm-excitation a luminous flux which, after the material has been subjected for 15 minutes to ultraviolet radiation consisting substantially of the wavelengths 185 and 254 nm, having a radiation density between 150 and 500 W/m^2 and having a ratio of 185 nm power to 254 nm power between 0.20 and 0.40, is not more than 5% lower than the initial luminous flux of the material at 254 nm excitation and measured under identical circumstances.
- 3 An invention as described in claim 2, wherein the combination of cations (as hereinbefore defined) in the luminescent material has an electronegativity of not more than 1.4.

As may be gathered from this example, the claims define the scope of the monopoly. They are typically structured as a series of claims of increasing specificity. This way, if one of the more general claims is invalidated, the remaining (more specific claims) may still be valid. In general, this will mean that a patent is hindered by invalidity to the minimum extent possible.

III Application Process

A Nature and Scope

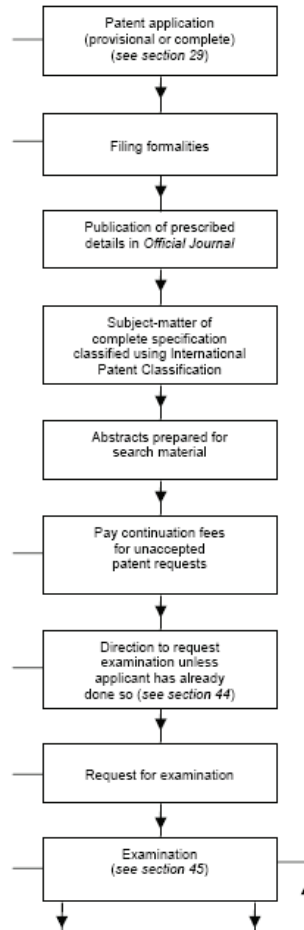
The patent system protects the functionality of an invention for a limited term. Registration of an invention is necessary in order for any patent rights to exist in respect of it. An application is necessary for registration. The *Patents Act* sets out the procedures and requirements involved in such an application:

Patents Act 1990 (Cth) s 4 — What are the typical steps in getting and maintaining a standard patent?

The following diagram shows most of the typical steps involved in getting and maintaining a standard patent. ...

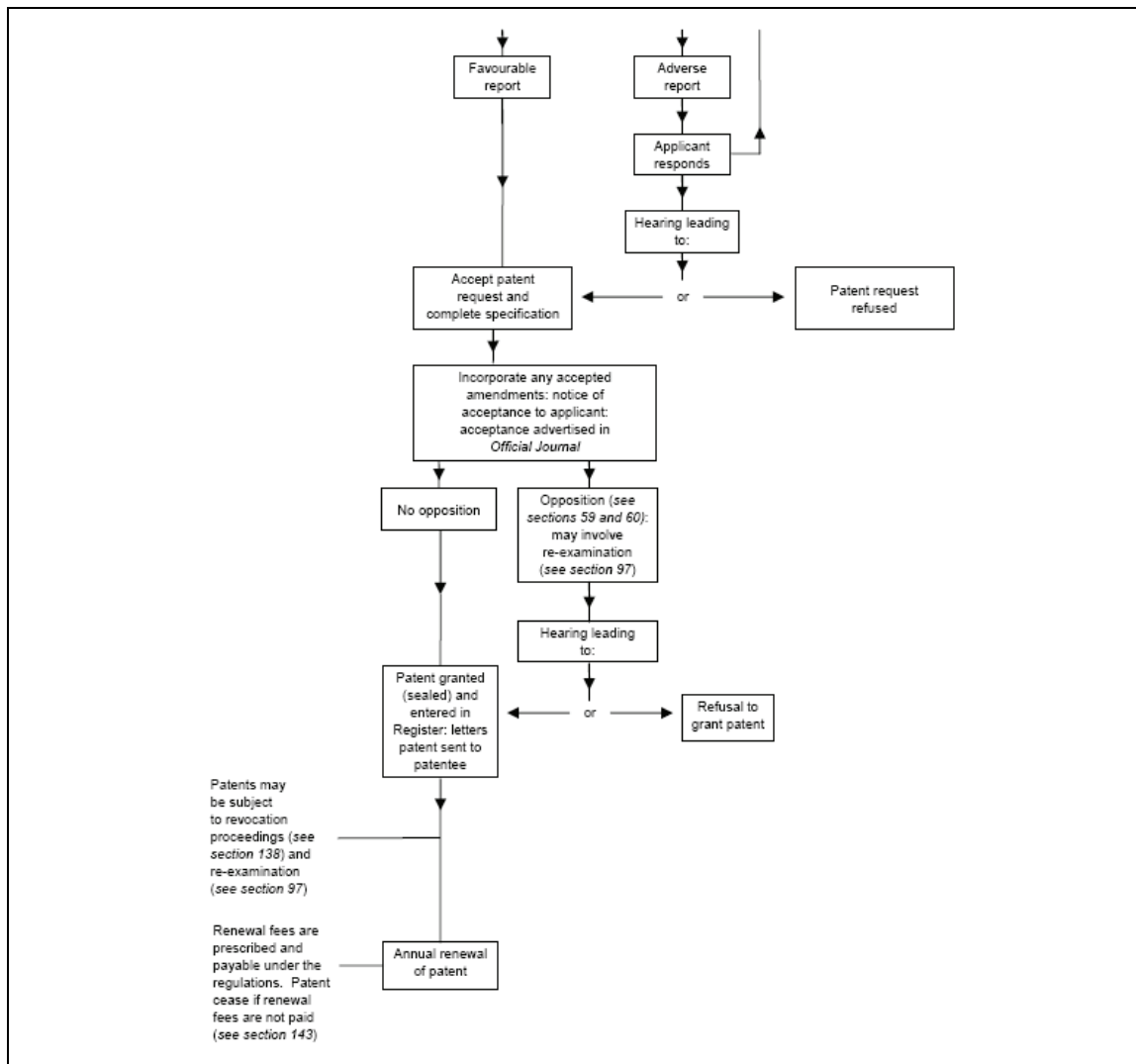
TABLE 1—GETTING AND MAINTAINING A STANDARD PATENT

