

## Laboratory Intellectual Property

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A common question that comes up in our meetings with inventors around New Zealand is what exactly can be protected using intellectual property (IP) rights. Finding the appropriate mix of IP assets is an important strategic decision that will depend on the nature of the IP, the market conditions, expected return on investment and a host of other factors. However, of most relevance to laboratory-based scientists will be patents. In this article we provide an outline of what constitutes an invention and how it can be protected using a patent.

A patent grants the owner an exclusive monopoly to make, use, license and sell the invention for a period of twenty years from the application date of the patent. In return for this state-sanctioned monopoly, the inventor must disclose how to work the invention to the public. Knowledge of the invention can then be built upon for the greater good and any person can make, use or sell the invention after the monopoly period expires. Importantly, this monopoly is limited by territory; an NZ-granted patent cannot be used to take legal action against someone who makes, uses or sells the patented invention in, for example, Australia.

In order to be granted a valid patent, the invention must be novel and involve an inventive step in light of what has previously been published or used. An inventive step is defined as a step that a person with skill in the field of the invention would not consider to be an obvious extension of what is already known.

The subject matter of the invention must also not be excluded from patentability. The following exclusions from patentability exist in New Zealand and some other countries:

- Substances in the form as they are found in nature. This exclusion means that genes or proteins themselves are not patentable although an isolated gene, *i.e.* a recombinant nucleic acid sequence, or an isolated protein is potentially patentable
- Inventions or discoveries of a purely theoretical nature. For example discovery of a theory to describe the polymerisation of a compound would not be patentable. However, a method of producing a polymer using the theory, or the polymer itself when made by the method would potentially be patentable
- Methods of medical treatment of humans. In New Zealand and Europe (although not in Australia and the USA) medical methods are excluded on the grounds it would be inconvenient to the state to allow the possibility of legal action being taken against medical practitioners for treating their patients
- Inventions deemed to be contrary to morality. In New Zealand this includes methods involving the use of human embryos and methods of cloning humans

There are checks and balances that ensure consistency in application of patent law over time. However, the subject matter excluded from patentability does evolve in response to government policy - enacted by the Intellectual Property Office of New Zealand (IPONZ), legislative reform and patent cases that come before the Commissioner of Patents or the Court. This evolution is an inevitable part of patent law as science and technology will always push the boundaries of the legislation and what we are morally willing to accept. As an example, there has been recent debate about whether software should be excluded from patentability. The new Patents Act due to be introduced in the latter half of 2011 will likely exclude some software from patentability, although deliberations regarding the definition of *software* and the effects of this exclusion are ongoing.

### The patent specification

The patent specification is a legal document that describes the invention and sets out the limits of the monopoly claimed. All specifications are published by IPONZ after the application has been examined and accepted. A specification must contain a detailed description of the invention and how it is put into practice. In the chemistry and biotech fields this will typically include examples of research that demonstrates the invention. The specification must also include a set of claims – a series of numbered statements that set out the limits of the monopoly covering the invention. Specifications also typically include a description of the background to the invention (termed the prior art).

A patent specification should be drafted, or at least reviewed, by a patent attorney to ensure that it covers the potential commercial uses of the invention and provides a strong position to take action against any party that makes, uses, sells or imports the invention without the patentee's permission. If such infringement proceedings ever need to be taken, the potentially infringing party is likely to analyse the patent for weaknesses that may raise questions about the validity of the patent. Accordingly, the skill of drafting a patent specification is not only in enabling the patentee to enforce their rights to the invention but also in potentially avoiding a legal battle by limiting the possibility that a question of invalidity can even be raised.

### What can be claimed?

The claims define particular aspects of the invention that can be protected and may include claims to the following:

- a product/compound/polymer, *etc.* – for example, a novel compound to treat a disease or a novel catalyst to enhance the efficiency of a reaction
- a composition/formulation – often a composition/formulation will include the raw compound of the invention in combination with suitable additives typically required for use. Alternatively it may be that the active ingredient is not novel but the formulation is new.

- an apparatus/device – for example, a novel analytical machine
- a method of production – for example, a novel synthesis
- a method of treatment of a disease – as noted above, in New Zealand and Europe this form of claim will need to be limited to methods of treating non-human animals or in vitro methods to treat cells
- a use of a compound – for example, the use of a novel compound to produce a pharmaceutical
- a system – a combination of one or more novel components that forms a system
- a kit – at least one part of the kit must be novel or the kit is constructed so that when used, it achieves a novel result
- isomers/enantiomers – often one isomer or enantiomer is more active or has a different biological effect to the other isomers or enantiomer. If this was not expected or predicted it may be possible to get a patent for the single isomer or enantiomer even if the mixture of isomers or the racemic mixture is already known.
- an isolated or recombinant nucleic acid/protein – for example an isolated gene that when expressed in a plant confers resistance to a herbicide.
- a non-naturally occurring microorganism – for example a novel microorganism that has undergone selective breeding so that it breaks down crop silage at a faster rate.

The claims of a patent are drafted so that they target parties that are likely to infringe the patent by producing or selling the invention. For example, the production of a new agrochemical could result in several parties infringing the claims. The chemical manufacturers may infringe method of manufacture and compound claims. The agrochemical producers or distributors may infringe compound, composition and kit claims. The end-user may infringe compound, composition, kit and possibly method of use claims. In this

way, the patent owner protects their position in the market and is in a position to make the best use of their competitive advantage through licensing or selling the invention.

### Selection inventions

In chemistry, the situation often arises that a general class of compounds is known but researchers have identified a subset of compounds with a specific desirable and unexpected property. This type of invention is often referred to as a *selection* invention and a patent may be granted for the subset of compounds provided that:

- all compounds of the subset have the particular unexpected property
- the unexpected property is restricted to the subset of compounds
- the compounds in the subset have not been specifically described or made
- the unexpected property is not obvious in light of the prior art.

This type of patent rewards research into areas where there is existing knowledge but where further research unearths useful properties.

Patents are recognised as essential parts of the knowledge ecosystem that sustains our competitiveness on the world stage. Recognising which aspects of our research are potential IP assets and taking steps to protect them in the most effective way possible is an important step in developing and commercialising the fruits of our labour in New Zealand.

**A reminder: if you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact:**

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Katherine Hebditch and Tim Stirrup of Baldwins Intellectual Property in Auckland specialise in chemistry and biotechnology patents. Katherine obtained her PhD in organic chemistry from the University of Manchester in the UK in 2004. She is currently working towards registration as a patent attorney. Tim obtained his PhD in molecular biology from the University of Southampton in the UK in 2007. He is also working towards registration as a patent attorney.