Fee payable.
A complete application must be associated with a provisional application within the prescribed period.
Provisionals which lapse at this stage are not published.
Applicant may be required to correct deficiencies. Application will lapse if applicant does not comply.



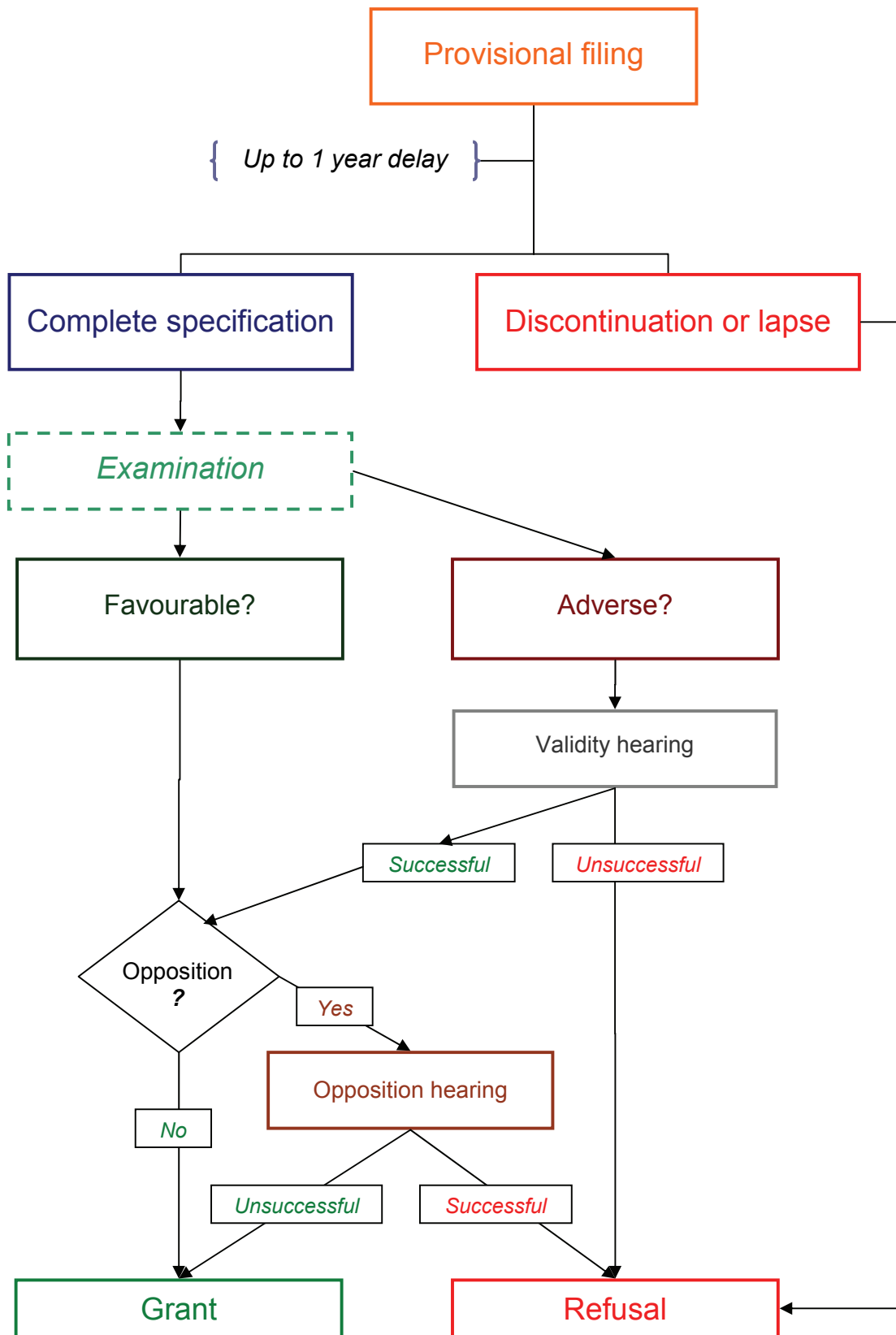
Continuation fees are prescribed and payable under the regulations.
Applications lapse if continuation fees are not paid (see section 142).
Applicant must request examination as directed or application will lapse (see section 142).

Fee payable.
Application lapses if patent request and complete specification not accepted within the prescribed period (see section 142).



This diagram is perhaps not as helpful as its designers intended. The process may more usefully be described as follows in the diagram overleaf. The essential phases of application are:

- **Filing**
A complete application, or a provisional application followed by a complete application;
- **Examination**
For validity, by the Commissioner of Patents and associates;
- **Opposition**
A hearing to determine an application opposed by an interested party;
- **Grant of letters patent**
Successful issue of the patent and publication of the filed specification; and
- **Revocation**
The grant of the patent does not guarantee its validity; it may later be revoked.



B Basic Concepts

1 Types of patents

There are two types of patents whose existence is provided for under the *Patents Act*:

Patents Act 1990 (Cth) sch 1 — Dictionary:

patent means a standard patent or an innovation patent.

Standard patents occupy the bulk of our focus in this and subsequent Chapters. Innovation patents are dealt with briefly in section D below.

2 Specification

A patent specification describes the nature of the invention, the state of the prior art and the 'thing' that is said to embody the inventiveness claimed. The specification will normally be a technical document referring with specificity to the functioning of the claimed invention.

3 Claims

Patents confer rights to the extent of the claims for which the patent is granted. In this way, claims define the boundaries of a grant of letters patent. They specify the scope of the invention as legal property. Further details about the nature of a claim are provided in Chapter X below.

More specifically, a claim is a part of the complete specification of a patent, or application for a patent, that states the particulars of the claimed invention. This is why it is called a 'claim': it represents the format in which inventiveness is 'claimed' in relation to an invention. This is essentially the definition given in sch 1 to the *Patents Act*:

Patents Act 1990 (Cth) sch 1 — Dictionary:

claim means:

- (a) when used as a noun in relation to a patent — a claim (including a dependent claim) of the specification relating to the complete application on which the patent was granted; and
- (b) when used as a noun otherwise than in relation to a patent — a claim (including a dependent claim) of a complete specification; and
- (c) when used as a verb — to claim in a claim (including a dependent claim) of a complete specification.

Because of their intrinsic link to patent validity, it is crucial to use precise language in patent claims. As will be seen below, even minor differences in expression can have far-ranging implications for the validity of a patent, or for success in a subsequent infringement proceeding.

For this reason, the subtleties and complexities arising out of claim drafting are best handled by a specialist legal professional, and claims are typically drafted by a patent attorney.

C Procedural Features

1 Eligibility for application

Anyone may apply for a patent, whether an inventor or not: s 29(1). Potential applicants include both a body corporate and a natural person: s 29. The application may be provisional, meaning that it does not include claims, or complete: s 29(2). However, it must be in the approved form in either case: ss 29(3), (4):

Patents Act 1990 (Cth) s 29 — Application for patent:

- (1) A person may apply for a patent for an invention by filing, in accordance with the regulations, a patent request and such other documents as are prescribed.
- (2) An application may be a provisional application or a complete application.
- (3) A patent request in relation to a provisional application must be in the approved form and accompanied by a provisional specification.
- (4) A patent request in relation to a complete application must be in the approved form and accompanied by a complete specification.
- (5) In this section:

person includes a body of persons, whether incorporated or not.

Although anyone may *apply* for a patent, a patent can only be granted to specified classes of eligible people. Section 15(1) specifies who may be eligible to receive a grant of letters patent:

Patents Act 1990 (Cth) s 15 — Who may be granted a patent?:

- (1) ... a patent for an invention may only be granted to a person who:
 - (a) is the inventor; or
 - (b) would, on the grant of a patent for the invention, be entitled to have the patent assigned to the person; or
 - (c) derives title to the invention from the inventor or a person mentioned in paragraph (b); or
 - (d) is the legal representative of a deceased person mentioned [above].
- (2) A patent may be granted to a person whether or not he or she is an Australian citizen.

Sub-section 15(2) implements Australia's non-discrimination obligations pursuant to the *Agreement on TRIPS* by permitting patent grants to be made to non-citizens.

The notion of an 'inventor' under *Patents Act* s 15(1)(a) is similar to that of an 'author' of works under the *Copyright Act*. An inventor must be human (that is, a natural person), and their invention must be the result of an exercise of some inventive faculty — an emanation of the intellect.

2 Examination

A patent must be examined before it can be enforced. This can occur at the request of the applicant (reg 3.17(2)) or by the suggestion of the Commissioner (ss 44(2)–(4)). Examination must have been requested within five years of filing the complete specification (s 44(1); reg 3.15), or within six months of a direction so to request (s 44(2); reg 3.16(2)). Otherwise the application lapses: s 142(2)(a).

The criteria for examination are specified in *Patents Act* s 45. Section 45(1)(d) provides that additional criteria may be prescribed by regulation. If these are read alongside the s 45(1) factors, the criteria include whether:

- the person to be granted the patent is eligible under s 15;
- the application satisfies the requirements of form set out in s 29;
- the content of the specification is internally valid within s 40;
- the invention is a 'manner of new manufacture': s 45(1)(b);
- the invention is novel: s 45(1)(c)(i);
- the invention involves an inventive step: s 45(1)(c)(ii);
- the invention is excluded from patentability under s 18(2);
- the application could be refused under s 50; and
- the application contravenes s 64(2), which prevents 'double patenting'.

Importantly, the examiner does not consider issues of utility or secret use. Section 45 simply reads:

Patents Act 1990 (Cth) (Cth) s 45 — Examination:

- (1) Where an applicant asks for an examination of a patent request and complete specification relating to an application for a standard patent, the Commissioner must examine the request and specification and report on:
 - (a) whether the specification complies with section 40; and
 - (b) whether, to the best of his or her knowledge, the invention, so far as claimed, satisfies the criterion mentioned in paragraph 18(1)(a); and
 - (c) whether, to the best of his or her knowledge, the invention, so far as claimed in any claim and when compared with the prior art base as it existed before the priority date of that claim:
 - (i) is novel; and
 - (ii) involves an inventive step; and
 - (d) such other matters (if any) as are prescribed.

3 Grant

Upon the acceptance of an application, the patent is sealed: *Patents Act* ss 61 (standard patents) and 62 (innovation patents):

Copyright Act 1968 (Cth) s 61 — Grant of standard patent:

- (1) Subject to section 100A, the Commissioner must grant a standard patent, by sealing a standard patent in the approved form, if:
 - (a) there is no opposition to the grant; or
 - (b) in spite of opposition, the Commissioner's decision, or the decision on appeal, is that a standard patent should be granted.
- (2) A standard patent must be granted within the prescribed period.

The prescribed period under s 61(2) is six months within the advertisement of the acceptance: reg 6.2. Section 62 sets out a similar provision, excepting that the innovation patent issues immediately:

Copyright Act 1968 (Cth) s 62 — Grant and publication of innovation patent:

- (1) If:
 - (a) the Commissioner accepts a patent request and complete specification filed in respect of an application for an innovation patent; and
 - (b) a prohibition order is not in force under subsection 152(3) or 173(1) in relation to the application;
 - (c) the Commissioner must grant the innovation patent by sealing an innovation patent in the approved form.
- (2) If an innovation patent is granted, the Commissioner must publish a notice in the *Official Journal* stating that:
 - (a) the innovation patent has been granted; and
 - (b) the patent request and complete specification are open to public inspection.

4 Divisional applications

A divisional application grants an applicant the opportunity to make a further application for a patent in respect of an invention already disclosed in the complete specification of an earlier application. This earlier application is referred to as the 'parent' application. The divisional application may concern either a standard or an innovation patent: *Patents Act* s 79B.

Patents Act 1990 (Cth) s 79B — Divisional applications prior to grant of patent:

- (1) If a complete patent application for a patent is made (but has not lapsed or been refused or withdrawn), the applicant may, in accordance with the regulations, make a further complete application for a patent for an invention:
- (a) disclosed in the specification filed in respect of the first-mentioned application; and
 - (b) where the first-mentioned application is for a standard patent and at least 3 months have elapsed since the publication of a notice of acceptance of the relevant patent request and specification in the *Official Journal* — falling within the scope of the claims of the accepted specification.
- (1A) The reference to a complete patent application first-mentioned in subsection (1) does not include a reference to a divisional application for an innovation patent provided for in section 79C.

Section 79(1A) has the effect of preventing a divisional application for a standard patent from being lodged in relation to an existing application for an innovation patent. That is, an innovation patent cannot be 'converted into' a standard patent midway through the application process.

Section 79C sets out the circumstances in which a divisional application may be made in relation to an existing innovation patent:

Copyright Act 1968 (Cth) s 79C — Divisional applications for innovation patents may be made after grant of an innovation patent:

Applications may be made

- (1) A patentee of an innovation patent (the **first patent**) may make a complete application for another innovation patent for a further invention disclosed in the first patent if the invention was disclosed in the complete specification filed in respect of the application on which the first patent was sealed.

When further applications must be made

- (2) The patentee may only make the further complete application during the period that commences on the day an examination of the first patent begins and ends at the end of a period prescribed in the regulations.

When does an examination begin?

- (3) For the purposes of subsection (2), an examination of the patent begins:
- (a) if the examination has been requested under paragraph 101A(b) — on the day the request was made; or
 - (b) if the Commissioner decided to examine the patent under paragraph 101A(a) — on the day the Commissioner made that decision.

5 Duration

The duration of patent protection is defined in ss 67 (standard patents) and 68 (innovation patents) as 20 and 8 years, respectively.

Patents Act 1990 (Cth) s 67 — Term of standard patent:

The term of a standard patent is 20 years from the date of the patent.

Patents Act 1990 (Cth) s 68 — Term of innovation patent:

The term of an innovation patent is 8 years from the date of the patent.

The phrase 'date of patent' is defined in s 65 to mean the date from the filing of the complete specification. However, note that this does *not* extend to the filing of the provisional specification.

Section 57 provides that the exclusive rights of a patentee are effective from the date on which a specification is published. This means that rights may be held prior to grant, subject to sub-s (2):

Patents Act 1990 (Cth) s 57 — Effect of publication of complete specification:

- (1) After a complete specification relating to an application for a standard patent has become open to public inspection and until a patent is granted on the application, the applicant has the same rights as he or she would have had if a patent for the invention had been granted on the day when the specification became open to public inspection.
- (2) Subsection (1) does not give the applicant a right to start proceedings in respect of the doing of an act unless:
 - (a) a patent is granted on the application; and
 - (b) the act would, if done after the grant of the patent, have constituted an infringement of a claim of the specification.

6 Revocation

The grant of a patent is no guarantee of its validity: *Patents Act* s 20. Although it may have passed through the initial examination, and been unopposed, it may still be the case that it should never have been granted. For this reason, the *Patents Act* provides for a mechanism that allows any interested person to challenge the validity of a patent on the Register.

Any interested Australian citizen will have standing to challenge a patent. They need simply bring an action to revoke it from the Register. The Court sits in the same position as the Court in *Darcy v Allin*, being called upon to decide whether the grant of the monopoly is appropriate in light of the Registrar's statutory power to do so. This decision is *de novo* — that is, none of the preceding steps in the application are relevant.

Upon the activation of the appropriate procedure, a patent may be revoked by the Federal Court of Australia or by the Commissioner. The Court may act either on petition of the Minister or of any other person: *Patents Act* s 138.

Section 138(3) of the *Patents Act* sets out the grounds for revocation. They are that:

- (a) the patentee is not entitled to the patent;
- (b) the invention is not patentable;
- (c) the patentee has contravened a condition in the patent;
- (d) the patent was obtained by fraud or misrepresentation;
- (e) an amendment to the request or specification was made or obtained by fraud or misrepresentation; or
- (f) the specification does not comply with the requirements of s 40.

In practice, the two grounds of primary relevance are that the invention is not patentable (within the meaning of the s 18 external validity factors) and that the specification fails one or more of the internal validity requirements set out in s 40.

7 Counter-claim

The most common petitioner for revocation is, unsurprisingly, a defendant accused of infringing a patent. Typically this occurs by way of counterclaim in a proceeding against that party for alleged infringement of the patent:

Patents Act 1990 (Cth) s 121 — Counter-claim for revocation of patent:

- (1) A defendant in infringement proceedings may apply by way of counter-claim in the proceedings for the revocation of the patent.
- (2) The provisions of this Act relating to proceedings for the revocation of a patent apply, with the necessary changes, to a counter-claim.

Revocation by virtue of invalidity is the archetypal 'defence' in a proceeding for patent infringement. This pattern of infringement–counter-claim–revocation is quite common in the case law, and will frequently be observed in the analysis that follows.

D Innovation Patents

Innovation patents are a variant on the standard patent. They offer cheaper, quicker protection to sole inventors and small businesses, albeit for a shorter term, and a simplified application procedure. They replace the petty patent system.

1 *Old regime: petty patents*

Under the petty patent regime there was no substantive examination or opposition. A petty patent could be filed and then later upgraded by applying for a standard patent. There were no subject matter restrictions upon petty patents; the only requirement was that they contain no greater than three claims. Infringement proceedings were able to be commenced from the date of grant.

Petty patents were useful in that they could be granted more rapidly than a standard patent. However, the term of protection was a comparatively six years.

2 *New regime: innovation patents*

The innovation patent provisions abolish the petty patent system and create a new alternative to standard patent protection. The new second-tier patent still confers a shorter term of protection, but this has been increased to 8 years.

The primary distinction between innovation patents and standard patents relates to the external validity requirements: where standard patents require an 'inventive step', innovation patents require an 'innovative step'. The standard of 'innovativeness' is unclear, though presumably lower than 'inventiveness'.

Innovation patents are granted automatically upon their filing. If the formalities have been complied with, the patent will immediately be issued. This is a fairly controversial aspect of the system, as it allows patents to be granted without prior examination. This has led to some patents being granted that were clearly invalid. For example, John Keogh famously sought innovation patent protection for the wheel:

(12) GRANTED INNOVATION PATENT		(11) Application No. AU 2001100012 A4	
(19) AUSTRALIAN PATENT OFFICE			
(54)	Title Circular transportation facilitation device		
(51) ⁷	International Patent Classification(s) B60B 001/00		
(21)	Application No: 2001100012	(22)	Application Date: 2001.05.24
(45)	Publication Date: 2001.08.02		
(71)	Applicant(s) John Keogh		
(72)	Inventor(s) Keogh, John Michael		
(74)	Agent/Attorney Sandercock Cowie 69 Robinson Street Dandenong Victoria AU		

However, despite the automatic nature of the grant, an innovation patent cannot be enforced until a procedure known as certification has occurred. Certification occurs by way of examination. Consequently, before infringement proceedings can be brought on the basis of an innovation patent, it must be examined for validity in the same way as a standard patent (albeit subject only to the validity factors befitting an innovation patent).

E Ownership Rights

1 Co-ownership

A patent may be owned by more than one person: s 16(1). The rights will be held as joint tenants in 'equal undivided share[s]': s 16(1)(a). Each patentee will be entitled to deal independently with the patent as its exclusive owner. However, subject to sub-section (2) it may not be licensed or assigned without the consent of all patentees:

Patents Act 1990 (Cth) s 16 — Co-ownership of patents:

- (1) Subject to any agreement to the contrary, where there are 2 or more patentees:
 - (a) each of them is entitled to an equal undivided share in the patent; and
 - (b) each of them is entitled to exercise the exclusive rights given by the patent for his or her own benefit without accounting to the others; and
 - (c) none of them can grant a licence under the patent, or assign an interest in it, without the consent of the others.
- (2) Where a patented product, or a product of a patented method or process, is sold by any of 2 or more patentees, the buyer, and a person claiming through the buyer, may deal with the product as if it had been sold by all the patentees.
- (3) This section does not affect the rights or obligations of a trustee or of the legal representative of a deceased person, or rights or obligations arising out of either of those relationships.

By sub-section (1), the default incidents of joint ownership under paragraphs (a), (b) and (c) may be overridden by prior agreement, as commonly occurs in employment or academic contexts.

Sub-section (2) appears to provide that any assignment by two or more patentees will entitle the purchaser (and any reliant parties) to treat that assignment as effective notwithstanding the fact that others may not have consented to the assignment.

Sub-section(3) simply provides that a patent that is held on trust is subject to the normal incidents of trusteeship, viz, duties imposed upon the trustee not to profit from its use without consent, and not to bring him or herself into a position of conflict with his or her duties as trustee.

2 Joint applications and ownership

Similarly, joint applications may be made by any two or more people: *Patents Act* s 31. However, this is not strictly required since the grant of letters patent may be to both inventors despite being applied for only by one.

Patents Act 1990 (Cth) s 31 — Joint applicants:

2 or more persons (within the meaning of section 29) may make a joint patent application.

The resulting patent is owned jointly by the applicants as joint patentees: *Patents Act* s 63.

Patents Act 1990 (Cth) s 63 — Joint patentees:

A patent may be granted to 2 or more nominated persons jointly.

3 *Assignment*

A patentee has the right to allow others to exploit their invention by way of assignment: *Patents Act* s 14(1). To be effective, such an assignment must be in writing and signed by the parties to be charged:

Patents Act 1990 (Cth) s 14 — Assignment of patent:

- (1) An assignment of a patent must be in writing signed by or on behalf of the assignor and assignee.
- (2) A patent may be assigned for a place in, or part of, the patent area.

Section 14(2) provides for some level of divisibility in patent rights. Although not as extensive as the divisibility of, say, copyrights, it appears that a patent may be assigned with respect only to a geographic region.

Further, the Court in *National Phonograph v Menck* held that assignments and licences of patents may be limited in any way. Naturally, this is subject always to legislative prohibition (eg, by the *Trade Practices Act*).

4 *Right to obtain registration*

One interesting (if largely theoretical) question is that concerning the nature of the right to obtain registration under the *Patents Act*. Is it an equitable right or a mere equity? If the latter, is it proprietary or non-proprietary? This author would liken the prospective right to amend the Register as akin to an equity of rectification in the context of Torrens title land, and as such, a personal mere equity that converts to a full equitable interest upon the fulfilment of certain conditions: see, eg, *Latec*. The issue remains a live one.

5 *Importation*

Case law from the United Kingdom in the early twentieth century evidenced a treatment of importers as relevant 'inventor[s]' for the purposes of the *Patents Act*. This notion was expressly rejected in the *Patents Act 1952* (UK).

Unlike historical patent legislation, importers of inventive products are no longer treated as inventors themselves. Strange though it may sound to the modern scholar of patent law, such treatment was previously regarded as a routine incentive to encourage the flow of goods between nations. As international trade became progressively easier and less restrictive, market forces began to provide sufficient incentive of their own to import useful items. Consequently, an importer will no longer be granted any special protection under the *Patents Act*. To the contrary, importation of a patented article may well amount to an indirect infringement of the patentee's rights: see below Chapter X.

6 Competition law and patents

Note competition issues arising from the grant of licences that are tied to other conditions, such as sourcing materials for manufacture from the licensor: see especially *Trade Practices Act 1974* (Cth) s 46.

E Licensing

1 Voluntary licences

A licence is defined by the Dictionary to the *Patents Act* as follows:

Patents Act 1990 (Cth) sch 1 — Dictionary:

licence means a licence to exploit, or to authorise the exploitation of, a patented invention.

In essence, a licence permits the licensee to do something that would otherwise infringe the patent. Licences may be qualified in any way, and provide for any number of conditions upon the type, kind, extend or other nature of the exploitation that they purport to authorise.

Much of the commercial advantage associated with the grant of a patent is derived from the capacity of the patentee to license aspects of its exploitation. The effective and precise delineation of licence terms is therefore crucial.

Licensing serves three main purposes. First, it permits market specialisation. Companies that focus on research and development, for example, may not wish actually to exploit the results of their research, and may instead license the right to do so to a third party manufacturer, such as a pharmaceutical company. Second, it permits partnership or joint venture arrangements for the shared exploitation of patent rights by a patentee and non-patentee simultaneously. Third, it permits the temporary or partial transfer of technology from one person to another.

Note that a licence may only be granted in respect of a jointly-owned patent if all co-owners consent to its grant: *Patents Act* s 16(1)(c).

There are no formalities requirements for the grant of a licence. Thus, it need not necessarily be in writing, and can instead be oral or implied from a party's conduct.

Section 187 of the *Patents Act* permits licences to be registered, which registration is taken as evidence of the licence agreement. It also protects a licensee from the otherwise good title that

would pass to a *bona fide* purchase of the licensed patent without notice of the interest of the prior licensee.

If a licence purports to apply for a period going beyond the term of the patent monopoly, either party will be granted a statutory right of termination upon the expiration of the patent: ss 145(1), (2).

2 Compulsory licences

Chapter 12 of the *Patents Act* set out the provisions for compulsory licensing of patents. These provisions permit the Federal Court of Australia to grant a licence to an applicant in circumstances where the patentee has failed to make his or her invention available to the market.

Such an applicant must establish that:

- Three years have passed since the sealing of a patent;
- The patentee has failed to satisfy the 'reasonable requirements of the public';
- The patentee has give no satisfactory reason for failing to exploit the patent (*Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp*); and
- He or she has attempted unsuccessfully to obtain a licence from the patentee using reasonable measures (*Patents (World Trade Organization) Amendments Act 1994* (Cth); pursuant to *Agreement on TRIPS* art 31).

In these circumstances, if the Court considers it just, an order will be made to grant a compulsory licence to the applicant: s 133; reg 12.1. The order must provide for reasonable payment to be made to the patentee.

As a result of recent reforms in the *Intellectual Property Law Amendment Act 2006* (Cth) sch 8, a new ground for compulsory licensing has been added, which commenced on 28 September 2006. This ground provides that a violation of pt IV of the *Trade Practices Act 1974* (Cth) is a basis for the grant of a compulsory licence under ss 133–140.

F Crown Use

Chapter 17 of the *Patents Act* deals with use of patents by the Crown. Because patents are monopolies issued by the Crown, they are subject to the condition that the Crown is able to reserve patents for itself and to exploit them as it sees necessary. Sections 161–72 provide for various uses of patents by the Crown:

- Compulsory acquisition: *Patents Act* s 171;
- Assignment to the Crown: *Patents Act* s 172; and
- Exploitation of a patent, or pending patent, by the Commonwealth or a state without infringement, or authorisation of another person so to do: s 163.

Exploitation is subject to the caveat that the use be 'for the services of the Commonwealth or State'. This will be where such exploitation is 'necessary for the proper provision of those services': s 163(3).

Pursuant to s 51(xxxi) of the *Constitution*, any acquisition of property by the Crown must be on just terms. Consequently, principles of eminent domain and fair remuneration apply to any acquisitions under these provisions.

G Recent Reforms to Patent Law

The *Intellectual Property Laws Amendment Act 2006* (Cth) is now in force, having received royal assent on 27 September 2006. It creates several new exceptions and defences to patent infringement, and amends several provisions relating to remedies and statutory licences.

These changes are summarised as follows:

- **Introduction of the prior use defence**
An alleged infringer who has used the invention prior to the priority date has a defence to an action in respect to the continuation of those activities after grant of the patent: s 119;
- **Regulatory approval of generic manufacturers**
Exploitation of invention will not infringe if it occurs for the purposes of obtaining regulatory approval; for example, to establish 'bio-equivalence' of the generic medicine with previously-approved medicines the subject of patent protection: s 119A
 - This exception now encompasses activities done at *any* time for the purpose of obtaining regulatory approval;
 - It also extends relevant 'regulatory approval' to encompass that needed to be obtained outside Australia; and
- **The unresolved issue of experimental use**
This remains the subject of continuing discussion; two law reform bodies (Australian Committee on Intellectual Property and the Australian Law Reform Commission) have offered similar but slightly different recommendations
 - IP Australia is currently considering the two approaches; several suggestions have been made; eg, by the Law Council of Australia.

The most significant of these additions is the inclusion of the regulatory approval exception. The exception will permit manufacturers of generic pharmaceuticals that are intended to be sold after the expiration of the patent to exploit ('piggyback') the efforts of the patentee *during the life of the patent*. Pioneer drug companies must currently bear an expensive 'stage 3' regulatory approval process for the sale of new pharmaceuticals. This would substantially delay the entry of lower-cost generic medicines onto the market after expiration of the patent, effectively extending the duration of patent protection in substance if not in form.

The provision is addressed at this inevitability. What it permits is also known as 'spring-boarding' — establishing bioequivalence with a prior pharmaceutical, which is cheaper and quicker to do, and then obtaining regulatory approval based on that equivalency and the data previously submitted by the pioneer company. The generic manufacturer can reduce the cost and time of market entry, minimising the delay between expiration of the patent and introduction of the generic product onto the market.